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NUCLEAR LEGISLATION: ANALYTICAL STUDY

Regulatory and Institutional Framework for Nuclear Activities

2002-2003 Update

NUCLEAR ENERGY AGENCY
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Pursuant to Article 1 of the Convention signed in Paris on 14th December 1960, and which came into force on 30th September 1961, the Organisation for Economic Co-operation and Development (OECD) shall promote policies designed:

- to achieve the highest sustainable economic growth and employment and a rising standard of living in member countries, while maintaining financial stability, and thus to contribute to the development of the world economy;
- to contribute to sound economic expansion in member as well as non-member countries in the process of economic development; and
- to contribute to the expansion of world trade on a multilateral, non-discriminatory basis in accordance with international obligations.

The original member countries of the OECD are Austria, Belgium, Canada, Denmark, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The following countries became members subsequently through accession at the dates indicated hereafter: Japan (28th April 1964), Finland (28th January 1969), Australia (7th June 1971), New Zealand (29th May 1973), Mexico (18th May 1994), the Czech Republic (21st December 1995), Hungary (7th May 1996), Poland (22nd November 1996), Korea (12th December 1996) and the Slovak Republic (14th December 2000). The Commission of the European Communities takes part in the work of the OECD (Article 13 of the OECD Convention).

NUCLEAR ENERGY AGENCY

The OECD Nuclear Energy Agency (NEA) was established on 1st February 1958 under the name of the OEEC European Nuclear Energy Agency. It received its present designation on 20th April 1972, when Japan became its first non-European full member. NEA membership today consists of 27 OECD member countries: Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Luxembourg, Mexico, the Netherlands, Norway, Portugal, Republic of Korea, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The Commission of the European Communities also takes part in the work of the Agency.

The mission of the NEA is:

- to assist its member countries in maintaining and further developing, through international co-operation, the scientific, technological and legal bases required for a safe, environmentally friendly and economical use of nuclear energy for peaceful purposes, as well as
- to provide authoritative assessments and to forge common understandings on key issues, as input to government decisions on nuclear energy policy and to broader OECD policy analyses in areas such as energy and sustainable development.

Specific areas of competence of the NEA include safety and regulation of nuclear activities, radioactive waste management, radiological protection, nuclear science, economic and technical analyses of the nuclear fuel cycle, nuclear law and liability, and public information. The NEA Data Bank provides nuclear data and computer program services for participating countries.

In these and related tasks, the NEA works in close collaboration with the International Atomic Energy Agency in Vienna, with which it has a Co-operation Agreement, as well as with other international organisations in the nuclear field.

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I. GENERAL REGULATORY REGIME

1. Introduction

There are currently seven units producing nuclear energy through the use of Pressurised Water Reactors (PWR) in Belgium, four located in Doel and three in Tihange, with a total installed capacity of 5 728 MWe. The reactors, owned and operated by Electrabel, provided 57% of the total electricity production in 2002.

In addition, there are four research reactors operating in Belgium. At the Nuclear Energy Research Centre (*Centre d'études de l'énergie nucléaire* – CEN) in Mol-Dessel there is a zero-power reactor (BR1), a material test reactor (BR2) and a research pressurised water reactor (BR3), which is in the process of being decommissioned. There is also a research reactor (THETIS) located at the University of Gand.

Belgonuclaire, a firm operating out of Mol-Dessel, specialises in the production of mixed oxide fuel (MOX) for light water reactors. Finally, a portion of the radioactive waste produced in Belgium is treated by Belgoprocess, a branch of the National Organisation for Radiactive Waste and Enriched Fissile Materials (*Organisme national des déchets radioactifs et des matières fissiles* – ONDRAF). A study on the storage of vitrified high-level waste and spent fuel deep geological respository on the Nuclear Energy Research Centre is in progress. The waste is currently stored in Belgoprocess' temporary storage facilities.

In Belgium, nuclear energy is not a state monopoly. Most nuclear power production is in private hands, although under the surveillance of public authorities.

The principal federal authority for nuclear activities is the Federal Agency for Nuclear Control (*Agence fédérale de contrôle nucléaire* – AFCN), a public interest organisation under the authority of the Minister for Home Affairs.

The legislative and regulatory framework has evolved in line with developments in nuclear science and technology. Until 1994, the pillar of Belgian nuclear legislation was the Act of 29 March 1958 on Protection of the Public against the Hazards of Ionising Radiation, as amended. In implementation of this act, the Royal Order of 28 February 1963 laying down General Regulations concerning the Protection of the Public and Workers against the Hazards of Ionising Radiation, as amended, constituted the basic law regulating the nuclear field as a whole. In particular, it governed the licensing of nuclear installations, radiation protection, radioactive waste management, the import, transit and distribution of radioactive substances as well as their transport, and appropriate penal provisions. On 15 April 1994, the parliament passed an Act on the Protection of the Public and the Environment against Radiation and relating to the Federal Agency for Nuclear Control. This act, which has been amended several times since 1994, repeals and replaces the basic Act of 29 March 1958.

On 1 September 2001, the Royal Order of 20 July 2001 containing the General Regulation on the Protection of the Public, Workers and the Environment against the Hazards of Ionising Radiation was promulgated; thereby replacing the former Order of the same title from 1963. As of this date the Act of 1994 and its Executory Orders came into effect and the AFCN became operational.

Belgium underwent a significant change in its energy policy on 31 January 2003 with the adoption of the Act on the Phase-out of Nuclear Energy for the Purposes of the Industrial Production of Electricity. It is appropriate to mention here the role played by the Commission for the Analysis of the Modes of Electrical Production and Redeployment of Energy (AMPERE Commission) that was instituted by the Royal Order of 19 April 1999. This Commission was appointed to examine the feasibility of implementing a plan under which nuclear power plants would be shut down after 40 years of service. Its mandate concerned studying the general economic and energy context, the demand for electricity in Belgium and electricity production technologies.

The final report of the AMPERE Commission was published in October 2002. The Commission concluded, "to ensure the operational safety of the electro-nuclear sector, public safety and health, it is necessary to maintain a scientific and technological capacity which will allow electricity producers to ensure that their production takes place in the most efficient manner possible and under optimum safety conditions."

The Act of 31 January 2003 only applies to the industrial production of electricity that results from the fission of nuclear fuel. It provides that the oldest nuclear power plant (namely Doel 1) will be deactivated beginning in 2015. The other plants will then follow according to the date upon which they entered into service, so that in 2025, no nuclear power plants will be in operation in Belgium.

Two closely related principles are established in the second chapter of the Act:

- Section 3 states that no new nuclear power plant for the industrial production of energy resulting from the fission of nuclear fuel may be established or operated;
- Section 4 states that existing nuclear power plants should be deactivated and may no longer produce industrial electricity 40 years after their entry into service. In practice, this provision refers to the four nuclear power plants at Doel and the three plants at Tihange.

The act provides that all individual operating licences for the industrial production of electricity, granted in the past for an unlimited period, will expire 40 years after the date of entry into industrial service of the installation concerned. Section 9 of the act empowers the King to postpone the planned closure of nuclear power plants in the case of *force majeure* and, if necessary, to authorise the construction of new nuclear power plants (upon Royal Order examined in the Council of Ministers).

The Act of 31 January 2003 makes some amendments to the Act of 15 April 1994 on Protection of the Public and the Environment against Radiation and relating to the Federal Agency for Nuclear Control and the Act of 29 April 1999 on the Organisation of the Electricity Market.

The Act of 11 April 2003 on funds for the dismantling of nuclear power plants and the management of irradiated fissile materials in such plants completes this framework.

2. Mining Regime

Belgian regulations concerning prospecting and the export of ores contain no special provisions regarding nuclear ores.

3. Nuclear Installations

a) Licensing and inspection, including nuclear safety

The basic Belgian legislation in the field is found in the Royal Order of 20 July 2001 establihing the General Regulations on Protection of the Public, Workers and the Environment against the Dangers of Ionising Radiation, which implements the above-mentioned Act of 15 April 1994, as modified.

Civil nuclear installations are categorised in Classes I to IV according to their nature and the quantity of radioactive substances held at the installation. Installations within Classes I to III are subject to a prior licensing system consisting of two phases. First, one must obtain a licence for the establishment and operation of the site permitting construction of the installation. Second, one must receive confirmation of this licence after delivery of the installation, which thereby allows for the delivery of radioactive substances to the installation and its start-up. Class IV installations, which use smaller quantities of radioactive materials, are exempt from this system.

Since the adoption of the Act of 31 January 2003 on the Phase-out of Nuclear Energy for the Purposes of the Industrial Production of Electricity, no new nuclear power plants may be built and/or put into operation for the purpose of producing industrial electricity. In addition, the nuclear power plants in use will be shut down forty years after the date of their entry into service and may not be used to produce electricity after that time.

Class I installations include nuclear reactors (with the exception of reactors for the production of industrial electricity, which are now prohibited); installations in which the quantities of fissile substances processed or held are above half the minimum critical mass; plants for the reprocessing of enriched or non-enriched irradiated nuclear fuel; centres where the primary activity of the company is to collect, treat, condition, store or manipulate radioactive waste; and final disposal sites for radioactive waste. Licensing requests for Class I installations are sent to the Federal Agency for Nuclear Control (*Agence fédérale de contrôle nucléaire* – AFCN), and detailed requirements for such requests are found in the General Regulations [Section 6.2]. The decision to grant a licence for a Class I installation is made by the King, in the form of an order countersigned by the Minister of the Interior [Sections 6.1 and 6.7] with advice of the Scientific Board of the Agency and the European Commission [as provided for under Section 37 of the Euratom Treaty]. The ruling is made following a public inquiry and consultation with the Board of Aldermen (*collège échevinal*) of the communities located within a five-kilometre perimeter around the installation, as well as a Provincial Executive Body (*députation permanente du Conseil provincial*) [Sections 6.3 and 6.6]. The Scientific Board may affix conditions to its authorisation, for example, making authorisation contingent upon the results of a safety report [Section 6.7].

Licenses to establish and operate Class II installations are granted by the AFCN upon consultation with the Board of Aldermen of the community located within a range of 100 metres surrounding the installation [Section 7.3.1]. Certain Class II installations require an environmental impact study, for example those in which radioactive substances are produced from irradiated fissile material and where such material is processed for sale, and particle accelerators or installations that use or hold radionucleides whose activity total exceeds 500 000 times the fixed exemption level. In addition, before granting a licence, the Agency takes into consideration the opinion of the Board of Aldermen from the community or communities located within a range of 500-metres surrounding the installation and a public inquiry is made in the community. If the installation may affect a neighbouring state, it should be consulted. Finally, pursuant to Section 37 of the Euratom Treaty, the Agency solicits the opinion of the European Commission [Section 7.3.2].

Class III nuclear installations, such as those in which certain X-ray producing machines are used, must be notified to the AFCN to obtain a licence for their establishment and operations [Section 8].

The installations in which professional activities making use of natural radioactive sources are performed [Section 4] must be notified to the Agency within a set time limit [Section 9]. The Agency can impose corrective measures if the fixed dose limits for the public and exposed professionals are, or may be, exceeded [Section 9.3].

In the case of ceasing all activity, the operators of Class I, II and III installations, as well as the operators performing professional activities which use natural radioactive sources, must notify the Agency and the National Organisation for Radioactive Waste and Enriched Fissile Materials (*Organisme national des déchets radioactifs et des matières fissiles enrichies* – ONDRAF) [Section 17.1]. The dismantling of Class I and II installations is subject to authorisation delivered by the King or AFCN [Section 17.2].

The Law of 15 April 1994 entrusts the AFCN with the mission to inspect nuclear installations [see Part 2 "Institutional Framework" *infra*]. It now undertakes all investigations that were previously performed by two public services, namely, the Special Committee on Ionising Radiation and Provincial Advisory Committees on Nuclear Installation.

Supervision to ensure observance satisfactory operation of safety and protection systems in nuclear installations is entrusted to experts in the particular firm's health service. The operators of Class I installations are required to employ their own health service, headed by an expert certified by the AFCN, which inspects the performance of such services. In Class II and III installations, the operator is not subject to the same requirement, however, if a Class II installations employs such a service headed by an expert certified by the AFCN, then it is subject to a similar inspection. Where there is no such service, inspections are entrusted to accredited private bodies that are supplemented by a final inspection at the AFCN level. Nuclear inspectors examine the operator's compliance with regulations and make use of private recognised bodies for the assessment.

At the international level, Belgium ratified the 1994 Convention on Nuclear Safety on 13 January 1997.

b) Protection of the environment against radiation effects

There is no specific legislation in Belgium concerning the protection of the environment against radiation. This subject is dealt with throughout the whole of related legislation, and in particular the Royal Order of 20 July 2001 containing the General Regulation on the Protection of the Public, Workers and the Environment against the Hazards of Ionising Radiation. Notably, Part IV "Radioactive Waste" [Chapter III] includes provisions [Sections 34(1), 34(2), 34(3), 36(1) and 37(3)] which prohibit the release of liquid radioactive waste into surface waters, soil, sewers or underground conduits and prohibits the discharge of radioactive substances in the atmosphere in the form of gas, dust, smoke or vapour, when their radionuclide content or radioactive substances exceed a certain maximum permissible concentration. They also prohibit the storage of radioactive waste on the surface or underground.

c) Emergency response

Section 72 of the General Regulation on the Protection of the Public, Workers and the Environment against the Hazards of Ionising Radiation governs emergency response.

A Royal Order of 17 October 2003 on emergency response to nuclear risks in Belgian territory succeeds the prior plan laid down by the Royal Order of 27 September 1991. This emergency plan is to serve as a guide for the measures to be taken whenever necessary to protect the public and the environment [Annex, Section 1(2)]. It establishes the duties of the different services and bodies, in accordance with their responsibilities under national laws and regulations, and describes the general organisation. The plan is to be supplemented by intervention plans at the different levels involved: the provincial authorities, the communal authorities and the different institutions concerned [Annex, Section 1(3)(2)]. It is the Minister of the Interior's responsibility to decide on projects thus established [Section 2]. This Minister is also responsible for co-ordinating all measures required to implement the emergency plan [Annex, Section 2(1)(1)]. The Federal Agency for Nuclear Control is responsible for examining radioactivity for the entirety of the territory. It is also charged with co-ordinating in the establishment and updating of the national emergency plan for nuclear risks. The AFCN organises a consultative group for the emergency plan and presides over it. In case of an accident, it is this group's task to put into effect all logistical means necessary, in terms of manpower and material, to evaluate the situation of land at risk of radiation contamination or which has been contaminated by radioactive waste.

The plan mainly concerns large nuclear installations and the transport of nuclear fuels and radioactive materials, although lower risks from other activities are also covered [Annex, Sections 1(3)(1) and 1(3)(2)].

At the international level, it is of relevance to note that Belgium is a Party to both the 1984 Convention on Early Notification of a Nuclear Accident and the 1984 Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency since 4 January 1999.

d) Decommissioning

Pursuant to the Royal Order of 30 March 1981 determining the Duties and Conditions of Operation of the Public Body Responsible for Radioactive Waste and Fissile Materials Management (ONDRAF) modified by the Royal Decree of 16 October 1991, ONDRAF is the institution with jurisdiction over the decommissioning of nuclear installations.

All nuclear installation operators, including anyone applying to operate a nuclear installation, must provide ONDRAF with all information relating to the planned decommissioning of their installation; the nature and quantities of resulting waste and the date of the waste's transfer to ONDRAF. Such information must be provided within a reasonable time and in any case no later than three years before the installation's final closure. ONDRAF shall also establish, in consultation with the operators concerned, the financing conditions for decommissioning nuclear installations that have been closed-down and for the management of their waste. The operators of nuclear power plants are exempted from this provision, but must provide ONDRAF access with the information necessary to carry out its responsibilities in this regard.

ONDRAF shall come to an agreement with each operator of a nuclear installation defining the nature of this information. In case the operator, or the party financially responsible for the installation

to be closed down, wishes to transfer the carrying out of these activities, ONDRAF and the operator negotiate an agreement defining the technical and financial terms of shutting down the installation.

Financing for the cleaning-up of the Eurochemic re-treatment pilot plant, the Nuclear Energy Research Centre (*Centre d'études de l'énergie nucléaire* – CEN) installations (including the former "Waste" Department installations such as BR 1, BR 2, BR 3, high- and medium-level activity laboratories, etc.) and the National Radioisotope Institute (*Institut national des radioéléments* – IRE) installations, including the resulting waste, are insured as follows:

Regarding the former Eurochemic plant and the former "Waste" department (called passive BP 1/BP 2), Section 432 of the provisional law of 24 December 2002 provides for the levy of an excise tax, called federal dues, which is calculated on the basis of kWh consumed. These dues constitute a fund intended to finance responsibilities resulting from the decommissioning of the BP 1 and BP 2 sites at Mol-Dessel, as well as the treatment, processing, storage and evacuation of accumulated radioactive waste. The manager of the group shall collect the amount owed as dues and transfer the portion pertaining to BP 1 and BP 2 to ONDRAF who is responsible for their management and cleaning-up.

Beyond the amount fixed for the year 2003, the Royal Order of 24 March 2003 states that the amount intended for the financing of cleaning-up reactors, to be deducted on the basis of kWh consumed, shall be fixed by a Royal Order deliberated in the Council of Ministers on the basis of a five year financing plan set-up by ONDRAF. This plan shall be submitted to the Minister responsible for energy issues, at the latest, six months before the beginning of the period concerned. The manager of the group shall transfer a quarter of the amount to a special ONDRAF bank account at the end of each trimester. This Royal Order was adopted 19 December 2003 and published 31 December 2003 in the Official Journal of Belgium.

Regarding the other CEN installations, the Royal Order of 16 October 1991 regarding the Rules of Control and Mode of Subsidising and Modifying the Status of the Centre defines the *passif technique* in the same way as the debits of BP 1/BP 2. It further states that the Ministers responsible for economic and energy issues shall plan in their annual budgets the grants earmarked for the Centre's *passif tehnique*. These grants shall be transferred to a special ONDRAF account.

Finally, the Royal Order of 16 October 1991 establishing the IRE Rules of Control and Mode of Subsidising and Modifying the Status of the Centre, contains the same provisions for the former installations of the IRE as those described above for the CEN.

4. Trade in Nuclear Materials and Equipment

Belgium is active in the nuclear equipment and services market and participates in various industrial undertakings in this field.

The Royal Order of 20 July 2001 laying down the general Regulation on Protection of the Public, Workers and the Environment against the Dangers of Ionising Radiation contains provisions relating to radioactive material and nuclear equipment, and in particular [Section 1]:

- to the import, production, manufacture, possession, transport, and use for commercial, industrial, scientific, medical or other purposes, of apparatus, equipment or substances capable of emitting ionising radiation;

- to the offer for sale or assignment for consideration or free of charge, of substances capable of emitting ionising radiation or of apparatus or equipment containing such substances.

The order applies to all natural or legal persons who build and operate nuclear installations using fissile substances, radionucleides or apparatus generating X-rays, facilities for the storage and reprocessing of nuclear fuels and particle accelerators. A licensing system is laid down for each of these activities.

Persons and firms involved in the import into, or transit through Belgium of radioactive substances and apparatus emitting ionising radiation, must be duly licensed by the Federal Agency for Nuclear Control (*Agence fédérale de contrôle nucléaire* – AFCN) [Section 38(1)]. Licences may be either general or specific, and are granted for a given period. Licensing applications must include certain information such as the identity of the applicant, the types of use, the characteristics of the substances and apparatus involved and the insurance policy covering third party liability [Section 38(2)]. Special accounting procedures are used with regard to the delivery of radioactive substances [Section 41]. Importers and distributors are required to supply the AFCN on a monthly basis with information about imports and deliveries made and the consignees involved [Section 42].

Persons in possession of nuclear substances must take the necessary measures to prevent their theft, loss or misuse [Section 66]. Should the need arise, it is the Minister of Interior's responsibility to prohibit the distribution of certain radioactive substances [Section 64(4)].

The order also lays down the special conditions governing the import, transit, export and processing of radioactive wastes.

5. Radiation Protection

The basic legislative instruments in Belgium governing the field of radiation protection are the Act of 15 April 1994 on Protection of the Public and the Environment against the Dangers of Ionising Radiation, and on the Federal Agency for Nuclear Control [*Moniteur belge* of 29 July 1994], as modified, and the Royal Order of 20 July 2001 containing the General Regulation on the Protection of the Public, Workers and the Environment against the Hazards of Ionising Radiation [*Moniteur belge* of 30 August 2001].

The Royal Order of 20 July 2001 ensures the implementation of the Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation and Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure. The order aims to ensure the protection of workers, the public and the environment against the risk of exposure to ionising radiation, emanating from natural or artificial sources, which are associated with practices or professional activities posing such a risk, with emergency interventions or with long-term exposure.

In practice, it reinforces the protection of exposed workers, the general public, apprentices and students as well as the protection for mothers performing breastfeeding. Stricter dose limits are set up for all categories of exposed persons. The Federal Agency for Nuclear Control (*Agence fédérale de contrôle nucléaire* – AFCN) may revise the current practices whenever new and important knowledge concerning their effectiveness or their consequences is obtained. A new concept, dose constraint, has

been introduced as an additional restriction upon doses under which only one source, practice or task can be issued or required of individuals, even when the dose limits are respected.

Chapter VI of the Royal Order regulates the use of ionising radiation sources for medical purposes. The protection provided in the order's scope of application is widened and the application of the principles of justification and optimisation reinforced by very detailed prescriptions.

The principal mission of the Federal Agency for Nuclear Control [Sections 14 to 27 of the Act of 15 April 1994] is to make sure that the population and the environment are protected in an effective way against the danger of ionising radiation. In this context, it proposes laws and regulations and ensures that these laws and regulations are observed.

The Agency is responsible for gathering scientific and technical documentation, as well as distributing neutral and objective information in the domain of nuclear safety and radiation protection. It also promotes and co-ordinates the research and development work for these disciplines.

Several government bodies and various agencies are concerned with radiation protection questions, such as the Higher Council for Public Health and the Higher Council for the Enhancement of Workplaces.

Finally, the Medical Inspectorate of the Federal Public Service for Employment, Labour and Social Dialogue gathers data relating to the irradiation of professionally exposed workers to ionising radiation and distributes its conclusions. Accredited doctors assure the medical supervision of workers.

The Royal Order on the Protection of Workers against the Hazards of Ionising Radiation was adopted on 2 April 2002 and entered into force on 20 June 2002. It amends the Royal Order of the same title of 25 April 1997 in order to harmonise the Belgian legislation with the provisions of Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas.

Pursuant to this royal order, a radiological passport is established for each outside worker operating in controlled areas. Outside workers are subject to an evaluation of their exposure and to medical surveillance, details of which are recorded in the radiological passport. The dosimetric data of each worker is considered to be personal medical information and is protected. The royal order specifies the tasks of the Industrial Health and Medicine Department and the physical protection services of nuclear operators.

The Interministerial Commission for Nuclear Safety and State Security in the Nuclear Field draws up co-ordination plans for the various ministerial departments concerned with a view to improving the health protection of workers and the public. The Industrial Health and Medicine Department of the Ministry of Employment and Labour collects data on the radiation received by persons exposed to ionising radiation in the course of their work and draws relevant inferences.

The Royal Order on the Treatment of Food and Food Ingredients by Ionising Radiation of 12 March 2002, which entered into force on 14 March 2002, amends the Royal Order of 20 July 2001 establishing General Regulations for the Protection of the Population, Workers and the Environment against the Dangers of Ionising Radiation. It repeals the Order of 16 July 1980 regulating the treatment by ionising radiation of food for human and animal consumption. The royal order aims furthermore to implement Directive 1999/2/EC of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation, Directive 1999/3/EC of the European Parliament and of the Council of

22 February 1999 on the establishment of a Community list of foods and food ingredients treated with ionising radiation and Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs.

Pursuant to this order, operators of irradiation facilities are required to participate in dosimetric controls and they must maintain a register for each batch of foodstuffs treated. The import and export of foodstuffs treated by ionising radiation are regulated by the order. Their import is permitted where the irradiation has taken place at an authorised installation pursuant to the list published in the Official Journal of the European Communities. Where this is not the case, import is subject to a licence granted by the Federal Agency for Nuclear Control.

6. Radioactive Waste Management

The Radiation Protection Order of 20 July 2001 contains a number of provisions concerning radioactive waste and waste storage [Chapter II, Part II, and Chapter III, Part IV].

Under the licensing regime, detailed information has to be given about the measures to be taken for the storage, treatment and disposal of any radioactive waste, whether in liquid, solid or gaseous form [Sections 6.2, 7.2 and 8.2].

The Order of 16 October 1991, amending the Royal Order of 30 March 1981 laying down the tasks and rules of procedure of the National Organisation for Radioactive Waste and Enriched Fissile Materials (*Organisme national des déchets radioactifs et des matières fissiles* – ONDRAF) (see *infra* Part II "Institutional Framework") regulates the relationship between ONDRAF and the operators of nuclear installations. All persons in possession of radioactive waste or who operate installations producing such waste, including those who plan to build such installations, must provide ONDRAF with all the necessary information.

ONDRAF concludes an agreement with the operators of nuclear installations, whom it considers to be regularly producing a significant quantity of radioactive waste, which relates to the implementation of the general radioactive waste management programme and lays down the rights and obligations of the parties concerned.

In addition, an agreement is concluded between the person in possession of the waste and the Organisation relating to the taking over of the radioactive materials by ONDRAF for processing, storage and transport. These agreements specify in particular the arrangements for the transfer of responsibility and the financial and technical conditions that apply.

The Act of 11 April 2003 on the Reserve Fund for the Dismantling of Nuclear Power Plants and the Management of Fissile Irradiated Materials in Nuclear Power Plants was adopted 11 April 2003. Under the terms of this Act, Synatom, the Belgian corporation for nuclear fuel, assures cover for the costs of dismantling nuclear power plants and costs tied to the management of the irradiated fissile material in these plants. To this end, the corporation keeps sufficient funds in its accounts for dismantling and managing irradiated fissile materials.

The operators of nuclear power plants are required to transfer any funds to Synatom that they have already collected, as well as any amount that they should add to these funds for the future operation of the power plant, until they constitute a sufficient amount.

Dismantling will be carried-out by the operators for Synatom, and dismantling costs will be charged to the reserved funds under the control of the latter. If, during the dismantling operations, the funds prove to be insufficient to pay dismantling costs, the operators will transfer to Synatom the amount necessary to cover costs of dismantling at the time it is due.

The funds for the management of irradiated fissile materials are increased annually by Synatom according to the quantity of the irradiated fissile materials produced in the corresponding year. The same conditions apply to this management as for dismantling.

The Royal Order of 2 October 1997 implements Council Directive 92/3/Euratom of 3 February 1992 on the supervision and control of shipments of radioactive waste between Member States and into and out of the Community. In this respect, the Order sets out a model uniform document for the supervision and control of these transfers.

7. Non-Proliferation and Physical Protection

a) International aspects

Any persons or enterprises in any way producing, using or storing source and special fissile materials on Belgian territory must comply with the provisions in Chapter VII "Safeguards (Security Control)" of the Treaty establishing the European Atomic Energy Community and its implementing regulations, which form an integral part of Belgian law [Act of 2 December 1957].

They must also allow and facilitate inspections and checks by the International Atomic Energy Agency (IAEA) in order to verify the results obtained by the safeguards system of the European Atomic Energy Community [Act of 20 July 1978].

In addition, on 9 February 1981, an act was adopted laying down a prior licensing system for the export of nuclear materials and equipment as well as of technological data, the details of which were to be specified in a royal order in the light of the international agreements entered into by Belgium in the nuclear field. This was done by the Royal Order of 12 May 1989 relating to the transfer to non-nuclear weapon states of nuclear materials, equipment, technological data and derivatives.

After obtaining the opinion of an advisory committee composed of representatives of the various ministries concerned, the Minister holding the portfolio of Energy verifies that the transfers will be carried out exclusively with a view to the peaceful use of atomic energy and subject to the required controls (safeguards system – physical protection) and in compliance with Belgium's commitments under the 1968 Treaty on the Non-proliferation of Nuclear Weapons, which it ratified on 2 May 1975. Belgium also ratified the 1996 Comprehensive Nuclear Test Ban Treaty on 29 June 1999, as well as the 1979 Convention on the Physical Protection of Nuclear Material on 6 September 1991.

b) National control and security measures

Under the Act of 4 August 1955 concerning state security in the field of nuclear energy, research, materials and production methods carried out or used by institutions, establishments or physical or legal persons which have at their disposal information, documents or nuclear materials obtained either directly from the government or with its permission and which, in the interests of the defence of the national territory and of state security, come under the rules of secrecy, must comply with the security measures laid down in the Royal Order of 14 March 1956.

These measures govern the fitting out, protection and surveillance of premises, the classification of documents and materials, the safe-keeping of documents and the preservation of materials, the determination of criteria for their dissemination and the requirements for conducting an activity in or entering premises where such research and work is carried out [Order of 14 March 1956, as amended by Order of 18 October 1974].

In principle, Belgian nationality is required in this respect. Nevertheless, an exception may be made by decision of the Minister holding the portfolio of Energy if the foreign applicant possesses specialised knowledge.

Section 37 *bis* of the Royal Order of 20 February 2001 containing the General Regulation on the Protection of the Public, Workers and the Environment against the Hazards of Ionising Radiation provides that, without prejudice to the provisions of the Royal Order of 1956 concerning implementation of the abovementioned 1955 Act, it is prohibited to enter the sites or premises referred to in the said order or to visit them without the specific permission of the person in charge of the enterprise or his deputy. Official inspectors are exonerated from the obligation to seek such permission.

Section 19 of the Act of 2 April 2003 modifying the Law of 15 April 1994 repeals the Law of 4 August 1955. However, as Section 19 has not yet entered into force, the Act of 4 August 1955 still applies until a royal order is issued to bring Section 19 into force.

In addition, the disclosure of manufacturing secrets and inventions relating to the nuclear field which are not subject to the Act of 4 August 1955 but whose disclosure is declared jointly by the Minister holding the portfolio of Energy (responsible for industrial property) and the Minister of National Defence to be contrary to the interests of the defence of the territory or of state security, is prohibited, or else the conditions in which they may be exploited are temporarily determined and controlled by the said Ministers in accordance with the Act of 10 January 1955 relating to the disclosure and use of inventions and manufacturing secrets concerning the defence of the territory or state security. Prohibitions or limitations may be partly or totally lifted at any time by joint decision of the ministers who issued them. An application may be made by the holder of the rights for the prohibition or limitation to be lifted.

The purpose of the Act of 17 April 1986 on implementation of the Convention on the Physical Protection of Nuclear Material is to implement Sections 7 and 8 of the Convention of 3 March 1980 in Belgian national law. Section 7 requires Contracting Parties to provide penalties for a number of serious criminal offences with respect to nuclear material. Section 8 specifies the cases in which measures Contracting Parties must take measures to establish their jurisdiction over such offences. The 1986 Act therefore specifies that sanctions for these offences must be inserted into the Penal Code. It also states that provisions must be inserted into the Code of Criminal Procedure to the effect that Belgian courts have jurisdiction to hear cases in which such offences are committed in the territory of Contracting Parties to the Convention or on board a vessel or aircraft registered in one of those states if suspect is within national territory and the government of Belgium has made no arrangements with the state concerned regarding extradition.

8. Transport

The transport of nuclear materials in general is governed by the amended Royal Order of 20 July 2001 laying down the General Regulation on the Protection of the Public, Workers and the Environment against the Hazards of Ionising Radiation.

The requirements laid down by the royal order embody the IAEA Regulations for the Safe Transport of Radioactive Materials, the International Regulations concerning the Carriage of Dangerous Goods by Rail (RID), the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), the IMO International Maritime Dangerous Goods Code, the Ordinance concerning the Transportation of Dangerous Goods on the River Rhine (ADNR) and the Technical Instructions for the Safe Transport of Dangerous Goods by Air of the International Civil Aviation Organisation (ICAO) [Act of 24 January 1973, Act of 10 August 1960, Royal Order of 14 January 1960 as amended by Royal Order of 5 March 1971, Royal Order of 2 December 1971 as amended by Royal Orders of 29 December 1976, 1 February 1977, 24 December 1978 and 7 September 1979].

A licence issued by the Federal Agency for Nuclear Control (*Agence fédérale de contrôle nucléaire* – AFCN) is required for the transport of radioactive substances. Licences may be of a general nature, when the carrier transports radioactive substances on a regular basis, specific, where the carrier occasionally transports such substances, or special, in the case of substances with a level of radioactivity above certain thresholds.

The AFCN is also empowered to verify that all decisions authorising transportation are correctly applied and respected. In case of violation, the Agency may demand immediate corrective actions or, if need be, withdraw transportation authorisation and thereby restrict it. If necessary, it issues a verbal order. The AFCN also assures the certification of drivers of vehicles transporting radioactive substances.

Lastly, the National Organisation for Radioactive Waste and Enriched Fissile Materials (*Organisme national des déchets radioactifs et des matières fissiles* – ONDRAF) is responsible for organising the transport of radioactive waste from the installations producing it and for the transport of enriched fissile materials or plutonium-bearing materials whose quantity and enrichment rate exceed certain limits set by Section 2(2)(2)(a) of the Royal Order of 30 March 1981 as amended by the Royal Order of 16 October 1991; this may also cover surplus quantities of fresh or spent fuel it should take over.

9. Nuclear Third Party Liability

Belgian rules on nuclear third party liability are contained in the Act of 22 July 1985 on Third Party Liability in the Field of Nuclear Energy published in the *Moniteur belge* of 31 August 1985, modified by the Act of 11 July 2000 [*Moniteur belge* of 4 October 2000]. This act implements the 1960 Paris Convention and the 1963 Brussels Supplementary Convention, ratified by Belgium on 3 August 1966 and 20 August 1985 respectively.

The 1985 Act, as modified, lays down the principle of strict liability, limited in amount and time, channelled to the operator of a nuclear installation. In this respect, Section 7 of the act establishes the maximum amount of the operator's liability for nuclear damage at Belgian francs (BEF) 12 billion [Section 7(1)]. This sum is equivalent to approximately 300 million euros. The King is empowered to raise or reduce this amount in order to fulfil Belgium's international obligations as well to take into account low risk installations or transport, however he may not set a level lower than that required by the Paris Convention [Section 7(2)]. Pursuant to the terms of the act, the operator is obliged to take out an insurance policy, or another form of financial guarantee, to cover his liability up to the amount set out in the act [Section 8]. The act further establishes, as a corollary of this obligation, a procedure whereby the King recognises the operator as such [Sections 9 to 13].

Although the act provides that the operator remains liable during the carriage of nuclear substances, it does not exclude the possibility of transferring liability to the carrier [Section 14]. In any event, the carrier is required to hold a certificate stating that he satisfies the financial security conditions [Section 15].

Section 23 of the act establishes a prescription period of ten years from the date of the nuclear incident in respect of the right to claim compensation. Beyond this period, the state is responsible for the payment of compensation in respect of claims for damage which are time-barred, within a maximum period of 30 years from the date of the incident.

Several orders have been adopted to implement the 1985 Act, in particular:

- the Royal Order of 28 April 1986, determining the financial security certificate for transport of nuclear substances, whose purpose is to ensure that financial security certificates (given to all carriers of nuclear substances by the operator liable) comply with the Paris Convention requirements in this respect, as prescribed by the 1985 Act;
- the Ministerial Order of 9 March 1987 on the register concerning nuclear installations, which aims to implement Section 13 of the 1985 Act regarding the obligation to make available to the public the register containing the texts granting recognition to the operators of nuclear installations. This register contains a certified copy of the royal orders of recognition and a card of the installations indicating the limits of each site. It may be consulted at the Federal Public Service for Economy, SME's, Self-Employed and Energy. The local authority for the territory where the installation is located must comply with a similar obligation.

At the international level, Belgium ratified the 1971 Convention relating to Civil Liability in the Field of Maritime Carriage of Nuclear Material on 15 June 1989.

II. INSTITUTIONAL FRAMEWORK

1. Regulatory and Supervisory Authorities

a) Federal Agency for Nuclear Control (AFCN)

i) Legal Status

The Federal Agency for Nuclear Control (*Agence fédérale de contrôle nucléaire* – AFCN) is a public body with legal personality (Category C public interest group), established by the Act of 15 April 1994 on Protection of the Public and the Environment against Radiation and Relating to the Federal Agency for Nuclear Control. This status grants the Agency broad independence, which is indispensable for the impartial carrying out its responsibilities for the public good. The AFCN has been completely operational since 1 September 2001, the date on which the Royal Order establishing General Regulations for the Protection of the Population, Workers and the Environment against the Dangers of Ionising Radiation came into force. This order brought into effect the Act of 15 April 1994

and lays out the circumstances and methods under which the Agency is to carry out its mission. It comprises the majority of Belgium's regulations in the area of protection of the public and the environment against the dangers of ionising radiation.

ii) Responsibilities

The AFCN's mission [Sections 14 to 17 of the Act of 1994] is to ensure that the public and the environment are effectively protected against the dangers of ionising radiation. In this context, it puts forth proposals for laws and regulations and makes certain that they are observed. It is responsible for managing a wide range of requests for authorisation and, if needed, makes suggestions or decisions with an opinion from its scientific board or other advisory body. The AFCN also carries out the monitoring, control and inspection of all practices and activities involving ionising radiation, including activities for the control of nuclear materials meant to guarantee that they are used only for their intended purpose (non-proliferation guarantee).

The AFCN participates in the work programme of international organisations (such as the European Union and the International Atomic Energy Agency) in which directives, recommendations and international regulations are formed. It manages the "Telerad" group for monitoring radiation in Belgian territory, and plays an important role in the operation of the nuclear emergency plan, notably in regards the effects of an accident and communicating with the public and media.

The AFCN is responsible for maintaining scientific and technical documentation as well as distributing neutral and objective information in the area of nuclear safety and radiation protection. It encourages research and development projects in these same fields.

iii) Structure

The AFCN is run by a Council of Administration, whose members (comprised of equal numbers of French and Flemish speakers) are appointed by the King upon recommendation by the government. The Director-General is likewise appointed by the King upon recommendation by the government. He is assisted by three department heads (Regulation and Authorisation, Monitoring and Control, Administration and Finance). The Agency employs specialised personnel who either come from its own recruitment efforts or as the result of different ministries who loan their agents and experts (Minister of Social Affairs, Public Health and the Environment, Minister of Employment and Work, Minster of Foreign Affairs and Minister of Justice).

The AFCN also has a scientific board [Section 37 of the Act of 15 April 1994; Royal Order of 18 December 2002] that is responsible for advising the Agency on issues concerning its monitoring policy, and more specifically to provide a preliminary opinion on authorisations for new nuclear installations or the renewal of such authorisations. The Council membership is composed of scientists nominated by the competent ministry for a period of six years.

The provisional law of 12 December 1997 [*Moniteur belge* 18 December 1997] modifies Section 45 of the Act of 15 April 1994, which governs the transfer of personnel from two services to the Agency: the Service for Technical Security of Nuclear Installations of the Minister of Employment, Labour and Social Cohesion and the Service for Protection against Ionising Radiation of the Minister of Social Affairs, Public Health and the Environment.

The costs of the AFCN are financed by licensing fees [Royal Order of 24 August 2001 fixing the amount and the manner of license fees payments in application of the regulations on ionising radiation] paid by the people and firms that request an authorisation required by regulation or who are subject to controls and inspections performed by the Agency.

b) Federal Public Service for Home Affairs

The Ministry of the Interior was designated by the Royal Order of 3 July 1995 as the authority competent in matters concerning technical security of nuclear installations. The Order of 7 August 1995 attributes competence to him in the area of protecting the public and the environment from the dangers resulting from ionising radiation.

Pursuant to Section 81 of the Order of 20 July 2001, the tasks previously bestowed upon the Service for Protection against Ionising Radiation and the Service for Technical Security of Nuclear Installations were transferred to the Federal Agency for Nuclear Control, under the authority of the Ministry for Home Affairs.

Responsibility for emergency policy in the case of an accident in a nuclear power plant or in another nuclear installation belongs to the Federal Public Service for Home Affairs. On this basis, the Royal Order of 17 November 2003 was promulgated to provide emergency plans for nuclear risks inside Belgium.

c) Federal Public Service for Economy, SME's, Self-Employed and Energy

The Minister holding the portfolio of Energy is responsible for nuclear energy in the same manner as he is for other types of electricity production.

The Minister is also responsible for the export of nuclear materials, nuclear equipment and nuclear technology information and their by-products. The export of nuclear materials is subject to certain conditions, including permission from the Federal Public Service.

The Minister holding the portfolio of Economic Affairs is responsible for supervising ONDRAF.

d) Federal Public Service for Employment and Labour

The Minister of Employment and Labour is responsible for the safety and health of workers exposed to the dangers inherent in nuclear installations. He approves the dosimeters to be worn by the workers exposed to ionising radiation in the course of their work.

He is the supervisory authority for the Industrial Health and Medicine Department, which is responsible for the protection and medical supervision of workers. Responsibility for technical monitoring of nuclear installations was transferred to the Federal Agency for Nuclear Control.

e) Federal Public Service for Defence

The Minister of National Defence has general authority over nuclear activities in military establishments.

f) Federal Public Service Foreign Affairs, Foreign Trade and Development Co-operation

The Minister of Foreign Affairs is responsible for all international matters concerning nuclear energy. In particular, he handles negotiations for Belgium's adhesion to, or participation in, international, bilateral or multilateral agreements and treaties and represents Belgium in international organisations.

Jointly with the other ministers involved, the Minister of Foreign Affairs is also responsible for international trade matters and for ensuring that Belgium's international commitments are honoured.

g) Minister for Science Policy

The Minister for Science Policy is responsible for generally co-ordinating the Federal government's activities relating to science policy. He shares the responsibility for nuclear research with the Minister holding the portfolio of Energy [Royal Order of 18 May 1971].

2. Advisory Bodies

a) Interministerial Commission for Nuclear Safety and State Safety in the Nuclear Field

The Interministerial Commission for Nuclear Safety and State Security in the Nuclear Field (*Commission interministérielle de la sécurité nucléaire et de la sûreté de l'État dans le domaine nucléaire*) was set up by the Royal Order of 15 October 1979. For administrative and financial purposes, the Commission is under the auspices of the Minister of Public Health. The Commission comprises ten members, including the president of the Special Commission for Ionising Radiation and nine members nominated by the ministries concerned. The mission of this Commission is to seek ways of ensuring the protection of workers and the public against any hazards that might arise from activities connected with the use, processing, storage and transport of radioactive substances both within and outside installations where such activities are carried on. The Commission consults experts whom it may invite to attend its meetings in an advisory capacity, whenever it considers they might be able to help resolve a specific problem. The amendments to the Royal Order of 15 October 1979 introduced by the Royal Order of 14 February 1984 provide that the government of the Brussels-Capital Region, the Walloon government and the Flemish government may, if they so wish, each appoint a delegate to take part in the Commission's meetings in an advisory capacity. The Commission sends a report to the government at least twice per year to keep it informed of its activities.

b) Higher Council for Public Health

The Higher Council for Public Health (*Conseil supérieur d'hygiène*) is under the auspices of the Minister of Social Affairs, Public Health and the Environment. It may submit opinions to the public

health authorities on any matter concerning public health and environment, including the domain of ionising radiation.

c) Higher Council for Safety, Hygiene and Enhancement of Workplaces

This Higher Council (*Conseil supérieur de sécurité, d'hygiène et d'embellissement des lieux de travail*) provides opinions, of its own initiative or upon demand, concerning measures taken by firms on safety in the workplace, physical and mental health of workers, ergonomics, improvement of working conditions and actions undertaken in regard of the environment.

d) Advisory Commission for the Non-Proliferation of Nuclear Weapons

In order to ensure that international agreements on the non-proliferation of nuclear weapons are honoured, Belgian law has imposed a licensing system on exports of nuclear materials and equipment, nuclear technological data and their by-products [Act of 9 February 1981].

Licences are granted by the Minister responsible for Energy after obtaining the opinion of this Advisory Committee (formerly the *Commission consultative pour l'exportation des matières et équipements nucléaires, ainsi que des données technologiques nucléaires*) on the non-proliferation of nuclear weapons, responsible for ensuring that the transfer concerned is intended for the peaceful use of nuclear energy.

The members of this Committee are appointed by the King and represent the chief ministries involved.

Leading scientists may be requested by the Committee to give their opinions on specific matters.

e) Federal Council for Science Policy

Pursuant to the Royal Order of 8 August 1997, the mission of the Council is:

- to submit opinions on the proposals for collaboration provided for in Section 6 *bis*, paragraph 3, of the Special Act of 8 August 1980 on Institutional Reforms;
- to formulate, on its own initiative or upon request of the federal or regional governments, opinions and recommendations concerning questions pertaining to science policy at the national level while taking account of the European and international contexts; and
- to formulate, at the request of the federal government, opinions on science policy issues pertaining to the competence of the federal authority provided for in Section 6 *bis*, § 2, 1-4, of the above-mentioned Special Act.

f) Electricty and Gas Regulatory Committee (CREG)

This Commission is an independant organisation with legal personality created by the Act of 29 April 1999 on the Organisation of the Electricity Market. This Commission is endowed with the responsibility to council public authorities regarding the functioning of the electricity market, on the

one hand, and a function of general monitoring of the application of related laws and regulations on the other.

Pursuant to the Act of 29 April 1999 on the Organisation of the Electricity Market, the Commission shall establish a strategic plan on the means of producing electricity in collaboration with the General Energy Directorate of the Federal Pulic Service for Economy, SME's, Self-Employed and Energy, *le Bureau fédéral du plan*, the Interdepartmental Commission for Sustainable Development and the regional governments. The strategic plan, designed as a ten year outlook to be adjusted every three years, is submitted for approval to the Minister holding the portfolio of Energy, and shall contain the following elements:

- an estimate of the evolution of demand and identification of the production requirements that result;
- a summary of the developments of choices of primary energy sources taking care to ensure an appropriate diversification of fuel;
- a summary of favoured sources of production taking care to promote technologies which produce few greenhouse emissions; and
- an evaluation of the obligations of public services in the area of electricity production.

3. Public and Semi-Public Agencies

a) Institute of Science for Public Health

The Royal Order of 6 March 1968 establishing the Institute as a state scientific establishment defines one of its tasks as the study of scientific problems relating to the prevention and correction of factors likely to impair the health and well being of mankind.

In practice, the Institute is the Ministry of Public Health's laboratory and scientific service. Its task is to supply permanent scientific assistance in various fields, including that of radioactivity, to the authorities concerned with public health and environmental protection at national, regional and local levels.

The Institute may, in the performance of its duties, call on the co-operation of outside bodies (CEN, universities, etc.).

b) Nuclear Energy Research Centre (CEN)

The development of nuclear energy applications, which resulted in the Nuclear Energy Applications Research Centre being faced with increasingly complex and diversified activities involving heavy investment which private industry could no longer finance on its own, led the Belgian government to replace this non-profit-making association, set up on 19 April 1952, by the Nuclear Energy Research Centre (*Centre d'études de l'énergie nucléaire* – CEN), a public service (*établissement d'utilité publique*) with administrative headquarters in Brussels and scientific facilities in Mol.

i) Legal status

The Royal Order of 23 July 1957 [amended subsequently by Royal Orders of 4 August 1958 and 7 March 1963] founded the Nuclear Energy Research Centre as a public service. The relationship between the CEN and the national government was regulated by a Convention concluded between the Centre and the Minister holding the portfolio of Energy on 1 February 1963. It provided in particular that the Minister was the supervisory authority of the CEN. This Convention was replaced by a Royal Order of 16 October 1991 which lays down the rules for supervising the Centre and provides for its funding. The royal order also amended its Statute.

In accordance with the Special Act on institutional reforms of 8 August 1988 amending the Act of 8 August 1980, the Special Act for financing the communities and regions of 16 January 1989 and the Royal Order of 16 October 1991 concerning the transfer of some of the tasks, assets, rights and obligations of the Nuclear Energy Research Centre to the Flemish region, the Centre's responsibilities, except for nuclear tasks and administration of the nuclear fuel cycle, were transferred to the Flemish region together with the physical and real property corresponding to the tasks transferred and the members of staff involved.

ii) Responsibilities

The CEN is historically a nuclear research centre, with specific responsibility for basic and applied research (nuclear reactor and fissile fuel safety, radiation protection, safe processing and storage of radioactive waste, protection of nuclear infrastructures from attack, nuclear energy applications, update of scientific documentation, etc.). It therefore offers a major scientific and technical resource potential in the nuclear field, and its role is to pass that potential on to other bodies concerned and to industry.

iii) Structure

The CEN is run by a board of directors with a chairperson, two vice-chairpersons and a maximum of ten other members. A director-general is responsible for carrying out the decisions taken by the board.

iv) Financing

The CEN's budget is funded by public appropriations derived primarily from the budget of the Federal Public Service for Economy, SME's, Self-Employed and by its own revenue in the form of fees for services rendered and research contracts.

c) National Radioisotope Institute (IRE)

Because of the growth in the applications and uses of radioisotopes, the government set up a specialised national body: the National Radioisotope Institute (*Institut national des radioéléments* – IRE), based in Fleurus.

i) Legal status

The Royal Order of 20 October 1971 set up the National Radioisotope Institute as a public service. Its relationship with the national government was regulated by a Convention between the Institute and the Minister holding the portfolio of Energy signed on 28 July 1980. This Convention provided in particular that the IRE is subject to the control of the Minister. It was replaced by the Royal Order of 16 October 1991 laying down the rules relating to the supervision and financing of the National Radioisotope Institute, and amending its Statute.

In accordance with the Special Act on institutional reforms of 8 August 1988 amending the Act of 8 August 1980, the Special Act for financing the communities and regions of 16 January 1989 and the transfer of several activities within the competence of the Walloon region to private companies, the Institute only carries out work related to the nuclear fuel cycle.

ii) Responsibilities

The main tasks of the IRE are:

- to produce and condition radioisotopes;
- to study, promote and encourage applications of radioisotopes;
- to study and develop techniques for processing the radioactive waste arising from such activities; and
- to study, from the standpoint of radiation protection, the safety of persons employed in Belgian firms and institutes using and applying radio-isotopes.

iii) Structure

The IRE is run by a board of directors consisting of a chairperson, two vice-chairpersons and ten other members. A director-general is responsible for carrying out the board's decisions.

d) Higher Institute for Emergency Planning

The Higher Institute for Emergency Planning (*Institut supérieur de planification d'urgence*) was set up by the Royal Order of 29 July 1991 in pursuance of national legislation on protection against major industrial risks and Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency.

i) Legal status

The Institute is a public institution placed under the supervision of the Minister of the Interior.

ii) Responsibilities

The Institute's duties include:

- organising training for emergency planning and assistance;
- promoting the exchange of ideas on emergency planning between the authorities and operators of installations preventing potential major risks (including nuclear installations); and
- disseminating adequate and regularly updated information to persons involved in emergency assistance about the risks they incur and the protection measures to be taken.

In the performance of its duties, the Institute organises conferences and seminars, sets up study groups and undertakes simulation exercises.

iii) Structure

The board of the Institute includes representatives of the different ministries and regional authorities concerned and of various industries, as well as scientists and insurers. Members are appointed for a period of six years by the Minister of the Interior on the proposal of the Minister, regional governments and the institution or body concerned.

iv) Financing

The Institute's operating costs are included in the budget of the Minister of the Interior and of the Civil Service.

e) National Organisation for Radioactive Waste and Enriched Fissile Materials (ONDRAF)

In pursuance of Section 179(2) of the Act of 8 August 1980 relating to the 1979-80 budget proposals, as amended by the Act of 11 January 1991, Belgium set-up a National Organisation for Radioactive Waste and Enriched Fissile Materials (*Organisme national des déchets radioactifs et des matières fissiles* – ONDRAF). The tasks and operating conditions of this Organisation were laid down in the Royal Order of 30 March 1981, amended by a Royal Order of 16 October 1991.

Until ONDRAF began operations in 1982, responsibility for radioactive waste management lay with the waste producers in accordance with the licence granted to them by the authorities. In this context, the "Waste" Department of the Nuclear Energy Research Centre (CEN), which undertook the processing of radioactive waste, played an important role. ONDRAF was set up in order to ensure the long-term coherence and safety of the management of all radioactive waste produced in Belgium. The functions of the "Waste" Department were transferred to ONDRAF, which in turn transferred the operation to its subsidiary Belgoprocess. Since the transfer, several installations of the "Waste" department have been closed down and replaced by new installations.

i) Legal status

ONDRAF is a financially independent public body and legal entity. It is answerable to the Ministers responsible for Economic Affairs and Energy [Order of 16 October 1991, Section 6(3)]. It is also supervised by two government representatives, one appointed by the Minister holding the portfolio of Energy, and the other by the Minister of Employment and Labour, and these representatives take part in the meetings of the board of directors.

ii) Responsibilities

Under the act, ONDRAF is responsible for the management of all radioactive material, wherever its place of origin, as well as certain tasks related to the management of enriched fissile material, plutonium-bearing materials, irradiated fuel and the decommissioning of nuclear installations that have been closed down. The act specifically states that the Organisation may not take charge of waste from a foreign source without first receiving permission from its authorised supervisor.

ONDRAF's tasks include:

- the organisation of transporting processed and non-processed waste;
- the treatment and processing of radioactive waste on behalf of producers who have no equipment approved for such use, as well as the approval and monitoring of the operations necessary for the processing of radioactive wastes at the site of producers who do possess such equipment;
- the storage of radioactive waste outside the producers' facilities;
- the disposal of processed radioactive waste;
- the creation and maintenance of a qualitative and quantitative inventory of processed and non-processed waste, as well as forecasts of the short, medium and long-term production of waste;
- establishing criteria for accepting processed and non-processed waste on the basis of general rules proposed and approved by competent authorities;
- the definition, in dialogue with producers, of the methods for the treatment and processing of non-processed radioactive wastes; and
- the assurance that the quality of radioactive waste conforms to accepted criteria.

In the area of management of surplus quantities of enriched fissile material, plutonium-bearing materials and irradiated or fresh fuel, the Organisation:

- periodically collects the information necessary to allow it to evaluate when and how it shall eventually take possession of these surplus quantities;
- establishes criteria for accepting these surplus quantities with a view to their storage on the basis of general rules proposed and approved by competent authorities; and
- ensures that the properties of the surplus quantities conform to the criteria of acceptance referred to above.

ONDRAF sees to the following aspects of decommissioning closed-down nuclear installations:

- gathering and evaluating all information that allows the Organisation to set-up management programmes for resulting waste;
- approval of the decommissioning plan for contaminated installations;
- carrying-out the decommissioning plan at the request of the operator, or failing this on its own initiative.

With regard to decommissioning, the Organisation follows the development of methodologies and techniques for dismantling and the associated costs, with a view to the approval and the eventual carrying-out of decommissioning programmes.

In order to carry out its tasks, ONDRAF draws up a general programme for radioactive waste management, prepares an inventory of all existing nuclear installations and the sites containing radioactive substances [Act of 12 December 1997]. This responsibility includes the establishment of a register, to be updated every five years, of the locations and state of every nuclear installation and site containing radioactive substances, an estimate of the cost of their decommissioning and cleaning-up, and an evaluation of the sufficiency of financing for these future operations.

Section 9 of the Act of 12 December 1997 states that the Organisation's costs for setting-up the register shall be covered by a licence fee paid by operators of nuclear installations and the persons in possession of radioactive sources or, by way of default, the owners. The amounts of the licence fees were set by the provisional law of 30 December 2001 [Section 90]. This law also sets-up the procedures to follow for the payment of the license fee as well as how to appeal against its levy.

In general terms, ONDRAF provides a public service. Its duties give it no right to encroach on the domain of the authorities responsible for protection or state security in the nuclear field. It must comply with the legislation in force and is subject to the national controls exercised by Minister of Home Affairs, which has certain powers in such matters, and to the international controls exercised within the framework of Euratom and the IAEA.

iii) Structure

ONDRAF is run by a board of directors made up of a chairperson, two vice-chairmen and a maximum of eleven other members selected for their scientific or professional knowledge in the Organisation's fields of activity [Royal Order of 16 October 1991, Section 7(1)].

The chairperson and vice-chairpersons are appointed by the King after consideration by the Council of ministers and on the proposal of the Minister holding the portfolio of Energy.

The other members of the board come either from the Ministerial departments and bodies concerned, or from the scientific and technical world. They are appointed by the Minister holding the portfolio of Energy, after consideration by the Council of Ministers.

Before taking any decision concerning waste management policy or financing, the board hears the opinion of a Standing Technical Committee made up of representatives of the waste producers.

iv) Financing

ONDRAF's income is made up of appropriations from the Ministry of Economy for use as working capital, bequests and grants made to it, statutory and regulatory payment for services rendered, subsidies and occasional revenues. The cost of ONDRAF's activities is recovered in full from the firms and bodies which have benefited from its services.

ONDRAF is obliged to balance its books. It may, however, be authorised to take out loans to finance its investments.

In furtherance of its programme of information and communication ONDRAF created ISOTOPOLIS, an information centre on radioactive waste, which is set-up nearby the site where radioactive waste is treated.

f) Synatom

Section 179, paragraph 1 of the Act of 8 August 1980 on Budgetary Proposals for 1979-80 authorises the state to own at least a 50% stake in a company whose shares are held by both public and private investors, when it manages activities related to the nuclear fuel cycle, with the exception of the management of radioactive waste. The particular company targeted by this legislation was the *Société belge des Combustibles Nucléaires Synatom*, also called Synatom. The participation of the state in Synatom was governed by the Royal Order of 8 March 1983.

Under the Act of 22 July 1993, Belgium decided to sell, among other holdings, its stake in Synatom. The relations between Synatom and the state were thereafter governed by the Royal Order of 10 June 1994 granting a share of Synatom providing privileges to the state. This order summarises the special rights that the state possesses as a result of its privileged share. These rights are:

- to deny certain transfers of property; and
- to name two representatives from the federal government to the Board of Directors of Synatom. These representatives have the right to appeal all Board decisions that it considers to be contrary to the guidelines of the national energy policy to the Minister holding the portfolio of Energy, and that compromise the objectives of the government concerning the supply of energy.

The Royal Order of 10 June 1994 repealed the Order of March 8 1983.

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I. GENERAL REGULATORY REGIME

1. Introduction

There are 22 (CANDU) heavy water reactors in Canada, located at five sites. In 2002 there were 16 operational reactors with a combined installed capacity of 10.3 GWe. Nuclear power provided 70.2 TWh, comprising 12.1% of Canada's total electricity supply.

All of the reactors in Canada are government owned. The government of Ontario owns Ontario Power Generation Inc. (OPG), which operates four units at Darlington, each with an installed capacity of 935 MWe, and eight units at Pickering, five of which are operational, with a combined installed capacity of 2702 MWe. OPG plans to restart the three non-operational units at Pickering between 2004 and 2006, which have a combined installed capacity of 1626 MWe. In 2001, OPG leased the eight units at Bruce NPP to a private sector consortium of investors called Bruce Power for 18 years with an option to renew for 25 years. By the end of 2003, Bruce Power had restarted two previously laid up units. The combined installed capacity of the six operating units at Bruce is 5010 MWe. The Quebec provincial government owns Hydro Quebec, which operates the Gentilly-2 power reactor. Gentilly-2 has an installed capacity of 675 MWe. New Brunswick Power Nuclear Corporation, a subsidiary of the public utility New Brunswick Power, operates Point Lepreau GS, which has one nuclear reactor with an installed capacity of 680 MWe.

There are 16 research reactors in Canada; eight are in operation, five are shut down and three have been decommissioned. Two of the operating research reactors are located at the Chalk River Laboratories site of Atomic Energy of Canada Limited (AECL), and six are located at various universities across the country. The National Research Universal (NRU) reactor at Chalk River produces the majority of the world's supply of critical medical isotopes that are used for diagnosis and treatment of cancer and other illnesses. AECL has completed the pre-project activities for the state of the art research reactor, the Canadian Neutron Facility for Materials Research (CNF). It is designed to replace the NRU's neutron capabilities later in this decade. AECL has designed and constructed two MAPLE reactors and an associated processing facility at the Chalk River site for MDS Nordion, a private health and life sciences company. These reactors will be dedicated to isotope production and will be operated by AECL.

Canada does not reprocess any of its commercial spent fuel. High-level nuclear waste is stored in concrete canisters at the various nuclear power plant sites in Ontario. Hydro Quebec stores spent fuel from Gentilly-2 in an on-site CANSTOR modular storage facility. Spent fuel at Pont Lepreau GS is stored first in wet irradiated fuel bays and then placed in dry storage silos. Low-level waste from the reactors in Ontario is stored at a central facility at the Bruce NPP site. Wastes from small producers are transported to and stored at AECL's Chalk River laboratories; very low-level waste is buried in unlined trenches, and low-level waste is stored in concrete bunkers.

The Canadian uranium mining output amounts to 32% of world supply, more than any other nation. The principal mines in Canada are located at McArthur/Key Lake, McClean Lake and Cluff Lake, which produced a combined 9 700 tons of uranium in 2003.

On 20 March 1997, Canada's Nuclear Safety and Control Act [S.C. 1997, C-9] (hereinafter referred to as "the Act") received Royal Assent and on 31 May 2000, it came into force. This comprehensive legislation replaces the Atomic Energy Control Act, first adopted in 1946, as the means by which the Canadian nuclear industry is to be regulated and by which Canada will comply with its international commitments with respect to the peaceful uses of nuclear energy. It dissolves the former Atomic Energy Control Board (AECB), establishes a new Canadian Nuclear Safety Commission (hereinafter referred to as "the Commission" or CNSC) and clearly distinguishes the regulatory role of the new Commission from that of the federal research, development and marketing organisation known as Atomic Energy of Canada Limited (AECL). The Act is binding upon the Crown, both federal and provincial and upon the private sector.

Under the Act, the Commission has a clear mandate to establish and enforce health, safety, security and environmental protection standards in connection with nuclear activities. The objectives of the Commission also extend to achieving compliance with Canada's international commitments regarding nuclear non-proliferation, safeguards and security. Equally, it is charged with providing objective scientific, technical and regulatory information to the public concerning its own activities and concerning the effects of the nuclear industry on health, safety and the environment [Section 9]. Like its predecessor, the AECB, the Commission has extensive authority to regulate a broad range of activities involving nuclear energy or nuclear materials in Canada including the import, export and transportation of nuclear materials and other prescribed substances, nuclear equipment and nuclear technology [Section 44].

a) Licensing system

The principal regulatory mechanism used by the Commission is a licensing system. Section 26 of the Act prohibits almost every activity associated with nuclear substances, prescribed equipment, prescribed information and nuclear facilities, except in accordance with a licence issued by the Commission; the Commission is also empowered to issue, renew, suspend, amend, revoke or replace a licence, subject to any term or condition that it considers necessary and subject to the payment of the prescribed fee [Nuclear Safety and Control Act, Section 24]. In Canada, there are over 4 000 licensees carrying out activities in the areas of power and research reactors, uranium mines and mills, accelerators, waste management facilities, nuclear medicine, packaging and transport of radioactive materials, industrial gauges and research involving radioisotopes.

The general requirements applicable to all licence applications are found in Section 3 of the General Nuclear Safety and Control (GNSC) Regulations [SOR[1]/2000-202; 31 May 2000]. An applicant must, in particular, provide information on proposed measures for complying with radiation protection and nuclear security regulations and for properly managing and disposing of any radioactive waste. It must also submit information on its organisational management structure to the extent that such structure may affect its compliance with the Act and any regulations made thereunder. Additional information requirements are imposed upon an applicant for a licence to abandon a licensed activity, for the renewal, amendment, revocation or replacement of a licence [Sections 4 to 6].

1. SOR = Statutory Orders and Regulations.

The GNSC Regulations also impose a number of general obligations on all licensees, such as taking all reasonable precautions to protect the environment, to maintain security, to protect the health and safety of persons, and to control the release of radioactive nuclear substances or hazardous substances into the environment. Licensees are equally obliged to train and instruct their workers properly and to ensure that they observe all required safety and health procedures, to implement measures for alerting the licensee to acts of sabotage and to take all necessary measures to facilitate Canada's compliance with safeguards agreements [Section 12]. Obligations are also specifically imposed upon workers to ensure that they, too, comply with and respect the measures and precautions implemented by the licensee for whom they work [Section 17].

There are extensive reporting requirements imposed upon all licensees [Sections 27 *et seq.*], including the obligation to file both preliminary and full reports with the Commission of any potentially dangerous situation, such as unauthorised releases of radioactive nuclear substances, excessive exposure of persons to radiation, a breach of security or attempted act of sabotage, any component or system failure which could have serious adverse effects on the environment or is likely to constitute a serious risk to the health and safety of persons or the maintenance of security and any situation which could interfere with or interrupt the operation of safeguards equipment including theft, loss, sabotage, damage, illegal use, possession or removal of safeguards equipment or samples.

As a result of Canada's federal system, certain nuclear activities have sometimes been subjected to overlapping or duplicative regulation by both the federal and provincial governments. In order to address this concern, the Commission is empowered to establish administrative arrangements with other provincial legislative requirements. The Act, for example, authorises the Commission to enter into agreements with other jurisdictions that may provide for an integrated regulatory regime in respect of specific activities. It also recognises the possibility of incorporating provincial laws, standards and codes into the Commission's regulations [Section 44(6)]. The Commission also co-chairs the Federal-Provincial-Territorial Radiation Protection Committee that provides a national forum on radiation protection issues and develops standards and practices to protect people from radiation exposure.

b) Offences, compliance and enforcement

Under Section 48 of the Act, it is an offence to alter, except as permitted by the regulations or a licence, or to misuse any thing whose purpose is to protect the environment or the health or safety of persons from any risk associated with the development, production or use of nuclear energy or from any risk associated with the possession or use of a nuclear substance, prescribed equipment or prescribed information. It is equally an offence to so alter or misuse any thing whose purpose is to maintain national security or implement international obligations to which Canada has agreed, at a nuclear facility or place where nuclear substances are located. There are, in addition, many other designated offences, including failing to comply with the Act, the regulations made thereunder or a licence condition, unauthorised disclosure of prescribed information, failure to comply with an order of the Commission and falsifying records required to be kept under the Act.

The Commission is empowered under the Act [Section 29] to designate trained inspectors who are authorised to inspect nuclear facilities and places where nuclear substances, prescribed equipment or prescribed information may be kept, for the purpose of verifying compliance with the Act, any regulation, order, or decision made under the Act, or any licence condition. Amongst other things, inspectors are empowered to order a licensee to take any measures considered necessary to protect the environment or the health or safety of persons or to maintain national security or compliance with

Canada's international obligations [Section 35]. Nuclear power plant licensees have resident inspectors from the Commission working full-time on site at their facilities.

In addition, the Commission has the authority to nominate and empower designated officers to perform a variety of duties, including certification of prescribed equipment, issuing, renewing, suspending, amending, revoking or replacing a licence, making any remedial action order that an inspector may make and confirming, amending, revoking or replacing any order made by an inspector [Section 37]. In most cases, orders by inspectors or designated officers must be made in accordance with prescribed rules of procedure [Section 38] and it is an offence under the Act to fail to comply with an order of a designated officer or an inspector [Section 48(e)].

Violations can be penalised by an escalating range of actions, including warnings, orders by inspectors or designated officers, licence suspension and prosecution. In addition, for offences under the Act, a convicted offender may be required by the court to pay compensation to any person who has suffered loss of, or damage to property as a result of the offence [Section 62]. Punishment for summary conviction offences consists of fines ranging up to 500 000 Canadian dollars (CAD) or imprisonment for up to 18 months or both, whereas for indictable offences the punishment ranges from fines up to CAD 1 000 000 or imprisonment for up to five years or both [Section 51(3)]. For unauthorised possession of a nuclear substance, prescribed equipment or prescribed information capable of being used to produce a nuclear weapon or a nuclear explosive device, the punishment is imprisonment for up to ten years [Sections 50 and 51(2)]. For all offences except the last, the defence of having exercised due diligence to prevent its commission is available [Section 51.1].

The AECB Cost Recovery Fees Regulations 1994, which have been continued in force by Section 80 of the Act, implement the Commission's authority under Section 44 of the Act to prescribe fees that may be charged for the provision of information, products and services by the Commission and for licences or a class of licence. The regulations apply to most licence applications although publicly funded health care and educational institutions and federal departments and agencies are exempt from the fees.

c) Regulatory documents

The Commission operates within a legal framework that includes both legally enforceable instruments such as acts, regulations, licences and directives, and regulatory documents that are used to support and provide further information on these instruments. Regulatory documents are a means of informing applicants of the Commission's regulatory expectations. During the development of each regulatory document, the Commission engages in extensive consultation on all aspects of the document with all those who will be affected by it. These documents are classed as follows:

- *Regulatory policy*: a document that describes the philosophy, principles and fundamental factors used by the Commission in its regulatory programme.

- *Regulatory standard:* a document that is suitable for use in compliance assessment and describes rules, characteristics or practices which the Commission accepts as meeting the regulatory requirements. Regulatory standards can become legally enforceable when incorporated as conditions in a licence.

- *Regulatory guide:* a document that provides guidance or describes characteristics or practices that the Commission recommends for meeting regulatory requirements or improving administrative effectiveness.

- *Regulatory notice:* a document that provides case-specific guidance or information to alert licensees and others about significant health, safety or compliance issues that should be acted upon in a timely manner.

- *Regulatory procedure:* a document that describes work processes that the Commission follows to administer the regulatory requirements for which it is responsible.

d) Other relevant legislation

Certain activities that are regulated by the Commission also require an environmental assessment under the Canadian Environmental Assessment (CEA) Act of 23 June 1992 [C-15.2]. This act requires, subject to specific exclusions [Section 7], that an environmental assessment be carried out in respect of projects for which federal, provincial or territorial government approval is needed or for which federal land or funding is needed [Section 5]. The assessment identifies whether the project is likely to cause significant adverse environmental effects and an "environmental effect" is defined as any change that a project may cause to land, water, air, living organisms or to the natural system in which these components interact. If possible adverse effects can be identified before they occur, then decision-makers can modify the project so as to mitigate such effects.

Under both the CEA Act and the Commission licensing process, the public is given ample opportunity to participate. The Commission maintains up-to-date information on all of its current environmental assessments and the Canadian Environmental Assessment Agency, which is established under the CEA Act [Section 61], maintains a public registry of all environmental assessments conducted by Canadian government departments and agencies, including the Commission [Section 55].

The Commission also monitors the environmental performance and compliance of its licensees to ensure that their activities are consistent with Commission licence conditions and Canada's international obligations.

There are, in addition, the Transportation of Dangerous Goods Act 1992 [T-19.01] and the Transportation of Dangerous Goods Regulations [SOR/85-77]. These regulations establish classes of dangerous goods, an identification list of common dangerous goods and the safety requirements for identification, packaging and shipment of these dangerous goods in a manner similar to the United Nations Recommendations on the Transport of Dangerous Goods. For radioactive material, the act and regulations refer to the Nuclear Safety and Control Act and the Packaging and Transport of Nuclear Substances Regulations 1983 [SOR/83-740] for the specifics of health and safety protection requirements for packaging and transport. For international air and sea transport, the Transportation of Dangerous Goods Regulations refers to the appropriate international regulations of the International Civil Aviation Organisation (ICAO) and the International Maritime Organisation (IMO).

Another important Canadian statute passed by the Canadian parliament in 1970 is the Nuclear Liability Act [R.S.[2] 1985, C-N-28]. This legislation addresses the issue of civil liability for damage suffered by third parties as a result of nuclear incidents at defined nuclear installations. The act is based upon the same principles that form the basis of international conventions in this field, even though Canada is not party to any such conventions. However, in light of the rather low operator liability limit that is provided for, it is likely that the act will be amended in the future.

2. R.S. = Revised Statutes.

2. Mining Regime

Canada's constitutional arrangements result in a division of jurisdiction between the federal and the provincial governments in relation to uranium mining and milling activities. While the federal government has jurisdiction to legislate in respect of the uses of uranium, the provincial governments are responsible for enacting legislation in respect of the exploitation of all mineral resources (including uranium). As a result, uranium mining and milling activities have sometimes been subjected to regulation by both levels of government. In order to avoid such situations in the future, the Nuclear Safety and Control Act authorises the incorporation by reference of provincial laws, standards and codes into the regulations of the CNSC [Section 44(6)] and authorises the Commission to enter into arrangements with provincial jurisdictions that may provide for an integrated regulatory regime in respect of specific activities [Section 21(1)(a)].

In November 2000, the President of the Commission and the Ministers of Saskatchewan Environment and Resource Management and Saskatchewan Labour signed a Memorandum of Understanding under which the Commission and the provincial regulators agreed to collaborate in the development and implementation of a harmonised regulatory regime for uranium mines and mills in Saskatchewan. Discussions between staff of the Commission and officials from the Province are currently underway.

In addition, Human Resources Development Canada, which is responsible under the Canada Labour Code for regulating labour standards, labour relations and conventional (non-nuclear) occupational health and safety matters at nuclear facilities, has, in consultation with Saskatchewan Labour, finalised regulations excluding Saskatchewan uranium mines and mills from application of Part II (occupational health and safety) of the Code, and incorporating by reference in its place a number of provincial statutes regulating conventional occupational health and safety. The administration of these regulations will be delegated to Saskatchewan Labour.

The Commission is also given the authority to make regulations respecting the mining, production and refinement of a nuclear substance [Nuclear Safety and Control Act, Section 44(1)(b)], and the term "nuclear substance" is defined in Section 2 of the Act to specifically include "uranium". The Act prohibits anyone from, *inter alia*, mining, producing or refining a nuclear substance except in accordance with a licence [Section 26(b)]. The Commission is authorised to issue, renew, suspend, amend, revoke or replace licences for that purpose [Section 24(2)] and to attach conditions to those licences [Section 24(5)].

In exercising its authority under the Act, the Commission has made the Uranium Mines and Mills Regulations [SOR/2000-206; 31 May 2000] which comprise, essentially, the same requirements as were contained under the now repealed Uranium and Thorium Mining Regulations [SOR/88-243, as modified]. The regulations do not apply to uranium prospecting or surface exploration activities [Section 2(2)], but they do impose comprehensive licensing requirements upon anyone who wishes to prepare a site for, construct, operate, decommission or abandon a uranium mine or mill.

Licence applications must be accompanied by detailed information on the activity to be licensed, the plan and description of the facility, associated environmental and waste management measures, health and safety concerns and security measures [Sections 3 and 5-8]. In addition, licence applicants (other than a licence to abandon) must provide a Code of Practice that describes the measures and procedures which the applicant will take where a specific dose of radiation or other parameter is reached, possibly indicating a loss of control of part of a licensee's radiation protection programme or environmental protection programme, and triggering a requirement for a specific action to be taken [Section 4].

In addition to setting out licensing requirements, the regulations impose a number of specific obligations upon licensees with respect to operating procedures, worker training programmes, maintenance of ventilation systems, use of respirators, gamma radiation dose rate notices, and maintenance and availability of records required to be kept in respect of the licensed activity [Sections 9 to 16].

3. Nuclear Substances and Radiation Devices

Under the Nuclear Safety and Control Act, the Commission is authorised to make regulations respecting, *inter alia*, the conversion, enrichment, processing, reprocessing, possession, import, export, use, packaging, transport, management, storage, disposal and abandonment of nuclear substances [Section 44(1)(b)]. Pursuant to that authority, the Commission has made the Nuclear Substances and Radiation Devices Regulations [SOR/2000-207; 31 May 2000], supplementing the General Nuclear Safety and Control Regulations, and applying to all nuclear substances, sealed sources and radiation devices not already covered by other regulations.

A "nuclear substance" is broadly defined as: deuterium, thorium, uranium, an element with an atomic number greater than 92 or any derivative or compound of any of them, a radioactive nuclide, a substance prescribed by regulation as being capable of releasing nuclear energy or as being required for the production or use of nuclear energy, a radioactive by-product of the development, production or use of nuclear energy; and a radioactive substance or thing that was used for the development or production, or in connection with the use, of nuclear energy [Nuclear Safety and Control Act, Section 2(2)]. A "radiation device" is defined under these new regulations to mean a device that contains more than the exemption quantity of a nuclear substance and that enables the nuclear substance to be used for its radiation properties, as well as a device that contains a radium luminous compound [Section 1]. The new regulations also contain criteria for consumer products such as smoke detectors and safety signs using tritium. Given their broad application, these regulations apply to almost every licensee.

In general, the regulations reflect international practice but there are some minor variations based upon Canadian policy and circumstances. Licence applicants must provide very detailed information concerning the substance or device in respect of which a licence is sought, including information on the methods, procedures and equipment to be used to carry on the licensed activity, to be used during or following an accident to monitor nuclear substance releases, to detect and record radiation dose rates and quantities and to limit the spread of radioactive contamination within and from the site. Information is also required on the methods, procedures and equipment used to calibrate radiation survey meters and dosimeters and to conduct leak tests and surveys as well as on equipment and system inspection programmes, instructions for dealing with accidents, worker training programmes and a number of other safety related matters [Section 3(1)].

Activities that are exempt from the licensing requirements are set out in Sections 5 to 8 of the regulations. Generally, they include activities involving a nuclear substance which does not exceed its exemption quantity as set out in the Schedule to the regulations or where the quantity is considered to be an acceptable function of that exemption factor [Section 5]. In addition, exempted activities extend, under specified conditions and circumstances, to smoke detectors containing a nuclear substance [Section 6], tritium-activated self-luminous safety signs [Section 7] and other devices containing a radium luminous compound [Section 8].

Many of the regulations' provisions deal specifically with radiation protection in the context of industrial radiography [Sections 30 to 35]. They impose detailed obligations on licence holders in

respect of the use or possession of radiography equipment including qualifications and training of the licensee's staff, dose limits applicable to workers and non-workers, the levels of maintenance and security to be observed in relation to the equipment, procedures to be followed by anyone operating the equipment, and measurement and recording of radiation doses received by anyone who has operated the equipment. They also provide for the certification of radiation devices [Sections 11 to 15] and impose general obligations upon licensees with respect to the safe and proper use of nuclear substances and radiation devices by workers or others who might come into contact with such substances and devices [Sections 16 to 23].

Specific requirements are set out for the operation of exposure devices [Sections 24 to 34], including radiation sources used to radiograph structures such as pipeline welds, aircraft components and pressure vessels. The new regulations require all exposure device operators to wear an audible alarming dosimeter to alert them to dangerous levels of radiation before significant exposures occur. Previously only trainees were required to wear these devices.

Every licensee is required to keep and retain detailed records of nuclear substances in its possession or which it received, disposed of or abandoned, of workers who handled nuclear substances and the training they received, and of inspections and servicing performed by the licensee [Section 36(1)]. Similarly detailed record-keeping requirements are imposed on licensees of exposure devices [Section 37]. Finally, licensees who become aware of potentially dangerous situations, such as where an exposure device or sealed source assembly is lost, are required to make both preliminary and full reports to the Commission concerning the circumstances of the situation and what corrective or remedial measures the licensee has taken or proposes to take [Section 38].

4. Nuclear Facilities

Under the Nuclear Safety and Control Act, the definition of nuclear facilities includes reactors, particle accelerators, uranium processing plants, waste management facilities and, because their level or risk falls within the range of other nuclear facilities, plants that possess, process or use large quantities of radioactive material [Section 2]. However, since licensing criteria vary significantly for these various facilities, they are divided into two classes of facilities, with the Class I Nuclear Facilities Regulations [SOR/2000-204; 31 May 2000] applying to major facilities such as reactors, high-energy accelerators and uranium processing facilities, and Class II Nuclear Facilities and Prescribed Equipment Regulations [SOR/2000-205; 31 May 2000] covering such things as low-energy particle accelerators, irradiators and radiation therapy installations because of the low risk these types of facilities represent.

The licensing requirements for both Class I and Class II are essentially the same as those applicable under the former legislation. Separate licences are required for constructing, operating and decommissioning the facility. In respect of Class I nuclear facilities, separate licences are also required in respect of preparing the site for the facility [Class I Nuclear Facilities Regulations, Section 4] and for abandoning the facility [Section 8]. A licence is also required in respect of the use of Class II prescribed equipment [Class II Nuclear Facilities and Prescribed Equipment Regulations, Section 6] and the equipment must either be certified by the Commission or a designed officer authorised under the act, or be used in accordance with a licence authorising its use for development purposes [Section 10].

The regulations set out detailed information requirements in respect of all such licence applications. These include (i) the general requirements provided for in Sections 3 and 4 of the General Nuclear Safety and Control Regulations; (ii) more specific requirements such as providing a

site description and plan, quality assurance programme, proposed worker health and safety policies, environmental protection policies and decommissioning plans; and finally (iii) the precise requirements relevant to each particular type of licence, as set out in Sections 4 to 8 of the Class I Nuclear Facilities Regulations and in Sections 3 to 6 of the Class II Nuclear Facilities and Prescribed Equipment Regulations. In addition, the Class II Regulations set out special radiation protection requirements for both nuclear facilities [Sections 15 to 17] and prescribed equipment [Sections 18 to 20] to ensure personal safety of both the user of the facility or equipment and the recipient of the radiation dose administered.

The Class I Nuclear Facilities Regulations provides that senior control room staff of nuclear power reactors will now need to be re-certified as competent every five years. In order to attain such re-certification, the staff will be required to successfully complete a continuing training programme and re-qualification tests, both of which are to be administered by the licensee and evaluated regularly by the Commission [Section 9].

The Class II Nuclear Facilities Regulations requires nuclear safety service providers to be licensed. In the past, there was no regulatory control over the work performed by companies who provided technical services to Class II nuclear facility operators and to nuclear substance licence holders, such as repairing safety systems. The new regulations now require such service providers to be licensed where they are providing nuclear-safety related services and the information required to be submitted in respect of a licence application is set out in Section 3 of the General Nuclear Safety and Control Regulations and in Section 7 of the Class II Nuclear Facilities Regulations.

Extensive record keeping requirements are imposed upon licensees of both Class I and Class II nuclear facilities and Class II prescribed equipment. For Class I facilities, these relate primarily to the results of effluent and environmental monitoring programmes, operating and maintenance procedures, the nature and amount of radiation, nuclear substances and hazardous substances within the facility, the status of each worker's qualifications and training and special reports in respect of the decommissioning of the facility [Section 14]. For Class II facilities and equipment, records shall be kept of, amongst other things, radiation surveys, radiation output from equipment, employee training, the transfer of equipment, and sealed source leak test results [Section 21].

On 18 December 2001, the Canadian government enacted the Anti-Terrorism Act [Statutes of Canada 2001, Chapter 41]. The act provides for measures to identify, prosecute, convict and punish terrorist groups and provides new investigative tools to law enforcement and national security agencies. The Anti-Terrorism Act has relevance to the nuclear field in that it defines as "terrorist activity" the existing offences in the Canadian Criminal Code that implement the 1980 Convention on the Physical Protection of Nuclear Material (see Section 4 – which adds a new Part II.1 to the Criminal Code).

The Anti-Terrorism Act defines terrorist activity as an act or omission, in or outside Canada, that takes place or is threatened for political, religious or ideological purposes and threatens the public or national security by killing, seriously harming or endangering a person, causing substantial property damage that is likely to seriously harm people or by interfering with or disrupting an essential service, facility or system.

The Canadian Nuclear Safety Commission issued an order aiming to increase security at major nuclear installations on 18 October 2001. Pursuant to the Nuclear Safety and Control Act, the Commission is empowered to make any order that it considers necessary to protect the environment or the health and safety of persons or to maintain national security and compliance with Canada's international obligations [Section 47].

This order imposes specific security arrangements and measures on the five leading nuclear operators in Canada. It requires increased screening of personnel (background checks) and more stringent measures to verify the identity of personnel entering the facilities. Further, it provides for the presence of armed guards on site for security reasons, improved equipment for security personnel, enhanced measures to prevent forced entry by vehicles and more effective searching of personnel and vehicles entering a facility site.

At the international level, Canada is a Party to the 1994 Convention on Nuclear Safety, ratified on 12 December 1995. It also ratified the 1986 Convention on Early Notification of a Nuclear Accident on 18 January 1990.

5. Trade in Nuclear Materials and Equipment

The import or export of prescribed equipment, prescribed information or a nuclear substance is prohibited except in accordance with a licence [Nuclear Safety and Control Act, Section 26]. The Commission is authorised to issue licences for those activities [Section 24]. In addition, the Commission is authorised to make regulations respecting the import and export of nuclear substances, prescribed equipment and prescribed information [Section 44]. That authority has resulted in the Nuclear Non-proliferation Import and Export Control Regulations [SOR/2000-210; 31 May 2000] which apply to the import and export of controlled nuclear substances, controlled nuclear equipment and controlled nuclear information [Section 2]. These include nuclear-related dual-use items.

Controlled nuclear substances are listed in the Schedule to the regulations as including in Part A certain categories of special fissionable material, source material, deuterium and heavy water, nuclear grade graphite and tritium. Controlled nuclear equipment is shown in the same Schedule to include nuclear reactors, plants for the reprocessing of irradiated fuel elements, plants for the fabrication of nuclear reactor fuel elements, plants for the separation of isotopes of uranium, plants for the production or concentration of heavy water, deuterium and deuterium compounds, plants for the conversion of uranium and certain equipment especially designed or prepared for such reactors and plants together with parts for such reactors and plants. “Controlled nuclear information” is defined to include technical data of any kind and in any form, other than data available to the public, respecting any item listed as a controlled nuclear substance or controlled nuclear equipment. Part B of the Schedule includes nuclear-related dual-use items.

Applicants for a licence to import or export any controlled substance, equipment or information must submit an application containing specific information such as its origin, its description, its supplier and final consignee, its intended end-use and its intended end-use location [Section 3]. In general, the new regulations increase the number of items for which import licences are required so that Canada will be in a better position to implement its international obligations with respect to the control of nuclear equipment. However, in practice, Canada imports relatively little of this equipment. Certain activities are exempt from licensing, such as the import of a controlled nuclear substance that is classified as a dual-use item and that is not a radioactive nuclide, or the import of controlled nuclear equipment that is classified as parts or a nuclear-related dual-use item [Section 4].

a) Exports

Canada is a Party to the Treaty on the Non-Proliferation of Nuclear Weapons. Canada’s exports of uranium, heavy water and nuclear equipment and technology for nuclear fuel cycle use are subject

to Canada's nuclear non-proliferation policy (see Section 8 "Non-Proliferation and Nuclear Security", *infra*).

Canada exports uranium, heavy water, nuclear reactor and other fuel cycle equipment and technology for nuclear power use. Canada also exports radioisotopes, deuterium and uranium for agricultural, medical and industrial use. Apart from the Nuclear Safety and Control Act and the Nuclear Non-proliferation Import and Export Control Regulations, Canada's nuclear export activities are governed by the Export and Import Permits Act [R.S. 1985, c. E-19]. That act permits the government to establish an Export Control List, whose basic purpose is to prevent the export of articles with "a strategic nature or value" if such export could be detrimental to Canada's security. It also permits Canada to implement its international commitments, and control the export of its natural resources [Section 5]. Anyone wishing to export an item on the Export Control List must apply to the Minister of Foreign Affairs for a permit which may be made subject to specific terms and conditions [Section 7]. Administrative arrangements ensure that terms and conditions of the permit issued under the Export and Import Permits Act do not duplicate conditions imposed on the licence issued by the Commission.

b) Other imports

The possession, sale and importation of certain categories of equipment emitting radiation, but not intended for the production of nuclear energy within the meaning of the Nuclear Safety and Control Act, are governed by the Radiation Emitting Devices Act (REDA) [R.S. 1985, c. R-1]. The Minister of Health and Welfare is responsible for implementing this act. The REDA regulates the sale, lease and importation of all devices capable of producing and emitting radiation except those that are designed primarily for the production of nuclear energy [Section 3]. The act creates various classes of device, and regulations made under the act prescribe standards relating to the design, construction and functioning of each class. The sale, lease or importation of a radiation emitting device that does not comply with the appropriate standard is prohibited [Section 4]. The prohibition is reinforced by the criminal law; a person convicted of an offence under the act may be fined or imprisoned or both [Section 14].

6. Radiation Protection

The Radiation Protection Regulations [SOR/2000-203; 31 May 2000] contain the radiation protection requirements applicable to all licensees as well as others who fall under the jurisdiction of the Commission. Their primary focus is the protection of nuclear energy workers from the effects of ionising radiation and minimising health risks to the general public. The regulations do not apply to medical doses, doses to non-professional caregivers and doses to volunteers in biomedical research [Section 2(2)].

Every licensee is required to implement a radiation protection programme which includes keeping the amount of exposure to radon progeny (defined as specific radioactive decay products of radon 222) and the effective dose and equivalent dose received by and committed to persons as low as is reasonably achievable, social and economic factors being taken into account [Section 4]. Amongst other obligations, licensees must also ascertain the quantity and concentration of any nuclear substance released as a result of the licensed activity, and must comply with specific obligations regarding methods of ascertaining and recording doses of radiation, actions to be taken when a specific dose of radiation is reached (action level), and providing nuclear energy workers with full particulars of the risks associated with radiation to which they may be exposed [Sections 5 to 9].

The regulations prescribe the maximum permissible doses and exposures for nuclear energy workers, pregnant nuclear energy workers and members of the public [Sections 13 and 14 and Schedules I and II]. Except with respect to pregnant nuclear energy workers, the new dose limits reflect the 1991 Recommendations of the International Commission on Radiation Protection (ICRP) which call for lowering the dose limits for nuclear energy workers from 50 millisievert (mSv)/year to 100 mSv for five years and for members of the public from 5 mSv/year to 1 mSv/year. As regards pregnant nuclear energy workers, the maximum effective dose to the worker during the period of pregnancy is set at 4 mSv/year.[3] The regulations provide for exceptions to the dose limits in emergency situations [Section 15], as well as prescribing actions to be taken by licensees when the dose limits received by any person exceed the applicable limit [Sections 16 and 17].

Sections 18 and 19 of the regulations prescribe the requirements for a licence application in respect of the operation of a dosimetry service as well as the obligations imposed upon the licensee who operates such services. The latter include the obligation to file with the National Dose Registry of the Department of Health, specified information with respect to each nuclear energy worker for whom it has measured and monitored a dose of radiation.

An amendment to the Nuclear Safety and Control Act came into effect on 13 February 2003 varying the classes of persons that the Canadian Nuclear Safety Commission may order to clean up contaminated places.

Under the heading "Exceptional Powers", Section 46 of the NSCA provides the Commission with the authority to hold a public hearing to determine whether contamination has occurred in any place and if so, to order certain persons to take measures to reduce the level of contamination [Subsection 46(3)]. The provision now reads as follows:

"Where, after conducting a hearing, the Commission is satisfied that there is contamination referred to in subsection (1), the Commission may, in addition to filing a notice under subsection (2), order that the owner or occupant of, or any other person who has the management and control of, the affected land or place take the prescribed measures to reduce the level of contamination."

Finally, Sections 20 to 22 of the regulations set out the labelling requirements in respect of containers or devices that contain a radioactive nuclear substance, together with the radiation warning symbol and sign posting requirements in respect of an area, room, enclosure or vehicle where there are specified quantities of radioactive nuclear substances or where there is a reasonable probability that a person will be exposed to a specified dose rate.

7. Radioactive Waste Management

Section 26 of the Nuclear Safety and Control Act prohibits the storage or disposal of nuclear substances, the abandonment of prescribed equipment, and the decommissioning or abandonment of a nuclear facility or a nuclear-powered vehicle except in accordance with a licence issued by the Commission. Disposal must be carried out in accordance with the conditions of a licence that has been issued by the Commission in relation to that particular substance, equipment or facility. Licence

3. The 1991 ICRP Recommendations call for lowering the dose limits for pregnant nuclear workers from 10 mSv/year to 2 mSv/year. However, in light of comments received concerning the extent to which such a significant reduction could affect employment opportunities for women in the nuclear industry, and as a result of a comprehensive consultation process and a thorough review of the risks of radiation, the maximum effective dose was set at 4 mSv in the new regulations.

conditions in relation to waste management are aimed at ensuring the protection of health, safety, security and the environment.

Radioactive waste management facilities are nuclear facilities for the purposes of the Nuclear Safety and Control Act [Section 2], and therefore can only be operated according to the terms and conditions of a licence issued under the relevant regulations.

An important innovation in the licensing system under the new legislation is the authority given to the Commission to impose a licence condition requiring a licensee to provide a financial guarantee for decommissioning and waste management costs associated with the licensed nuclear facility [Nuclear Safety and Control Act, Section 24(5)]. This requirement is implemented through the General Nuclear Safety and Control Regulations that require licence applicants to provide information on proposed financial guarantees and to describe their plans for decommissioning and waste management at the end of the life of the nuclear facility [Section 3(1)]. Substantial flexibility is permitted in the ways in which licensees can meet these financial requirements, but the objective remains constant: to eliminate the risk of such liabilities having to be borne by the public such as might occur in the case of a licensee's insolvency.

In June 2000, the Commission issued two related regulatory guides, G-219, "Decommissioning Planned for Licensed Activities", and G-206, "Financial Guarantees for the Decommissioning of Licensed Activities". Together they provide guidance regarding the preparation of decommissioning plans for activities licensed by the Commission and the criteria used to evaluate financial guarantee mechanisms that a licence applicant may propose.

The Nuclear Fuel Waste Act [Statutes of Canada 2002, Chapter 23] was enacted on 13 June 2002 and entered into force on 15 November 2002. The act provides a framework for the long-term management of nuclear fuel waste in Canada by putting the onus on the owners of the waste to study approaches to managing the waste, to recommend an approach to the government of Canada and to finance the long-term management of the waste.

The act requires nuclear energy corporations to establish a non-profit waste management organisation (WMO) which must propose to the government of Canada, within three years of the coming into force of the act, approaches for the management of nuclear fuel waste and must implement the approach that is selected by the government. Each of the following methods must be the sole basis of at least one approach studied by and reported to the government by the WMO:

- deep geological disposal in the Canadian Shield;
- storage at nuclear reactor sites; and
- centralised storage, either above or below ground.

The act provides that the WMO must consult with the general public, and in particular aboriginal peoples, on each of the proposed approaches for the management of the waste.

In relation to requirements under the act, the new legislation assigns responsibility for oversight of the WMO, the nuclear utilities and Atomic Energy Canada Limited (AECL) to the government of Canada. This oversight responsibility will reside within Natural Resources Canada.

Under the provisions of the act, nuclear energy corporations and AECL must finance the long-term management of nuclear fuel waste by establishing trust funds. The amounts that they must contribute to the trust funds are specified in the act. These amounts vary for each entity. The funds

may only be used by the WMO to implement the approach selected by the government and the first withdrawal of funds may only be made for an activity in respect of which a construction or operating licence has been issued under the Nuclear Safety and Control Act after the government has made a decision on the approach. Once the approach is implemented, the WMO is required to offer its waste management services at a reasonable cost to AECL and all owners of nuclear fuel waste produced in Canada.

The WMO must report to the government of Canada annually on its activities. The study, reports and financial statements that the WMO is required to submit to the Minister of Natural Resources must be made available to the public.

The act sets out offences and punishments if a nuclear energy corporation, AECL or the WMO fail to comply with it.

At the international level, Canada ratified the 1997 Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management on 7 May 1998. Canada is also Party to the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and other Matter (ratified on 13 November 1975) and to its 1996 Protocol (ratified on 15 May 2000). Canada has ocean dumping control legislation[4] which reflects its obligations under the Convention, that is, the prohibition of dumping of high-level radioactive waste, but the legislation provides for the licensing of dumping low-level radioactive waste at sea. Recent amendments to the Convention extending the ban on dumping to low-level radioactive waste[5] mean that Canada is now obliged to prohibit the dumping at sea of all radioactive waste.

8. Non-Proliferation and Nuclear Security

Canada ratified the 1968 Treaty on the Non-Proliferation of Nuclear Weapons (NPT) on 8 January 1969, as well as the 1996 Comprehensive Nuclear Test Ban Treaty on 18 December 1998 and it participates actively in international atomic energy control measures. The Department of Foreign Affairs and International Trade is responsible for negotiating Canada's bilateral nuclear co-operation agreements with other countries, covering trade in nuclear materials, equipment and technology, and it does so with the participation of the Canadian Nuclear Safety Commission. It is the Commission, however, which administers them and there are currently 38 such agreements signed by Canada. In accordance with Canada's nuclear non-proliferation policy, nuclear co-operation will be authorised only for those non-nuclear weapon states that have either ratified the NPT or have taken an equivalent binding step and have thereby accepted the International Atomic Energy Agency (IAEA) safeguards on the full scope of their nuclear activities. Furthermore, nuclear exports can go forward only to those states (both nuclear and non-nuclear weapon states) that have undertaken to accept in a formal nuclear co-operation agreement a number of additional requirements designed to minimise the proliferation risk associated with Canadian nuclear exports.

Safeguards inspectors from the IAEA carry out regular inspections of Canadian nuclear installations to ensure that Canada complies with its own NPT-type full scope safeguards agreement with the Agency. The Commission facilitates the implementation of this agreement [IAEA: INFCIRC/64] by providing information on and access to nuclear material for accounting and verification.

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4. The Canadian Environmental Protection Act, assented to 14 September 1999 [R.S. 1999, C-33].

5. The ban, which is to remain in force for 25 years, became effective on 20 February 1994.

Canada ratified the 1979 Convention on the Physical Protection of Nuclear Material on 21 March 1986. As a result of Canada's obligations as a party to that Convention, and having regard to IAEA recommendations, the Physical Security Regulations [SOR/83-77] were made under Section 9 of the now repealed Atomic Energy Control Act. With the replacement of that act by the Nuclear Safety and Control Act came the replacement of those regulations by the Nuclear Security Regulations [SOR/2000-209; 31 May 2000].

The new regulations define the licensing requirements and security measures required for the physical protection of certain nuclear materials and of nuclear reactors that may exceed 10 MW thermal power during normal operation [Section 2]. These nuclear materials are divided into Categories I, II or III, depending upon their level of risk. The composition of the three categories is set out in the Schedule to the regulations.

A licence is required for all nuclear materials and reactor facilities covered by the regulations [Sections 3 and 4]. In all cases, except for Category III nuclear materials which pose the least risk, the applicant must provide, amongst other information, a security plan which describes its protection arrangements with a response force, a description of its proposed security equipment, systems and procedures, its on and off-site communications equipment, system and procedures, the structure and organisation of its nuclear security guard services and its proposed plan and procedures to respond to breaches of security [Section 3].

A separate licence is required for the transport of Category I, II or III nuclear material. Applicants must submit, in particular, a transportation security plan that includes a threat assessment, proposed security measures, communications arrangements between the licensee, the vehicle operator, the recipient of the material and any response force along the route, arrangements with that response force and planned and alternate emergency routes [Section 5].

The regulations also impose general obligations upon licensees with respect to the areas in which licensed nuclear materials may be processed, used and stored: an inner area for Category I material, a protected area for Category II material, and either a controlled access, visually surveyed or protected area for Category III material [Section 7]. Nuclear facilities to which the regulations apply must also be located in a protected area [Section 8]. The requirements concerning the physical protection of both protected areas and inner areas are specifically set out in the regulations as are the measures to be taken in respect of entry into and exit from those areas.

A protected area must be enclosed by a barrier constructed to prohibit any unauthorised entry into that area [Section 9] and be surrounded by an unobstructed area, maintained to ensure that the barrier is not breached [Section 10]. Protected areas must be continuously illuminated and equipped with devices that detect any intrusion and that facilitate an immediate assessment of the cause of the alarm [Section 11]. Inner area requirements are more stringent, and include a barrier constructed to prevent unauthorised access to the area or removal of Category I material therefrom before a response force can effectively intervene, more tightly secured access requirements in respect of openings in the barrier, and greater security requirements in respect of intrusion detection devices [Sections 13 and 14].

The regulations prohibit unescorted access of any person into a protected area except with the written authorisation of the licensee [Section 17]. Unescorted access into an inner area is only allowed with the written authorisation of the Commission [Section 18]. Both the licensee and the Commission are given the power to revoke authorisations to enter a protected area or an inner area [Sections 21 and 22]. Special provisions in the regulations exempt Commission appointed inspectors from the authorisation requirements regarding entry into protected and inner areas [Section 29].

New security requirements under these regulations mean that licensees must install and continuously maintain additional alarm assessment equipment in protected areas and an alarm assessment system in inner areas to facilitate the immediate assessment of the cause of the alarm. In addition, licensees are required to search or otherwise monitor persons without an authorisation, and their possessions, when entering or leaving a protected and inner area. Searches can be carried out by technical means and are similar to Canadian airport security standards [Section 27].

In respect of nuclear facilities covered by the regulations, the licensee is required to have available a sufficient number of trained security guards to enable him to comply with the Regulations [Section 30] and the Commission must give its consent to the appointment of such guards upon application by the licensee [Section 31]. The licensee must also make written arrangements with a response force to provide for the protection of Category I and II nuclear materials and nuclear facilities [Section 35], and in addition, he must conduct security drills every six months to test the operation of security equipment, systems and procedures [Section 36].

9. Transport

The Commission has the power to make regulations governing the transport of nuclear substances [Nuclear Safety and Control Act, Section 44(1)] and it has principally exercised this power by making the Packaging and Transport of Nuclear Substances Regulations [SOR/2000-208; 31 May 2000]. These regulations revise the Transport Packaging of Radioactive Materials Regulations, 1983 [SOR/83-740], and are based upon the 1985 IAEA Recommendations for such packaging requirements, as amended in 1990. In fact, since these new regulations make such numerous references to the IAEA Regulations for the Safe Transport of Radioactive Material (Safety Series No. 6), the Commission has reproduced that reference material with the IAEA's approval, and it is freely available to all licence applicants.

The regulations apply to all aspects of the packaging and transport of nuclear substances, including the design, production, use and maintenance of packaging and packages, and the preparation, consigning, handling, loading, carriage, storage during transport, receipt at final destination and unloading of packages [Section 2(1)]. They require a licence for the transport of Category I, II and III nuclear material in accordance with the Nuclear Security Regulations (see Section 8 "Non-Proliferation and Nuclear Security" *supra*), except where the nuclear substances are in transit or are packaged and transported under a "special arrangement" as defined in the IAEA Regulations [Section 3]. In these latter two cases, for which licences are also required, Sections 4 and 5 describe the extensive information requirements imposed upon licence applicants.

The regulations impose general obligations and divide nuclear materials into various categories; one category covers all fissile material while other categories apply to radioactive material of differing levels of activity. The regulations stipulate different packaging requirements for each category of substance to be transported and set out in great detail the specifications for each type of package. Radioactive material must not be transported unless it is contained in a package whose design has been approved by the Commission. The certificate may be made subject to any limitations or conditions on the use or transport of the package that the Commission considers to be necessary in the interest of health, safety or security.

For packages originating in a foreign country, the Commission may issue a Canadian certificate that has the effect of endorsing a certificate issued by a competent authority in that country. The endorsement indicates that the Commission accepts that the design of the package meets requirements substantially equivalent to the requirements of the Canadian regulations.

The regulations also provide for various different safety marks which must be affixed to any package or container containing radioactive material.

10. Nuclear Third Party Liability

The Nuclear Liability Act [R.S. 1985, C-N-28] was passed by the Canadian parliament in 1970 and it came into force on 11 October 1976.[6] It provides for compensation on a no-fault basis to third parties who have suffered injuries or damages as a result of a nuclear incident that has occurred at a designated nuclear installation or in the course of transport. The Canadian Nuclear Safety Commission is empowered under the Nuclear Safety and Control Act to designate nuclear facilities as "nuclear installations" for the purposes of the Nuclear Liability Act. Although Canada is not a party to any of the international conventions on nuclear third party liability, the Nuclear Liability Act is largely based on the principles laid down in the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy as amended, and in the 1963 Vienna Convention on Civil Liability for Nuclear Damage, as amended.

The major elements of the act are described below.

i) Transboundary damage

The operator of a nuclear installation in Canada is not liable for damage occurring outside Canada. However, the act contains a mechanism for the making of reciprocal arrangements with other countries [Section 33(3)]. This mechanism was used in 1976, resulting in the Canada – United States Nuclear Liability Rules. Under these Rules, Canadian operators are liable for injury or damage that is suffered in the United States but caused by a nuclear incident occurring in Canada.

ii) Nature of liability

The operator of a nuclear installation has a duty to ensure that no personal injury or property damage is caused by nuclear material within that operator's control [Section 3]. In the event of a breach of this duty, the operator's liability is absolute; in other words, there is no need to establish fault on the operator's part [Section 4].

Two or more operators may be jointly and severally liable, but apart from this case, the operator's liability is exclusive; no other person is liable for the damage [Section 11].

iii) Time limits for making claims

A person seeking compensation from an operator of a nuclear installation for injury (other than loss of life) or for property damage must bring an action within three years from the date on which the person knew, or ought reasonably to have known, of the injury or damage; in the case of a claim for loss of life, the action must be brought within three years of the death. Regardless of these three-year rules, no action can be commenced after the end of the period of ten years from the date of the breach of the operator's duty [Section 13].

6. A consolidation of the act was passed in 1985 [R.S. 1985, C-N-28].

iv) Insurance and other financial arrangements

The Canadian Nuclear Safety Commission, with the approval of the Treasury Board, prescribes a basic level of insurance for each designated nuclear installation. The amount prescribed is not to exceed 75 million Canadian dollars (CAD) [Section 15]. Where the basic insurance amount for a particular facility is less than CAD 75 million, supplementary insurance to make up the difference must be obtained, with the Canadian government acting as reinsurer [Section 16].

The act allows for the possibility of state intervention to provide compensation where either the CAD 75 million is likely to be insufficient to meet the claims, or the nuclear incident is such that it is in the public interest for special compensation measures to be provided [Section 18]. In such a situation, the operator's liability to claimants ceases, but in its place a liability arises to indemnify the government for amounts awarded by the Nuclear Damage Claims Commission [Sections 19 and 20]. The Commission, consisting of judges or experienced barristers, has exclusive jurisdiction to hear every claim arising from the nuclear incident and to award amounts of compensation [Section 24].

Where there is no state intervention, a person seeking compensation as a result of a nuclear accident must bring an action against the operator of the nuclear installation that caused the accident. The action must be brought in a court exercising jurisdiction in the place in Canada where the injury or damage was suffered, or, if this would result in several courts hearing claims in respect of the same incident, in a court exercising jurisdiction in the same place as the nuclear facility which caused the incident [Section 14].

II. INSTITUTIONAL FRAMEWORK

In Canada, the Canadian Nuclear Safety Commission (hereinafter referred to as "the Commission") has the power to regulate nuclear activities and it exercises this power in co-operation with other federal and provincial government departments concerned. However, with regard to promoting the peaceful uses of nuclear energy, it is the Crown Corporation, Atomic Energy of Canada Ltd. which is responsible for ensuring the transfer of nuclear technology for the benefit of private industry, and for supporting the Canadian nuclear industry in international markets.

1. Regulatory and Supervisory Authorities

a) Governor in Council

Regulations made by the Canadian Nuclear Safety Commission concerning the development, production and use of nuclear energy or any other matter in respect of which it is empowered to make regulations under the Nuclear Safety and Control Act, are subject to approval by the Governor in Council. The Governor in Council appoints the members of the Commission and designates one of them as the Commission's President.

The Governor in Council may issue, by order, directives to the Commission on broad policy matters with respect to the objectives of the Commission. Such orders are binding upon the

Commission and must be presented to each House of Parliament (Senate and House of Commons) [Nuclear Safety and Control Act, Section 19]. In addition, the Governor in Council is empowered to make regulations as are considered necessary for carrying out the purposes of the Nuclear Safety and Control Act [Section 44(5)].

b) Minister of Natural Resources

The Minister of Natural Resources is currently the Minister for the purposes of the Nuclear Safety and Control Act and for the Nuclear Liability Act.

Both the Canadian Nuclear Safety Commission and Atomic Energy of Canada Limited report to parliament through annual reports submitted to the Minister of Natural Resources.

c) Other Ministerial Authorities

Various other departments of the federal government have powers or functions that may relate to the nuclear energy field, the most important of which are Health, Environment, Foreign Affairs and International Trade, Human Resources Development, and Transport.

d) Canadian Nuclear Safety Commission (CNSC)

The Canadian Nuclear Safety Commission is established under the Nuclear Safety and Control Act as an independent agency of the government of Canada, replacing the Atomic Energy Control Board. It governs the use of nuclear energy and materials to protect health, safety, security and the environment and to respect Canada's international commitments on the peaceful uses of nuclear energy.

i) Legal status

The Commission is a departmental corporation. It is for all purposes an agent of the federal Crown and may only exercise its powers in that capacity. While it submits annual reports on its activities to the Minister of Natural Resources, who in turn submits those reports to parliament, the Commission remains an independent agency and is not under the supervision of the Minister.

ii) Responsibilities

The Commission is responsible for regulating the development, production and use of nuclear energy and the production, possession and use of nuclear substances, prescribed equipment and prescribed information. It does so in order to prevent unreasonable risk to the environment, to the health and safety of persons and to national security, and in order to achieve conformity with control measures and international obligations to which Canada has agreed. The Commission is also responsible for disseminating objective scientific, technical and regulatory information to the public concerning its activities, and concerning the environmental, health and safety effects of the activities which it regulates [Nuclear Safety and Control Act, Section 9].

Regulatory Powers

The Commission has the authority to regulate a broad scope of activities involving the development, production and use of nuclear energy in Canada. With the approval of the Governor in Council, it may make regulations covering activities in all stages of the nuclear fuel cycle, from the mining of nuclear substances to the disposal of a major nuclear facility and including the import, export and transportation of nuclear materials. It is also empowered to make regulations respecting measures to ensure national security and compliance with Canada's international obligations in the development, production and use of nuclear energy. A detailed description of its regulatory powers is provided in Part I of this study "General Regulatory Regime".

Administrative Powers

The Nuclear Safety and Control Act makes the Commission a court of record and it has all the powers necessary to carry out its duties with respect to the appearance, summoning and examination of witnesses, the production and inspection of records, the enforcement of its orders, and any other matter necessary for the due exercise of its jurisdiction [Section 20]. In particular, any decision or order of the Commission may, for the purposes of enforcement, be made a rule, order or decree of the Federal Court or of a superior court of a province and be enforced accordingly.

The Nuclear Safety and Control Act requires the Commission to hold public hearings in certain specified situations and to give a reasonable opportunity for affected parties to be heard. Section 40 of the act, for example, sets out the circumstances in which the Commission is required to provide an opportunity to be heard in accordance with rules of procedure prescribed by it; for example, before refusing to issue or renew a licence, or before confirming an order made by an inspector or a designated officer requiring a licensee to take measures to protect the environment or the health or safety of persons. This Section also sets out the circumstances under which the Commission may, on its own initiative, conduct proceedings in accordance with prescribed rules of procedure and under which it must hold public hearings. The Canadian Nuclear Safety Commission Rules of Procedure are contained in P.C. 2000-791 of 31 May 2000. Additional provisions in the act address the Commission's powers to rehear and redetermine decisions and orders and to hear appeals in specified cases [Section 43].

Pursuant to Section 15 of the act, the Commission has made bylaws with regard to the management and conduct of its affairs [SOR/2000-213; 31 May 2000]. These bylaws determine the procedures to be followed in proceedings other than those to which the Canadian Nuclear Safety Commission Rules of Procedure apply. The bylaws are used for administrative requirements, such as when the Commission meets on internal matters or makes regulations or policies, or when it wishes to discuss matters of general applicability.

Other activities

The Commission intends to continue the practice of its predecessor, the Atomic Energy Control Board, of granting public access to information on regulatory matters such as the granting of licences. Under this practice, the public may examine documents supporting licence applications, the reports of advisers to the Commission and the final report by the Commission's staff on any licence application, as well as the reports that licence holders are required to submit under the General Nuclear Safety and Control Regulations or the terms of licence. In addition, the Commission reports regularly, through the media, on the process of issuing licences for nuclear installations, on important events requiring that

remedial action be taken or ordered and on situations where the Commission is aware of any present or future concern for the public and the environment.

Dissemination of this information to the public is controlled by the Commission and respects the Access to Information Act [R.S. 1985, c. A-1] and the Privacy Act [R.S. 1985, c. P-21].

iii) Structure

The Canadian Nuclear Safety Commission consists of seven permanent members each of whom are appointed by the Governor in Council for a term of five years which may be renewed. The President of the Commission, designated to hold that office by the Governor in Council, is a full-time member of the Commission and is its Chief Executive Officer.

The President may establish a panel of the Commission, consisting of one or more members, to exercise or perform certain powers, duties and functions of the Commission [Nuclear Safety and Control Act, Section 22].

The Commission staff implements the policies of the Commission and makes recommendations to it concerning the issuing of licences, and other regulatory matters. Some aspects of licensing are delegated to "designated officers" on the staff of the Commission.

iv) Financing

The Commission's financial resources derive in part from appropriations voted by parliament, but as well from licensing fees or through fees charged for the provision of information, products or services. Such fees are authorised by Section 44 of the Act and are prescribed in the Cost Recovery Fees Regulations, 1994 which have been continued in force pursuant to Section 80 of the act.

The Auditor General of Canada is responsible for auditing the Commission's accounts and financial statements.

2. Public and Semi-Public Agencies

a) National Research Council (NRC)

Created in 1916 under the National Research Council Act [R.S. 1985, C-N-15] the National Research Council (NRC) is a departmental Crown corporation reporting to parliament through a designated minister. Since its inception, the NRC has played a major role in Canada's scientific development. Today, it constitutes a national scientific laboratory which performs much of its research in collaboration with industry and universities. It also operates a national library for science and engineering and provides support to industrial research through financial contributions and technical assistance.

The President of the NRC is currently an appointed member of the Canadian Nuclear Safety Commission, but is no longer an ex-officio appointee as was the case under predecessor legislation.

b) Natural Sciences and Engineering Research Council

Formed in 1978, the Natural Sciences and Engineering Research Council is a departmental Crown corporation under the Natural Sciences and Engineering Research Council Act [R.S. 1985, C-N-21] and reports to parliament through a designated minister. The Council promotes and supports research in the natural sciences and engineering, except the medical sciences, and advises the Minister on aspects of such research, on request.

c) Atomic Energy of Canada Ltd. (AECL)

i) Legal Status

Atomic Energy of Canada Limited (AECL) was incorporated by the Minister of Natural Resources pursuant to powers granted under Section 10(2) of the former Atomic Energy Control Act, now renamed the Nuclear Energy Act [Nuclear Safety and Control Act, Section 89]. Its incorporation was carried out by way of patent letters issued in 1952 and, since 1977, AECL has continued its corporate status under the Canada Business Corporations Act. It is a Crown corporation wholly owned by the government of Canada.

ii) Activities

AECL is a vendor of CANDU® power reactors, MAPLE (Multipurpose Applied Physics Lattice Experiment) research reactors and the MACSTOR advanced spent fuel storage systems. It engages in a wide range of research and development activities and provides nuclear engineering products and services to customers world wide in nuclear and related industries.

iii) Structure

AECL is managed by a board of directors, comprising 13 members who are appointed by the Governor in Council for a three-year term that is renewable. The chairperson of the board and the president and chief executive officer of AECL are equally appointed by the Governor in Council. The appointment of subordinate officers is the prerogative of the board of directors and there are currently seven vice-presidents responsible for various aspects of the corporation's activities.

AECL has more than 3 500 staff at its head office and engineering design centre in Mississauga, Ontario. Most of AECL's nuclear projects are managed from this location, as are AECL's international marketing initiatives. It also has major research and development laboratories at Chalk River, Ontario, and at Pinawa, Manitoba. It has business offices in Ottawa, Ontario and Montreal, Quebec.

AECL also has international offices in Seoul, Republic of Korea; Beijing, China; Bucharest, Romania; Ankara, Turkey; Jakarta, Indonesia; Bangkok, Thailand; and Buenos Aires, Argentina.

iv) Financing

The financial resources of AECL come from two primary sources: moneys which are appropriated by parliament and revenues derived from supplying goods and services to Canadian and

foreign utilities and to other companies requiring nuclear or nuclear related goods, services or technology.

Despite AECL's commercial mandate, it is an agent of the federal Crown. As a result, its research and development expenditures, capital expenditures, loans, and major transactions or undertakings are ultimately subject to either government or parliamentary approval.

AECL's annual financial statements are audited by the Auditor General of Canada and both the financial statements, together with the Auditor General's report, are submitted annually to parliament by the Minister of Natural Resources.

CZECH REPUBLIC

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I. GENERAL REGULATORY REGIME

1. Introduction

On 1 January 1993, Czechoslovakia was divided into the Slovak Republic and the Czech Republic. To ensure a smooth and continuous transition, it was agreed that all acts, regulations and decisions in the field of nuclear energy and ionising radiation would continue to apply until subsequent legislation was enacted. Since then, multiple acts and regulations have been adopted to establish a comprehensive legal system in this field.

In the Czech Republic, nuclear power generated electricity already constitutes more than 40% of the country's supply (2002). There are two nuclear power stations, at Dukovany in South Moravia and at Temelin in South Bohemia. The Dukovany nuclear power plant has four operational units (VVER-440/213), each of which has a thermal power of 1 375 MWt, representing a total installed capacity of 1 760 MWe. The Temelin nuclear power plant has two operational units (VVER-1000), the first of which began trial operation in mid-2002. The construction of Temelin 2 has been completed and it began trial operation on full power (1 000 Mwe) in April 2003. The two units will each have a thermal power of 3 000 MWt, representing a total installed capacity of 1 962 Mwe.

In addition, the Czech Republic has three research reactors, several radioactive waste storage facilities and a spent fuel interim storage facility and low-level radioactive waste repository, both of which are operated at Dukovany. Finally, the Czech Republic has also uranium ore mining and production facilities and Diamo, a state-owned company, acts as operator of all the uranium production facilities.

In the former Czechoslovakia, the predominant regulatory body was the Czechoslovak Atomic Energy Commission. By Constitutional Act No. 4/1993 of 15 December 1992, the functions and responsibilities of the Commission were transferred to the State Office for Nuclear Safety (*Státní úrad pro jadernou bezpecnost* – SÚJB), which is the state supervisory and regulatory body responsible for the safe use of nuclear energy and ionising radiation for peaceful purposes.

The general act governing all activities in the field of nuclear energy was adopted on 24 January 1997, and is entitled Act on the Peaceful Uses of Nuclear Energy and Ionising Radiation and on Amendments and Additions to Related Acts [No. 18/1997] (the Atomic Act). The act fully entered into force on 1 July 1997 and has been amended several times since then. One of the most important amendments was made by Act No. 13/2002, which aims to ensure full compliance of the Czech legislation in the nuclear field with EU law. It entered into force on 1 July 2002 with the exception of certain provisions which will enter into force upon the date of accession of the Czech Republic to the European Union.

The main purpose of the 1997 Act is to create the legal basis for the regulation of all activities involving the utilisation of nuclear energy and ionising radiation, and to protect the public and the environment against their harmful effects. The act aims to ensure that nuclear energy and ionising radiation are used exclusively for peaceful purposes, and that the benefits of their use are balanced against their potentially harmful effects. The act covers administrative issues, but it also incorporates rules on civil law while addressing other areas, such as criminal law, labour law, environmental law, trade law, transport law and public health.

Part I of the Atomic Act lays down the general conditions governing activities related to the use of nuclear energy and ionising radiation, the rules related to radioactive waste management and third party liability for nuclear damage, state supervision and penalties. Parts II-IV are entirely devoted to necessary amendments of the related legislation, while Part V contains general transitional and final provisions. An annex lists the documentation required for particular licensed activities pursuant to Section 13 of the act.

The following activities involving the use of nuclear energy and radiation practices are covered by the Atomic Act [Part I, Chapter 1, Section 2(a) and (b)]:

- siting, design, construction, commissioning, operation, reconstruction and decommissioning of nuclear installations;
- design, manufacturing, repair and verification of nuclear installation systems or their components, including materials used for their production;
- design, production, repair and verification of packaging assemblies for transport, storage or disposal of nuclear materials;
- management of nuclear materials, selected items and, where used in nuclear activities, dual use items;
- research into and development of the activities mentioned above;
- professional training of personnel;
- transport of nuclear materials;
- any practice resulting in exposure to ionising radiation.

Numerous decrees and regulations have been adopted to implement the 1997 Act, as are described hereinafter within the appropriate section according to subject matter.

2. Mining Regime

Uranium mining in the Czech Republic started in 1946 and reached its peak in 1960 with an annual production of 3 000 tonnes. There is now only one uranium mine in operation. The operator of all uranium production facilities is the exclusively state-owned company *Diamo* (formerly *Ceskoslovensky Uranovy Prumysl* – CSUP).

In 1988, the former Czechoslovak Republic adopted Act No. 44/1988 on the Protection and Use of Mineral Wealth, which laid down general rules concerning the use of resources and the protection

of mineral wealth. That same year, the Czech National Council adopted Act No. 61/1988 on Mining Operations, Explosives and the State Mining Administration, which more specifically dealt with the safety and procedures of mining operations. The licensing of mining activities is regulated by the Decree on Mining Licences [No. 15/1995].

The last uranium mine is due to close by the end of 2005 and Diamo is currently implementing a programme for the restoration of former uranium mines under the supervision of the Ministry of Industry and Trade.

3. Radioactive Substances, Nuclear Items and Spent Fuel

The rules specifying procedures for the handling, use and safety of ionising radiation sources, nuclear items and spent fuel have now largely been incorporated into the Atomic Act and implementing decrees such as Decree No. 307/2002 on requirements for radiation protection, and Decree No. 317/2002 on type-approval.

a) Ionising radiation sources

According to Section 2(c) of the Atomic Act, an "ionising radiation source" means a substance, equipment or installation capable of emitting ionising radiation or releasing radioactive substances.

Ionising radiation sources are divided into five categories, the criteria for which are laid down by regulation [Decree No. 307/2002]. These are: 1) insignificant sources, the handling of which neither poses a risk of a radiation incident nor generates any radioactive waste; 2) minor sources, the handling of which does not create a risk of a radiation accident, although it may generate radioactive waste; 3) simple sources, the management of which creates a risk of a radiation accident, but no resulting acute health effects; 4) significant sources, the management of which might produce a radiation accident with acute health effects, but not a radiation emergency; and finally 5) very significant sources, which may cause a radiation emergency. A licence is required for all ionising radiation sources, except insignificant sources or type-approved minor sources used in accordance with the instructions approved by SÚJB. Finally, an "ionising radiation source workplace" is defined as an area where such sources are used or handled in a conscious and intentional manner, justifying special ionising radiation protection measures.

Decree No. 215/1997 sets out criteria for the siting of nuclear facilities and very significant ionising radiation sources.

b) Nuclear items

The 1997 Atomic Act [Section 2(j)] defines the term "nuclear items" as follows:

- nuclear materials, such as source materials, special fission materials and other materials so determined by regulation [Decree No. 145/1997];

- selected items which are materials, equipment and technology designed and manufactured to be used in the nuclear industry as set out by regulation [Decree No. 179/2002];

- dual-use items, *i.e.* materials, equipment and technology not designed and manufactured for use in the nuclear field, but which may be so used, as set out by regulation [Decree No. 179/2002].

Pursuant to the act, "source materials" are uranium containing a mixture of isotopes occurring in nature, uranium depleted in isotope ^{235}U, and thorium in whatever form they are found, as well as other substances or materials containing one or more of these items in a concentration or an amount exceeding the limits laid down by Decree No. 145/1997. "Special fission materials", on the other hand, are ^{239}Pu, ^{233}U, uranium enriched in the isotope ^{235}U and/or ^{233}U and materials containing one or more of these radionuclides, except source materials, in concentration or amount exceeding the limits laid down by a regulation. With respect to the international transfer of nuclear items, the act prohibits such transfers where they would be in breach of the international commitments of the Czech Republic [Section 5].

c) Spent fuel

In the former Czechoslovakia, spent fuel from the Dukovany station was originally sent to Russia for disposal, until such time as Russia decided to accept it only for reprocessing, following which it was sent to an interim spent fuel storage facility at the Bohunice plant in the Slovak Republic. However, in 1993 the Slovak utility SEP, which operated the Bohunice plant, decided to no longer accept the fuel and in November 1995, the Slovak utility began shipping Dukovany's spent fuel back to the Czech Republic, aiming to return all such spent fuel by 1997.

To address this problem, Dukovany began re-racking the fuel assemblies in its spent fuel ponds, which increased capacity by about 90%. In addition, the utility *Ceske Energeticke Zavody a.s.* (CEZ) built a 600 metric ton interim dry storage facility on site, which began trial operation in March 1997, and whose extension is already planned. A similar facility is planned for the Temelin plant. CEZ has also made a site characterisation (by geological and hydrological prospecting) of the locality for siting a central interim storage facility that could store fuel assemblies from the Dukovany and Temelin plants. In addition, the Czech Republic has launched a project, under the auspices of the Nuclear Research Institute, to study the disposal of waste in a deep geological repository. The chosen repository site is not due to become operational until 2065.

The management of spent or irradiated fuel will be subject to the same requirements as for radioactive waste, if the generator and SÚJB declare it to be radioactive waste [Section 24(3)] (See, *infra*, Section 7 "Radioactive Waste Management").

4. Nuclear Installations

The definition of a "nuclear installation" under the Atomic Act [Section 2(h)] covers a variety of facilities: constructions or operational units which make up a nuclear reactor using a fission chain reaction; facilities for production, processing, storage and disposal of nuclear materials; repositories of radioactive waste, with the exception of repositories containing exclusively natural radionuclides; and facilities for the storage of radioactive waste, for which the radioactivity exceeds the limits laid down by regulation.

a) Licensing and inspection, including nuclear safety

i) Licensing

In accordance with the Atomic Act [Section 9(1)], a licence granted by SÚJB is required for:

- siting and construction of a nuclear installation or workplace with a very significant ionising radiation source;
- particular commissioning stages, operation and decommissioning of a nuclear installation or a workplace with a significant or very significant ionising radiation source;
- restart of a nuclear reactor following a fuel reload;
- reconstruction or other changes affecting nuclear safety, radiation protection, physical protection and emergency preparedness of a nuclear installation or workplace with a significant or a very significant ionising radiation source;
- discharge of radionuclides into the environment;
- handling of ionising radiation sources, as specified by Decree No. 307/2002;
- radioactive waste management;
- import or export of nuclear items and transit of nuclear material and selected items;
- handling of nuclear materials;
- transport of nuclear material and radionuclide sources, as specified by Decree No. 317/2002;
- training of classified personnel at a nuclear installation or ionising radiation source workplace;
- re-importation of radioactive waste resulting from the processing or re-processing of material exported from the Czech Republic.

Under the act, licence applications must be submitted to SÚJB with documents giving basic information about the licence applicant and the proposed activity for which a licence is sought. Further specific documents required by SÚJB for each licensed activity are set out in the Appendix to the act. The act also makes an environmental impact assessment a necessary condition for the issuance of a licence for siting or decommissioning [Section 13(4)]. The requirements for this assessment are set out in Act No. 244/1992 on Environmental Impact Assessment.

SÚJB's decision must be issued within a specified time period after the applicant has submitted its documentation. This period varies, depending upon the type of licence sought [Section 14]. SÚJB has the exclusive power to change, revoke or terminate a licence under conditions specified in the act. Termination of the licence will generally take place after its expiry or upon the licensee's bankruptcy or ceasing to exist. The revocation of a licence, on the other hand, can be imposed in the case of non-compliance with requirements under the act or can be sought by the licensee upon written

application, provided that nuclear safety and radiation protection concerns are satisfied [Section 16]. All licensees are registered by SÚJB in its national register.

After the issue of a licence therefor, the commissioning and operation of a nuclear installation remain subject to the provisions of the Atomic Act, and its implementing decrees. Some of the more relevant implementing decrees in this field are listed below:

- Decree No. 144/1997 on Physical Protection of Nuclear Materials and Nuclear Facilities and their Classification;
- Decree No. 214/1997 on Quality Assurance during Activities Connected with the Utilisation of Nuclear Energy and Practices Leading to Exposure, and establishing Criteria for Categorisation of Selected Equipment into Safety Classes;
- Decree No. 106/1998 on Nuclear Safety and Radiation Protection Assurance during Commissioning and Operation of Nuclear Facilities;
- Decree No. 195/1999 on Basic Safety Criteria for Nuclear Installations with Respect to Nuclear Safety, Radiation Protection and Emergency Preparedness.

ii) Inspection

Inspection activities are performed by nuclear safety and radiation protection inspectors appointed by the chairperson of SÚJB. An inspector must be competent to perform legal acts, have a relevant degree and three years of professional experience, be competent and of moral integrity and fulfil other requirements [Section 39(2)].

Inspectors verify whether licensees (and other registered owners of radiation sources) under the Atomic Act are adhering to the Act's provisions, its implementing regulations and the relevant licence conditions. Inspectors are authorised to:

- at any time, enter the licensee's premises and other workplaces where activities involving nuclear energy utilisation or resulting in radiation exposure take place;
- check compliance with requirements and conditions of nuclear safety, radiation protection, physical protection and emergency preparedness;
- carry out measurements and collect samples;
- perform a physical inspection of nuclear items or ionising radiation sources, including checks on accounting and control procedures;
- verify professional competence.

An inspector identifying discrepancies is authorised under Section 40 of the Atomic Act to:

- require the licensee to remedy the situation, within a determined time period;
- order the licensee to perform technical inspections, reviews or tests to verify nuclear safety status;

- revoke a licence attesting to the special competence of an employee of the licensee;

- recommend a penalty.

SÚJB is also authorised to impose provisional corrective measures at the licensee's cost [Section 40(2)].

iii) Nuclear Safety

Under the Atomic Act, nuclear safety falls entirely under the jurisdiction of SÚJB [Section 3(2)]. Responsibility for nuclear safety lies with the licence-holder [Section 17(1)]. "Nuclear safety" is defined as the condition and ability of a nuclear installation and its servicing personnel to prevent the uncontrolled development of a fission chain reaction or an inadmissible release of radioactive substances or ionising radiation into the environment, and to reduce the consequences of accidents [Section 2(d)]. Anyone engaged in activities associated with nuclear energy utilisation or radiation practices is required to ensure that nuclear safety and radiation protection are matters of priority [Section 4(3)].

The Czech Republic is a Party to the 1994 Convention on Nuclear Safety, which was approved on 18 September 1995.

b) Emergency response

The Czech Republic succeeded to both the 1986 Convention on Early Notification of a Nuclear Accident and the 1986 Convention on Assistance in the Case of Nuclear Accident or Radiological Emergency on 24 March 1993. The Atomic Act sets out the general rules for emergency response in accordance with these Conventions. A "radiation incident" is defined as an event resulting in an inadmissible release of radioactive substances or ionising radiation, or an inadmissible exposure of people. A "radiation accident" is defined as a radiation incident requiring measures to be taken to protect the public and the environment [Section 2(k) and (1)].

An "emergency plan" is defined as a set of planned measures to deal with a radiation incident or radiation accident and to limit their consequences. According to the act [Section 2(m)] there are three types of emergency plans:

- an on-site emergency plan, designed for nuclear installations or ionising radiation source workplaces;

- an emergency rule for the transport of nuclear materials or ionising radiation sources; and

- an off-site emergency plan for the region in the vicinity of a nuclear installation or ionising radiation source workplace where an emergency planning zone has been established.

The act lays down the licensees' obligations in the event of a radiation incident [Section 19]. The licensee must have an on-site emergency plan, approved by SÚJB and, in the event of an existing or potential radiation accident, the licensee must immediately notify the relevant local authority, SÚJB and other relevant bodies, and ensure that a warning is issued to the public within the emergency planning zone. In addition, the licensee must stop or limit the consequences of a radiation accident

while taking protective measures for employees. In the event of a radiation accident, the licensee must, in addition, participate in the operation of the National Radiation Monitoring Network [Governmental Regulation No. 11/1999] (see *infra*, Section 6 "Radiation Protection"). For radiation incidents or accidents during transport, similar obligations apply. Emergency rules should be included in the documentation for a licence to transport nuclear materials and radionuclide sources.

The licensee must also submit information to the relevant regional authority to help it prepare an off-site emergency plan and co-operate to ensure emergency preparedness in the emergency planning zone. In addition, the licensee is also obliged to contribute financially to the National Radiation Monitoring Network. Finally, it must participate in running a press and information campaign to ensure that the public is prepared for radiation emergencies.

In the event of a radiation accident, SÚJB is obliged to ensure mobilisation of its Emergency Crises Staff (ECS) and the changeover of the RMN into emergency mode. Based on its assessment of the radiation situation [Section 3(2)(p)] and current information from the operator [Section 19(1)(a) and (e)], the ECS prepares the background information necessary to take decisions aimed at reducing or averting radiation exposure. Expert and technical support is provided to the ECS by the Emergency Response Centre.

Decree No. 318/2002 sets out details on the emergency preparedness of nuclear facilities and workplaces with ionising radiation sources and on requirements on the content of on-site emergency plans and rules. This decree, which specifies the scope and requirements of compulsory documentation relating to emergency preparedness (e.g. on-site emergency plans, emergency rules) entered into force on 18 July 2002. It transposes certain provisions of Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency, and specifies conditions for the application of Council Decision 87/600/Euratom of 14 December 1987 on Community arrangements for the early exchange of information in the event of a radiological emergency.

c) Decommissioning

"Decommissioning" means activities aimed at releasing nuclear installations or ionising radiation source workplaces, following the termination of their operation, for their utilisation for other purposes or to exempt them from the effect of the Atomic Act [Section 2(n)]. The decommissioning of a nuclear installation or a Type III or IV Workplace requires a licence from SÚJB, which in turn requires an environmental impact assessment, a quality assurance programme, an on-site emergency plan and methods of ensuring physical protection [Section 13]. Decree No. 185/2003 sets out further details on the decommissioning of nuclear installations or Type III or IV Workplaces.

Finally, the operator of a nuclear installation or ionising radiation source workplace is required to keep a financial reserve for the decommissioning of his facility. Control over these reserves is exercised by the Radioactive Waste Repository Authority (see, *infra*, Section 7 "Radioactive Waste Management" and Part II). Further details in this respect are set out in Decree No. 360/2002 establishing reserves for the decommissioning of nuclear installations or Type III or IV workplaces.

5. Trade in Nuclear Materials and Equipment

Nuclear trade is now regulated by the Atomic Act and Decrees No. 145/1997 and No. 179/2002.

A licence is required from SÚJB for the import or export of nuclear items or transit of nuclear materials and selected items [Section 9 of the Atomic Act], as is a licence from the Ministry of Industry and Trade under Act No. 21/1997 on Control of Export and Import of Goods and Technologies Subject to International Inspection Modes. In principle, the Atomic Act prohibits the international transfer of nuclear items into states that would contravene its international commitments under the Non-Proliferation Treaty and the Treaty on the Prohibition of the Emplacement of Nuclear Weapons and Other Weapons of Mass Destruction on the Seabed and the Ocean floor and in the Subsoil thereof. Import of radioactive waste into the Czech Republic is prohibited. However, the act does allow the re-import of ionising radiation sources and radioactive waste from materials exported from the Czech Republic for processing or reprocessing, if approved by SÚJB.

Decree No. 179/2002 establishes a list of selected items and dual use items in the nuclear sector, taking into account the applicable international legislation (especially IAEA Recommendations in this field and Council Regulation (EC) No. 1334/2000 of 22 June 2000 setting up a Community regime for the control of exports of dual-use items and technology). It entered into force on 1 June 2002.

6. Radiation Protection

The Atomic Act defines “radiation protection” as a system of technological and organisational measures to reduce exposure of persons and the environment [Section 2(e)]. State supervision over radiation protection is entrusted to SÚJB pursuant to the Atomic Act [Section 3]. Dose limits, constraints and guidance levels are set out in Decree No. 307/2002.

Dose limits must take into account exposures from other practices. Medical exposures, natural exposures and exposures received during a radiation accident are regulated by guidance levels corresponding to reasonably achievable levels of radiation protection. In general, the extent to which natural radiation exposures must be reduced is dependent upon the detriment caused, balanced against the benefits to be gained.

Radiation protection must also be respected during transportation of nuclear materials and in radioactive waste management activities. Compliance with applicable limits will be verified by SÚJB’s inspectors and violations can result in the imposition of penalties.

The act, together with the implementing legislation in the field of radiation protection, is based on the 1990 Recommendations of the International Commission for Radiological Protection (ICRP) and the International Basic Safety Standards for Protection against Ionising Radiation and for the Safety of Radiation Sources, and corresponds to Council Directive 96/29/Euratom. The general principles of radiation protection, such as justification of radiation practices and the optimisation of radiation protection and dose limitation are covered. Dose limits for the public are decreased from 5 mSv to 1 mSv per year or, as an exception, 5 mSv per five consecutive years starting from the year 1998, and for radiation workers from 50 mSv per year to 100 mSv per five consecutive years starting from the year 2000.

Several new decrees were adopted in 2002 in order to bring domestic radiation protection legislation in line with EU requirements and to further implement the provisions of the Atomic Act:

- Decree No. 307/2002 on Radiation Protection, which entered into force on 12 July 2002, lays down basic safety standards for protection of the health of workers and the general public against the dangers arising from ionising radiation. It aims to implement Council Directives 96/29/Euratom of 13 May 1996 and 97/43/Euratom of 30 June 1997;

- Decree No. 315/2002 on the Professional Qualifications and Training of Personnel in Relation to Nuclear Safety and Radiation Protection, which entered into force on 16 July 2002, amends a previous decree on the same subject [No. 146/1997] in relation to requirements on qualifications and professional training of personnel in the nuclear field, on methods to be used for the verification of their special professional qualifications and on the issue of authorisations to selected members of personnel. This decree also aims to implement Council Directives 96/29/Euratom and 97/43/Euratom;

- Decree No. 319/2002 on Performance and Management of the National Radiation Monitoring Network, which entered into force on 18 July 2002, establishes the details of the functioning and the organisation of the National Radiation Monitoring Network established under the supervision of the SÚJB. It implements certain provisions of Council Directive 89/618/Euratom on Informing the General Public about Health Protection Measures to be Applied and Steps to be Taken in the Event of a Radiological Emergency and also provides for the application of Council Decision 87/600/Euratom on Community Arrangements for the Early Exchange of Information in the Event of a Radiological Emergency and relevant provisions of the Euratom Treaty;

- Decree No. 419/2002 on Personal Radiation Passports established details on the issue, registration, verification and use of personal radiation passports. This radiological monitoring document is to be used until a uniform Community system is established governing the operational protection of outside workers performing activities in controlled areas. The decree aims to implement Council Directive 90/641/Euratom on the Operational Protection of Outside Workers Exposed to the Risk of Ionising Radiation during their Activities in Controlled Areas.

The Radiation Monitoring Network (RMN) of the Czech Republic is co-ordinated by SÚJB. Under normal circumstances, it monitors radiation levels for the early detection of accidents; under emergency conditions, it evaluates the consequences of a radiation accident. Normal monitoring involves the following:

- an early warning network, which comprises 60 measuring points;

- a territorial network of 206 measuring points equipped with thermoluminescent dosimeters (TLD);

- local TLD networks with 90 measuring points in the surroundings of the Dukovany and Temelin nuclear power plants;

- a territorial network of 11 air contamination measuring points;

- a network of 9 laboratories with gamma spectrometric and radiochemical analytical instrumentation.

The monitoring results are published in the Annual Reports on the Radiation Conditions in the Czech Republic.

7. Radioactive Waste Management

The handling, disposal and management of radioactive waste are governed by the Atomic Act and corresponding regulations such as Decree No. 307/2002 on Radiation Protection. According to the act, "radioactive waste" means substances, objects or equipment containing or contaminated by radionuclides for which no further use is foreseen. Such waste will have to be disposed of in radioactive waste repositories, *i.e.* an area, structure or facility at the surface or underground, for the purpose of radioactive waste disposal. "Radioactive waste and spent fuel storage" refers to the temporary emplacement of radioactive waste or spent or irradiated nuclear fuel into areas, facilities or installations designed for this purpose, whereas "disposal" refers to the permanent emplacement of radioactive waste into areas, facilities or installations without the intention of its retrieval. [Section 2(r), (s), (t) and (u)]. Both storage and disposal of radioactive waste and spent fuel require a licence issued by SÚJB [Section 9(1)(j)].

The Atomic Act further provides that the owner or generator of radioactive waste is financially responsible for its management, from its time of origin to its disposal, including monitoring after closure of the radioactive waste repository, and any necessary research and development activities [Section 24]. A "generator" is an owner of radioactive waste or any other person or entity managing an owner's assets in such a manner that radioactive waste is generated. The state, on the other hand, is responsible for guaranteeing the safe disposal of all radioactive waste, including monitoring and supervision of repositories after their closure, and for this purpose the act required the Minister of Industry and Trade to establish the Radioactive Waste Repository Authority as a state organisation.

The Authority, established on 1 June 1997, is funded through levies imposed on generators of radioactive waste, and is responsible for accepting all radioactive waste, including spent or irradiated fuel, and providing for its safe disposal, including monitoring and supervising repositories after their closure (see *infra* Part II]. The Authority's activities are, in part, determined by the term of its agreement with the waste generator. Waste will be accepted only if it meets the acceptance criteria for disposal, as determined by SÚJB. Upon acceptance of the waste, it becomes state property under the exclusive supervision of the Authority [Section 31].

Governmental Order No. 416/2002, adopted on 28 August 2002, established details concerning the amounts and method of payment of contributions to the Nuclear Account by generators of radioactive waste and provides for the annual administration of these resources. The Nuclear Account is a special fund provided by the state to finance all activities regarding radioactive waste disposal including those of the Radioactive Waste Repository Authority. The order further provides for an annual contribution to be made to municipalities having a radioactive waste repository on their cadastral area.

At the international level, the Czech Republic approved the 1997 Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management on 25 March 1999.

8. Non-Proliferation and Physical Protection

The Atomic Act defines "physical protection" as a system of technological and organisational measures preventing unauthorised activities with nuclear installations, nuclear materials and selected items [Section 2(j)]. It provides that SÚJB is responsible for physical protection and non-proliferation issues, and authorises it to maintain a national system of accounting for and control of nuclear materials. SÚJB approves the inclusion of a nuclear installation or its components and nuclear materials into a category for physical protection and approves methods of physical protection

[Section 3(2)(r)]. It also makes decisions concerning the management of nuclear items, if the owner or other person responsible fails to comply with requirements under the act [Section 3(2)(u)]. In addition, the act makes the police responsible for ensuring emergency services to protect nuclear installations and for participating in the physical protection of nuclear material during its transportation [Section 44]. The licensee is responsible for ensuring physical protection of nuclear material [Section 17].

In respect of non-proliferation, the Czech Republic succeeded to the 1968 Treaty on the Non-Proliferation of Nuclear Weapons on 1 January 1993 and succeeded to the 1979 Convention on the Physical Protection of Nuclear Material on 24 March 1993. The provisions of these Conventions are implemented by the Atomic Act and by Decree No. 145/1997 on Accounting for and Control of Nuclear Materials and their Further Delimitation (as amended by Decree No. 316/2002), Decree No. 144/1997 on Physical Protection of Nuclear Materials and Nuclear Facilities and their Classification, and Section 186 of Act No. 412/2002 – the Criminal Code – provision on Illegal Production and Handling of Radioactive Materials. The Czech Republic also ratified the 1996 Comprehensive Nuclear Test Ban Treaty on 11 September 1997.

Inspectors from the International Atomic Energy Agency, together with those from SÚJB, are authorised to inspect nuclear material and the accounting and control system, according to the Non-Proliferation Treaty and the Treaty on the Prohibition of the Emplacement of Nuclear Weapons and Other Weapons of Mass Destruction on the Seabed and the Ocean Floor and in the Subsoil thereof [Section 39(5)].

9. Transport

The Atomic Act also addresses the transport of nuclear materials and radionuclide sources [Section 20]. Such transport is subject to a licence to be issued by SÚJB in accordance with Decree No. 317/2002. The licence does not have to be obtained by the carrier unless that person is also the shipper, consignor or consignee [Section 9(m)], but the licensee must ensure that the consignee is authorised to handle nuclear materials or ionising radiation sources according to the rules set out in the act, and that the packaging assemblies are "type-approved" by SÚJB [Section 20(1)(a) and (c)].

The licensee must also comply with specific legislation on transport, including Act No. 111/1994 on Road Transport and its associated Decree No. 187/1994, Act No. 266/1994 on Railways, Appendix 1 to Decree of the Minister of Foreign Affairs No. 8/1985 on the Convention on International Rail Transport (COTIF), Act No. 114/1995 on Inland Navigation, Decree No. 17/1966 on Air Transport Rules in the wording of Decree No. 15/1971 and Decree No. 307/2002 and Decree No. 144/1997 on physical protection. The licensee must also report to a border customs office, the transfer, entry into or exit from the Czech Republic of nuclear items or radionuclide sources, other than dual-use items. Breach of this condition could result in the withholding of the goods to be transported.

Decree No. 317/2002 on Type Approval of Packaging Assemblies for Transport, Storage and Disposal of Nuclear Materials and Radioactive Substances, on Type Approval of Ionising Radiation Sources and on Transport of Nuclear Materials and Specified Radioactive Substances entered into force on 18 July 2002. It establishes a list of nuclear materials and radioactive substances which must be transported, stored or disposed in type-approved packaging assemblies only, sets out prerequisites for such type approvals and lays down details on the transport of nuclear materials and specified radioactive substances. It aims to implement certain provisions of Council Directive 92/3/Euratom of 3 February 1992 on the Supervision and Control of Shipments of Radioactive Waste between Member

States and Into and Out of the Community, and further provides for application of Regulation (Euratom) No. 1493/93 of 8 June 1993 on Shipments of Radioactive Substances between Member States.

10. Nuclear Third Party Liability

The Czech Republic succeeded to the 1963 Vienna Convention on Civil Liability for Nuclear Damage and the 1988 Joint Protocol Relating to the Application of the Vienna Convention and the Paris Convention, on 24 March 1994. As a result, the Atomic Act incorporates the basic principles of nuclear third party liability found in the Vienna Convention, including the exclusive liability of the operator for any third party nuclear damage resulting from an accident at his nuclear power plant and compulsory insurance coverage for any such damage. Furthermore, the state will provide compensation for any such damage exceeding the amount of the operator's financial security limit.

The act defines an "operator of a nuclear installation", by reference to the Vienna Convention, as the holder of a licence to operate a nuclear installation, to perform any other activity in relation thereto or to transport nuclear material [Section 33(1)]. The act specifies that the extent and manner of compensation for nuclear damage is to be regulated by Civil Act No. 40/1964 [Section 34(1)]. Nuclear damage is defined to include the cost of preventive measures and measures of reinstatement of the impaired environment [Section 34(2)]. The operator's liability is limited to Czech Republic koruna CZK 6 billion (approximately 150 million Special Drawing Rights (SDR)] per nuclear installation, whereas for facilities with reduced risk and transport the liability limit is CZK 1.5 billion (approximately SDR 37.5 million) [Section 35]. The time limit for bringing claims for compensation is ten years from the occurrence of the nuclear incident with a "discovery period" of three years [Section 38].

To cover this liability, the operator is obliged to have insurance or other financial security of not less than CZK 1.5 billion for nuclear power plants and their stipulated associated activities, or CZK 200 million for lesser risk facilities and transport [Section 36(3)]. This security must be obtained from an authorised insurer and the policy conditions must be approved by a state insurance supervision authority. To cover these liability claims, a nuclear insurance pool was established in the Czech Republic in July 1995.

The Atomic Act further provides for state guarantees to ensure compensation up to the established liability limits if liability claims exceed the mandatory insurance of the operator [Section 37].

The provisions contained in general regulations on liability for ordinary damage apply only if international agreements to which the Czech Republic is a Party or the Atomic Act do not provide otherwise [Section 32(2)].

II. INSTITUTIONAL FRAMEWORK

1. Regulatory and Supervisory Authorities

a) State Office for Nuclear Safety (SÚJB)

In 1993, pursuant to its Constitutional Act No. 4/1993, and to Act No. 21/1992, the Czech Republic transferred supervisory functions and responsibilities in the nuclear safety area from the former Czechoslovak Atomic Energy Commission to the State Office for Nuclear Safety (*Státní úrad pro jadernou bezpecnost* – SÚJB). Its competence as the regulatory authority responsible for supervising the use of nuclear energy and ionising radiation sources is set out in the Atomic Act of 1997 [Section 3(2)]. In general, SÚJB supervises nuclear safety, physical protection, radiation protection and emergency preparedness on the premises of a nuclear installation or in ionising radiation source workplaces, as well as the management of radioactive waste. The chairperson of SÚJB is nominated by the government of the Czech Republic.

SÚJB is empowered to issue licences for activities regulated by the act and to maintain a register of such licences. In addition, it approves types of packaging assemblies for transport and storage of nuclear materials and radionuclide sources. SÚJB maintains the state system of accounting for and control of nuclear materials and determines the requirements for their registration and inspection. It maintains a registration system of radiation exposure of the general public and of persons who have working contact with ionising radiation sources. It also establishes commissions to verify the special qualifications of selected personnel.

Furthermore, SÚJB provides data to municipalities and District Councils on radioactive waste handling within their area of administration, co-ordinates the operation of the National Radiation Monitoring Network, ensures the operation of the Emergency Response Centre (ERC), provides international data on radiation levels and ensures international co-operation with the IAEA.

SÚJB has three sections: nuclear safety, radiation protection and management and technical support, each with its own Deputy Chairperson.

The Nuclear Safety Section comprises three departments: Assessment of Nuclear Installations, Control of Nuclear Installations and Nuclear Materials.

The Radiation Protection Section comprises three departments: Radiation Sources, Exposure Regulation and Radiation Protection in the Fuel Cycle Sector. This Section also co-ordinates seven Regional Centres which report via the various departments to the Head of the Radiation Protection Section.

The Management and Technical Support Section consists of the Departments of International Co-operation, Financial Management and Administration (Budget & Finance) and the Office Bureau, which includes a legal division.

Within SÚJB, the Emergency Response Centre and the EU Unit report directly to the Chairperson. Finally, SÚJB supervises the functioning of the National Radiation Protection Institute and the National Institute for Nuclear, Chemical and Biological Protection.

b) Ministry of Industry and Trade

The Ministry of Industry and Trade is responsible for:

- developing domestic legislation and preparing intergovernmental treaties in the nuclear field;
- proposing strategic reserves of nuclear materials;
- co-operating with other government agencies in developing emergency preparedness plans and environmental protection principles;
- co-ordinating activities in the nuclear field in relation to the government's economic policy;
- developing governmental policy in the nuclear area including the management of radioactive waste and spent nuclear fuel;
- monitoring the operation of the Dukovany and Temelin NPPs.

The construction, operation and decommissioning of nuclear installations as well as waste management are the responsibility of the Ministry of Industry and Trade.

c) Ministry of the Interior

The Ministry of the Interior is responsible for establishing details of Crisis Regional Plans, Regional Emergency Plans and off-site emergency plans. The police are also responsible for providing emergency protection of nuclear installations and for participating in the physical protection of nuclear materials during their shipment.

d) Ministry of the Environment

The Ministry of the Environment is responsible for regulating nuclear activities to ensure that they comply with environmental laws. It also ensures that the procedures for environmental impact assessment are applied as a prerequisite to obtaining a licence, based on Act No. 244/1992 on Environmental Impact Assessment.

2. Public and Semi-Public Agencies

a) CEZ, a.s.

i) Legal Status

Before the dissolution of Czechoslovakia, the utility *Ceske Energeticke Zavody, a.s.* (CEZ) was state-owned. As part of its move to a market economy, the Czech Republic aimed to privatise the CEZ, and now 32% of its stock is publicly owned, while almost all of the remaining 68% is held by the Czech government. This will be reduced to 51% when privatisation has been completed. CEZ reports directly to the Czech Ministry of Industry and Trade.

ii) Responsibilities

CEZ is predominately responsible for electricity generation and very high-voltage transmission on 220-400 kV level in the Czech Republic. It is also responsible for implementing regulatory decisions and for the operational performance of nuclear undertakings. It sells electricity to regional distribution companies.

b) National Radiation Protection Institute (NRPI)

i) Legal Status

NRPI is a state organisation founded on 1 June 1995 by SÚJB, as its expert advisor in the field of radiation protection. The budget of the Institute is fully covered by the state through SÚJB. The chairperson of SÚJB appoints the director of NRPI.

ii) Responsibilities

The major task of NRPI is to perform all scientific activities necessary to support SÚJB as the main regulatory body in the field of radiation protection. NRPI participates in the monitoring of the radiological situation within the national territory and supports SÚJB in the co-ordination of the nation-wide Radiation Monitoring Network.

c) Radioactive Waste Repository Authority (RAWRA)

i) Legal Status

The Radioactive Waste Repository Authority – RAWRA (*Sprava ulozist radioaktivnich odpadu*) was established by the Ministry of Industry and Trade on 1 June 1997. It is a state organisation responsible for ensuring the safe disposal for radioactive waste and the monitoring and supervision of repositories after their closure.

ii) Responsibilities

The Authority is responsible for the following waste management activities:

- preparation, construction, commissioning, operation and closure of radioactive waste repositories and the monitoring of their impact on the environment;
- conditioning of spent or irradiated nuclear fuel into a form suitable for its disposal or further utilisation;
- record keeping of accepted radioactive waste and its generators;
- administration of levies for the Nuclear Fund;
- promotion and co-ordination of research and development in the field of radioactive waste management.

iii) Structure

The Authority has a management board and a director who are appointed by the Minister for Industry and Trade. The director, who is the statutory representative of the Authority, may act on its behalf and may participate in board meetings.

The board consists of 11 members, three of whom are representatives of the state administration bodies, four of whom represent the waste generators and a further four represent the public. The board supervises the efficiency with which resources are spent on the Authority's activities and recommends activity plans and budgets to the Minister.

iv) Financing

The Authority is funded through levies imposed on the producers of radioactive waste. The levies are put into a "nuclear account" managed by the Ministry of Finance and are used to finance the various operations by the Authority.

d) Diamo

Diamo (formerly *Ceskoslovensky Uranovy Prumysl* – CSUP) is an exclusively state-owned company acting as operator of all uranium production facilities. It is responsible for the extraction and processing of uranium ore and for the implementation of the state programmes on reducing the uranium industry and rehabilitation of former uranium production sites. As the last uranium mine is due to close by the end of 2005, Diamo is currently implementing a programme for the restoration of former uranium mines under the supervision of the Ministry of Industry and Trade.

e) Nuclear Physics Institute (NPI)

The Nuclear Physics Institute was founded in 1955 and has undergone various changes since, including having served as the Nuclear Research Institute of the former Czechoslovak Commission for Atomic Energy. In 1993, after the dissolution of Czechoslovakia, the Nuclear Physics Institute became part of the Czech Academy of Sciences and now includes the Institute of Radiation Dosimetry and the Neutron Activation Analysis Laboratory. The NPI is comprised of the Departments of Theoretical Nuclear Physics, Nuclear Spectroscopy, Neutron Physics, Nuclear Reactions and Radiation Dosimetry.

f) Nuclear Research Institute Rez, a.s. (NRI)

The NRI is the successor to the Nuclear Research Institute which was founded in 1955. In 1971, it came under the authority of the Czechoslovak Atomic Energy Commission and in 1992 it was transformed into a joint-stock company with the Czech Government holding 50% of its shares, CEZ holding 26%, the Skoda Holding Company 9.8% and Skoda Nuclear Engineering 2.7%.

The NRI's objective is to carry out research and development in nuclear technologies and to implement the results achieved. Employing 600 staff members, NRI operates the divisions/departments of Nuclear Power and Safety, Integrity and Materials, Fuel Cycle Chemistry, Reactor Services, Radiopharmaceuticals. It provides support services to SÚJB.

FRANCE

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I. GENERAL REGULATORY REGIME

1. Introduction

France possesses a highly developed electro-nuclear programme; its 59 operational nuclear reactors located at 20 sites had a total installed capacity of 63.3 GWe in 2002. These reactors supplied 416.5 TWh of electricity, which amounted to 77.9% of the total electricity generated in France. *Électricité de France* (EDF), a state-owned supplier of electricity, owns the vast majority of the commercial reactors, however Electrabel has a stake in a few of them. With the exception of one Phenix (233 MWe) fast breeder reactor, all of the operational power reactors are PWR of three standard types: there are 34 reactors with a gross capacity of 900 MWe, 20 with a gross capacity of 1300 MWe and four with a gross capacity of 1450 MWe. France's gas-cooled reactors are shut down and are being decommissioned.

The Atomic Energy Commission (*Commissariat à l'Énergie Atomique* – CEA) owns the 31 research reactors in France; 15 are operating; 11 are shut down and five have been decommissioned. One planned research reactor, the Jules Horowitz project, calls for a 100 MWe tank-in-pool type reactor. The principal operating research reactors are the PHENIX 233 MWe fast breeder reactor, the SCARABEE 100 MWe and OSIRIS 70 MWe pool reactors and the HFR 58.3 MWe heavy water reactor.

The national policy in France is to reprocess spent fuel so as to recover uranium and plutonium for re-use and to reduce the volume of high-level wastes for disposal. High-level waste is currently vitrified and stored pending the development of a final deep repository. In 1996 the National Agency for Radioactive Waste Management (*Agence nationale pour la gestion des déchets radioactifs* – ANDRA), selected three sites on which it could eventually build long-term disposal facilities. There is an active near-surface low-level waste disposal facility at the *Centre de l'Aube* and one that ceased operation in 1994 at the *Centre de la Manche*. On 14 August 2003, ANDRA opened the world's first centre dedicated to the disposal of very-low-level waste.

Cogéma (*Compagnie Générale des Matières Nucléaires*), a state-owned company, is the world's biggest supplier of uranium. It provides almost half of the nuclear power plants worldwide from its uranium mines in Canada, the United States, Niger, Senegal, Gabon, Australia and France. Cogéma owns a majority share (51.5%) of Eurodif, which owns the world's largest uranium enrichment plant and supplies one-third of the world's total enriched nuclear fuel.

Nuclear legislation in France does not derive from any one general framework act. It has developed in successive stages in line with technological advances and growth in the atomic energy field.

Many of the legal provisions governing nuclear activities in France are, therefore, to be found in the general legislation such as the environmental protection legislation, the Act on Water, the Act on Air and the Rational Use of Energy, the Act on the Control of Atmospheric Pollution and Odours (Acts which form part of the Environment Code since 18 September 2000), the Public Health Code and the Labour Code.

Nevertheless, parliament has adopted a number of specific nuclear acts. Examples include Act No. 68-943 of 30 October 1968, as amended, laying down special rules as to third party liability in the field of nuclear energy (different from the ordinary French law on third party liability), Act No. 52-844 of 19 July 1952, now part of the Public Health Code, specifying licensing requirements for the use of radioelements, Act No. 80-572 of 25 July 1980, as amended, on the protection and control of nuclear materials and Act No. 91-1381 concerning research on radioactive waste management [Sections L.542-1 *et seq.* of the Environment Code].

Although French nuclear law is characterised by its variety of sources, as in other countries where nuclear energy has developed, the original features of this legislation derive chiefly from international recommendations or regulations. For example, radiation protection standards are derived from the Recommendations of the International Commission on Radiological Protection (ICRP) and directives issued by the European Union. Likewise, the French Act of 1968 on the liability of nuclear operators is directly derived from the Paris Convention of 29 July 1960.

French nuclear legislation began to develop from the time the Atomic Energy Commission (*Commissariat à l'énergie atomique* – CEA), a public establishment set up by the state in 1945 [Ordinance No. 45-2563 of 18 October 1945, as amended], which formerly reported directly to the Prime Minister, no longer held a monopoly for nuclear activities. This corresponded with the period when nuclear energy applications were entering the industrialisation stage, thus requiring the involvement of other electricity-generating and industrial fuel cycle operators. This development had several landmarks: in 1963, a system for licensing and controlling major nuclear installations was introduced, making central government responsible for decisions taken to ensure the safety of the population and workers. Prior to this, procedures concerning the licensing and control of industrial activities had been dealt with by the prefect for each *département*. In 1973, this system was expanded to cover the development of the nuclear power programme, and the role of the state authorities was clearly defined at that time. Finally, Decree No. 66-450 of 20 June 1966, as amended, implemented Euratom Directives into French radiation protection legislation.

In the course of the 1980s, the legal texts establishing the CEA were amended so as to strengthen its interministerial status and to back up the Atomic Energy Committee, which acts as a select interministerial committee on nuclear energy matters, by a tripartite Board of Administration including staff representatives.

The CEA is answerable to the Minister for Industry. The main task of the CEA was laid down in September 1992 by the state authorities: to concentrate on developing the control of the atom for purposes of energy, health, defence and industry, while remaining attentive to the requests made by its partners in industry and research.

An important reform was introduced in 2001, strengthening the institutional arrangements with respect to security, monitoring and environmental health warnings. The French Agency for Environmental Health Safety (*Agence française de sécurité sanitaire environnementale* – AFSSE) and the Institute for Radiation Protection and Nuclear Safety (*Institut de radioprotection et de la sûreté nucléaire* – IRSN) were both set up. The IRSN was created by merging the Office for Protection against Ionising Radiation (*Office de protection contre les rayonnements ionisants* – OPRI) and the

Institute for Protection and Nuclear Safety (*Institut de protection et de sûreté nucléaire* – IPSN), forming a new public utility company (an EPIC – *établissement public à caractère industriel et commercial*).

2. Mining Regime

French nuclear mining legislation is governed by the Mining Code and its implementing legislation. The code contains few specific provisions on nuclear substances [Decree No. 56-838 of 16 August 1956 laying down the Mining Code, as amended by Act No. 70-1 of 2 January 1970, partially repealed, Act No. 77-620 of 16 June 1977, as amended, and Act No. 99-245 of 30 March 1999]. Here, as with other substances, the French state does not hold a monopoly for prospecting and mining.

Decree No. 95-427 of 19 April 1995, as amended, on mining concessions contains all the rules relating to the issue, amendment and relinquishing of mining concessions, while underlying rules concerning prospecting continue to be incorporated – without modification – into the Mining Code. A special procedure has been laid down for the issue and control of mining concessions for substances of use in nuclear energy, whereby the Atomic Energy Committee must give its opinion before the application is sent to the General Mining Board (*Conseil général des mines*). After a procedure involving a public inquiry, the decision is taken by the minister responsible for mining.

Act No. 93-3 of 4 January 1993 concerning quarries made general amendments to the Mining Code and to Act No. 76-663 of 19 July 1976, as amended, relating to installations classified for environmental protection purposes [Sections L.511-1 *et seq.* of the Environment Code]. It specifies that the start-up of installations (defined by decree of the Council of State), presenting a significant risk of pollution or accident, or of quarries and waste storage facilities, whether after an initial licence or after a licence for a change of operator, is subject to the provision of financial guarantees [Act No. 93-3, Section 4(2)]. A Departmental Quarries Commission is set up in each *Département* [Section 16(2)]. This Commission studies applications for licences to operate quarries, and issues a reasoned opinion thereon.

3. Radioactive Substances and Nuclear Equipment

Neither natural nor artificial radioelements are dealt with in one single instrument. They are governed by different pieces of legislation, some of which are grouped under the Public Health Code depending on the activities for which they are used.

For example, radioelements are:

- included in Table A of toxic products in the regulations on the import, trade, possession and use of poisonous substances [Decree of 9 November 1937, as amended];
- covered, as radioactive materials (Class VII), by the general regulations concerning the carriage of dangerous substances [Order of 15 April 1945, partially repealed];
- covered by Sections L.511-1 *et seq.* of the Environment Code, which apply to premises where they are handled;

- referred to in the mining regulations of 1959 [Decree No. 59-285 of 27 January 1959, as amended] and in Act No. 61-842 of 2 August 1961, as amended, on the Control of Atmospheric Pollution and Odours;

- subject to Decree No. 2002-460 of 4 April 2002 relating to protection against ionising radiation and to other radiation protection legislation.

The Public Health Code foresaw a special regime for naturally occurring radioelements [Sections L.44(1) to (3)], but it has never been put in place due to the failure to implement legislation pursuant to Section 44(1).

New provisions concerning the protection of the public were introduced into the Public Health Code by Ordinance No. 2001-270 and Decree No. 2002-460 relating to the general protection of persons against the dangers of ionising radiation. A reform has been carried out of the general licensing and notification regime for medical and research applications. This concerns the manufacture, possession, distribution (including import and export) and use of radionuclides, or products or devices containing them, and the use of X-ray machines. The new rules replace the system which had been set up under the auspices of the Interministerial Commission for Artificial Radioelements (*Commission interministérielle des radioéléments artificiel* – CIREA), abolished by the decree.

4. Nuclear Installations

a) Licensing and inspection, including nuclear safety

The basic instruments currently in force were adopted pursuant to Act No. 61-482 of 2 August 1961 on the Control of Atmospheric Pollution and Odours, which expressly provides that decrees will regulate the establishment, operation and supervision of nuclear installations [Section 8].

France approved the 1994 Convention on Nuclear Safety on 13 September 1999.

Lastly, Section 2 of Act No. 95-101 of 2 February 1995 [Section L.121-1 *et seq.* of the Environment Code] on Strengthening Environmental Protection, as amended, established a Commission for public discussion. This Commission itself is not the medium through which the discussions are organised, but its opinion is sought on the opportuneness of holding such discussions. Decree No. 96-388 of 10 May 1996, as amended, relating to consultations with the public and with those involved in decision-making, defines the operation of this Commission and sets out the conditions and terms for public discussion. The result of these texts is that, with regard to nuclear matters, a public discussion may be organised in the event of the establishment of a major nuclear installation on a new site, if this installation will produce electricity or if it constitutes an investment of more than 2 billion French francs (FRF) (EUR 304 898 034).

Nuclear installations are divided into three main categories: major nuclear installations (*installations nucléaires de base* – INB), major nuclear installations classified as secret (*Installations nucléaires de base secrètes* – INBS) and the other nuclear installations which are classified for environmental protection purposes (*Installation classé pour la protection de l'environnement* – ICPE). Technical criteria are used to classify installations in one of these categories.

i) Major nuclear installations (INB)

Implementing the Act of 2 August 1961, Decree No. 63-1228 of 11 December 1963 on nuclear installations (as amended in 1973, 1985, 1990 and 1993) lays down the criteria governing major nuclear installations (*installations nucléaires de base* – INB).

Major nuclear installations include:

- nuclear reactors, except for those forming part of a means of transport;
- particle accelerators (whose characteristics are defined by order) [Order of 27 April 1982];
- plants used for preparing, manufacturing or converting radioactive substances, and in particular for manufacturing nuclear fuels, separating isotopes, reprocessing spent fuel or processing waste (whose characteristics are defined by order) [Order of 11 March 1996];
- facilities for storing, stockpiling or using radioactive substances, including waste (whose characteristics are defined by order) [Order of 11 March 1996].

The Order of 11 March 1996 takes into account the regrouping of radioelements which resulted from Decree No. 88-521 of 18 April 1988 on the general principles for protection against ionising radiation. In substance, the new thresholds are the same as the old ones. The minimum activity thresholds of major nuclear installations and the maximum activity thresholds of installations classified for environmental protection purposes have been fixed so that depending on the activity or nature of the substances used, one or other of the two administrative systems is applicable.

Under the 1963 Decree, as amended, a licensing decree based on a report by the Minister for Industry is required for the establishment of major nuclear installations. This decree is issued following an inquiry procedure at central and local government levels.

Licensing applications are sent to the General Directorate for Nuclear Safety and Radiation Protection (*Direction générale de la sûreté nucléaire et de la radioprotection* – DGSNR) – answerable to the Ministers for Industry, the Environment and Health – which conducts the inquiry. The DGSNR informs the ministers concerned and submits the preliminary safety report supplied by the operator to the appropriate standing group of safety experts, which is assisted by the Institute for Radiation Protection and Nuclear Safety (*Institut de radioprotection et de sûreté nucléaire* – IRSN).

At the same time, the prefect concerned opens the public inquiry into the application, except where the installation has already been the subject of an inquiry prior to a declaration that the installation is in the public interest, and it has not undergone any changes.

The public inquiry opens as soon as the application is filed, and is widely publicised with organised discussion of opposing viewpoints, principally on the impact study. In fact, important major nuclear installations, such as *Électricité de France* (EDF) power plants, are subject to the declaration of public interest procedure, which is carried out by means of a public interest inquiry which follows the same rules as public inquiries. This procedure leads to a decree declaring the installation to be of public interest; however this decree does not exempt the future operator from compliance with the licensing procedure for establishment of the nuclear installation by decree.

In all cases, the procedure laid down in Act No. 83-630 of 12 July 1983 [Sections L.123-1 *et seq.*], as amended, on the Democratisation of Public Inquiries and Protection of the Environment must be followed. This act provides for a public inquiry procedure for projects likely to affect the environment (inquiry to last at least a month, appointment of an inquiry commissioner by the chairperson of the Administrative Tribunal, etc.). A Circular of 27 September 1985 defines the workings of the various decrees adopted in implementation of the 1983 Act (not all of which relate to the nuclear field):

- Decree No. 85-449 of 23 April 1985, as amended, provides that the procedure applies to major nuclear installations governed by Decree No. 63-1128 of 11 December 1963, and defines the thresholds and criteria involved. The classification of the major nuclear installations contained in the Annex of the Decree of 23 April 1985 was modified by Decree No. 96-198 of 11 March 1996 to bring it into line with the revised classification for the installations classified for environmental protection purposes;

- Two other decrees deal with amendments to the provisions adopted in implementation of the Mining Code [Decree No. 85-448], and the conditions for safeguarding national defence secrets [Decree No. 85-693], respectively.

The purpose of these decrees is to ensure that the provisions relating to public inquiries are incorporated within the existing procedures.

The Circular of 27 September 1985 also defines the scope of the Act of 12 July 1983, together with certain arrangements for the holding of the inquiry procedure.

Once the standing group has given its opinion, the results of the inquiry have been received and the ministers consulted have submitted their comments, the DGSNR prepares a draft licensing decree and sends it for opinion to the Interministerial Commission for Major Nuclear Installations and to the Minister for Health for approval before submitting it to the Prime Minister for signature. If approval is not given by the Minister for Health within three months, the decree may be adopted in the Council of Ministers.

The decree authorising construction fixes the perimeter of the installation, the conditions imposed on the operator and details of the commissioning procedure. Under the Ministerial Instruction of 27 March 1973, the start-up of a major nuclear installation is subject to approval by the Ministers for Industry and Research of the final safety report and the general operating rules.

The amendments to the 1963 Decree affected by Decree No. 90-78 of 19 January 1990 relate to the licensing procedure and are designed to harmonise the 1963 Decree with Act No. 87-565 of 22 July 1987, as amended, on the Organisation of Public Safety Measures, Forestry Protection against Fire and the Prevention of Major Risks. It provides that henceforth, licence applications must also be forwarded to the Minister for the Environment accompanied by a document describing, on the basis of the preliminary safety report, the measures necessary to address the particular risks which the installation presents and limit the consequences of any possible accident. As far as major nuclear installations are concerned, this document constitutes a risk analysis within the meaning of the Act of 1987. Licence applications must also specify the measures to be applied for dismantling the installation.

Decree No. 93-816 of 12 May 1993 amends the 1963 Decree as regards the licensing procedure for nuclear installations. The public inquiry procedure may now be extended by a further month (i.e. a

total of three months maximum) by decree adopted following a report by the Ministers responsible for energy and for major technological risks.

Major nuclear installations are inspected by specialised nuclear energy inspectors who report to the Minister for Industry [Decree No. 63-1128 of 11 December 1963, as amended]. Safety is monitored by the DGSNR, with the technical back-up of the Institute for Radiation Protection and Nuclear Safety (IRSN). The IRSN is the expert body responsible for ensuring protection of the public in this field.

The Order and Circular of 10 August 1984 concern the design quality, construction and operation of major nuclear installations. Operators must ensure that the quality of the structures, equipment and operating conditions are commensurate with the importance of their functions from the viewpoint of the safety of the installation concerned [Order of 10 August 1984, Sections 1 and 2]. They must also exercise control over all suppliers of equipment and services. The order prescribes the general principles to be applied for organising quality control, while the purpose of the circular is to explain further the provisions of the order.

These provisions were completed by the adoption on 31 December 1999 of an order establishing the general technical regulations designed to warn against and limit any inconveniences or external risks resulting from the operation of major nuclear installations.

This order was adopted in implementation of Section 10 *bis* of the Decree of 11 December 1963 on nuclear installations, which provides that "the general technical regulations governing the safety of major nuclear installations shall be adopted by order of the Minister for Industrial and Scientific Development". It establishes the general technical regulations designed to warn against and limit any inconveniences and risks in relation to the general condition of the neighbourhood, public health, safety or hygiene, agriculture, protection of nature and the environment, and the conservation of sites and monuments, which may result from the operation of major nuclear installations (INB) and major nuclear installations classified as secret (INBS).

This order does not cover installations classified for environmental protection purposes situated within the perimeter of major nuclear installations; for such installations, the requirements established pursuant to Sections 7, 10 or 10(1) of the Act of 10 July 1976 apply.

The main provisions of this order relate to the following areas:

- noises and vibrations;
- prevention of atmospheric pollution;
- prevention of water pollution;
- management of waste;
- prevention of other risks, in particular fire and nuclear risks.

The order establishes transitional provisions for existing installations, to which the provisions of this text will apply two years after its publication.

ii) Major nuclear installations classified as secret (INBS)

Major nuclear installations classified as secret (*installations nucléaires de base classées secrètes* – INBS) by decision of the Prime Minister, upon proposal of the Minister for Defence and the Minister for Industry, are not subject to the provisions of the 1963 Decree, as amended.

Until 2001, they were regulated by Decree No. 99-873 of 11 October 1999. This was replaced by Decree No. 2001-592 on the safety and radiation protection of defence-related nuclear installations and activities. This decree lays down the legal framework governing the safety of defence-related nuclear installations and activities. The technical criteria for defining INBS are the same as those for major civilian nuclear installations [Decree of 11 December 1963, Section 2]. Major nuclear installations are classified as secret when special protection is justified against nuclear proliferation, malicious intent or the disclosure of classified information [Section 6]. The construction of an INBS is subject to a licence, issued after obtaining the opinion of the Special Commission for major nuclear installations classified as secret, set up by Decree No. 2001-417 of 11 May 2001 [Section 8], as amended.

INBS are subject to licensing, surveillance and inspection, as laid down by Decree No. 2001-592, completed by an Order of 27 July 2001. A delegate for the nuclear safety and radiation protection of defence-related activities and installations is responsible for proposing to the Minister for Defence and the Minister for Industry, nuclear safety regulations applying to defence-related nuclear installations and activities, and for ensuring enforcement by means of inspections. The delegate also has authority to investigate applications for a licence to establish a major nuclear installation classified as secret, and to take all necessary measures to prevent nuclear accidents, and limit the consequences of any that do occur.

The surveillance of major nuclear installations classified as secret is carried out under the responsibility of the nuclear weapons' inspector, who directs the work of the inspectors made available to the delegate by the Minister for Defence and the Minister for Industry, in particular. These ministers set up information boards, by order, with the task of informing the public about the impact of nuclear activities on health and the environment.

Major nuclear installations classified as secret are subject to a regime of licensing, control and inspection, widely based on the Decree of 11 December 1963 (with the exception of measures related to information of the public). This regime is primarily implemented by the High Commissioner for Atomic Energy and under his authority. It should be noted that the supervision of discharge of effluents and the management of waste is carried out without prejudice to the supervision exercised by the bodies competent in the field of ionising radiation protection.

Decree No. 2000-571 of 26 June 2000 extends the provisions of Decree No. 88-622 of 6 May 1988 on emergency plans, to INBS, which must draw up a special action plan (*Plan particulière d'intervention* – PP1).

iii) Non-major nuclear installations

Nuclear installations other than major ones are subject to the general regime for installations classified for environmental protection purposes (*installations classées pour la protection de l'environnement* – ICPE) as established by Act No. 76-663 of 19 July 1976 [Section L.511-1 *et seq.* of the Environment Code], which provides that a notification or licence is required for their construction,

depending on the scale of the potential pollution or risk involved. These installations are under the jurisdiction of the Minister for the Environment.

Licences are issued by the prefect following a public inquiry and consultation of the local government bodies concerned. Where hazards are likely to affect several *départements* or regions, the construction licence is granted by the Minister for the Environment, if necessary after obtaining the opinion of the Higher Council for Classified Installations (*Conseil supérieur des installations classées*).

Decree No. 77-1133 of 21 September 1977, which implemented the abovementioned Act of 19 July 1976, has been modified on several occasions. The last modification, introduced by Decree No. 96-18 of 5 January 1996, takes into account certain provisions of Act No. 92-3 of 3 January 1992 on Water, as amended [Sections L.210-1 *et seq.* of the Environment Code], and of the Act of 2 February 1995 relating to Strengthening Environmental Protection [Section L.121-1 of the Environment Code]. The 1977 Decree applies to all installations subject to the 1976 Act, but does not apply to installations belonging to government departments or agencies. Decree No. 86-1289 of 19 December 1986 amended the provisions governing installations subject to licensing, adding specifications as to the procedure; no changes were made, on the other hand, in respect of installations subject to notification.

Generally speaking, nuclear installations also require planning permission; for facilities intended for the production, transfer, distribution or storage of energy, including those using nuclear materials, planning permission is issued by the state [Town Planning Code/Act of 7 January 1983, as amended], unlike the situation under the ordinary law, when this task is given to the local mayor.

Decree No. 96-197 of 11 March 1996 modifies headings 385 *bis* to six, and in doing so modifies the categorisation of installations classified for the purposes of the protection of the environment in relation to radioactive substances. This revision aims to make the headings of categories classifying installations for the protection of the environment more consistent with those of the radiation protection regulations. It provides, notably, that the classification of radionuclides by reference to their radiotoxicity will now result in there being four groups, rather than three as envisaged previously. In the same way, the classification of nuclear installations was modified by Decree No. 96-198 of 11 March 1996.

Lastly, as concerns provisions relating to the prevention of serious accidents involving the hazardous substances or preparations found in certain categories of installation classified for environmental purposes and subject to licensing, a Circular of 10 May 2000 clarifies the new provisions introduced by Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances (Seveso II Directive) and concerning the policy of preventing serious accidents and the safety management system, risk assessments, recourse to a third party expert, urban planning and an inventory of establishments.

b) Emergency response

In 1994, the International Nuclear Event Scale (INES), used by the International Atomic Energy Agency (IAEA) to measure the severity of nuclear incidents and accidents, was adopted. This scale ranges from 1 to 7, in the same manner as that used to measure the severity of earthquakes: the more serious the accident, the higher the figure. It is intended to facilitate agreement and understanding both within the nuclear industry and for the general public.

Act No. 87-565 of 22 July 1987 on the Organisation of Public Safety Measures, Forestry Protection against Fire and the Prevention of Major Risks, clarifies the previous system for organising assistance and emergency response, and introduces a new right to information about major risks. The act thus deals with the conditions for preparing preventive action and for implementing necessary measures in case of major risks or disasters. The preparation and organisation of assistance are determined within the framework of ORSEC and emergency plans.

Nuclear-related risks are included amongst technological risks. The act provides that the public has a right to be informed about the risks to which they are exposed and about the preventive measures concerning them. Operators for whose installations a special action plan (*plan particulier d'intervention* – PPI) has been drawn up (see below), must help in providing the public with general information about measures taken in the vicinity of such installations. The Minister for the Interior draws up preventive measures and co-ordinates the assistance provided by the state, regional authorities and public bodies for France as a whole [Section 6].

Two Decrees have been adopted in implementation of the Act of 22 July 1987: the first of these is Decree No. 88-622 of 6 May 1988 on emergency plans. This decree, as amended, contains provisions concerning emergency plans, including the category entitled "special action plans" (PPIs). An Order of 30 November 2001 lays down the obligations of nuclear operators with regard to emergency warning procedures. Emergency plans are prepared by prefects in liaison with the competent authorities, services and agencies, and adopted by them [Section 1]. Each emergency plan details the risks in relation to which it has been drawn up, specifies the intervention procedures and defines the tasks of government services, public agencies, regional authorities, etc. [Section 2]. The area covered by the emergency warning arrangements is defined, in light of the risk assessment, by the Prefect of the PPI who first consults the relevant administrative authority responsible for monitoring nuclear safety on the basis of risk assessment. A PPI must be prepared for all nuclear sites including at least one nuclear installation and meeting certain criteria, for example facilities for producing radioactive materials for military use and facilities for manufacturing, assembling or activating elements incorporating radioactive materials for military use [Decree No. 2000-571].

The PPI includes a description of the installation concerned, a list of the communes on whose territory it applies, the measures for protecting and informing the public and diagrams for evacuation of local populations, including information on alternative accommodation [Section 7]. Also listed are the emergency measures for neighbouring populations to be taken by the operator before action is taken by or on behalf of the police authorities. Once a PPI has been finalised [Section 8], it is immediately brought to the attention of the mayors concerned and of the operator. A notice is placed in local or regional newspapers indicating the area to which it applies and places where it may be consulted [Section 9]. The operator is obliged to set up and maintain channels of communication to inform local populations about emergency warning procedures. The operator must be able to launch these procedures from his nuclear installation in the circumstances defined by the Prefect in the PPI. The Order of 21 February 2002 specifies the information destined for the populations living in the area covered by the plan that must be given in the documents prepared by the operators of installations or works for which a PPI is necessary. These information documents must be prepared within three months of the start-up of new installations. This time limit is increased to two years (before 27 February 2004) for already existing installations in relation to which the information arrangements do not comply with the provisions of the order.

The second of these instruments adopted in implementation of the 1987 Act is Decree No. 90-918 of 11 October 1990, as amended, on the exercise of the right to information on major risks. This decree specifies the content and type of information to which persons likely to be exposed to major risks must have access, in accordance with the Act of 22 July 1987. Its provisions apply in

particular to communes for which a PPI has been prepared [Section 2]. The mayor prepares an information document containing a list of the preventive measures he has taken in respect of the risk on the territory of the commune concerned. The public is informed of the existence of this report by posters put up in the town hall, specifying that it may be freely consulted on the spot [Sections 3 and 6].

At the international level, France approved the 1986 Conventions on Early Notification of a Nuclear Accident and on Assistance in the Case of a Nuclear Accident or Radiological Emergency on 6 March 1989.

5. Trade in Nuclear Materials and Equipment

a) General provisions

Trade in nuclear techniques, materials and equipment is a highly sensitive area, and France has developed complex regulations in this respect. These aim on the one hand to establish strict control over the movement of materials and ensure the safety of these materials and of the establishments in which they are held (see Section 8 "Non-Proliferation and Physical Protection" *infra*), and on the other hand, to control exports and imports.

The export and import of nuclear materials and equipment involve general policy decisions taken at the highest level. Thus, the Council for Foreign Nuclear Policy, which was created in 1976 and is chaired by the president of the republic, defines the different aspects of policy to be followed in respect of exports.

The French authorities exercise very strict control over the import and export of sensitive products, substances, materials and equipment. In this context, lists of sensitive products are published in the Official Journal in the form of a notice supplementing existing provisions, and are regularly updated: Notice of 12 August 1988 to exporters concerning products it is prohibited to export, supplementing and updating the provisions of the initial Notice published on 24 November 1964; Notice of 29 November 1990 to importers and exporters relating to the products and technology subject to final destination control, etc.

Act No. 80-572 of 25 July 1980 on the Protection and Control of Nuclear Material is the basic item of legislation in this field, and has been supplemented by Act No. 89-434 of 30 June 1989. It provides that the import, export, manufacture, possession, transfer, use and transport of nuclear materials are subject to prior licensing and control [Section 2]. Decree No. 81-512 of 12 May 1981 on the protection and control of nuclear materials, Chapter II of which deals with import and export licences, was adopted in implementation of the act.

More generally, France has adopted the IAEA system of safeguards to ensure that the nuclear equipment it exports is not used for military purposes. Act No. 92-574 of 1 July 1992 authorised the accession of France to the 1968 Treaty on the Non-Proliferation of Nuclear Weapons, which was approved on 2 August 1992.

The export of dual-use goods and technology – i.e. products, including software and technology, which can be used for both civilian and military purposes, including all products which may be used both for non-explosive purposes and in some way for the manufacture of nuclear weapons or other explosive nuclear devices – is subject to regulation. The provisions applicable are set out in Decree No. 2001-1192 of 13 December 2001, adopted pursuant to Council Regulation (EC) No. 1334/2000 of

22 June 2000 setting up a Community regime for controlling the export of dual-use products and technology through customs procedures. Persons importing dual-use goods, listed in Annex I of the Council Regulation and coming from a non-EU country, can now apply for an international import certificate thus enabling their foreign supplier to obtain an export licence from his national authorities. This certificate is issued by the minister in charge of customs in accordance with the provisions laid down by order. Two Orders of 13 December 2001 specify the formalities to be completed by persons exporting dual-use goods to third countries or transferring them to Member States of the European Union, as well as the formalities for obtaining and using international import certificates and delivery verification certificates.

b) Patents

In France, nuclear industrial property is subject to the normal legal rules set out in the Industrial Property Code [Act No. 92-597 of 1 July 1992, partially repealed].

The only nuclear legislation which deals with invention patents is Decree No. 72-1158 of 14 December 1972 relating to the Atomic Energy Commission (*Commissariat à l'énergie atomique* – CEA), which states that invention patents arising from CEA activities are to be filed in its name [Section 7]. Inventors may receive an award, details of which are determined by the administrator general, having regard to the opinion of the Atomic Energy Committee or in accordance with rules approved by it.

Special provisions exist for inventions relating to national defence or economic development, including those involving nuclear techniques. The state may, by decree, wholly or partially expropriate patents in return for payments to the inventor. Likewise, it may *ex officio* grant licences to certain bodies for patents related to national defence.

The French Nuclear Patent Management Company (BREVATOME), set up in 1958, is responsible for bringing together and managing French nuclear patents. For non-patentable knowledge, BREVATOME has organised know-how transfer through consultancy or co-operation agreements both for systems and for components. Manufacturing secrecy is protected by including clauses on classified information, secrecy or non-transfer of rights in these contracts, termed succession clauses.

6. Radiation Protection

a) Protection of workers

French legislation concerning the radiation protection of workers was substantially overhauled in 2003.

The main instrument in force is now Decree No. 2003-296 of 31 March 2003 on the protection of workers against the dangers of ionising radiation. This Decree completes the implementation into French law of Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation. The new provisions have been incorporated into the Labour Code in Book II, Title III, Chapter I, Section VIII. The following decrees, which previously governed the radiation protection of workers, have been partly or totally repealed:

- Decree No. 66-450 of 20 June 1966, as amended, on general principles for protection against ionising radiation (which laid down the basic principles applicable to workers and the public);

- Decree No. 75-306 of 28 April 1975, as amended, on the protection of workers in major nuclear installations;

- Decree No. 86-1103 of 2 October 1986, as amended, concerning the protection of workers against the hazards of radiation.

Decree No. 2003-296 provides that the head of the establishment is obliged to take the general, administrative and technical measures (in particular, as regards the organisation of work and working conditions) required to prevent work accidents and occupational illness which could be caused by exposure to ionising radiation.

It reaffirms the principle that individual and collective occupational exposure to ionising radiation must be kept as low as reasonably possible and lowers the annual effective dose limit for workers exposed from 50 mSv to 20 mSv. For a period of two years from the date of entry into force of the decree, the maximum total effective dose received by external and internal exposure is set at 35 mSv a year and must not exceed 100 mSv over five consecutive years as from the same date.

In addition, the decree contains a set of technical rules for fitting out places of work (delineating supervised and controlled areas and posting warning signs, technical control of sources and devices emitting ionising radiation, protective and warning measures as well as the measuring instruments used, etc.).

Workers exposed to ionising radiation are classified in two categories depending on the dose they might receive (effective annual dose above or below 6 mSv). These workers are given radiation protection training, and are also monitored by dosimeters measuring their individual external and internal exposure. Operational monitoring is also carried out by dosimeters for workers carrying out activities in controlled areas (who might receive an effective annual dose exceeding 6 mSv). The nominative operational dosimetric results are sent to the head of the establishment.

In addition, the decree sets out details concerning the medical supervision of exposed workers, the rules on abnormal work situations, the functional organisation of radiation protection (designation and tasks of a person qualified in radiation protection, the role of the different authorities such as the occupational physician and the Institute for Radiation Protection and Nuclear Safety) as well as the rules applicable in the event of occupational exposure linked to natural radioactivity.

Decree No. 2003-295, adopted on 31 March 2003, specifies the conditions under which staff and authorised persons should intervene in the event of an emergency resulting from nuclear installation failure. It implements Directive 96/29/Euratom into French law and incorporates new provisions in the Public Health Code in Book I, Title I, Chapter V-I, Section 7. A radiological emergency is defined as an incident or accident which could lead to an emission of radioactive materials or a level of radioactivity which could affect public health. The decree provides that in the event of a radiological emergency, the person in charge of nuclear activity must take the measures for which he is responsible in relation to nuclear and radiological safety, implement, where appropriate, the internal emergency plan and immediately inform the competent authorities. The prefect directs emergency assistance operations and informs the public.

The decree introduces a two-group classification for those intervening: the first group comprises the personnel forming special technical, medical or health intervention teams, constituted in advance to cope with radiological emergencies. This group is subject to radiological monitoring and medical aptitude tests, and should not receive an effective dose of more than 100 mSv. This limit is set at 300 mSv when action is required to protect persons. The second group is made up of individuals who do not belong to the special teams but who intervene as part of their functions. The effective dose limit for such persons is set at 10 mSv.

Several orders have been adopted in implementation of Decree No. 86-1103 of 2 October 1986, in particular:

- the Order of 1 June 1990 defining methods of control pursuant to Decree No. 86-1103 of 2 October 1986 on the Protection of Workers against the Dangers of Ionising Radiation;

- the Order of 1 October 1990 setting out conditions and methods of accreditation of bodies responsible for carrying out controls in relation to the protection of workers against the dangers of ionising radiation and the characteristics of the licence described in Section 29 of Decree No. 86-1103 of 2 October 1986;

- the Order of 2 October 1990 establishing rules on the frequency of controls on sealed sources, installations of electrical apparatus which emits ionising radiation and the protective measures set out in Decree No. 86-1103 of 2 October 1986 on the Protection of Workers against the Dangers of Ionising Radiation.

Two orders were adopted on 23 March 1999. The first of these orders, which establishes rules governing the external dosimetry of radiation workers, specifies that the control of dose equivalents received by workers in Category A, or those who work in a controlled zone and are subject to a risk of external exposure, is carried out using individual dosimeters which measure the exposure in real time (operational dosimetry) and at predetermined times (passive dosimetry). It repeals the Order of 19 April 1968 establishing the conditions for use of individual dosimeters designed to monitor dose equivalents, which was adopted pursuant to the now-repealed Decree of 15 March 1967. The technical modes of implementation of the dosimetry, particularly operational, as well as the transfer of the data involved, are set out in an annex. The second order, which lays down rules concerning the accreditation by OPRI (IRSN) of persons qualified in radiation protection, defines the method of accreditation of "persons qualified in radiation protection or from the service responsible for radiation protection" who have access to the individual results of the exposure of particular workers subject to this control, over a reference period which shall not be longer than the last 12 months.

An Order of 12 May 1998 amending the Order of 8 October 1990, as amended, establishes a list of tasks which may not be performed by workers on fixed-term work contracts or by employees of a temporary employment agency. It further provides that such workers may not carry out activities in zones where the hourly dose rate is likely to be higher than 2 millisieverts.

The rules for the calculation and the transmission of statistical data on exposure to ionising radiation of personnel working in mines producing radioactive substances were laid down by an Order of 15 January 1990. This order provides that operators mining radioactive substances must establish each year statistical data on exposure of mining personnel to ionising radiation [Section 1]. Once completed, the tables should be sent to the regional director for industry and research as well as to OPRI (IRSN). The transmission of this data to OPRI (IRSN) is, however, unconnected with the communication of data which that board centralises, uses and maintains, in implementation of Decree No. 66-450 of 20 June 1966, as amended in 1988.

Decree No. 90-222 of 9 March 1990, as amended, completing the general regulations on extractive industries introduced by Decree No. 80-331 of 7 May 1980, as amended, implements Council Directive 80/836/Euratom, of 15 July 1980, as amended, into French law. This decree inserts in the abovementioned general regulations, Part 2 relating to environmental protection. Part 1, concerning the protection of workers, was introduced by Decree No. 86-1103 of 2 October 1986. The provisions of the 1990 Decree apply to surface facilities and workings of radioactive substances. They determine the annual admissible exposure limits to ionising radiation [Sections 5 to 7], and the monitoring of releases and of the environment [Sections 11 to 16]. It also specifies that work must be conducted in such a way as to ensure that its radiological impact on the environment is as low as possible [Section 3].

Lastly, the Order of 15 October 1992, on the qualifications of persons licensed to use unsealed sources for medical purposes, amended the previous provisions of the Order of 26 March 1974 on the topic, and added further conditions. Thus, users of such sources must henceforth hold the diploma of additional specialised studies in nuclear medicine as established by the Order of 26 July 1983, as amended, or the diploma of specialised studies in nuclear medicine as established by the Order of 23 May 1990, as amended, which sets out the list of diplomas for specialised medical studies, or the diploma of additional specialised radiopharmaceutical and radiobiological studies as established by Order of 29 April 1988, as amended.

It is primarily the responsibility of the specialised services of the Ministry for Health, in particular OPRI (IRSN), to determine the conditions which must be met by nuclear activities in order to comply with radiation protection standards and to ensure that public health is not endangered.

b) Protection of the public

The general protection of the public against the dangers of ionising radiation is governed at European level by Council Directive 96/29/Euratom of 13 May 1996 setting out the basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation, and Directive 97/43/Euratom of the Council of 30 June 1997 on Health Protection of Individuals against the Dangers of Ionising Radiation in relation to Medical Exposures. These directives were implemented into French law by Ordinance No. 2001-270 of 28 March 2001, Decree No. 2002-460 of 4 April 2002, Decree No. 2003-270 of 24 March 2003 and Decree No. 2003-295 of 31 March 2003.

Ordinance No. 2001-270 addresses all activities involving a risk of the exposure of persons to ionising radiation, whether for medical, industrial or research purposes. It introduces into the Public Health Code the fundamental principles of radiation protection, namely justification, optimisation and dose limitation. Provisions regarding prohibitions and authorisations in regard to the use of ionising radiation are brought up to date and completed by a new system of criminal sanctions. Moreover, the rules for managing radionuclides are made stricter and take account of exposure to natural radiation.

Decree No. 2002-460 of 4 April 2002 redefines the basic standards for the health protection of the general public and workers in the context of the implementation of Directive 96/29/Euratom. It redrafts Chapter V-1 of Title I of Book I, and repeals Chapter II of Title III of Book V of the Public Health Code. It also takes account of the reform of the control and expertise bodies effected in the nuclear field by the establishment, on 22 February 2002, of the Institute for Radiation Protection and Nuclear Safety (IRSN) and the General Directorate for Nuclear Safety and Radiation Protection (DGSNR).

As regards the general measures for protecting the public against ionising radiation, the decree confirms the lower annual effective dose limit for members of the public, adopted by Decree No. 2001-215 of 8 March 2001, which is now fixed at 1 mSv a year.

A national network for collecting environmental radioactivity measurements has been set up. It is administered by the IRSN which has also been given responsibility for the national inventory of ionising radiation sources. This network gathers the various results of the environmental analyses imposed by law, and those carried out by the different services of the state and statutory bodies, regional authorities and associations which so request. These results are made available to the public.

The decree extends the provisions on banning the intentional addition of radioactive substances to consumer goods, and lays down the principle of prior authorisation for any planned release of liquid or gaseous effluents and of waste contaminated by radionuclides from nuclear activities with the exception of installations subject to special regulations. Waste and effluents produced by hospitals are included.

Provisions concerning exposure to natural ionising radiation are extended to all professional activities using materials naturally containing radionuclides which are not used for their radioactive properties but which could lead to exposure such as to endanger the health of workers and the public. The monitoring of exposure to radon will be reinforced in establishments open to the public.

In addition, the decree provides for a reform of the general licensing and notification regime for medical and research applications which was previously regulated by Section L.1333-4 of the Public Health Code. This applies to the manufacture, possession, distribution – including import and export – and the use of radionuclides and products and devices containing them, and to the use of X-ray machines. These provisions replace the regime which had been placed under the responsibility of the Interministerial Commission for Artificial Radioelements, abolished since publication of this Decree.

Lastly, in accordance with Section L.1333-4 of the Public Health Code, licences issued to industries falling under the Mining Code, major nuclear installations (INB), major nuclear installations classified as secret (INBS) and installations classified for environmental protection purposes (ICPE), serve as a licence for radiation protection purposes.

Decree No. 2003-270, adopted on 24 March 2003, implements into French law Council Directive 97/43/Euratom of 30 June 1997 on the health protection of individuals against the dangers of ionising radiation in relation to medical exposures, and incorporates new provisions in the Public Health Code [Book I, Title I, Chapter V-I, Section 6].

The health protection of individuals against the dangers of ionising radiation in relation to medical exposures is strengthened by the decree which lays down general principles such as the principle of the justification of exposures to ionising radiation and the principle of optimisation of such exposures. These provisions apply to persons exposed to ionising radiation for medical purposes, whether diagnosis or therapy, or as part of occupational medical supervision or organised screening for a specific illness. Persons participating voluntarily in biomedical research programmes are also covered, as are persons exposed during medical/legal procedures.

The decree provides for the introduction of practical support measures (reference levels, quality assurance). Guides for prescribing and carrying out acts and examinations involving exposure to ionising radiation and containing specific information for acts concerning children, pregnant women and nursing mothers, will be issued by the Minister for Health.

Training in radiation protection for persons authorised to use ionising radiation is given by accredited bodies.

Decree No. 2001-1097 of 16 November 2001 implements into French law Directives 1999/2/EC and 1999/3/EC of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation and establishing a Community list of foodstuffs and ingredients treated in this way.

7. Radioactive Waste Management

a) General Regulations

Under Act No. 75-633 of 15 July 1975, as amended, on Waste Disposal and the Recycling of Materials [Sections L.541-1 *et seq.* of the Environment Code], "waste" means any residue from production, processing or use, any substance, material, product or more generally any personal property abandoned or which its owner intends to abandon.

Section L.541-1 of the Environment Code also provides that waste is ultimately anything, "whether resulting from waste processing or not, which cannot, given the technical and economic circumstances of the time, be processed further, notably by extracting anything of value or reducing its polluting or hazardous nature." Section L.541-2 of the Environment Code requires any producer or possessor of waste to dispose of it in such a way as to avoid any harmful effects. Start-up of a waste storage facility is subject to the provision of financial guarantees by the owner or operator of the facility.

b) Radioactive Waste Regulations

Waste is packaged in a form preventing dispersal and the hazards of irradiation. The integrity of the package is calculated having regard to the nature of the waste and the concentration and half-life of the radionuclides present.

Radioactive waste management in France is based on the fundamental principle of safety, consisting of isolating the waste from the environment for as long as it represents a hazard.

Activities relating to radioactive waste require an official licence and are subject in particular to environmental protection and public health legislation as well as to the Labour Code.

Any nuclear installation, whether producing radioactive waste incidentally or intended for managing or storing such waste, requires a construction licence. Depending on the level of activity of the radioactive substances or waste produced or handled in the installation, the licence will be issued under Sections L.511-1 *et seq.* of the Environment Code or under Decree No. 63-1228 of 11 December 1963 relating to major nuclear installations. Licences are accompanied by technical conditions.

On 30 December 1991, Act No. 91-1381 relating to Research on Radioactive Waste Management [Sections L.542-1 *et seq.* of the Environment Code] was adopted. The act provides that in the management of high-level long-lived radioactive waste, consideration should be given to protecting nature, the environment and health, account being taken of the rights of future generations [Section 1]. The act establishes a programme of work and research in this respect.

Act No. 91-1381 also specifies the conditions for the construction and operation of underground laboratories for the study of deep geological formations in which high-level long-lived radioactive waste might be stored or kept [Sections 6 to 12].

The act also provides that within a maximum period of 15 years from its adoption, the government must submit to parliament an overall assessment of the research undertaken together with a bill authorising, where necessary, the establishment of a storage facility for high-level long-lived radioactive waste, and laying down the obligations attaching to such facility [Section 4].

Furthermore, the Act of 30 December 1991 establishes the National Radioactive Waste Management Agency (*Agence nationale pour la gestion des déchets radioactifs* – ANDRA) and defines its statute and duties.

Several Decrees have been adopted in implementation of the 1991 Act. These are as follows:

- Decree No. 92-1366 of 29 December 1992 concerning public interest groups set up under Section 12 of the act, which determines the conditions for creating public interest groups which may be constituted to provide assistance and to manage equipment for installing and operating each laboratory;

- Decree No. 92-1391 of 30 December 1992 on the National Radioactive Waste Management Agency;

- Decree No. 93-940 of 16 July 1993 deals with the construction and operating licence for underground laboratories for the study of the appropriateness of deep geological formations for the storage of radioactive waste [in this respect, by Decree of 3 August 1999, ANDRA was licensed to install and operate, on the territory of the Bure Commune (Meuse), an underground laboratory designed to study deep geological formations where radioactive waste could be stored];

- Decree No. 99-686 of 3 August 1999 implementing Section 14 of the 1991 Act, providing for the establishment, at the site of each underground laboratory, of a local information and monitoring committee;

- Decree No. 99-687 of 3 August 1999 implementing Section 6 of the 1991 Act, providing for the establishment of a collegiate mission responsible for organising preliminary consultations before a choice is made in relation to one or more granite sites where the initial work leading to the establishment of an underground laboratory could be carried out.

The Ministers for Industry, Research, Health, and the Environment all play a vital role in drawing up a coherent waste management policy and supervising waste-producing installations.

At the international level, France ratified the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter on 3 February 1977.

c) Discharge of effluents

Decree No. 95-540 of 4 May 1995 on liquid and gaseous discharges and on sampling of water from major nuclear installations establishes the procedure to be applied for liquid and gaseous

discharges from major nuclear installations and from installations classified for purposes of environmental protection within the perimeter of a major nuclear installation.

Liquid radioactive effluent releases from major nuclear installations are subject to licensing, according to the classification contained in the Annex to Decree No. 93-743 of 29 March 1993. Gaseous radioactive effluent releases into the atmosphere are also subject to licensing when they are likely to cause atmospheric pollution or release odours as defined in Act No. 61-842 of 1961.

Radioactive releases from installations classified for purposes of environmental protection, within the perimeter of a major nuclear installation, are subject to the same procedure.

Decree No. 95-540 lays down two separate procedures depending on whether an activity is subject to licensing or to notification. Licensing applications as well as notifications must be sent to both the Minister for Industry and the Minister for the Environment. Furthermore, the licensing procedure provides for prior consultation of the Minister for Health and the Minister responsible for public safety. The licence is granted after public inquiry by joint order of the Ministers for Industry, for the Environment and for Health.

Under the decree, the monitoring of radioactive effluents is carried out under the authority of the Minister for Health. When he notes any irregularities, he informs the prefect and the head of the establishment concerned accordingly. The Ministers for Industry and for the Environment are also informed of the event.

A Circular of 20 May 1998 was adopted in order to establish the procedural requirements for licence applications. As regards notification, a receipt is provided to the sender of the notification by the competent ministers [Section 16].

The regime defined by the Decree of 4 May 1995 was complemented by an Order of 26 November 1999 laying down the general technical requirements related to the limits and modes of sampling and releases subject to licence, carried out by major nuclear installations. These requirements concern:

- limits and technical requirements of water sampling and liquid and gaseous releases;
- means of analysing, measuring and controlling licensed activities, as well as the monitoring of their impact on the environment;
- information of state authorities on sampling and releases carried out and their impact on the environment;
- controls carried out by the IRSN and state services; and
- public information.

Individual licence orders shall comply with these general requirements as a minimum. They may include more stringent requirements.

These new requirements apply to licences for sampling and discharges from major nuclear installations and classified installations within their perimeter, as well as to changes introduced into such licences after 5 January 2001.

The General Directorate for Nuclear Safety and Radiation Protection, established by Decree No. 2002-255 of 22 February 2002, is responsible for monitoring liquid and gaseous effluents as well as waste from major nuclear installations.

8. Non-Proliferation and Physical Protection

France has undertaken, notably through its ratification on 2 August 1998 of the 1968 Treaty on the Non-Proliferation of Nuclear Weapons, not to encourage the proliferation of nuclear weapons. France also ratified the 1996 Comprehensive Nuclear Test Ban Treaty on 6 April 1998. This instrument is not yet in force. To this end, it has adopted measures to prevent and control the dissemination of nuclear materials and techniques.

The marketing of materials is regulated by Act No. 80-572 of 25 July 1980 on the Protection and Control of Nuclear Materials (already referred to in Section 5 "Trade in Nuclear Materials and Equipment" *supra*). It deals essentially with the safety of nuclear materials, and with protection against any theft, diversion or loss. "Nuclear materials" are defined as those containing fusible, fissile or fertile elements (plutonium, uranium, thorium, deuterium, tritium, lithium), excluding ores.

The act is based on a system of licensing and control in respect of the possession, import, export and transport of nuclear materials, the physical protection measures depending on the category to which the materials belong (these categories are in line with those contained in international agreements concerning the physical protection of nuclear materials).

Licences are issued by the Minister for Industry after consultation with the Minister for the Interior, and possibly the Minister for Foreign Affairs where nuclear materials are to be imported or exported, and with the Commission for the Protection of the Carriage of Nuclear Materials, where transport is involved, these authorities having 15 days in which to give their opinion. Should there be no reply, their opinion is assumed to be favourable.

Where the quantities of nuclear materials are below certain defined thresholds, a simple notification to the Minister for Industry is sufficient.

Licence holders are obliged:

- to keep accounts and records of nuclear materials;
- to ensure the physical protection of nuclear materials and of installations, buildings or facilities containing such materials;
- to ensure the protection of nuclear materials during transport.

The purpose of these regulations is to be able to obtain prompt information on quantities and location of materials and to protect against any risk of loss, theft, damage, dispersal, etc., regardless of the nature of the events leading to such risk (accident or deliberate interference).

The enforcement of these regulations is carried out by officials sworn to secrecy and appointed by the Minister for Industry, who is backed up by the Institute for Radiation Protection and Nuclear Safety (*Institut de Radioprotection et de Sûreté Nucléaire* – IRSN) on technical control aspects. The Minister thus checks records and accounts concerning nuclear materials drawn up by the possessor himself or stipulated by the Minister. Likewise, he receives prior notice of transport operations and

approves, jointly with the Minister for the Interior, the conditions of carriage on the basis of an opinion from the Commission for the Protection of the Carriage of Nuclear Materials.

The Minister for Industry must be notified as soon as possible of any theft, loss or misappropriation of nuclear materials. Failure to notify is a criminal offence.

An Order of 14 March 1984 lays down measures for the follow-up, control and physical protection of nuclear materials subject to a notification requirement. This order was promulgated in implementation of the above-mentioned Act of 25 July 1980 and of Decree No. 81-512 of 12 May 1981. Notifications must be sent to the IRSN which centralises the information and where necessary, prescribes the conditions to be complied with by the holder of the materials, in implementation of the order.

The 1980 Act was amended by Act No. 89-434 of 30 June 1989, adopted at the same time as the Act approving the 1979 Convention on the Physical Protection of Nuclear Material [Act No. 89-433 of 30 June 1989], which was approved by France on 6 September 1991. The purpose of this act was to bring French law into line with the Convention and to extend the jurisdiction of French criminal courts to cover relevant offences committed abroad.

Compliance with the legislation on the protection and control of nuclear materials in no way exempts the parties concerned from complying with the other regulations in force (radiation protection, carriage of dangerous goods, classified information, etc.).

Research and work on protection are carried out by the IRSN, at the request of the ministerial departments concerned.

9. Transport

The basic law on transport is contained in Act No. 42-263 of 5 February 1942 relating to the Carriage of Dangerous Materials by Rail, Road or Inland Waterway.

The act outlines the general legal framework, leaving detailed provisions to subsequent orders [Section 1] such as the Order of 15 April 1945 approving the regulations on the carriage of dangerous goods by rail, road and inland waterway. These provisions also apply to the transport and handling of dangerous materials in ports.

The 1945 Order has been supplemented and amended on several occasions, including:

- as regards radioactive materials, by an Order of 24 June 1974 relating to the carriage and handling of dangerous materials: transport of radioactive materials, Class VII(b);

- various orders adopted in 1985 relating to the transport and handling of dangerous materials, and laying down certain technical requirements (labelling and warning signs, safety notices, alphabetical listings, etc.). These were followed by an additional order bearing the same name and dated 5 November 1986, introducing wider-ranging amendments. Under this order, it is now possible, by means of ministerial instructions, to define specific measures for implementing the 1945 Regulations concerning defence-related hazardous materials; and nuclear materials in Categories I and II (with the exception of spent fuel) as defined in the Table annexed to the Decree of 12 May 1981 on the protection and control of nuclear materials;

- lastly, the specific requirements under the 1945 Order for the overland transport of dangerous materials (road transport) were almost all repealed by the Order of 15 September 1992, as amended, [Section 1]. The provisions covering both overland transport and at least one of the other two modes of transport no longer apply to road transport, except for Appendix 6 which concerns flexible lead and equipment for pumping hydrocarbons. The repealed provisions have been replaced by provisions annexed to the 1992 Order, and include [Section 2]: Annex A concerning materials and their mode of transport; Annex B concerning transport equipment and transport; and an alphabetical list of the materials concerned. Radioactive materials are covered by both Annexes.

Sea transport is governed by the Order of 12 July 1954, as amended, regulating the carriage of dangerous goods by sea. Furthermore, an instruction on measures to be taken by the state authorities in case of an accident during the maritime transport of radioactive materials was adopted on 7 September 1989. This instruction, entitled "*Plan Nucmar*", defines the general principles for the organisation of measures to be taken by the state authorities in case of an accident occurring during the civilian maritime transport of radioactive materials (Class VII), entailing or possibly entailing damage which could affect the health of man or the maritime environment. The plan applies to any accident occurring within French territorial waters and beyond them when the coast and related interests are endangered, and provides for the formulation of specialised Nucmar emergency plans.

Air transport is governed by an Order of 31 July 1987 concerning protection and control of nuclear materials transported by air.

Consignments through the post are governed by an Order of 22 March 2001 designed to protect workers handling and delivering post, and the environment, from the risks presented by radioactive materials. The international transport of radioactive materials by post is prohibited. Radioactive materials can be accepted for national transport by post subject to the provisions of the ADR (transport of dangerous goods by road), the RID (transport of dangerous goods by rail) and OPSI (technical conditions for operating aircraft by a public air transport company) except for the transport document requirements. Postal consignments of radioactive materials which may be sent by post must be made by a person accredited by the competent authority in a depot it has specially designated for this purpose. Persons already accredited under the previous Order of 18 August 1972, now repealed, are authorised to continue sending consignments provided they comply with the provisions of the new order within a year of its publication. Pursuant to Act No. 80-572 of 25 July 1980 on the Protection and Control of Nuclear Materials [Section 1], Decree No. 81-512 of 12 May 1981 establishes a licensing procedure for the carriage of nuclear materials, whereby a licence is issued by the Minister for Industry following consultation with the Minister of the Interior and the Commission for the Protection of the Carriage of Nuclear Materials. The technical requirements for transport operations are set out in the Order of 26 March 1982 on the protection and control of nuclear materials in the course of carriage, as amended, *inter alia*, by an Order of 12 June 1986. This latter order contains specific provisions on sub-contracting the transport of spent fuel and nuclear materials in Category III (the category requiring the least stringent physical protection controls as provided for by the Decree of 12 May 1981). Thus, carriers of fuel and materials in that category may sub-contract their transport, provided that the sub-contractors concerned are approved by the Minister for Industry [Section 8].

Three orders have been adopted pursuant to the following items of legislation: the Act of 25 July 1980, the Decree of 12 May 1981 and the Order of 26 March 1982.

The Order of 12 June 1986 relates to the protection and control of spent fuel and nuclear materials carried by rail. As for the Order of 31 July 1987, it relates to the protection and control of

nuclear materials carried by air, while the Order of 17 November 1988 concerns the protection and control of nuclear materials carried by sea. These orders detail the conditions to be complied with by the approved carrier, namely the French carrier or foreign licence-holder as provided for by the above-mentioned Act of 25 July 1980. The approved carrier must in particular communicate certain information (planned dates, times and places of departure and arrival, nature and quantity of the nuclear materials) to the Transport Operational Service (*Échelon opérationnel des transports* – EOT), of the IRSN, the Civilian Protection Directorate of the Ministry of the Interior and to the consignee. Other provisions describe the conditions for transporting the materials and fuels covered by the said Orders, the protection measures to be applied during transport and the conditions for monitoring transport.

In the case of transport by rail, road or inland waterway, the National Civil Protection Service is kept informed of consignments of materials in nuclear safety Categories I, II and III [Orders of 12 July 1954, 22 August 1957 and 24 June 1974, as amended]. The IRSN is kept informed of contamination checks which must be carried out on vehicles specialising in the carriage of radioactive materials. Approval certificates and licences for carriage by sea are granted by the minister responsible for shipping. The Navigation Inspectorate issues licences for the shipping of nuclear cargoes. For air transport, licences are issued by the Secretary-General for Civil and Commercial Aviation. Such licences are not required for air freight operators complying with the recommendations of the International Air Transport Association (IATA).

In general, French legislation on the physical protection of radioactive materials is based on the 1973 Recommendations of the IAEA. Transport safety is based on the definition of criteria for classifying materials in accordance with certain risks (radiotoxicity, dispersal, criticality) and for selecting appropriate packaging.

As regards international transport, France has adhered to the International Regulations concerning the Carriage of Dangerous Goods by Rail (RID) [Decree No. 67-880 of 20 September 1967 and the Order of 5 June 2001 which, repealing the previous orders, implements into French law the 2001 amendment of the regulations concerning the international carriage of dangerous goods by rail]. France is also party to the European Agreement concerning the international carriage of dangerous goods by road (ADR) [Decree No. 60-794 of 22 June 1960 and Order of 5 December 1996, as amended]. An Order of 1 June 2001 implements into French law the 2001 amendment of the ADR Agreement which completely restructures the agreement, and modifies the special national provisions which France wanted to keep. France has also adhered to the regulation on the carriage of dangerous substances on the Rhine (ADNR) [Decree No. 96-1056 of 3 December 1996].

Since the adoption of Decree No. 97-715 of 11 June 1997, the Minister for the Environment and the Minister for Industry jointly exercise responsibility for the drafting and implementation of nuclear safety policy, including aspects related to the transport of radioactive and fissile materials for civil purposes.

10. Nuclear Third Party Liability

French law on nuclear third party liability is based on the 1960 Paris Convention and the 1963 Brussels Supplementary Convention which France ratified on 9 March 1966 and 30 March 1966, respectively. French legislation supplements the provisions of these Conventions as regards matters under the jurisdiction of national governments. Act No. 90-397 of 11 May 1990 authorised ratification of the two Protocols of 16 November 1982 amending the Paris Convention and the Brussels Supplementary Convention, published in Decree No. 91-27 of 4 January 1991. Ratification took place

on 6 July 1990. Furthermore, France ratified the 1971 Convention relating to Civil Liability in the Field of Maritime Carriage of Nuclear Material on 2 February 1973.

Act No. 68-943 of 30 October 1968, as amended by Act No. 90-488 of 16 June 1990, sets out measures left to the initiative of the Contracting Parties by the Paris and Brussels Conventions. It governs the third party liability of the operators of land-based nuclear installations. Its main provisions concern:

- the liability amount of the operators of nuclear installations which is fixed at FRF 600 million (EUR 91 469 410.34); this amount is reduced to FRF 150 million (EUR 22 867 352.99) when only low-risk installations are operated on the same site. Decree No. 91-355 of 12 April 1991, adopted in implementation of the 1968 Act, as amended by the Act of 16 June 1990, lays down the definition of low-risk installations;

- the operator's maximum liability amount which is fixed at FRF 150 million (EUR 22 867 352.99) for transport of radioactive substances regulated by the Paris Convention;

- compensation of damage in excess of the operator's liability amount: this compensation is paid by the state out of public funds under the conditions and within the limits specified in the Brussels Supplementary Convention [namely 300 million Special Drawing Rights (SDR)];

- compensation of nuclear damage caused by military installations, which is assumed by the state in the same manner as other installations;

- the competent national court: jurisdiction is attributed to the *Tribunal de Grande Instance* of Paris.

Decree No. 73-322 of 15 March 1973, as amended, on insurance and re-insurance of exceptional and nuclear risks, empowers the Central Re-Insurance Fund to cover, with state guarantee, the risks for which operators of land-based and mobile nuclear installations are liable and regarding which provision is made for state intervention.

Act No. 68-1045 of 29 November 1968 deals with the third party liability of the operators of nuclear ships. It was supplemented by Decree No. 69-690 of 19 June 1969. The liability regime is based on that of the Act of 30 October 1968, as amended. Another Act No. 88-1093 of 1 December 1988 lays down the liability rules for the operators of such ships assigned to public service. In the event of nuclear damage caused outside French territory, the amount of liability is determined by the law of the state on whose territory or within whose territorial waters the damage was caused. Should there be no limit under the legislation of this state, responsibility is then unlimited.

II. INSTITUTIONAL FRAMEWORK

After World War II, the French government, which was then led by General de Gaulle, felt that there was a pressing need at national and international level to take steps to enable France to hold its own in the field of atomic energy research.

As a result, the Prime Minister was made personally responsible for atomic energy, and a specialised agency – the Atomic Energy Commission (*Commissariat à l'énergie atomique* – CEA) was set up directly under his authority for this purpose. Responsibility for atomic energy was later entrusted to a minister. Since 1969, this task has been carried out by the Minister for Industry.

When nuclear energy entered the industrial stage, it was necessary to reorganise existing structures. While defining their respective roles, it was decided to link up the Atomic Energy Commission (which remained the specialised agency for research and development, becoming the holding company for an industrial group specifically concerned with fuel cycle activities) and *Électricité de France* (EDF) (which, with a monopoly for the distribution of electricity, became the chief nuclear operator, with responsibility for constructing and operating nuclear power plants).

At the same time, it was decided to establish clear boundaries between the authorities responsible for supervising nuclear activities and operators.

In view of the implications of nuclear energy, the main ministries play an active role in their respective fields of jurisdiction and are involved in licensing and control procedures for nuclear activities, while numerous interministerial committees provide the necessary co-ordination between the various authorities.

1. Regulatory and Supervisory Authorities

a) President of the Republic

The president of the republic is the guarantor of national independence, territorial integrity and observance of treaties.

Since it is vital to control exports of nuclear materials and equipment with a view to preventing the proliferation of nuclear weapons, the Council for Foreign Nuclear Policy has been set up. It is chaired by the president of the republic [Decree No. 76-845 of 1 September 1976].

Council for Foreign Nuclear Policy

The Council was set up in 1976 to define the major principles of French foreign nuclear policy, especially with regard to the export of sensitive nuclear technology, equipment and products [Decree No. 76-845 of 1 September 1976, as amended by Decree No. 81-822 of 4 September 1981, Section 1].

The Council, chaired by the president of the republic, includes, in addition to the Prime Minister, the ministers for industry, research, foreign affairs and defence, as well as the administrator-general of the Atomic Energy Commission. Other ministers and certain senior civil

servants or military officials may be invited to participate in the Council's work on matters falling within their field.

The secretary-general of the office of the president of the republic handles secretariat duties for the Council.

b) Prime Minister

The Prime Minister plays a leading role in the adoption of important decisions at governmental level and is also the chairperson of the specialised committees in the field of nuclear energy.

Interministerial Committee for Nuclear or Radiological Emergencies (CICNR)

Decree No. 2003-865 of 8 September 2003, creating the Interministerial Committee for Nuclear or Radiological Emergencies (*Comité interministériel aux crises nucléaires ou radiologiques* – CICNR), makes changes to the general rules for organising and implementing nuclear safety. The CICNR in fact replaces the Interministerial Committee for Nuclear Safety (CISN), set up by Decree No. 75-713 of 4 August 1975, which is abolished by the above-mentioned Decree of 8 September 2003.

The CISN, placed under the authority of the Prime Minister, had wide-ranging duties with regard to nuclear safety. It was, in particular, responsible for co-ordinating measures to ensure the protection of persons and property against any hazards arising from the creation, operation or shut down of nuclear installations or the storage, transport, use or processing of radioactive substances. The CISN's duties did not cover nuclear installations intended exclusively for defence purposes and classified as secret. This is not, however, the case for the CICNR, which is competent to monitor defence-related nuclear issues.

The task of the CICNR is to propose to the Prime Minister the measures to be taken "in the event of an accident occurring in a major nuclear installation, a major nuclear installation classified as secret, during the transport of nuclear or radioactive materials concerning the civilian sector or defence or any military nuclear system, and in the event of an attack or threatened attack having or potentially having nuclear or radiological consequences" [Section 1 of the Decree].

The CICNR may therefore meet, at the request of the Prime Minister, if a nuclear or radiological emergency has arisen concerning the civilian or defence sectors, but also in a preventative manner, should there be the threat of an attack.

The CICNR brings together around the Prime Minister the Ministers for Foreign Affairs, Defence, the Environment, Industry, the Interior, Health and Transport. The Secretary-General for National Defence handles secretariat duties for the Committee.

Other government services or establishments, as well as the nuclear operators concerned may be invited to CICNR meetings. However, at the request of the Prime Minister, the CICNR may be convened on a select basis.

The Secretary-General for National Defence plays a key role in the organisation set up by the Decree of 8 September 2003. In conjunction with the ministries and services concerned, his main task [Section 2 of the Decree] is to co-ordinate, plan and ensure the coherence of any measures to help

prevent the situations referred to in Section 1 of the decree, and of the means of action implemented in the event of a nuclear or radiological emergency.

The Decree of 8 September 2003 also provides that the Secretary-General for National Defence should be informed without delay of any accident, attack or threat of a nuclear or radiological nature. He then prepares a report for the President of the Republic and the Prime Minister.

The decree provides that the ministries, establishments, advisory bodies and nuclear operators concerned shall if necessary assist the Secretary-General for National Defence in carrying out the abovementioned tasks.

Secretary-General for National Defence

The Secretary-General assists the Prime Minister in his duties relating to overall defence matters. He handles secretariat duties for defence boards and committees. He thus co-ordinates nuclear safety matters connected with defence installations.

Interministerial Technical Committee for Matters Relating to the Application of the Treaty Establishing the European Atomic Energy Community

Chaired either by the Prime Minister or the minister responsible for atomic energy, this Committee (*Comité technique interministériel pour les questions relatives à l'application du Traité instituant la Communauté européenne de l'énergie atomique*) examines and implements directives and decisions connected with Euratom, under the authority of the Interministerial Committee for European Economic Co-operation Matters [Decree No. 58-344 of 3 April 1958].

The CEA provides secretariat facilities. The Interministerial Technical Committee is responsible for drawing up directives defining the French government's position within the various bodies set up under the Euratom Treaty, and ensures that Community legislation is implemented.

Atomic Energy Committee

The existence of this Committee is mentioned here merely for the record, since it was set up under the CEA Statute and will therefore be dealt with later, in the section on the CEA.

The reform introduced by the Decree of 24 August 1982 amending the Decrees of 29 September 1970 and 14 December 1972 on the CEA means that the Atomic Energy Committee is now basically a select interministerial committee for this specific field.

The Committee is chaired by the Prime Minister or by a minister delegated by the Prime Minister for this purpose. It has 12 *ex officio* members, namely the Administrator-General of the CEA, the Army Chief of Staff, the Secretary-General of the Ministry for Foreign Affairs, the Delegate-General for Weaponry, the Secretary-General for Administration of the Ministry for Defence, the Director-General for Energy and Raw Materials, the Director-General for the Information Technology Industry and the Post Office, the Budget Director, the Director-General for Nuclear Safety and Radiation Protection, the Director of Research, the Director of Technology and the Chairperson of the Management Board of the National Scientific Research Centre, a person of standing selected by the Prime Minister, a person of standing selected by the Minister for the Environment, and three

experts in science and industry, one of whom acts as High Commissioner [Decree No. 2000-599 of 29 June 2000].

Apart from its CEA duties (deciding CEA programmes, adopting the CEA budget, and approving share acquisitions and sales), the Atomic Energy Committee may be asked to look into general nuclear policy matters.

c) Minister for Industry

The Minister for Industry is responsible for keeping abreast of all industrial or energy applications in the nuclear field. He is jointly responsible with the Minister for the Environment for drawing up and implementing nuclear safety policy, including the transport of radioactive and fissile materials for peaceful uses [Decree No. 97-710 of 11 June 1997 on the duties of the Minister for Economy, Finance and Industry]. The Prime Minister may request him to chair the Atomic Energy Committee of the CEA.

The main directorates of the Ministry for Industry involved in the nuclear energy field are the following [Decree No. 93-1272 of 1 December 1993 as amended; Decree No. 97-710 of 11 June 1997 on the duties of the Minister for Economy, Finance and Industry, Decree No. 2002-255 of 22 February 2002].

As regards industrial activities, nuclear energy is one of the responsibilities of the General Directorate for Energy and Raw Materials (*Direction générale de l'énergie et des matières premières* – DGEMP), which draws up and implements government policy in regard to energy and raw materials [Decree No. 93-1272 of 1 December 1993 on the organisation of the central administration of the Ministry for Industry, Post and Telecommunications and Foreign Trade, as amended]. It now includes the Directorate for Energy and Mineral Resources and the Directorate for Energy Demand and Markets.

The DGEMP, on behalf of the Minister for Energy, is the supervisory authority for all the public establishments and enterprises falling within its jurisdiction, including the Atomic Energy Commission (CEA), the National Agency for the Management of Radioactive Waste (ANDRA) and the Institute for Radiation Protection and Nuclear Safety (IRSN). The DGEMP is also responsible, within its jurisdiction and on behalf of the Minister, for relations with other countries and international authorities. It helps formulate the position of the French government and takes part in the negotiation of international agreements.

The tasks of the DGEMP are:

- to formulate and implement the policy designed to ensure the security of the supply of energy and raw materials, in economically competitive conditions, as well as government decisions concerning the civilian nuclear sector, subject to the powers of the authorities responsible for nuclear safety and radiation protection;

- to propose all measures helping to develop policy concerning the nuclear industry in France and abroad;

- to help monitor exports of sensitive materials and nuclear equipment, co-ordinate the preparatory work for the transport of waste from foreign spent fuel reprocessing, and

draft regulations concerning in particular third party liability and nuclear non-proliferation.

Pursuant to Decree No. 2002-255 of 22 February 2002, a General Directorate for Nuclear Safety and Radiation Protection (*Direction Générale de la Sûreté Nucléaire et de la Radioprotection* – DGSNR) was created within the Ministry of Economy, Finance and Industry. This Directorate combines the tasks of the former Directorate for the Safety of Nuclear Installations (DSIN) of the State Secretary for Industry, the Radiation Office of the General Directorate for Health, and the section of the Office for Protection against Ionising Radiation (OPRI) responsible for monitoring radiation protection. It is placed under the authority of the Ministers for Industry, the Environment and Health.

The task of the DGSNR is to formulate, propose and implement government nuclear safety policy, except as regards defence-related nuclear installations and activities, and in matters of radiation protection. To perform its mission, it must in particular:

- prepare and implement all measures concerning the safety of major nuclear installations and of the transport of radioactive and fissile materials for peaceful uses;
- prepare and implement, in liaison with the other competent services, all measures designed to prevent or limit the health risks related to exposure to ionising radiation;
- organise safety inspections of major nuclear installations and, in conjunction with the competent services of the Minister for Transport, of the transport of radioactive and fissile materials for peaceful uses;
- organise the radiation protection inspections provided for by the Public Health Code;
- organise the permanent monitoring of radiation protection, notably the radiological monitoring of the environment throughout the country;
- monitor releases of gaseous and liquid waste, and waste from major nuclear installations;
- gather all relevant information in the field of nuclear safety and radiation protection and on the measures taken in this field in France and abroad, and circulate such information to the services concerned;
- help to inform the public about issues relating to nuclear safety and radiation protection.

Consequently, the DGSNR prepares technical regulations concerning nuclear safety, and arranges and carries out inspections of nuclear installations. In order to carry out its tasks, the DGSNR relies on the resources of the Minister for Industry in regard to nuclear safety, i.e. principally:

- standing groups of experts, which examine technical problems arising in regard to nuclear safety and the construction, commissioning, operation and shut down of nuclear installations;
- the IRSN, which looks into the technical aspects of safety matters and acts as *rapporteur* to the standing groups;
- the Higher Council for Nuclear Safety and Information.

Owing to the size of the French nuclear programme, the state authorities have decided to decentralise supervision of nuclear installations to the regional directorates for research and industry. These provide the natural link between operators and local authorities. Within the main regional directorates whose areas contain nuclear installations, special nuclear divisions have been set up in order to play a key role in the supervision of such installations.

Regarding the safety of nuclear materials, the senior defence official under the Minister for Industry assists the Minister in his defence duties [Decree No. 93-1272 of 1 December 1993 on the organisation of the central administration of the Ministry for Industry, Post and Telecommunications and Foreign Trade]. He is also responsible for security matters concerning the protection and transport of such materials. To this end, he chairs the Commission for the Protection of the Carriage of Nuclear Materials, which is consulted in the course of the licensing procedure for the transport of nuclear materials. This Commission also helps to draw up regulations relating to the physical protection and control of nuclear materials during transport.

A Nuclear Engineering Terminology and Neology Commission under the Minister for Industry has also been set up [Order of 23 May 1997]. This Commission is responsible for drawing up an inventory of the gaps in French nuclear engineering vocabulary, taking into account user needs, for proposing the necessary terms and for monitoring the harmonisation of terms between French-speaking countries.

Lastly, the Minister for Industry, working in conjunction with the Minister for Defence, formulates policy regarding the safety of defence-related nuclear installations and activities [Decree No. 2001-592 of 5 July 2001].

d) Minister for the Environment

The Minister for the Environment has two major functions in the nuclear field:

- installations classified for environmental protection purposes are under his jurisdiction; in this respect he chairs the Higher Council for Classified Installations [Decree No. 76-323 of 29 December 1976];

- he plays a leading role in pollution and water control and is responsible for the water agencies.

He is co-signatory of the decrees which authorise the establishment of major nuclear installations. Lastly, the environmental impact studies accompanying licensing applications for nuclear installations are submitted to him.

The Minister for the Environment, together with the Minister for Industry and the Minister for Research, is also the supervisory authority for the National Radioactive Waste Management Agency [Decree No. 93-787 of 8 April 1993, Section 3(6)].

In relation to nuclear safety, the Minister for the Environment exercises, jointly with the Minister for Industry, responsibilities in respect of the definition and implementation of nuclear safety policy, including transport of radioactive and fissile materials for peaceful purposes; moreover, he exercises authority, in conjunction with the Minister for Industry and the Minister for Health, over the General Directorate for Nuclear Safety and Radiation Protection.

e) Minister for Research

The Minister for Research is responsible for proposing and implementing government policy in the field of research and technology, in conjunction with the other ministers concerned. He is also responsible for technical and technological instruction in higher education establishments.

If necessary, he may call on the services of the General Directorate for Industry and the General Administrative Directorate of the Ministry for Industry, and the regional directorates for industry and research.

He may, if so requested by the Prime Minister, chair the Atomic Energy Committee of the CEA.

As far as research activities are concerned, including nuclear research, funds for public bodies carrying out technological research and development activities come out of the budget of the Minister for Research.

The Scientific and Technical Unit advises the Minister on scientific and technical aspects of matters for which he is responsible.

The Directorate for Technology is responsible for developing means to use to best advantage the results of public research and technical cooperation with industry, to participate in the setting up of research and technological development programmes financed by the European Union and to follow their implementation.

The Directorate for Research draws up policy relating to research, training by research and scientific employment and ensures its implementation. Moreover, those research bodies which do not report to the Directorate for Technology come under its jurisdiction. This Directorate is also responsible for preparing the budget for civilian research and technological development, and its co-ordination.

f) Minister for Health

The Minister for Health is responsible for protecting the health of the population. Decree No. 2002-986 of 12 July 2002 defines his/her responsibilities in this field. The Minister for Health has authority over the General Directorate for Health and the General Directorate for Nuclear Safety and Radiation Protection. The IRSN also reports to this Minister.

The French Agency for the safety of health products (*Agence française de sécurité sanitaire des produits de santé* – AFSSAPS) also reports to the Minister for Health. AFSSAPS is in particular responsible for issuing licences for the manufacture, possession, distribution, import and export of radionuclides and for testing ionising radiation emitting devices for medical use.

All licences to establish a major nuclear installation must be approved by the Minister for Health.

g) Minister for Employment

The Minister for Employment has powers in the field of the safety, health and welfare of employees directly exposed to ionising radiation at work.

As mentioned above, he receives support from the IRSN. He is also assisted by the Industrial Health Commission which gives opinions on all legislation concerning occupational health and safety. At local level, he has *département* labour offices. Labour inspectors are responsible for checking compliance with the legislation within firms.

h) Minister for the Interior

The Department of Defence and Public Safety

The Department of Defence and Public Safety (*Direction de la défense et de la sécurité civiles*) assists the Minister for the Interior in the exercise of his duties in relation to the preparation and implementation of defence measures within his own services as well as in other state services under his responsibility. The Defence and Public Safety Director, a senior civil servant in the defence field, has authority over all the departments and services of the Ministry for the Interior for the exercise of his duties in this field.

The duties of the Defence and Public Safety Director are as follows:

- he provides a permanent link with the Secretary-General for Defence, prefects, chiefs of staff, the general Inspectorate for national operational defence as well as with senior civil servants in the defence field within different ministerial departments;
- he performs secretariat duties and organises the operations of the Standing Commission on Defence;
- he assists the Minister or represents him in the commissions, committees, working groups and meetings dealing with defence issues both at interministerial level and within the various ministries concerned;
- he co-ordinates the preparation and, where necessary, the implementation of defence plans, exercises and measures under the responsibility of the Minister for the Interior;
- he is responsible for implementing the provisions relating to defence security and secrecy protection.

Under the authority of the Defence and Public Safety Director, the services of the Department of Defence and Public Safety include:

- Unit for Defence and Maintenance of National Services;
- Inspectorate for Public Safety;
- Sub-Directorate for Administration and Modernisation;
- Sub-Directorate for Preventive Measures and the Protection of the Population;
- Sub-Directorate for Emergency Services and the Fire Brigade;
- Sub-Directorate for Emergency Organisation and Civil Defence.

The Defence and Public Safety Director has ultimate authority over the military personnel of public safety services.

In the exercise of his tasks of defence and public safety, the Defence and Public Safety Director is assisted by members of personnel on secondment from central administration, the permanent professional staff of the police force and professionals from other services under the authority of the Ministry for the Interior. Military personnel may be seconded from the Ministry for Defence.

Act No. 87-565 of 22 July 1987 on the Organisation of Public Safety Measures, Forestry Protection against Fire and the Prevention of Major Risks states that public safety measures aim to prevent all types of risk and to protect persons, property and the environment against accidents, disasters and catastrophes [Section 1].

The preparation of preventive measures and the implementation of measures necessary to deal with major risks and catastrophes are addressed in the emergency plans, including the "Orsec plans".

The Minister for the Interior must intervene in order to organise emergency services in the event of an incident or to deal with any terrorist action.

Central Office for the Prevention of Illicit Trading in Weapons, Ammunition, Explosives and Nuclear, Biological and Chemical Materials

This Office (*Office central pour la répression du trafic des armes, des munitions, des produits explosifs et des matières nucléaires, biologiques et chimiques*) was set up within the Ministries for the Interior and for the Environment (General Directorate for the National Police Force, Central Directorate for Criminal Investigation) [Decree No. 82-1050 of 13 December 1982].

It has the twofold task of preventing and prosecuting unlawful acts or offences concerning the possession of nuclear materials.

i) Minister for Transport and Housing

The Interministerial Commission for the Carriage of Dangerous Goods (*Commission interministérielle du transport des matières dangereuses*) was set up in 1941 to help develop regulations for the carriage of dangerous materials by rail, road, inland waterway or air and for the handling of these materials in seaports [Decree No. 95-1029 of 13 September 1995 on the Interministerial Commission for the Carriage of Dangerous Goods, Orders of 15 April 1945 approving the Regulations on carriage of dangerous or infectious goods and 11 October 1948, Regulations of 1952 for the carriage of dangerous goods by sea]. Under transport Regulations, nuclear materials form part of the Commission's responsibilities [Class VII(b)]. The Commission has a membership of 50 and holds four plenary sessions per year.

The transport of dangerous goods by sea is dealt with by a commission under the authority of the General Directorate for Shipping. As far as air transport is concerned, IATA rules apply and therefore a Commission has not been set up.

j) Minister for Defence

The Minister for Defence is responsible for the safety and radiation protection of defence-related nuclear installations and activities. These include major nuclear installations classified as secret as well as weapons systems and nuclear-powered ships (military nuclear systems), defence-related nuclear experimental sites and installations, and the transport of fissile or radioactive materials for military use.

He has joint powers with the Minister for Industry to formulate and implement safety policy for defence-related nuclear installations and activities.

A delegate for the nuclear safety and radiation protection of defence-related activities and installations is appointed by decree on the joint proposal of the Minister for Defence and the Minister for Industry, for a renewable period of five years [Decree No. 2001-592 of 5 July 2001]. He is responsible for proposing to the Minister for Defence and the Minister for Industry, nuclear safety regulations applying to defence-related nuclear installations and activities, proposing technical measures to protect against ionising radiation in relation to the same installations or activities, and investigating licensing applications for the establishment of a major nuclear installation classified as secret and for the development of new types of military nuclear systems.

The Nuclear Weapons Inspectorate, the organisation and functioning of which are laid down in Decree No. 2002-702, is headed by a nuclear weapons inspector, and is placed under the direct authority of the President of the Republic. The task of the Inspectorate is to enforce application of the measures to ensure government control of nuclear weapons so as to guarantee that the head of state is able to unleash such weapons at any time, and also that weapons are not used without legitimate government authority [Section 3].

The Weapons Delegate-General, the Chief of Staff of the Navy, the Chief of Staff of the Air Force and the Director of Service with national jurisdiction (DCN) share responsibility for using military nuclear systems and major nuclear installations classified as secret falling within the jurisdiction of the Minister for Defence [Order of 27 July 2001]. These responsibilities are shared by:

- the authorities responsible for analysis, who define general organisational principles with a view to reaching and maintaining the level of safety defined by the Minister for Defence for military nuclear systems, major nuclear installations classified as secret or the transport of related fuel elements, help define safety and radiation protection rules and co-ordinate, at central level, the measures to be taken to prevent accidents, the action to be taken in the event of such accidents and the radiological monitoring of the environment;

- the authorities responsible for implementation, who organise the material and human resources required, apply the rules and obligations relating to nuclear security and ensure their application by subordinate authorities;

- territorial military authorities, who co-ordinate the measures taken on the one hand by force commanders of bases and military nuclear systems, directors of establishments and those in charge of major nuclear installations classified as secret, individual installations or the transport of fuel elements, and on the other hand by the competent government services in the fields of the prevention of accidents or incidents and of the radiological monitoring of the environment.

Each of these authorities organises an internal control carried out by an "inspector of nuclear security measures", who reports to them directly.

A Council for Nuclear Defence in the field of defence-related nuclear activities (*Conseil de l'exploitation nucléaire de la défense pour les activités nucléaires intéressant la défense* – CEND) has been set up under the Minister for Defence [Order of 13 March 2002]. The task of the CEND is to ensure the coherence of the measures taken by the Ministry for Defence in relation to the requirements of nuclear security and operational, industrial and financial imperatives. It also gives opinions and recommendations with regard to these measures. The CEND is chaired by the chief of staff of the army.

2. Specialised Committees or Boards

In the previous section on the powers of the main ministries concerned with nuclear activities, the roles of the Interministerial Committee for Nuclear or Radiological Emergencies, the Council for Foreign Nuclear Policy, the Interministerial Technical Committee for Matters Relating to the Implementation of the Euratom Treaty, and the Interministerial Commission for the Transport of Dangerous Materials have already been described. The following is a brief description of the Interministerial Commission for Major Nuclear Installations, the Special Commission for Major Nuclear Installations classified as Secret and the Higher Council for Nuclear Safety and Information. It may be noted that the Interministerial Commission for Artificial Radioelements (CIREA), set up in 1952, was abolished by Ordinance No. 2001-270 of 28 March 2001.

a) Interministerial Commission for Major Nuclear Installations (CIINB)

This Commission (*Commission interministérielle des installations nucléaires de base* – CIINB) is asked for its opinion on licensing applications for establishing or modernising major nuclear installations and on specific provisions applicable to such installations. It is also consulted and makes proposals regarding the preparation and application of regulations relating to such installations [Decree No. 63-1228 of 11 December 1963, as amended by Decree No. 73-405 of 27 March 1973, Section 8]. Draft legislation on the safety and protection of workers is submitted to it.

The chairperson is a Counsellor of State, and the vice-chairperson, the CEA High Commissioner [Section 7].

It has 29 full and 29 deputy members appointed for five years by order of the Prime Minister and representing the various ministries and bodies concerned.

A permanent secretary is appointed by the Prime Minister on the proposal of the Minister for Industry, and is entitled to vote [Section 9]. On the basis of the licensing applications for establishing nuclear installations received by him, he draws up the reports to be considered by the Commission.

When investigating a specific matter, the CIINB may call on experts from the scientific and technical fields.

The Commission holds at least one meeting a year at the request of its chairperson. Voting is by majority of the members present. If the votes are split equally, the chairperson has the casting vote.

The Commission has set up a select group within its structure, i.e. the Permanent Section, consisting of the chairperson, the vice-chairperson and the permanent secretary together with nine representatives of ministerial departments concerned, co-opted by the chairperson. The Permanent Section gives an opinion on licensing applications in cases of minor importance.

b) Special Commission for Major Nuclear Installations classified as Secret

The Special Commission for Major Nuclear Installations classified as Secret was set up by the Decree of 11 October 1999 [Section 4], as amended. The Commission has been given the same powers as the Interministerial Commission for Major Nuclear Installations. It is asked to give an opinion on licensing applications for the establishment or modernisation of major nuclear installations classified as secret, and on the particular requirements applying to such installations.

The composition of the Commission is laid down by the Decree of 11 May 2001. Members of the Commission are appointed for a maximum period of five years.

c) Higher Council for Nuclear Safety and Information

Created on 13 March 1973 under a slightly different name by Decree No. 73-278 and placed under the authority of the Minister for Industry, this Council (*Conseil supérieur de la sûreté et de l'information nucléaires*) was given its current name in 1987 along with new powers [Decree No. 87-137 of 2 March 1987 on the Higher Council for Nuclear Safety and Information].

The composition of the Council was broadened in order to include members belonging neither to the government nor to public services. At present, its members include the heads of ministerial departments and specialised agencies, members of parliament, experts, representatives of trade unions and nature conservation and environmental protection associations.

The Council's activities cover [Section 1]:

- all matters relating to nuclear safety, defined as "all technical measures taken at the design, construction and operating stages to ensure normal operation, prevent incidents or reduce the impact of any incidents that might occur";

- all matters concerning the information of the public and the media and related to the safety of nuclear installations, or concerning information of the public in the event of an incident or accident occurring in a nuclear installation.

On the request of the Minister for Industry or if it deems it necessary, the Council may set up expert working groups to study specific scientific questions or to promote information [Section 4].

The Council has power to make recommendations on ways of improving nuclear safety.

3. Public and Semi-Public Agencies

a) Atomic Energy Commission (CEA)

In 1945, the provisional government of the republic presided by Général de Gaulle, foreseeing the potential applications of nuclear energy and their impact in economic, financial, political and military areas, became aware of the need to allow the state to take the initiative in the nuclear field. An Ordinance of 18 October 1945 created the Atomic Energy Commission (*Commissariat à l'énergie atomique* – CEA) [Ordinance No. 45-2563 of 18 October 1945, Corrigendum of 3 December 1945, as amended by Act No. 47-1497 of 13 August 1947 Allowing the Levy of Taxes, Duties, State Proceeds and Revenue, Establishing the General Budget for 1947 and on Miscellaneous Financial Provisions, Decree No. 70-878 of 29 September 1970, as amended, on the Atomic Energy Commission and Decree No. 78-662 of 22 June 1978 on the Atomic Energy Commission].

Decree No. 70-878 of 29 September 1970, as amended by Decree No. 82-734 of 24 August 1982, and Decree No. 74-584 of 14 June 1974 also concern the CEA.

i) Legal status

The CEA was given the status of a public scientific, technical and industrial establishment. It is an administratively and financially independent legal entity.

Following the Decree of 29 September 1970 reorganising the CEA, and the resulting creation of subsidiary companies (such as TECHNICATOME in 1972 and COGEMA in 1976), the CEA continues itself to carry out tasks in the field of fundamental and applied research, nuclear safety and military applications. In addition, through the intermediary of a holding company, it is a shareholder (sometimes majority, sometimes minority) in private law companies, and the companies in which it, directly or indirectly, owns more than 50% of the capital, form the CEA group.

The CEA is responsible for its own financial management and for submission of accounts in accordance with normal trade practice. In other words, it operates largely as a private enterprise [Decree No. 72-1158 of 4 February 1972, Section 8]. What is more, by derogation from the Decrees of 25 and 30 October 1935 and from the Ordinance of 13 November 1944, the CEA is exempt from the *a priori* financial control applicable to state-owned independent public establishments. It is audited by an *ad hoc* audit team consisting of four officials belonging to each of the main state auditing bodies.

Originally answerable to the President of the provisional government and then to the President of the Council and afterwards to the Prime Minister, the CEA has since 1969 been placed under the authority of the Minister for Industry.

ii) Responsibilities

The CEA's duties, as defined in the 1970 Decree and subsequently confirmed, can be classified under the following main headings:

Fundamental research: the CEA conducts scientific research into the nature of matter (atomic physics and particle physics) and applies the research opportunities offered by atomic or nuclear phenomena to a wide variety of fields such as biology, chemistry and astrophysics.

As regards nuclear legislation, under the General Secretariat of the Interministerial Committee for Nuclear Safety, the CEA helps to draw up regulations concerning the safety of nuclear materials both on-site and during transport.

The CEA works in co-operation with other fundamental research laboratories, both French – in particular the CNRS and its National Institute for Nuclear Physics and Particle Physics (IN2P3), the National Institute for Health and Medical Research (INSERM) – and foreign or international laboratories (the Max Planck Institute, the University of Heidelberg, the Danish Space Research Institute, the DESY Laboratory in Hamburg, and the CERN in Geneva).

The National Institute for Nuclear Science and Technology (*Institut national des sciences et techniques nucléaires* – INSTN), set up in 1956 [Decree No. 56-614 of 18 June 1956], is a higher education establishment specialised in nuclear science with its headquarters at Saclay and supervised both by the Minister for Research and the Minister for Industry [Decrees No. 58-602 of 11 July 1958, No. 58-1045 of 30 October 1958, No. 66-266 of 26 April 1966 and No. 79-276 of 2 April 1979].

Through the INSTN, the CEA provides scientific training for top engineers and physicists in the field of atomic energy.

Protection and nuclear safety: By virtue of Act No. 2001-398 of 9 May 2001, the Institute for Protection and Nuclear Safety, created in 1976 and responsible, on behalf of the CEA, for the protection of persons and property against the effects of nuclear energy, was merged with the Office for Protection against Ionising Radiation into a single industrial and commercial public establishment, namely the Institute for Radiation Protection and Nuclear Safety (IRSN – see description above).

Nuclear materials: the CEA ensures that users receive adequate supplies. It is empowered to prospect, produce, store and transport nuclear raw materials either directly or through enterprises in which it is a shareholder. Since it was set up in 1976, the CEA's fully-owned subsidiary COGEMA, which specialises in all kinds of activities concerning the nuclear fuel cycle, has been responsible for industrial and commercial operations in that area.

Nuclear energy applications: to maintain and improve the reliability and safety of electronuclear facilities, on which France depends for its power supplies, the CEA provides technical support to the nuclear industry and to *Électricité de France* (EDF) for the development of new reactor fuels and fuel cycle processes.

Non-nuclear programmes: in accordance with government directives, the CEA has, on the basis of Decree No. 70-878 of 29 September 1970, developed a diversification policy in conjunction with the subsidiaries set up over the years, in order to promote research and development activities in the non-nuclear field.

Having acquired technological know-how through its work on nuclear energy, the CEA applies this knowledge to other sectors, thus meeting demand from industry or from public and private research bodies. It is involved in a wide variety of fields: electronics, components, scientific apparatus, biological and medical engineering, mechanical engineering, metallurgy, environmental protection, oceanology and radioelements in fields allied to the nuclear sector. Decree No. 82-734 of 24 August 1982 confirms this approach under which the CEA, through its various activities, contributes to the technological development of the regions.

Military applications: in national defence, the CEA is responsible for producing nuclear explosive devices and warheads as well as propulsion reactors for nuclear submarines. Matters relating to the carrying out of nuclear arms programmes are examined by a joint Defence-CEA Committee.

A joint Armed Forces-CEA Commission on Nuclear Security has been set up to report to the government authorities, and give its opinion on the security of weapons systems, nuclear-propelled ships and related equipment, from the design stage until withdrawal from service [Order of 3 July 1989 regulating the powers and organisation of the said Commission, Section 1]. However, the Commission is not empowered to monitor nuclear materials used for defence purposes [Section 11].

Information and the dissemination of know-how: in line with its primary involvement with nuclear activities, the CEA follows scientific, technical and economic developments in the nuclear field abroad, and takes an active part in the life of the scientific community in France and in other countries. The CEA is responsible for advising the government, especially in the course of the negotiation of international agreements.

iii) Structure

The CEA Statute provides for a number of central bodies.

Atomic Energy Committee

Under the chairmanship of the Prime Minister or a minister delegated to this effect by the latter, this Committee is composed of:

- the Administrator-General;
- the Army Chief of Staff;
- the Secretary-General of the Ministry for Foreign Affairs;
- the Delegate-General for Weaponry;
- the Secretary-General for Administration of the Ministry for Defence;
- the Director-General for Energy and Raw Materials;
- the Director-General for the Information Technology Industry and the Post Office;
- the Budget Director;
- the Director-General for Nuclear Safety and Radiation Protection;
- the Director of Research;
- the Director of Technology;
- the Chairperson of the Management Board of the National Scientific Research Centre (CNRS);

- a person of standing selected by the Prime Minister;
- a person of standing selected by the Minister for the Environment;
- three experts in the scientific and industrial fields, one of them acting as High Commissioner.

The High Commissioner and the non-*ex officio* members are appointed for three years by decree of the Council of Ministers [Decree No. 76-951 of 19 October 1976].

The Atomic Energy Committee acts as a select interministerial committee in the nuclear field [Decree No. 72-1158 of 14 December 1972]. It also draws up the research and work programme of the CEA, approves the CEA budget and authorises share acquisitions and transfers.

The Committee must meet at least once a month. It is usually convened by its chairperson but in exceptional cases by the Administrator-General. Decisions are taken by majority vote of the members present, with the chairperson holding the casting vote if the votes are split equally.

Management Board

Under Decree No. 82-734 of 24 August 1982, some of the functions of the Atomic Energy Committee relating to management and general organisation, staff employment, adoption of the budget, the acquisition and transfer of shareholdings and the authorisation of loans were transferred to a tripartite Management Board.

Chaired by the Administrator-General, the Board is composed of 18 members including government representatives, representatives of the staff of the CEA and its subsidiaries, and leading experts. Appointments are for a period of five years. The Management Board meets at least six times a year [Decree of 13 April 1984].

Administrator-General

The Administrator-General acts as head of the CEA. He is appointed by Decree of the Council of Ministers for a period of five years [Decree No. 70-878 of 29 September 1970, Section 4].

He has full powers to act within the terms of reference of the CEA, which he represents, except for powers delegated to the Atomic Energy Committee and the Management Board [Decree No. 72-1158 of 14 December 1972, Section 5]. He may delegate all or part of his powers to the High Commissioner or to one or more heads of department.

The Administrator-General may appoint a deputy.

High Commissioner

The High Commissioner is the technical and scientific adviser to the Administrator-General on CEA technical and scientific policy [Decree No. 70-878 of 29 September 1970, Section 5].

Selected from among leading scientists on the Atomic Energy Committee, he is consulted on all protection matters and may be given responsibilities in education.

The High Commissioner chairs a Scientific Board which assists him in the exercise of his duties [Decree of the Council of Ministers No. 82-734 of 24 August 1982 on the Atomic Energy Commission]. Apart from persons appointed on proposals of the Administrator-General and of ministers, the Scientific Board includes staff representatives appointed after consultation with the trade unions.

Under the Decree of 11 October 1999 [Section 2], supplemented by the Decree of 17 July 2000, delegating signatory powers to the High Commissioner, the latter is appointed safety authority for all major nuclear installations falling within the jurisdiction of either the Minister for Defence or the Minister for Industry.

iv) Financing

The activities of the CEA are financed mainly by civilian or military grants from the government budget. Government grants are used to cover expenditure in applied research, nuclear power generation, the reprocessing of spent fuel and the manufacture of weapons. Furthermore, the industrial and commercial activities of CEA subsidiaries produce their own income. This outside income derives in particular from technical work and services, research contracts, sales of radioelements and energy, and fees for industrial property licences.

b) Électricité de France (EDF)

Under the Act of 8 April 1946 nationalising the production, transport, distribution and marketing of electricity, an industrial and commercial public establishment, *Électricité de France* (EDF) was made responsible for these activities.

EDF also produces nearly all the electricity distributed through the national grid. As such, EDF is the operator of almost all French nuclear power plants except for the fast breeders in service today.

In accordance with Decree No. 70-878 of 29 September 1970 [Section 2(5)], the CEA co-operates with EDF in the research sector and in the supply of nuclear fuels [Agreement of April 1967 and annexed Protocol of March 1968]. This co-operation consists of permanent exchanges of information, and the heads of the two bodies have adopted the practice of consulting one another on major issues.

EDF is run by a president appointed by decree of the Council of Ministers. It has a management board composed of 14 members appointed by decree following an opinion by the Minister for Industry, and a chairperson appointed by decree of the Council of Ministers.

c) National Radioactive Waste Management Agency (ANDRA)

Initially, ANDRA (*Agence nationale pour la gestion des déchets radioactifs*), created within the CEA by Order of 7 November 1979, had no independent legal personality but did enjoy a certain budgetary autonomy. It was responsible for the long-term management of radioactive waste.

Act No. 91-1381 of 30 December 1991 on Research into Radioactive Waste Management [Section L.542-12 of the Environment Code] replaced the former Agency by a new body with the same name. Decree No. 92-1391 of 30 December 1992, in implementation of the 1991 Act, laid down the new ANDRA statute, its new administrative structure and various other provisions relating to its operation.

i) Legal status

ANDRA is an industrial and commercial public establishment under the joint authority of the Minister for the Environment, the Minister for Industry and the Minister for Research (Section L.542-12 of the Environment Code).

ii) Responsibilities

ANDRA thus carries out the duties entrusted to it by Section L.542-12 of the Environment Code and by Section 1 of Decree No. 92-1391 of 30 December 1992. It is therefore responsible for operations concerning the long-term management of radioactive waste, and in particular for the following activities:

- in co-operation with the CEA, helping to define and contributing towards research and development programmes concerning the long-term management of radioactive waste;
- ensuring the management of long-term storage centres either directly or through the intermediary of a third party acting on its behalf;
- designing, selecting the site for and constructing new storage centres in the light of long-term forecasts for waste production and management, and carrying out all studies required for this purpose, in particular the construction and operation of underground laboratories to study deep geological formations;
- defining, in compliance with the safety rules, specifications for the treatment and storage of radioactive waste;
- recording the state and location of all radioactive waste on French territory.

Each year, ANDRA must submit to its ministerial supervisory authorities a report reviewing the work achieved and to be achieved. The Agency must also submit, no later than 31 December 2005 and after obtaining the opinion of the Scientific Board, a report analysing the results achieved together with, if appropriate, a project for an underground storage site for high-level, long-lived radioactive waste [Decree No. 92-1391 of 30 December 1992, Section 1].

iii) Structure

ANDRA is administered by a Director-General, a management board, a financial committee and a Scientific Board.

The Management Board of the Agency includes [Section 2]:

- a member of parliament or a senator appointed by the Parliamentary Office for the Evaluation of Scientific and Technological Policies;

- six government representatives, appointed on proposal of the Ministers for Energy, Research, the Environment, the Budget, Defence, and Health, respectively;

- five persons of standing representing economic circles concerned by the work of the Agency, one of whom should be proposed by the Minister for Health;

- two persons of standing, qualified in fields within the competence of the Agency, one of whom should be proposed by the Minister for the Environment; and

- seven representatives of the staff of the Agency.

The members of the Board are appointed for a term of five years.

The chairperson of the Management Board is selected from among its members, and appointed by decree following a joint report by the ministers responsible for the Agency.

The Management Board meets at least three times a year. Decisions are adopted by a majority of votes of the members present or represented. The Management Board settles the affairs of the Agency (general functioning, programme of work, forecasts of income and expenditure, loans, acquisitions, conclusion of contracts, etc.).

The Director-General for Energy and Raw Materials is the Government Commissioner for the Agency and acts as an intermediary between ANDRA and the government.

The Director-General of the Agency is appointed on the proposal of the chairperson of the Board by decree made following a report by the ministers responsible. He manages the services of the Agency, prepares the meetings of the Management Board and implements its decisions.

As for the Financial Committee, it is consulted on the conditions and price-levels for the services of ANDRA, and its investment programmes. For its part, the Scientific Board gives opinions on the research and development programmes carried out by the Agency.

iv) Financing

The resources of ANDRA include in particular:

- remuneration for services rendered;

- subsidies from the state, local governments and any other public or private, national or international bodies;

- proceeds from loans, etc.

The Agency is subject to economic and financial control by the government as provided by the Decrees of 29 August 1953 and 26 May 1955. Control of the financial management is carried out by a government auditor.

d) Institute for Radiation Protection and Nuclear Safety (IRSN)

The Institute for Radiation Protection and Nuclear Safety (*Institut de Radioprotection et de Sûreté Nucléaire* – IRSN) was set up by Act No. 2001-398 of 9 May 2001, the purpose of which was to strengthen existing institutional arrangements with regard to health and environmental safety, monitoring and warnings. Decree No. 2002-254 of 22 February 2002 lays down the structure and tasks of the IRSN.

i) Legal status

The IRSN is a state-owned industrial and commercial public establishment. It is placed under the joint authority of the Ministers for Defence, the Environment, Research and Health. The IRSN brings together the former Institute for Protection and Nuclear Safety (IPSN) and the Office for Protection against Ionising Radiation (OPRI).

ii) Responsibilities

The IRSN performs expertise and research tasks in the fields of nuclear safety, the safety of the transport of radioactive and fissile materials, the protection of man and the environment against ionising radiation, the protection and control of nuclear materials and the protection of nuclear installations and the transport of radioactive and fissile materials against acts of malicious intent.

In order to carry out its tasks, the IRSN:

- conducts expertises, research and work, in particular in relation to analyses, measurements or doses, for public or private bodies, whether French or foreign;
- defines research programmes which it carries out itself or contracts out to other French or foreign research agencies with a view to maintaining and developing the expertise required in its fields of activity;
- helps to give radiation protection training to health workers and persons exposed at work;
- provides technical back-up to the General Directorate for Nuclear Safety and Radiation Protection, to the Delegate for nuclear safety and radiation protection for defence-related activities and installations, and to public authorities and services which so request;
- in the event of an accident or incident involving ionising radiation sources, proposes to the General Directorate for Nuclear Safety and Radiation Protection or the delegate for nuclear safety and radiation protection for defence-related activities and installations, technical, health and medical measures to ensure the protection of the population, workers and the environment, and to re-establish the security of installations;
- help in permanent monitoring as regards radiation protection, in particular by participating in the radiological monitoring of the environment and by managing and using dosimetric data on workers exposed to ionising radiation and managing the inventory of ionising radiation sources.

iii) Structure

The IRSN is administered by a Director-General, a Management Board, a Directorate for Nuclear Defence Expertise, a Scientific Board and an Advisory Commission on Markets.

The Management Board comprises:

- ten state representatives appointed by decree;
- six experts in the fields of activity of the Institute including a member of parliament or a senator who is a member of the Parliamentary Office for assessing scientific and technological policy and proposed by that Office;
- eight representatives of the staff of the Institute, elected in accordance with the conditions and procedures laid down in Chapter (ii) of Title II of the Act of 26 July 1983 and by the Decree of 26 December 1983.

The members of the Management Board are appointed for a period of five years. The Board meets at least four times a year as convened by its chairperson. Decisions are taken by a majority of votes of the members present or represented.

The Director-General of the IRSN is appointed on the proposal of the chairperson of the Management Board, by decree adopted following a report by the ministers responsible.

The Scientific Board is composed of 12 scientific or technical experts appointed for five years by the joint order of the ministers responsible. The Board gives its opinion on the programme of work of the IRSN and monitors the research programmes decided by the Institute after ensuring their relevance. It assesses the results obtained and may make recommendations about the orientation of the Institute's work.

iv) Financing

The financial resources of the IRSN include in particular:

- subsidies from the state, and public or private, national or international bodies;
- proceeds from sales of publications;
- income from patents and inventions;
- income from the Institute's property and real estate, and the proceeds from disposing of them.

e) French Agency for Environmental Health Safety (AFSSE)

The French Agency for Environmental Health Safety (*Agence française de sécurité sanitaire et environnementale* – AFSSE) was set up by Act No. 2001-398 of 9 May 2001, the purpose of which was to strengthen existing institutional arrangements with regard to environmental health safety, monitoring and warnings. Decree No. 2002-299 of 1 March 2002 lays down the structure and

organisation of the Agency. The regulations concerning the Agency have been incorporated into the Public Health Code.

The task of the Agency is to ensure health safety in the field of the environment, to evaluate environment-related health risks and to provide the government with the expertise and scientific and technical support required for the formulation and implementation of legislation and regulations.

The AFSSE is an administrative public establishment. It comprises a Management Board composed of 24 members appointed for a three-year period by joint order of the Minister for Health and the Minister for the Environment. The Management Board is headed by a chairperson, assisted by a vice-chair, both also appointed for a period of three years. The Agency also includes a director-general appointed for three years and a Scientific Board which helps define national research policy with regard to health and environmental safety.

f) National Institute for Nuclear Physics and Particle Physics (IN2P3)

Within the National Centre for Scientific Research (*Centre national de la recherche scientifique* – CNRS), the Institute includes experts on nuclear physics and on particle physics [Decree No. 84-667 of 17 July 1984, Section 3]. Its purpose is to prepare and co-ordinate research in the fields of nuclear physics and particle physics.

IN2P3 carries out its duties within bodies placed under the supervision of the Minister for Research, except for the CEA [Section 1].

The Institute is headed by a director appointed by order of the Minister for Research after an opinion by the Director-General of the CNRS and the Director-General of Higher Education and Research at the Ministry for Research. He is assisted by an administrative deputy director and by one or more scientific deputy directors appointed by the Director-General of the CNRS on a proposal by the Director of the Institute, after obtaining the opinion of the Director-General for Higher Education and Research with the Ministry for Research.

The Director of IN2P3 is, in addition, assisted by a Management Board and a Scientific Board.

The Management Board is composed of 16 members including the CNRS Director-General, who acts as chairperson, members appointed from among ministerial representatives and leading scientists. It holds meetings at least twice a year, and on one such occasion it examines the budget. The Institute's budget is separate from that of the CNRS but is approved and amended in the same way as that of the CNRS. The Management Board decides on applications from laboratories and research centres to work in association with the Institute. In general, it fulfils the usual functions of management boards of public establishments.

The Scientific Board is consulted on the drawing up of research programmes, preparation of the plan and equipment programmes. It meets at least twice a year, and comprises representatives from different scientific bodies together with scientists and heads of laboratories, whether independent or associated with the Institute.

GERMANY

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I. GENERAL REGULATORY REGIME

1. Introduction

There are 18 operating nuclear power reactors at 15 sites in Germany; six units are boiling water reactors (BWR) and 12 are pressurised water reactors (PWR). In 2002, nuclear power produced 155.8 Net TWh, accounting for 29% of the nation's total electricity production. When Germany was reunited in 1990, four operating VVER-440 MWe reactors in the east were shut down for safety reasons and are being decommissioned. In addition, Germany shut down the PWR reactor at Stade in 2003.

Several power companies own the shares of the various nuclear power generating stations in Germany: EnBW, EON, HEW, RWE Power, TWS Stuttgart, Nekarwerke AG and Vattenfall Europe.

Prior to 1994, German utilities were obliged to reprocess spent fuel, however the policy of the present coalition government is for direct geological disposal of spent fuel. As all types of waste are planned to be disposed of in deep repositories, wastes are only separated into two categories; heat-generating and non heat-generating. The utilities are responsible for interim storage and have formed joint companies to build and operate off-site facilities at Ahaus and Gorleben. In line with the intentions of the federal government, a final repository should be available after 2030 for high-level (heat-generating) radioactive waste. The exploration work in the salt dome of Gorleben, planned for the storage of high-level waste has been interrupted for a minimum of three and a maximum of ten years to clarify conceptual issues. In the middle of 2002, permission was granted to establish a repository for low- and medium-level radioactive waste in the Konrad mineshaft. Complaints, however, were lodged against the authorised plan, and these complaints are pending in court.

There are 12 operational research reactors in Germany. In addition, 12 have been shut down, 22 have been decommissioned and one is under construction. The principal research reactors are the FRJ-2 DIDO heavy water reactor (23 MWe), and the BER-II (10 MWe) and FRG-1 (5 MWe) pool reactors.

The legal basis for the regulation of the peaceful uses of nuclear energy in the Federal Republic of Germany was created in 1959 by an addition to the Basic Law (the Federal Constitution – *Grundgesetz*). Under Article 74, No. 11a, the scope of the concurrent legislative power of the federal state (*Bund*) was broadened to include the production and use of nuclear energy for peaceful purposes, the construction and operation of installations for such purposes, protection against hazards arising from the release of nuclear energy or from ionising radiation, and the disposal of radioactive substances. Article 87c of the Basic Law provides that laws promulgated under Article 74, No. 11a may, with the consent of the federal council (*Bundesrat*), which is composed of representatives of the *Länder* governments, stipulate that they are to be implemented by the *Länder* (states making up

Germany) on behalf of the federal authorities (so-named *Bundesauftragsverwaltung*) [Act of 23 December 1959 amending the Basic Law, BGBl[1] I p. 813].

Against this background the Act on the Peaceful Use of Atomic Energy and Protection Against its Hazards (Atomic Energy Act) became law on 23 December 1959.[2] In accordance with Article 87c of the Basic Law, the Atomic Energy Act provides that it is to be implemented by the federal authorities and the *Länder*. The *Länder* are subject to federal supervision of both the regularity and appropriateness of measures taken by them to give effect to the act [Article 85 of the Basic Law]. For the purpose of exercising such supervision, the competent supreme federal authorities (i.e. in the case of nuclear safety and radiation protection, the Federal Minister for the Environment, Nature Conservation and Nuclear Safety) may issue instructions [Section 24 of the Atomic Energy Act].

The 1959 Atomic Energy Act in its version as last amended in 2001 was intended to:

- promote nuclear research and the development and use of nuclear energy for peaceful purposes;
- protect life, health and property from hazards associated with nuclear energy and from the harmful effects of ionising radiation and provide compensation for damage caused by nuclear energy or ionising radiation;
- prevent the domestic or external security of Germany from being endangered by reason of the use or release of nuclear energy;
- ensure fulfilment of the international obligations of Germany in the field of nuclear energy and radiation protection [Section 1 of the Atomic Energy Act].

The government of the Federal Republic of Germany elected in 1998 decided to phase out the use of nuclear energy for electricity-generating purposes. This decision led to the introduction of substantial changes in the nuclear legislation. The legal instrument to implement the phasing-out decision was the Act on the Structured Phase-Out of Nuclear Power for the Commercial Production of Electricity (*Gesetz zur geordneten Beendigung der Kernenergienutzung zur gewerblichen Erzeugung von Elektrizität*) dated 22 April 2002 [BGBl 2002 I p. 1351]. The same act introduced consequential amendments into the 1977 Nuclear Financial Security Ordinance and the 1981 Nuclear Costs Ordinance.

While the 1959 Atomic Energy Act in its 2001 version, in accordance with Section 1, was aimed at promoting the use of nuclear energy and at preventing damages caused by the use of nuclear energy, the new act changed its purpose substantially. The promotion purpose of the act was deleted, and Section 1 of the 2002 Atomic Energy Act now reads as follows:

"The purpose of this act is:

1. to phase out the use of nuclear energy for the commercial generation of electricity in a structured manner, and to ensure on-going operation up until the date of discontinuation;
2. to protect life, health and property against the hazards of nuclear energy and the detrimental effects of ionising radiation and to provide compensation for damage and injuries caused by nuclear energy or ionising radiation;

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1. BGBl: *Bundesgesetzblatt* = Federal Gazette.
2. Consolidated version published on 15 July 1985 [BGBl I p.1565], last amended on 13 December 2001 [BGBl I p.3586].

3. to prevent danger to the internal or external security of the Federal Republic of Germany from the application or release of nuclear energy;

4. to enable the Federal Republic of Germany to meet its international obligations in the field of nuclear energy and radiation protection."

The new act is the result of intensive preparation and discussions conducted within the government and between the government and the German energy industry. A 1999 government working group reviewed the framework conditions of national and international law with regard to the envisaged phasing-out of nuclear energy. In particular, there was one legal question which needed to be clarified, namely to which extent the limitation of the previously unrestricted operating licences for German nuclear power plants was in line with constitutional law. The outcome of this discussion was that an unconditional restriction in time of the operators' licences could be seen as an expropriation of the energy utilities, which would entail claims for compensation of a very considerable size. After difficult negotiations, the government and the utilities agreed on the restriction of the future operation of existing nuclear power plants. They also agreed that a high standard of safety has to be maintained for the remaining operational period. This agreement was initialled on 14 June 2000 and signed on 11 June 2001. This agreement is of a political nature and is not a legally binding instrument. The Phasing-Out Act of 2002 is, in substance, the implementation of the major elements of that agreement.

The key provisions of the Phasing-Out Act:

- replace the original promotional purpose of the act with the objective of phasing out the use of nuclear energy for the commercial generation of electricity in a structured manner as quoted above;
- phase out the use of nuclear power and ensure safety during the remaining operating period of the respective licences;
- establish new requirements governing nuclear waste management;
- stipulate a ten-fold increase in the financial security to be provided by the operators of nuclear power plants (up to EUR 2.5 billion);
- repeal the amendment of the Atomic Energy Act of 6 April 1998.

The aim of affording protection, which underlies the Atomic Energy Act, is given practical effect through provisions dealing with licences, surveillance, liability and insurance cover, and in provisions relating to offences and penalties. In the event of a conflict concerning the purposes of the act, the principle of protection against hazards and risks prevails, as the well-established case law of the Federal Administrative Court and other courts has shown.

The Atomic Energy Act empowers the federal government (in certain cases with the consent of the *Bundesrat*) to issue ordinances for the achievement of the objectives set out in the act. So far the following instruments have been issued:

- Ordinance of 20 July 2001 on protection against damage caused by ionising radiation (*Strahlenschutzverordnung* – Radiation Protection Ordinance) as last amended by Ordinance of 18 June 2002 [BGBl 2001 I p. 1714; 2002 I p. 1459, 1869, 1903];
- Ordinance of 14 October 1992 on persons responsible for nuclear safety and on the notification of safety-related events (*Atomrechtliche Sicherheitsbeauftragten und Meldeverordnung* – Safety Officers and Notification Ordinance) as last amended by Ordinance of 18 June 2002 [BGBl 1992 I p. 1766; 2002 I p. 1459, 1869, 1903];

- Ordinance of 8 January 1987, as amended, concerning protection from damage by X-rays (*Röntgenverordnung* – X-ray Ordinance) as last amended by Ordinance of 18 June 2002 [BGBl 1987 I p. 114; 2002 I p. 1869];
- Ordinance of 18 February 1977 concerning the procedure for licensing of installations pursuant to Section 7 of the Atomic Energy Act (*Atomrechtliche Verfahrensverordnung* – Nuclear Installations Ordinance) in its consolidated version of 3 February 1995 and as last amended by Act of 25 March 2002 [BGBl 1977 I p. 280; 1995 I p. 180; 2002 I p. 1193, 1217];
- Ordinance of 25 January 1977 concerning financial security pursuant to the Atomic Energy Act (*Atomrechtliche Deckungsvorsorge Verordnung* – Nuclear Financial Security Ordinance) as last amended by Ordinance of 18 June 2002 [BGBl 1977 I p. 220; 2002 I p. 1869, 1906];
- Ordinance of 17 December 1981 concerning costs under the Atomic Energy Act (*Atomrechtliche Kostenverordnung* – Nuclear Costs Ordinance) as last amended by Act of 22 April 2002 [BGBl 1981 I p. 1457; 2002 I p. 1351, 1359];
- Ordinance of 28 April 1982 on advance contributions towards construction of federal installations for safe containment and final disposal of radioactive waste *(Endlagervorausleistungsverordnung* – Final Disposal Ordinance) as last amended by Ordinance of 18 June 2002 [BGBl 1982 I p. 562; 2002 I p. 1869, 1906];
- Ordinance of 27 July 1998 on the movement of radioactive waste into or out of the territory of the Federal Republic of Germany (*Atomrechtliche Abfallverbringungsverordnung* – Nuclear Waste Shipment Ordinance) as last amended by Ordinance of 20 July 2001 [BGBl 1998 I p. 1918; 2001 I p. 1714, 1840];
- Ordinance of 1 July 1999 on the assessment of reliability regarding theft or significant release of radioactive substances under the Atomic Energy Act (*Atomrechtliche Zuverlässigkeitsüberprüfungs Verordnung* – Nuclear Reliability Assessment Ordinance) as last amended by Ordinance of 20 July 2001 [BGBl 1999 I p. 1525; 2001 I p. 1714, 1837].

Nuclear and radiation protection law is not, however, to be found exclusively in the Atomic Energy Act and the above ordinances. Another important piece of legislation is the Preventive Radiation Protection Act of 19 December 1986, as last amended by the Act of 14 December 2001 (*Gesetz zum vorsorgenden Schutz der Bevölkerung gegen Strahlenbelastung – Strahlenschutzvorsorgegesetz*) [BGBl 1986 I p. 2610; 2001 I p. 3714, 3718]. This Act has been complemented by the 1st-5th Ordinances of 1989, 1991, 1997, 1998 and 2002 to Assign Competence for Measurements and Evaluation in Accordance with the Preventive Radiation Protection Act [BGBl 1989 I p. 1582; 1991 I p. 1768; 1997 I p. 2474; 1998 I p. 2009; 2002 I p. 3184].

There are also numerous relevant provisions in other specialised fields. The principal ones are:

- national and international provisions on the transport of radioactive materials;
- foreign trade law;
- environmental law;
- provisions of water law dealing with protection and liability in regard to the disposal of radioactive sewage into surface waters;

- the Mining Act with regard to the search for radioactive minerals and the design of installations for the deep underground disposal of radioactive waste;
- provisions of the law relating to foodstuffs and medicine;
- radiation protection law regarding female civil servants including soldiers.

One of the objectives of the Atomic Energy Act is to ensure the fulfilment of Germany's international obligations in regard to nuclear energy. Consequently, nuclear energy law, including the enforcement of the Atomic Energy Act in Germany, is influenced by and, in part, directly subject to international treaties, particularly within the framework of Euratom, the OECD and the IAEA.[3]

2. Mining Regime

The search for radioactive minerals requires a permit and mining operations require a licence or a concession for the mine, in accordance with the provisions of the Federal Mining Act of 13 August 1980, as amended, which regulates such matters in detail [BGBl 1980 I p. 1310; 2001 I p. 3138, Sections 6 to 8]. A licence for handling radioactive materials under the Radiation Protection Ordinance is not required for activities to which the Federal Mining Act applies, but the radiation protection provisions of that Ordinance are applicable [Radiation Protection Ordinance, Section 7(3), 3(2), No. 34 (the concept of "handling radioactive substances" includes mining activities); see also: Sections 93 *et seq.*].

In accordance with Section 118 of the Radiation Protection Ordinance, two ordinances of the former GDR remain valid:

- the Ordinance of 1984 on Nuclear Safety and Radiation Protection (*Verordung über die Gewährleistung von Atomsicherheit und Strahlenschutz* – VOAS) [GBl GDR I, p. 341] and its implementing Regulation of 1984 [GBl GDR I, p. 348; 1987, p. 196];
- the Order of 1980 on Radiation Protection in relation to Slagheaps and Industrial Repositories [GBl GDR I, p. 347].

These regulations, however, only apply to the remediation and restoration of the detrimental consequences of GDR activities in relation to the uranium industry. In all other cases, the provisions of the Radiation Protection Ordinance apply.

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3. Note on the Unification of Germany: In accordance with Section 2(2) of the Act of 21 June 1990 bringing into force the regulations of the Federal Republic of Germany (FRG) in the German Democratic Republic (GDR) (so-called *Mantelgesetz*) [GBl of the GDR I, p. 357], the Atomic Energy Act of the FRG entered into force in the GDR on 1 July 1990, with the status of GDR law. At the same time, the implementing Ordinances of the Act became valid, and the corresponding legislation of the GDR expired. Following the conclusion of the Treaty of 31 August 1990 between the FRG and the GDR on the establishment of the unity of Germany (Unification Treaty) [BGBl 1990 II pp. 885, 889], federal law including the Atomic Energy Act, the Radiation Protection Ordinance, and all other implementing and complementing legal instruments entered into force on 3 October 1990 in the five new *Länder* in the territory of the former GDR.

   The unification further brought about some minor amendments of the nuclear law in force. Thus the Atomic Energy Act was amended to provide for necessary transitional rules, e.g. concerning limited continuation of old licences [Section 57(a)]. The Radiation Protection Ordinance was also amended, to provide that in the new *Länder* the Ordinance would not be applicable to mining of radioactive minerals [Section 89(a)].

The Radiation Protection Commission (*Strahlenschutzkommission* – SSK) in 1991 issued recommendations concerning the use of areas and material contaminated by the uranium mining activities of the former Soviet-German public limited company *Wismut* in the *Länder* of Saxony and Thüringen [BAnz[4] 1991, pp. 5461, 5684, 7858]. *Wismut*'s activities were terminated following the unification of Germany in accordance with an Agreement between Germany and the USSR of 16 May 1991 [BGBl II p. 1142].

3. Radioactive Substances, Nuclear Fuel and Equipment

a) Definitions

Sections 3 to 6, 9, and 17 to 19 of the Atomic Energy Act provide for a regime of licensing and permanent surveillance of export and import, transportation, storage, and any kind of handling and processing of nuclear fuel material. Other radioactive substances which are not nuclear fuel are covered by the licensing regime established by the Radiation Protection Ordinance of 2001, in particular in Sections 7 to 10 and 16 to 22.

The terms "radioactive substances", "nuclear fuel", and "other radioactive substances" are defined in Section 2 of the Atomic Energy Act. The term "radioactive substances" is the overall generic term, which includes "nuclear fuel" as well as "other radioactive substances". The term "nuclear fuel" refers to special fissionable material in the form of:

- ^{239}Pu and ^{241}Pu;
- uranium enriched in isotopes ^{235}U or ^{233}U;
- any material containing one or more of the substances cited under points 1 and 2;
- substances which permit a self-sustaining chain reaction to be maintained in a suitable installation and which are defined in a statutory ordinance.

The term "uranium enriched in isotopes 235 or 233" shall mean uranium containing the isotopes ^{235}U or ^{233}U or both in such quantities that the sum total of the amounts of these two isotopes is greater than the amount of isotope ^{238}U multiplied by the naturally occurring ratio of isotope ^{235}U in relation to isotope ^{238}U.

The activity or specific activity of a substance in the sense of Section 2, paragraph 1, sentence 1 of the Atomic Energy Act may be disregarded if certain prerequisites are fulfilled as listed in Section 2, paragraph 2 of the act.

With regard to the application of licensing requirements under the Atomic Energy Act or implementing ordinances, substances in which the proportion of isotopes ^{233}U, ^{235}U, ^{239}Pl and ^{241}Pl does not exceed 15 grams in total or the concentration of the isotopes listed does not exceed 15 grams per 100 kilograms shall be classified as "other radioactive material". This rule, however, does not apply to solidified high-level fission product solutions derived from the processing of nuclear fuel [Section 2, paragraph 3 of the Atomic Energy Act].

Furthermore, Section 2 of the Atomic Energy Act stipulates that with regard to nuclear liability and coverage of liability, the definitions of the Paris Convention on Third Party Liability in the Field of Nuclear Energy of 29 July 1960, as amended, apply. It follows that the definitions of "nuclear fuel"

4. BAnz: *Bundesanzeiger* = Federal Bulletin.

and “other radioactive substances” as listed above only apply to the parts of the Atomic Energy Act and its implementing ordinances which do not deal with nuclear liability and financial security [Section 2, paragraph 4 of the Atomic Energy Act].

b) Licensing requirements

In accordance with Section 3 of the Atomic Energy Act, the import and export of nuclear fuel requires a licence. The licensing and notification regime for other radioactive substances is regulated in Sections 19 *et seq*. of the Radiation Protection Ordinance. For further details, see *infra*, Section 5 “Trade in Nuclear Materials and Equipment”.

The transport of nuclear fuel and other radioactive substances requires a licence under Sections 4 *et seq.* of the Atomic Energy Act and Sections 16-18 of the Radiation Protection Ordinance respectively. For further details, see *infra*, Section 9 “Transport”.

The storage of nuclear fuel and other radioactive substances requires a special licence under Section 6 of the Atomic Energy Act and Sections 7 *et seq.* of the Radiation Protection Ordinance in connection with the definition in Section 3, paragraph 2, No. 34 of the Radiation Protection Ordinance.

Section 9a, paragraph 2 of the Atomic Energy Act requires the operator of a nuclear power plant to ensure that an interim storage facility for spent fuel is available on or close to the site of the installation. The interim storage facility must be licensed under Section 6, paragraphs 1 and 3 of the Atomic Energy Act.

Nobody is entitled to possess nuclear fuel without an appropriate licence under Sections 4, 6, 7 or 9a to 9c of the Atomic Energy Act. Persons who are in possession of nuclear fuel without the necessary licence are required to either deliver those materials to a person who is authorised to possess them, or to deliver the material to the Federal Office for Radiation Protection, which has to store such material [Section 5, paragraphs 2 to 4 and Section 23, paragraph 1, No. 1 of the Atomic Energy Act].

The treatment, processing, or any other use of nuclear fuel other than in installations which require a licence under Section 7 of the Atomic Energy Act are subject to a licence [Section 9 of the Atomic Energy Act]. The same applies to any substantial deviation from procedures for processing, treatment or other uses covered by the licence and to any change in the location of operations as defined in the licence. As regards “dealing with” other radioactive substances outside an installation, Sections 7 to 10 of the Radiation Protection Ordinance set out licensing requirements. The concept of “dealing with” (“*Umgang*”) comprises the production, storage, processing, treatment, and any other utilisation and disposal of radioactive substances [Section 3, paragraph 2, No. 34 of the Radiation Protection Ordinance].

The Radiation Protection Ordinance provides for an exemption from licensing requirements for low-level risk radioactive material: such exemptions apply in respect of Section 8 (handling and any kind of dealing with radioactive material), Section 17 (transport), Sections 19, 20 (import and export) and Section 21. In some of these cases, the ordinance requires a notification to the competent authority.

The construction and the operation of nuclear facilities for the production of ionising radiation (accelerators) which exceed a specified energy level require a licence [Section 11 of the Radiation Protection Ordinance]. There is an exemption from the licensing requirement for plasma facilities and

accelerators with a low energy level as defined in Section 12 of the Radiation Protection Ordinance. There is a special licensing regime for X-ray appliances in accordance with the X-Ray Ordinance [Sections 3 and 6].

4. Nuclear Installations

a) Licensing regime

Any person who constructs, operates or otherwise holds, or who substantially alters any installation for the production, treatment, processing or fission of nuclear fuel, or for the reprocessing of irradiated nuclear fuel must obtain a licence in accordance with Section 7, paragraph 1 of the Atomic Energy Act. However, no further licences will be granted for the construction or operation of nuclear power plants or reprocessing facilities [Section 7, paragraph 1, sentence 2 of the Atomic Energy Act].

In accordance with Section 7, paragraph 1a of the Atomic Energy Act, the authorisation to operate a nuclear power plant shall expire once the electricity volume for that installation as listed in Appendix 3, column 2, of the act or the electricity volume derived from transfers from other installations in accordance with paragraph 1b of Section 7 has been produced. The electricity volume listed in the Appendix corresponds to a standard operating life of 32 years per plant.

In order to ensure the correct implementation of this provision, the licensee must:

- notify the responsible authority, on a monthly basis, of the volumes of electricity generated in the previous month;
- submit to the responsible authority the results of the checks and certificates pursuant to paragraph 1c2, sentence 3, within one month of receipt; and
- notify the responsible authority of any transfers implemented between installations pursuant to paragraph 1b within one week of determining the transfer.

A licence to construct, operate or otherwise hold a nuclear installation may only be granted if the following prerequisites are fulfilled:

- there are no known facts giving rise to any doubts as to the reliability of the applicant or of the persons responsible for the construction and management of the installation and the control of its operation, and the latter persons possess the requisite specialised knowledge;
- the persons who are otherwise engaged in the operation of the installation possess the necessary knowledge concerning the safe operation of the installation, its possible hazards, and the safety measures to be applied;
- every necessary precaution has been taken in the light of existing scientific knowledge and technology to prevent damage resulting from the construction and the operation of the installation;
- the necessary financial security has been provided to cover all legal liability to pay compensation for damage;
- all necessary protection is provided against disturbance or other interference by third parties (physical protection);

- the choice of the site of the installation, in particular with respect to non-contamination of water, air, and soil, is not contrary to overriding public interests.

The decommissioning, safe confinement, or dismantling of a nuclear installation require a licence, which may be granted if the prerequisites listed in Section 7, paragraph 2 are met. A licence shall not be required if the decommissioning, etc. has already been the subject of a licence to construct, operate or otherwise hold an installation [Section 7, paragraph 3 of the Atomic Energy Act].

Licences under Section 7 are issued by the supreme *Land* authorities (i.e. ministries) [Section 24, paragraph 2 of the Atomic Energy Act].

The administrative procedures to obtain a licence are set out in the Nuclear Installation Ordinance of 1977 as amended and in the general Administrative Procedure Act 1976 as amended [BGBl 1976 I p. 1253; 1986 I p. 265].

The licensing procedure is conducted in several stages and involves consultation and intervention of the public and local authorities. Technical bodies are involved at the federal as well as at the *Land* level. When the application is filed, the licensing authority of the *Land* concerned forwards copies of the request for the licence to the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, which is advised on licensing questions by the Reactor Safety Commission and the Radiation Protection Commission. After consultations with the Commissions have been concluded, the ministry informs the *Land* authorities of the findings and issues the relevant instructions. In addition, the *Land* authorities request expert opinions from independent experts.

As regards the different stages of the licensing procedure, provisional site approval is not a mandatory step within this procedure: it is at the discretion of the applicant whether he applies for that approval or not. Such approval is limited to the question of whether a given site is suitable for construction and operation of a nuclear installation, but it does, however, provide the opportunity to settle certain questions which would be likely to cause public controversy. This provisional site approval is binding in nature, but it will become invalid if the applicant does not apply for the final licence within two years from the date on which this approval is no longer subject to appeal [Section 7a of the Atomic Energy Act].

The construction permit may be and is normally granted in several stages: a partial construction permit concerning, *inter alia*, a specified construction volume, the site and the basic safety design of the installation. The operating licence may also be applied for and granted in several stages. Before issuing an operating licence, the licensing authority must be certain that other provisions of public law, such as those relating to buildings and zoning, water and environmental protection, trade and nuisance control, have been observed and the requisite permits and licences have been granted by the appropriate (*Bund*, *Land* or local) authorities.

Costs connected with decisions and rulings and with the official custody of nuclear fuels, or other official acts by the competent authorities under the Atomic Energy Act are dealt with in accordance with the relevant provisions of the act, or in the 1981 Nuclear Costs Ordinance made under it and in the Administrative Costs Act (*Verwaltungskostengesetz*) [Atomic Energy Act, Sections 21, 21a, 21b; Nuclear Costs Ordinance].

Finally, the construction, operation and possession of nuclear installations are subject to continuous government supervision [Atomic Energy Act, Section 19]. The supreme authorities of the *Länder* are responsible for exercising supervisory and control functions, which they may delegate to

subordinate agencies in individual cases. For further details, see *infra* Section 4(d) "Surveillance of installations and activities".

The holder of a licence to operate an installation referred to in Section 7, paragraph 1 of the Atomic Energy Act must appoint a person to be responsible for nuclear safety (*kerntechnischer Sicherheitsbeauftragter* – Safety Officer). This person shall supervise and assess the measures aiming at guaranteeing nuclear safety in the installation, including, *inter alia*, assessing safety-related events, elaborating measures to improve nuclear safety, and informing the operator on deficiencies in the nuclear safety of the installation. The operator must support the safety officer in fulfilling his tasks and, in particular, must provide the necessary personnel for his assistance [Safety Officers and Notification Ordinance of 14 October 1992, BGBl I p. 176].

Germany is a Contracting Party to the 1994 Convention on Nuclear Safety since 20 January 1997 [Act of 7 January 1997 on the Convention on Nuclear Safety, BGBl 1997 II p. 130].

b) Protection of the environment against radiation effects

Where a licence or land planning permission is required for a nuclear installation or waste disposal facility, an environmental impact assessment must be included in the procedure leading to a decision. [Section 7, paragraph 2, No. 6 and Section 9b of the Atomic Energy Act; Section 3 of the Act on Environmental Impact Assessment of 12 February 1990, as amended, BGBl 1990 I p. 205; 2002 I p. 1921]. This act was originally promulgated as Article 1 of the Act of 12 February 1990 to implement Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment [BGBl 1990 I p. 205].

According to Sections 4 to 6 of the 2001 Radiation Protection Ordinance, radiation protection is governed by three main principles:

- justification;
- optimisation;
- dose limits.

A person who is intending to handle radioactive substances as listed in Section 2 of the Radiation Protection Ordinance is required to plan the technical design and the operation of the installation or equipment in such a manner that the dose limits set out in Sections 46, 47, 55, 56 and 58 will not be exceeded. Any unnecessary radiation exposure or contamination of man or the environment must be avoided. The licence-holder has to ensure that radioactive releases from installations or facilities will be notified to the competent authority [Section 48]. The Penal Code, as amended in particular by two Acts Concerning Criminal Acts Against the Environment [Act of 28 March 1980, BGBl I p. 373 and Act of 27 June 1994, BGBl I p. 1440] and as last amended by Act of 22 August 2002 [BGBl I p. 3390], covers offences committed in connection with the use of nuclear energy or ionising radiation, as well as non-compliance with licence conditions or an order of the authorities.

c) Emergency response

In accordance with Section 6 *et seq.* of the 1992 Safety Officers and Notification Ordinance, the operator is obliged to notify accidents, incidents and other safety-related events to the competent

authority. The criteria for a notifiable event are laid down in detail in Annexes 1 and 2 of that Ordinance which also provides for a formal notification procedure. The safety officer must supervise the notification by the operator to check that it is correct and complete.

The 1986 Preventive Radiation Protection Act sets out the respective administrative responsibilities of the *Bund* and the *Länder* in relation to monitoring radioactivity and taking protective measures following an incident [Sections 2 and 3]. It also establishes a federal information system on "Radioactivity in the Environment" [Section 4]. The Federal Minister for the Environment, Nature Conservation and Nuclear Safety has the power to fix acceptable dose levels [Section 6]. These dose levels may be implemented by ordinances prescribing restrictions on trade in, and use of, foodstuffs, tobacco products and drugs [Sections 7 and 8]. Border police and customs officers have special powers for controlling transborder traffic and trade with regard to radioactive contamination.

Five Ordinances to implement the Preventive Radiation Protection Act were adopted in 1989, 1991, 1997, 1998 and 2002 in order to assign competence for measurements and evaluations in accordance with that act (for further details, see *supra* Section 1 "Introduction").

The Federal Minister for the Environment, Nature Conservation and Nuclear Safety has the exclusive power to issue recommendations to the population as to the conduct they should adopt in order to protect themselves [Section 9 of the Preventive Radiation Protection Act].

At international level, Germany is a Party to both the 1986 Convention on Assistance in the Case of Nuclear Accident or Radiological Emergency and the 1986 Convention on Early Notification of a Nuclear Accident since 14 September 1989 [BGBl 1989 II p. 434, 444]. Germany has also concluded numerous bilateral agreements on information and assistance with its neighbouring states, in particular with a view to implementing the 1986 Conventions.

d) Surveillance of installations and activities

All installations, facilities, and activities which fall under the scope of application of the Atomic Energy Act and its implementing and supplementing ordinances are under permanent surveillance by the competent authorities. The legal basis for this surveillance under the Atomic Energy Act is its Section 19, "Government Supervision".

Paragraph 1 of this provision describes in detail the duties and installations to which the provision applies:

- handling of and dealing in radioactive material, construction, operation, and possession of nuclear installations;
- handling of and dealing in the facilities and equipment as listed in Section 11, paragraph 1, No. 3 of the act;
- the carriage of such material, installations, equipment and devices, as well as work of the type defined in Section 11, paragraph 1, No. 7 of the act.

It is the task of the authorities to ensure that all activities are conducted in compliance with the requirements of the legal framework and the respective licence conditions. The competent authority and its experts have the right of access at any time to those places where radioactive material, installations, and other equipment are located. They are entitled to obtain the necessary information from personnel and to verify such information if necessary. The competent authority may even order

that compliance with the legal framework and the licence conditions be reinstated. The authority may in particular order that protective measures shall be taken and at which places certain radioactive material shall be stored.

Section 19a, which was introduced by the 2002 amendment of the Atomic Energy Act, obliges the operator of a nuclear power plant to conduct a safety review on a regular basis. Appendix 4 to the act specifies for each nuclear power plant in Germany the date by which such safety review has to be performed (periodical safety evaluation). Ten years after the first safety review, the results of a renewed safety review should be submitted. Paragraph 2 of Section 19a exempts licensees from the requirements in relation to safety reviews where they provide a binding declaration to the supervisory authority that the installation will be permanently shut down no later than three years after the date specified in Appendix 4 to the act.

5. Trade in Nuclear Materials and Equipment

Nuclear trade in general (both domestic and foreign) is subject to the provisions of the Atomic Energy Act and its implementing ordinances. Therefore, the applicable norms concerning licensing and supervision, radiation protection, financial security and physical protection must be observed. In addition, the international obligations of Germany must be respected, notably European Union legislation, international transport agreements, the nuclear third-party liability conventions and the Treaty on the Non-Proliferation of Nuclear Weapons.

Foreign trade in nuclear material is subject also to the general foreign trade legislation contained in the Foreign Trade Act (*Außentwirtschaftgesetz*) of 28 April 1961 [BGBl I p. 481] as last amended [BGBl 2002 I p. 3202], as implemented by the Foreign Trade Ordinance (*Außentwirtschaftsverordnung*) of 18 December 1986 [BGBl 1986 I p. 2671; 1993 I p. 2493], last amended in 2002 [*Bundesanzeiger* 2002 p. 26497]. The Foreign Trade Act lays down the principle that all economic transactions with other countries are unrestricted, subject to the limitations provided for by the act itself, other laws and international agreements. The act allows restrictions to be prescribed by ordinance and the Foreign Trade Ordinance specifies such restrictions in relation to trade in nuclear material, installations and equipment. The Foreign Trade Ordinance also incorporates the restrictions on nuclear trade imposed by the recommendations of the Nuclear Suppliers' Group (London Club) and by the so-named Trigger List. The Import and Export Lists annexed to the Foreign Trade Ordinance were last revised in 2002 [*Bundesanzeiger* 2002 pp. 26681, 26498].

The import and export of nuclear fuel or other radioactive substances require either a licence or a declaration, depending on the substances involved [Atomic Energy Act, Section 3; Radiation Protection Ordinance, Sections 19 to 22]. Exemptions from these requirements are made for certain low-risk radioactive substances and for other radioactive substances which are imported/exported by the Armed Forces [Radiation Protection Ordinance, Section 19, paragraph 3 and Sections 20 and 21]. Both the Atomic Energy Act and the Radiation Protection Ordinance expressly stipulate that other legal provisions on import and export remain unaffected. In this respect, the Foreign Trade Act and the Foreign Trade Ordinance are of particular relevance, as are the Import List and the Export List which are annexed to them, respectively. The Export List comprises a Nuclear Energy List, which enumerates nuclear material, installations and equipment which are subject to a special regime under the Foreign Trade Act and Ordinance, while both lists provide country lists which provide details on countries with which trade has been liberalised and those which are subject to restrictions.

Additional provisions to be observed when importing or exporting radioactive substances are the Nuclear Waste Shipment Ordinance of 1998/2001 (for further details, see *supra* Section 1

"Introduction") and Council Regulation No. 1493/93/Euratom on shipments of radioactive substances between Member States [EC Official Journal 1999 No. L 148].

6. Radiation Protection

The Radiation Protection Ordinance of 13 October 1976, as amended, was totally revised on 20 July 2001 [BGBl I p. 1714; 2002 I p. 1459, 1869, 1903]. This revision results from the implementation at national level of Council Directives 96/29/Euratom of 14 May 1996 and 97/43/Euratom of 30 June 1997 [EC Official Journal 1996 No. L 159, 1997 No. L 180]. The revised ordinance comprises 118 Sections and 14 Annexes, which are mostly of a technical nature.

a) General

Section 1 states that the objective of the ordinance is to regulate principles and requirements in relation to the protection of man and the environment against the detrimental effects of radioactive substances and ionising radiation of natural or man-made origin.

The ordinance covers activities and practices involving artificial and natural radioactive substances including, *inter alia*, transportation, storage, construction, and operation of facilities for the production of ionising radiation and the use of radioactive substances in connection with the production of foodstuffs and medicine. The revised ordinance extends for the first time to the protection of persons against natural radiation sources, e.g. in aircraft.

The revised ordinance entered into force on 1 August 2001.

b) Principal elements of the Radiation Protection Ordinance

In implementing the Euratom Directives, the ordinance establishes a regime of licensing and notification which complements the corresponding regime in the Atomic Energy Act. While the Atomic Energy Act deals essentially with nuclear fuel and nuclear installations and the ordinance covers other radioactive substances and ionising radiation, the ordinance does nonetheless contain certain provisions which are applicable to nuclear fuel and nuclear installations. The act is the enabling statute for the ordinance and the two instruments should be read in parallel.

The Radiation Protection Ordinance deals, in five parts, with the following principal elements of radiation protection:

- Objective, scope and definitions of the ordinance [Sections 1-3].
- Principle of justification of practices [Sections 4, 80]
- Decrease of the dose limits for the general public from 1.5 to 1 millisievert (mSv) per year and for occupationally exposed workers from 50 to 20 mSv per year [Sections 46 and 55].
- Maintenance of the existing dose limit for the entire professional life of 400 mSv and of a comprehensive dose limit system for organs and tissues [Sections 55 and 56].
- Special radiation limits and improved protection requirements for occupationally exposed female workers with a view to protecting women of childbearing age, pregnant women and nursing mothers [Section 55, paragraph 4, 80, 95].

- Establishing procedures and principles to define exemption limits, etc. from the Euratom Directives and from the International Commission on Radiological Protection (ICRP): Annex III.
- Release of insignificantly contaminated objects from control under Atomic Energy Act (*Freigabe*) [Section 29, Annex IV].
- Establishing general conditions for the definition of design requirements to prevent incidents (*Störfalle*) [Section 50].
- Introduction of a more stringent regime governing the use of radioactive substances and ionising radiation in medicine, including quality assurance requirements [Sections 82 and 83].
- Transfer of the competence to license activities in the field of medical research to the Federal Radiation Office in co-operation with a Special Committee on Ethics [Sections 23 and 92].
- Radiation protection requirements and control of exposure of workers dealing with natural radioactive sources, in particular aircraft personnel; also the protection of the general public against risks from the disposal and use of radioactive residues [Sections 95 to 103].
- New requirements for achieving expertise in radiation protection [Section 30].
- Limitation and replacement in part of GDR radiation protection law by federal law with regard to the protection of workers in the field of mediation and restoration of GDR uranium mining sites [Section 118].
- Introduction of a more severe regime of notification and of state control governing radioactive waste [Sections 42, 48, 70].
- Improvement of emergency preparedness measures, in particular by strengthening the powers of the competent authorities [Section 51].

Section 117 of the ordinance provides for transitional rules regarding licences issued under the old law prior to 1 August 2001. The revision of the Radiation Protection Ordinance also led to a consequential amendment of the Ordinance on Weights and Measures of 12 August 1998 as last amended on 13 December 2001 [BGBl 1988 I p. 1657; 2001 I p. 3586].

c) Additional radiation protection norms

The operation of X-ray apparatus is regulated by the X-Ray Ordinance of 8 January 1987 as last amended on 18 June 2002 [BGBl 1987 I p. 114; 2002 I p. 1869]. The governing principles are identical to those established in the Radiation Protection Ordinance including the principles of justification, dose limits, and optimisation [Sections 2a to 2c]. Section 3 of the X-Ray Ordinance establishes a licensing requirement for the operation of X-ray apparatus, with the exception of low-risk apparatus which only require a notification in accordance with Section 4.

The Law on the Marketing of Medicines (*Arzneimittelgesetz*) of 24 August 1976 as last amended on 9 August 1994 [BGBl 1976 I p. 2445, 2448; 1994 I p. 2071] is designed to ensure safety in the use of medicines. The law provides that it is unlawful to market radioactive medicines or medicines produced with the aid of ionising radiation without the appropriate permit. Based on this act, the Ordinance on Radioactive Medicines or Medicines Treated with Ionising Radiation of

28 January 1987 as last amended on 20 July 2001 [BGBl 1987 I p. 502; 2002 I p. 1714] establishes a special system of licensing and control.

Under Section 13 of the Foodstuffs and Consumer Goods Act of 15 August 1974 as last amended by Act of 8 August 2002 [BGBl 1974 I p. 1945; 1997 I p. 2296; 2002 I p. 3116], the treatment of foodstuffs with ultraviolet light and ionising radiation and the marketing of irradiated foodstuffs for commercial purposes are prohibited. Exceptions are set out in the Food Irradiation Ordinance of 14 December 2000 as amended on 29 October 2001 [BGBl 2000 I p. 1730; 2001 I p. 2785]. Prohibited foodstuffs must not be introduced into Germany, with the exception of products which have been brought lawfully into circulation in the territory of a Member State of the European Union. This exception also applies to states in the European Economic Area. The Federal Minister for the Environment, Nature Conservation and Nuclear Safety is, in consultation with other ministers, entrusted with the right to forbid or limit the sale of foodstuffs affected by radioactive contamination of the environment.

According to the Drinking Water Ordinance of 22 May 1986 as last amended on 20 December 2002 [BGBl 1986 I p. 760; 1990 I p. 2612; 2002 I p. 4695, 4709], drinking water must not contain radioactive substances in such concentration as to be capable of affecting human health.

7. Radioactive Waste Management

a) Atomic Energy Act 2002

Major changes were introduced into the law of radioactive waste management by the 2002 Act to Phase-Out the Use of Nuclear Energy.

According to Section 9a, paragraph 1, sentence 2 of the Atomic Energy Act, as amended, the delivery of spent nuclear fuel originating from the operation of nuclear power plants for electricity production to a reprocessing installation shall become unlawful as of 1 July 2005. Such spent fuel elements are nuclear waste.

The Atomic Energy Act does not contain an express definition of the term “nuclear waste”. However, Section 9a, paragraph 1 of the act clearly implies that the definition should read: “Radioactive waste is residual radioactive material which is to be disposed of in a regulated manner.”

This definition is confirmed by an express definition in Section 3, paragraph 2, number 1, lit. a of the Radiation Protection Ordinance, which defines radioactive waste as follows: “Radioactive waste is radioactive material within the meaning of Section 2, paragraph 1 of the Atomic Energy Act which, in accordance with Section 9a of the Atomic Energy Act, has to be disposed of in a regulated manner.”

In principle, the Atomic Energy Act establishes an option for persons in possession of radioactive waste to either reuse such waste in a non-detrimental way or to dispose of it. The first option, namely reuse of the waste, is excluded with regard to spent nuclear fuel waste from nuclear power plants. It follows that, in principle, this spent fuel must be disposed of by delivery to a final repository. Since a repository for highly radioactive waste is not yet available in Germany, paragraph 1b of Section 9a obliges the operator of a nuclear power plant to erect a local interim storage facility on the site or close to the site of the installation and to store the irradiated fuel therein until its surrender to a facility for final disposal is possible.

With regard to nuclear waste which is not spent fuel from a nuclear power plant, the producers of the waste have to surrender it to collection points for interim storage to be established and operated by the *Länder*.

The federal authorities are responsible for the establishment and operation of facilities for the safe containment and final disposal of radioactive waste. The construction and operation of these facilities, which are under the responsibility of the Federal Radiation Protection Office, must be approved pursuant to a land-use planning procedure carried out by the *Land* in which the facility is situated.

The Federation and the *Länder* may call upon the services of third parties to meet their obligations with regard to waste disposal. The federal state is expressly authorised to wholly or partially transfer the performance of its duties regarding final disposal to third parties, provided that they are capable of fulfilling such tasks [Section 9a, paragraph 3, sentence 3 of the Atomic Energy Act].

To cover the necessary costs associated with the construction and operation of a final disposal repository, the federal state is entitled to levy advance contributions from those persons who are obliged to surrender nuclear waste to the repository [Section 21b of the Atomic Energy Act, Ordinance on Advance Contributions Towards Construction of Federal Installations for Safe Containment and Final Disposal of Radioactive Waste of 28 April 1982, as amended].

b) Radiation Protection Ordinance

The 2001 Radiation Protection Ordinance [Sections 72 to 79] contains provisions on nuclear waste which implement and complement the basic standards set out in the Atomic Energy Act.

In accordance with Section 72 of the ordinance, the licence holder is obliged to provide, in advance, a plan on the amount of radioactive waste which he expects to incur from his activities and the manner in which such waste will be disposed of. These notifications have to be provided every year on 31 December. The licence holder has also to establish an inventory of the radioactive waste in accordance with the forms contained in Annex X, parts A and B of the Radiation Protection Ordinance [Section 33]. The competent authority may require information about the manner in which the waste has to be treated and packed prior to its surrender to the repository [Section 74]. The transfer of radioactive waste to third parties or carriers is only permitted if the receiving party agrees in writing [Section 75]. Sections 76 to 78 provide detailed regulations on how to surrender the waste to a federal repository.

Of major practical importance is Section 79, which prohibits the diluting of radioactive waste generated from activities which are subject to licensing, with a view to decreasing its radioactivity and thereby meeting provisions on exemptions from licensing.

c) International obligations

Germany is a Party to numerous international agreements dealing with the disposal of radioactive waste. These agreements include the 1972 Convention on the Prevention of Marine Pollution by Dumping of Waste and Other Matter [BGBl 1977 II pp. 165, 180] and its Protocol of 7 November 1996 [BGBl 1998 II p. 1345] and the Joint Convention on the Safety of Spent Fuel

Management and on the Safety of Radioactive Waste Management of 5 September 1997 [BGBl 1998 II p. 1753].

8. Non-Proliferation and Physical Protection

a) Non-proliferation regime

By Acts of 4 June 1974, the Federal Republic of Germany approved:

- the 1968 Treaty on the Non-Proliferation of Nuclear Weapons (ratification took effect on 2 May 1975) [BGBl 1974 II p. 785; 1976 II p. 552];
- the Agreement of 5 April 1973 between Belgium, Denmark, the Federal Republic of Germany, Ireland, Italy, Luxembourg, the Netherlands, Euratom and the IAEA in implementation of Article III(1)(4) of the Treaty on the Non-Proliferation of Nuclear Weapons (Verification Agreement) [BGBl 1974 II p. 794; 1980 II p. 102].

The Agreement of 5 April 1973 was given effect in the Federal Republic of Germany by an act containing detailed provisions regarding the safeguarding of fissionable materials. Alongside Commission Regulation (Euratom) No. 3227/76 of 19 October 1976 concerning the application of the provisions on Euratom safeguards [OJ EC 1976 No. L 363] there exists extensive regulations to give effect to the Non-Proliferation Treaty and the Verification Treaty [Act of 7 January 1980, BGBl 1980 I p. 17; 2001 I p. 2785].

The Act on Control of Military Weapons of 22 November 1990, as amended, forbids development, production, import and export (including transit), trade in or possession of nuclear weapons [BGBl I p. 2506; 2002 I p. 3970]. In order to enhance control over foreign trade and to prevent proliferation of atomic, biological and chemical weapons, the Federal Minister for the Environment, Nature Conservation and Nuclear Safety may inform the appropriate authorities of any facts which become known to him in connection with nuclear licensing procedures which arouse suspicion of an infringement of the Foreign Trade Act [Atomic Energy Act, Sections 19(1) and 24(a)]. The Foreign Trade Act and the Foreign Trade Ordinance (*Außenwirtschaftsverordnung*) of 22 November 1993 [BGBl I, pp. 1934, 2493] were repeatedly amended in order to improve supervision and control of the export and transit of sensitive material and equipment, including nuclear material, goods and technology (for further details, see *supra* Section 5 "Trade in Nuclear Materials and Equipment").

Germany is a Contracting Party to the following additional international agreements which prohibit or limit the proliferation and use of nuclear weapons: the Treaty of 5 August 1963 banning nuclear weapon tests in the atmosphere, in outer space, and under water [BGBl 1964 II p. 906]; the Treaty of 11 February 1971 on the proliferation of the emplacement of nuclear weapons or other weapons of mass destruction on the sea-bed and the ocean floor and in the subsoil thereof [BGBl 1972 II p. 325]; the Comprehensive Nuclear Test-Ban Treaty of 24 September 1996 [BGBl 1998 II 1210; implementing act BGBl 1998 I p. 1882].

b) Physical protection regime

One of the prerequisites for granting a licence under the Atomic Energy Act or the Radiation Protection Ordinance is that the applicant has to ensure the necessary protection against interference or other action by third parties (physical protection) [See e.g. Section 4, paragraph 2, No. 5; Section 6

paragraph 2, No. 4; Section 7, paragraph 2, No. 5; Section 9, paragraph 2, No. 5; Section 12, paragraph 1, No. 10; Section 12b of the Atomic Energy Act; Section 9, paragraph 1, No. 8; Section 13, No. 5; Section 18, paragraph 1, No. 5 of the Radiation Protection Ordinance].

Germany ratified the 1979 Convention on the Physical Protection of Nuclear Material on 6 September 1991, and has given effect to it through provisions in the Penal Code [Law on the Convention on the Physical Protection of Nuclear Material, of 24 April 1990, BGBl II p. 326, as amended by the Second Act Concerning Criminal Acts Against the Environment of 27 June 1994, BGBl 1994 I p. 1440].

9. Transport

The transport of radioactive substances is subject not merely to the provisions of the Atomic Energy Act and the Radiation Protection Ordinance, but also to the provisions applicable to each type of carrier (Ordinances on the Transport of Dangerous Goods by Road, Rail, Sea and Inland Waterways), which are based on the Act on the Transport of Dangerous Goods (*Gesetz über die Beförderung gefährlicher Güter*) of 6 August 1975, as amended [BGBl I, p. 2121; 1998 I, pp. 2037, 3114; 2002 I p. 3082]. This act does not, however, apply to carriage on the sites of installations where dangerous goods are produced, stored, used or disposed of. Furthermore, the act does not apply to the transboundary shipment of dangerous goods to the extent that regulations of the European Union or international agreements apply to that carriage, and it does not apply to transportation by mountain railway. The provisions relating to the transport of radioactive substances follow the IAEA Regulations for the Safe Transport of Radioactive Materials.

Germany is a party to the following international agreements concerning the transport of dangerous goods:

- European Agreement of 30 September 1957 concerning the International Carriage of Dangerous Goods by Road (ADR) including the Protocol of 1975 [BGBl 1969 II p. 1489; 1979 II p. 1334; 1998 II p. 2618 (annex volume)];
- Regulations for the Transport of Dangerous Goods on the Rhine (ADNR) [BGBl 1994 II p. 3830; Special annex volume to BGBl 1997 II, No. 48];
- Agreement of 9 May 1980 on International Transport by Rail (COTIF) [BGBl 1985 II p. 130] including the Protocol of 17 February 1984 [BGBl 1985 II, p. 666] and including the International Regulations concerning the Carriage of Dangerous Goods by Rail (RID) [Annex 1 Attachment B as amended; Special annex volumes to BGBl 1985 II No. 18; 1997 II No. 51].

The Ordinance on Domestic and Transboundary Transportation of Dangerous Goods by Road and Rail (*Gefahrgutverordnung Straße und Eisenbahn*) (Dangerous Goods Ordinance – Road and Rail) of 11 December 2001 [BGBl 2001 I p. 3529] implements and complements the ADR and COTIF Agreements including their Protocols.

In addition, the transport of radioactive materials requires a licence under nuclear legislation. This licence is available in the case of nuclear fuel and major sources of radiation from the Federal Office for Radiation Protection, and in the case of other radioactive substances from the competent authorities of the *Länder* [Atomic Energy Act, Sections 4, 23 and 24; Radiation Protection Ordinance, Sections 16 to 18].

Specific exemptions apply to certain low-level radioactive substances and articles containing small quantities of radioactive substances [Radiation Protection Ordinance, Section 17, Annexes I and III].

As regards the domestic transport of radioactive substances, carriers are subject to a large number of instruments, which are in conformity with international agreements and recommendations.[5]

10. Nuclear Third Party Liability

The operator of a nuclear installation is liable under the 1960 Paris Convention, ratified by Germany on 30 September 1975, and the 1963 Brussels Supplementary Convention, ratified on 1 October 1975, as supplemented by the provisions of the Atomic Energy Act [Section 25 of the Atomic Energy Act]. Germany has also been party to the 1971 Convention relating to Civil Liability in the Field of Maritime Carriage of Nuclear Material since 1 October 1975.

The liability of the operator of a nuclear installation for damage occurring within Germany is unlimited, unless the incident is due to war, insurrection or a grave natural disaster, in which case liability is limited to the amount of the state guarantee, which is set at EUR 2.5 billion. The maximum in the case of damage occurring abroad is determined in accordance with the principle of reciprocity, i.e. the extent to which the state in which the damage occurs has equivalent compensation arrangements in relation to Germany. In relation to states which do not operate a nuclear installation in their territory, liability is limited to the maximum amount under the Brussels Supplementary Convention, which currently is 300 million Special Drawing Rights (SDR) [Section 31 of the Atomic Energy Act].

The licensing authorities are responsible for defining the nature, extent and amount of cover necessary to meet the legal liability for compensation (financial security), which is not to exceed EUR 2.5 billion for nuclear installations. The Financial Security Ordinance of 1977 as last revised in 2002 [BGBl 1977 I p. 220; 2002 I p. 1869, 1906] regulates in detail how and in which individual amounts financial security has to be provided.

The maximum amount of financial security of EUR 2.5 billion is provided by a two-tiered system. Up to EUR 256 million is covered by third party liability insurance taken out by each operator. Between this amount and EUR 2.5 billion, cover is provided in the framework of a contract jointly subscribed to by all nuclear power plant operators in Germany.

The operator of a nuclear installation will be indemnified against claims for damages of up to EUR 2.5 billion to the extent that they are not covered by private financial security or that claims cannot be paid out of such security. Such indemnification is borne, up to the amount of EUR 500 million, as to 75% by the federal authorities and as to 25% by the *Land* within which the installation is situated. The federal state covers the amount between EUR 500 million and 2.5 billion alone [Atomic Energy Act, Sections 34 and 36].

In certain circumstances, the state will pay compensation for damage suffered in Germany following a nuclear incident in another country, if adequate compensation is not obtainable under the law of that country [Atomic Energy Act, Section 38]. Following the Chernobyl accident in 1986,

5. These may be found in a loose-leaf collection: Eberhard Ziegler (ed.), *Bestimmungen über die Beförderung radioaktiver Stoffe* (Provisions applicable to the transport of radioactive substances), NOMOS Publ., Baden-Baden.

guidelines were issued concerning the compensation to be paid to persons who had suffered damage [Equity Guidelines of 2 June 1986, BAnz 12 June 1986, No. 105, p. 7237; Guidelines of 21 May 1986, BAnz 27 May 1986, No. 95, p. 6417; Equity Guidelines of 24 July 1986, BAnz 2 August 1986, No. 140, p. 10388].

An act which, *inter alia*, amends Annex 1 to the Atomic Energy Act was adopted on 6 April 1998 [BGBl 1998 I, p. 694]. This Annex, which contains the definitions applying to the liability chapter of the act, is identical to Article 1(a) of the Paris Convention. Following the NEA Steering Committee's decision of 11 April 1984 [NE/M (84) 1], "installations for the disposal of nuclear substances" are included in the list and are now "nuclear installations" governed by the Paris Convention.

A catch-all clause covers all other cases of liability; this clause is particularly relevant in the case of handling of radioisotopes and particle accelerators as well as for nuclear material not covered by the Paris Convention, *e.g.* transit through German territory of nuclear fuel being transported from the United States to Austria [Section 26]. Section 26 establishes strict and unlimited liability of the holder of radioactive substances. However, the liability is not exclusive, and the person liable is exempted from liability upon proof that the incident occurred despite all necessary precautionary measures (so-called modified strict liability). This exemption, however, does not apply if the material involved in the incident is radioactive substances or material in the sense of the Paris or the Vienna Conventions [paragraphs 1, sentence 2, 1a].

On 22 October 1986, an Agreement on Third Party Liability in the Nuclear Field was concluded between Germany and Switzerland to expressly declare reciprocity in regard to the amount of compensation and to provide for greater uniformity in the compensation regimes in the two countries [BGBl 1988, p. 598]. It entered into force on 21 September 1988.

Non-nuclear damage resulting from activities involving certain nuclear installations is covered by the Act on Liability for Damage to the Environment of 10 December 1990 [BGBl I p. 2634, 2002 I p. 2674] and by general tort law.

II. INSTITUTIONAL FRAMEWORK

1. Regulatory and Supervisory Authorities

Germany's federal structure plays a crucial role in implementing nuclear and radiation protection. As mentioned above, an amendment to the Constitution gave the *Bund* concurrent legislative power in the field of the peaceful use of atomic energy. Due to the special safety needs in this field, the *Länder* are responsible for enforcing existing federal legislation not on their own behalf but as agents for the *Bund* to the extent that the *Bund* has not established its own agencies for this purpose [Article 87c of the Basic Law and Section 24, paragraph 1 of the Atomic Energy Act].

Implementation of the Atomic Energy Act and of ordinances to give effect to it by the *Länder* on behalf of the *Bund* has the following consequences:

- the establishment of the appropriate agencies remains the responsibility of the *Länder* except where federal legislation otherwise provides;
- the federal government, with the approval of the Federal Council can regulate general administration and the standardised training of officials and other employees;
- the *Land* authorities must comply with the directions of the supreme federal authorities (federal ministries), such directions to be addressed as a general rule to the supreme authorities of the *Länder*;
- federal supervision covers the legality and appropriateness of measures taken by the *Länder*; for this purpose the federal government may require the submission of reports and may inspect documents [Article 85 of the Basic Law].

The Atomic Energy Act defines the distribution of the administrative duties between the federal authorities and those of the *Länder* [Sections 22 to 24a of the Atomic Energy Act].

A. Federal Authorities

a) Federal Minister for the Environment, Nature Conservation and Nuclear Safety

The Federal Minister for the Environment, Nature Conservation and Nuclear Safety is responsible for nuclear safety and radiation protection pursuant to the Atomic Energy Act. He has the power to issue directions in this field and he supervises the legality and appropriateness of the acts of authorities responsible for enforcing the Atomic Energy Act and the 2001 Radiation Protection Ordinance [Article 85, paragraph 3 of the Basic Law].

The Federal Minister for the Environment, Nature Conservation and Nuclear Safety and the authorities of the *Länder* responsible for enforcing the Atomic Energy Act work together within the *Länder* Committee for Nuclear Energy (*Länderausschuß für Atomkernenergie*) [BAnz 1977 No. 206].

In carrying out his duties the Minister is advised by two commissions, namely the Reactor Safety Commission (*Reaktorsicherheitskommission* – RSK) and the Radiation Protection Commission (*Strahlenschutzkommission* – SSK). The Nuclear Technology Committee (*Kerntechnischer Ausschuß* – KTA) was also set up to develop standards in the nuclear field. Its members represent all groups active in the nuclear field (nuclear operators, industry, etc.) and its Secretariat is part of the Federal Office for Radiation Protection which is under the authority of the Ministry for the Environment, Nature Conservation and Nuclear Safety.

Under the Act on Preventive Protection of the Public against Radiation (Preventive Radiation Protection Act) of 19 December 1986 [BGBl I p. 2610, as last amended on 14 December 2001, BGBl I p. 3714, 3718], the Minister for the Environment, Nature Conservation and Nuclear Safety has power to fix dose levels, which may be implemented by ordinances jointly issued with other interested federal ministers [Sections 6 and 7]. The Minister also has exclusive power to issue recommendations to the population as to the conduct they should adopt following a nuclear incident, but must do so in close contact with other competent authorities of the *Bund* or *Länder* [Section 9].

In 1994, the Minister for the Environment, Nature Conservation and Nuclear Safety published a comprehensive list of the authorities which are competent in the field of nuclear licensing and nuclear surveillance in Germany, covering both federal authorities and authorities of the *Länder*

[*Gemeinsames Ministerialblatt* 1994 No. 28 p. 838]. This list provides precise information about the powers of each authority and indicates the respective legal bases of those powers.

b) Federal Minister for Education, Science, Research and Technology

The Federal Minister for Education, Science, Research and Technology is responsible for nuclear research.

c) Federal Minister for Finance

The Federal Minister for Finance and the customs authorities answerable to him are responsible for supervising the import and export of nuclear fuels and other radioactive substances [Section 22, paragraph 2 of the Atomic Energy Act].

d) Federal Minister for Transport

The German railway authorities designated by the Federal Minister for Transport are responsible for the supervision of the transport of radioactive substances by rail and by boat within Germany [Section 24, paragraph 1 of the Atomic Energy Act].

e) Federal Minister for Economy and Labour

The Federal Minister for Economy and Labour is responsible for international nuclear co-operation, in particular with the IAEA, OECD/NEA, and Euratom.

f) Federal Minister for Defence

The Federal Minister for Defence has the competence to license and supervise nuclear activities within the army, the navy and the air force. As Germany does not have any nuclear weapons, these activities largely comprise the use of radioisotopes in the military field. The Minister for Defence acts in all cases in agreement with the Federal Minister for the Environment, Nature Conservation and Nuclear Safety [Section 24, paragraph 3 of the Atomic Energy Act].

g) Federal Office for Radiation Protection (BfS)

The Federal Office for Radiation Protection (*Bundesamt für Strahlenschutz* – BfS) is an independent federal authority (*selbständige Bundesoberbehörde*) within the portfolio of the Federal Minister for the Environment, Nature Conservation and Nuclear Safety [Law of 9 October 1989, as amended, BGBl I p. 1830; 2001 I p. 636, 640]. Pursuant to Section 23, paragraph 1 of the Atomic Energy Act, it is responsible for:

- government custody of nuclear fuels;
- construction and operation of federal installations for the safe containment and final disposal of radioactive waste, including the transfer of these functions to third parties and their supervision;

- licensing of the transport of nuclear fuels and large sources;
- licensing of the storage of nuclear fuels outside government custody to the extent such storage is not preliminary to or part of a practice requiring a licence pursuant to Sections 7 or 9 of the Atomic Energy Act;
- withdrawal or revocation of transport and storage licences;
- establishment and maintenance of a register of the radiation exposures of occupationally exposed persons;
- establishment, operation, and revocation of an ethics commission, as defined in Section 12, paragraph 1, sentence 1, No. 3a of the Atomic Energy Act;
- the obtaining, preparation, and publication of diagnostic reference figures, determination of the radiation exposure of individuals for medical purposes, and related surveys required under an Ordinance pursuant to Section 12, paragraph 1, sentence 1, No. 3b of the Atomic Energy Act;
- the acceptance and publication of information pursuant to Section 7, paragraph 1c of the Atomic Energy Act;
- decisions pursuant to Section 9a, paragraph 2, sentence 4 of the Atomic Energy Act.

It also has administrative responsibilities, and undertakes scientific research in the fields of radiation protection, nuclear safety, transport of radioactive substances and radioactive waste management.

h) Federal Export Office

This body (*Bundesausfuhramt*), which is an independent federal authority (*selbständige Bundesoberbehörde*) within the portfolio of the Federal Minister for Economy and Labour, is responsible for the issue of import and export licences for nuclear material. In carrying out this function, it is bound by the technical instructions issued by the federal minister responsible for nuclear safety and radiation protection (the Minister for the Environment, Nature Conservation and Nuclear Safety) [Section 22, paragraph 1 of the Atomic Energy Act, Act on the establishment of a Federal Export Office of 28 February 1992, BGBl I p. 376; BGBl 2001 I p. 2785].

B. Authorities of the Länder

Administrative duties (licensing and supervision) under nuclear and radiation protection law not performed by the federal authorities are exercised by the *Länder* on behalf of the *Bund*, subject to technical and legal supervision by the Federal Minister for the Environment, Nature Conservation and Nuclear Safety [Article 87c of the Basic Law and Sections 19 and 24, paragraph 2 of the Atomic Energy Act].

For the purpose of enforcing nuclear and radiation protection law the *Länder* designate their authorities responsible in accordance with their own rules for determining competence. The *Länder* can make administrative regulations for the implementation of nuclear and radiation protection law; in practice, however, the guidelines and recommendations adopted by the *Länder* Committee for Nuclear Energy serve as the basis for decisions by the *Land* authorities.

The main duty of the authorities designated by the *Länder* is the issue of licences for the construction and operation of nuclear installations. The licensing procedure however involves the participation of all competent federal, *Land* and local authorities. In the event of differences of opinion between the licensing authorities of the *Land* and a federal agency, the licensing authority must obtain directions from the Federal Minister for the Environment, Nature Conservation and Nuclear Safety [Section 7, paragraph 4 of the Atomic Energy Act].

2. Advisory Bodies

As part of the supervision by the Federal Minister for the Environment, Nature Conservation and Nuclear Safety of the legality and appropriateness of action by subordinate authorities, advisory bodies have been set up within the Ministry for that purpose.

a) Reactor Safety Commission (RSK)

i) Legal status

A Reactor Safety Commission (*Reaktor Sicherheitskommission* – RSK*)* was set up within the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety and consists of some twelve members representing all specialist fields involved in nuclear safety [Notification of 22 December 1998, BAnz 9 January 1999 p. 201].

ii) Responsibilities

The Commission is responsible for advising the Federal Minister for the Environment, Nature Conservation and Nuclear Safety on all matters concerning the safety of nuclear installations and related issues as well as in the field of radioactive waste management. The Commission thereby backs up the Federal Minister for the Environment, Nature Conservation and Nuclear Safety in exercising federal supervision over the *Länder* as regards the performance of tasks delegated to them by the *Bund*.

As a result of its deliberations the Commission issues recommendations and opinions, which require a majority of two-thirds of its members in the case of recommendations and opinions relating to the siting, design and commissioning of nuclear installations or to intermediate storage facilities for spent fuel elements. The Reactor Safety Commission has set out the safety requirements for the design, construction and operation of nuclear power plants equipped with pressurised water reactors in the form of guidelines. The latter are used as a basis for deliberations and recommendations in individual cases.

iii) Structure

The Federal Minister for the Environment, Nature Conservation and Nuclear Safety normally appoints the members of the Reactor Safety Commission for a period of three years, usually renewable for one further three-year term. Membership is a personal honorary office and as such cannot be delegated. Members are independent and may not receive instructions from any higher authority. In the event of bias the member concerned will be excluded from the deliberations of the Commission. In order to ensure that the Commission provides well-balanced advice, its members should represent the

entire spectrum of views (*Brandbreite*) on the state of science and technology. The Minister has entrusted the Federal Office for Radiation Protection with the operation of the Secretariat of the Commission. This Secretariat functions independently from the Office.

iv) Financing

The Federal Minister for the Environment, Nature Conservation and Nuclear Safety is responsible for the financing of the Reactor Safety Commission and for reimbursement of the expenses of its members.

For further details see homepage www.rskonline.de (available in English).

b) Radiation Protection Commission (SSK)

i) Legal status

A Radiation Protection Commission (*Strahlenschutzkommission* – SSK) has been set up within the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety and is comprised as a rule of 14 well-known and experienced specialists from the fields of radiation biology, radiation genetics, radiation protection medicine, radiation protection technology, radiation physics, biophysics, radiochemistry and radioecology [Notification of 22 December 1998, BAnz 9 January 1999 p. 202]. In the same manner as the RSK, its members should represent the entire spectrum of views (*Brandbreite*) on the state of science and technology.

ii) Responsibilities

The Radiation Protection Commission is responsible for advising the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety on all major issues of radiation protection. It does not cover matters dealt with by the Reactor Safety Commission. The Radiation Protection Commission has six committees and specialist groups which help in the preparation of opinions and recommendations. The Commission was consulted with regard to the preparation of the Radiation Protection Ordinance of 13 October 1976 and subsequent amendments and has also in recent years issued a series of significant recommendations on basic radiation protection matters. It also gives its views via its Committee on Radiation Protection in Nuclear Installations on questions arising in connection with the licensing of nuclear installations.

iii) Structure

As for the SSK, the Federal Minister for the Environment, Nature Conservation and Nuclear Safety appoints the members of the Radiation Protection Commission for a period of three years. Reappointment for a consecutive period is possible only once. Membership is a personal honorary office. Members are independent and may not receive instructions from any higher authority. The Secretariat of the Commission, which is subject to instructions from the Minister, is provided by the Federal Office for Radiation Protection.

iv) Financing

The Federal Minister for the Environment, Nature Conservation and Nuclear Safety is responsible for the financing of the Commission and for reimbursement of the expenses of its members.

For further details see homepage www.rskonline.de.

c) Nuclear Technology Committee (KTA)

The general reference in nuclear law to the state of science and technology means that the relevant rules and guidelines for deciding what that state is, are of decisive importance. Private associations and organisations, with objectives independent of those of the authorities, concern themselves with the definition of technical and scientific rules and guidelines.

i) Legal status

In 1972, in view of the multiplicity of existing bodies, a Nuclear Technology Committee (*Kerntechnischer Ausschuß* – KTA) comprised of experts reflecting the interests concerned was set up within the Federal Ministry for the Interior and is now attached to the Ministry for the Environment, Nature Conservation and Nuclear Safety [Notification of 20 July 1990, BAnz 1990 No. 144, Procedural Rules of the KTA: BAnz 1986 No. 183].

ii) Responsibilities

The Committee is responsible in areas of nuclear technology where, on the basis of experience, specialists working for manufacturers, constructors and operators of nuclear installations, experts and the authorities consensually agree to prepare technical safety rules and to promote their application. Rules adopted by the Committee are published by the Federal Minister for the Environment, Nature Conservation and Nuclear Safety in the *Bundesanzeiger*; proposed rules are published in the Bulletin before being adopted so as to give the public an opportunity to present their views.

iii) Structure

The Committee consists of fifty expert members in the following proportions:

- ten represent manufacturers and constructors of nuclear installations;
- ten represent operators of nuclear installations;
- ten represent the competent authorities of the *Länder* and of the Federal Minister for the Environment, Nature Conservation and Nuclear Safety;
- ten represent expert advisory bodies;
- ten represent various specified authorities, organisations and other bodies.

Members and their deputies are designated by the agencies they represent and appointed by the Federal Minister for the Environment, Nature Conservation and Reactor Safety for a period of four years. The office of member or deputy member is an honorary one. The Committee is led by a board

and its business is conducted by a secretariat established within the Company for Nuclear Safety and run by a manager acting on the instructions of the board. The Committee establishes its own rules of procedure. The adoption of technical safety rules by the Committee requires a majority of five-sixths of its members. The rules must be published by the Federal Minister for the Environment, Nature Conservation and Nuclear Safety in the *Federal Bulletin.*

iv) Financing

Responsibility for the expenses of the Committee is borne in accordance with a general agreement between the Federal Minister for the Environment, Nature Conservation and Nuclear Safety and the three private interest groups.

For further details see homepage www.kta-gs.de (available in English)

3. Public and Semi-Public Agencies

a) Technological Surveillance Associations (TÜV)

The Technological Surveillance Associations (*Technische Überwachungsvereine* – TÜV) are autonomous economic bodies in the form of private registered associations. They exist in all the *Länder* and may be entrusted by the competent official bodies to act on their behalf with respect to the implementation of nearly all control and surveillance measures required by law in relation to technical equipment and installations. In the nuclear technology field the licensing authorities also as a rule entrust the Technological Surveillance Associations with the implementation of detailed safety inspections and the preparation of opinions and reports.

The Technological Surveillance Associations all belong to the private Union of Technological Surveillance Associations (*Vereinigung der technischen Überwachungsvereine eV*), and the latter body has in turn set up a central unit for nuclear technology (*Leitstelle Kerntechnik*). This unit issues instructions to ensure uniformity of controls and technological standards. Where there is disagreement on the application of these instructions, the *Länder* Committee for Nuclear Energy is responsible for ensuring uniformity of practice among licensing authorities in the *Länder*.

b) Company for Reactor Safety (GRS)

The Company for Reactor Safety (*Gesellschaft für Anlagen und Reaktorsicherheit mbH* – GRS), whose headquarters are in Cologne, originated from the Institute for Reactor Safety of the Technological Surveillance Associations. Its founding members were the Federal Republic of Germany, the *Länder* of Bavaria and North-Rhine-Westphalia, several technological surveillance associations and *Germanischer Lloyd* Company. The Company for Reactor Safety has the prime duty of advising the Federal Minister for the Environment, Nature Conservation and Nuclear Safety in the performance of his supervisory duties over the *Länder* in implementation of the Atomic Energy Act. It is also responsible for collecting and evaluating knowledge on nuclear safety matters and participating in an expert capacity in nuclear licensing and supervisory proceedings.

For further details see homepage www.grs.de (available in English).

c) Karlsruhe Research Centre for Technology and Environment

The Karlsruhe Research Centre (*Kernforschungszentrum Karlsruhe für Technik und Umwelt GmbH*) was created in 1956 with the participation of the federal authorities, the *Land* of Baden-Württemberg and German industry. Following the transfer of the shareholding of industry to the federal authorities and the *Land* in 1963, the federal share has since 1972 been 90% and that of the *Land* of Baden-Württemberg 10%.

The Centre makes an important contribution to the development of German nuclear research and nuclear technology in co-operation with nearby universities and industry.

The main concerns of the Centre in the nuclear field are the technological development of heavy water reactors, fast breeders, uranium enrichment, reprocessing, final disposal of radioactive substances, and basic and safety research into fusion reactor technology.

For further details see homepage www.fzk.de (available in English).

d) Jülich Research Centre

The Jülich Research Centre (*Forschungzentrum Jülich GmbH*) was founded in 1967 by the federal authorities and the *Land* of North-Rhine-Westphalia. The Centre originated from a nuclear physics research establishment of the *Land* of North-Rhine-Westphalia set up in 1956. The federal authorities now have a 90% share in the company and the *Land* 10%.

The Centre's main concerns include the development of high temperature reactors, nuclear fusion, basic nuclear research and solid state physics.

e) GKSS Research Centre Geesthacht

The GKSS Research Centre Geesthacht (*Forschungszentrum Geesthacht GmbH*) was established in 1956 as the Centre for the exploitation of nuclear energy in shipbuilding and shipping (*Gesellschaft für Kernenergieverwertung in Schiffbau und Schiffahrt GmbH* – GKSS).

The *Bund* has a 90% share in the company and the *Länder* of Schleswig-Holstein, Lower Saxony, Bremen and Hamburg a 10% share.

The GKSS began its work with the testing of engines for nuclear-powered ships, leading to the operation of the nuclear-powered research and trading vessel Otto Hahn from 1968 to 1979. Today the research and development programme of the GKSS covers the exploitation of the sea and the coasts as well as the use of nuclear energy. The nuclear side of its activities covers projects in the field of reactor safety and forms part of the reactor safety programme of the Federal Minister for Education, Science, Research and Technology.

For further details see homepage www.gkss.de (available in English).

f) Hahn-Meitner Nuclear Research Institute in Berlin (HMI)

The Institute (*Hahn-Meitner-Institut für Kernforschung Berlin GmbH* – HMI) began its scientific work in 1959 and since 1971 has become a major research establishment of the *Bund* and the *Land* of Berlin, which have 90% and 10% holdings respectively.

The Institute's research is directed mainly to heavy ion nuclear physics, nuclear solid state research, radiation and photochemistry, nuclear chemistry, and data processing and electronics.

For further details see homepage www.hmi.de (available in English).

g) The Electron-Synchrotron in Hamburg (DESY)

This Synchrotron (*Deutsches Elektronen-Synchrotron* – DESY) was set up in 1959 as a private law foundation. The *Bund* provides 90% of its financing, with the balance being provided by the *Land* of Hamburg.

DESY is mainly concerned with high-energy physics and elementary particle physics.

For further details see homepage www.desy.de (available in English).

h) Max-Planck Institute for Plasma Physics at Garching/Munich (IPP)

The Institute (*Max-Planck-lnstitut für Plasmaphysik* – IPP) was established in 1960 and receives 90% of its financing from the *Bund* and 10% from the *Land* of Bavaria.

It deals mainly with plasma physics and controlled nuclear fusion.

For further details see homepage www.mpg.de (available in English).

i) Company for Heavy Ion Research (GSI)

The Company for Heavy Ion Research (*Gesellschaft für Schwerionen forschung mbH* – GSI) was established in 1969 with headquarters in Darmstadt and receives 90% of its financing from the *Bund* and 10% from the *Land* of Hesse.

The GSI carries out research work on heavy ions in the fields of nuclear physics, nuclear chemistry and solid state physics.

For further details see homepage www.gsi.de (available in English).

j) Rossendorf Association for Nuclear Technology and Analysis

This Association (*Verein für Kernverfahrenstechnik und Analytik Rossendorf eV* – VKTA) is an establishment entirely financed by the Free State of Saxony. It disposes of waste from the nuclear facilities and nuclear material located at the Rossendorf research station, and undertakes practically oriented research on the disposal of radioactive waste and fissile material, as well as on the technology

of processing radioactive substances. It also undertakes basic research on the environmental restoration of old waste disposal sites.

The VKTA runs the *Land*'s collection point for radioactive waste and the official intake measurement centre of Saxony.

For further details see homepage www.vkta.de (available in English).

IRELAND

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I. GENERAL REGULATORY REGIME

1. Introduction

There are no nuclear power plants or nuclear research reactors within Ireland's territorial boundaries. Likewise, there is no uranium mining production in Ireland. Nevertheless, Ireland has developed legislation in the area of radiation protection for the purpose of protecting its people, the food supply and the environment from radiation's harmful effects.

The framework legislation governing the nuclear and radiation protection sectors in Ireland is the Radiological Protection Act of 11 May 1991 [No. 9 of 1991]. This act repealed the Nuclear Energy Act, 1971.

The Radiological Protection Act 1991 was amended by Section 26 of the Energy (Miscellaneous Provisions) Act, 1995 and by Section 65 of the Food Safety Authority of Ireland Act, 1998. References in this study to the Radiological Protection Act, 1991 should be construed as references to the Radiological Protection Act, 1991, as amended. Sections of the 1991 Act referred to in this study which were amended by the 1995 and 1998 Acts are identified accordingly.

Before 1991, the Nuclear Energy Act, 1971 [No. 12 of 1971] was the central piece of legislation on nuclear matters, giving major responsibility to the then Minister for Industry and Energy, who was advised and assisted by the then Nuclear Energy Board. Under the Radiological Protection Act, 1991, the then Minister for Public Enterprise had the major ministerial role in relation to nuclear and radiological protection matters. The Radiological Protection Institute of Ireland established under that act, and which replaced the Nuclear Energy Board, is the national expert body responsible for, *inter alia*, advising the Minister and the government on nuclear safety and radiological protection matters and for regulating, in particular through advance licensing, the custody, use, manufacture, transportation, disposal etc. of radioactive substances, irradiating apparatus and other sources of ionising radiation.

The Radiological Protection Act, 1991, as amended, sets out the functions of the Radiological Protection Institute of Ireland as well as the functions of the Minister for the Environment, Heritage and Local Government. It also sets out specific responsibilities of other government ministers and the functions of the Food Safety Authority, essentially in regard to the protection of individuals from radiological hazards in food.

The Radiological Protection Act, 1991, as amended, would apply to nuclear installations as well as radioactive substances and irradiating apparatus [Section 2]. However, Section 18(6) of the Electricity Regulation Act, 1999 prohibits the construction of a nuclear power plant in Ireland and there are no nuclear installations in this country at the present time.

The other legislation directly relating to or impinging on nuclear matters and radiological protection is as follows:

Acts:

- Health Act, 1953 [No. 26 of 1953];
- Safety Health & Welfare at Work Act, 1989;
- Dumping at Sea Act, 1996;
- Harbours Act, 1996;
- Electricity Regulation Act, 1999.

Regulations:

- European Communities (Medical Ionising Radiation) Regulations, 1988 [S.I.[1] No. 189 of 1988];
- European Communities (Vocational Training for Drivers of Vehicles Carrying Dangerous Goods) Regulations, 1992 [S.I. No. 204 of 1992];
- European Communities (Supervision and Control of Certain Shipments of Radioactive Waste) Regulations, 1994 [S.I. No. 276 of 1994];
- European Communities (Radiological and Nuclear Medicine Installations) Regulations, 1998 [S.I. No. 250 of 1998];
- European Communities (Minimum Requirements for Vessels Carrying Dangerous or Polluting Goods) (Amendment) Regulations, 1998 [S.I. No. 3 of 1998];
- European Communities (Minimum Requirements for Vessels Carrying Dangerous or Polluting Goods) (Amendment) Regulations, 1999 [S.I. No. 96 of 1999];
- Carriage of Dangerous Goods by Road Regulations, 2001 [S.I. No. 492 of 2001] that include Class 7 material. These regulations implement the ADR Agreement and the Carriage of Dangerous Goods by Road Act, 1998;
- European Communities (Safety Advisors for the Transport of Dangerous Goods by Road and Rail) Regulations, 2001 [S.I. No. 6 of 2001]. These include Class 7 material.

Orders:

- Radiological Protection Act, 1991 (General Control of Fissile Fuels, Radioactive Substances and Irradiating Apparatus) Order, 1993 [S.I. No. 151 of 1993];

1. S.I.: Statutory Instrument.

- Radiological Protection Act, 1991 (Ionising Radiation) Order, 2000 [S.I. No. 125 of 2000].

2. Mining Regime

There are no specific provisions governing uranium mining in Ireland.

3. Radioactive Substances, Nuclear Fuel and Equipment

The Radiological Protection Act, 1991, as amended, provides that the Minister for the Environment, Heritage and Local Government may, after consultation with the ministers concerned, make orders regulating the use of radioactive substances and equipment [Section 30]. At present, the main legislation dealing with these matters is the Radiological Protection Act, 1991 (General Control of Fissile Fuels, Radioactive Substances and Irradiating Apparatus) Order, 1993 [S.I. No. 151 of 1993]. The order provides that the custody, use, manufacture, import, export, distribution, transport or other activity involving fissile fuels, radioactive substances and devices, and irradiating apparatus is permitted only under a licence issued by the Radiological Protection Institute of Ireland. The Institute may attach to any licence under this order any conditions it considers necessary, and may do so either at the time of issue of the licence or later.

Applications for a licence, which must be made to the Institute, must contain the particulars required on the planned activity so as to enable the Institute to assess the application. It may ask for additional information relating to the suitability of the applicant in the safe use and handing of the fuel, substance or device that is the subject of the application.

The Institute may, at its discretion, refuse or revoke a licence if, in its opinion, this is necessary to ensure the protection of persons or property against hazards arising from fissile fuels, radioactive substances, devices, or irradiating apparatus.

Products (except toys, foodstuffs, household products, medicinal products, cosmetics, etc.) whose activity levels do not exceed certain limits as provided by the order, are excluded from the scope of the order.

Section 26 of the Energy (Miscellaneous Provisions) Act, 1991 amends Section 7 of the Radiological Protection Act, 1991 dealing with the general functions of the Radiological Protection Institute of Ireland. It removes the restrictions imposed on the functions of the Institute on the use of ionising radiation for medical purposes.

At the international level, Ireland ratified the 1994 Convention on Nuclear Safety on 11 July 1996.

4. Nuclear Installations

There are no nuclear installations in Ireland.

5. Trade in Nuclear Materials and Equipment

Under the Radiological Protection Act 1991 and the Radiological Protection Act, 1991 (General Control of Fissile Fuels, Radioactive Substances and Irradiating Apparatus) Order, 1993 [S.I. No. 151 of 1993], and in compliance with Ireland's international obligations under the Nuclear Non-proliferation Treaty (NPT), the export and import of nuclear materials are subject to a licence issued by the Radiological Protection Institute of Ireland.

6. Radiation Protection

a) Radiation protection standards

Legislative provisions relating to the protection of workers and the public from radiation are contained in a number of different acts, regulations and orders. The most important of these are the Radiological Protection Act, 1991, as amended, and the following instruments: the European Communities (Medical Ionising Radiation) Regulations, 1988 [S.I. No. 189 of 1988]; the European Communities (Radiological and Nuclear Medicine Installations) Regulations, 1998 [S.I. No. 250 of 1998]; and the Radiological Protection Act, 1991 (Ionising Radiation) Order, 2000 [S.I. No. 125 of 2000]. Other relevant provisions that deal more generally with health and safety are to be found in the Safety, Health and Welfare at Work Act, 1989 and the Health Act, 1953.

The Radiological Protection Act, 1991, as amended, confers extensive powers in relation to the protection of agriculture, livestock, fisheries and water supplies. Under Section 31 of the act, as amended by Section 65 of the Food Safety Authority of Ireland Act, 1998, the Minister for the Environment, Heritage and Local Government may prescribe acceptable levels of radioactivity in respect of animals, fauna, poultry, eggs, crops, fish etc. intended for human consumption or any food. For the purpose of protecting individuals from radioactivity contained in food in circumstances where specified levels of activity are, or are likely to have been exceeded, the Minister for Agriculture and Food, the Minister for Communications, Marine and Natural Resources, the Minister for Health and Children and the Minister for Finance in co-operation with the Food Safety Authority of Ireland are given wide regulation-making powers in respect of the harvesting and movement of crops, slaughter of animals, taking of fish, sale and export of food, and taking and sale of fauna [Section 32, as amended by Section 65 of the Food Safety Authority of Ireland Act]. The responsible ministers are empowered to order the slaughter of animals and destruction of food products where the prescribed levels of activity have been exceeded [Section 32, as amended]. These provisions are designed to protect individuals and the public in general from radiological hazards.

Another element in the legislative framework of protection of the public is the power of the Institute, the Food Safety Authority of Ireland and specified ministers to appoint inspectors [Section 28 of the Radiological Protection Act, 1991, as amended] authorised to obtain information, take samples, enter premises, evacuate land or buildings and take control of any radioactive substance, nuclear device or irradiating apparatus [Section 29].

The European Communities (Medical Ionising Radiation) Regulations 1988, [S.I. No. 189 of 1988] and the European Communities (Radiological and Nuclear Medicine Installations) Regulations, 1998 [S.I. 250 of 1998] give effect to Council Directive 84/466/Euratom of 3 September 1984, laying down basic measures for the radiation protection of persons undergoing medical examination or treatment. The 1998 Regulations establish criteria of acceptability for radiological and nuclear medicine installations. They give effect to the provisions of Council Directive 84/466/Euratom relating to efficiency of such installations and their equipment. The two basic principles expressed by

the 1998 Regulations are that the exposure of a patient to ionising radiation must be medically justified [Regulation 3] and that the dose to the patient must be as low as is reasonably achievable [Regulation 4]. The regulations make it an offence for a person to expose a patient to ionising radiation in the course of medical or dental treatment, unless that person has completed a course of training in radiation protection techniques [Regulations 5, 7 and 10]. Medical and dental practices must meet the requirements under the 1998 Regulations and the 1991 Regulations (referred to above). The 1991 Regulations require the authorisation of the Radiological Protection Institute of Ireland before a medical or dental practice may begin to expose patients to radiation [Regulation 4(4)], and give the Institute a continuing supervisory role [Regulation 4]. On the other hand, the Medical Council and the Dental Council are given the function, under the 1988 Regulations, of ensuring that practitioners have been adequately trained in radiation protection and techniques [Regulations 5, 6 and 7].

The Radiological Protection Act, 1991 (Ionising Radiation) Order, 2000 [S.I. No. 125 of 2000] replaces both the European Communities (Ionising Radiation) Regulations 1991 [S.I. No. 43 of 1991] and the European Communities (Protection of Outside Workers from Ionising Radiation) Regulations, 1994 [S.I. No. 144 of 1994]. It gives effect to Council Directive 96/29/Euratom of 13 May 1996, laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation, and Council Directive 90/641/Euratom of 4 December 1990, on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas. The order applies to all practices which involve a risk from ionising radiation emanating from an artificial source or from a natural radiation source, in cases where natural radionuclides are being, or have been, processed in view of their radioactive, fissile or fertile properties.

General occupational health and safety provisions are to be found in the Safety, Health and Welfare at Work Act, 1989. The act covers all aspects of health and safety at work, including nuclear hazards. It establishes the Health and Safety Authority (HSA). Employers are required to identify and assess risks in the workplace and to establish consultation mechanisms between employers and employees.

The European Communities (Drinking Water) Regulations, 2000 [S.I. No. 439 of 2000] came into operation on 1 January 2004. The regulations give effect to provisions of EU Council Directive 98/83/EC on the quality of water intended for human consumption, and prescribe quality standards to be applied in relation to certain supplies of drinking water. This instrument stipulates that the radiation dose arising from one year's consumption of drinking water should not exceed 0.1 mSv. It further stipulates that the dose calculation should include contributions from all natural and artificial radionuclides with the exception of tritium, potassium-40, radon and radon decay products.

The European Communities (Foodstuffs Treated with Ionising Radiation) Regulations, 2000 [S.I. No. 297 of 20 September 2000] implement Directive 1999/2/EC on the approximation of the laws of Member States concerning foods and food ingredients treated with ionising radiation, and Directive 1999/3/EC on the establishment of a Community list of foods and food ingredients treated with ionising radiation, both adopted by the European Parliament and the Council on 22 February 1999. The regulations should be read together with these Directives.

The regulations lay down general provisions for the treatment of food with ionising radiation. Any person proposing to carry on the business of irradiating food is required, in particular, to obtain both a licence from the Radiological Protection Institute of Ireland as well as a permit from the Food Safety Authority of Ireland. These bodies may attach any conditions which they deem appropriate to the licence or permit, which is issued for a period up to three years.

The regulations also provide for the appointment of an authorised officer or inspector whose mission is to carry out examinations, tests, inspections and checks of the irradiation facility premises, any food, article or substance used in food irradiation, and any equipment, machinery or plant at the premises. The regulations refer to a positive list of foods authorised for treatment with ionising radiation and their maximum radiation doses, which are contained in Directive 1999/3/EC.

b) Emergency response

At the international level, Ireland ratified both the 1986 Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency and the 1986 Convention on Early Notification of a Nuclear Accident on 13 September 1991. One of the purposes of the Radiological Protection Act, 1991, as amended, is to give effect to the provisions of these two Conventions. The Radiological Protection Institute of Ireland is statutorily responsible under Section 7 of the 1991 Act for assisting in radiological emergency planning and for the implementation of measures to deal with such emergencies. The Institute is also responsible for giving assistance to and co-operating with other states in the event of a radiological emergency. The 1991 Act, as amended, also gives specific powers to inspectors in the event of any suspected radiological hazard [Section 29(2)], and extensive powers to ministers to order the slaughter of animals, destruction of crops, etc., or other food and disposal of the remains, when specified levels of radioactivity have been exceeded [Section 33, as amended by Section 65 of the Food Safety Authority of Ireland Act 1998].

A person who is licensed by the Institute under the 1991 Act, as amended, to deal with radioactive material is obliged under Section 34 of the act to notify the Institute of any accident, loss or theft of any such material.

7. Radioactive Waste Management

One of the general functions of the Radiological Protection Institute of Ireland is to advise the government on radiological safety matters, including the disposal of radioactive substances [Radiological Protection Act, 1991 Section 7(1)(d)]. More specifically, the Minister for the Environment, Heritage and Local Government has the power, after consultation with the various ministers concerned to make an order regulating the disposal of radioactive substances [Section 30(1)]. The order may prohibit disposal, save under licence issued by the Institute.

The Radiological Protection Act, 1991 (General Control of Fissile Fuels, Radioactive Substances and Irradiating Apparatus) Order, 1993 [S.I. No. 151 of 1993], which repealed and replaced the Nuclear Energy (General Control of Fissile Fuels, Radioactive Substances and Irradiating Apparatus) Order 1977, provides that activities involving radioactive waste products, including transport, may not be carried out without a licence from the Institute. The licence, which may be subject to conditions, is issued for a limited period and may be revoked by the Institute when the conditions of the licence are not being met.

The European Communities (Supervision and Control of Certain Shipments of Radioactive Waste) Regulations, 1994 [S.I. No. 276 of 1994] provide for the implementation of Council Directive 92/3/Euratom of 3 February 1992 on the supervision and control of shipments of radioactive waste between Member States and into and out of the Community, whenever quantities and concentrations of such waste exceed certain levels. The provisions of these regulations governing such shipments supplement the existing Council Directives on basic safety standards for the health protection of workers and the general public against the dangers of ionising radiation.

The Dumping at Sea Act 1996 enforces strict limitations on the types of substances that can be dumped at sea, with an express prohibition against the disposal of radioactive substances or materials irrespective of their activity level. The act also extends the limit of Ireland's control from 12 miles up to 200 miles off the Irish coast and in some areas up to 350 miles off the Irish coast.

In this respect, it is relevant to note that Ireland ratified the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter on 17 February 1982.

Ireland also ratified the 1997 Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management on 20 March 2001. Ireland, being the 25th Signatory State to ratify the Joint Convention, triggered the entry into force of the Convention, which took place 90 days thereafter on 18 June 2001.

8. Non-Proliferation and Physical Protection

Ireland ratified the 1968 Treaty on the Non-Proliferation of Nuclear Weapons on 1 July 1968 and the Comprehensive Nuclear Test Ban Treaty on 15 July 1999. It also ratified the 1979 Convention on the Physical Protection of Nuclear Material on 6 September 1991.

9. Transport

The transport of radioactive materials in Ireland is prohibited, save under licence of the Radiological Protection Institute of Ireland [Radiological Protection Act, 1991, Section 30]. The instrument setting out the current system of regulation is the Radiological Protection Act 1991 (General Control of Fissile Fuels, Radioactive Substances and Irradiating Apparatus) Order, 1993 [S.I. No. 151 of 1993]. The order provides that the transport of fissile fuel and other radioactive materials, including their import and export, can only be undertaken with a licence issued by the Radiological Protection Institute of Ireland. The licence may be made subject to whatever conditions the Institute considers necessary. These licence conditions specify general safety measures that must be observed by the licensee and require in particular that the radioactive material be shielded, packaged and transported in accordance with the International Atomic Energy Agency's Regulations for the Safe Transport of Radioactive Material.

Ireland has ratified the International Convention concerning the Carriage of Goods by Rail (CIM) and the licence granted by the Radiological Protection Institute of Ireland will, where appropriate, specify that the provisions of the International Regulations concerning the Carriage of Dangerous Goods by Rail (RID) which form Annex I of the Convention, be respected.

The maritime carriage of radioactive materials is undertaken in accordance with the Merchant Shipping (Dangerous Goods) Rules, 1992 [S.I. No. 391 of 1992] which was made under the Merchant Shipping (Safety Convention) Act, 1952 [No. 29 of 1952] and the European Communities (Minimum Requirements for Vessels Carrying Dangerous or Polluting Goods) Regulations, 1995 [S.I. No. 229 of 1995], as amended by the European Communities (Minimum Requirements for Vessels Carrying Dangerous or Polluting Goods) Regulations, 1995 (Amendment) Regulations 1998 [S.I. No. 3 of 1998] and by the European Communities (Minimum Requirements for Vessels Carrying Dangerous or Polluting Goods) Regulations, 1995 (Amendment) Regulations 1998 [S.I. No. 394 of 1998] and by the European Communities (Minimum Requirements for Vessels Carrying Dangerous or Polluting Goods) (Amendment) Regulations, 1999 [S.I. No. 96 of 1999] made under the European Communities Act, 1972 [No. 27 of 1972]. Observance of the International Maritime Dangerous Goods Code of the

International Maritime Organisation (IMO) is normally required in compliance with the obligations imposed by the Irish rules.

In Ireland, the domestic and international transport of radioactive materials by air is regulated by the Air Navigation (Carriage of Munitions of War, Weapons and Dangerous Goods) Orders, 1973 and 1989 [S.I. Nos. 224 of 1973 and 130 of 1989].

10. Nuclear Third Party Liability

There are no specific provisions in Irish legislation governing nuclear third party liability. Furthermore, Ireland is not a party to any of the international conventions relating to nuclear liability.

II. INSTITUTIONAL FRAMEWORK

In Ireland, responsibility for nuclear and radiological protection matters is shared among several ministers but rests mainly with the Minister for the Environment, Heritage and Local Government. Under the supervisory authority of the Minister, the Radiological Protection Institute of Ireland advises the government on radiological safety; administers a licensing system in respect of radioactive substances, irradiating apparatus and other sources of ionising radiation; monitors levels of radiation; carries out research; develops emergency plans and provides information to the public.

1. Regulatory and Supervisory Authorities

a) Minister for the Environment, Heritage and Local Government

The Minister for the Environment, Heritage and Local Government exercises general responsibility for nuclear and radiological protection matters, while other ministers have specific responsibilities over certain aspects of these. The Radiological Protection Institute of Ireland is accountable to the above Minister. It is obliged to make an annual report to the Minister, who in turn is required to lay it before parliament [Radiological Protection Act, 1991, Section 17].

The Minister's power to regulate, restrict or prohibit (save under licence issued by the Institute) any activity relating to radioactive substances is also exercised by means of orders made under the 1991 Act after consultation with the ministers concerned and the Institute [Section 30(1)]. The Order [S.I. No. 151 of 1993], referred to earlier, which sets up a system regulating the use, transport, storage, disposal etc. of fissile fuels and other radioactive substances or devices, is an example of the exercise of this ministerial power.

The Minister is also empowered under Section 30(2) of the 1991 Act to give effect to European Union decisions relating to the protection of workers and the general public from ionising radiation; again, the mechanism is a ministerial order made after consultation with other ministers. It is also the Minister for the Environment, Heritage and Local Government's responsibility to specify the permitted levels of activity in respect of animals, crops, water supplies, etc. intended for human

consumption [Section 31, as amended by Section 65 of the Food Safety Authority of Ireland Act, 1998]. These levels are prescribed by regulations made by the Minister after consultation with the Ministers for Agriculture and Food; Finance; Health and Children; Communications, Marine and Natural Resources; the Institute and the Food Safety Authority of Ireland.

b) Minister for Agriculture and Food

If there is a risk that prescribed levels of radioactivity have been exceeded, the Minister for Agriculture and Food may make regulations to control agricultural activities in a particular area [Radiological Protection Act, 1991, Section 32(1)(a) and (b), as amended]. The Minister can regulate the movement of animals, crops, food etc. into or out of the area, the harvesting of crops, the slaughter of animals and the sale, importation or exportation of animals, crops, food etc. The purpose of these powers is to protect the general public from levels of activity in food that exceed those specified. The Minister must, before making the regulations, consult with the Ministers for the Environment, Heritage and Local Government; for Health and Children; for Finance; the Institute and the Food Safety Authority of Ireland. Where animals have been affected by excessive levels of activity, the Minister may order the slaughter and disposal of these animals [Section 33(1), as amended]. Similarly, where crops or food have been affected, the Minister may order their destruction and disposal [Section 33(2), as amended].

The Minister also has the power, in the event of a radiological emergency, to compulsorily acquire animals, crops, food and water resources etc. [Section 32(2)]. This can only be done after consultation with the Minister for the Environment, Heritage and Local Government, the Institute and the Food Safety Authority of Ireland.

c) Minister for Communications, Marine and Natural Resources

The Minister for Communications, Marine and Natural Resources has the power to regulate fishing and aquaculture activities in an area where levels of activity, prescribed by regulations made under Section 31(1) of the Radiological Protection Act, 1991, as amended may have been exceeded [Radiological Protection Act, 1991, Section 32(1)(c) and (d), as amended]. The Minister must, before making the regulations, consult with the Ministers for the Environment, Heritage and Local Government; Health and Children; the Institute; and the Food Safety Authority of Ireland. Where fish, fishery products or seaweed have been affected by excessive levels of activity, the Minister for Communications, Marine and Natural Resources may order their destruction and disposal [Section 33(3), as amended by Section 65 of the Food Safety Authority of Ireland Act, 1998].

The Minister also has the power, in the event of a radiological emergency, to compulsorily acquire fish, seaweed or fishery products [Section 32(2), as amended by Section 65 of the Food Safety Authority of Ireland Act, 1998]. This can only be done after consultation with the Minister for the Environment, Heritage and Local Government; the Institute; and the Food Safety Authority of Ireland.

The Harbours Act, 1996 prescribes detailed provisions in relation to safety of navigation and security in harbours and provides broad statutory powers for harbour masters to give directions to ships masters including the prevention of ships navigating for safety reasons. Section 52(2) of the act specifically enjoins harbour masters from permitting entry of radioactive material (within the meaning of the IMO's International Maritime Dangerous Goods Code) without the consent of the Radiological Protection Institute of Ireland. In addition, Section 52(3) of the act specifically prohibits ships,

vehicles or conveyances which are nuclear powered or carrying nuclear weapons or nuclear material from entering a harbour unless a statutory exemption is granted or a ship is in distress.

d) Minister for Finance

Where prescribed levels of radioactivity may have been exceeded, the Minister for Finance can make regulations in relation to wildlife fauna, in order to protect the general public. Before doing so, the Minister must consult with the Ministers for the Environment, Heritage and Local Government; Health and Children; Agriculture and Food; the Institute; and the Food Safety Authority of Ireland [Radiological Protection Act, 1991, Section 32(1)(e), as amended]. The Minister for Finance can also order the destruction and disposal of any wildlife fauna affected by excessive levels of activity [Section 33(4), as amended].

e) Minister for Health and Children

Where prescribed levels of radioactivity may have been exceeded, the Minister for Health and Children may make regulations, as prescribed by European Union Directives, controlling the importation or exportation of any food into or out of Ireland. Before making such regulations, the Minister must consult with the Ministers for the Environment, Heritage and Local Government; Agriculture and Food; the Institute; and the Food Safety Authority of Ireland [Radiological Protection Act, 1991, Section 32(1)(f), as amended].

The Minister for Health and Children also has certain powers in relation to the medical use of radioactive substances and irradiating apparatus. The Minister is empowered to make regulations, as prescribed by European Union Directives, to prevent hazards to the health of persons using such substances or apparatus, and may also prohibit dealings with them except in accordance with specified conditions or the granting of a licence [Act No. 26 of 1953, Section 59].

f) Minister for Defence

It is the policy in Ireland that government departments and agencies take the lead role in planning for emergencies in the areas for which each has statutory responsibility. The responsibility for the co-ordination and oversight of government peacetime planning was conferred on the Minister for Defence by a government Decision [S180/46/01/0002] dated 2 October 2002, establishing an Office of Emergency Planning at the Department of Defence.

The role of this Office of Emergency Planning is prescribed by this government decision, which states that the Office will:

- take the lead role in emergency planning to meet the new threat from international terrorism and from any escalation in international tensions, including co-ordination of the responses by the various agencies involved; and

- exercise an oversight role in relation to peacetime planning in order to ensure the best possible use of resources and compatibility between different planning requirements.

The Minister for Defence also convenes and chairs the Government Task Force on Emergency Planning, established in October 2001, and is supported in this role by the Office of Emergency

Planning. The Office of Emergency Planning also convenes and chairs an Interdepartmental Working Group on Emergency Planning.

Government departments and agencies with responsibilities for emergency planning, including those responsible for nuclear safety and related nuclear emergency planning issues, report to the Minister for Defence at meetings of the Government Task Force on Emergency Planning. However, such government departments and agencies continue to be responsible to their Ministers for policy direction. The Minister Defence reports to the government on such emergency planning matters.

2. Public and Semi-Public Agencies

a) Radiological Protection Institute of Ireland

i) Legal Status

This Institute was established under the Radiological Protection Act, 1991, and replaced the Nuclear Energy Board which was dissolved by the act [Section 21]. All assets and liabilities of the Nuclear Energy Board were transferred to the new Institute [Section 22]. References to the Board in legislation predating the establishment of the Institute are to be read as references to the Institute [Section 21]. The Institute, like the Board, is a body corporate capable of suing and being sued in its corporate name, and able to acquire, hold and dispose of land and other property [1991 Act, Schedule 1, Item 1].

ii) Responsibilities

The Institute's functions are set out in the Radiological Protection Act, 1991, as amended. The Minister for the Environment, Heritage and Local Government may, by order, confer additional functions on the Institute following consultation with other ministers specified in Section 9 of the 1991 Act.

The Institute's responsibilities fall into the following categories:

- monitoring activity and ionising radiation [Section 7(1)(a) and (b)];
- advising the government on radiological safety matters and on the relevant international standards [Section 7(1)(d) and (f)];
- monitoring any scientific, technological, economic or other development relating to nuclear activity and keeping the government informed of such developments [Section 7(1)(h)];
- carrying out or co-ordinating research [Section 7(1)(j)]; and
- assisting in planning and implementation of measures to deal with radiological emergencies [Section 7(1)(e) and (i)], and giving information to the public on radiological safety [Section 7(i)(k)].

The act also specifies various specific functions for the Institute which make the Institute the main point of contact for Ireland in the international context. The Institute is responsible for

exchanging information and co-operating with its counterparts in other states, and for giving assistance to other states in the event of a radiological emergency [Section 8(a)-(e)]. It is also charged with collecting and disseminating information relevant to nuclear activities [Section 8(e)] and with advising the government on representation of the state on international bodies dealing in nuclear energy [Section 8(m)].

The Institute is the national competent authority for the purposes of the Convention on Early Notification and the Convention on Assistance in the Case of a Nuclear Accident, and is the central national authority responsible for the physical protection of nuclear material [Section 27].

The Institute is the licensing authority in relation to fissile fuel and other radioactive substances [S.I. No. 151 of 1993]. It is also responsible for the appointment of inspectors under the act [Section 28(1)].

iii) Structure

The members of the Institute are appointed by the Minister for the Environment, Heritage and Local Government with the consent of the Minister for Finance. The Minister may appoint up to twelve members, including the chairperson, and must appoint at least seven [1991 Act, Schedule 1, Item 2]. Each member's term of office is determined by the Minister upon appointment, but is not to exceed five years [Schedule 1, Item 9].

In addition to the members, the Institute has a full-time Chief Executive Officer and staff [1991 Act, Sections 11 and 12]. It also has the power to establish committees, consisting of members of the Institute and others, to assist and advise it in relation to its functions; however, any action of a committee is subject to confirmation by the Institute [1991 Act, Section 18].

iv) Financing

The Minister for the Environment, Heritage and Local Government may advance amounts of money, from sums provided by parliament (the *Oireachtas*), to the Institute for the purposes of its expenditure in performing its functions [1991 Act, Section 15]. In addition, the Institute may accept remuneration in return for services and facilities provided by it [Section 19(1)]. It may also accept donations, but only with the consent of the Minister for the Environment, Heritage and Local Government and the Minister for Finance [Section 19(2)].

The Institute is required to keep accounts, have them audited, and submit them to the Minister for the Environment, Heritage and Local Government. The Minister is required to lay copies of the Institute's Annual Report and Accounts before each House of Parliament [Section 16].

b) Food Safety Authority of Ireland

This Authority was established under the Food Safety Authority of Ireland Act, 1998 [S.I. No. 29 of 1998].

The principal function of the Authority is to ensure that food produced in Ireland and food distributed or marketed in Ireland meets the highest standards of food safety and hygiene reasonably achievable and complies with food legislation in respect of food safety and hygiene standards.

With regard to radioactivity in food, it is a function of the Authority to ensure that such food complies with the Radiological Protection Act, 1991 (General Control of Radioactive Substances, Nuclear Devices and Irradiating Apparatus), Order, 1993 [S.I. No. 151 of 1993]. Furthermore, Section 65 of the Food Safety Authority of Ireland Act, 1998 which amends certain sections of the Radiological Protection Act, 1991, specifies the role of the Authority in regard to the protection of individuals from levels of radioactivity in animals, fauna, poultry, eggs, crops, animal carcasses, feeding stuffs, fish, seaweed, bottled water or water supplied intended for human consumption or any food, where specified levels of radioactivity have been or are likely to be exceeded.

MEXICO

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I. GENERAL REGULATORY REGIME

1. Introduction

Mexico (the United Mexican States) currently has one nuclear power plant, *Laguna Verde*, located on the Gulf of Mexico. It consists of two boiling water reactors, with respectively a capacity of 650 and 700 MWe. The first unit has been operating since 1990 and the second since 1995. In 2002, these reactors produced 9.7 TWh of electricity, accounting for 5.5% of Mexico's total electricity production. The *Laguna Verde* reactors are owned by the Mexican government and operated by the Federal Electricity Commission (*Comisión Federal de Electricidad*). Operational waste from both *Laguna Verde* units can be stored onsite. In addition to the two commercial reactors, there is a 1 MWe TRIGA MARK III research reactor at the National Nuclear Research Institute (*Instituto Nacional de Investigaciones Nucleares*). Mexico also has uranium resources.

Mexico has a comprehensive body of laws and regulations governing its nuclear activities, the most important of which are described in the following paragraphs.

The Political Constitution of the United Mexican States provides, in relation to nuclear activities, that the development of strategic areas will be the exclusive responsibility of the public sector, and that the federal government will always maintain ownership and control over public bodies created for that purpose. The Constitution of Mexico provides that matters related to radioactive ores and nuclear power generation are within the scope of strategic areas [Sections 25 and 28].

The 1984 Act on Nuclear Activities, adopted pursuant to Article 27 of the Constitution (hereinafter referred to as the 1984 Act), was promulgated on 27 December 1984 and entered into force on 5 February 1985 [published in the Official Gazette (*Diario Oficial de la Federación*) on 4 February 1985]. It regulates all nuclear activities in Mexico and repeals and replaces a similar Act of 1978, also adopted pursuant to Article 27 of the Constitution.

The 1984 Act specifies that nuclear energy will be used solely for peaceful purposes, and that the federal government will establish regulations governing the use of radioactive materials [Section 2 – all references are to the 1984 Act unless otherwise specified]. The act regulates prospecting for and mining of radioactive ores, the use of nuclear fuels, research in nuclear science and technology, the nuclear industry and all related matters [Section 1]. These different aspects of nuclear activities will be dealt with under the appropriate headings below.

2. Mining Regime

With regard to the prospecting for, mining and use of radioactive ores, the Mexican Constitution contains provisions indicating that such ores will not be subject to any concession or contract, and that only the state may carry out such activities in accordance with the relevant law [Article 27 of the

Constitution]. Any person who has knowledge of a radioactive ore deposit must immediately notify the Ministry of Energy [Section 6 of the 1984 Act]. Any person with a mining concession who discovers radioactive ores on his land must inform the Ministry by written notification within ten days of this discovery in particular so that the property rights of the state are protected and assessment of the ores can be undertaken [Section 7].

The 1984 Act provides that the Ministry of Energy delegates exclusive responsibility for prospecting activities to a decentralised public body, the Mineral Resources Board (*Consejo de Recursos Minerales*). The Ministry determines the Board's programme of activities and technical conditions governing its work [Section 9]. The 1984 Act further specifies that the Ministry delegates exploration rights for radioactive ores to another decentralised public body, the Commission for Mining Development (*Comisión de Fomento Minero*) in accordance with the policies established for the achievement of the objectives or priorities of the national programme. This Commission was permitted to set up and operate plants for the use of such ores [Section 10], however it has since been dissolved by the Mining Act of 26 June 1992, which assigned all its activities to the Mineral Resources Board [Section 5 Provisional].

3. Radioactive Substances, Nuclear Fuel and Equipment

The regulatory regime governing radioactive substances, nuclear fuel and equipment is laid down in Chapter III of the 1984 Act under "Nuclear Industry". This definition includes, *inter alia*, the various stages of the fuel cycle, including uranium enrichment, fuel reprocessing, heavy water production, design and manufacture of nuclear equipment and components for steam supply systems in nuclear power plants, production and applications of radioisotopes. The nuclear industry is specified as being in the public interest [Section 11].

The 1984 Act provides that the production, use and application of radioisotopes are priority activities for the development of the national economy [Section 16]. These activities must be carried out within the context of programmes approved by the federal government, acting through the Ministry of Energy, in accordance with the research and technical development policy established by the federal government [Sections 12 and 18].

Radioactive materials and equipment used for medical purposes require a prior licence from the Ministry of Health in addition to the licence issued by the National Nuclear Safety and Safeguards Commission (*Comisión Nacional de Seguridad Nuclear y Salvaguardias*) [Section 29].

The production, use and application of radioisotopes may be undertaken by the public sector, in particular by the social services, on its own or in conjunction with the private sector; both require prior licensing from the Ministry of Energy. Licences for the production of radioisotopes based on the use of nuclear fuel are issued after hearing the opinion of the National Nuclear Research Institute (*Instituto Nacional de Investigaciones Nucleares*) and other competent authorities, depending on whether they are to be used for medical, industrial or agricultural purposes [Section 16].

The production of radioisotopes from nuclear reactors, on the other hand, may only be undertaken by public bodies, universities, institutes and research centres, licensed in accordance with the 1984 Act; such licences are granted by the Ministry of Energy. The Ministry also grants licences for the production of radioisotopes from nuclear fuels and publishes notification thereof in the Official Gazette [Section 16].

The possession, import, export, use, transfer, transport, storage and disposal of radioactive materials or ionising radiation-emitting equipment is prohibited without a licence of the National Nuclear Safety and Safeguards Commission [General Radiological Safety Regulations, Sections 189 and 190].

Nuclear fuels are the property of the state; only the federal government may authorise their use, in accordance with the provisions of the 1984 Act and under the control of the National Nuclear Safety and Safeguards Commission [Section 17].

4. Nuclear Installations

The 1984 Act makes a distinction between "nuclear" installations and "radioactive" installations [Section 3]. "Nuclear installations" are defined as those in which nuclear fuel is manufactured, processed, used, reprocessed or stored, while "radioactive installations" are those in which radioactive material or equipment containing such material is produced, manufactured, stored or used, or in which radioactive waste is treated, conditioned or stored.

Nuclear electricity generation falls under the sole jurisdiction of the Federal Electricity Commission (*Comisión Federal de Electricidad*) which is responsible for the design and construction of nuclear power plants, having regard to the opinion of the National Nuclear Research Institute [Section 15].

The use of nuclear reactors for purposes other than electricity generation is restricted to public bodies, universities, institutes and research centres, licensed in accordance with this act [Section 16].

a) Licensing and inspection, including nuclear safety

The siting, design, construction, operation, modification, shutdown, decommissioning and dismantling of nuclear and radioactive installations requires a licence granted by the Ministry of Energy. Licences for the construction and operation of such installations are valid for a limited period, and their renewal, modification, suspension or cancellation are regulated by the provisions of the relevant regulations [Section 26]. Nuclear and radioactive installations must meet the siting, design and construction, etc. requirements established under the act [Section 25].

Mexico ratified the 1994 Convention on Nuclear Safety on 26 July 1996.

i) Nuclear installations

Licences for the construction and operation of a nuclear installation are granted only following approval of the information submitted on the manner in which the safety objectives will be met and on the procedures and methods to be applied for the siting, design, construction, operation, modification, decommissioning and final shutdown of the installation. For each stage, the information necessary to assess environmental impact must be provided to the National Nuclear Safety and Safeguards Commission. The corresponding emergency plan must also be submitted. This information must be provided in accordance with the conditions laid down by the provisions of the 1984 Act [Section 28].

Under Mexican legislation, two environmental impact assessments are required for nuclear installations: the first considers the environmental impacts from their radiological, nuclear and

physical safety points of view, and the second covers all other aspects. The latter assessment is carried out under authority of the Ministry of the Environment and Natural Resources [General Act on Ecological Equilibrium and Environmental Protection, Section 154].

ii) Radioactive installations

The conditions for the licensing of radioactive installations are laid down by the General Radiological Safety Regulations of 22 November 1988. The National Nuclear Safety and Safeguards Commission, under the Ministry of Energy, is the licensing authority for such installations [Section 219]. The Commission issues, renews, revokes and suspends permits or licences [Section 50-V of the 1984 Act on Nuclear Activities].

Applications for licences for the construction, operation, modification, shutdown or decommissioning of radioactive installations require different procedures; all must provide information on the radiological safety of the installation concerned [Section 219].

Applicants for a licence to construct a radioactive installation must, in particular, provide the following information to the Commission [Section 220]:

- description of the radiological safety characteristics to be applied in the design of the installation, and the methods for controlling the processes and materials used;
- proposed activities;
- siting; and
- quality assurance programme.

Applicants for a licence to operate a radioactive installation must in particular provide the following information with respect to radiological protection [Section 221]:

- general specifications of the installation;
- organisational measures implemented by the applicant;
- radiological safety policy and quality assurance programme;
- type of ionising radiation sources;
- environmental impact assessment;
- risk analysis and emergency plan; and
- procedures for decommissioning, dismantling and final shutdown.

Applications for a licence to modify a radioactive installation must include information on the reasons for the request and the radiological safety implications of the modifications to be made [Section 222].

Finally, applications for a licence to decommission, dismantle or finally shut-down an installation must include a detailed report with information on the decommissioning and dismantling programme in the context of radiological safety operations; if there is radioactive waste, a report on the procedures for its processing, conditioning and final disposal; and documentation ascertaining that the radiological safety conditions comply with those stated in the operating licence [Sections 223 and 224].

iii) Inspections

The National Nuclear Safety and Safeguards Commission is responsible for inspecting and monitoring nuclear and radioactive installations to ensure compliance with radiological safety conditions, to account for radioactive materials and for safeguards purposes [Section 32].

Such inspections take place at the request of interested parties, or as frequently as the Commission deems necessary [1998 General Radiological Safety Regulations, Section 235].

b) Protection of the environment against radiation effects

As already mentioned, the 1984 Act on Nuclear Activities and the 1988 General Radiological Safety Regulations provide for an environmental impact assessment in the licensing procedure for nuclear and radioactive installations [Sections 28 and 221, respectively].

In addition, Section 154 of the General Act on Ecological Equilibrium and Environmental Protection of 1988 (which entered into force on 1 March 1988) applies to nuclear activities. The act provides that the Ministry of Energy together with the National Nuclear Safety and Safeguards Commission, and where relevant, the Ministry of Health, must ensure that all such activities are carried out in accordance with the nuclear safety and radiological protection regulations in force for nuclear and radioactive installations, so as to avoid any risk to human health and preserve the ecological equilibrium. The Ministry of the Environment and Natural Resources is the authority responsible for environmental impact assessments.

Nuclear activities referred to in the 1988 Ecological Equilibrium Act include prospecting for and mining of radioactive ores, nuclear fuel supply, all uses of nuclear energy and the nuclear industry in general. In addition, the Environmental Impact Regulations of 7 June 1988 were issued in implementation of the 1988 Ecological Equilibrium Act and entered into force on 8 June 1988. They contain detailed provisions on the subject and require, *inter alia*, risk studies, preventive and mitigating measures [Sections 3 and 5].

c) Emergency response

Both the 1984 Act and the 1988 General Radiological Safety Regulations specify that applications for licences for nuclear and radioactive installations must include emergency plans.

In the event of imminent danger or risk for the personnel of a nuclear or radioactive installation or for the population in general, the National Nuclear Safety and Safeguards Commission will order, or carry out, as the case may be, the removal, seizure and safe-keeping of ionising radiation sources or equipment containing such sources. The Commission may also order, as a preventive measure, the temporary or permanent shutdown of nuclear or radioactive installations and specify the relevant corrective measures. It may keep the installation permanently shut-down in case the measures taken are inadequate [Section 34].

Any person who has knowledge of an incident involving nuclear or radioactive materials or equipment containing such materials must immediately inform the Commission. Natural or legal persons licensed to carry out the activities regulated by the 1984 Act must inform the Commission immediately of such an incident, and then confirm in writing within 24 hours [Section 23].

The 1988 General Radiological Safety Regulations provide that before start-up of a radioactive installation, the operator must have established an emergency plan in accordance with the conditions of the National Civil Protection System and based on a study of the radiological consequences of any accident that might occur in the installation [Section 124]. The purpose of the plan is to restrict exposure to ionising radiation to a level as low as reasonably achievable (the ALARA principle), control any accident that may occur and obtain all the information required to determine the causes and consequences of such an accident. Pursuant to Section 125 it should include as a minimum:

- equipment processes for the radiological measures required to assess and determine the situation created by the accident;
- protection measures needed to reduce exposure to ionising radiation;
- intervention levels to serve as Standards for the application of the above measures;
- protection measures for the neighbouring population, in accordance with the National Civil Protection System.

The head of the radiological protection group of an installation, the occupationally exposed personnel or the licensee must also immediately report a radiological incident to the National Nuclear Safety and Safeguards Commission [Section 175].

All emergency plans should be carried out in accordance with the National Civil Protection System [Section 124]. As regards the *Laguna Verde* nuclear power plant, the External Radiological Emergency Plan (*Plan de Emergencias Radiológico Externo* – PERE) provides for the participation of the federal, local and municipal authorities and specifies their responsibilities. Like all emergency plans, it is co-ordinated by the Ministry of the Interior, which is the competent authority for the National Civil Protection System.

Furthermore, at the international level, Mexico has been a Party to the 1986 Convention on Early Notification of a Nuclear Accident, and the 1986 Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency since 10 May 1988.

5. Trade in Nuclear Materials and Equipment

The federal government, through the Ministry of Energy and in co-operation with other competent authorities, is the authority responsible for controlling the import and export of nuclear materials and fuels. Radioactive ores or material will be exported having regard to national needs, and will in no case exceed five percent of known resources, in accordance with the National Development Programme provided for in Article 26 of the Political Constitution of the United Mexican States [Section 18-V]. For the purposes of security, registration and control, the National Nuclear Safety and Safeguards Commission provides an expert opinion and final authorisation prior to the licensing of imports and exports of radioactive materials, equipment containing such material, and nuclear materials and fuels [Section 50-IX].

Applicants for a licence to import ionising radiation sources must, in particular, submit to the Commission, the following information: the number of their operating permit or licence, the activity level of the radioisotopes, their physical and chemical form, the specifications of the equipment containing the radioactive material, the type of packaging and a physical protection and radiological safety plan [1988 General Radiological Safety Regulations, Section 192]. The same procedure applies for exports of ionising radiation sources [Section 195].

A Decree of 27 December 1995, which entered into force on 1 January 1996, sets out the list of goods which require import and export licences. It provides for controls over the import and export of nuclear and radioactive materials including nuclear fuel, radioisotopes, radioactive waste and ionising radiation-emitting equipment. The scope of the decree also applies to materials used for medical purposes. Pursuant to the decree, all export and imports into Mexican territory, on a temporary or permanent basis, require a licence issued in advance by the Ministry of Energy through the National Nuclear Safety and Safeguards Commission [Sections 1 and 2]. The licence is to be presented by the applicant before any import or export of the listed material [Section 3].

The health authority also requires a health permit prior to the import or export of ionising radiation sources for medical purposes [1988 General Health Act, as amended in 1991, Section 125].

6. Radiation Protection

The regulations governing radiation protection in Mexico were adopted in implementation of the 1984 Act and the 1988 General Radiological Safety Regulations. Official Standards on Radiological Safety were issued by the Ministry of Health in 1993, and Official Standards on Safety at Workplaces involving ionising radiation sources were issued by the Ministry of Labour and Social Security the same year.

The 1984 Act provides that natural or legal persons authorised to operate nuclear or radioactive installations are directly responsible for radiation safety, and must arrange for the retention of the necessary personnel who will be responsible for providing advisory assistance, training, evaluating working procedures, monitoring and preparing safety manuals in all matters related to radiation protection in the workplace [Section 27].

Since June 1996, a federal agreement between the Ministry of Energy, the Ministry of Health and the National Nuclear Safety and Safeguards Commission, has established that the Ministry of Health is responsible for the evaluation, licensing, importation, exportation, checks, audits, verifications and inspections, etc. of X-ray equipment used for medical diagnosis.

The 1988 General Radiological Safety Regulations are the most important in this series of regulations covering all aspects of radiation protection, and the National Nuclear Safety and Safeguards Commission, under the control of the Ministry of Energy, is the competent authority in this respect [Section 4].

The regulations set out the dose limitation regime, specifying that the authorised limits are those set by the Commission on dose equivalent limits and exposure conditions, and on the measures to be taken for planned or emergency exposures [Title III].

The regulations provide, *inter alia*, that ionising radiation sources, sealed or unsealed, as well as ionising radiation-emitting equipment, must be equipped with a safety system. The licensees may only modify the design or operating conditions of these sources or equipment with prior approval of the Commission [Sections 56 and 57], and they cannot be transferred without a licence or authorisation from the Commission [Section 58]. As regards the use of X-ray equipment for medical diagnosis, the technical standards to be complied with are laid down by the Ministry, through the Commission [Section 91]. Nevertheless, radiation protection regulations relating to the use of ionising radiation sources exclusively for medical purposes are also within the competence of the Ministry of Health [General Health Act, 1991, Sections 124 and 125].

A Decree of 15 April 1997 amended the provisions of the General Health Act [Official Gazette of 7 May 1997] in relation to the use of toxic and dangerous medications. In particular, Section 125 of the act now provides that in the case of radioactive sources for medical or diagnostic use, the Ministry of Health will issue the necessary licences in co-ordination with the National Nuclear Safety and Safeguards Commission.

The 1988 Regulations lay down the obligations of licensees and radiation personnel. In particular, all licensees, as already specified in the 1984 Act, must establish a radiological protection group in their installations, responsible for implementation and surveillance of all radiation protection measures in the workplace [Section 145].

All occupationally-exposed personnel must have received appropriate training for their particular work and the relevant authorisation by the Commission. They must have knowledge of and apply the basic radiation protection principles and the instructions in the installation's radiological safety manual and emergency plan [Sections 159-IV and 160-I, V and XIII].

The regulations also provide for preventive measures in the event of an ionising radiation hazard and specify in this respect that the Commission may order the temporary, partial or total closure of the radioactive installation involved; as regards hazards from ionising radiation sources or ionising radiation-emitting equipment, the Commission may remove them or dispose of them whenever it considers it necessary for safety purposes [Section 182].

Since 1996, the Ministry of Energy, through the National Nuclear Safety and Safeguards Commission, has issued several technical regulations to implement the 1988 General Radiological Safety Regulations. These mandatory provisions are issued as Official Standards and deal, *inter alia*, with the following subjects: determination of dose limits for workers and the general public; classification of radioactive facilities, nuclear materials and radioactive waste; use of radioactive material for medical purposes; packaging and labelling for the transport of radioactive material; requirements for the conditioning, storage and disposal of radioactive waste; use of industrial radiography equipment etc.

The General Health Act, in force since 1 July 1988, and the General Radiological Safety Regulations [Official Gazette of 22 November 1988] made in implementation of the 1984 Act originally applied to all radioactive installations, transport of radioactive materials and waste and radiation sources. Both were modified by a Decree published on 14 June 1992, in force since September 1991. The modification restricts the authority of the Ministry of Health to activities involving radiation sources for medical purposes [Section 198]. The Ministry of Health is the authority responsible for implementing the regulation [Section 4]. The regulation prohibits the operation of an installation where radiation sources or radioactive materials are used or disposed of without a health licence issued by the Ministry of Health. Persons responsible for radiological safety must ensure that patients undergoing treatment are adequately protected, in accordance with the Ministry of Health's Standards for such establishments [Section 103].

A licence from the health authorities is still required for the possession, import and export of, trade in, transport and use of ionising radiation sources for medical uses [Section 125].

On 11 October 1994, the Ministry of Health issued the Official Standards No. NOM-002-SSA-2-1993, which repeal the Standards issued on 2 February 1988, for the organisation, operation and health engineering of radiotherapy services. They set out revised general rules which apply to personnel using ionising radiation for diagnosis and are mandatory in public and private establishments.

The Ministry of Health, as the competent authority, has also issued the Official Rule No. NOM-088-SSA1-1994, which is concerned with protecting the health of the public against the hazards which might arise from imported foodstuffs. This Rule sets up the maximum radionuclide level and is mandatory for any person or legal entity importing foodstuffs for retail within the national territory [Official Gazette of 28 June 1995].

Furthermore, the Ministry of Labour and Social Security revised the Standards issued on 15 February 1991 and on 20 December 1999 published a new Official Standard No. NOM-012-STPS-1999 (modifying the previous NOM-012-STPS-1993) on health and safety at workplaces where ionising radiation sources are handled, stored or transported, and which are capable of contaminating the working environment. This Standard entered into force on 20 February 2000. The Standard defines the duties of employers in such workplaces and provides that they must implement preventive measures and controls to ensure that employees do not receive radiation doses in excess of prescribed dose limits. The 1988 Regulations on Radiological Protection also establish employees' obligations in relation to medical examinations, restrictions due to radiological safety, etc. The tables set out the maximum permissible intake limits of radionuclides. A federal regulation relating to safety, health and the environment in the workplace of 20 January 1997 further extends the powers of the Ministry of Labour and Social Security to make rules governing the prevention of accidents in the workplace and ensuring that health and safety conditions for workers conform to those established by the federal labour legislation.

7. Radioactive Waste Management

The 1984 Act specifies that the federal government, through the Ministry of Energy, is responsible for the storage and disposal of nuclear fuels and radioactive waste irrespective of their origin [Section 18-VII].

The conditions governing applications for a licence for the establishment of a final repository and for the processing, conditioning and final disposal of low and intermediate level radioactive waste are the same as those for radioactive installations, as laid down in Sections 219, 220, 221 and 223 of the 1988 General Radiological Safety Regulations (see *supra*, Section 4 "Nuclear Installations") [Sections 202 and 206].

The National Nuclear Safety and Safeguards Commission classifies radioactive waste according to its specific activity, radiotoxicity, chemical and physical form, etc. [Section 207].

The final disposal of flammable, explosive, liquid or compressed gaseous radioactive waste is prohibited [Section 204]. Final disposal of radioactive waste at sea is also prohibited [Section 205]. It is also forbidden to mix radioactive waste with other materials, except as part of a conditioning process approved by the Commission [Section 208].

The Commission may authorise licensees of radioactive installations which produce low or medium level liquid radioactive waste from unsealed sources to dump the waste in the installation's drainage system under specific conditions laid down by the regulations [Section 211].

The National Nuclear Safety and Safeguards Commission has also issued Standard No. NOM-004-NUCL-1994, which sets out the criteria governing the identification and classification of radioactive waste produced by the nuclear industry, as defined by Section 11 of the 1984 Act. These Standards apply to the management, processing, storage, disposal and transportation of nuclear material [Official Gazette of 4 March 1996].

The processing, conditioning and final disposal of radioactive waste from high-level sealed and unsealed radioactive sources may only be undertaken in accordance with the Safety Regulations for Nuclear Installations [Section 214 of the General Radiological Safety Regulations].

In August 1996 the Ministry of Energy adopted three Regulations in the field of radioactive waste management. These Regulations, published in the Official Gazette on 12, 14 and 15 August 1996 respectively, entered into force on the day following their publication. The first of the regulations [NOM-018-NUCL-1995] defines the methods to be used to determine the concentration of radioactivity in radioactive waste containers so as to ensure proper treatment, conditioning and permanent storage of the waste. The second regulation [NOM-019-NUCL-1995] deals with the requirements for operating a permanent surface storage facility (up to 30 meters underground) for containers of low-level radioactive waste in gaseous, liquid or solid form. The third regulation [NOM-020-NUCL-1995] relates to the requirements for radioactive waste incineration facilities, and provides, *inter alia*, that such a facility must be constructed and operated so as not to permit a dose to the public in excess of 0.10 mSv per year.

The conditioning and final disposal of radioactive waste from ionising radiation sources arising from medical uses are also subject to a licence from the Ministry of Health, in co-operation with the National Nuclear Safety and Safeguards Commission [General Health Act, 1988, Sections 125 and 375-III, and 1988 Regulations, Sections 146-III and 149-V, as amended in 1991].

On 7 April 1975 Mexico ratified the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter.

8. Non-Proliferation and Physical Protection

According to Article 27, paragraph 7 of the Mexican Constitution, nuclear energy may only be used for peaceful uses. Section 2 of the 1984 Act reiterates this principle.

The 1984 Act on Nuclear Activities sets out definitions for non-proliferation and physical protection as follows:

- the purpose of safeguards is to organise and maintain a national system of control and registration of all nuclear materials to ensure that none of the said materials are diverted from peaceful applications to manufacture nuclear weapons or other non-authorised uses [Section 24];
- the purpose of physical protection in nuclear and radioactive installations is to avoid intentional acts which harm or may harm public health and safety, such as theft or the unauthorised use of nuclear or radioactive materials [Section 22].

The National Nuclear Safety and Safeguards Commission inspects nuclear and radioactive installations to account for materials, control and check the physical protection measures and the application of safeguards in installations [Section 32].

Following such inspections, the Commission will give its opinion on the deficiencies or anomalies noted, and propose the corrective measures required. It will then check that the measures have been implemented [Section 33].

Mexico ratified the 1968 Treaty on the Non-Proliferation of Nuclear Weapons on 21 January 1969 and the 1996 Comprehensive Nuclear Test Ban Treaty on 5 October 1999. It is also Party to the 1979 Convention on the Physical Protection of Nuclear Material, ratified on 4 April 1988.

Furthermore, Mexico is the depository of the 1967 Treaty for the Prohibition of Nuclear Weapons in Latin America (Tlatelolco Treaty) and has been party to the Treaty since 20 September 1967.

9. Transport

The Ministry of Energy is the authority responsible for regulating the transport and storage of nuclear fuels and radioactive waste [1984 Act, Section 18-VII]. The transport of radioactive materials and equipment that emits ionising radiation requires a licence from the Ministry of Energy, acting through the National Nuclear Safety and Safeguards Commission [Section 29]. Such licences are delivered in accordance with provisions set out in Section 30.

Pursuant to Section 198 of the 1988 Radiological Safety Regulations, applicants for a licence to transport radioactive materials must:

- identify the person to be responsible for radiation protection;
- describe the radioactive material to be transported, including the containers and packaging;
- describe in detail the physical protection and radiological safety plan;
- describe the safety equipment and devices;
- submit a risk analysis and emergency plan in the event of an accident involving radioactive materials during transport or during storage in transit;
- specify the route to be followed throughout the transport operation; and
- provide the name of the entity legally authorised to provide the security for any damage caused by ionising radiation.

The radiological safety rules applicable to the transport of radioactive materials are established in the transport regulations for each mode of transport [Section 199]. Regulations in that respect are to be issued by the National Nuclear Safety and Safeguards Commission. The transport of nuclear and radioactive materials is also subject to the Regulations for the Transport by Land of Dangerous Materials and Wastes, published in the Official Gazette on 7 April 1993, and in force since 8 April of the same year. The competent authority is the Ministry of Communications and Transport. These provisions apply to the transport of materials classified as No. 7 “Radioactive Materials” [Section 18], irrespective of the provisions to be issued by the National Nuclear Safety and Safeguards Commission.

The Ministry of Communications and Transport issued Official Rules NOM-003-SCT2/1994 to implement the Regulations for the Land Transport of Dangerous Materials and Wastes (which entered into force on 8 April 1993). These Rules set out the labelling requirements for packages of dangerous materials conveyed by land transport, including radioactive materials which are categorised as Class 7 dangerous materials. The obligation to have insurance cover for damage arising during the transportation of dangerous materials (as provided by Sections 109 and 122 of the 1993 Regulations), has been deferred by the Ministry of Communications and Transport in order to give the Mexican insurance industry time to respond to this requirement.

10. Nuclear Third Party Liability

The Act on Third Party Liability for Nuclear Damage was published in the Official Gazette on 31 December 1974 and entered into force on 1 January 1975. The act regulates third party liability for any nuclear damage caused by the use of nuclear reactors, nuclear fuels or the resulting radioactive waste [Section 1 – All references under this heading are to the Act on Third Party Liability unless otherwise specified].

"Nuclear damage" is defined as loss of life, personal injury, or any damage or material loss resulting directly or indirectly from the radioactive properties or a combination of such properties with toxic, explosive or other properties of nuclear fuel, radioactive products, waste or hazardous substances produced in, coming from or sent to a nuclear installation [Section 3(c)].

The "operator of a nuclear installation" is defined as the person designated or authorised as such by the competent authority of the state within whose jurisdiction the installation is situated [Section 3(e)].

A nuclear operator is strictly liable for nuclear damage [Section 4] caused by a nuclear incident occurring in a nuclear installation for which he is responsible, or by an incident involving hazardous nuclear substances produced in his installation [Sections 3(a) and 5].

Where nuclear damage involves the liability of more than one operator, the operators concerned are jointly and severally liable [Section 8]. The cumulative liability of those operators may not, however, exceed the maximum limits laid down by the act [Section 9].

The operator of a nuclear installation is liable for damage caused by a nuclear incident occurring during the transport of nuclear substances until such time as the substances are unloaded from the means of transport at the agreed location or at the delivery address or when the operator of another nuclear installation has assumed responsibility therefor [Section 6]. The carrier or shipping agent may take over the operator's liability with regard to the nuclear substances, provided he meets the requirements of the act and any applicable regulations [Section 7]. Before each transport operation, the operator must supply a certificate indicating his name and address, the nature and quantity of the substances shipped and specifying the statutory amount of his liability. The certificate must be accompanied, *inter alia*, by a certificate from his insurer or financial guarantor [Section 10].

If the liable operator shows that the nuclear damage resulted wholly or in part from the fault or deliberate omission of the person having suffered the damage or from that person's gross negligence, the competent court may decide to relieve the operator wholly or in part from his obligation to compensate that person [Section 13].

The operator is not liable for a nuclear incident which is the direct consequence of war, invasion, insurrection or a natural disaster [Section 11].

The maximum amount of the operator's liability is established at 100 million Mexican pesos (MXN) for each nuclear incident [Section 14]. However, in view of Mexico's obligations under the 1963 Vienna Convention on Civil Liability for Nuclear Damage, to which it has been a Party since 25 April 1989, the nuclear operator's liability cannot amount to less than the minimum set by the Convention.

The act contains no special provision regarding the type of insurance or financial security the operator must take out to cover his liability. However, this obligation, also referred to in transport

documents, appears indirectly in Section 23 which provides that public bodies are exempt from the requirement to obtain such insurance of financial security to cover the nuclear damage referred to in the act.

There is no provision for state funding.

The right to claim compensation for nuclear damage is extinguished ten years from the date of the incident [Section 19]. That term is extended to 15 years in case of deferred personal injury [Section 21].

In accordance with the Federal Code of Civil Procedure, the federal court where the defendant is domiciled has jurisdiction over cases in which this act applies [Section 25].

II. INSTITUTIONAL FRAMEWORK

The Federal Government

The federal government is the supreme authority in Mexico regarding nuclear matters. However it acts through the Ministry of Energy in accordance with Article 33 of the Organic Law of the Public Federal Administration. This Article entered into force on 29 December 1994 and granted the Ministry of Energy jurisdiction to issue all Official Standards dealing with, *inter alia*, nuclear safety, safeguards and radioactive materials. The Ministry delegates some of its responsibilities to the National Nuclear Safety and Safeguards Commission pursuant to the 1984 Act.

The 1984 Act on Nuclear Activities [Section 18] provides that the federal government, through the above Ministry, is responsible for:

- establishing the framework for the use and development of nuclear energy and technology, in accordance with the national energy policy;
- initiating, supervising and, as the case may be, approving the programmes of work of the Mineral Resources Board and the Commission for Mining Development in connection with radioactive ores so as to achieve congruity in the programmes and projects in the field of research, application and generation of nuclear energy and development of the nuclear industry;
- regulating nuclear and radiological safety and physical protection as well as safeguards and supervising the implementation thereof;
- establishing the stages of the nuclear fuel cycle;
- regulating the import and export of nuclear material and fuels, together with the other competent authorities;
- establishing the nuclear industry's research and technological development policy;
- regulating the transport and storage of nuclear fuels and radioactive waste;

- implementing the international agreements concluded in the nuclear field.

1. Regulatory and Supervisory Authorities

a) Ministry of Energy

An Internal Regulation of the Ministry of Energy of 4 June 2001 (which entered into force on 19 June 2001) sets out the structure of the Ministry and the responsibilities which, in accordance with the 1984 Act on Nuclear Activities, are delegated to it by the federal government.

The General Directorate for Electric Installations and Nuclear Resources has several duties in the nuclear field. In particular, the General Directorate may [Section 19-V to XII of the 1984 Act]:

- deliver formal opinions or propose a resolution with regard to the assignment, modification and cancellation of authorisations for the exportation or use of radioactive minerals;
- provide formal opinions concerning feasibility studies on the exploitation of radioactive minerals;
- co-ordinate and supervise activities related to Section 18 of the 1984 Act, except those pertaining to Chapter III;
- propose policies in furtherance of the peaceful use of nuclear energy;
- carry out and monitor tasks related to the radioactive waste management plan and radiological emergency programmes;
- co-ordinate inter-institutional activities for the transport of nuclear fuel;
- participate, in co-operation with the National Nuclear Safety and Safeguards Commission, in the elaboration of official standards governing the use of nuclear energy and nuclear materials.

The General Directorate for International Affairs and the National Nuclear Safety and Safeguards Commission are responsible for ensuring the proper application of Mexico's international agreements in the nuclear field [Section 15- I, IV, V and IX].

b) Ministry of Health

The Ministry of Health has responsibilities in the field of general health, as specified in Articles 26 and 39 of the Organic Law of the Federal Public Administration, including radiation protection and the use of ionising radiation for medical purposes. In addition to the licences required for activities involving nuclear or radioactive substances, a health permit from the Ministry of Health is required for medical establishments using radiation sources [Decree of 14 June 1991, amending the General Health Act, Section 125].

As already mentioned, the Ministry has issued Standards on radiation safety in establishments for medical diagnosis and treatment [Official Standard No. NOM-002-SSA2-1993 of 11 October 1994].

c) Ministry of Labour and Social Security

In relation to its responsibilities vis-à-vis workers and the workplace, and in accordance with Articles 26 and 40 of the Organic Law of the Federal Public Administration, the Ministry of Labour and Social Security issued technical standards, on 15 June 1994, on health and safety at workplaces where ionising radiation sources are used (see *supra* Section 6 "Radiation Protection").

d) Ministry of the Environment and Natural Resources

Pursuant to Articles 26 and 32 bis of the Organic Law of the Federal Public Administration, this Ministry is responsible, *inter alia*, for controlling pollution of the environment. In accordance with the 1988 Environmental Act, applicants for a licence to undertake activities in the nuclear field must first obtain approval from the Ministry, in addition to the assessment submitted to the National Nuclear Safety and Safeguards Commission.

e) Ministry of Communications and Transport

In accordance with Articles 26 and 36 of the Organic Law of the Federal Public Administration, this Ministry is responsible for the regulation of public transport. In addition to the licences required by the Ministry of Energy and the National Nuclear Safety and Safeguards Commission, licences for the transport by land of dangerous materials and wastes are issued by this Ministry [Official Gazette of 7 April 1993].

2. Public and Semi-Public Agencies

a) National Nuclear Safety and Safeguards Commission

i) Legal Status

The National Nuclear Safety and Safeguards Commission (*Comisión Nacional de Seguridad Nuclear y Salvaguardias*) is a semi-autonomous body, under the authority of the Ministry of Energy [1984 Act, Section 50].

ii) Responsibilities

The duties and responsibilities of the Commission as defined in the 1984 Act [Section 50] are of very wide scope. In particular, it must:

- ensure the proper application of regulations and safeguards for nuclear and radiation safety and for physical protection in nuclear and radioactive installations to ensure public safety;
- ensure, with the other competent bodies, the proper implementation of international agreements in the field of nuclear and radiological safety, physical protection and safeguards to which Mexico is a Party;
- revise, evaluate and approve the bases for siting, design, construction, operation and decommissioning of nuclear and radioactive installations and propose the relevant regulations; this also applies with regard to the manufacture, handling, storage,

reprocessing and transport of nuclear materials and fuels, radioactive materials and equipment containing such materials; and the processing, conditioning, disposal and storage of radioactive waste;

- provide opinions on the siting, construction, operation, etc. of nuclear installations prior to the delivery of a licence by the Ministry of Energy;
- deliver, renew, amend and suspend licences for radioactive installations;
- prior to the operation of nuclear or radioactive installations, approve the emergency plans; recommend and advise observance of nuclear and radiological safety measures and safeguards in emergency situations in such installations and close them down where required;
- establish and maintain the national system for registration and control of nuclear materials and fuels;
- give its opinion prior to the licensing of imports and exports of radioactive and nuclear materials, nuclear fuels and ionising radiation-emitting equipment;
- propose, revise and evaluate the regulations for the licensing of facilities for the treatment of radioactive ores;
- propose regulations governing nuclear and radiological safety, physical protection and safeguards in nuclear and radioactive installations and the safety and safeguards criteria for import and export of nuclear materials and fuels; and
- order and carry out inspections and verifications to ensure that the relevant regulations on nuclear and radiological safety, physical protection and safeguards are complied with.

iii) Structure

The Commission is headed by a Director-General appointed by the Minister of Energy, and is staffed by the personnel necessary to carry out its tasks.

The Commission also has an Advisory Board chaired by the representative of the Ministry of Energy. The Board includes representatives from the Ministries of the Interior; Foreign Affairs; National Defence; the Navy; Agriculture, Rural Development, Fisheries and Food; Communications and Transportation; Environment and Natural Resources; Health; and Labour and Social Security. With the agreement of the chairperson, representatives of other public bodies and experts in the nuclear field may also participate in the work of the Advisory Board.

The Board supplies the necessary technical co-operation to advise the Commission.

iv) Financing

The Commission is financed from the budget of the Ministry of Energy.

b) National Nuclear Research Institute

The 1984 Act on Nuclear Activities also sets forth the status and duties of the National Nuclear Research Institute (*Instituto Nacional de Investigaciones Nucleares*) [Sections 41 to 49].

i) Legal Status

The Institute is a decentralised public body under the federal government and it possesses status as a separate legal entity.

ii) Responsibilities

The purpose of the Institute is to undertake research and development in the field of nuclear science and technology, promote the peaceful uses of nuclear energy, and disseminate the progress made, so as to include this work in the economic, social, scientific and technical development of the country.

To achieve these objectives, the Institute has been assigned the following tasks:

- to carry out and promote activities conducive to scientific and technological development in the nuclear field and to encourage the transfer of scientific knowledge in that area;
- to provide assistance to public and private bodies in the design, construction and operation of nuclear and radioactive installations and, as necessary, in relation to contracts for those services;
- to promote national technological development in the nuclear industry;
- to initiate research and development activities in nuclear science and technology in research institutes and universities;
- to promote the application of radioisotopes in different fields;
- to organise training programmes on the application of nuclear technology;
- with the agreement of the Ministry of Energy, make arrangements with foreign institutes and international organisations to undertake joint projects and information exchange in the field of nuclear science and technology;
- give its opinion on research and development agreements on nuclear science and technology concluded by the Ministry of Energy and generally advise the federal government in its field of competence.

iii) Structure

The Institute is managed by a Board of Directors, a Director-General and a Supervisory Committee.

The Board of Directors is chaired by an Under-Secretary appointed by the Ministry of Energy, and is composed of the Directors-General of the Federal Electricity Commission, the National Science and Technology Council, the National Polytechnic Institute, the Rectors of the National University of Mexico and the National Metropolitan University and two additional persons appointed by the Ministry of Energy. The Board members each have an alternate member.

The Board, which is the directing body of the Institute, has many responsibilities, in particular:

- approving the internal regulations of the Institute;
- revising and approving the programmes of work;

- approving the budgets required to implement its programmes, checking the proper use of the economic resources and approving the financial accounts;
- evaluating the administrative operations and the results obtained, taking into account its own aims and the national objectives.

The Director-General of the Institute is appointed by the Ministry of Energy and:

- represents the Institute in all matters;
- implements the Board of Directors' decisions;
- proposes the measures required for operation of the Institute to the Board;
- establishes and proposes the programmes of work to the Board, and submits an annual activity report.

The Supervisory Committee is made up of one representative of the Institute, one representative of the Ministry of Energy and one representative of the Treasury. The latter co-ordinates the committee's activities and is responsible for reporting to the board of directors on the results of the committee's work.

The Committee supervises the implementation of the approved programmes and budgets and the measures adopted for efficient management and handling of resources. For this purpose, it may undertake the inspections and audits it deems necessary.

iv) Financing

Donations, federal government and private grants and remuneration for services rendered finance the Institute. It also owns revenue-generating property.

POLAND

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I. GENERAL REGULATORY REGIME

1. Introduction

There are no nuclear power plants in Poland at present. There are, however, two research reactors: the EWA reactor (TANK WWR type of 1 MWe), the decommissioning of which commenced on 24 February 1995, and the MARIA reactor (pool type), located at the Institute of Atomic Energy at Swierk. In addition, there is a radioisotope processing centre and a spent fuel storage facility in Swierk and a radioactive waste facility at Rozan.

The Atomic Energy Act of 29 November 2000 [Dz. U.[1] of 2001 No. 3, poz. 18, hereinafter referred to as "the Act"], which entered into force on 1 January 2002, is a framework act governing all nuclear activities in Poland. It sets out provisions governing the main supervisory body in the nuclear field, the National Atomic Energy Agency (*Prezes Panstwowej Agencji Atomistyki*, hereinafter referred to as "the NAEA"). The NAEA is a government body under the authority of the Minister of the Environment. In addition, there are various other competent bodies, such as the Central Laboratory for Radiological Protection (see Part II, Section 3 "Research Institutes" *infra*).

The Act recognises the need to develop nuclear energy for peaceful purposes, but in a manner which protects life, health, property and the environment. It establishes a licensing system which applies to:

- nuclear installations (from site selection to decommissioning) [Chapter 4];
- manufacture, use of and trade in nuclear materials [Chapter 5];
- manufacture and use of ionising radiation sources [Chapter 6];
- radioactive waste and spent nuclear fuel [Chapter 7];
- transport of nuclear materials, radioactive sources and waste [Chapter 8];
- nuclear third party liability [Chapter 12]; and
- construction and operation of radioactive waste repositories [Chapter 14].

In addition, the Act covers nuclear safety and radiation protection control, as well as training and protection of workers; assessment of the national radiological situation; radiological emergency management; functions of the president of the NAEA, and penal regulations. Several orders,

1. Dz. U.: *Dziennik Ustaw* = Law Bulletin of the Republic of Poland.

ordinances and decrees have supplemented the Act since it has come into force. The licensing procedures for nuclear installations are further detailed in decrees issued by the Council of Ministers.

The new Criminal Code, which entered into force in Poland on 1 September 1998 [Dz. U. No. 88, poz. 2677], contains two provisions pertaining to nuclear energy and ionising radiation. A person responsible for an event which poses a threat to the life and health of a significant number of persons or considerable damage to property, through release of nuclear energy or ionising radiation, will be liable to imprisonment for a period of one to ten years [Chapter XX, Article 163(4)]. The Criminal Code further provides that whoever, without permission or contrary to stipulated conditions, possesses, uses, produces, reprocesses, collects or deals with explosion devices or substances, radioactive materials, ionising sources or other objects dangerous to the life or health of a significant number of persons or subject to cause considerable damage to property, will be liable to imprisonment for a period of six months to eight years [Article 170(1)].

2. Mining Regime

There is no legislation dealing specifically with the prospecting for and mining of radioactive ores in Poland. These activities are therefore governed by the Mining and Geological Act of 4 February 1994 [Dz. U. No. 67, poz. 342].

3. Radioactive Substances, Nuclear Fuel and Equipment

a) Licensing

The Atomic Energy Act provides that a licence from the competent nuclear safety and radiation protection authority is required to carry out activities related to the application of atomic energy [Chapter 2, Article 4(1)]. Amongst the activities listed are the production, conversion, storage or use of nuclear materials and radioactive sources. Also included are the manufacture and use of devices incorporating radioactive sources or emitting ionising radiation, the manufacture of dosimetric equipment and equipment and devices for protection against ionising radiation. Practices involving the addition of radioactive substances to foodstuff, toys, personal jewellery or cosmetic products, as well as the import of such products into, and export from the territory controlled by Polish customs, are prohibited [Article 4(2)]. The Council of Ministers may exempt certain activities from the licence requirements [Article 6]. The Regulation exempting Certain Activities from Licensing was adopted on 6 August 2002. It exempts activities where the radiation source is of very low activity or concentration, or where low-level sources are contained in equipment in conformity to specified construction requirements, thereby assuring a satisfactory level of radiation protection. Although exempt from licensing, these activities must nevertheless be registered to permit some level of control by the NAEA.

"Nuclear material" is defined in the Act as material containing fissionable isotopes (nuclides), in particular the isotopes of uranium, plutonium or thorium, in quantities which may not be disregarded from the viewpoint of nuclear material accountancy, including nuclear fuel [Article 3(11)]. "Radioactive source" is defined in the Act as any radioactive substance prepared in such a manner as to allow use to be made of the ionising radiation it emits [Article 3(33)]. Licences are issued by the president of the National Atomic Energy Agency [Article 5(2)], with the exception of licences to manufacture, purchase, install and use X-ray apparatus emitting radiation of energy equal to or less than 300 keV, which are granted by the local sanitary inspector [Article 5(3)].

b) Registration and Monitoring of Nuclear Materials and Radioactive Sources

The Act requires any organisational unit licensed to manufacture, convert, store, use and trade nuclear materials, to register and monitor such materials [Article 5(4)]. The rules governing such registration and control are established by the Council of Ministers, pursuant to the Regulation of the Council of Ministers adopted on 31 July 2001 on the Physical Protection of Nuclear Materials [Mon. Pol.[2] No. 90, poz. 997] and the Regulation of the Council of Ministers adopted on 31 July 2001 on the Accounting of Nuclear Materials [Mon. Pol. No. 87, poz. 955].

The rules set out the principles which apply to the keeping of records and the control of nuclear materials during manufacture, processing, use, removal from one place to another and storage on national territory. Nuclear materials passing in transit through Polish territory are excluded from the application of these rules.

The system for recording and controlling nuclear materials includes internal plant records and audits of nuclear materials, as well as central record keeping and audit by the National Atomic Energy Agency.

4. Nuclear Installations

a) Licensing and inspection, including nuclear safety

"Nuclear facility" is defined in the Act as a facility or an installation designed for manufacturing, use, processing, storage or disposal of nuclear materials in quantities allowing a self-sustained nuclear fusion chain reaction [Article 3(13)]. This definition is further elaborated in Article 34 of the Act, which refers in particular to nuclear power plants, thermal-electric power plants and heating plants equipped with nuclear power reactors, research, experimental and other nuclear reactors.

In accordance with the Act, the obligation to fulfil the requirements of nuclear safety, radiological protection and physical protection of a nuclear facility applies during the stages of the lifetime of the nuclear installation [Article 35]. The respective licences to engage in these activities are granted by the president of the NAEA on the request of the investor until operation begins, and subsequently on the request of the operator.

Inspection powers are described in Chapter 9 of the Act, as part of a wider nuclear surveillance function. The nuclear surveillance tasks, including inspections, are performed by the president of the NAEA, the chief nuclear regulatory inspector and the regulatory inspectors responsible for nuclear control [Article 64]. The principal inspector for nuclear surveillance is appointed by and responsible to the president of the Agency, and directs the work of the inspectors responsible for nuclear surveillance [Article 52]. The president of the Agency may entrust the surveillance tasks to officials of organisational units subject to nuclear surveillance, who will have the same rights as inspectors responsible for nuclear surveillance.

Pursuant to Article 66, the inspectors are entitled to:

2. Mon. Pol.: *Monitor Polski* : Bulletin of the Council of Ministers of Poland.

- around the clock access to transport vehicles and the sites of organisational entities where nuclear materials, ionising radiation sources, radioactive waste and spent nuclear fuel are produced, used, stored, disposed of or transported;
- review the documentation concerning nuclear safety and radiological protection in the controlled organisational entity;
- check if the activities referred to in article 4(1) are conducted in compliance with nuclear safety and radiological protection regulations and with the requirements and conditions established in the licence;
- conduct independent technical and dosimetric measurements whenever needed;
- request written or oral information if this is necessary to clear up an issue.

The procedure to be followed in surveillance matters is governed by the Code of Administrative Procedure. Any decision involving nuclear safety and radiation protection may be contested before the Supreme Administrative Court (*Naczelny Sad Administracyjny*). "Nuclear safety" is defined in the Act as the conditions reached through the organisational and technical measures undertaken to prevent radiological emergencies related to practices involving nuclear materials, and to mitigate their consequences [Article 3].

Poland is Party to the Convention on Nuclear Safety, which it ratified on 14 June 1995.

b) Emergency response

The Act distinguishes the following types of radiological emergencies according to the extent of their impact:

- an on-site emergency is a radiological emergency occurring on the site of the organisational entity, with the impact limited to the area within the site boundaries of the organisational entity;
- a public emergency on a regional scale is a radiological emergency occurring on the site of the organisational entity or off-site during field works or during the transportation of nuclear materials, ionising radiation sources, radioactive waste and spent nuclear fuel, with the impact limited to the territory of one region only; and
- a public emergency on a national scale, which is a radiological emergency referred to in the preceding paragraph, if its impact extends or may extend to a territory larger than that of the region.

The Agency's president shall issue an order decreasing the power or stopping the operation of a nuclear facility if, in his assessment, further operation of this facility shall endanger nuclear safety. A subsequent increase of power or start-up of the facility shall require the consent of the Agency's president [Article 39].

If an inspection of the installation reveals a direct threat to nuclear safety or radiation protection, the president of the NAEA, the chief nuclear regulatory inspector or the regulatory inspectors responsible for nuclear control are required to impose emergency measures designed to eliminate the danger [Article 84].

Poland is party to the following international conventions dealing with emergency response:

- 1986 Convention on Early Notification of a Nuclear Accident (ratified on 24 March 1988);
- 1986 Convention on Assistance in Case of a Nuclear Accident or Radiological Emergency (ratified on 24 March 1988);
- Bilateral agreements on early notification of a nuclear accident and on co-operation in nuclear safety and radiological protection concluded with: Denmark (1987), Austria (1987), Norway (1989), Ukraine (1993), Belarus (1994), Russian Federation (1995), Lithuania (1995) and Slovak Republic (1996).

By order of the president of the NAEA, the International Contact Point (ICP) of the early warning system was established. The ICP operates on a 24-hour basis and serves as a channel for the exchange of information on radiation emergencies with the International Atomic Energy Agency (IAEA) in Vienna and neighbouring countries, in accordance with international conventions and bilateral agreements.

5. Trade in Nuclear Materials and Equipment

Under Article 62 of the Act, import into and export from the territory controlled by Polish customs of nuclear materials, radioactive sources and devices containing such sources, import of consumer goods emitting ionising radiation, as well as import and export of radioactive waste and spent nuclear fuel, shall be conducted on the basis of licensing conditions provided in Article 4(1)(2).

In addition, two Regulations of the Council of Ministers of 5 November 2002 lay down rules on imports into, exports from and transit through the Polish customs of radioactive waste and spent nuclear fuel and also of nuclear materials, radiation sources and devices containing such sources.

Nuclear materials, radioactive sources and equipment containing radioactive sources may be imported from abroad by an entity that has been licensed under Article 4 of the Act to:

- use such items;
- deal in nuclear materials or radioactive sources;
- manufacture and process nuclear materials and radioactive sources;
- manufacture devices containing radioactive sources; or
- manufacture articles of general use which emit ionising radiation.

Similarly, nuclear materials, radioactive sources or devices containing radioactive sources may be exported to foreign countries by an entity that has been licensed under Article 4 of the Act to:

- distribute nuclear materials or radioactive sources;
- manufacture devices containing radioactive sources;
- use nuclear materials and radioactive sources; or
- manufacture nuclear materials and radioactive sources.

An Act of 2 December 1993 provides for special control rules for the import, export and transit of certain goods and technologies in accordance with international agreements concluded by Poland [Dz. U. No. 129 of 24 December 1993]. These control rules apply to a variety of goods and

technologies, including those belonging to the nuclear fuel cycle and those capable of producing nuclear explosive devices. The list of such goods and technologies is established by the Minister for the Economy and the Minister for Foreign Affairs. The Minister for the Economy issues import and export certificates after the licence has been granted. The directors of customs offices issue permits for the transit of such goods. Control teams appointed by the Minister for the Economy, and which include a member of the National Atomic Energy Agency, carry out licence checks on Polish territory. The Minister for the Economy issued an Order on special controls in foreign trade pursuant to the 1993 Act [Dz. U. No. 19 of 25 March 1994]. This order contains provisions relating to articles capable of producing nuclear explosive devices.

6. Radiation Protection

Ongoing surveillance of nuclear safety and radiation protection is dealt with in Chapters 3 and 9 of the Act, with general responsibility being given to the president of the NAEA, the chief nuclear regulatory inspector and other regulatory inspectors responsible for nuclear surveillance. For further details of the nuclear surveillance tasks of the Principal Inspector and the inspectors, see *supra*, Section 4 "Nuclear Installations", subsection (a) "Licensing and Inspections".

Detailed rules for this surveillance function are set out in the Regulation of the Council of Ministers adopted on 3 December 2001 on the subsidy for activities in the field of nuclear safety and radiological protection [Dz. U. No. 145, poz. 1626].

The chief nuclear regulatory inspector and the other regulatory inspectors examine the documentation relating to nuclear safety and radiation protection submitted by applicants in licensing proceedings, provide opinions on the siting of nuclear plants and waste disposal facilities, review training programmes for employees in nuclear installations and give periodic reports on the nuclear safety and radiation protection situation in the country.

Chapter 3 of the Act deals with training and health protection of workers in the nuclear industry. Workers may only carry out activities involving nuclear materials, sources of ionising radiation or radioactive waste, if they have adequate knowledge of nuclear safety and radiation protection requirements in light of their position. Medical examinations are required to ensure that the worker is suitable for the post, and training programmes must be periodically organised to educate workers on nuclear safety and radiation protection issues. The Minister for Health and Welfare is responsible for establishing the general content and principles of the training programme for persons responsible for ensuring protection against ionising radiation in X-ray centres [Article 12]. The Act also requires medical surveillance of workers likely to be exposed to ionising radiation, and provides for compulsory systematic dosimetric readings as part of this surveillance.

The standards for such medical surveillance and dosimetric recordings in the workplace are set out in the Regulation of the Council of Ministers adopted on 3 December 2001 on the subsidy for activities in the field of nuclear safety and radiological protection [Mon. Pol. No. 145, poz. 1626]. Under that regulation, the results of measurements concerning the level of exposure for individuals must be kept for at least 30 years after termination of the work involving exposure to ionising radiation. Similarly, the results of atmospheric dosimetric measurements taken at the workplace must be kept for at least 30 years, unless such results have been handed over to the state nuclear safety and radiation protection surveillance body.

The relevant radiation dose limits are set out in the Regulation of the Council of Ministers adopted on 28 May 2002 on dose limits of ionising radiation [Mon. Pol. No. 111, poz. 969]. These

dose limits are for workers employed under conditions where there is a likelihood of exposure to ionising radiation and for persons residing in the proximity of ionising radiation sources, including nuclear installations.

The Appendices to the regulation set out the formulas used to calculate the applicable dose limits under the regulation. Generally, to identify ionising radiation hazards for workers, there is an annual limit on intake corresponding to one of the following:

- overall effective dose equivalent of 50 mSv;
- 100 mSv for lenses of the eyes; and
- 500 mSv for other tissues or organs.

In 1965, Poland ratified the 1960 ILO Convention No. 115 on Workers Protection against Ionising Radiation. As a result, the international safety standards for radiation protection and their amended versions were implemented in Poland. The present law is based on the 1994 Basic Safety Standards for Protection against Ionising Radiation and for the Safety of Radiation Sources (BSS) as approved by the IAEA. The recent revision of the BSS is the basis for bringing the existing regulations in Poland into line with European Union directives.

7. Radioactive Waste Management

Chapter 7 of the act sets out the general framework for the regulation of radioactive waste. Radioactive waste from the manufacture, conversion, temporary or final storage or use of nuclear materials and radioactive sources, and from the operation and decommissioning of nuclear installations, must be treated in such a way as to prevent its constituting a risk to persons or the environment [Article 50].

Radioactive waste must be registered at the place where it is produced or stored, and the rules governing the classification of waste, its characterisation and registration, and the conditions for its treatment and storage are determined by rules made by the Council of Ministers [Article 51]. Licences for the construction and operation of radioactive waste repositories are granted by the president of the NAEA [Article 53]. Further, a Regulation of the Council of Ministers of 3 December 2002 lays down rules on classification of radioactive wastes, their characterisation, controlling and records keeping as well as on conditions for the storage of radioactive waste and spent fuel.

At the international level, Poland ratified the 1997 Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management on 5 May 2000. Poland also ratified the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter on 23 January 1979.

8. Non-Proliferation and Physical Protection

Poland is party to the following international conventions, treaties and agreements dealing with non-proliferation and physical protection in the nuclear field:

- 1968 Treaty on the Non-Proliferation of Nuclear Weapons (ratified on 12 June 1969);
- Safeguards Agreement with the IAEA (ratified in 1972; published in INFCIRC/179);

- 1979 Convention on the Physical Protection of Nuclear Material (ratified on 5 October 1983); and

- 1996 Comprehensive Nuclear Test Ban Treaty (ratified on 25 May 1999).

Poland is also a member country of the Nuclear Suppliers Group (NSG – London Club) and, as a result, observes the NSG guidelines set out in IAEA publication INFCIRC 254/rev.2/Part 1 and Part 2 (export and import control by the state, as laid down by the Act of 2 December 1993; see *infra*).

As discussed *supra*, under Section 5 "Trade in Nuclear Materials and Equipment", an Act of 2 December 1993 provides for special control rules for the import, export and transit of certain goods and technologies in accordance with international agreements concluded by Poland [Dz. U. No. 129 of 24 December 1993].

Under the Act, the physical protection of nuclear materials is the responsibility of the organisational unit to which a licence has been granted to manufacture, convert, store, use or trade in those materials [Article 41].

Detailed rules governing physical protection of nuclear materials are provided by the Regulations of the Council of Ministers of 31 July 2001 on physical protection of nuclear materials and on accountancy of nuclear materials; which took effect on 1 January 2002. Regulation on Physical Protection of Nuclear Materials sets out the various categories of nuclear materials and establishes adequate protection levels for each of them. It further determines the organisational methods and technologies which should be used in the field of physical protection, as well as the appropriate procedures for the periodic controls carried out by the president of the NAEA. The Regulation on the Accountancy of Nuclear Materials defines nuclear materials subject to accountancy requirements, specifies methods and means of maintaining balance, establishes control procedures and presents detailed models of the documents to be submitted.

9. Transport

Chapter 8 of the Act deals in particular with the transport of nuclear materials and radioactive sources and waste. Licences to transport nuclear materials and radioactive sources are granted by the president of the NAEA. The nuclear materials must be prepared for transport and transported in such a way as to prevent any possibility of a self-sustained fission reaction. To the extent that they are not regulated by separate provisions, the conditions for the safe transport of nuclear materials and radioactive sources and waste are determined by the Minister responsible for the mode of transport in question, in agreement with the Minister for Internal Affairs and the president of the NAEA. The radiation doses to which persons involved in the transport operation are exposed must be monitored and must not exceed the dose limits specified under the Act.

The Regulation of the Council of Ministers of 31 July 2001 on Physical Protection of Nuclear Materials contains specific provisions to ensure safety during the transport of nuclear material falling into one of the three categories set out in the Appendix to that regulation.

The conditions and requirements applying to transport within the site of the entities which produce, store or use nuclear materials or radioactive sources and waste are to be specified by the president of the NAEA in the licence for the activity authorised.

10. Nuclear Third Party Liability

Poland acceded to the 1963 Vienna Convention on Civil Liability for Nuclear Damage and the 1988 Joint Protocol on the Application of the Vienna Convention and the Paris Convention on 23 January 1990. The legislative provisions to meet its obligations under the Vienna Convention were already largely in place under Chapter 12 of the Act, although there are provisions in the Convention which are not specifically addressed under the Act. As a matter of basic principle, however, the Act, like the Convention, channels liability for nuclear damage to the operator of a nuclear installation, with the exception of damage caused directly by acts of war or armed conflict [Article 101(1)].

If a person who suffers nuclear damage, by intentional behaviour has caused or aggravated that damage, the court of justice may relieve the operator, wholly or partially, from his obligation to pay compensation in respect of the damages suffered by such individual.

Pursuant to Article 100(5) nuclear damage includes any one of the following:

- personal injury;
- damage to property;
- damage to the environment – the costs of measures of reinstatement which aim to restore the impaired environment viewed as common property to its natural state, unless such impairment is insignificant;
- loss of potential income which the injured party could have obtained if it were not for the damages referred to in subparagraphs (a) and (b), as well as the loss of income related to the damage to the environment viewed as common property.

In the event of nuclear damage occurring during the transport of nuclear materials, the operator sending the material remains liable for third party damage unless an agreement between nuclear operators provides for the liability of the other person [Article 101(2)].

The operator's liability is limited to the amount of 150 million Special Drawing Rights (SDR) [Article 102(1)].

The operator of a nuclear installation is required to maintain a financial security covering this liability [Article 103(1)]. The National Treasury shall guarantee the payment of compensation for nuclear damage incurred by an individual, where such amount could not be settled from the financial security [Article 103(3)].

The right to compensation for personal injury due to nuclear damage is not subject to a prescriptive time limit. Nuclear damage to property or the environment is subject to a ten-year prescription period and to a three year discovery rule, i.e. the injured party must file suit within three years of the date that he knew or should have known of the injury [Article 105].

To the extent not covered by Chapter 12 of the Act, the provisions of the Civil Code apply to claims for nuclear damage [Article 107]. Similarly, the provisions of Chapter 12 of the Act do not prejudice the application of other provisions on benefits for industrial injuries or occupational illness [Article 108].

II. INSTITUTIONAL FRAMEWORK

1. Regulatory and Supervisory Authorities

a) National Atomic Energy Agency (NAEA)

The National Atomic Energy Agency – NAEA (*Panstwowa Agencja Atomistyki*) is the governmental agency responsible for the use of nuclear energy in Poland. As such, it is responsible for the co-ordination and control of activities related to the research and safe use of nuclear energy, safeguards for nuclear materials, storage of radioactive waste, education and information of the public, as well as international co-operation in the field of nuclear energy.

The NAEA is directed by its president, who is appointed by the Prime Minister upon proposal of the Minister competent in environmental matters and reports to this Minister. The president of the NAEA is assisted by an advisory body, the Atomic Energy Council.

The Act sets out the powers and responsibilities of the NAEA and the president of the NAEA [Chapter 13]. In addition, various decrees and regulations specify the NAEA powers and functions, in particular the Regulation of the Minister of Environment of 15 July 2002 on the Statute of the National Atomic Energy Agency [Mon. Pol. No. 33, poz. 519].

The nuclear legislative scheme attributes a particularly important role to the president of the NAEA, especially with relation to the granting of licences and the overall supervision of the nuclear sector [Article110]. The president is responsible for governmental supervision of all aspects of the peaceful uses of atomic energy related to nuclear safety and radiation protection. He is also responsible for radiological emergency preparedness and for decontamination measures. In the event of a radiation emergency, the president puts the emergency plan into operation and establishes protective zones around nuclear facilities. The president also supervises control over foreign trade in and transit through Polish territory of nuclear materials and equipment. Finally, the president, in co-operation with the Minister for Foreign Affairs, co-ordinates international relations in the field of the peaceful and safe use of atomic energy, and represents the government of Poland in the governing bodies of specialised international organisations.

In addition, the National Atomic Agency Board is the consultative body of the Agency. It is composed of a chairperson, who is also the president of the Agency, a vice-president (chief nuclear regulatory inspector) along with representative of the Ministers in charge of Economic Affairs, National Education, Defence, Internal Affairs and Administration, Foreign Affairs, Health and Environment. The aim of the Board is to resolve problems encountered in the Agency's various activities by preparing programmes of action and studying the Agency's annual activity reports.

b) Minister for Health and Welfare

The Minister for Health and Welfare is responsible under the Act for making regulations laying down the conditions for the safe application of ionising radiation for medical purposes. Pursuant to the Act, the Minister establishes conditions for the safe use of ionising radiation in medical applications, and methods of internal control for the fulfilment of these conditions. To this end, he enacted the

Regulation of 24 December 2002 [Mon. pol. No. 241, poz. 2098], which has been in force since 1 January 2003.

c) Minister for the Environment

According to Atomic Energy Act (as modified by the Act on the Organisation of the Central Authorities in the Republic of Poland of 21 December 2001), the Minister of the Environment supervises the president of the NAEA and nominates the deputy presidents. Pursuant to the Regulation of 30 December 2002 [Dz. U. No. 241, poz. 2094], in force since 1 January 2003, the Minister established detailed rules regarding restricted access around nuclear facilities.

2. Advisory Bodies

Council for Atomic Affairs

The Council for Atomic Affairs is an advisory body which assists the president of the National Atomic Energy Agency by providing its opinion on questions relating to the NAEA's activities and in particular on radiological protection and nuclear safety [Article 112]. It comprises a chairperson appointed by the Prime Minister on the recommendation of the president of the NAEA, together with members of the Council appointed by the president of the NAEA.

3. Public and Semi public Bodies

Radioactive Waste Management Plant

This plant, established by the Atomic Energy Law of 2000, is a state-owned public utility located in Otwock-Swierk. It shall be established to conduct activities involving radioactive waste management and spent nuclear fuel management and, above all, ensuring permanent feasibility of radioactive waste and spent nuclear fuel disposal.

Radioactive Waste Management Plant shall be supervised by the Minister for the Economy, and is headed by a director nominated by this Minister. The Minister for the Economy shall control the plant's activities and submit those activities to an annual evaluation which he shall present to the Prime Minister.

4. Research Institutes

a) Central Laboratory for Radiological Protection

Regulation No. 164 of 13 July 1957 of the Prime Minister established the Central Laboratory, and the president of the NAEA approved its Statute on 12 February 1993. Its main activities include supervision and control of radiation hazards, the scientific research programme in radiation protection, the formulation of standards on radiation protection, the safe handling of radioactive sources and the personal dose monitoring service. It also serves as an emergency service centre and an international contact point of the early warning system, in the event of a nuclear accident.

b) Institute of Atomic Energy

The Institute was founded by Regulation No. 31 of 13 December 1982 of the Prime Minister, and the president of the NAEA approved its Statute on 29 January 1993. Its main activities include VVER reactor safety studies, fuel and structural material studies for gas-cooled reactors, analysis of nuclear safety and radiological protection, processing of radioactive wastes and production of equipment applied in reactor technology.

c) Institute of Nuclear Physics

The Institute was founded by decision of the Council of Ministers of 20 July 1960, and its Statute was approved by the president of the NAEA on 7 April 1992. It is responsible for conducting research in high and low energy physics, condensed matter physics, accelerator techniques and applied nuclear physics.

d) Institute of Nuclear Chemistry and Technology

The Institute was founded by Regulation No. 31 of 13 December 1982 of the Prime Minister, and the president of the NAEA approved its Statute on 14 July 1992. Its main fields of activity include material studies, studies on the use of radioisotope instruments and research and studies in the areas of radiochemistry, radiobiology and health protection, chemical engineering, metallurgy, hydrology and environmental protection.

e) Institute for Nuclear Studies

The Institute was founded by Regulation No. 31 of 13 December 1982 of the Prime Minister, and the president of the NAEA approved its Statute on 8 October 1996. Its main fields of activity include basic and applied physics and work on nuclear electronic instrumentation and nuclear apparatus.

f) Radioisotope Centre

The Centre was founded by Regulation No. 8 of 18 September 1989 of the president of the NAEA, and the president of the NAEA approved its Statute on 30 May 1997. The activities of the Centre consist of production of radioactive materials for biochemical and industrial purposes and research work in the fields of radioimmunology, radioactive preparations, ionising radiation sources, metrology and analysis.

g) Institute of Plasma Physics and Laser Microfusion

The Institute was founded by Regulation No. 44 of 25 July 1975 of the Prime Minister, and the president of the NAEA approved its Statute on 1 July 1993. Its main fields of research are basic and applied sciences in the nuclear field.

PORTUGAL

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I. GENERAL REGULATORY REGIME

1. Introduction

Portugal does not have an electro-nuclear power programme. The Technological and Nuclear Institute (*Instituto Technologico e Nuclear* – ITN) owns and operates, for research purposes, a light-water pool reactor (1 MWe) that uses highly enriched uranium.

There is no single framework act governing the nuclear sector in Portugal; instead, a series of laws, regulations and decrees contain detailed provisions governing nuclear activities. Responsibility for these activities is shared between the Ministry for Economic Affairs, the Ministry for Health, the Ministry for Urban Affairs, Territorial Planning and Environment and the Ministry for Science and Higher Education.

The institutional framework for nuclear activities in Portugal has undergone a number of successive changes, the most recent of which took place in 2002. These changes are summarised below.

The Ministry for Industry was reorganised in 1977, with new departments being created and others closed down, including the *Junta de Energia Nuclear* (JEN) [Decree-Law No. 548/77 of 31 December 1977]. The tasks of the JEN were redistributed both amongst existing departments and new bodies created for that purpose [Order No. 126/78 of 31 May 1978]. The latter included the Protection and Nuclear Safety Bureau (*Gabinete de Protecção e Segurança Nuclear* – GPSN), the National Industrial Engineering and Technology Laboratory (*Laboratorio Nacional de Engenharia e Tecnologia Industrial* – LNETI), and the General Directorate for Geology and Energy (*Direcção Geral de Geologia e Energia* – DGGE), all of which were placed under the responsibility of the Ministry for Industry. In 1996, another reorganisation took place: the Ministry for Industry and Energy and the Ministry for Trade and Tourism were merged together to form the Ministry of Economic Affairs.

The LNETI was reorganised in 1979, by Decree-Law No. 361/79 of 1 September 1979, following which it was transformed into a public institute, the National Industrial Engineering and Technology Institute (*Instituto Nacional de Engenharia e Tecnologia Industrial* – INETI) by Decree-Law No. 240/92 of 29 October 1992.

In 1995, control over INETI and the DGGE was transferred from the Ministry for Industry to the Ministry for Economic Affairs [Decree-Law No. 296/95 of 17 November 1995].

In 1987, the GPSN was transferred to the Ministry for the Environment and Natural Resources [Decree-Law No. 329/87 of 23 September 1987]. Following the reorganisation of the Ministry for the Environment by Decree-Law No. 189/93 of 24 May 1993, the GPSN was merged with other

directorates into a new General Directorate for the Environment (*Direcção Geral do Ambiente* – DGA). Under the provisions of this same decree-law the Department of Radiological Protection and Safety of INETI was also transferred to the DGA. In 1998, that Department was transferred to the Technological and Nuclear Institute pursuant to Decree-Law No. 311/98 of 14 October 1998 [Section 4]. Under Decree-Law No. 97/03 on the Ministry for Urban Affairs, Territorial Planning and Environment, adopted on 7 May 2003, the DGA was merged with the Environmental Promotion Institute into the Environment Institute (*Instituto do Ambiente* – IA).

Under Decree-Law No. 10/93 of 15 January 1993, the General Directorate for Fundamental Health Care (*Direcção Geral dos Cuidados de Saúde Primários*) and the General Directorate for Hospitals were merged into a single directorate, the General Directorate for Health (*Direcção Geral de Saúde*). The statute of this new general directorate was established by Decree-Law No. 345/93 of 1 October 1993.

Finally, Decree-Law No. 122/93 of 16 April 1993 restructured the General Directorate for Geology and Mines into a public institute, the Institute for Geology and Mines (*Instituto Geologico e Mineiro* – IGM).

For consistency, these bodies will generally be referred to by their new names in this study.

The main legislative instruments regulating nuclear activities are as follows: the above-cited Decree-Law No. 548/77, Decree-Law No. 49.398 of 24 November 1969 which lays down the licensing system for nuclear activities, Decree No. 487 of 5 December 1972, adopted in implementation of Decree-Law No. 49.398, which provides specifically for the licensing of nuclear power plants, Decree-Law No. 165/02 of 17 July 2002, Decree-Law No. 348/89 of 12 October 1989 (insofar as it does not conflict with Decree-Law No. 165/02) setting out the framework for radiation protection as implemented by Decree No. 9/90 of 19 April 1990 and amended by Decree No. 3/92 of 6 March 1992 and, to a certain extent, Decree-Law No. 186/90 on environmental protection of 6 June 1990 (insofar as it does not conflict with Decree-Law No. 165/02).

2. Mining Regime

In Portugal, a number of decree-laws have been issued since 1950 to regulate the prospecting for and exploitation of radioactive ores. Pursuant to Decree-Law No. 37.986 of 27 September 1950 and Decree-Law No. 40.135 of 20 April 1955, the Minister for Finance was authorised to fix export taxes for radioactive materials and their concentrates.

Decree-Law No. 426/83 of 7 December 1983 and Decree No. 34/92 of 4 December 1992 regulate radiation protection and environmental impacts in respect of uranium mining activities. The 1992 Decree sets out the radiation protection standards to be applied to such activities [Chapter III]. This decree, which repeals Decree No. 78/84 on the same subject, was adopted to take into account more recent international radiation protection standards. It sets out the obligations of persons in charge of such activities [Section 6] and those of workers performing such activities [Section 7]. It specifies that any unnecessary exposure to radiation or contamination of the environment must be avoided; it also provides that such exposure levels must be as low as possible and in any event always below the limits fixed by the national radiation protection standards [Section 9]. All mining projects or related treatment and recovery facilities must be for approved by the Institute for Geology and Mines [Section 43].

Two decisions define, respectively, the rules to be complied with when concluding contracts for the prospecting and exploitation of radioactive ore deposits and for the licensing of bodies engaged in such activities [Decisions Nos. 2 and 3 of 19 March 1971 of the JEN Presidency].

According to Decrees Nos. 348/89, 34/92, 187/93, 189/93, 345/93, 165/02 and 113/03, the responsible authorities for uranium mining and related activities are the Institute for Geology and Mines, the General Directorate for Health, the Ministry for Urban Affairs, Territorial Planning and Environment and the Regional Directorates for Economy.

The Technological and Nuclear Institute (ITN) is responsible for monitoring the environment in mining areas.

3. Radioactive Substances, Nuclear Fuel and Equipment

Activities involving production of and trade in radioactive substances and nuclear fuel are regulated by Decree-Law No. 49.398 of 24 November 1969.

The Institute for Geology and Mines (*Instituto Geologico e Mineiro* – IGM) is responsible for controlling the production of and trade in nuclear fuel for industrial uses [Order No. 126/78 of 31 May 1978, Section 1 and Decree No. 7/93 of 19 March 1993, Section 2].

The General Directorate for Geology and Energy is responsible for licensing nuclear fuel cycle facilities and for the transfer of nuclear fuel on national territory and between Portugal and other EU Member States.

The import, production, use and transport of radioactive substances and radiation-emitting equipment are subject to prior authorisation by the General Directorate for Health, in accordance with the conditions laid down by Sections 6, 7 and 8 of Decree-Law No. 348/89 and Section 34 of Decree No. 9/90 of 19 April 1990.

In accordance with Decree No. 9/90 [Section 35] substances and apparatus whose radioactivity does not exceed certain levels specified in Annex II of the decree are exempted from prior authorisation or licensing; such exemptions do not apply to radioactive substances for medical or diagnostic purposes or to radioactive substances added to toys, cosmetics or household products [Section 36 as amended by Decree No. 3/92 of 6 March 1992].

The import and export of concentrates of radioactive substances, the fabrication, import and export of nuclear fuel, the treatment of and trade in irradiated fuel and other activities of an industrial nature are subject to licensing [Decree-Law No. 49.398, Sections 1 and 2]. Licences are issued for a limited period on a case-by-case basis, upon proof that the establishment concerned has the necessary technical knowledge and financial resources. Its premises are subject to inspection by the competent authorities, being the regional delegations of the Ministries for Economic Affairs, Health and the Environment. In addition, contracts whose purpose is the establishment, modification or transfer of associations concerned with the above activities are subject to ministerial approval [Section 4].

The Technological and Nuclear Institute is responsible for the evaluation and inspection of the security conditions governing nuclear fuel transport.

4. Nuclear Installations

a) Licensing and inspection, including nuclear safety

Decree-Law No. 165/02 of 17 July 2002 designates the competent authorities for licensing nuclear installations and nuclear activities in Portugal. Decree-Law No. 487 of 5 December 1972 made in implementation of Decree-Law No. 49.398, sets out the licensing procedure for nuclear power plants. Decree-Law No. 48.568 of 4 September 1968 establishes the nuclear installations inspection regime (these provisions are not, however, applied at present as there are no nuclear power plants in Portugal).

The General Directorate for Geology and Energy (*Direcção General de Geologia e Energia* – DGGE) under the Ministry for Economic Affairs and the Environment Institute (IA) under the Ministry for Urban Affairs, Territorial Planning and Environment are the competent authorities for licensing activities related to the nuclear fuel cycle, and in particular the transfer and transit of nuclear fuel between Portugal and other EU Member States as well as on national territory. The DGGE is not responsible for licensing the detention, transfer, sale or any other transmission of radioactive sealed sources, as the Nuclear and Technology Institute carries out this task [Decree-Law No. 165/02, Sections 13 and 14(a)].

According to Decree No. 487/72 [Section 1], nuclear power plants must be established in compliance with Decree-Law No. 49.398 of 1969. The licensing procedure takes place in three stages, each one of which results in delivery of a preliminary licence for site approval, construction and operation, respectively.

The application for a preliminary licence for site approval must contain all the information required to assess the technological, economic and safety aspects of the installation concerned, and the local population must be informed of the application by notification in the Official Gazette [Sections 2 and 3]. When a preliminary licence is granted, the applicant must then apply for a construction licence and attach a preliminary safety report [Section 6]. Requests for a construction licence are examined from the viewpoint of the design of the facility, construction techniques, etc. The operating licence is then issued on the basis of a final safety report.

Nuclear facilities must be inspected regularly, in accordance with the provisions of Decree-Law No. 48.568 of 4 September 1968. The inspections are scientific and technical and are intended to check the effectiveness of radiation protection and nuclear safety measures. The Environment Institute (IA) is the authority in charge of inspections from the viewpoint of nuclear safety [Decree-Law No. 425/91, Section 1].

The General Directorate for Health, with the support of the General Labour Inspectorate and technical assistance from other bodies is responsible for inspections and controls from the radiation protection point of view [Decree No. 9/90, Section 54].

At the international level, Portugal is a Party to the 1994 Convention on Nuclear Safety which was ratified on 20 May 1998.

b) Protection of the environment against radiation effects

Act No. 11/87 of 7 April 1987 on the environment provides the basis for the environmental policy in Portugal. Section 25 of the act deals with radioactive substances and specifies that control of any contamination likely to be caused by such substances should be undertaken as follows, with a view to preventing its effects on the health and welfare of the population:

- the effects of radioactive substances on ecosystems should be assessed;
- disposal limits should be set for chemical and physical radioactive effluents resulting from activities involving extraction, transport, conversion and use of radioactive substances;
- preventive measures should be established to respond immediately to any radioactive contamination;
- the effects of transboundry contamination should be assessed and monitored;
- rules should be set governing the transit, transfer and deposit of radioactive substances on the national territory, in the territorial seas and the exclusive economic zone.

Decree-Law No. 186/90 of 6 June 1990 was made in implementation of Council Directive 85/337/EEC on assessing the effects of certain public and private projects on the environment. It provides that approval of nuclear power plant projects and other nuclear reactor projects, as well as radioactive waste repositories, is subject to a prior environmental impact assessment [Section 2 and Annex I]. Decree No. 38/90 of 27 November 1990, made in implementation of the decree-law, specifies the procedure to be followed for environmental impact assessments. Prior to any licence being granted, the licensing authority, according to the type of project being assessed, must be provided with an environmental impact study of the planned project. The authority competent to direct the study is designated by order of the Minister for Urban Affairs, Territorial Planning and Environment [Section 3]. The study must include, *inter alia*, a description of the project, its site, operational characteristics, physical, geological, hydrogeological, ecological, and demographic data, as well as information on the quality of the environment (water, soil, etc.) [Section 2]. The public is consulted on the study and must provide its views within a given time limit [Section 4].

c) Emergency response

Decree No. 9/90 of 19 April 1990 provides for emergency response in the event of an accident or emergency. In the context of the radiation protection plan for installations to be submitted to the General Directorate for Health, the person responsible for the installation involved must include a plan of action in the event of accidental exposure to radiation or emergency situations in accordance with the intervention plan specified in the decree [Section 7]. The General Directorate for Health, on its own initiative or on proposal of the competent authority, the Environment Institute, and following consultation with the National Radiation Protection Commission, establishes intervention plans including measures to be adopted in emergency or accident situations likely to involve abnormal radiation levels for workers and members of the public [Section 46(1)]. Those measures must take into account radiation protection rules so as to be fully effective [Section 46(2)]. In an accident situation, the General Directorate for Health immediately informs the competent authorities, namely the National Service for Fire and Civil Protection, on the methods of intervention in terms of personnel and equipment it considers necessary for protecting public health [Section 46(3)].

The Environment Institute is the national contact point for radiological emergencies occurring outside Portugal's borders and the National Service for Fire and Civil Protection is the contact point for radiological emergencies occurring within Portuguese jurisdiction.

Where the magnitude of the accident so warrants, the competent authorities inform the EU Member States likely to be affected by its occurrence [Section 46(4)].

Portugal is a Party to the 1986 Convention on Early Notification of a Nuclear Accident, which was ratified on 30 April 1993. Portugal has also ratified the 1986 Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, which was ratified on 12 September 2003.

5. Trade in Nuclear Materials and Equipment

The regulations on trade in nuclear materials and equipment in Portugal can be found in Decree-Law No. 375/90 which provides for the physical protection of nuclear materials on the national territory. The Environment Institute is the competent authority regarding physical protection matters.

Accordingly, the import, manufacture, possession, purchase, sale or transfer of nuclear material, as well as its transport whether national or international when it takes place on the national territory, are subject to prior licensing by the Environment Institute, without prejudice to the competence assigned to other authorities [Section 3].

Also, Decree No. 165/02 on radiation protection provides that the import of radioactive materials and that of equipment emitting radiation for scientific, medical or industrial purposes as well as for any activity involving the production of ionising radiation requires a prior licence from the General Directorate for Health following consultation of the National Radiation Protection Commission.

In accordance with Decree-Law No. 72/91 on medical products and equipment for human use, the marketing of medical products containing radionuclides requires a licence from the Ministry of Health, following consultation with the General Directorate for Pharmaceutical Questions [Sections 2 and 30]. Applications for such licences are described in Section 6 "Radiation Protection" *infra*.

6. Radiation Protection

The radiation protection of workers and the public is governed by several decree-laws including, *inter alia*, No. 348/89 of 12 October 1989, as well as 2002 Decree Nos. 165/02, 167/02 and 174/02. Decree-Law No. 348/89 established the National Radiation Protection Commission as an advisory body to the General Directorate for Health and set out the institutional framework for radiation protection. Decree-Law on the protection of the population against the dangers of ionising radiation [No. 165/02 of 17 July 2002] aims to implement part of Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation. It sets out the basic principles governing radiation protection and describes the powers and duties of the different authorities involved in this field. The General Directorate of Health is responsible for issuing licences for installations and equipment producing ionising radiation and the General Directorate for Geology and Energy is empowered to issue licences for nuclear fuel cycle installations. The Regional Health Authorities conduct inspections and control radiological installations. This decree-law applies to all practices involving natural or artificial ionising radiation sources. It incorporates the principles of justification,

dose limitation and the ALARA principle in respect of exposure and provides for the notification of any practice involving ionising radiation. Decree No. 9/90 of 19 April 1990, made in implementation of Decree-Law No. 348/89 [Section 15], establishes the basic principles of radiation protection applicable to occupationally exposed persons, to individuals and to the public at large. It implements Council Directives 80/836/, 84/467/ and 84/466/Euratom which contain basic radiation protection standards and lay down safety measures for radiation protection of persons undergoing medical treatment. It should be noted however that this decree-law is only applicable in accordance with Decree-Law No. 165/02. Radiation protection provisions are also to be found in Decree No. 34/92 relating to uranium mining and related activities, referred to under Section 2 "Mining Regime" *supra*.

Decree-Law No. 348/89 is still applicable in all areas not regulated by Decree-Law No. 165/02, for example, in matters concerned with nuclear third party liability.

As mentioned above, the Decree-Law No. 165/02 provides that the General Directorate for Health within the Ministry for Health is responsible for radiation protection on the national territory and sets up a National Radiation Protection Commission to advise the General Directorate on radiation protection matters and related legislation [Sections 1 and 2]. The operation of radiation-emitting devices or equipment is subject to a prior licence delivered by the General Directorate for Health [Section 1].

Decree No. 9/90 defines the duties of persons responsible for installations or activities likely to involve exposure to radiation [Sections 3 to 6]. In particular, they must submit to the General Directorate for Health, for approval, a radiation protection plan to be applied in their installations or which will cover their activities, as the case may be; the plan must include measures for regular control of all radiation protection devices [Section 7].

The decree makes a distinction between occupationally exposed persons, individual members of the public and the population as a whole [Section 2] and provides for different annual dose limits according to each category as specified in annex [Section 31]. The annual dose limit for occupationally exposed persons is 50 mSv (5 rem), subject to a cumulative limit of 100 mSv for any five consecutive years, while the limit for members of the public is 5 mSv (0.5 rem) [Annex IV].

The decree allows certain exemptions from the prior licensing requirements provided under Section 7 of Decree-Law No. 348/89 [Section 36]; these exemptions are listed in Annex II. Decree No. 3/92 of 6 March 1992 amends Section 36, specifying that such exemptions do not apply to radioactive substances administered for diagnosis, research or treatment or to foodstuffs, medical products, household articles, cosmetics or toys containing radioactive substances. Decree-Law No. 337/01 on the treatment of food by ionising radiation aims to implement Directive 1999/2/EC of 22 February 1999 of the European Parliament and of the Council on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation and Directive 1999/3/EC of 22 February 1999 of the European Parliament and of the Council on the establishment of a community list of foods and food ingredients treated with ionising radiation. It applies to the manufacture, trade and import of food and food ingredients treated with ionising radiation.

The decree-law establishes the conditions which must be fulfilled for authorisation of the treatment of foodstuffs with ionising radiation. It also establishes conditions governing the import of foods and food ingredients from third countries.

The General Directorate of Health has competence to approve the design and operation of installations where such treatment takes place. It is obliged to retain records for several years on each used radiation source, and on the nature and quantity of irradiated food and food ingredients.

Order No. 53/71 of 3 February 1971 approving general health and safety regulations for workers in industrial facilities provides that premises where radioactive substances or radiation-emitting devices are used, handled or produced must comply with the special safety regulations in force [Section 28].

As explained under Section 2 "Mining Regime" *supra*, Decree No. 34/92 of 4 December 1992 regulates radiation protection in uranium mining and related activities. Persons in charge of such activities must submit to the General Directorate for Health the protection and safety plan to be applied in their installations, or which will cover their activities, as the case may be; in particular, the plan must include measures for regular monitoring of radiation protection devices. Such persons must also inform workers of the possible risks and the measures to be complied with to avoid exposure to radiation, and ensure that they are observed [Section 6]. For their part, workers must comply with such measures and use the equipment and dosimeters provided for their protection; they must also take every precaution to keep such equipment in good condition [Section 7].

This decree also calls for an administrative service to ensure compliance with the safety provisions required by the decree as well as with specified radiation levels [Section 27]. The Radiological Protection Service must be made up of at least one technician specialised in radiation protection who will co-ordinate the Service, one physician and one ventilation specialist [Section 28].

Decree-Law No. 72/91 of 8 February 1991 lays down regulations for the manufacture, marketing and quality control of medical products and apparatus for human use. The regulations take account of a series of directives on this subject issued by the European Community and establish a licensing system for medical products and apparatus, including those containing radioisotopes [Section 4].

The manufacture of medical products containing radioactive substances and their marketing is subject to prior licensing [Sections 30 to 32]. In addition to information to be provided in licence applications for all medicines (e.g. information on the applicant, composition of medicine, intended use, etc.), applications for licences to market irradiating apparatus must also contain a general description of the system and the qualitative and quantitative characteristics of the radioactivity released [Section 31]. The Decree-Law provides that its provisions are without prejudice to the application of the radiation protection legislation in force [Section 35].

Decree-Law No. 36/95 of 14 February 1995 implements into national law Council Directive 89/618/Euratom of 27 November 1989 on informing the general public of the health protection measures to be applied and steps to be taken in the event of a radiological emergency.

Decree-Law No. 153/96, adopted on 10 August 1996, regulates activities involving the use of sealed radioactive sources which could pose a risk of ionising radiation exposure or of radioactive contamination, so as to ensure the protection of the public and of the environment [published in *Diario da Republica*, 30 August 1996].

With the entrance into force of Decree-Law No. 165/02, the Technological and Nuclear Institute (ITN) becomes the licensing authority for the possession, sale, transport, import and any other transfer of sealed sources. Persons responsible for such acts must submit a request for a licence to the ITN in accordance with the prescribed conditions of Decree No. 156/96 and the criteria set forth jointly by the Ministers for Health, for Urban Affairs, Territorial Planning and Environment, and for Science and Higher Education, or on the advice of the General Directorate for Health. A public register of all licensees is to be kept.

Decree-Law No. 492/99, of 17 November 1999 [as amended by Decree-Law No. 240/00, of 26 September 2000] approves the legal regime for licensing and inspection of private medical facilities that use ionising radiation for diagnostics, therapy and prevention. This decree-law sets out conditions governing installations and organisation of private medical facilities.

The Decree-Law on protection against ionising radiation in relation to medical exposure [No. 180/02 of 8 August 2002] aims to implement Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure. This decree-law sets out conditions governing the control and inspection of radiological equipment and installations and the duties and responsibilities of the owner and personnel of medical facilities.

7. Radioactive Waste Management

Decree-Law No. 348/89 of 12 October 1989 provides that the storage and disposal of radioactive products or waste require a licence from the General Directorate for Health, following consultation with the National Radiation Protection Commission [Section 8].

Decree No. 9/90, which implements Decree-Law No. 348/89, specifies the principles governing radioactive waste management. It provides that the disposal and storage of radioactive waste must be planned in such a way as to avoid or reduce its dispersal into the environment, whether under normal or emergency conditions [Section 44]. Furthermore, in order to obtain a licence from the General Directorate for Health, the applicant must submit an environmental impact assessment, information on the planned radiation protection and nuclear safety measures and operations as well as storage conditions, whether temporary or final [Section 45(1) and (2)]. The General Directorate for Health grants a licence, provided that all the radiation protection and nuclear safety measures it has approved have been complied with, and also fixes a dose limit for radioactive releases, taking into account the need to keep radioactivity levels in the environment as low as possible [Section 45(3) and (4)].

In accordance with Decree No. 34/92 of 4 December 1992 on radiation protection in uranium mining and related activities, products resulting from prospecting deposited in slag heaps must be monitored to control their radioactivity levels; adjacent areas must also be monitored so as to detect the quantity of radionuclides released into bodies of water, sediments or the air [Section 64(1)]. Premises where radioactive residues from uranium treatment are stored must be kept in such a way as to ensure that dust releases are reduced to a minimum [Section 64(2)]. Repositories for radioactive waste must be established in accordance with the most recent recommendations of the International Atomic Energy Agency. Plans for repositories must provide guarantees that they will remain stable for periods running from 200 to 1 000 years, taking into account extreme technical and meteorological phenomena [Section 65(1)]. The disposal into the environment of radioactive materials from facilities for the treatment of ores and uranium recovery must be carried out in compliance with the radiation dose limits set by the Environment Institute (*Instituto do Ambiente* – IA) [Section 67].

Also, Order No. 16/90 of 21 August 1990 provides for the treatment of solid hospital residues of all types. It specifies that radioactive waste must be disposed of in accordance with the regime established by Decree-Law No. 348/89 and Decree No. 9/90 [Section 3(5)].

Decree-Law No. 138/96 of 25 July 1996 aims to incorporate into Portuguese domestic law Council Directive 92/3/Euratom on the monitoring and control of shipments of radioactive waste between Member States, as well as their entry into and exit from the European Community [published in *Diario da Republica*, 14 August 1996]. The decree-law describes in detail the licensing procedure

for each import, export or shipment of radioactive waste within the Community, between a third country and the Community, or between two third parties where part of the shipment crosses the territory of a Member State of the Community. The Environment Institute is, in principle, the agency with jurisdiction to grant licences and to define the transfer of procedures. Permission may be given to return waste resulting from the reprocessing of irradiated fuel to the country of origin where such fuel originated in that country or it was agreed in advance by the parties that such waste would be returned.

The Technological and Nuclear Institute is responsible for the temporary storage of solid radioactive waste and for authorising the transfer of radioactive waste inside its borders and within the European Union [Decree-Law No. 165/02 – Section 14(c) and (j)].

Finally, Portugal is a Party to the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and other Matter, which it ratified on 14 April 1978.

8. Non-Proliferation and Physical Protection

Portugal has no domestic legislation on non-proliferation. However, it is a Party to the 1968 Treaty on the Non-Proliferation of Nuclear Weapons (NPT), which it ratified on 15 December 1977, and has concluded the subsequent safeguards arrangement with the International Atomic Energy Agency on 7 August 1978 [IAEA INFCIRC/272]. Resolution No. 102/01 of 29 August 2001 establishes the National Authority for matters related to the NPT.

Decree-Law No. 319/03 of 20 December 2003 establishes the ITN as the entity responsible for implementation of the Additional Protocol to the NPT Treaty and as national contact for issues related to the Additional Protocol.

Portugal is also a Party to the 1979 Convention on the Physical Protection of Nuclear Material, ratified on 6 September 1991. Following the adoption of Presidential Decree No. 14/90 of 15 March 1990 authorising ratification of the Convention, Decree-Law No. 375/90 of 27 November 1990 designates, in accordance with the Convention, the Office for Nuclear Protection and Safety (*Gabinete de Protecção e Segurança Nuclear* – GPSN) as the competent authority in relation to physical protection matters [Section 2]. Subsequently, the Environment Institute has assumed the rights and responsibilities of the GPSN.

9. Transport

The Regulations for the Transport of Dangerous Goods [Order No. 977/87 of 31 December 1987] deal with radioactive substances under Class 7, in accordance with the recommendations of the International Atomic Energy Agency.

Decree-Law on the Transport of Dangerous Goods by Road [No. 267-A/03, of 27 October 2003] aims to implement Commission Directive 2001/7/CE of 29 January 2001 and Commission Directive 2003/28/CE, of 7 April 2003 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road. The decree-law creates sanctions for non compliance with legal requirements. It further establishes the following bodies as competent to evaluate the technical condition of vehicles, traffic conditions and road security: the General Inspectorate for Public Construction, Transport and Communications, the General Directorate of Traffic, the regional Directorates for Economic Affairs, the Republic National Guard, the Public Security Police and the General Inspectorate for Economic Activities.

The Decree-Law on the Transport of Dangerous Goods by Sea [Law No. 169/00 of 8 August 2000], modifies Decree-Law No. 94/96 and aims to implement Council Directive 93/75/EEC of 13 September 1993 concerning minimum requirements for vessels bound for or leaving European Community ports and carrying dangerous or polluting goods.

The Decree-Law on the Transport of Dangerous Goods by Rail [No. 227-C/2000 of 22 September 2000] aims to implement Council Directive 96/49/EC of 23 July 1996 and Commission Directives 96/87/EC of 13 December 1996 and 1999/48/EC of 21 May 1999 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail. It applies to all activities involving the transport of dangerous goods or waste by rail taking place, in part or whole, on national territory. This includes all loading and unloading operations and also the transfer to another type of vehicle or breaks due to transport conditions. The National Institute of Rail Transport is responsible for enforcing these rules.

Decree-Law No. 348/89 provides that the regulations on radiation protection in force apply to the transport of radioactive substances [Section 1]. Decree No. 9/90, made in implementation of this decree-law specified that the transport of radioactive materials requires a licence delivered by the General Directorate for Health. These responsibilities have been taken over by the Environment Institute [Decree-Law No. 97/03], and the Technological and Nuclear Institute [Decree-Law No. 165/02] is the authority delivering licences for the transport of sealed radioactive sources.

Decree-Law No. 165/02 states that the Technological and Nuclear Institute assesses and examines the conditions for the safe transport of fresh or spent nuclear fuel and for the transport of radiation sources for nuclear installations as well as radioactive waste from such installations. [Section 14(i)].

Decree-Law No. 72/91 on medical products and apparatus for human use specifies, as regards medicines containing radionuclides and irradiating apparatus, that they must be packed in accordance with the requirements set out in the International Atomic Energy Agency's Regulations for the Safe Transport of Radioactive Materials, and that their labels must indicate their levels of radioactivity [Section 33].

10. Nuclear Third Party Liability

Portugal has not yet enacted specific nuclear third party liability legislation. However, Decree-Law No. 348/89 on radiation protection provides that the person responsible for installations, equipment or materials emitting ionising or non-ionising radiation is liable for damage resulting from their use, unless it is proved that at the time the damage was caused, the installations, equipment or materials had been used in conformity with the technical rules in force and were in perfect condition, or the damage was due to a case of *force majeure* [Section 10]. Such persons, with the exception of the state or public entities, must cover their liability through an insurance company authorised to operate in Portugal, in accordance with regulations to that effect, to be established by decree [Section 11].

Some special provisions of Decree-Law No. 153/96 of 10 August 1996, concerning the use of sealed radioactive sources, also cover third party liability. This decree-law establishes that licence-holders are strictly liable for damage caused to persons, to property and to the environment by a sealed radioactive source, even if they have complied with applicable legal requirements [Section 3]. At the international level, Portugal is a Party to the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy, which it ratified on 29 September 1977.

II. INSTITUTIONAL FRAMEWORK

In Portugal, responsibility for the control and management of nuclear activities is vested in the Minister for Economic Affairs and the Minister for Finance, the Minister for Urban Affairs, Territorial Planning and Environment, the Minister for Health and the Ministry for Science and Higher Education as mentioned in Part I of this Study.

Decree-Law No. 358/76 of 14 May 1976 provides for the general organisation of the Ministry for Industry and Energy and also provides for greater involvement of the state in such matters. Based on that decree-law, Decree-Law No. 548/77 of 31 December 1977 set up new departments within the Ministry and closed down others, in particular the *Junta de Energia Nuclear*. Order No. 126/78 of 31 May 1978 reorganised the energy sector, in particular to combine nuclear energy with the overall energy sector and to merge nuclear activities with other industrial and research activities.

1. Regulatory and Supervisory Authorities

a) Minister for Economic Affairs

The Minister for Economic Affairs is responsible for nuclear policy in Portugal. He is empowered to prepare and propose the energy and industry plan within the general national development programme; he supervises and directs the management of public and nationalised companies in the industry and energy sector, without prejudice to the competence of other ministers concerned, and he promotes research and development in that sector as well as agreements on technical and scientific co-operation; he also controls activities in the industrial and energy sectors [Decree-Law No. 186/03 of 20 August 2003, Chapter 1].

More generally, he makes proposals in respect of industrial and technological policy and is responsible for the implementation of these policies in the framework of the general policy determined by the government.

b) Minister for Health

The Minister for Health is competent for all questions of radiation protection through the General Directorate for Health [Decree-Law Nos. 165/02, 167/02, 174/02, 180/02 and Decree-Law No. 348/89]. The Minister is empowered to make regulations in his field of competence [Decree-Law No. 10/93 of 15 January 1993, Section 1].

c) Minister for Urban Affairs, Territorial Planning and Environment

The Minister is the supervising authority of the Environment Institute. It is also responsible for uranium mining and related activities [Decree-Law No. 97/03 of 7 May 2003]. According to Decree-Law No. 165/02, it is the competent authority for the approval of mining areas that need to be recovered.

According to Decree No. 38/90 of 27 November 1990, implementing Decree-Law No. 186/90 of 6 June 1990, it plays a direct role in the protection of environment against radiation effects, since it

designates the competent authority to direct the environmental impact study that is required prior to any licence being granted for nuclear power plant projects and other nuclear reactor projects [Section 3].

d) Minister for Science and Higher Education

The Ministry for Science and Technology [Decree-Law No. 296-A/95 of 17 November 1995] is now the Ministry for Science and Higher Education [Decree-Law No. 205/02 of 7 October 2002]. The latter is involved in Portuguese nuclear energy policy through the activities of the Technological and Nuclear Institute [Decree-Law 324-A/94], for which it is responsible.

e) Minister for Finance

The Minister for finance is involved in the nuclear energy policy as, in this field, the Minister for Economic Affairs acts in co-ordination with it. The Minister for finance is generally competent, together with the Minister for Economic Affairs, for financing public industrial activities [Decree-Law No. 40.135 of 20 April 1955], and for establishing customs duties in connection with radioactive ores and products made therefrom.

As regards the National Uranium Enterprise (*Empresa Nacional de Urânio* – ENU), the Minister for Economic Affairs, jointly with the Minister for Finance had originally established by decree the authorised capital of the Company [Decree No. 490/76 of 23 June 1976], before it was transformed into a private limited company (see *infra*, under Section 3 "Public and Semi-Public Agencies").

In connection with the National Industrial Engineering and Technology Institute (*Instituto Nacional de Engenharia e Tecnologia Industrial* – INETI), the Minister for Finance and the Minister for Economic Affairs are empowered to establish by order the conditions of operation of the INETI Administrative Board [Decree-Law No. 361/79 of 1 September 1979, Section 13].

2. Advisory Bodies

a) National Radiation Protection Commission (CNPCR)

The National Radiation Protection Commission (*Comissão Nacional de Protecção contra Radiações* – CNPCR) was originally set up within the General Directorate for Health by Decree-Law No. 348/89 [Section 4]. Decree-Law No. 165/02 granted additional competences to the Commission. It has an advisory task and is made up of representatives of the following:

- the General Directorate for Health, which holds the chair;
- specialists in nuclear medicine, radiology, radiotherapy and dermatology from departments of the College of Physicians;
- the College of Dentists;
- the Technological and Nuclear Institute;

- the Institute for Development and the Inspectorate for Working Conditions;
- the General Directorate for Geology and Energy.

The CNPCR advises the General Directorate for Health on all questions within its competence. The Chairman of the CNPCR may set up working groups made up of members of the Commission and other specialists to study and assess specific questions in its field [Section 21].

b) Commission for Radiological Protection and Nuclear Safety

Decree-Law No. 311/98 of 14 October 1998 established the Commission for Radiological Protection and Nuclear Safety (*Comissão para a Proteccão Radiologica e Segurança Nuclear*) whose principal objective is to minimise risks to public health and to the environment as a result of ionising radiation, radioisotopes and nuclear installations.

This Commission comprises representatives from the three ministries competent in this field, namely the Ministry for Urban Affairs, Territorial Planning and Environment, the Ministry for Health and the Ministry for Science and Higher Education.

The decree-law entrusts the Commission with the following duties:

- to draft bills and regulations in the above-mentioned sectors;
- to verify compliance with conditions set out in licences for the storage, production or transport of radioactive material and equipment or for nuclear installations which generate radioactive residues or nuclear waste;
- to guarantee the respect of international obligations related to radiological protection and nuclear safety;
- to co-operate with similar bodies working in these fields in other countries and with the competent international organisations;
- to assist in the preparation of national radiological and nuclear emergency plans.

Technical assistance is provided to the Commission by the Technological and Nuclear Institute (*Instituto Tecnológico e Nuclear* – ITN), through its Department of Radiological Protection and Nuclear Safety. This Department was formerly part of the General Directorate for the Environment, before its transfer to the ITN pursuant to Section 4 of Decree-Law No. 311/98 mentioned above. The tasks assigned to this Department are listed in the decree-law and are of a strictly technical nature in order to guarantee that it complement the Commission's duties.

c) National Commission for Radiological Emergencies (CNER)

Decree-Law No. 165/02 established the National Commission for Radiological Emergencies (*Comissão Nacional para Emergências Radiológicas*). It carries out advisory functions and is made up of representatives from the following organisations:

- the National Service for Fire and Civil Protection, which holds the chair;
- the General Directorate for Health;
- the National Institute for Medical Emergencies;
- the Environment Institute;
- the Meteorology Institute;
- the Commission for the Planning of Agriculture, Fisheries and Emergency Food ;
- the Technological and Nuclear Institute;
- the General Directorate for Geology and Energy.

The CNER advises the National Service for Fire and Civil Protection on all questions within its competence. The Chairman of the National Radiation Protection Commission (CNPCR) may establish working groups comprised of members of the CNER and other specialists to study and assess specific questions in its field [Section 23].

The Commission has competence to enter opinions on emergency plans and to collaborate with the National Service for Fire and Civil Protection in preparatory actions for radiological national emergencies.

3. Public and Semi-Public Agencies

The different departments under the Ministries for Economic Affairs, Health and Urban Affairs, Territorial Planning and Environment enjoy a certain extent of autonomy and, in view of their responsibilities, it is appropriate to discuss them in this part of the study.

a) General Directorate for Geology and Energy (DGGE)

The General Directorate for Geology and Energy (*Direcção Geral de Geologia e Energia* – DGGE), is under the authority of the Ministry for Economic Affairs [Decree-Law No. 186/03, of 20 August 2003]. It covers the operational aspects of the whole energy sector, namely, the production, transport, distribution and use of various forms of energy, including nuclear energy

The DGGE is run by a director-general and two deputy-directors.

b) Institute for Geology and Mines (IGM)

As explained in Part I, Section 1 "Introduction" *supra*, the General Directorate for Geology and Mines was restructured into the Institute for Geology and Mines (*Instituto Geologico e Mineiro* – IGM) by Decree-Law No. 122/93 of 16 April 1993. The IGM is under the authority of the Ministry of Economic Affairs and is generally responsible for the management of mineral resources [Decree-Law No. 548/77, Section 7]. In particular, it is responsible for prospecting for, inventorying and assessing radioactive ores [Decree-Law No. 122/93 of 16 April 1993, Section 18].

c) Environment Institute (IA)

The Environment Institute (*Instituto do Ambiente*) is a public entity created under the Ministry for Urban Affairs, Territorial Planning and Environment, which is responsible for continuing environment and sustainable development policies [Decree-Law No. 97/03 approving the Organic Law of Ministry for Urban Affairs, Territorial Planning and Environment, 7 May 2003]. The Environment Institute was established by merging the former Directorate for the Environment (*Direcção Geral do Ambiente* – DGA) with the Environmental Promotion Institute.

Decree-Law No. 97/03 defines, *inter alia*, the IA's responsibilities, which are to co-ordinate activities related to environment and public safety. In this respect, it is in charge of early notification in the event of a nuclear accident and is in charge of the assessment of the risks posed by radiation emissions. The Environment Institute is chaired by a president and two vice-presidents. Decree-Law No. 113/03 details the internal structure of the Environment Institute.

d) National Industrial Engineering and Technology Institute (INETI)

The National Industrial Engineering and Technology Institute (*Instituto Nacional de Engenharia e Tecnologia Industrial* – INETI), previously under the authority of the Ministry for Industry and Energy [Decree-Law No. 548/77], is now under the authority of the Ministry for Economic Affairs [Decree-Law No. 296/95 of 17 November 1995]. It incorporates the Nuclear Energy and Engineering Institute, formerly the Research Centre of the JEN.

As already explained, the National Laboratory of Industrial Engineering and Technology was merged into the above Institute (INETI) by Decree-Law No. 240/92 of 29 October 1992. Order No. 592-A/93 of 15 June 1993 sets out the internal organisation and operation of the Institute.

i) Legal Status

The INETI is an institute for technological research and development which provides support to the different industrial sectors in the ambit of the Ministry of Economic Affairs [Section 24]. It is endowed with the status of a separate legal entity, owns property and enjoys administrative and financial autonomy [Decree-Law No. 361/79 of 1 September 1979, Sections 1 and 2].

ii) Responsibilities

The responsibilities of the INETI are the following [Decree-Law No. 548/77, Section 24]:

- to undertake applied research in accordance with the objectives of the national programme;
- to provide technological assistance to industrial undertakings, with a view to improving manufacturing processes and supplying innovative techniques;
- to provide the analytical assistance required for quality control of products and related inspection and technical surveillance;

- to collect, co-ordinate and disseminate information of interest to the ministerial services and undertakings concerned;

- to train specialists in techniques of interest to the different industry sectors.

In particular, the INETI co-ordinates and carries out research and development programmes and projects directly related to industrial development, through contracts with industrial undertakings or in association with national or international bodies [Decree-Law No. 361/79, Sections 5 and 6]. INETI is also responsible for promoting, participating in and ensuring co-operation with similar foreign and international agencies in the technological, energy and industrial fields, and participates in international scientific and technical co-operation agreements [Ordinance No. 172/79].

iii) Structure

The INETI is made up of institutes, technical and scientific services, central services and regional delegations [Order No. 592-A/93, Annex, Section 4].

The governing bodies of INETI are the Board of Management, the Technical Board and the Inspectorate [Section 2].

iv) Financing

In addition to funds allotted from the general state budget, the revenue of INETI is derived from remuneration for services supplied to public and private undertakings as well as income from property and profits from patented inventions.

e) Technological and Nuclear Institute (ITN)

Decree-Law No. 324-A/94 of 30 December 1994 established the Technological and Nuclear Institute (*Instituto Technológico e Nuclear* – ITN) to replace the Nuclear Energy and Engineering Institute (ICEN).

i) Legal Status

The Institute has the status of a separate legal entity and was given scientific, technical and, administrative autonomy under the supervising authority of the Ministry for Land Planning and Administration. Following the establishment of the thirteenth Portuguese constitutional government in 1995, supervision over ITN was transferred to the Ministry for Science and Technology [Decree-Law No. 296-A/95 of 17 November 1995], which is now the Ministry for Science and Higher Education [Decree-Law No. 205/02 of 7 October 2002].

ii) Responsibilities

The ITN is, in particular, responsible for:

- promoting and undertaking scientific research and technical development in the peaceful applications of nuclear energy;
- providing scientific and technical assistance to the government when implementing its policies on nuclear safety, pharmaceutical and meteorological control, as well as in the application of both radioisotopes and ionising radiation;
- organising and undertaking training in the above fields;
- ensuring technology transfers to public and private agencies;
- establishing exchanges with national, international and foreign institutes pursuing the same objectives; and
- studying and implementing bilateral and multilateral co-operational programmes in its field of competence.

Decree-Law No. 165/02 and Decree-Law No. 167/02 entrusted the ITN with further tasks. It is the now responsible for monitoring the environment in mining areas and for licensing possession, sale, transport, import and any other transmission of sealed sources. In particular, Decree-Law No. 165/02 states that the Technological and Nuclear Institute shall assess and examine the conditions for the safe transport of fresh or spent nuclear fuel and for the transport of radiation sources for nuclear installations as well as radioactive waste from such installations [Section 14(i)]. It is also responsible for the temporary storage of solid radioactive waste and for authorising the transfer of radioactive waste on national territory and within the European Union [Decree-Law No. 165/02 – Section 14 (c) and (j)].

In addition, Decree-Law No. 319/03, of 20 December 2003 establishes the ITN as the entity responsible for implementation of the Additional Protocol to the NPT treaty and as national contact for issues related to the Additional Protocol.

iii) Structure

The structure and internal organisation of ITN is established by Decree-Law No. 324-A/94 of 30 December 1994.

iv) Financing

The ITN is financed in two ways: partly through the General State Budget that allocates funds annually and partly through income from the supply of services to public and private organisations [Decree-Law No. 324/94 of 30 December 1994, Sections 1 and 5].

f) National Uranium Enterprise (ENU)

i) Legal Status

Originally the National Uranium Enterprise (*Empresa Nacional de Urânio* – ENU) was a public corporation pursuant to Decree No. 67/77 of 6 May 1977 which established this Enterprise. However, Decree-Law No. 376/90 of 30 November 1990 of the Minister for Economic Affairs converted it into a private limited company, with the majority of shares held by the state [Section 1]. It retains its legal personality and the rights and obligations it held when it was converted [Section 2].

ii) Responsibilities

According to its Statute [Decree-Law No. 376/90, Annex, Chapter I, Section 3], the purpose of the ENU is to prospect for uranium and other nuclear ores, market those substances and provide related services and supplies, study the advantages of other natural and energy sources and related activities.

iii) Structure

The governing bodies of the ENU are a General Assembly, made up of its shareholders which hold voting rights (one hundred shares equals one vote), a board of directors, made up of a chairperson, and a maximum of six members and a board of controllers made up of one chairperson, two members holding voting rights and an alternate member, elected by the General Assembly [Statute of the ENU].

The General Assembly examines the reports of the board of directors and the board of controllers, and studies the application of measures requested; it elects from among the shareholders and other persons the directors and members of the board of controllers. It may furthermore authorise the setting up of companies and deals with any business for which it has been convened, within the limits of its legal attributions [Statute of the ENU, Section 10].

The General Assembly is convened and chaired by the chairperson of the Assembly's Bureau, made up of the chairperson and vice-chairperson and a secretary, elected by the General Assembly [Section 11(1)]. It is convened at thirty days' notice, and has a specific agenda [Section 11(2)]. It meets at least once a year; extraordinary meetings are held if the board of directors or the board of controllers consider it necessary, or at the request of shareholders representing at least 20% of the authorised capital [Section 12]. Decisions are adopted by a majority of the votes present or represented [Section 10(2)].

The board of directors is responsible for managing the assets of the ENU and may acquire or sell all the ENU's physical or real property, represent the ENU in court proceedings, set up companies or participate in established ones, set up the technical and administrative organisation of the Enterprise and internal operating rules, determine salaries of personnel, etc. [Statute of the ENU, Section 14(1)].

The board sets the dates and frequency of its ordinary meetings; extraordinary meetings are held at the request of the chairperson or that of two directors or two members of the board of controllers [Section 16(1)].

The board of controllers may be assisted by experts or auditors nominated specifically for this purpose. Its decisions are adopted by a majority of the votes expressed, the majority of members being present; the chairperson has a casting vote [Statute of the ENU, Section 19]. Every three months, the board of controllers must send to the Ministries for Finance and Economic Affairs a report on the controls carried out, the anomalies detected and the differences noted as compared to the estimates [Decree-Law No. 376/90, Section 6(2)].

On 2 October 1992, the ENU was merged with the holding company entitled Development Mining Enterprise (*Empresa de Desenvolvimento Mineiro* – EDM).

iv) Financing

The authorised capital of the ENU is set at Portuguese Escudos (PTE) 1 billion at present entirely subscribed by the state and made up of one million shares, each with a nominal value of PTE 1 000 [Statute of the ENU, Section 4]. The board of directors may increase the authorised capital up to a maximum of PTE 3 billion [Section 5].

SWEDEN

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I. GENERAL REGULATORY REGIME

1. Introduction

There are 11 operating nuclear power reactors in Sweden; eight are boiling water reactors and three are pressurised water reactors. There are three PWR at Ringhals (with a combined installed capacity of 3 540 MWe), three BWR at Forsmark (3 100 MWe), three BWR at Oskarshamn (2 210 MWe), one BWR at Barsebäck (600 MWe), and one BWR at Ringhals (830 MWe). In 2002 the 11 reactors produced 65.6 billion kWh, accounting for about 45.9% of Sweden's total electricity production in that year.

Several power companies (Skydraft, Mellansvesk Kraftgrupp, Fortum and Vatenfall) own the shares of the various companies licenced to operate nuclear power generating stations in Sweden. These larger companies are themselves owned by private shareholders with the exception of Vatenvall which is partly state owned. Vatenvall has a stake in every operating company except OKG AB, which operates the units at Oskarshamn.

Sweden does not reprocess spent fuel. Since 1988 Sweden's low- and intermediate-level nuclear waste is deposited in the Repository for Radioactive Operational Waste (SFR) located at Forsmark. SFR receives short-lived low- and intermediate-level waste from nuclear power plants, hospitals, industry and research facilities in Sweden. Spent nuclear fuel and other high-level nuclear waste are placed in temporary storage at the Central Interim Storage Facility for Spent Nuclear Fuel (CLAB) located near Oskarshamn.

Studvik Nuclear AB operates two operational research reactors, one tank type (50 000 kW), and one pool type (1 000 kW). The tank type reactor is used primarily for fuel testing, fuel investigations, isotope production and neutron doping of silicon. The pool reactor is used for BNCT-therapy, and supplies neutrons to the Neutron Research Laboratory.

The framework of Sweden's nuclear law is to be found in five acts:[1]

- the Nuclear Activities Act [SFS 1984:3], which concerns mainly security and control issues and the overall safety of nuclear operations;
- the Environmental Code [SFS 1998:808], which addresses environmental aspects of nuclear activities, and lists "nuclear activities" among several other "environmentally hazardous activities";
- the Radiation Protection Act [SFS 1988:220], adopted in 1988, aims to protect people, animals and the environment from the harmful effects of radiation;

1. All Swedish acts are published in the Swedish Statute Book, herein referred to as "SFS".

- the Act on the Financing of Future Charges for Spent Nuclear Fuel [SFS 1992:1537], contains provisions for the future costs of spent fuel disposal, decommissioning of reactors and research in the field of nuclear waste; and
- the Nuclear Liability Act [SFS 1968:45], which implements Sweden's obligations as a Party to the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy and the 1963 Brussels Convention Supplementary to the Paris Convention.

The provisions of the Nuclear Activities Act, the Environmental Code and the Radiation Protection Act supply the general principles of the regulatory regime. These acts are supplemented by a number of ordinances and other secondary legislation containing more detailed provisions for particular aspects of the regime. Operation of a nuclear facility can only be conducted in accordance with a licence issued under the Nuclear Activities Act and a licence issued under the Environmental Code. Thus, operation of a nuclear facility requires two separate licences.

In 1995, a number of amendments were made to the Swedish legislation on nuclear safety and radiation protection: two amendments stem from Sweden's accession to the European Union, one concerns waste disposal and another concerns exports. To this extent the Nuclear Activities Act and the Radiation Protection Act were amended to conform to European Community legislation.

The export of nuclear material and equipment is governed by the Act on Control of Export of Dual-use Products and Technical Assistance [SFS 2000:1064] and the Act on Inspections according to International Agreements on Non-proliferation of Nuclear Weapons [SFS 2000:140]. Previously, such matters had been regulated by the Strategic Products Act [SFS 1998:397].

On 18 December 1997, the Swedish parliament adopted the Act on the Phasing-Out of Nuclear Power [SFS 1997:13320], which entered into force on 1 January 1998. This act formed part of the inter-party agreement on guidelines for energy policy, which was initiated by the Swedish government in 1995 to create conditions for the efficient use and cost effective supply of energy.

2. Mining Regime

The Mineral Act [SFS 1991:45], which replaced the 1974 Act on certain mineral deposits, provides that the investigation of ore deposits and working of certain minerals are subject to a special licence. This applies to numerous minerals, including those containing uranium and thorium.

3. Radioactive Substances, Nuclear Fuel and Equipment

Both the Nuclear Activities Act [SFS 1984:3] and the Radiation Protection Act [SFS 1988:220] are relevant to this topic. The Nuclear Activities Act applies to all "nuclear activities", and these include the acquisition, possession, transfer, handling, processing, transport and other dealings with nuclear material and waste [Section 1]. Generally speaking, none of these activities may be carried on without a licence issued under the act [Section 5], although there is also provision in the act for exemptions to its requirements [Section 2(a)]. For example, universities and research institutes etc. may acquire, possess and handle small amounts of natural or depleted uranium and thorium and their compounds without a licence. Natural or depleted uranium may also be used as counterweights in aircraft or in the production of radiation-protection screens, ceramic or glass production etc. without a licence. However, the possession of the substances must be reported to the Swedish Nuclear Power Inspectorate (*Statens Kärnkraftinspektion* – SKI).

In addition, the Radiation Protection Act imposes obligations on people engaged in activities involving ionising radiation. Any dealings with radioactive substances or with equipment capable of generating or emitting ionising radiation can be carried on only in accordance with a licence issued under the act [Section 20]. However, if the activity in question is also covered by the Nuclear Activities Act, the requirement for a licence under the Radiation Protection Act is automatically waived unless stated otherwise in the licence issued under the Nuclear Activities Act [Section 23].

The Radiation Protection Act also provides that manufacturers and importers are required to provide radiation protection information about their products (by means of labelling, etc.) and to ensure that the products are fitted with appropriate radiation protection equipment [Sections 9 to 11]. Persons responsible for handling the waste that results from radiation activities must store and dispose of radioactive waste and discarded sources of radiation in a way that is "satisfactory from the viewpoint of radiation protection" [Sections 13 and 14].

In the event of serious breaches of the Radiation Protection Act, criminal sanctions may apply [Sections 35 to 37] and the radioactive substances or equipment used in such a breach may be forfeited [Section 40].

The Pharmaceuticals Act [SFS 1992:859] contains provisions imposing licence obligations for the manufacture, importation and sale of radioactive pharmaceuticals.

4. Nuclear Installations

Most aspects of Sweden's nuclear facilities are regulated by the Nuclear Activities Act [SFS 1984:3] (containing general provisions) and the Nuclear Activities Ordinance [SFS 1984:14] (containing more detailed rules).

The fundamental provisions of the act provide that nuclear activities are to be conducted in such a manner that all safety measures needed to prevent a radiological accident shall be taken [Section 3]. The act defines nuclear activities to include: the construction, possession and operation of a nuclear installation; the acquisition, possession, transfer, handling, processing, transport or other dealings with nuclear substances and nuclear waste; and the importation of nuclear substances and nuclear waste, and exportation of nuclear waste.

a) Licensing and inspection, including nuclear safety

Licences for nuclear installations are decided upon and issued by the government, with a few exceptions. The government authority with major responsibility for the administration and supervision of the licensing procedure is the Swedish Nuclear Power Inspectorate (SKI). The responsibilities for the SKI are laid down in the Ordinance with Instructions for the Swedish Nuclear Power Inspectorate [SFS 1988:523]. The SKI may attach safety conditions to any licence it issues under the act [Section 8], and has the power to require access to the site where nuclear activities are carried to obtain any information or documentation needed to ensure compliance with the act [Section 17]. The SKI may give directions to a licencee in a particular situation to ensure compliance, and if the licencee fails to take the necessary action, it may proceed to carry out the action at the licencee's expense [Section 18]. The act also contains criminal sanctions for non-compliance with its requirements [Sections 22, 25-29].

The act places responsibility for the safety of every aspect of a nuclear activity squarely with the person who is the licence-holder in respect of that activity. In addition to a general responsibility to maintain safety, the licence-holder is responsible for ensuring the safe handling and final storage of nuclear waste arising from the activity and the safe shut-down and decommissioning of plants in which nuclear activities are no longer conducted [Section 10]. If the licencee fails to comply with conditions attached to the licence or with safety obligations arising in any other manner under the Nuclear Activity Act, the government or the SKI has the authority to revoke the licence altogether [Section 15]. The decision lies with the authority that has issued the licence.

Although the SKI carries the main responsibility and authority in relation to the operation of nuclear installations, the Swedish Radiation Protection Institute (*Statens Strålskyddsinstitut* – SSI) also participates in inspections of installations in order to ensure compliance with the Radiation Protection Act [SFS 1988: 220].

It is mandatory to submit an Environmental Impact Assessment (EIA) together with an application for a permit to construct, possess or operate a nuclear installation. The EIA aims to facilitate an overall assessment of the planned operation's effects on the environment, health and management of natural resources, thus providing a better basis for deciding whether to issue a licence. Procedures for carrying out the EIA are contained in the Environmental Code. The government or appropriate appointed authority may issue regulations calling for an EIA to be included in an application for permits for nuclear matters other than those mentioned.

The Act on Nuclear Activities was amended in 1987 to prohibit the issue of a licence for the construction of a nuclear power reactor [Section 5(a)]. This 1987 amendment reflected parliament's decision after a referendum held in 1980, following which the Swedish parliament decided that no new nuclear power facilities would be constructed in Sweden, and that existing facilities should gradually cease operations. At the time that this policy was announced, it was envisaged that the last nuclear power reactor in Sweden would cease to operate in 2010. That specific date is no longer topical on the political agenda. The licensing provisions will continue to apply in relation to the operation of those nuclear power facilities that had already been constructed at the time of the 1987 amendments. Thus, the only new installations to be subject to the act's licensing procedure will be those constructed for the handling, storage and final disposal of nuclear waste, including spent nuclear fuel.

In 1995 an inter-party agreement was made between the parties forming the majority in the parliament on guidelines for a new Swedish energy policy. The aim was to create conditions for the efficient use and cost-effective supply of energy, thereby facilitating the creation of an "ecologically sustainable society". As a result of this agreement, the Act on the Phasing-out of Nuclear Power was adopted in 1997 and entered into force on 1 January 1998.

The Phasing-out Act gives the Swedish government the right to revoke a permit to operate a nuclear power reactor. It further provides that the order and timing of closures will depend on the transformation of the energy system. In deciding when a reactor should be taken out of operation, due regard should be taken of its location, age, design, and its importance for the national energy supply system. The act confirms that the licensee is entitled to compensation from the state for losses incurred due to a forced closedown.

On the basis of this act, the Swedish government decided on February 5, 1998 that the nuclear power reactor Barsebäck No. 1 was to be closed down. The state and the reactor owner reached an agreement, approved by the parliament, pursuant to which reactor Barsebäck No. 1 was closed 30 November 1999.

At the international level, Sweden has ratified:

- the 1994 Convention on Nuclear Safety (on 11 September 1995);
- the 1997 Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (on 29 July 1999);
- the 1986 Convention on Early Notification of a Nuclear Accident (on 27 February 1987); and
- the 1986 Convention on Assistance in the Case of Nuclear Accident or Radiological Emergency (on 24 June 1992).

b) Protection of the environment against radiation effects

The Act on Nuclear Activities was amended in 1998 to incorporate references to the Environmental Code [SFS 1998:808]. The amendments, which entered into force on 1 January 1999, state that the General Rules of Consideration and the Environmental Quality Standards of the Environmental Code shall apply when considering matters under the Nuclear Activities Act. In the preparatory work to the Environmental Code the operation of nuclear installation is specified as an example of a hazardous activity.

i) The Environmental Code

The General Rules of Consideration state that operations must be conducted and measures taken so that harm to human health and to the environment is avoided, and provide the following fundamental principles:

- the burden of proof principle;
- the knowledge requirement;
- the precautionary principle;
- the best possible technology principle;
- the appropriate location principle;
- the resource management and eco-cycle principles;
- the product choice principle;
- the principle of reasonableness.

The Environmental Quality Standards specify the maximum levels of pollution or disturbance to land, water, air or the environment in general, that humans may be exposed to without any significant risk. Permits, approvals or exemptions may not be issued for a new operation that would contravene an Environmental Quality Standard, unless precautionary measures to alleviate the negative effects are taken.

ii) Environmental impact statement

The Nuclear Activities Act requires an environmental impact statement (EIS) as part of the application for a licence to construct, possess or operate a nuclear power plant. The purpose of the EIS

is to assess the effects of the planned operation on human health and the environment and on the management of natural resources. The procedure to be followed when making the assessment is described in the Environmental Code [Chapter 6]. In addition, the Ordinance on Environmental Impact Assessments [SFS 1998:905] provides that nuclear reactors and installations for the storage of nuclear waste and spent nuclear fuel shall always be considered to have a significant impact on the environment [Section 3]. Prior to the drafting of an EIS, the operator must obtain and compile available data and consult the other parties, authorities and organisations concerned, including the general public.

iii) Permit under the Environmental Code

According to the Ordinance on Environmentally Hazardous Activities and Health Protection [SFS 1998:899], a nuclear activity may not be carried out without a permit issued under the Environmental Code [Section 5]. This means that such operations are required to have two permits, one issued in pursuance to the Code and the other in pursuance to the Nuclear Activities Act.

Applications for a permit to conduct nuclear activities are submitted to the Swedish Nuclear Power Inspectorate (SKI). The Inspectorate is required to assess whether the following provisions in both the Nuclear Activities Act and the Environmental Code have been satisfactorily complied with:

- the safety regulations according to the Nuclear Activities Act;
- the general rules of consideration in Chapter 2 of the Code and the measures proposed by the applicant to avoid any environmental hazards;
- the environmental quality standard in Chapter 5 of the Code; and
- the environmental impact assessment, i.e. its contents as well as the extent of the consultations with concerned parties.

The Inspectorate will, as part of its preparation of the matter, obtain the necessary opinions and statements from concerned parties, such as the Swedish Radiation Protection Institute (SSI) and local authorities. Other parties affected by the operation will also be given the opportunity to express their opinions at local hearings. Before handing over the matter to the government, SKI includes in its expert opinion any special conditions that it deems necessary to be part of a future permit, such as precautionary measures to minimise the hazards involved, and the conditions concerning radiation protection considered by SSI.

An application to conduct nuclear activities and an environmental impact statement, similar to those submitted to SKI, must also be submitted to an appropriate environmental court for consideration under the Environmental Code. During its deliberation, the court will assess whether the provisions in the Code regarding emissions and disturbances, including those caused by radioactive substances and ionising radiation, have been satisfactorily complied with.

Once the environmental court has considered the matter, it hands the application over to the government, which assesses its permissibility under Chapter 17 of the Environmental Code, and whether the proposed location for the operation is suitable. It is of great importance that the expert opinions prepared by SKI, SSI and the environmental court are available to the government before deciding the matter of permissibility.

Finally, the appropriate municipal council must have approved the operation before the government issues a permit. This is known as the municipal veto. However, regarding facilities for

intermediate storage or final disposal of nuclear material or waste, the Code provides that the municipal veto may be overturned if the operation is of the utmost importance to the national interest. This exception does not apply, however, where another site is considered more appropriate for the activity or if an appropriate site has been designated for the activity in another municipality which is likely to approve the site [Chapter 17, Section 6].

5. Trade in Nuclear Materials and Equipment

The export of nuclear material and equipment is governed by the Act on Control of Export of Dual-use Products and Technical Assistance, as well as by EC Council Regulation No. 1334/2000 of 22 June 2000 setting up a Community Regime for the Control of Exports of Dual-Use Items and Technology. The procedure to grant permission for export requires an application to be made to the Swedish Inspection for Strategic Products (ISP), which makes the decision whether or not to grant the necessary permission. SKI has jurisdiction to decide certain cases on the export of dual-use products, which are connected to nuclear activities, such as nuclear fuel.

In special cases, however, the government grants permission for export of such products. The ministry in charge of such cases is the Ministry for Foreign Affairs. In the event of trade in nuclear materials or equipment in breach of the regime established under the Act on Control of Export of Dual-use Products and Technical Assistance or under the Nuclear Activities Act, the sanctions contained in each respective act apply, including criminal prosecution.

The Ordinance on Nuclear Activities [SFS 1984:14] deals with the import of nuclear substances and nuclear waste as well as the exportation of nuclear waste at a more detailed level. The ordinance provides for a hierarchy of licensing and notification, depending on the category of material or equipment to be imported. The Swedish Radiation Protection Institute (SSI) issues licences for the import and export of nuclear waste.

An application to import nuclear substances or nuclear waste from a foreign nuclear installation shall contain information on how long the material will stay in Sweden. The application will be granted only if it is clear that the material will either be conveyed out of Sweden within a certain time, or that a licence for terminal storage within Sweden has been granted. An application to export nuclear waste from nuclear activities in Sweden shall contain information as to how it will finally be disposed of. The application shall further contain an assurance from the exporter that the waste will be taken back if it is not disposed of as described in the application.

Sweden ratified the 1968 Treaty on the Non-Proliferation of Nuclear Weapons on 9 January 1970. It has also concluded bilateral agreements with its major suppliers, agreeing not to re-export material or equipment except with the approval of the original supplier. Thus, these international commitments will be taken into account in decisions about the issue of export licences.

6. Radiation Protection

On 1 July 1988, a Radiation Protection Act [SFS 1988:220] came into force, replacing the previous act of the same name which dated from 1958. The 1988 Act states that its purpose is, “to protect people, animals and the environment against the harmful effects of radiation” [Section 1]. The act establishes a system of licences that applies to both ionising radiation (radiation from gamma rays, X-rays and the like) and non-ionising radiation (optical radiation, radio-frequency radiation, ultrasound radiation, etc.) [Section 2].

The act's main obligations are imposed on the people who conduct activities involving ionising radiation. These activities include the manufacture, importation, transport, sale, acquisition, possession, use or dealing with a radioactive substance, and the use of any technical device capable of generating ionising radiation [Section 5]. Generally speaking, a licence must be obtained from the Swedish Radiation Protection Institute (*Statens Strålskyddsinstitut* – SSI) before any of these activities can be commenced [Section 20]. The licence may be issued for a limited period, may be subject to conditions and may be revoked if the licensee fails to comply with the act, regulations or conditions in any significant respect [Sections 24, 26 and 28].

The act places broad obligations on people conducting activities involving ionising radiation, including: taking measures that are necessary to prevent or counteract injury to people and animals and damage to the environment; supervising and maintaining radiation protection at the site where radiation occurs; and properly maintaining all the equipment used in radiation related activities [Section 6].

In addition, the act provides specific duties owed to employees: employers must ensure that people working in places where radiation activities occur are fully informed of the risks associated with their work, and of the regulations and conditions to be observed in carrying out their work. The employer is also responsible for adequately training employees in relation to the functioning of radiation protection systems [Section 7]. A complementary duty is placed on employees to use the safety systems provided by the employer [Section 8]. The act provides certain conditions for the radiation protection of employees. No person under the age of 16 may perform work involving ionising radiation [Section 16]. Medical examinations are compulsory for persons engaged in ionising radiation work [Section 18]. SSI may intervene to impose additional procedures for a particular kind of work, or to prohibit it altogether [Section 17].

Criminal sanctions apply in the case of serious breaches of the act [Sections 35-37], and radioactive substances or equipment used in such a breach may be confiscated [Section 40].

While the Radiation Protection Act imposes duties and responsibilities on various groups of people in general terms, most of the details of specific aspects of the radiation protection regime are set out in two ordinances, the Radiation Protection Ordinance [SFS 1988:293], and the Ordinance with Instructions for the Swedish Radiation Protection Institute [SFS 1988:295]. The Radiation Protection Ordinance designates the SSI as the government's central agency for the purposes of the act, lists certain substances and equipment that are exempt from the requirements of the act, and sets out topics on which the Institute may issue regulations. The Ordinance with Instructions for the Swedish Radiation Protection Institute deals with some other functions of the Institute, such as granting it responsibility for research and development in the field of radiation protection, dissemination of information on the subject, establishment of international radiation protection standards in the national context, and provision of advice to public authorities in the event of a nuclear accident affecting Sweden.

Although the main supervisory responsibility in relation to radiation protection lies with the SSI, this body may delegate partial responsibility to local authorities engaged in public health and environment protection [Sections 29 and 30]. In such a case, the local authorities are endowed with certain information-gathering powers, the right of access to facilities and authority to give directions, in order to enforce effectively the act and its regulations [Sections 31-33].

In accordance with the Radiation Protection Ordinance, the SSI has issued nine regulations implementing Council Directive 96/29/Euratom of 13 May 1996. This Directive lays down basic safety standards for the protection of the health of workers and the general public against the dangers

arising from ionising radiation. It is based on the recommendations of the International Commission on Radiological Protection (ICRP). The nine regulations are entitled SSI's Regulations on: Monitoring and Reporting of Individual Radiation Doses [SSI FS 1998:5]; Categorisation of Workers and Workplaces at Work with Ionising Radiation [SSI FS 1998:3]; Dose Limits at Work with Ionising Radiation [SSI FS 1998:4]; Medical Surveillance of Exposed Workers [SSI FS 1998:6]; Radiation Protection of Workers Exposed to Ionising Radiation at Nuclear Plants [SSI FS 2000:10]; Radiation Protection Managers at Nuclear Plants [SSI FS 2000:11]; Radiation Protection of Human Health and the Environment from the releases of Radioactive Substances from Certain Nuclear Facilities [SSI FS 2000:12]; Handling of Radioactive Waste and Nuclear Waste at Nuclear Facilities [SSI FS 2001:1]; and Planning for and during Decommissioning of Nuclear Facilities [SSI FS 2002:4].

7. Radioactive waste management

Management and disposal of radioactive waste is regulated principally by provisions of the Nuclear Activities Act [SFS 1984:3] and Ordinance [SFS 1984:14] and the Radiation Protection Act [SFS 1988:220] and Ordinance [SFS 1988:293].

Nuclear waste is defined in the Nuclear Activities Act as:

- radioactive substance formed in a nuclear plant and which has not been produced or removed from the plant to be used in education or research, or from medical, agricultural or commercial purposes;
- material or other items which have belonged to a nuclear plant and become contaminated with radioactivity, and are no longer to be used in such a plant;
- radioactive parts of a nuclear plant which is being decommissioned.

Responsibility for the management of nuclear waste lies with the licencee carrying out the activities that produce the waste. The Nuclear Activities Act states that the licensee must ensure the safe handling and final storage of nuclear waste and the safe decommissioning and dismantling of nuclear plants which are no longer in use [Section 10]. In practice this means that the producer of nuclear waste is responsible for its collection, transport, treatment and interim storage. A licensee of a nuclear power reactor is, according to the act, specifically required to conduct research and development into the safe handling and final storage of spent nuclear fuels and long-lived nuclear waste, in consultation with other reactor operators. The research and development program, which must cover a period of six years, is subject to government approval. The program is reviewed every three years by the Swedish Nuclear Power Inspectorate (*Statens Kärnkraftinspektion* – SKI) and the Swedish Radiation Protection Institute (*Statens Strålskyddsinstitut* – SSI) and reported to the government through SKI. The government may require changes to the program and may impose certain specified conditions [Sections 11 and 12]. If the operator of the nuclear facility does not comply with these obligations relating to research and development, and this non-compliance has serious implications as far as the safety of the facility is concerned, the operator's licence may be revoked [Section 15].

A final repository for low and intermediate level reactor waste (the SFR facility) has been constructed at the nuclear power plants in Forsmark. The repository operates under the terms and conditions of an operating licence that is issued by the government, but it is supervised by both the SKI and the SSI. Since 1985, the Central Interim Storage Facility for Spent Nuclear Fuel (the CLAB facility constructed by the power plants in Oskarshamn) has been in use, serving as an intermediate storage facility prior to final disposal of the fuel. The implementation of the research and development

programme is performed in stages over a period of many years and involves SKI, SSI, numerous other government agencies and consultations with the general public. Currently discussions are being held on plans for a final repository for spent nuclear fuel and it is expected that a decision on this project will be made within the next few years.

A separate act deals with the question of financing the final disposal of nuclear spent fuel and waste as well as the decommissioning of nuclear reactors. The Act on the Financing of Future Costs of Nuclear Waste Management [SFS 1992: 1537] requires the producers of nuclear power to pay an annual fee to the state. The amount of the fee is calculated according to the energy output of each nuclear facility and according to information provided by the producers as to the estimated costs of carrying out their legal obligations in relation to nuclear waste (i.e. its safe handling, storage, and research and development).

The fees are paid into a fund the assets of which are earmarked to cover the future costs of spent fuel disposal, decommissioning of reactors and research in the field of nuclear waste. The fund also covers the ongoing costs of the safe handling and storage of nuclear waste, and of the research and development programs carried out by the producers in fulfilment of their obligations under the Nuclear Activities Act. The SKI is responsible for reviewing the calculations of the annual fees and for proposing the amount to be paid by operators of nuclear reactors.

The handling and disposal of waste generated by activities other than nuclear power production, defined as radioactive waste, is dealt with in the Radiation Protection Act [SFS 1988:220] and is under the supervision of the SSI. The act states that people who have conducted activities involving either radiation or devices capable of emitting radiation are responsible for ensuring that any radioactive waste (or discarded radioactive source) is handled and, if necessary, stored "in a manner that is satisfactory from the viewpoint of radiation protection" [Sections 13 and 14]. The SSI also issues regulations applicable to radioactive emissions from nuclear power plants. The Regulations provide that releases of radioactive substances from nuclear power plants into the water or the air should be monitored, analysed and reported to the Institute. The provisions are based on the ALARA (as low as reasonably achievable) principle.

Through the Environmental Code [SFS 1998:808], the dumping at sea of any kind of waste, including radioactive waste, is prohibited. The rules in the Code replace the Marine Dumping Prohibition Act of 1971 [SFS 1971:1154]. It is also of note that, at the international level, Sweden ratified the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter on 21 February 1974. It furthermore ratified the 1997 Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management on 29 July 1999.

8. Non-Proliferation and Physical Protection

Sweden has ratified both the 1968 Treaty on the Non-Proliferation of Nuclear Weapons (on 9 January 1970) and the 1979 Convention on the Physical Protection of Nuclear Material (on 1 August 1980). Sweden also ratified the 1996 Comprehensive Test Ban Treaty on 2 December 1998. Sweden's obligations under these treaties are given effect by means of several general provisions in the Nuclear Activities Act [SFS 1984:3] and wide regulation-making powers conferred on the Swedish Nuclear Power Inspectorate under the Nuclear Activities Ordinance [SFS 1984:14]. The fundamental provisions of the Nuclear Activities Act state that nuclear activities are to be carried out in a manner that honours Sweden's obligations with the aim to: prevent nuclear explosions; non-proliferation of nuclear weapons and unauthorised dealings with nuclear material [Section 3]. The act expressly states

that one of the main methods of achieving safety in nuclear activities is to prevent unlawful dealings with nuclear material [Section 4].

At a more specific level, the act places obligations on people who have been licensed to conduct nuclear activities to ensure that international inspectors have access to the nuclear installations and have sufficient information at their disposal in order to facilitate their task of supervising Sweden's non-proliferation obligations [Section 17].

The Nuclear Activities Ordinance entrusts the Swedish Nuclear Power Inspectorate with the responsibility for issuing regulations dealing with the following matters:

- measures to maintain safety in nuclear activities, as required by Section 4 of the Nuclear Activities Act;
- measures to ensure fulfilment of Sweden's obligations regarding non-proliferation of nuclear weapons and unauthorised dealings with nuclear material;
- the powers to be exercised by the international observers referred to in Section 17 of the Nuclear Activities Act [Section 20(a)].

The ordinance also gives the Swedish Nuclear Power Inspectorate the task of drafting regulations relating to the supervision and inspection of all aspects of nuclear activities (for example, handling, processing, transport) so as to ensure that the safety requirements referred to in Sections 3 and 4 of the act are met [Section 21].

The Act on Inspections according to International Agreements on Non-proliferation of Nuclear Weapons provides the legal basis for international inspectors to conduct inspections in accordance with the additional protocol to the Agreement between Sweden, EU and the IAEA.

9. Transport

The transport of nuclear substances and nuclear waste is included within the scope of "nuclear activities" and is therefore subject to the licensing system of the Nuclear Activities Act. A licence must be obtained, and it may be subject to time limits and other conditions. The Ordinance [SFS 1984:14] on Nuclear Activities specifies that in the case of transport of nuclear material or highly radioactive waste, the Swedish Nuclear Power Inspectorate determines the question of licences after consultation with the Swedish Radiation Protection Institute about conditions that will need to be imposed in the interests of radiation protection [Section 18].

The transport of radioactive substances comes within the scope of the Radiation Protection Act [SFS 1988:220] since it is included in the list of "activities involving radiation" [Section 5]. People involved in the transport of radioactive substances are therefore subject to the general obligations of the act (to take measures necessary to protect people, animals and the environment from radiation damage and to provide proper safety systems, training and information to the employees). They are also required to obtain a licence for transport activities [Section 20], unless the activity is subject to the licensing requirements of the Nuclear Activities Act [Section 23]. The Swedish Radiation Protection Institute is empowered to impose conditions on the licence [Section 27] and to issue regulations relating to transport licences [Section 21]. Licensees are subject to the provisions of the act that require information and access to be given to the supervisory authority (the Institute) [Section 31], and they are of course also subject to the penalty provisions of the act [Sections 35 to 40].

The Transport of Dangerous Goods Act [SFS 1982:821] applies to the transport of radioactive substances including their loading, unloading, storage and other handling. The Act and the Ordinance [SFS 1982:923] on the Transport of Dangerous Goods transpose the Conventions and other international agreements on the subject – International Regulations concerning the Carriage of Dangerous Goods by Rail (RID), International Convention concerning the Carriage of Goods by Rail (CIM), European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), International Convention for the Safety of Life at Sea (SOLAS), the International Maritime Dangerous Goods Code (IMDG), International Civil Aviation Organisation ICAO agreements etc. – into Swedish national law.

The Ordinance on the Transport of Dangerous Goods designates the Swedish Nuclear Power Inspectorate as the competent authority for nuclear materials and the Swedish Radiation Protection Institute for other radioactive materials as concerns the issuing of certain certificates etc. The regulatory authority for transport by road is the National Rescue Services Agency, for transport by sea, the Swedish Administration of Shipping and Navigation and for transport by air, the Swedish Civil Aviation Administration.

10. Nuclear Third Party Liability

Sweden is a Party to the following instruments on nuclear third party liability:

- the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy, and the 1963 Brussels Convention Supplementary to the Paris Convention as amended by the 1982 Protocols; Sweden ratified these two Conventions on 1 April 1968 and 3 April 1968 respectively;
- the 1971 Brussels Convention on Civil Liability in the Field of Maritime Carriage of Nuclear Material, which it ratified on 22 November 1974;
- the 1988 Joint Protocol relating to the Application of the Paris Convention and the Vienna Convention, which it ratified on 27 January 1992.

a) The Nuclear Liability Act

The Nuclear Liability Act [SFS 1968:45] implements Sweden's obligations under the above mentioned treaties. The act has been amended several times in order to keep it in line with developments at the international level, and to make increases from time to time in the amounts of the operator's liability. The act provides that the operator of a nuclear installation, which is the source of a nuclear incident, is strictly and exclusively liable to provide compensation to those who have suffered personal injury, damage to property or loss as a result of the incident. The amount of the operator's liability has been raised progressively since the act was first passed in 1968. Originally the limit was 50 million Swedish kronor (SEK) per incident [Section 17]. This sum has progressively increased; the current limit of Special Drawing Rights (SDR), which came into effect on 1 April 2001, is now SDR 300 million, corresponding to approximately SEK 3 300 million.

The liability limit for incidents occurring at installations that produce, treat or store only unirradiated uranium and for incidents occurring in the course of transport of such uranium has remained at the amount of SEK 100 million per incident. Except in the case where a nuclear installation is operated by the state, every Swedish nuclear operator must have insurance, approved by the government, to cover his liability as set out by the legislation.

The act provides for compensation over and above that available under the terms of the Paris Convention and the Brussels Supplementary Convention. Should a nuclear incident occur, for which the operator of a nuclear installation located in Sweden is liable, and the amounts available under the two Conventions are insufficient to allow compensation in full, the state will compensate the victims from a maximum sum of SEK 6 000 million per incident. This extra tier of compensation is available only in relation to nuclear damage suffered in Sweden, Denmark, Finland, and Norway or on the territory of any other Party to the Brussels Supplementary Convention, only to the extent that the Party concerned provides similar additional compensation for damage suffered in Sweden.

A person wishing to claim compensation under the Nuclear Liability Act must do so within three years of becoming aware of his or her entitlement to compensation, or, in any case, within ten years of the nuclear incident which caused the damage in question [Section 21]. The act also contains provisions establishing which Swedish courts have jurisdiction over a particular claim for compensation [Sections 36 and 37].

b) Chernobyl Legislation

Following the Chernobyl accident in 1986, Sweden passed legislation dealing specifically with compensation for those who had suffered economic loss in Sweden as a result of the accident. This legislation established various measures regarding emergency systems and allocated the sum of SEK 250 million as compensation to claimants who had been obliged to discard animal carcasses, vegetable products and milk, rehabilitate horticultural areas, abandon commercial hunting activities, etc. In addition, a number of ordinances were made dealing with specific economic activities which were adversely affected by the accident [for example, the Ordinance on compensation to agricultural, garden and reindeer-raising enterprises for costs and losses resulting from radioactive fallout, SFS 1986:621]; the latest Ordinance on this matter was passed in 1994 [SFS 1994:246].

II. INSTITUTIONAL FRAMEWORK

Under the Swedish Constitution, ministers are responsible for making proposals on matters within their portfolios. However, decisions are made collectively by the whole government rather than by one minister.

Various national bodies exist with regulatory or supervisory responsibilities in the nuclear field. As a general rule these bodies enjoy considerable independence within the broad policy framework laid down by the government.

1. Regulatory and Supervisory Authorities

a) Ministry of the Environment

The Ministry of the Environment is responsible for drawing up and implementing legislation and state financing for nuclear safety and radiation protection as well as legislation on nuclear liability.

b) Ministry of Industry and Trade

The Ministry of Industry and Trade is responsible for energy policy in general, including nuclear energy policy.

c) Ministry of Justice

The Ministry of Justice is responsible for drawing up and implementing civil and criminal law.

d) Ministry of Foreign Affairs

The Ministry of Foreign Affairs is responsible for drawing up and implementing legislation concerning dual-use products.

e) Swedish Nuclear Power Inspectorate (SKI)

i) Legal Status

On 1 July 1974, the Swedish Atomic Energy Board was renamed the Swedish Nuclear Power Inspectorate (*Statens Kärnkraftinspektion* – SKI). Its functions are set out in the Ordinance on Instructions for the Swedish Nuclear Power Inspectorate [SFS 1988:523]. SKI comes under the authority of the Ministry of the Environment and is the "authority appointed by the government" under the Nuclear Activities Act to be the main regulatory body for the Swedish nuclear power industry.

ii) Responsibilities

SKI's principal duties, conferred by the Nuclear Activities Act and secondary legislation enacted pursuant to it, are as follows:

- to follow developments in the field of nuclear energy, in particular regarding safety issues;
- to investigate issues and initiate measures to increase the level of safety of nuclear facilities;
- to follow developments with regard to methods for handling and final disposal of spent nuclear fuel and radioactive waste, and to the shutdown and decommissioning of nuclear facilities;
- to initiate research and development work on the safety of nuclear power plants and other nuclear installations, the safe transport of nuclear material and waste, and, finally, safe methods for handling and storage of spent nuclear fuel and nuclear waste. Also to initiate research and development on methods for the shutdown and decommissioning of reactor facilities, to the extent that no other authority has jurisdiction over such tasks, and otherwise to initiate any other research necessary for the Inspectorate to carry out its assignments;
- to actively contribute towards providing members of the general public with information about work carried out in the fields of nuclear safety and radioactive waste;

- to ensure control of nuclear materials pursuant to Sweden's international obligations or as otherwise required;
- to provide technical advice to authorities responsible for the protection of the public in the event of a nuclear accident in Sweden or elsewhere;
- to account for funds that SKI administers in accordance with the Act on the Financing of Future Expenditure on Spent Nuclear Fuel and the Ordinance of 1981 on the Financing of Future Expenditures on Spent Nuclear Fuel, etc;
- to recommend to the government on a yearly basis the amount of the fee which is to be paid by producers of nuclear power to the Inspectorate, and accumulated in a fund managed by SKI; and
- to issue regulations concerning safety aspects of nuclear activities, and these constitute SKI's own Code of Statutes (identified by the reference SKI FS).

iii) Structure

A board appointed by the government governs SKI, and the chairperson of the board is the Director-General of SKI. Among the members of the board are representatives from bodies such as the Swedish Radiation Protection Institute, Universities, the Supreme Court and representatives from the *Riksdag* (the Swedish parliament). The SKI is divided into several departments: Reactor Safety, Nuclear Materials Control, Nuclear Waste Safety, Research, Information Technology, Information, Administration and Personnel. In addition, SKI is supported by three Advisory Committees (Reactor Safety, Safeguards and Research).

iv) Financing

Funding for SKI's activities comes from statutory licensing fees under a special ordinance on fees, revised annually.

f) Swedish Radiation Protection Institute (SSI)

i) Legal Status

The Swedish Radiation Protection Institute (*Statens Strålskyddsinstitut* – SSI) is the central national authority under the responsibility of the Ministry of the Environment, appointed for the purposes of the Radiation Protection Act of 1988.

ii) Responsibilities

SSI is the principal authority responsible for protection against ionising and non-ionising radiation. Its functions are set out in the Ordinance on Instructions to the Swedish Radiation Protection Institute [SFS 1988:295]. SSI is involved in regulating and supervising aspects of both the inner and outer environments of nuclear power plants, the use of radioactive substances in industry, medicine and research, dental and veterinary X-ray diagnostics, and the use of non-ionising radiation (for example, in sun lamps and lasers).

SSI's functions also include:

- acting as the central co-ordinating body for radiation protection research, as well as conducting research in this field;
- taking account of international standards in the formulation of national radiation protection requirements; and
- disseminating information to the public on radiation hazards and radiation protection.

The Radiation Protection Act empowers the Institute to issue regulations on numerous aspects of radiation protection, and these constitute the Institute's own Code of Statutes (identified by the reference SSI FS).

iii) Structure

A board appointed by the government governs SSI, the chairperson of which is the Director-General of the Institute. The members of the board represent bodies such as the National Board of Health and Welfare, the National Environment Protection Board, the National Board of Occupational Health and Safety, the Swedish Nuclear Power Inspectorate and the *Riksdag* (the Swedish parliament).

The following three departments carry out most of the Institute's operations:

- Occupational and Medical Exposures;
- Waste Management and Environmental Protection;
- Emergency Preparedness and Environmental Assessment.

The Institute is supported by an Advisory Scientific Board. Its task is to decide upon grants for basic radiation protection research and to give advice on other scientific matters.

iv) Financing

A proportion of SSI's activities is funded by licence fees. The remainder of its funding is provided by the government.

SWITZERLAND

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I. GENERAL REGULATORY REGIME

1. Introduction

It was in 1946 that the peaceful use of nuclear energy was first regulated by the Swiss Confederation in the form of a Federal Order, dated 18 December 1946, encouraging research in the field of nuclear energy.

Given the complexity of the issues raised by the use of nuclear technology and the fact that large sums of money are required to put it into effect, the federal parliament in June 1957 authorised an amendment to the Constitution [Article 24 quinquies] so that nuclear legislation should fall within the sole jurisdiction of the Confederation, and this was approved in a referendum and by all the cantons in November 1957. Cantons, therefore, are not responsible for nuclear safety questions and have a residual jurisdiction only with regard to the licensing of nuclear installations (building permits, mining legislation, fire permits, water samples and use, etc.). This division of jurisdiction between federal and cantonal authorities was sanctioned at federal tribunal level in decisions of 18 August 1973 and 23 March 1977.

In Switzerland, the development and use of nuclear energy is not a state monopoly, and a large place is left to private industry. The first commercial nuclear power plant was brought into service in 1969. Many local authorities, however, have a direct or indirect interest in the operation of nuclear installations. There are at present five nuclear power reactors located on four sites with a total capacity of 3220 MWe: Beznau-1 and Beznau-2 are located at Döttingen, Goesgen is at Soleure, Leibstadt in Aargau and Muehleberg at Bern. Nuclear energy electricity represents almost 40% of electricity annually produced in the country. In addition, Switzerland operates three nuclear research reactors located at the Institute of Physics of the University of Bale, the Institute for Applied Radiophysics of the University of Lausanne, and the Paul-Scherrer Institute.

It should also be noted that referenda on nuclear energy were held on 22 and 23 September 1990. The Swiss population and the cantons had to take a decision on three questions of major importance for the country's energy policy: a public motion, as set out in the Constitution, calling for the progressive and final abandonment of nuclear energy (rejected by a 52.9% majority); a public motion calling for a ten-year moratorium on the construction of all new nuclear power plants accepted by a 54.6% majority); and a government proposal to amend the Constitution in order to give the Confederation authority to promote energy savings (accepted by a 71% majority). The cantons unanimously accepted the constitutional article on energy, while a majority of cantons decided in favour of the moratorium and against abandonment. Following a further referendum hold on 18 May 2003, the population and the cantons rejected two popular constitutional initiatives called "Moratorium Plus" ("*Moratoire Plus*") and "Phase-out Nuclear" ("*Sortir du nucléaire*"). On the same day, the Swiss population accepted the new Act on Nuclear Energy of 21 March 2003, presented by the government as a counter-proposal to the two initiatives.

Nuclear legislation in Switzerland will be essentially based until 31 December 2004 (this date is still provisional) on a federal act, the Act of 23 December 1959 on the Peaceful Use of Atomic Energy and Protection Against Radiation. On 21 March 2003, the Federal Assembly (the Swiss parliament) adopted a new Federal Act on Nuclear Energy. This act should enter into force on 1 January 2005, at the same time as its implementing ordinance, which is currently being drafted. As soon as it enters into force, the new act will replace the current 1959 Atomic Act as amended, as well as the Federal Order of 1978. Likewise, the new Ordinance on Nuclear Energy will replace, among others, the current implementing Ordinance of 18 January 1984 amended on several occasions. The Swiss atomic legislation needed to be amended in order to centralise some elements contained in several ordinances of the Federal Council (decommissioning of nuclear installations, disposal of radioactive waste and financing of such activities) and to introduce new elements (obligations to be complied with by operators of nuclear installations, adaptation of licensing procedures and reprocessing of radioactive waste). The new act maintains the nuclear energy option: the construction of new nuclear plants will remain possible, as long as the most recent technology is used; however, a decision in principle of the parliament will be necessary in respect of new nuclear installations, and is subject to an optional referendum.

Within this study, we have retained certain references to the 1959 Act and the 1978 Federal Order as well as to their joint implementing Ordinance of 18 January 1984, pending the entry into force of the new legislation.

2. Mining Regime

There are no special mining regulations in Switzerland relating to nuclear ores.

At present, nuclear ores (uranium and thorium) are not considered as nuclear fuels within the meaning of the Ordinance of 18 January 1984 on definitions and licences in the field of atomic energy [Section 1]. However, this ordinance will be repealed with the entry into force of the new Ordinance on Nuclear Energy.

3. Radioactive Substances, Nuclear Fuel and Equipment

Given the special properties and possible uses of nuclear fuels, current Swiss nuclear legislation contains more detailed rules with regard to them than to other radioactive substances.

The Act of 21 March 2003 simplifies the categories of radioactive substances. In this context, “nuclear fuel” does not exist any more as a distinct category. In addition to “nuclear waste”, the act identifies the three following sub-categories within the general category of “nuclear articles” [Section 3]:

- nuclear materials, which include substances which may be used to produce energy from the fission of the nucleus of an atom;
- components and equipment intended or necessary for the use of nuclear energy;
- the technology necessary for the development, production or use of the materials, components and equipment intended or necessary for the use of nuclear energy.

a) Nuclear fuels

The regime described herein will be amended with the entry into force of the Act of 21 March 2003 and its implementing ordinances, as the Federal Act of 23 December 1959 and several ordinances including the Federal Council Ordinance of 18 January 1984 on definitions and licences in the field of atomic energy will be repealed.

The Federal Act of 23 December 1959 on Atomic Energy already contained the basic provisions as to the possession and use of nuclear fuels (and residues). Their import and export is governed by the Federal Council Ordinance of 18 January 1984 on definitions and licences in the atomic energy field. However, these provisions do not apply to source materials which are not used to produce energy, to special fissile materials whose level of radioactivity does not exceed 1 000 kilobecquerels (1 kilobecquerel = 0.027 microcuries) or to uranium-bearing ores, these being governed by the Act of 22 March 1991 and the Ordinance of 22 June 1994 on radiation protection.

The possession, transport, import and export of nuclear fuels are subject to licensing by the Confederation [Act of 23 December 1959, Section 4]. The Federal Energy Office is the body competent to deal with licensing applications [Ordinance of 18 January 1984, Section 9]. It grants licences on the advice of the Principal Division for the Safety of Nuclear Installations (*Direction principale de la sécurité des installations nucléaires* – DSN). It is also the DSN which certifies that the international regulations on the transport of dangerous goods have been complied with. In accordance with the Ordinance of 18 January 1984, any proposed export of sensitive nuclear equipment or products is considered in the light of the London Club guidelines on nuclear transfers, subject to the provisions relating to the transfer of nuclear technology, and is submitted to the Federal Energy Office and the Secretariat of State for the Economy (*Secrétariat d'*.

The revocation of a licence to possess nuclear fuels results in a transfer of the nuclear materials either to another licence-holder or to the Confederation [Act of 23 December 1959, Section 9]. If necessary, the Confederation may arrange for such materials to be seized at the expense of the person whose licence has been revoked [Section 39].

The possession of nuclear fuels is subject to supervision by the Confederation, to which end the Confederation or any bodies designated by it may take all necessary steps to protect persons, property and important rights. In practice, supervision is mainly carried out by the principal Nuclear Safety Division of the Federal Energy Office. The Federal Council has the general task, in the context of the possession and use of nuclear fuels, of laying down implementation standards and setting up any necessary bodies [Act of 22 May 1991 on Radiation Protection, Sections 37.1a.1 and 38]. The Act of 21 March 2003 establishes a ten-year moratorium on the reprocessing of spent nuclear fuel as from 1 July 2006. Until then, operators may continue to honour their contracts with French or English reprocessing firms. The ten-year moratorium may be extended for a further period of ten years by the parliament [Act of 21 March 2003, Sections 9 and 106, paragraph 4].

b) Radioactive substances and equipment generating ionising radiation

The Radiation Protection Ordinance of 22 June 1994 contains provisions regulating substances, objects and waste with a level of activity, concentration, contamination, dose rate or mass in excess of the values listed in the Annex. The licensing authorities are the Federal Office of Public Health (*Office fédéral de la santé publique* – OFSP) and, for activities performed in nuclear installations and for tests using radioactive substances in the framework of preparatory measures as defined in the Federal Order

of 6 October 1978 concerning the Atomic Energy Act, the Federal Energy Office (*Office fédéral de l'énergie* – OFEN).

The OFEN grants licences for: activities performed in nuclear installations; activities performed in the Paul-Scherrer Institute (IPS) in Villigen which do not involve the application of radiation or radioactive substances to the human body; the import and export of radioactive waste from nuclear power plants.

The OFSP is the competent licensing authority in all other cases.

A licence is required for the handling of radioactive substances or of equipment or objects containing such substances, for the manufacture, marketing, construction, or use of installations or equipment capable of emitting ionising radiation and for the application of radiation or radioactive substances to the human body [Radiation Protection Act, Section 28].

A licence must also be obtained by anyone who, in an enterprise subject to licensing, employs persons who are exposed to radiation in the course of their duties in accordance with the Radiation Protection Act or the Atomic Energy Act. Licences are not required for: work with radioactive substances the activity of which does not exceed a given threshold per day; the use of radioactive substances authorised under Section 128 of the ordinance; the sale, use, storage, transportation, disposal, import, export or transit of ready-made watches containing radioactive substances if they satisfy the requirements of ISO 3157 and 4168 and watch components containing luminescent radioactive paint. Equipment and radioactive sources may be authorised for general use by the Federal Office of Public Health if the following conditions are satisfied:

- design features ensure that persons are not exposed to radiation or contaminated in an inadmissible fashion;
- provision is made for the disposal, in the same manner as radioactive waste, of any radioactive source as necessary after use; and
- the ambient dose rate at a distance of ten centimetres from the surface does not exceed one microsievert per hour.

Licensing applications must be submitted, along with the necessary documentation, to the competent licensing authority. The authority issuing the licence (for a maximum period of ten years) communicates its decision to the canton concerned, to the supervisory authority and, in the case of enterprises subject to labour legislation, to the competent Federal Labour Inspectorate.

The Act of 21 March 2003 establishes a licensing regime for persons handling nuclear materials. The licensing authority and the licensing procedure are set out by the Federal Council. The licence is limited in time and is subject to licensing conditions [Act of 21 March 2003, Section 6 *et seq*.]. In particular, the competent authority checks whether the required financial cover for nuclear third party liability is provided.

The licence holder is subject to certain obligations. In particular, he/she shall notify the supervisory authorities of activities or special occurrences which could endanger nuclear security or safety. He/she shall also check stock and keep accounts [Act of 21 March 2003, Section 11]. The Act of 21 March 2003 on Nuclear Energy provides for penal provisions which, generally speaking, are applicable to persons who intentionally infringe provisions laid down in the field of nuclear energy [Section 88 *et seq*.]. This includes breaches of security and safety measures, offences relating to

nuclear articles or radioactive waste, breach of the obligations imposed by a nuclear installation licence, breach of confidentiality, relinquishing possession of nuclear materials or radioactive waste.

4. Nuclear Installations

a) Licensing and inspection, including nuclear safety

The regulations currently in force were adopted pursuant to the Federal Act of 1959 on Atomic Energy which provides for a system of licensing for the construction and operation of nuclear installations [Section 4]. However, the Federal Order of 6 October 1978 concerning the Act on Atom Energy had already amended the licensing procedure by requiring nuclear operators first of all to obtain a so-called "general licence" determining the site and outline of the project [Section 1]. A "need requirement" was attached to this licence which would not be granted unless it was shown that construction of the planned nuclear installation met a real need in the country, and unless plans had been made for the decommissioning of the installation and disposal of the radioactive waste arising from it [Section 3].

The Act of 21 March 2003 confirms this tendency by requiring a general authorisation (decision in principle) for new nuclear installations. This general authorisation is granted by the Federal Council and is made subject to optional referendum. The concerns of the canton in which a nuclear site is to be located, as well as the cantons and states in the immediate proximity shall be taken into account [Section 44]. However, the authorisation of the canton in which a nuclear site is to be located is not required.

It is relevant to note that, at the international level, Switzerland ratified the 1994 Convention on Nuclear Safety on 12 September 1996.

Granting of general licences

The Federal Council is the body which decides upon applications for general licences [Act of 21 March 2003, Section 12]. Applications shall be sent to the Federal Energy Office, which decides whether the disposal of expertise is necessary, relating in particular to the protection of man and the environment, and disposing radioactive waste. After having invited the canton in which the installation is to be located, as well as the cantons and states in the immediate proximity to give their opinions, an enquiry must be opened and published in respect of applications for a general licence, the opinions of the cantons and specialised services, and of the expertise. The decision of the Federal Council on applications for a general licence is then submitted to the Federal Assembly for approval [Act of 21 March 2003, Section 48(2)]. General licences are granted after an enquiry procedure organised by the Federal Council provided the following conditions are met:

- the protection of man and the environment can be ensured;
- there is no other ground for refusing it under federal legislation, in particular as regards environmental protection;
- there is a plan for decommissioning or for an observation phase and a plan for closing the installation;
- radioactive waste produced shall be disposed of;
- Switzerland's external security is not affected;

- there is nothing in any international undertaking by Switzerland to oppose it;
- as regards deep geological repositories, geological studies confirm that the site is a suitable one.

The general licence determines the site to be selected for the installation, the licence holder, the purpose of the installation, the general outline of the project, the maximal exposure limit of persons to radiation in proximity to the installation, and, in the case of a deep waste repository, the criteria for deciding that a proposed site is unsuitable, and a provisional protection area [Act of 21 March 2003, Section 14(1)].

Granting of construction and operating licences

Under the Act of 21 March 2003, these licences are granted by Federal Department of the Environment, Transport, Energy and Communications (*Département fédérale de l'Environnement, des Transports, de l'Énergie et de la Communication* – DETEC) [Act of 21 March 2003, Sections 15 and 19].

The applications considered by the Federal Energy Office are sent to the cantons concerned and the specialised services of the Confederation for their opinion [Act of 21 March 2003, Sections 43, 47 and 53]. If the DETEC issues a licence contrary to the opinion of the canton in which the installation is to be located, the latter shall have a right of appeal against this decision, however no licence granted by the canton is required [Act of 21 March 2003, Section 49(3)]. The Act of 21 March 2003 differs therefore from the Act of 23 December 1959 on the Peaceful Uses of Atomic Energy and Protection against Radiation, which provides that canton authorities are competent for granting licences in relation to the regulations of installation construction, fire brigade (fire-fighting) and water police (use of cooling water) [Section 4(3)]. By virtue of the Federal Work Act, nuclear industrial enterprises are required over and above the specific nuclear licences, to obtain approval of plans and a special licence.

The applicant shall have a right of expropriation in order to construct, operate and decommission a nuclear installation requiring a general licence, as well as to proceed with geological studies which require a licence, construct the service facilities and prepare sites for the storage or recycling of digging, excavation or demolition materials which are in direct use to the installation [Act of 21 March 2003, Section 51].

Technical advisory and supervisory bodies

The principal Nuclear Safety Division (*Division principale de la sécurité des installations nucléaires* – DSN) of the Federal Energy Office (which is part of the Federal Department of the Environment, Transport, Energy and Communications – DETEC) gives an expert opinion on safety reports relating to the various nuclear installations. The Federal Commission for the Safety of Nuclear Installations (*Commission fédérale de la sécurité des installations nucléaires* – CSN) draws up an opinion at the same time on certain particular aspects of the project. This CSN report completes the opinion of the DSN [Ordinance of 14 March 1983]. On the basis of these documents, the Federal Council takes a decision as to the licences. The Federal Energy Office is responsible for implementing licensing procedures for nuclear installations.

Nuclear installations are supervised by the Confederation [Act of 21 March 2003, Section 70]. To this end, the Federal Council and the bodies designated by it may establish measures, and monitor the implementation of such measures, in order to protect persons, property and important rights, to

insure Switzerland's external security and to guarantee that its international commitments will be fulfilled. In practice, it is the principal Nuclear Safety Division (DSN) which carries out most technical inspections of installations although the DSN may call on experts from outside the federal administration.

The Federal Commission for the Safety of Nuclear Installations and the DSN advise the authorities competent to decide on measures that are necessary for the technical safety of installations [Ordinance of 14 March 1983].

Collection of fees

Under Chapter 8 of the Act of 21 March 2003, the Federal Council decides on the fees payable for the granting, transfer, modification or withdrawal of licences, as well as for the establishment of an expertise, surveillance activities and controls.

Since 1971, the operators of nuclear power plants reimburse every year the federal supervisory authorities for the expenses they incur as a result of the construction and operation of such installations. An Ordinance on Fees in the Nuclear Field, adopted by the Council on 30 September 1985, now defines in detail the activities subject to fees and fixes the criteria for calculating the scale. This ordinance will not be repealed with the entry into force of the future Ordinance on Nuclear Energy.

Decommissioning of nuclear installations

To meet the expenses of the decommissioning and dismantling of nuclear installations which are no longer in operation and of the disposal of the resulting waste, a Fund for the decommissioning of nuclear installations was set up on 5 December 1983 under the responsibility of the Federal Council [Ordinance of 5 December 1983, Section 1, supplemented by the Regulations of the Federal Department of the Environment, Transport, Energy and Communications of 21 February 1985], to collect the necessary payments from the operators of nuclear installations. Chapter 7 of the Act of 21 March 2003 contains more detailed provisions on the topic: the Decommissioning Fund shall ensure the financing of the decommissioning and dismantling of nuclear installations withdrawn from service, and that of the disposal of the waste produced thereby (decommissioning costs), whereas the Waste Disposal Fund shall ensure the financing of the disposal of radioactive operating waste and spent fuel assemblies, after withdrawal from service of nuclear installations (disposal costs). Each fund has legal personality and is managed by an administrative board acting as the directing body [Act of 21 March 2003, Section 81]. A board shall establish the amount of the contributions paid by each contributor to the fund it manages, and the amount of the payments made by the latter. Operators pay annual contributions, the amount of which is fixed in accordance with the anticipated cost of decommissioning and dismantling the installation.

b) Protection of the environment against radiation effects

The Federal Office of Public Health (*Office fédéral de la santé publique* – OFSP) is responsible for the constant monitoring of radioactivity in the air, in precipitation, water and the soil. The Federal Commission for the Monitoring of Radioactivity is the competent technical advisory body. In the event of an increase in radioactivity, it proposes measures to be taken to ensure the protection of the population. The Federal Council is regularly informed of the monitoring results.

c) Emergency response

On 15 April 1987, the Federal Council adopted the Ordinance relating to the Federal Emergency Organisation on Radioactivity (*Organisation d'intervention en cas d'augmentation de la radioactivité* – OIR), which replaced the previous Ordinance of 9 September 1966 on alert in the event of increased radioactivity.* The 1987 Ordinance establishes the organisation responsible for such emergency response and describes the tasks to be performed in the event of a hazard being caused by a nuclear installation [Section 1]. The situation in Europe resulting from the Chernobyl accident highlighted the need to set up an organisation in Switzerland to co-ordinate the measures to be taken by the different public services concerned, so as to achieve optimum results. Accordingly, the ordinance lists a number of bodies in which these services are represented, lays down the conditions for their involvement, and provides for a coordinated network to enable an appropriate response to be made to an increase in radioactivity [Sections 5 to 16].

The Ordinance of 28 November 1983 on emergency measures for protection of the population in the neighbourhood of nuclear installations is also applicable [Ordinance of 15 April 1987, Section 1.3]. It lays down the measures to be taken, the tasks of nuclear operators [Ordinance of 28 November 1983, Section 4], of the federal services [Section 5] and of the cantons and communes [Section 6]. It also establishes the apportionment of the costs incurred from the organisation of emergency measures and the alarm system [Section 9].

In the event of an alarming increase in radioactivity, the emergency organisation monitors developments and proposes or recommends the measures required. At the head of this organisation is the Radioactivity Steering Committee, which is answerable to the Federal Department of the Interior. Among other resources at the disposal of the organisation is the National Alarm Centre which is responsible for alerting the authorities and the population [Ordinance of 3 December 1990].

For this purpose, the Federal Department of the Environment, Transport, Energy and Communications must, in consultation with the Federal Department of the Interior and the cantons concerned, define two zones around each installation. Zone 1 covers the area in which a serious incident occurring in the installation could give rise to a hazard for the population requiring rapid protection measures. Zone II, immediately beyond Zone I, covers an area with a 20 kilometre radius (with the nuclear installation at its centre) divided into sectors [Ordinance of 28 November 1983, Section 2]. Depending on the circumstances, a simple warning, a general alarm or a radioactivity alarm may be triggered [Sections 3 to 7]. The nuclear operator is responsible for providing for the appropriate emergency measures for his installation, for installing the necessary equipment and co-operating with the emergency organisation.

The distribution of iodine tablets to the population is provided for in an Ordinance of 1 July 1992. These tablets are to be used in the event of an accident leading to the emission of radioactive particles representing a potential danger to the public [Section 1]. The Federal Office of Public Health is responsible for organising the supply so as to enable the appropriate bodies to distribute the tablets according to defined geographical criteria within three areas, and to build up sufficient reserves [Section 2]. In Area 1, tablets are given as a preventive measure and in sufficient quantities to all persons regularly in the Area [Section 3]. Moreover, the Ordinance imposes on cantons and communes an obligation to build up sufficient stocks, and prescribes storage conditions which are identical to those for medicines [Sections 6 and 7]. Operators of nuclear installations

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* The Ordinance of 15 April 1987 will not be repealed with the entry into force of the future Ordinance on Nuclear Energy.

participate with the Swiss Confederation in financing the costs generated by these operations [Section 13].

At the international level, Switzerland ratified both the 1986 Convention on Early Notification of a Nuclear Accident and the 1986 Convention on Assistance in the case of a Nuclear Accident or Radiological Emergency on 31 May 1988.

5. Trade in Nuclear Materials and Equipment

The Swiss Confederation has committed itself internationally to co-operate in the campaign against the proliferation of nuclear weapons. It ratified the 1968 Treaty on the Non-Proliferation of Nuclear Weapons (NPT) on 9 March 1977, and in the same year became a member of the London Club, a group of the main states involved in the export of nuclear items. Since the adoption of an Ordinance in 1978 on definitions and licences in the atomic energy field, replaced in 1984 by a new Ordinance, nuclear items have been subject to an export licence in accordance with the London Club Guidelines [IAEA Document INFCIRC/254]. There was, however, no legal basis upon which control could be exercised, as provided for in the Guidelines, over exports of "technology" (unpublished technical information on installations for enriching and reprocessing nuclear fuels and for producing heavy water). With the amendments of 2 March 1987 and 15 November 1995 to the 1984 Ordinance, the Swiss government has been able to make exports of technology subject to the granting of a licence [Section 11].

The granting of licences for the export of sensitive nuclear equipment and materials is assessed by the competent federal authorities in the light of the London Club Guidelines and of internal legislation. The "non-proliferation of nuclear weapons" is one of the licensing criteria laid down by the act [partial revision of 9 October 1986 of the Act of 23 December 1959, Section 5.1].

The Act of 21 March 2003 provides that, notwithstanding the licensing regime, the Federal Council or the authority designated by it may prohibit or impose conditions on the import, export, transit or brokerage of nuclear articles to ensure non-proliferation of nuclear weapons. Likewise, the Federal Council may provide that no licence shall be granted in relation to certain states or groups of states [Section 8].

The Act of 23 December 1959 prohibits the export of nuclear energy when it is contrary to the public interest [Act of 23 December 1959, Section 4.5]. The Act of 21 March 2003 does not contain such an express prohibition.

Following the Ordinance of 28 October 1987, amending the Ordinance of 18 January 1984, the export of fissile materials and nuclear equipment were to be authorised twice over: first by the import and export branch of the Trade Division of the Federal Department of Economy (DFE), and secondly, a joint authorisation from the Federal Energy Office, the Federal Foreign Affairs Department (DFAE) and the Secretariat of State for Economy [Sections 11 and 15]. The Ordinance of 18 January 1984 will be repealed with the entry into force of the future Ordinance on Nuclear Energy.

Swiss nuclear legislation does not include any regulation dealing specifically with nuclear industrial property. Accordingly, the ordinary law on patents applies in the nuclear field.

6. Radiation Protection

In general, radiation protection measures taken by the Confederation are based on the recommendations of the International Commission on Radiological Protection (ICRP), and on the joint standards of international bodies (IAEA, NEA, ILO, WHO).

Aware for many years of the need to carry out a total revision of the Federal Act of 23 December 1959 on the Peaceful Uses of Atomic Energy and Protection against Radiation, the Federal Council decided in August 1982 to separate the field of radiation protection from that of the use of nuclear energy and asked the Department of the Interior to prepare a draft Bill on Radiation Protection [Message relating to a Bill on Radiation Protection of 17 February 1988]. The proposed Bill was based on Section 24 quinquies, sub-section 2 of the Constitution and covers the whole field of radiation protection (the objective being to protect man and his environment against the hazards caused by ionising radiation), but the Chapter on "Licences and Supervision" does not cover activities (nuclear installations) subject to licensing under the Atomic Energy Act.

The Radiation Protection Act of 22 March 1991 is a framework act designed to protect man and the environment against the dangers arising from ionising radiation. It applies to all activities, installations, events and situations which could present a radiation hazard, and in particular to the use of radioactive substances and equipment, installations and objects containing such substances or capable of emitting ionising radiation. The act lays down the broad principles of protection against radiation and gives the Federal Council power to promulgate detailed implementing regulations which can thus be adapted rapidly to keep pace with scientific and technological progress. The comprehensive revision of the Radiation Protection Ordinance is an example of such adaptation.

The new Radiation Protection Ordinance of 22 June 1994 is based largely on the most recent recommendations of the International Commission on Radiological Protection (ICRP). Increased protection is afforded to persons exposed to radiation in the course of their work and to the public, especially to unborn children. Dose limits and derived guideline levels have been reduced and brought into line with the new ICRP recommendations.

The ordinance introduces new rules concerning the upkeep, modernisation and control of medical X-ray equipment. Routine controls are now to be carried out by private firms, which means that controls will be more frequent than before.

Limits and guideline levels have been introduced for concentrations of radon in housing, temporary accommodation and the workplace. The cantons are the competent executive authorities in this connection. Measures to decrease levels will be imposed having regard to the seriousness of each case and the financial implications involved.

Another new provision is that limits and tolerance levels for radioactive substances in foodstuffs are established in accordance with the Radiation Protection Act. These levels will be adopted also in the Ordinance on foreign bodies in, and the contents of, foodstuffs.

Lastly, the transport of radioactive substances has for the first time been made subject to licensing. In order to obtain a licence, firms transporting radioactive substances, whether on their own account or on behalf of others, must now prove that they have the technical know-how required and a suitable quality assurance programme.

Both the Act and the Ordinance on Radiation Protection entered into force on 1 October 1994.

The Federal Department of the Interior (*Département fédéral de l'Intérieur* – DFI) and the Federal Department of the Environment, Transport, Energy and Communications (DETEC) are responsible for implementing regulations in the field of radiation protection. They concentrate particularly on the protection of persons, and thus are concerned with health risks which may affect certain groups of people – workers or patients – or the population as a whole, when exposed to ionising radiation. Those who, in their work, handle radioactive substances or use radiation-producing equipment are required to have received adequate radiation protection training.

The Federal Commission for Protection against Radiation (*Commission fédérale de la protection contre les radiations* – CPR) gives advice on matters concerning radiation protection to the Federal Council, the Federal Department of the Interior (DFI) the Federal Department of the Environment, Transport, Energy and Communications (DETEC), interested services and the Swiss National Accident Insurance Office (*Caisse nationale suisse d'assurance en cas d'accidents* – CNA).

It gives its opinion, *inter alia*, on:

- the interpretation and evaluation of international recommendations concerning radiation protection with a view to their application in Switzerland;
- the preparation and development of standard principles for applying radiation protection requirements.

The competent authorities for granting licences to use ionising radiation are the Federal Office of Public Health (OFSP) and, for activities carried on in nuclear installations and tests involving radioactive substances in the framework of preparatory measures within the meaning of Section 10.2 of the Federal Order of 6 October 1978 concerning the Atomic Energy Act, the Federal Energy Office.

The OFSP, the CNA and the principal Nuclear Safety Division (*Division principale de la sécurité des installations nucléaires* – DSN) are responsible for supervising the protection of persons and the neighbourhood.

The OFSP exercises control over firms in which the primary concern is to protect the public, in particular, medical companies and research and training institutes in higher education establishments.

The CNA exercises control over firms in which the primary concern is protection of workers, in particular, industrial firms and small businesses.

The DSN supervises:

- nuclear installations;
- preparatory measures within the meaning of Section 10.2 of the Federal Order of 6 October 1978 concerning the Atomic Energy Act;
- the Paul-Scherrer Institute (IPS), except for applications of ionising radiation or radioactive substances to the human body;
- the radioactive waste collection centre. The collection is carried out by the IPS.

The Act of 21 March 2003 partially amends the 1991 Act on Radiological Protection, but maintains its main principles. In particular, it amends the sections designating the authorities granting licences for activities in nuclear installations and trials involving radioactive substances in the context of preparatory measures. The Federal Council shall designate the licensing authorities. It may also delegate to DETEC or to subordinate services the power to lay down radiological protection

requirements for the activities for which a licence is required by the Act of 21 March 2003 [Act of 22 March 1991 as amended by Act of 21 March 2003, new Sections 30 and 47].

7. Radioactive Waste Management

It should be pointed out in this context that in the current Swiss regulations, and until the entry into force of the Act of 21 March 2003 and of the future Ordinance on Nuclear Energy, the term "residues" (*résidus*) is used for a particular category of materials. The 1984 Ordinance on definitions and licences in the atomic energy field stipulates that residues are the radioactive materials (including activation products) whose activity does not exceed 100 gigabecquerels and which are formed from nuclear fuels after the nuclear transmutation process [Ordinance of 18 January 1984, Section 2, as amended on 18 October 1987]. The Federal Council may also include in this category, by assimilation, integral parts of nuclear installations which have become radioactive during atomic energy production [Act of 23 December 1959, Section 1]. The term "radioactive waste" applies to nuclear materials and articles contaminated by such materials which are not to be used again [Ordinance of 18 January 1984, Section 3]. In practice, radioactive waste (*déchets*) is mainly material resulting from the use of radioisotopes. Such radioactive waste results from the handling of radioactive sources of all kinds; it broadly includes waste produced as a result of industrial, medical, research and educational uses.

In fact, Swiss regulations do not always make this distinction and, for convenience, the term waste has been used in this section. When residues are concerned, this is indicated in brackets.

The Ordinance of 18 January 1984 will be repealed and replaced by the future Ordinance on Nuclear Energy. Following the Act of 21 March 2003, "radioactive waste" shall mean radioactive substances or materials contaminated by radioactivity which are not re-used [Section 3].

Pursuant to the Act of 21 March 2003, the disposal of radioactive waste is based on a new concept defined by an expert group. Following a long observation phase, the underground repository of radioactive waste is sealed and placed under the authority of the state. Until the repository is sealed, costs are covered by nuclear operators, who shall therefore submit to the government a waste disposal plan including a schedule, as well as technical aspects of the different disposal stages and a financial plan.

The act provides in Section 30 that radioactive waste produced in Switzerland shall, in principle, be disposed of in Switzerland, in such a way that the lasting safety of man and the environment is ensured. A licence to export radioactive waste for conditioning must be issued, provided that a number of conditions are met: in particular, the destination state shall have a suitable disposal facility. It shall also have approved, in an international convention, the import of radioactive waste for the purpose of conditioning. In addition, transit states must have approved the transit and there must be an agreement with the receiver on the return of waste [Section 34].

It is relevant to note that, at the international level, Switzerland has ratified the 1997 Joint Convention on the Safety of Spent Fuel management and on the Safety of Radioactive Waste Management.

a) Waste from nuclear installations

Licensing system

The Federal Atomic Energy Act of 1959 dealt with the question of radioactive waste (residues) only from the viewpoint of a licence, or the revocation of a licence, for its possession and transport [Act of 23 December 1959, Sections 4 and 9].

Provisions dealing with the question of waste are now included in the Federal Order of 6 October 1978, supplementing the Atomic Energy Act [Sections 1 and 10]. A Federal Council Ordinance of 27 November 1989 contains details as to the implementation of the licensing procedure, and lays down the preparatory steps to be taken in constructing a repository for radioactive waste provided for in Section 10 of the Federal Order of 1978.

The Federal Council lays down implementing provisions and designates the relevant administrative bodies and the Commissions responsible for studying nuclear energy questions. The possession, transport, import and export of radioactive waste (residues) require a licence from the Confederation [Act of 23 December 1959, Section 4].

The licensing regime applicable to radioactive waste repositories follows the same procedure and involves the same authorities as those involved in the licensing of nuclear installations (general licences) [Ordinance of 18 January 1984, Section 6 and amendment of 2 March 1987]. The general licence, which fixes the site and the general outline of the project, also determines the storage capacity and the categories of waste as well as the structure of the underground or surface installations. Before granting a licence, the Federal Council consults the local communities concerned and the services of the Confederation specialised in the field.

The Federal Energy Office is responsible for implementing the procedure for licences for installations for the disposal of nuclear waste after consultation with the Federal Commission for the Safety of Nuclear Installations. The latter gives its opinion after having seen the first safety assessment reports by the principal Nuclear Safety Division of the Federal Energy Office [Ordinance of 14 March 1983, Section 2].

Should a licence to possess radioactive waste (residues) be revoked, the waste is transferred either to another licence-holder or to the Confederation [Act of 23 December 1959, Section 9.4].

The Confederation is responsible, as it is for nuclear installations, for supervising the possession of radioactive waste (residues) [Section 8], and this task is carried out by the principal Nuclear Safety Division of the Federal Energy Office. The supervisory bodies are empowered to have any radioactive waste which constitutes a radiation protection hazard seized or disposed of, at the producer's expense [Act of 23 December 1959, Sections 9 and 39; Federal Order of 6 October 1978, Section 10].

A licence is also required for the transport or possession of wastes (residues) [Section 4.1]. The granting of such licences is the responsibility of the Federal Energy Office [Ordinance of 18 January 1984, Section 9]. The task of supervising these activities is carried out by the principal Nuclear Safety Division.

Storage and disposal of waste

As provided for by the Federal Order of 6 October 1978 supplementing the Atomic Energy Act, different principles apply to the management and disposal of radioactive waste, such as the responsibility of producers of waste to organise its safe disposal [Section 10.1]; the introduction by the Federal Council of a special procedure authorising preparatory measures for the construction of a radioactive waste repository [Section 10.2]; the obligation for waste producers to become members of a public body and to pay equitable contributions to cover the costs of waste disposal [Section 10.3]; the guarantee of the safe disposal of radioactive waste (transitional provisions having been made for installations in operation or being built] being made a condition for the granting of general licences for nuclear power plants [Section 3.2].

Repositories must conform to the safety conditions and technical criteria laid down by the Federal Commission for the Safety of Nuclear Installations and the Federal Energy Office in Directives R-21 of October 1980.

A Confederation working group on radioactive waste management (*Groupe de travail de la Confédération pour la gestion des déchets nucléaires* – AGNEB) was set up by the Federal Council on 15 February 1978. This Group is responsible for following the work carried out in this sector by other bodies, and for preparing the technical elements necessary for making an evaluation and which will serve as an aid to the Federal Council and the Federal Department of the Environment, Transport, Energy and Communications when taking decisions in this field. It ensures that the Confederation respects the time limits prescribed for licensing procedures and reports once a year to the Department.

In 1972, the producers of radioactive waste, including the Confederation, formed a private company – the National Corporation for the Disposal of Radioactive Waste (*Société coopérative nationale pour l'entreposage des déchets radioactifs* – NAGRA) – which has the task of managing the radioactive waste for which waste producers are responsible.

With respect to operating licences for nuclear power plants not covered by the provisions of the Federal Order of 6 October 1978 as they were already in operation or under construction, the Federal Department of the Environment, Transport, Energy and Communications made prolongation of their validity beyond 1985 subject to the guarantee of a satisfactory method of disposing of the waste from the installation. The electricity companies concerned were thus obliged to submit proposals offering such a guarantee to the Federal Council before 31 December 1985.

Since then, the National Corporation for the Disposal of Radioactive Waste (NAGRA), commissioned by the Swiss nuclear power plants, has been at work to demonstrate the feasibility of waste disposal. In January 1985, NAGRA submitted a "1985 Guarantee Project" ("*projet garantie 1985*") to the Swiss safety authorities (namely the principal Nuclear Safety Division and the Federal Commission for the Safety of Nuclear Installations, both answerable to the Federal Energy Office). The Confederation Inter-Agency Working Group entrusted with supervising work on nuclear waste management (AGNEB) was made responsible for submitting a prior opinion on the NAGRA project to the Federal Council. Swiss and foreign experts were called upon to assist in preparing this opinion.

Since the assessment of such a project is time-consuming, the Federal Council, so as not to compromise its exhaustive and scientific nature, decided to extend the time limit for establishing the "Guarantee" until such time as it was able to judge the contents of the said report. Until then, operating licences for nuclear power plants were to remain valid.

In June 1988, following a detailed examination by the safety authorities, the federal government decided that a sufficient guarantee of safety had been established for all categories of waste, although a site still had to be found for high and medium-level waste.

On 27 November 1989, the Federal Council adopted an Ordinance on preparatory measures for the construction of radioactive waste repositories, thus repealing the Ordinance of the same name of 24 October 1974. The Federal Order of 6 October 1978 concerning the Atomic Energy Act provides that the Federal Council must grant a licence before preparatory measures can be undertaken for constructing a radioactive waste repository (in practice, the research carried out by the National Corporation for the Disposal of Radioactive Waste – NAGRA), the licensing procedure being determined by ordinance [Section 1]. Under the 1989 Ordinance, the federal licensing procedure, which has been simplified, is restricted mainly to nuclear safety. Some work, such as seismic research and surface drilling, must be notified to the supervisory authorities, but they no longer require a licence from the Federal Council [Ordinance of 27 November 1989, Section 2.2]. This new ordinance should enable NAGRA to accelerate its work.

Over and above the licences required for nuclear installations, a special licence is necessary in the case of waste repositories in order to proceed with preparatory steps to set up such a repository [Ordinance of 27 November 1989, Section 2]. The Federal Council is the competent authority to grant such licences [Section 14] by virtue of an instruction issued to the Federal Department of the Environment, Transport, Energy and Communications; the cantons concerned and the specialised services of the Confederation are invited to make observations [Sections 10 to 12]. Supervision of the preparatory and follow-up measures and work is carried out jointly by the specialised services of the Confederation designated by the Federal Council, and by the cantons concerned [Section 15]. The Federal Order of 6 October 1978 gave the Federal Council the power of compulsory purchase in order to establish repositories, and this power may be transferred to the beneficiary of the compulsory purchase [Section 16].

b) Waste from industrial, research, medical and educational uses

These types of waste are governed by the Radiation Protection Ordinance of 22 June 1994 [Sections 79 to 93] as amended on 3 June 1996 by the Federal Council. The Ordinance of 8 July 1996 on the transport of radioactive waste [RS 814.557] regulates the method of treating radioactive waste both before and during its transport and for the purposes of its declaration to the Paul-Scherrer Institute (IPS). It co-ordinates the collection activity organised by the Federal Office of Public Health together with the IPS. The ordinance entered into force on 1 August 1996 and repeals the Ordinance of the Federal Department of the Interior of 18 March 1977. Annexes 1 to 4 specify the types and classes of radioactive waste, the type of packaging required (including technical details) and the proper accompanying documentation for each delivery.

In accordance with the Radiation Protection Ordinance, all radioactive waste producers must make provision for the temporary storage of waste at the site of production, and submit details of their proposal for approval either to the Swiss National Accident Insurance Office in the case of enterprises subject to the Federal Accident Insurance Act, or to the Federal Office of Public Health in all other cases. This procedure is necessary before the Insurance Office or the Office of Public Health can take a decision as to the licences for the possession and use of radioactive substances, and equipment containing such substances [Ordinance of 22 June 1994, Sections 84 to 86; Act of 22 March 1991].

It is the Confederation's responsibility to collect all the radioactive waste produced by the institutes and enterprises within its territory. The collection of this waste is organised jointly by the

Federal Office of Public Health and the Paul-Scherrer Institute (IPS). The waste is sent to collection centres designated by the public authority, either to be stored in a repository set up under the responsibility of the Federal Department of the Interior, or to be disposed of [Ordinance of 22 June 1994, Sections 82 to 86]. The modification of the Ordinance of 8 July 1996 now requires that radioactive waste not derived from the use of nuclear energy must be delivered to the IPS at Villigen (Canton of Argovie) after having been properly treated.

The Federal Department of the Interior is the regulatory authority responsible for making any implementing provisions required for radioactive waste management [Ordinance of 22 June 1994, Section 87.3].

8. Non-Proliferation and Physical Protection

There is no legislation dealing specifically with nuclear security in Switzerland. However, special provisions have been included in nuclear instruments adopted by the Confederation.

The general licence required for the operation of a nuclear power plant is granted only to Swiss citizens resident in Switzerland. Section 5(3) of the Federal Act of 23 December 1959 on Atomic Energy provides that "the Federal Council may make licences to construct or operate nuclear installations subject to the condition that the applicant be a Swiss citizen residing in Switzerland. For licences requested by corporations, the Federal Council may require that at least two-thirds of the Board of Management be Swiss citizens residing in Switzerland and that the registered office be located in Switzerland". Similarly, Section 3(3) of the Federal Order of 6 October 1978 amending the said federal act provides that "general licences are granted only to Swiss citizens resident in Switzerland and to corporations regulated by Swiss law which have their registered office in Switzerland and are under Swiss control". In this regard, the Act of 21 March 2003 provides for less restrictive conditions to be fulfilled by applicants for a general licence. The latter may be granted to limited liability companies, cooperative societies or corporate bodies governed by public law. A foreign company shall have a Swiss subsidiary company listed on the commercial register. However, if not in breach of any international undertaking, the Federal Council may refuse a general licence to a company governed by foreign law when the state in which it has its headquarters does not grant reciprocity [Act of 21 March 2003, Section 13.2].

General licences for nuclear installations and licences to handle nuclear articles shall be granted provided that this would not be in breach of any international commitment and that Switzerland's external security is not affected [Act of 21 March 2003, Sections 7(e) and 13.1(e), (f)].

Pursuant to Section 8 of the Act of 23 December 1959, in supervising nuclear installations and the possession of nuclear fuels, the Federal Council, or the body appointed by it, takes all steps which may be necessary for the external security of the country and for the fulfilment of its international commitments. The Act of 21 March 2003 does not contain a similar express provision, however, it grants wide powers of investigation to the nuclear supervisory authorities. The latter shall inform the public of the state of nuclear installations and of the situation relating to nuclear articles and radioactive waste; in addition they may not process personal sensitive data [Act of 21 March 2003, Sections 72 *et seq.*]. When national defence is at stake, the supervisory authorities in the radiation protection field have the power to waive health requirements.

Generally speaking, all licences required by the Act of 21 March 2003 are granted provided the protection of man and the environment is ensured [Sections 7, 13, 16, 20]. Moreover, a licence to handle nuclear articles shall be granted provided that there are no grounds for refusal it relating to the

non-proliferation of nuclear weapons, in particular international control measures supported by Switzerland, even if not formally binding in international law.

It should be noted that, at the international level, Switzerland ratified the 1968 Treaty on the Non-Proliferation of Nuclear Weapons, on 9 March 1977, and the 1996 Comprehensive Test Ban Treaty, on 1 October 1999. It also ratified the 1980 Convention on the Physical Protection of Nuclear Materials.

9. Transport

The transport of radioactive or fissile materials in Switzerland is governed by a number of different regulations, each dealing with a particular form of transport. In general, these instruments implement in Switzerland the international regulations in this field.

Thus, for road transport, the basic text is the Federal Council Ordinance of 24 May 1972 (as amended on 1 January 1979), relating to the transport of dangerous goods by road (SDR). The ordinance provides that foreign vehicles which do not fully satisfy the technical norms which it prescribes shall nevertheless be allowed into Switzerland provided that the transport operation meets the standards laid down in the European Agreement of 30 September 1957 (as revised on 1 October 1978), concerning the International Carriage of Dangerous Goods by Road (ADR) [Ordinance of 24 May 1972, Section 1.4].

For transport by rail, the legislation in force is contained in the Regulations concerning transport by rail and by water, known as the Transport Regulations, of 2 October 1967 (updated on 1 January 1990) whose Annex I incorporates the International Regulations concerning the Carriage of Dangerous Goods by Rail (RID). This Annex is itself entitled the Swiss International Regulations concerning the Carriage of Dangerous Goods by Rail (RID/RSD).

The transport of radioactive or fissile materials by inland waterway is governed by the above-mentioned Transport Regulations (RID/RSD), and if on the Rhine, is subject to the Regulations for the Transport of Dangerous Goods on the River Rhine (ADNR) of 29 April 1970.

The Air Transport Regulations of 3 October 1952 apply to the transport by air of radioactive or fissile materials authorised by the Federal Civil Aviation Office, on condition that the transport is carried out in accordance with the regulations laid down by the International Air Transport Association (IATA) concerning the transport of restricted articles by air [Regulations of 3 October 1952, Sections 13 and 14, approved by the Federal Order of 16 December 1952. Decision of 1 July 1963]. The Act of 21 March 2003 on Nuclear Energy prohibits the transport of nuclear materials containing plutonium in Swiss air space [Section 10].

The sending by post of radioactive or fissile materials whose specific activity does not exceed 0.002 microcurie per gramme is governed by the Federal Council Ordinance of 1 September 1967 as amended on 21 November 1979, which amends the implementing Ordinance of the Post Office Act. In cases where the specific activity of the materials exceeds this figure, the Transport Regulations (RID/RSD) applies.

The Federal Department of the Environment, Transport, Energy and Communications is responsible for transport operations by road, rail and inland waterway. This Department has the task, along with the other bodies concerned, of drawing up regulations in the field of the transport of radioactive or fissile materials. In the case of air transport, the Federal Civil Aviation Office may

impose additional requirements to be observed during transport operations, as long as these do not contradict the regulations laid down in this field by IATA [Air Transport Regulations of 3 October 1952, Section 14]. As for sea transport, the relevant international regulations are applied directly [Decision of 1 July 1963, Section 1].

10. Nuclear Third Party Liability

Switzerland has signed the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy, and the 1963 Brussels Supplementary Convention, but has not ratified them. On 14 December 1992, the Federal Council decided not to ratify the Paris Convention and the Brussels Supplementary Convention in the near future, on the grounds that Switzerland had adopted relatively recently an Act on Nuclear Third Party Liability dated 18 March 1983, and that certain provisions adopted differed from those of the Paris Convention. Moreover, a comprehensive review of Swiss nuclear energy legislation is being undertaken. Ratification of the two Conventions has thus been postponed until a later date. Switzerland, however, continues to follow with great interest international developments in the law of nuclear third party liability, and participates in the discussions carried out in this field. In addition, it signed the Protocols to amend the Paris Convention and the Brussels Convention on 12 February 2004.

Provisions relating to nuclear third party liability were originally contained in the Federal Act of 23 December 1959. These provisions were completed on 13 June and 19 December 1960 respectively by a Federal Council Ordinance and Order. This legislation, whose purpose was to regulate the operation of the Fund for Delayed Atomic Damage provided for under Section 19 of the 1959 Federal Act, has since been repealed.

The Federal Council decided to exempt operators of nuclear installations, whose nuclear fuel and waste has an activity of less than 1 curie, from the legal provisions on third party liability and mandatory insurance.

Meanwhile, questions of third party liability were regulated in a general fashion by the Act of 18 March 1983 on Nuclear Third Party Liability (*Loi sur la responsabilité civile en matière nucléaire* – LRCN), which was followed by an implementing Ordinance of 5 December 1983. This Act abides by two basic principles, namely that of strict liability and that of the channelling of liability to the operator of a nuclear installation. On the other hand, the LRCN rejects the principle of the limitation of third party liability in amount and provides that the person liable must commit himself for an unlimited amount. The Federal Council is obliged under this Act to increase the minimum amount covered by private insurance once the insurance market offers higher cover on acceptable terms. Accordingly, on 19 November 1997, the government further amended the Ordinance of 5 December 1983 on Nuclear Third Party Liability (ORCN), which had already been amended in December 1985, in October 1990 and in December 1996. The general situation on the insurance market changed dramatically after the events of 11 September 2001. The Swiss National Insurance Pool decided to modify private policies covering nuclear installations on Swiss territory and to limit the cover for damage due to terrorist acts. This modification to private policies led to an amendment of the ORCN.

Liability is covered as follows:

- by private insurance up to Swiss francs (CHF) 1 billion for each nuclear installation (CHF 50 million for each operation involving the transport of nuclear goods across Switzerland) [LRCN of 18 March 1983, Section 11; ORCN of 5 December 1983,

Section 3, as amended on 4 December 2000]; this amount may be limited to CHF 500 million for damage caused by a terrorist act [ORCN of 5 December 1983, as amended by the Ordinance of 29 November 2002, Section 4(1)(a^{bis})];

- by the Confederation up to CHF 1 billion when the damage exceeds the amount covered by private insurance, or is excluded therefrom [LRCN of 18 March 1983, Section 12];
- by all the assets of the person liable;
- according to a special procedure with regard to "catastrophes".

The adoption of an Ordinance of 19 November 1997, which entered into force on 1 January 1998, modified the method of calculating federal nuclear third party liability insurance premiums to be paid by potentially liable persons. As of 1 January 1998, these amounts are fixed in Swiss francs rather than as a percentage of the premiums collected by private insurers for third party liability coverage.

The Fund for Delayed Atomic Damage has been tranformed into a Fund for Nuclear Damage. Fees are levied from nuclear operators and holders of transport licences so as to cover the contributions made by the Confederation [Sections 14 and 15].

The Federal Council Ordinance of 5 December 1983 (ORCN) specifies the scope, insurance conditions, coverage of costs by the Confederation and the management of the Fund for Nuclear Damage set up by the LRCN. The Fund is not a separate legal entity but is financially independent. The ORCN also provides for the assignment of the costs of preventive measures taken by the appropriate authorities.

The Act of 21 March 2003 has amended the provisions of LRCN relate to deep repositories: it provides that, where damage is caused by a deep geological repository which is no longer governed by nuclear energy legislation, the Confederation shall cover nuclear damage out of general funds and up to CHF 1 billion.

II. INSTITUTIONAL FRAMEWORK

The Act of 21 March 2003 contains few provisions related to the institutional framework to be introduced by the new nuclear legislation. These provisions will be further developed in the ordinances implementing the act and in particular in the future Ordinance on Nuclear Energy. The following chapter describes the new elements contained in the Act of 21 March 2003, however, it mainly describes the current institutional framework which will remain until the entry into force of the Act of 21 March 2003 and its implementing ordinances.

Since 24 November 1957, when Article 24 quinquies (now Article 90 of the amended Swiss Constitution which entered into force on 18 April 1999) was inserted into the Swiss Constitution, nuclear energy has been declared to be the responsibility of the federal legislature. Thus the Confederation supervises all nuclear activities and is very active in their organisation and development. The Confederation also plays an important role in the field of research and the training of nuclear specialists [Act of 23 December 1959, Section 2]. Lastly, it may acquire the nuclear

materials necessary or forbid the export of such materials (although it is normally the operators of nuclear power plants who acquire and possess nuclear fuels, with the authorisation of the Confederation) [Sections 3 and 5].

The Federal Council has the necessary regulatory and administrative powers to adopt the regulations required for the development of the use of nuclear energy and for radiation protection. The Federal Department of the Environment, Transport, Energy and Communications, and the Federal Department of the Interior are responsible for implementing the provisions adopted by the Federal Council in the field of the use of atomic energy and the field of protection against ionising radiation, respectively. Various commissions study questions relating to the use of atomic energy, each in its specific field of competence.

Apart from the federal departments and the specialised services of the Confederation, the public sector is also represented by a public scientific research centre, the Paul-Scherrer Institute.

1. Regulatory and Supervisory Authorities

a) Federal Council

The Federal Council, which represents the executive branch of government in Switzerland at federal level, plays an important role in the organisation and running of nuclear activities. The Act of 21 March 2003 maintains the Federal Council as a key body in the nuclear institutional framework.

In the first place, the Federal Council assists in the development of regulations in the atomic energy field, and ensures their implementation [Act of 23 December 1959, Sections 11 and 37; Act of 21 March 2003, Section 101]. More particularly, the Federal Council has the power to broaden the category of activities for which a preliminary licence is required [Act of 23 December 1959, Section 4.2; Act of 21 March 2003, Section 6]. On the other hand, under the Act of 23 December 1959, it may also waive the rules on licences, third party liability and insurance, in the case of activities which give rise to only a very low risk of radiotoxicity [Section 1.4]. Under the Act of 21 March 2003, the Federal Council or the authority designated by it may make exceptions to the licensing regime by taking special measures against specific destination states [Section 8]. It may also exclude from the scope of this act low-level nuclear articles and radioactive waste.

On an administrative level, the Federal Council has been made responsible for examining and deciding upon applications for preliminary general licences for nuclear installations, prior to construction and operating licences [Federal Order of 6 October 1979, Sections 1 and 5 to 8; Ordinance of the Federal Council of 11 June 1979, Sections 3 and 4]. This provision is maintained in the Act of 21 March 2003 [Section 12]. The Federal Council also grants licences for taking preparatory steps for the setting up of a radioactive waste repository [Federal Order of 6 October 1978, Section 10; Ordinance of the Federal Council of 27 April 1989, Section 2]. Under the Act of 21 March 2003, the DETEC is the competent licensing authority [Section 35]. However, the act provides that the Federal Council may exclude from the licensing regime studies which involve only minor prejudice.

In general, the Federal Council licenses and supervises nuclear installations and materials. It may take measures necessary for the protection of persons, property and important rights, as well as for Switzerland's external security and fulfilment of its international commitments [Act of 23 December 1959, Section 8; Ordinance of 18 January 1984, Section 6]. The Act of 21 March 2003 does not maintain such an express provision, however, it grants wide powers of investigation to nuclear supervisory authorities.

The Federal Council may set out procedures to regulate activities relating to nuclear installations, including a licensing regime for handling nuclear articles [Act of 21 March 2003, Section 6] and the procedure organising reliability tests. It lays down the minimum requirements which specialised staff of nuclear installations and the surveillance team have to meet [Act of 21 March 2003, Sections 22 and 23]. It lays down the criteria applicable to protection zones [Section 40].

In general, the Federal Council sets up the necessary administrative bodies, and the commissions responsible for studying questions relating to the use of nuclear energy and to radiation protection [Act of 23 December 1959, Sections 37 and 38; Act of 21 March 2003, Sections 6, 24, 32, 70, 71, 81].

Within the nuclear legislative framework applicable until the entry into force of the Act of 21 March 2003, and for the purposes of promoting nuclear research, the Federal Council is authorised to give financial assistance to research agencies.

b) Federal Assembly

The Federal Assembly, Switzerland's parliament, is involved in the nuclear field in approving the Federal Council's decisions as to general licences for nuclear installations [Federal Order of 6 October 1978, Sections 1 and 8; Ordinance of the Federal Council of 11 July 1979, Section 4; Act of 21 March 2003, Sections 48 and 67]. The Act of 21 March 2003 provides that, if the Federal Council refuses to grant a general licence and the Federal Assembly does not approve this decision, it shall instruct the Federal Council to grant the general licence with any requirements decided by it and to submit to it a new decision for approval. The decision of the Federal Assembly regarding the approval of a general licence shall be subject to referendum.

The Assembly is also competent in respect of third party liability and insurance [Act of 18 March 1983, Section 29]. Thus, in the case of catastrophes, the Federal Assembly is empowered to draw up indemnification rules determining the general principles of compensation for victims. A special independent body may be set up by the Federal Assembly to ensure that these principles are applied.

The Act of 21 March 2003 requires that the Federal Council regularly inform the Federal Assembly of the progress of the programme prepared by the persons responsible for disposing of radioactive waste [Section 32].

c) Federal Department of the Environment, Transport, Energy and Communications (DETEC)

The general task of the Federal Department of the Environment, Transport, Energy and Communications (*Département fédéral de l'Environnement, des Transports, de l'Énergie et des Communications* – DETEC) is to prepare legislation on the use of nuclear energy [Ordinance of the Federal Council of 9 May 1979]. In conjunction with the Federal Department of the Interior, and after having consulted the competent supervisory bodies, it lays down guidelines on the supervisory measures which should be taken to protect the population, and on co-ordinating the work of the bodies responsible for supervision [Ordinance of the Federal Council of 30 June 1976, Section 20].

The DETEC has the task of following the licensing procedure in the case of applications for licences to take preparatory steps for studying sites with a view to setting up radioactive waste repositories [Ordinance of 27 November 1989, Sections 4, 10 *et seq*.].

Under the Act of 21 March 2003, the DETEC is the competent authority to grant construction and operating licences [Sections 15 and 19], as well as licences for geological studies carried out in a possible location in order to gather information about the feasibility of constructing a deep geological repository [Section 35].

Lastly, under the Ordinance of 9 May 1979, the Federal Commission for the Safety of Nuclear Installations reports to the DETEC. The Law of 21 March 2003 maintains this provision [Section 71].

d) Federal Energy Office (OFEN)

Under the Order of the Federal Council of 23 December 1968 on the reorganisation of Swiss administrative authorities, the Federal Energy Office (OFEN), which forms part of the Federal Department of the Environment, Transport, Energy and Communications, was given the powers which previously belonged to the Delegate for Atomic Energy Questions, except for those which were expressly conferred on the Science and Research Division [Order of the Federal Council of 23 December 1968, Section 5; Federal Act of 19 September 1978 on the organisation of the Administration; Ordinance of 9 May 1979].

The OFEN therefore is competent to prepare and apply legislation in the field of nuclear energy, and also to prepare, in conjunction with the Federal Department of Foreign Affairs, international nuclear treaties and to ensure that they are properly implemented. The Office also has the task of examining and co-ordinating studies carried out in the field of nuclear energy. Under the Ordinance of the Federal Council of 18 January 1984, the OFEN is responsible for examining applications for the construction, operation or modification of nuclear installations, and in the case of nuclear installations which do not produce electricity, it also grants the licences. Under the Act of 21 March 2003, applications for a general licence shall be sent to the OFEN, which checks the application file and decides whether an expertise is necessary [Sections 42 and 43].

Furthermore, the Office is the competent authority for licensing the transport, import and export of nuclear materials and equipment, and for the storage of nuclear fuels and radioactive waste [Section 9].

The Federal Energy Office includes a principal Nuclear Safety Division (*Division principale de la sécurité des installations nucléaires* – DSN). This Division is called upon to give an expert opinion on the technical safety reports relating to the various licences required under Swiss nuclear law: general licences and licences for the construction and operation of nuclear installations, licences for the transport and marketing of nuclear materials and equipment, and licences in the field of radioactive waste management. The Division also ensures that technical checks are carried out on nuclear installations and on the Paul-Scherrer Institute, and concentrates on measures to be taken to prevent nuclear catastrophes.

e) Federal Department of the Interior

As regards nuclear matters, the Federal Department of the Interior (*Département fédéral de l'intérieur*)has been given regulatory and administrative powers in the area of radiation protection. It is

also competent with regard to nuclear research questions and co-ordinates activities with the universities and federal *Écoles Polytechniques* [see Section 3(a) – Paul-Scherrer Institute].

With regard to its regulatory powers, the Federal Department of the Interior has a general responsibility for radiation protection questions. It has the task of laying down the necessary rules for applying measures enacted by the Federal Council for protection against ionising radiation. In particular, the Federal Department of the Interior, with the assistance of the Federal Department of the Environment, Transport, Energy and Communications, and after consulting the competent supervisory bodies, lays down guidelines for supervisory activities to be carried out in the radiation protection field.

In addition, the Federal Department of the Interior, in agreement with the Federal Commission for Protection against Radiation, lays down guidelines on measures to be adopted for the protection of persons exposed to radiation for medical purposes. With regard to foodstuffs, the Federal Department of the Interior determines the maximum concentrations of radionuclides which may be incorporated in food products.

Moreover, the Federal Department of the Interior determines the training programme, the method of examination, and rights in relation to the training and advanced courses offered by the Confederation in the field of radiation protection. Courses given by private institutions must first be approved by the Federal Department, or the competent supervisory body, if they are to benefit from subsidies which will be fixed by the Federal Department of the Interior. In any event, in order to use radioactive materials or equipment generating ionising radiation in a professional context, it is necessary to have completed training recognised by the Federal Department of the Interior or the competent supervisory body. By reason of its administrative powers, the Federal Department of the Interior, with the assistance of the Federal Department of the Environment, Transport, Energy and Communications, co-ordinates the activities of nuclear bodies involved in radiation protection.

The Federal Department of the Interior also has the power to impose any necessary measures with regard to the medical supervision of persons exposed to ionising radiation at work.

In the radioactive waste management field, the Federal Department of the Interior ensures the disposal by the Paul-Scherrer Institute (IPS) of radioactive waste other than that coming from electricity-producing nuclear installations and facilities for the reprocessing of spent fuel.

Lastly, the Federal Office of Public Health and the Federal Office of Education and Science both report to the Federal Department of the Interior [Order of the Federal Council of 23 December 1968, Section 1]. It may hear appeals from decisions made by the Federal Office of Public Health.

f) Federal Office of Public Health (OFSP)

Through the agency of its Radiation Protection Division, the Federal Office of Public Health (*Office fédéral de la santé publique* – OFSP) enjoys wide administrative and supervisory powers in the field of protection against radiation.

Administrative powers

The Office is the competent authority for the granting or revocation of licences for the production, use, possession, disposal, import and export of radioactive substances and for nuclear equipment, whether used for industrial, scientific, medical or agricultural purposes, with the exception of nuclear installations, nuclear fuel and radioactive waste (residues). If, however, a negative response is given by the Swiss National Accident Insurance Office (*Caisse nationale Suisse d'assurance en cas d'accidents* – CNA), which considers applications from bodies subject to the Federal Act on Accident Insurance, then the Federal Office is bound by this opinion. Persons possessing radioactive substances or equipment emitting ionising radiation for which no licence is required because the quantity or activity of the nuclear material concerned is below a given threshold, must make a declaration to the Federal Office. Persons manufacturing or trading in such substances or equipment which are not freely available or are for restricted use, must submit an annual report to the Federal Office on their activities. The Office may allow certain types of radioactive substances and equipment emitting ionising radiation or containing radioactive substances to be used generally or for specific purposes. The Federal Office of Public Health grants the necessary licence for the restricted use of substances and equipment, and receives the declarations of persons possessing substances or equipment available for general use, unless it waives such formalities.

The Federal Office of Public Health, in consultation with a panel of experts representing various interests, is also the competent authority for approving radioactive substances intended to be used for medical purposes. It must authorise any work involving unsealed radioactive sources which a company wishes to carry out outside its own premises.

Supervisory powers

An expert designated by the Federal Office of Public Health checks those parts of equipment used for radiotherapy which determine the radiation dose given, every time the equipment is modified in such a way that this dose could be affected and in any event at least once a year [Section 58]. The licence-holder keeps a record of the results of these verifications. The Federal Office may require that equipment used for diagnosis be checked annually over a period of four weeks in normal working conditions. A record is kept of the number and location of radiographic and radioscopic examinations carried out during this period, as well as of the conditions under which they took place.

In general, the Office advises the Federal Department of the Interior and that of Transport, Communications and Energy on the guidelines to be adopted with regard to the carrying out of inspections.

The Federal Office of Public Health supervises enterprises in which the primary concern is protection of the public, while the Swiss National Accident Insurance Office supervises those in which the primary concern is protection of workers.

The principal Nuclear Safety Division on the other hand is responsible for inspecting the safety of nuclear installations. The Federal Office of Public Health and the Federal Energy Office, each in its own sphere, control the import and export of radioactive substances as well as equipment and objects containing such substances.

Other powers

The Radiation Protection Section of the Federal Office of Public Health is responsible for the collection and dispatch of radioactive waste from industrial, research, and medical activities. It sends a circular to listed waste producers to inform them that waste will be collected from the centre which has been assigned to them. The Office works in co-operation with the Paul-Scherrer Institute with respect to the collection and conditioning of this waste. The Office represents the central administration responsible for collecting radioactive waste other than that from nuclear installations, within the National Corporation for the Disposal of Radioactive Waste (NAGRA).

The Office also organises, along with other federal services and non-governmental organisations, training and advanced courses in radiation protection. It is responsible for the payment of subsidies allocated by the Confederation to private institutions organising such courses.

g) Federal Office of Education and Science (OFES)

The Federal Office of Education and Science (*Office fédéral de l'éducation et de la science* – OFES), set up in 1968, replaced the Delegate for Atomic Energy Questions. It is part of the Federal Department of the Interior where, together with the Federal Council of *Ecoles polytechniques*, it forms part of the Science and Research Group, whose activities are administered by a directing body *(état-major)*.

The OFES co-ordinates research activities carried out in university circles, the private sector, and by government authorities. It represents the government in bodies carrying out fundamental and applied research. It also deals with research into thermal nuclear fusion, and high and medium-energy nuclear physics.

h) Other authorities

Other federal departments are called on to regulate questions falling within the nuclear energy field, and in particular: the Federal Department of Justice and Police, for the transport by road of dangerous goods, and in relation to public protection measures; the Federal Department of Foreign Affairs and the Federal Economics Department for the export of nuclear materials of particular significance; the Department of Public Protection and Sport for radiation protection on behalf of the army; and the Federal Finance Department with respect to legislation on nuclear measurement units.

2. Advisory Bodies

a) Federal Commission for the Safety of Nuclear Installations

i) Legal status

The Federal Commission for the Safety of Nuclear Installations (*Commission fédérale de la sécurité des installation nucléaires*) was set up by Ordinance of the Federal Council dated 13 June 1960. The Commission, which is administratively attached to the Federal Energy Office, acts as an advisory body to the Federal Council and the Federal Department of the Environment, Transport, Energy and Communications [Ordinance of the Federal Council of 13 June 1980, Section 1; Act of 21 March 2003, Section 71].

ii) Responsibilities

The Commission's functions were redefined by a Federal Council Ordinance of 14 March 1983 which repealed the 1960 Ordinance. The Commission is henceforth less involved with operational aspects. In particular, the Commission studies fundamental nuclear safety issues, monitors the operation of nuclear installations and gives its opinion on applications for general licences as well as for licences for the construction, start-up, operation and modification of nuclear installations [Act of 21 March 2003, Section 71].

In particular, it stipulates whether, in view of experience gained and the state of the art of science and technology, all necessary measures of a reasonable nature have been taken to protect man and the environment from ionising radiation. The Commission may restrict itself to dealing with basic nuclear safety questions, or with points on which a project diverges from solutions which have proved satisfactory in other cases.

With regard to the protection of installations against attacks by third parties, it gives its opinion on the technical aspects of design and operation inasmuch as they are connected with nuclear safety. It comments on the expert reports prepared on this topic by the principal Nuclear Safety Division and by other federal services.

The Commission monitors the operation of nuclear installations in Switzerland and abroad in relation to the basic aspects of nuclear safety. It suggests measures it considers necessary and which may reasonably be required in the light of experience and the current state of science and technology [Section 3].

The Commission provides an opinion when nuclear safety legislation is being drawn up or amended. It follows the development of regulatory requirements concerning nuclear safety. It may recommend the adoption or amendment of requirements applying to nuclear power plants, and may participate in any work of this kind carried out by other bodies.

The Commission analyses basic nuclear safety questions concerning installations themselves, and studies the general difficulties involved in assessing their degree of safety. It may recommend measures to increase the safety of installations, and improvements to the licensing procedure and the supervision of the operation of installations.

It follows nuclear safety research at home and abroad, and proposes relevant research that could be carried out in Switzerland, or suggests that Switzerland be involved on a bilateral or multilateral basis in the implementation of projects.

The Federal Department of the Environment, Transport, Energy and Communications, and the Federal Energy Office may submit other nuclear safety questions to the Commission for consideration.

iii) Structure

The Federal Commission for the Safety of Nuclear Installations comprises a maximum of thirteen nuclear experts, proposed by the Federal Department of the Environment, Transport, Energy and Communications, and nominated by the Federal Council. The chairperson of the Federal Commission is appointed by the Federal Council on the proposal of the said Department. Members of the Commission carry out their duties in a private capacity, and not as part of their main professional

activities. They are not bound by any instructions and may not nominate a substitute to take their place.

In order to carry out its duties properly, the Federal Commission may set up internal permanent sub-commissions and specialised groups of experts. If necessary, it may, with permission of the Federal Energy Office, invite external experts to assist with its work.

Representatives of the principal Nuclear Safety Division (DSN) may attend meetings and inspections of the Federal Commission.

The quorum for discussions within the Federal Commission is fixed at two-thirds of its members, and its decisions are taken on a simple majority basis. Should there be an equal number of votes on each side, the chairperson of the Federal Commission has the casting vote.

The Federal Commission's work is confidential and an obligation of professional secrecy is imposed on experts. The chairperson of the Federal Commission may nevertheless, with the permission of the Federal Department of the Environment, Transport, Energy and Communications, send inspection results to the competent cantonal or local authorities, and to the insurers of the installation involved. The Federal Commission for the Safety of Nuclear Installations is served by a secretariat attached to the principal Nuclear Safety Division.

b) Federal Commission for Protection against Radiation

The Federal Commission for Protection against Radiation (*Commission fédérale de la protection contre les radiations)* is attached to the Federal Department of the Interior.

i) Responsibilities

The Commission is responsible for giving general advice to the Federal Department of the Interior on questions relating to the protection of the population against hazards from ionising radiation. Thus, the Commission is consulted in particular on the changes or additions to be made to maximum permissible dose definitions for persons exposed to radiation, and on guideline activity levels and surface contamination in the environment.

If there are medical grounds for removing, whether temporarily or permanently, a person occupationally exposed to ionising radiation from his workplace, the Federal Department of the Interior must ask for the Federal Commission's opinion on the matter.

Guidelines relating to requirements for the protection of patients exposed to radiation for medical examination purposes are adopted by the Federal Department of the Interior.

ii) Structure

Members of the Federal Commission come from university and medical circles and from the Administration.

c) Federal Commission for the Monitoring of Radioactivity

The Federal Commission for the Monitoring of Radioactivity (*Commission fédérale de surveillance de la radioactivité*), which is under the authority of the Federal Department of the Interior, keeps a permanent check on radioactivity in the environment. It regularly informs the Federal Council of the results of its monitoring activities, and prepares information to be given to the public in the event of an increase in the level of ambient radioactivity. If necessary, the Federal Commission may propose to the Federal Council the measures that should be taken to ensure the protection of the population. Work carried out involving unsealed radioactive sources and taking place outside a firm's premises, must be notified to the Federal Commission by the Federal Office of Public Health when there is a risk of contamination of the environment.

Members of the Federal Commission for the Monitoring of Radioactivity include experts from university circles and from the Federal *École polytechnique*. They are appointed by the Federal Council on the proposal of the Federal Department of the Interior.

d) Federal Emergency Organisation on Radioactivity

In the event of a dangerous increase in radioactivity, a Federal Emergency Organisation on Radioactivity (*Organisation d'intervention en cas d'augmentation de la radioactivité* – OIR) is called upon to follow developments in the situation and to propose or recommend appropriate protection measures. The organisation is headed by a Radioactive Steering Committee (*Comité directeur de la radioactivité* – CODRA) which is under the aegis of the Federal Department of the Interior. The Warning Committee has at its disposal an alarm post, a monitoring centre and other resources such as the National Alarm Centre.

Members of the CODRA include representatives from federal departments, government services, the cantons and directors of the different federal offices and other bodies. CODRA also has at its disposal various federal commissions.

e) Technical Commission for the Practical Application of Ionising Radiation

The Technical Commission for the Practical Application of Ionising Radiation (*Commission technique pour l'application pratique des radiations ionisantes)* reports to the Federal Department of the Environment, Transport, Energy and Communications. It is responsible for giving advice to the Confederation and interested firms on the subject of Swiss participation in national or international projects concerning the use of ionising radiation.

3. Public and Semi-Public Agencies

a) Paul-Scherrer Institute (IPS)

On 30 November 1987, the Federal Council decided on the merger, on 1 January 1988, of the Federal Institute for Reactor Research (IFR) and the Swiss Institute for Nuclear Research (ISN), into a research establishment, the Paul-Scherrer Institute (*Institut Paul-Scherrer* – IPS). While the IFR and the ISN worked on fundamental research and applied research covering industrial applications, respectively, the Paul-Scherrer Institute is more of a multi-disciplinary research establishment for natural sciences and engineering [Ordinance of 13 January 1993, Section 2].

i) Legal status

The IPS is a Confederation research establishment governed by public law. This independent legal entity is answerable to the Federal *Écoles polytechniques* Council.

ii) Responsibilities

The Paul-Scherrer Institute is entrusted with research activities in the following fields:

- nuclear physics and particle physics;
- radiation medicine, radiobiology and radiological hygiene;
- research on solids and material sciences;
- nuclear energy techniques (especially relating to nuclear safety and radioactive waste disposal);
- non-nuclear energy techniques and environmental sciences related to energy.

It is thus responsible for the development of large facilities for complex research. The Paul-Scherrer Institute is also competent as regards education and training in colleges (*hautes écoles*), with which it has close ties. The IPS may make its research facilities available to such colleges which may also manage laboratories jointly with the IPS.

The Institute also provides various services to the government and to other public bodies and the economy, in particular in the fields of nuclear safety, radioactive waste disposal and environmental protection in relation to energy use. The IPS may advise federal bodies and carry out research on their behalf. It also provides support to the supervisory authorities responsible for nuclear safety.

Lastly, the Institute collaborates with the international scientific community in preparing joint research and development programmes.

iii) Structure

The Paul-Scherrer Institute is divided into different research and administrative sectors. The Federal *Écoles polytechniques* Council is responsible for organising the administration of the Institute. Management is entrusted to the following bodies:

- the Federal *Écoles polytechniques* Council;
- an Advisory Committee; and
- the Management of the Institute.

The Federal *Écoles polytechniques* Council directs and generally supervises the IPS and its installations. For this purpose, it draws up internal rules and drafts guidelines for the efficient functioning of the Federal Institute.

After consulting the Committee, the Council approves the annual programme of work prepared by the Management of the Institute.

The Advisory Committee, composed of between five and nine members, assists the Federal *Écoles polytechniques* Council with important questions for IPS activities. The Council appoints the chairperson and the members for a period of four years.

The Management of the Institute includes the Director and other members who are answerable to him and who are responsible for specific sectors as determined by the *Écoles polytechniques* Council. The Director administers the IPS and has overall responsibility for the establishment's management and safety. He is answerable in this to the *Écoles polytechniques* Council, which lays down the tasks and responsibilities of the Management.

iv) Financing

Fees are payable for the Institute's services and must cover the cost thereof. The *Écoles polytechniques* Council decides on what fees should be charged, after hearing the opinion of the Federal Finance Department.

b) Fund for the Decommissioning of Nuclear Installations

i) Legal status

Provision was made in the Federal Order of 6 October 1978 concerning the Atomic Energy Act for the setting up of a fund for financing the decommissioning and dismantling of nuclear installations no longer in service (*Fonds pour le financement de la désaffectation et le démantèlement des installations nucléaires mises hors service)*. This fund was set up on 1 January 1984 and is managed under the supervision of the Federal Council. It has been given its own legal personality, and has its headquarters in Bern.

Chapter 7 of the Act of 21 March 2003 contains more specific provisions: it separates the Decommissioning Fund from the Waste Disposal Fund, both of which still report to the Federal Council and have legal personality.

ii) Responsibilities

The fund for financing the decommissioning and dismantling of nuclear installations no longer in service was set up to cover costs arising from the decommissioning and dismantling of nuclear installations no longer in use and from the management of the waste produced.

The Decommissioning Fund established by the Act of 21 March 2003 shall ensure the financing of the decommissioning and dismantling of nuclear installations withdrawn from service, and that of the disposal of the waste produced thereby (decommissioning costs). The Waste Disposal Fund shall ensure the financing of the disposal of radioactive operating waste and of spent fuel assemblies, after withdrawal from service of nuclear installations (disposal costs) [Section 77].

iii) Structure

The fund for financing the decommissioning and dismantling of nuclear installations no longer in service is administered by a Commission with a maximum of eleven members appointed by the

Federal Council and including representatives of operators, the Confederation, and various economic circles.

Each fund established by the Act of 21 March 2003 shall be administered by a board acting as a directing body and nominated by the Federal Council [Section 81].

iv) Financing

The resources of the fund for financing the decommissioning and dismantling of nuclear installations no longer in service are constituted by the contributions paid by the owners of nuclear installations subject to the Ordinance of 5 December 1983 concerning the Fund for the Decommissioning of Nuclear Installations. Every three years, the Commission of the fund fixes the annual amount due by each owner.

The boards administering the funds established by the Act of 21 March 2003 shall set the amount of contributions to be paid by each contributor to the funds.

c) National Corporation for the Disposal of Radioactive Waste (NAGRA)

i) Legal status

The National Corporation for the Disposal of Radioactive Waste – NAGRA (*Société coopérative nationale pour l'entreposage des déchets radioactifs*) is a private co-operative company set up in 1972 by the waste producers (the Confederation and six electricity companies), to undertake, at national level, the study and final disposal of the various categories of radioactive waste.

ii) Responsibilities

NAGRA is responsible for locating sites suitable for the storage of radioactive waste.

In conjunction with the competent federal authorities and the Paul-Scherrer Institute, NAGRA undertakes research programmes with a view to establishing new permanent repositories for waste storage. This research concerns in particular the physical and chemical properties of the geologic formations envisaged as potential storage sites, the safety of solidified waste, packaging material, proposed repositories, the organisation of storage sites and the identification of new ideas for the safe disposal of waste.

To ensure the exchange of information and to promote co-operation in the field of waste management, NAGRA maintains contact with similar organisations in foreign countries.

iii) Structure

All Swiss producers of waste of nuclear origin, including the Confederation, are members of NAGRA. The Confederation participates on two counts, first as a producer of waste from research reactors and from the processing of radioactive materials, and secondly as the collector of waste produced in the fields of industry, research, medicine and education.

The Board of Directors of NAGRA is composed of persons from Ministerial Departments and from industry circles concerned with the disposal of radioactive waste. Particular responsibility for studying the technical and safety aspects of waste processing has been given to a Technical Commission made up of specialists in the nuclear energy field. To accomplish its task, the Commission may call upon external experts.

iv) Financing

NAGRA is a non-profit making co-operative organisation. Expenses are paid out of capital and members' subscriptions. The cost of radioactive waste disposal is borne entirely by the producers of the waste concerned.

UNITED KINGDOM

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I. GENERAL REGULATORY REGIME

1. Introduction

There are at present 27 operational nuclear power units with a total capacity of 12.3 GWe at 11 sites in the United Kingdom. Nuclear energy generates approximately 23% of the country's annual electricity production. A low-level waste disposal site is operated by British Nuclear Fuel (BNFL) at Drigg in Cumbria and the United Kingdom Atomic Energy Authority operates another disposal facility for low-level waste at Dounreay. There is also one research reactor in operation. A mixed oxide (MOX) fuel fabrication plant is in operation at Sellafield. This manufactures MOX fuel from uranium and plutonium separated from spent fuel, which is mainly processed at BNFL's Thermal Oxide Reprocessing Plant (THORP), also located at Sellafield.

In the United Kingdom, the legislation dealing specifically with nuclear energy dates from 1946, in step with the development of the uses of this type of energy for peaceful purposes [Atomic Energy Act 1946]. In discussing nuclear legislation, a division is sometimes made between laws and regulations primarily directed at the protection of people, such as the Radioactive Substances Act 1993, the Health and Safety at Work etc. Act 1974, the Ionising Radiations Regulations 1999 and legislation dealing with nuclear installations, primarily concerned with licensing and controlling the safe operation of nuclear plants and also dealing with third party liability for nuclear damage, such as the Nuclear Installations Act 1965 as amended.

The purpose of this part is to provide an overall picture of the law governing all civil nuclear activities in the United Kingdom. The following part will deal in greater detail with the institutional framework for such activities.

2. Mining Regime

There are no mining activities connected with uranium extraction in the United Kingdom. However, the Secretary of State (in practice the Secretary of State for Trade and Industry) is empowered to search for and work minerals and may authorise other persons to do the same on his behalf [Atomic Energy Act 1946, Section 6]. He is also empowered to provide for the compulsory vesting of the right to work minerals either in himself or in the United Kingdom Atomic Energy Authority (UKAEA) [Section 7], and may compulsorily acquire certain minerals, and plants designed or adapted for the production or use of atomic energy or research [Section 8].

3. Radioactive Substances

The keeping and use of radioactive material and accumulation and disposal of radioactive waste are controlled mainly by the Radioactive Substances Act 1993 ("RSA 1993"). As a result of the Environment Act 1995, enforcement of RSA 1993 is the responsibility of the Environment Agency in

England and Wales and the Scottish Environment Protection Agency in Scotland. In Northern Ireland enforcement is carried out by the Environment and Heritage Service through its Industrial Pollution and Radiochemical Inspectorate (IPRI), an agency within the Department of the Environment for Northern Ireland.

RSA 1993 regulates, by way of compulsory registration with the relevant Environment Agency, the keeping and use of radioactive material on any premises, and similar control is exercised on mobile radioactive apparatus [Sections 6 to 12]. It lays down general provisions for registration of users of radioactive material for the purposes of an undertaking carried on by them. It states certain exemptions from registration including premises covered by a nuclear site licence, and states that the Secretary of State (in Scotland, the Scottish Ministers) may grant further exemptions from registration through specific orders. These cover such things as gaseous tritium light devices [S.I. 1985, No. 1047], radioluminous articles [S.I. 1985, No. 1048], testing instruments [S.I. 1985, No. 1049] and certain substances of low activity [S.I. 1986, No. 1002].

The relevant Environment Agency is:

- for England and Wales, the Environment Agency;
- for Scotland, the Scottish Environment Protection Agency; and
- for Northern Ireland, the Industrial Pollution and Radiochemical Inspectorate (IPRI).

Accumulation of radioactive waste on non-nuclear sites is regulated under the act. Accumulation of radioactive waste on nuclear licensed sites is regulated by means of the nuclear licensing regime provided by the Nuclear Installations Act 1965.

The RSA also requires the authorisation by the relevant Environment Agency of disposals of radioactive waste from both nuclear and non-nuclear sites [Section 13].

In the public sector of education, radioactive substances with an activity in excess of 100 becquerels per gram may not be used in the course of instruction without the approval of the Secretary of State for Education in England and Wales, and Scottish ministers in Scotland. There is a similar restriction on the use of an apparatus (other than a television set or similar apparatus) in which electrons are accelerated by a potential difference of 5 kilovolts or more [in England and Wales: Education Reform Act 1988, Section 218(1)(e); The Education (Schools and Further and Higher Education) Regulations 1989, S.I. 1989, No. 351, Regulation 7; Education Act 1993, Sections 172(6), 189(2) and 301(6); The Education (Special Needs) (Approval of Independent Schools) Regulations 1994, Schedule 1, Section 7, S.I. 1994, No. 651. In relation to Scotland: the Dangerous Materials and Apparatus (Educational Establishments) (Scotland) Regulations 1984, S.I. 1984, No. 668, made under Section 19(a) of the Education (Scotland) Act 1980. In relation to Northern Ireland: the Ionising Radiations Regulations 2000].

4. Nuclear Installations

a) Licensing and inspection, including nuclear safety

The Nuclear Installations Act 1965, as amended, and the Nuclear Installations Regulations 1971 made under the act [S.I. 1971, No. 381] govern the construction and operation of nuclear installations

in the United Kingdom, and health protection at such installations is regulated by the Health and Safety at Work etc. Act 1974.

The competent authority for the licensing of nuclear installations is the Health and Safety Executive (HSE), which is responsible through the Health and Safety Commission (HSC) to the Secretary of State for Trade and Industry for civil nuclear safety questions [Nuclear Installations Act 1965, Section 1, as amended by S.I. 1974, No. 2056, and Regulations made thereunder, and Sections 10 to 12 of the Health and Safety at Work etc. Act 1974].

The Nuclear Installations Inspectorate (NII), part of the Nuclear Safety Directorate of the HSE, ensures that all statutory safety requirements relevant to nuclear installations are complied with. Its nuclear installation inspectors are appointed by the HSE and have the necessary powers to enforce the relevant legislation. The purpose of inspections is to verify that the requirements of the nuclear site licence are met throughout the construction, commissioning and operating period of the nuclear installation and its decommissioning. They also provide checks on the effectiveness of the safety measures taken by the licensee.

The Nuclear Installations Act 1965 makes provision for the licensing of nuclear installations by means of a nuclear site licence which sanctions the use of a particular site for a specific reactor type or plant. Previously, nuclear installations operated by the UKAEA were not subject to the licensing system of the 1965 Act. By Ministerial directive, the UKAEA was required to maintain equivalent standards to those imposed on other nuclear operators. However, the Nuclear Installations Act 1965 (Repeal and Modification) Regulations 1990 removed the UKAEA's exemption from licensing [S.I. 1990, No. 1918].

The 1971 Regulations prescribe as licensable various classes of installation in the nuclear field where nuclear hazards could arise. Sections 1, 3 to 6, 22 and 24(a) of, and Schedule 2 to, the 1965 Act are listed in Schedule 1 of the Health and Safety at Work etc. Act 1974 and are thus relevant statutory provisions within the meaning of Part 1 of that act.

The 1965 Act [Section 1] provides that no nuclear reactor (other than one comprised in a means of transport) or nuclear installation of a kind prescribed by regulations (currently the 1971 Regulations) may be installed or operated on a site unless a nuclear site licence has been granted by the HSE in respect of that site.

The installations prescribed by the 1971 Regulations [Regulation 3] are:

- an installation manufacturing fuel elements for the production of atomic energy from enriched uranium, plutonium or any alloy or chemical compound containing them;

- an installation used for producing alloys or chemical compounds from enriched uranium or plutonium or for producing enriched uranium or plutonium from any alloy or chemical compound containing them;

- an installation for the incorporation of enriched uranium or plutonium, or any alloy or chemical compound containing them, in devices designed for subsequent irradiation in a reactor or to form part of a nuclear assembly;

- an installation comprising a nuclear assembly for the production of neutrons, which contains enriched uranium, plutonium or any alloy or chemical compound of them and in

which a controlled chain reaction can be maintained with an additional source of neutrons;

- an installation for processing irradiated nuclear fuel;

- an installation for the storage of fuel elements, irradiated nuclear fuel or bulk quantities of other radioactive matter produced or irradiated in the course of producing or using nuclear fuel;

- an installation involved in the extraction of plutonium or uranium by the treatment of irradiated material, or in the enrichment of uranium;

- an installation for the production of radioisotopes from nuclear material.

A licence may be granted only to a corporate body [Nuclear Installations Act 1965, Section 3(1)]. It is not transferable and is granted in respect of a specific site [Sections 3(1) and 1(1)]. The licence enables the corporate body (the licensee) to install and operate a nuclear installation of a kind prescribed by regulations, or a nuclear reactor, on the site specified in the licence. Conditions attached to the licence provide the necessary checks and controls to be exercised during the design, construction, commissioning and operational stages of the installation as well as the decommissioning stages; these conditions may include, *inter alia,* provisions for [Section 4(1)]:

- securing the maintenance of an efficient system for detecting and recording the presence and intensity of ionising radiations emitted from anything on the site or from anything discharged on or from the site;

- regulating the design, siting, construction, installation, operation, modification, maintenance and decommissioning of any plant or installation on the site.

In addition to licensing requirements under the 1965 Act, the applicant for a nuclear site licence for a nuclear power plant requires the consent of the Secretary of State (in practice, the Secretary of State for Trade and Industry) under Section 36 of the Electricity Act 1989.

Under the Electricity Act 1989, the Secretary of State may, with the approval of the Treasury, make grants or loans for the decommissioning of nuclear installations licensed under the Nuclear Installations Act 1965 [Schedule 12].

The Secretary of State for Trade and Industry may exempt from the licensing requirements of Section 1 of the 1965 Act any installation described in Regulation 3 of the 1971 Regulations which he considers as not being a relevant installation [1971 Regulations, Regulation 4].

Finally, the 1965 Act provides that a permit granted by the UKAEA or a government department is required in addition to a nuclear site licence (where that is required) for the use of any site by any person other than the UKAEA or a government department, for any treatment of irradiated material involving the extraction of plutonium or uranium or for the enrichment of uranium. Permits granted by the UKAEA are limited to work for the purpose of research and development [Section 2(1A) as inserted by Section 17 of the Atomic Energy Authority Act 1971].

It is relevant to note that at the international level the United Kingdom ratified the 1994 Convention on Nuclear Safety on 17 January 1996.

b) Protection of the environment against radiation effects

In the United Kingdom, environmental protection provisions with respect to the harmful effects of radiation are not embodied in a single piece of legislation but are set out in several different texts dealing with health and safety, nuclear site licensing, pollution from radioactive waste and dumping at sea (environmental protection in the context of radioactive waste and dumping are dealt with under Section 7 "Radioactive Waste Management", *infra*).

The Environment Act 1995 created the Environment Agency in England and Wales and the Scottish Environment Protection Agency in Scotland. These Agencies enforce environmental protection legislation and specifically, with respect to radioactivity, are the enforcement organisations for the Radioactive Substances Act 1993 (RSA 1993). In Northern Ireland the Industrial Pollution and Radiochemical Inspectorate is the enforcement organisation for the Radioactive Substances Act 1993.

The RSA 1993 deals primarily with the control of radioactive waste. All authorisations under the RSA 1993 for nuclear licensed sites include a clause to apply the best practicable means with respect to minimising quantities and volumes of waste disposed of. The Environment Agencies have a duty to apply the provisions of Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora when exercising their powers under the RSA.

The Health and Safety at Work etc. Act 1974 provides [Section 5] that it is the duty of persons having control of premises of a kind prescribed by regulations to use the best practicable means to prevent the emission of noxious substances into the atmosphere and for rendering harmless substances so emitted. The premises prescribed include these in which any ore or material containing uranium is treated for the production of uranium, or in which any specific compounds of uranium are manufactured or used, or in which uranium or its compounds are manufactured or fashioned by methods giving rise to dust or fume, other than licensed nuclear sites of nuclear reactors (or facilities for the processing of irradiated fuel therefrom) for the purposes of removing fission products [The Health and Safety (Emissions into the Atmosphere) Regulations 1983, S.I. 1983, No. 943]. Section 1(1)(d) of the 1974 Act was, however, repealed, with effect from 1 April 1996 in relation to England and Wales. In Northern Ireland, Industrial Pollution Control (Northern Ireland) Order 1997 applies.

For nuclear installations, the Nuclear Installations Inspectorate attaches standard conditions to the nuclear site licence covering radioactive waste disposal, provisions relating to leaking and escape of radioactive material and radioactive waste.

c) Emergency response

Before 2001, the Nuclear Installations Act 1965 and the Ionising Radiations Regulations 1985 included provision for the making, implementation and testing of adequate arrangements to deal with nuclear emergencies by way of conditions attached to a nuclear site licence. The Radiation (Emergency Preparedness and Public Information) Regulations (REPPIR) came into force on 20 September 2001 and implement Title IX, Section 1 (intervention in case of emergency) of Council Directive 96/29/Euratom of 13 May 1996 laying down basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation. They also amended the Ionising Radiations Regulations 1999.

The Ionising Regulations 1999 apply to any work with ionising radiation, which involves having on any premises, or transporting by rail, or transferring through public places radioactive substances in

quantities exceeding specified thresholds. The competent authority for the purposes of the regulations is the Health and Safety Executive. The regulations contain provisions on hazard identification and risk evaluation, emergency plans and public information.

The operator or carrier is required to make an assessment as to hazard identification and risk evaluation before radiation work is carried out for the first time, and where the assessment reveals a radiation risk, to take all reasonably practicable steps to prevent a radiation accident or limit its consequences. The operator or carrier must also submit a report of each assessment made to the HSE.

Where it is reasonably foreseeable that a radiation emergency might arise that could have off-site consequences, the operator or carrier shall prepare an adequate emergency plan designed to secure the restriction of exposure to radiation and the health and safety of persons who may be affected by such emergencies. Furthermore, the local authority in whose area premises carrying out work with radiation are situated shall prepare an off-site emergency plan. The regulations also require the operator, the carrier and the local authority to review, revise and test emergency plans at suitable intervals.

Sections 16 and 17 of the regulations specify the duties of the operator or carrier in respect of the content and type of information which must be provided to the public prior to or in the event of a radiation emergency.

The Secretary of State for Trade and Industry is responsible for co-ordinating the framework for nuclear emergency plans in Great Britain. The Secretary of State for Northern Ireland is responsible for co-ordination of nuclear emergency planning in Northern Ireland and the 2001 Regulations do not apply here. Under an agreement with the Secretary of State for Trade and Industry, the Scottish Executive undertakes those functions relating to civil nuclear emergencies in Scotland.

The Radiation (Emergency Preparedness and Public Information) Regulations (Northern Ireland) 2001 [S.R. 2001, No. 436] apply in Northern Ireland. These regulations were made by the Department of Enterprise, Trade and Investment on 20 December 2001 and came into force on 4 February 2002.

The First Minister and Deputy First Minister within the Northern Ireland Assembly have overall responsibility for the implementation in Northern Ireland of emergency measures under the United Kingdom National Response Plan for dealing with a nuclear accident in peacetime. The Department of the Environment, Northern Ireland, however, is designated as the lead Department in responding to emergencies of this nature. If the Northern Ireland Assembly is suspended for any period, the Secretary of State is responsible for the implementation of emergency measures under the United Kingdom National Response Plan.

On 9 February 1990, the United Kingdom ratified the 1986 Convention on Early Notification of a Nuclear Accident and the 1986 Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency.

5. Trade in Nuclear Materials and Equipment

The keeping or use of radioactive substances is controlled under the Radioactive Substances Act 1993, and the Medicines Act 1968. Certain provisions of these acts do not apply, however, to nuclear installations licensed under the Nuclear Installations Act 1965, namely, reactors, fuel fabrication and reprocessing plants and fuel enrichment plants, including those which hold plutonium

extraction permits under Section 2 of the 1965 Act and are bodies corporate within the meaning of Schedule 1 to the act, and those which are designated companies under Section 19 of the Atomic Energy Authority Act 1971. Those are companies established in connection with the Agreement on the gas centrifuge process, Urenco Ltd. and CENTEC which are subject to security provisions (see below under Section 8 "Non-Proliferation and Physical Protection").

The Medicines Act 1968 is mainly the concern of the Secretary of State for Health and deals, *inter alia*, with the keeping and use of radioactive apparatus and substances for medicinal and therapeutic purposes. The Radioactive Substances Act 1993 is mainly the concern of the Secretary of State for the Environment, Transport and the Regions in England and Wales, the Scottish Ministers in Scotland and the Department of the Environment for Northern Ireland in relation to Northern Ireland. The act deals with the use and keeping of such substances from the point of view of public and environmental protection and control of radioactive waste.

The Medicines Act 1968 introduces a comprehensive system of licensing for medical products. This system includes subordinate instruments which relate to trade in and use of such products [S.I. 1978, No. 1004; S.I. 1978, No. 1006; S.I. 1995, No. 2147].

As regards exports, a licence is required for the export of dual-use goods, including nuclear material and equipment. Exportation of such goods from the United Kingdom is controlled by Council Regulation (EC) No. 3381/94 [EC OJ No. 367, 31 December 1994, p. 1] and associated Council Decision 94/942/CFSP [EC OJ No. 367, 31 December 1994, p. 8] as amended, which are directly applicable in Member States. However, licensing powers, penalties, enforcement and certain optional provisions of the EC Regulation, together with certain purely national controls, are given effect in the United Kingdom by the Dual-Use and Related Goods (Export Control) Regulations 1994 [S.I. 1994, No. 272] made under Section 2(2) of the European Communities Act 1972. Export controls are imposed for a variety of reasons, including non-proliferation policy and international treaty obligations and commitments, and these are matters that are taken into account in considering licence applications. The Secretary of State may grant licences and Community licences; a Community licence is an authorisation granted by a competent authority for the export of dual-use goods from the European Community.

The import of goods including nuclear materials and equipment into the United Kingdom is controlled by the Import, Export and Customs Powers (Defence) Act 1939. Section 1 of the act, as amended by the Secretary of State for Trade and Industry Order 1970, empowers the Secretary of State to make by Order such provision as he thinks expedient for prohibiting or regulating in all cases or any specified classes of cases the importation into the United Kingdom of all goods or goods of any specified description.

The Import of Goods (Control) Order 1954 prohibits all goods (other than most goods from the Channel Islands) from being imported into the United Kingdom except under a licence granted by the Secretary of State. The granting of licences is carried out by the Import Licensing Branch of the Department of Trade and Industry. Under the 1954 Order the Secretary of State from time to time grants an Open General Import Licence (OGIL), the effect of which is to permit the importation into the United Kingdom of all goods except those specified in the Schedule. Each OGIL revokes the previous one. The current OGIL was granted on 4 December 1987 and has been frequently amended. The effect of the 1954 Order and the current OGIL is that an individual licence is required for the importation into the United Kingdom of certain nuclear materials.

Controls on the import, export and supply and delivery of goods are also contained in Orders in Council made under the United Nations Act 1946 to give effect to United Nation trade sanctions. Orders exist in relation to Iraq, Libya, Serbia and Montenegro, Haiti, Liberia, Somalia, and Rwanda.

Council Regulation (Euratom) No. 1493/93 controls transboundary movements of radioactive sealed sources and radioactive waste between Member States of the European Union. The shipment of radioactive waste between Member States of the European Union, or into or out of the European Union, is also subject to Directive 92/3/Euratom, which has been implemented in the United Kingdom by the Transfrontier Shipment of Radioactive Waste Regulations 1993.

6. Radiation Protection

The protection of workers and the public against the hazards of ionising radiation is governed by several enactments and instruments, including the Ionising Radiations Regulations 1999 [S.I. 1999, No. 3232] [in Northern Ireland S.R. 2000, No. 355], the Radioactive Substances Act 1993, the Health and Safety at Work, etc. Order 1978, as well as the Medicines Act 1968 under which instruments have been made [e.g., the Medicines (Radioactive Substances) Order 1978, S.I. 1978, No. 1004; the Medicines (Administration of Radioactive Substance) Regulations 1978, S.I. 1978, No. 1006; the latter Regulations were made under both the Medicines Act and the European Communities Act 1972].

The Medicines (Administration of Radioactive Substances) Regulations 1978 now implement Article 5(a) of Council Directive 80/836/Euratom, which requires a system of prior authorisation of those persons who are to administer radioactive substances to persons for the purposes of diagnosis, treatment or research.

The competent authority for the protection of workers and the public from the industrial use of ionising radiation is the Health and Safety Executive (HSE) [Health and Safety at Work etc. Act 1974, Section 11]. The safety of workers in nuclear installations is also governed by the Ionising Radiations Regulations 1985. The HSE is responsible through the Health and Safety Commission to the Secretary of State in the Department for Work and Pensions for radiological protection questions. The relevant Environment Agency (see Section 3 above, “Radioactive Material”) has responsibility for regulation of the use of radioactive materials and disposal of radioactive waste; in doing so the Agencies have regard to United Kingdom government policy for public and environmental protection. The Health Ministers (i.e. those responsible for health in England, Scotland, Wales and Northern Ireland) are the authorities with overall responsibility for all aspects of health protection.

The Health and Safety at Work Act 1974 [or the Health and Safety at Work (Northern Ireland) Order 1978] provides generally for health, safety and welfare in connection with work, including the nuclear field.

The Ionising Radiations Regulations 1999 are the principal instrument implementing the provisions of Council Directive 96/29/Euratom, laying down the basic safety standards for health protection of the general public and workers against the dangers of ionising radiation. Other legislation which contributes to implementation includes: the Radioactive Substances Act 1993 and associated orders; and the Radiation (Emergency Preparedness and Public Information) Regulations (REPPIR) adopted on 20 September 2001. REPPIR implement the emergency preparedness provisions of the Directive (see Section 4(c) *supra* “Emergency Response”) for sites capable of having emergencies with off-site consequences. The Ionising Radiations Regulations 1999 also implement Council

Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas.

The HSE has produced a range of supporting guidance on prior authorisation, outside workers, pregnant and breast-feeding workers, monitoring equipment and equipment used for medical purposes, most of which is available on its website.[1]

7. Radioactive Waste Management

The Radioactive Substances Act 1993 governs the disposal and accumulation of radioactive waste in the United Kingdom [Sections 13 and 14]. The disposal of radioactive waste may not be undertaken without an authorisation granted by the relevant Environment Agency (see Section 3 "Radioactive Material" *supra*) [Sections 16 and 47(1)]. The accumulation of radioactive waste may not be undertaken without an authorisation by the relevant Environment Agency [Section 16(2)], except in the case of nuclear licensed sites, which are covered by separate legislation.

The Secretary of State for Defence has responsibility for the disposal of radioactive waste at Ministry of Defence sites, but the Agencies have agreements with Ministry of Defence establishments that they administratively apply the requirements of the Radioactive Substances Act 1993. However, Ministry of Defence sites operated by civilian contractors, for example, naval dockyards at Devonport and Rosyth and the Atomic Weapons Establishment, are regulated under the terms of the 1993 Act.

The Electricity Act 1989 provides that the Secretary of State (in practice the Secretary of State for Trade and Industry) may, with the approval of the Treasury, make grants or loans for the storage or reprocessing of nuclear fuel, the treatment, storage or disposal of radioactive waste or the decommissioning of any nuclear installation [Schedule 12].

Part II of the Environmental Protection Act 1990 relates to the disposal and recovery of waste on land. While Part II of the act does not apply to radioactive waste within the meaning of the Radioactive Substances Act 1993, Section 78 of this act empowers the Secretary of State (in Scotland the Scottish Ministers) to make regulations providing for appropriate provisions of Part II to have effect (with or without modifications) for the purposes of dealing with radioactive waste.

Previously, waste on land was subject to the provisions of Part I of the Control of Pollution Act 1974. Section 30(5) of that act contained a regulation-making power similar to that now found in Section 78 of the 1990 Act.

At present, radioactive waste which, apart from its radioactivity, is dangerous or difficult to dispose of ("special waste"), is controlled by the Control of Pollution (Special Waste) Regulations 1980 [S.I. 1980, No. 1709]. However, these regulations were replaced from 1 September 1996 by the Special Waste Regulations 1996. The 1996 Regulations continue to ensure that any waste which may possess hazardous properties in addition to its radioactivity remains subject to stringent controls over its movement.

Part II.A of the Environmental Protection Act 1990 (inserted by the Environment Act 1995) relates to (non-radioactively) contaminated land. Section 78 (YC) empowers the Secretary of State, in Scotland the Scottish Ministers, to make regulations providing for appropriate provisions of Part II.A to have effect (with or without modification) to radioactively contaminated land.

1. www.hse.gov.uk

As regards the pollution of water, for the purposes of Part II of the Control of Pollution Act 1974 (pollution of water), the power under Section 30(5) was applied by Section 56(6). The Control of Pollution (Radioactive Waste) Regulations 1976 [S.I. 1976, No. 959] made under Section 30(5) [as applied by Section 56(6)] of the 1974 Act provide that Sections 43 and 44 of the 1974 Act (control of discharges of trade effluent into public sewers in England and Wales) have effect in relation to radioactive waste although no account is to be taken in exercising the controls under those sections of any radioactivity possessed by any effluent, as its radioactivity is taken into account in exercising controls under the Radioactive Substances Act 1993 (note that Sections 43 and 44 of the 1974 Act have been repealed, and have been replaced by provisions to be found in Chapter III of Part IV of, and Schedule 8 to, the Water Industry Act 1991).

In addition, in relation to England and Wales, Section 98(2) of the Water Resources Act 1991 confers power for the Secretary of State to make regulations applying, with or without modifications, the provisions of Part III of the 1991 Act (which aim to prevent or control the pollution of water) in relation to radioactive waste. The Control of Pollution (Radioactive Waste) Regulations 1989 [S.I. 1989, No. 1158], made under Section 123 of the Water Act 1989, have effect as if made under Section 98(2) of the 1991 Act [see Section 2(2) of, and Schedule 2 to, the Water Consolidation (Consequential Provisions) Act 1991]. These regulations provide for Chapter I of Part III of the Water Act 1989, and now [by virtue of paragraph 1(3) of Schedule 2 to the Water Consolidation (Consequential Provisions) Act 1991] the corresponding provisions in Part III of the Water Resources Act 1991, to have effect in relation to any radioactive waste, although no account is to be taken of any radioactivity possessed by it (see now Section 40 of the Radioactive Substances Act 1993).

The Control of Pollution (Radioactive Waste) (Scotland) Regulations 1991 apply the provisions of the Control of Pollution Act 1974 to radioactive waste in Scotland. Again, no account is taken of any radioactivity possessed by the waste.

The Dumping at Sea Act 1974, now replaced by the Food and Environment Protection Act 1985 (FEPA), enabled the United Kingdom to ratify the 1972 Oslo Convention on Prevention of Marine Pollution by Dumping from Ships and Aircraft, and the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter ratified on 17 November 1975. The United Kingdom also ratified the 1996 Protocol to the 1972 London Convention. The FEPA provides that substances and articles may not be dumped at sea from a British ship or aircraft without a licence [Section 5]. There is no definition of “substances” and “articles” and thus radioactive substances are not excluded from the prohibition under Section 5. In 1994, the UK government accepted a complete ban on deep ocean disposal of intermediate-level waste and low-level waste, which had been adopted at the Consultative Meeting of the London Convention in 1993.

The Environment Act 1995 places general duties on the Environment Agencies which may impinge on their enforcement of the Radioactive Substances Act 1993. These include a duty to consider sustainable development, cost and benefits of any actions, special consideration of rural communities, as well as general consideration for protection of the environment.

Government policy in the United Kingdom was last set out in the White Paper, “Review of Radioactive Waste Management Policy: Final Conclusions” [Cm. 2919] (currently under review).

8. Non-Proliferation and Physical Protection

The Atomic Energy Act 1946 [Section 4] and the Nuclear Installations Act 1965, as amended by the Atomic Energy Authority Act 1971 [Schedule 1], confer wide powers on the Secretary of State (in

practice the Secretary of State for Trade and Industry) to prevent any improper use of fissionable materials.

The United Kingdom ratified the 1968 Treaty on the Non-Proliferation of Nuclear Weapons (NPT) on 27 November 1968. The Nuclear Safeguards and Electricity (Finance) Act 1978 gives effect to the agreement of 6 September 1976 for the application of safeguards in the United Kingdom in relation to the NPT [Agreement between the United Kingdom, the European Atomic Energy Community and the International Atomic Energy Agency (IAEA) – published by the IAEA as INFCIRC/263, October 1978]. The safeguards measures provided for in the Nuclear Safeguards and Electricity (Finance) Act are in addition to, and complement, those of Chapter VII of the Euratom Treaty. These Euratom safeguards require that operators of nuclear installations in the United Kingdom provide the European Commission with information on the installations and their receipts, shipments and holdings of nuclear material. The reporting requirements are, at present, amplified in Commission Regulation (Euratom) No. 3227/76 as amended. The Euratom Treaty also includes powers for the Commission to inspect the installations, nuclear material and records concerned, and thus ensure that the information provided by operators is correct and that material is present as reported. The Commission may, if necessary, impose sanctions in the event of infringement of the Treaty safeguards obligations.

The Nuclear Safeguards Act, adopted on 25 May 2000, implements the 1998 Additional Protocol to the 1976 safeguards agreement [INFCIRC/263]. The additional protocol includes measures that contribute to increasing the IAEA's capability to detect undeclared nuclear activities in Non Nuclear Weapon States (NNWS), or which would improve the effectiveness or efficiency of safeguards at facilities in the United Kingdom. This means that the United Kingdom must provide the IAEA with information (and associated access) when relevant nuclear activities are conducted in co-operation with a NNWS. Under the Nuclear Safeguards Act, the Secretary of State may serve notice on any person requiring him to provide information for the purposes of the Additional Protocol. The act also secures the exercise of the IAEA's rights, in particular of the Agency inspector, under the Additional Protocol. The Secretary of State may make regulations aiming to identify persons who are in possession of information referred to in the Additional Protocol.

Furthermore, the United Kingdom ratified the 1996 Comprehensive Nuclear Test Ban Treaty on 6 April 1998.

As regards the physical protection of nuclear material, the Official Secrets Acts 1911-1920 make provision for the security of certain Crown property by declaring that certain activities in relation to any such property shall be a criminal offence. They also provide that certain activities by Crown servants and those who have contact with the Crown shall be offences.

Section 3(c) of the 1911 Act provides that particular premises may be declared by order to be prohibited places for the purpose of the act. Section 6(3) of the Atomic Energy Authority Act 1954 brings any place belonging to or used for the purposes of the UKAEA within the definition of places which may be declared by order to be prohibited places. The current Order, made in 1994, declares two of the Authority's premises, Harwell and Windscale, to be such prohibited places [S.I. 1994, No. 968].

Further provision is made by Section 2 of the Nuclear Installations Act 1965, as amended by Section 17 of the Atomic Energy Authority Act 1971. This allows the Secretary of State to make orders applying Schedule 1 to the 1965 Act (added by the 1971 Act) to any premises in respect of which a permit under Section 2 of the act has been granted for purposes other than research or

development only. In particular, paragraph 3 of the Schedule brings any such site within the definition of places which may be declared to be prohibited places.

Section 19 of the 1971 Act [as amended by Section 16(4) of and Schedule 2 to the Official Secrets Act 1989] further provides that paragraphs 4 to 6 of the Schedule shall apply to any company registered in the United Kingdom and formed for the purposes of the Treaty of Almelo (relating to the gas centrifuge enrichment process).

These paragraphs have the additional effect of extending the powers of special constables in relation to those premises and allowing the Secretary of State to give directions for the security and safety of the site and restricting the termination of employment on certain grounds.

Orders have been made applying Schedule 1 to the 1965 Act to British Nuclear Fuels plc. (BNFL) and Urenco (Capenhurst) Ltd. [S.I. 1971, No. 569 and 1993, No. 687], declaring certain premises of the Atomic Energy Authority (UKAEA) and BNFL to be prohibited places [S.I. 1994, No. 968] and designating Urenco Ltd. and CENTEC Centrifuge Techniques Ltd, formed to implement the Almelo Treaty on the gas centrifuge enrichment process, as companies to which stringent security measures apply for the purpose of Section 19 of the 1971 Act [S.I. 1971, No. 1434; S.I. 1973, No. 17].

The Nuclear Material Offences Act 1983 enabled the United Kingdom to ratify the 1979 Convention on the Physical Protection of Nuclear Material on 6 September 1991. The act extends throughout the United Kingdom.

The scope of certain specified offences of a serious nature is extended so as to make it an offence in the United Kingdom to commit certain acts outside the United Kingdom in relation to, or by means of, nuclear material [Section 1].

It is an offence to receive, hold, or deal with nuclear material with the intention of doing any act which is a specified offence (offences against the person), or being reckless as to whether another person would do such an act; or to make threats that he or another person will do such an act by means of nuclear material, intending that the person to whom the threat is made shall fear that it will be carried out.

The act provides that the new offences are extraditable offences under the Extradition Act 1870 and specifies that, where there is no extradition arrangement with a state which is a Party to the Physical Protection Convention, an Order in Council may be made under the 1870 Act applying that act, as though the Convention itself constituted an extradition arrangement with that state [Section 5].

Nuclear material is defined by reference to the definition in the Convention [Schedule].

The security of nuclear generating stations, and laboratories for the examination of irradiated nuclear fuel by or on behalf of the operator of the generating station, is controlled by the Nuclear Generating Stations (Security) Regulations 1996 [S.I. 1996, No. 665], which were made under the Health and Safety at Work etc. Act 1974, and which came into force on 1 April 1996. They apply to generating stations and laboratories which are nuclear installations requiring a licence under Section 1 of the Nuclear Installations Act 1965.

The regulations require the operator to ensure that, at all times while any nuclear fuel is on-site, or in transit to or from a site, the site is subject to a security regime which conforms to a description ("security plan") of the security standards, procedures and arrangements adopted by the operator for the protection of the site. Before carrying out any work of alteration or extension to any construction

which is part of the generating station or laboratory, the operator must also satisfy the Secretary of State that the security regime to which the site will be subject in the course of the work and thereafter will conform to an approved security plan. The operator is also required to take all reasonable steps to secure that no nuclear fuel is transported to or from the site except in accordance with an approved security plan.

In addition, the regulations require the operator to comply with any directions given by the Secretary of State requiring the operator to adopt certain standards, procedures or arrangements specified in such directions. The operator is also required to have security assessments carried out periodically by a person approved by the Secretary of State, and to have a similar assessment carried out before bringing nuclear fuel for the first time onto the site or onto any newly altered or extended part of the generating station or laboratory.

The regulations cease to apply to a site when there ceases to be any nuclear fuel kept or proposed to be kept on the site, and cease to apply to an operator when the operator's "period of responsibility" under the 1965 Act comes to an end.

The Secretary of State for Trade and Industry is responsible for the enforcement of the regulations, in order to protect the civil nuclear industry against the threats of terrorism and the dangers of nuclear proliferation. The Department of Trade and Industry's Office for Civil Nuclear Security (OCNS) regulates security arrangements for the protection of nuclear material and proliferation-sensitive technology within the civil nuclear industry on behalf of the Secretary of State for Trade and Industry. OCNS exercises statutory powers granted to the Secretary of State for Trade and Industry under the Atomic Energy Act 1954, the Nuclear Installations Act 1965 and the Nuclear Generating Stations (Security) Regulations 1996. One of its specific tasks is to set out security requirements for nuclear sites regarding the use, storage and transport of special nuclear materials.

These provisions are completed by the Anti-terrorism Crime and Security Act 2001, a response to the events of 11 September 2001, which came into force on 14 December 2001. A number of the provisions of this act aim to reinforce the security of the nuclear industry.

For this purpose, it extends the jurisdiction of the United Kingdom Atomic Energy Authority's Constabulary, to enable it to exercise its powers on all licensed nuclear sites [Section 76]. Under Section 77 of the act, the Secretary of State is empowered to make regulations for the purposes of ensuring the security of nuclear sites and nuclear material, which will form the basis of a comprehensive nuclear security regime. Before making the regulations the Secretary of State shall consult the Health and Safety Commission and such other persons as considered appropriate. He/she has also the power to make regulations prohibiting the disclosure of information about the enrichment of uranium [Section 80].

Finally, a new criminal offence is established in respect of the disclosure of information which might prejudice the security of nuclear sites or nuclear material [Section 79].

9. Transport

The transport of radioactive materials is governed by different regulations, depending on the mode of transport used. Essentially however, all the regulations reflect the International Atomic Energy Agency's recommended Regulations on the Safe Transport of Radioactive Materials [TS-R-1] which are revised regularly.

The Secretary of State for Transport is the competent authority for road and rail transport in Great Britain, and air and sea transport in the United Kingdom. The Department of the Environment, Northern Ireland is responsible for road transport and the Department of Enterprise, Trade and Investment is responsible for rail transport in Northern Ireland.

The Radioactive Material (Road Transport) Act 1991 regulates the transport of radioactive materials by road, replacing Sections 5 and 7 of the Radioactive Substances 1948 Act (the 1948 Act has now been repealed). The act clarifies and extends the Secretary of State's power to make regulations regarding, *inter alia*, the design, packaging, labelling, transport of packages of radioactive materials [Section 2], and to enforce such regulations. He may also appoint inspectors to enforce the regulations [Section 1]. This only covers Great Britain.

The equivalent legislation in Northern Ireland is the Radioactive Material (Road Transport) (Northern Ireland) Order 1992 [S.I. 1992, No. 234 (N.I. 2)].

The national regulations governing transport, by mode of transport, are as follows:

- *Roads in Great Britain* – The Radioactive Material (Road Transport) (Great Britain) Regulations 2002 [S.I. 2002, No. 1093]. They are enforced by the Department for Transport (DfT).

- *Driver Training in Great Britain* – The Carriage of Dangerous Goods by Road (Driver Training) Regulations 1996 (amended in 1999) [S.I. 1996, No. 2094]. They are enforced jointly by DfT and the Health and Safety Executive (HSE).

- *Roads in Northern Ireland* – The Radioactive Substances (Road Transport) (Northern Ireland) Order 1992; The Radioactive Substances (Carriage by Road) Regulations (Northern Ireland) 1983 [S.R. 1983, No. 344]. The Radioactive Substances (Carriage by Road) (Amendment) Regulations (Northern Ireland) 1986 [S.R. 1986, No. 61]. They are enforced by the Department of the Environment, Northern Ireland.

- *Driver Training in Northern Ireland* – The Carriage of Dangerous Goods by Road (Driver Training) Regulations (Northern Ireland) 1997 [S.R. 1997, No. 249]. Amendment Regulations have been made and are the Carriage of Dangerous Goods (Amendment) Regulations (Northern Ireland) 2002 [S.R. 2002, No. 34]. These are the same as the Great Britain requirements and are enforced by the Department of the Environment, Northern Ireland and the Department of Enterprise, Trade and Investment.

- *Rail in Great Britain* – The Packaging, Labelling and Carriage of Radioactive Material by Rail Regulations 2002 [S.I. 2002, No. 2099]. They are enforced jointly by the HSE and DfT.

- *Rail in Northern Ireland* – The Packaging, Labelling and Carriage of Radioactive Material by Rail Regulations (Northern Ireland) 1998 [S.R. 1998, No. 132] ["RAMRail(NI)"]. They are enforced by the Department of Enterprise, Trade and Investment.

- *Sea* – The Merchant Shipping (Dangerous Goods and Marine Pollutants) Regulations 1997 [S.I. 1997, No. 2367]; Merchant Shipping Notice No. M1755(M), "The Carriage of Dangerous Goods and Marine Pollutants in Packaged Form". Amendment

30-00 to the International Maritime Dangerous Goods Code (IMDG Code). They are enforced by the Maritime and Coastguard Safety Agency, an agency of DfT.

- *Air* – The Air Navigation (No. 2) Order 2000 [S.I. 2000, No. 1562]; The Air Navigation (Dangerous Goods) Regulations 1994 [S.I. 1994, No. 3187 and Amendments 2001 S.I. 2001, No. 918]. These implement the International Civil Aviation Organisation's Technical Instructions for the Safe Transport of Dangerous Goods by Air (Class 7) into UK legislation. They are enforced by the Civil Aviation Authority.

- *Ports* – The Dangerous Substances in Harbour Areas Regulations 1987 [S.I. 1987, No. 37]. They are enforced by the HSE.

- *Inland Waterways* – There are no statutory regulations in the United Kingdom, but British Waterways applies provisions of the IMDG Code by way of its conditions of acceptance for carriage.

In the case of international transport of radioactive materials, the United Kingdom has ratified the following international agreements:

- *Roads in Europe* – European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) (Class 7); and

- *Rail in Europe* – Convention concerning the International Carriage by Rail (COTIF) Appendix B, Uniform rules concerning the contract for the International Carriage of Goods by Rail (CIM) Annex 1, Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) (Class 7).

These are now part of UK law via the statutory instruments listed above for road and rail.

The United Kingdom is also a member of the International Maritime Organisation and the International Civil Aviation Organisation.

10. Nuclear Third Party Liability

The basic legislation on nuclear third party liability in the United Kingdom is contained in the Nuclear Installations Act 1965, which implements the provisions of the 1960 Convention on Third Party Liability in the Field of Nuclear Energy ratified by the United Kingdom on 23 February 1966 and the 1963 Brussels Convention Supplementary to the Paris Convention, ratified on 24 March 1966.

The Nuclear Installations Act 1965 was amended by the Energy Act 1983. Part II of the 1983 Act is concerned with nuclear installations and has for its main purpose the amendment of the third party liability provisions of the Nuclear Installations Act 1965 to give effect to the provisions of the two 1982 Protocols to amend the above-mentioned Paris and Brussels Conventions. The provisions of Part II of the 1983 Act increase the sums available to meet claims for nuclear damage.

The 1983 Act [Section 27] amended Section 16 of the 1965 Act to increase the liability limit for operators of licensed sites from British pounds (GBP) 5 million to GBP 20 million per incident. The lower limit of GBP 5 million is retained in the case of certain small prescribed sites (see below). The act also provided for these two limits to be increased by order to avoid the need for further primary legislation if the liability limits in the Paris Convention are increased. Thus the operator's liability has

been increased by order from GBP 20 million to GBP 140 million (a little above 150 million Special Drawing Rights – SDRs) as from 1 April 1994 [S.I. 1994, No. 909]. Any such order requires approval by a resolution of the House of Commons before it is made.

The 1965 Act [Section 18] was further amended by the Energy Act 1983 [Section 28] to increase the total amount of funds available to meet claims from GBP 43 million to the pound sterling equivalent of SDRs 300 million. The amount may be increased by order with approval of the Treasury [Section 18(1B)]. Another amendment has been made to express in SDRs, in place of sterling, the minimum amount which must be left available (in an incident involving nuclear material in course of carriage) for general claims as opposed to claims in respect of damage to the means of transport. The minimum is set at SDRs 5 million which may be increased by order with the approval of the Treasury [Section 21(1) and (1A)].

The Nuclear Installations (Prescribed Sites) Regulations 1983 [S.I. 1983, No. 919] prescribe the sites, licensees of which are subject to a lower limit of liability under Section 16(1) of the Nuclear Installations Act 1965, as amended by the Energy Act 1983. Essentially, the sites prescribed are the sites of small installations [Regulation 3]. They are prescribed by reference to the type and designed thermal output of any nuclear reactor with its associated fuel, and by reference to the activity of other radionuclides which may also be present [Regulations 3 and 4]. The regulations provide for cases where nuclear material of different levels of activity is present, as well as for overall limits of mass for fissile material [Regulation 3(3) and (5)].

Under the 1965 Act as amended [Section 7], nuclear site licensees are under an absolute duty, and are liable for breach of this duty, to ensure that no occurrences involving nuclear matter on their sites cause personal injury or damage to property and are under a similar duty as regards ionising radiation emitted on their sites. The damage must be physical damage to tangible property; it does not include pure economic loss or damage to incorporeal property or property rights [Case law: *Merlin v BNFL* (1990) 3WLA 393]. The same duty lies upon the UKAEA and the Crown [Sections 8 and 9]. This duty on the UKAEA applies whether or not a nuclear site licence has been granted in respect of the site [S.I. 1990, No. 1918]. Moreover, the Congenital Disabilities (Civil Liability) Act 1976 [Sections 3 and 4] provides that if a child is born disabled as the result of an injury to either parent caused by a breach of such a duty, the child's disabilities are to be regarded for the purposes of the 1965 Act as injuries caused on the same occasion as those caused to the parent.

The Nuclear Installations Act 1965 [Section 19] was also amended by the Atomic Energy Act 1989 [Section 4(1)] to modify the definition of "cover period" so as to prevent the grant of a new nuclear site licence from bringing the current cover period to an end where the new licence is in effect, a continuation of the old licence with amendments [Section 19(2B) of the 1965 Act]. This is relevant to a nuclear operator's obligation to provide insurance cover not only for the current period but also for any cover period which ended in the last ten years.

II. INSTITUTIONAL FRAMEWORK

Nuclear legislation was introduced in the United Kingdom with the Atomic Energy Act 1946 [Section 1]. Responsibility for the development and control of nuclear activities was originally

entrusted to the Minister for Supply and further detailed in the Radioactive Substances Act 1948, with provision made for the appropriate minister to make regulations to prevent injury to health from ionising radiations and to secure the safe disposal of radioactive waste. In parallel with the development of nuclear energy, this responsibility was successively transferred to the Lord President of the Council in 1953, to the Prime Minister in 1957, to the Minister for Science in 1959, to the Secretary of State for Education and Science in 1964, and to the Minister for Technology in 1965.

Between 1970 and 1974, these duties were discharged by the Secretary of State for Trade and Industry, from 1974 to 1992 by the Secretary of State for Energy, and since 1992 by the Secretary of State for Trade and Industry once more, though responsibility for the control of radioactive material and radioactive waste lies with the Secretary of State for the Environment, Transport and the Regions and the Scottish ministers in Scotland.

Following a review of governmental functions in 1970, a reorganisation of central government took place with a view to improving the efficiency of government. This entailed changes both in methods of operation between government departments and within the departments themselves and, consequently, had a direct effect on the general regime governing nuclear activities.

As a consequence of this review certain functions in the nuclear field, formerly discharged by several ministers, were unified. In particular, the Department of Trade and Industry was formed to take over the responsibilities for general industrial policy which were previously divided between the Board of Trade and the Ministry of Technology. The Secretary of State for Trade and Industry was given responsibility for atomic energy and most of the related functions under the Atomic Energy Act 1946, the Atomic Energy Authority Act 1954 and the Nuclear Installations Act 1965. Between 1974 and 1992, these functions were exercised by the Secretary of State for Energy. Since the abolition of that office in 1992, however, they have returned to the Secretary of State for Trade and Industry.

Major changes were made in those parts of the government machine dealing with the environment. In particular, the Ministries of Housing and Local Government, of Public Building and Works and Transport were merged into a Department of the Environment, under a Secretary of State for the Environment, with responsibility for questions involving protection against the hazards of ionising radiation, radioactive substances and waste. The Department of Transport was separated from the Department of the Environment in 1976. In 1997, the Departments of Transport and the Environment were reunited to form the Department of the Environment, Transport and the Regions.

The United Kingdom Atomic Energy Authority (UKAEA) was set up by the Atomic Energy Authority Act 1954 as the statutory body responsible for the general development of nuclear energy in the United Kingdom, subject to the Secretary of State's overall duty in this respect; since 1989 it has been reorganised, and now operates commercially as AEA Technology, and is further discussed below.

The Health and Safety Commission (HSC) and the Health and Safety Executive (HSE) were established by the Health and Safety at Work etc. Act 1974 as bodies corporate, generally responsible, *inter alia*, for the regulation of hazardous activities, including risks arising from work with ionising radiations where these hazards arise from work-related activities.

1. Regulatory and Supervisory Authorities

No single authority has overall responsibility for nuclear energy in the United Kingdom. While the Secretaries of State for Trade and Industry and for the Environment, Transport and the Regions are competent for the development and the environmental protection aspects of nuclear energy respectively, they share those powers with other ministers when nuclear questions come within the latter's sphere of competence. In Scotland, Wales and Northern Ireland, in many cases the functions carried out by different ministers in England are exercised by the relevant ministers for these countries (this should be assumed to be the case in the following text unless otherwise stated).

a) Department of Trade and Industry (DTI)

i) Secretary of State for Trade and Industry

Under the Atomic Energy Act 1946, the Secretary of State (in practice, the Secretary of State for Trade and Industry) has a duty to promote and control the development of atomic energy [Section 1]. He may make orders (though no such order has been made) which, except under his licence (a) prohibit the acquisition, production, treatment, possession, use, disposal, export or import of (i) uranium, thorium, plutonium or neptunium or their compounds or any other prescribed substance used for the production or use of atomic energy or for related research or (ii) any plant for the production or use of atomic energy or related research, or (b) prohibit the working of any specified minerals from which any of the above substances can be obtained [Section 10]. The act also gives the Secretary of State powers to obtain information on materials, plant and processes; to authorise the entry and inspection of certain premises; to search for and to authorise other persons to search for certain minerals; and to acquire compulsorily substances, minerals and plant which are for the production or use of atomic energy or research into related matters, and rights under contracts relating to the production or use of atomic energy or related research [Sections 4, 5, 6, 8 and 9].

The Atomic Energy Authority Act 1954 which set up the United Kingdom Atomic Energy Authority (UKAEA) provides that the Secretary of State has the general duty of ensuring that the UKAEA attach proper degrees of importance to the various applications of atomic energy, and may give directions to the Authority [Sections 1 and 3]. He exercises general control over it and appoints the chairperson and members of the Authority and lays before parliament an annual report on its activities.

Pursuant to the provisions of the Anti-terrorism, Crime and Security Act adopted on 14 December 2001, the Secretary of State has the power to make regulations for the purposes of ensuring the security of nuclear sites and nuclear material. These are briefly described in Part I, paragraph 8 above.

The Secretary of State also has responsibility for ensuring that the United Kingdom continues to meet its international non-proliferation obligations. These include nuclear safeguards obligations as set out in the Euratom Treaty and in safeguards agreements with Euratom and the IAEA.

As already mentioned, the Electricity Act 1989 (which re-organised the electricity industry in the United Kingdom – for further details see below) provides that the consent of the Secretary of State for Trade and Industry is required for the construction, extension or operation of a generating station (including a nuclear generating station) [Section 36].

Also, the Import, Export and Customs Powers (Defence) Act 1939 [Section 1] empowers the Secretary of State by order to make such provisions as he may think expedient for prohibiting or regulating the import of goods. So far as the importation of nuclear materials are concerned, under the provisions currently in force [Import of Goods (Control) Order 1954 – S.I. 1954, No. 23 as amended] together with the Open General Import Licence dated 4 December 1987 a licence is required from the Secretary of State for the import of certain radioactive substances.

The Secretary of State is responsible for granting licences for the export of dual-use goods, including nuclear materials and equipment, pursuant to the provisions described under Part I, Section 5 "Trade in Nuclear Materials and Equipment" of this study *supra*.

ii) Office for Civil Nuclear Security (OCNS)

The Office for Civil Nuclear Security (OCNS), placed under the auspices of the DTI in October 2001 and which operates as an independent unit within the DTI, acts as the government's security regulator. One of its specific tasks is to set out security requirements for nuclear sites in respect of the use, storage and transport of special nuclear materials. This role includes, for instance, setting the right staffing levels for the police who guard the various sites. The OCNS reports annually to the Minister for Energy, and is advised by an Advisory Board.

b) Secretary of State for Environment, Food and Rural Affairs and the Secretary of State for Health

Under the Radioactive Substances Act 1993, in England, the Secretary of State for Environment, Food and Rural Affairs and the Secretary of State for Health acting jointly have powers to call in applications and issue directions to the Environment Agency. The Secretary of State for Health's functions under the 1993 Act were previously exercised by the Minister for Agriculture, Fisheries and Food. These functions were transferred to the Secretary of State for Health by virtue of the Food Standards Act 1999.

In Wales, the powers of call in and direction under the Radioactive Substances Act 1993 are exercisable by the National Assembly for Wales in respect of the Environment Agency. Scottish ministers have similar powers with respect to the Scottish Environment Protection Agency (SEPA), and in Northern Ireland, the Department of the Environment, Northern Ireland has power to call in applications and make regulations with respect to the Industrial Pollution and Radiochemical Inspectorate (see Part I "General Regulatory Regime", Section 3 "Radioactive Material" *supra*).

In addition to their functions under the Radioactive Substances Act 1993, the Secretary of State for Health in England and the National Assembly for Wales have more general responsibilities in matters of health, and they are administratively accountable for the National Radiological Protection Board (NRPB) [Radiological Protection Act 1970, Sections 1 and 2].

c) Secretary of State for Transport

The Secretary of State for Transport has the power to regulate the transport of radioactive material by road and rail in Great Britain, and air and sea in the United Kingdom. He is also the competent authority for those modes of transport in respect of the requirements of the IAEA's recommended Regulations on the Safe Transport of Radioactive Materials [TS-R-1].

d) Secretary of State for Education

As already mentioned, the Secretary of State for Education in England and Wales and Scottish ministers in Scotland must approve the use of radioactive substances in excess of 100 becquerels per gram in the course of instruction, as well as the use of electrical equipment emitting ionising radiation and containing components operating at a potential difference of more than 5 kilovolts. [In relation to England and Wales: Regulation 7 of the Education (Schools and Further and Higher Education) Regulations 1989, S.I. 1989, No. 351, made under Section 218(1)(e) of the Education Reform Act 1988; paragraph 7 of Schedule 1 to the Education (Special Needs) (Approval of Independent Schools) Regulations 1994, S.I. 1994, No. 651, made under Sections 172(6), 189(2) and 301(6) of the Education Act 1993. In relation to Scotland: the Dangerous Materials and Apparatus (Educational Establishments) (Scotland) Regulations 1984, S.I. 1984, No. 668, made under Section 19A of the Education (Scotland) Act 1980].

2. Advisory Bodies

a) Medical Research Council (MRC)

The Medical Research Council (MRC) is an autonomous body established by Royal Charter. It is grant-aided through the Office for Public Service and Science, and its functions include advising the government and authorities discharging responsibilities in that field on the somatic and genetic effects of ionising radiations [Science and Technology Act 1965]. The Council advises on the biological bases on which radiation protection standards rest, in the light of its own and the latest international findings.

b) Nuclear Safety Advisory Committee

In September 1976, the Standing Royal Commission on Environmental Pollution, which was set up in 1970, presented to parliament its Sixth Report, covering nuclear power and the environment. The Royal Commission expressed concern about "the need for a source of independent, expert advice to the government on technical matters and [matters] which are relevant to policy decisions on major and hazardous technological developments, whether nuclear or otherwise [...]. The Health and Safety Executive have a responsibility to give such advice and [...] should develop the capability to do so."

The government agreed with this recommendation, and in 1977 the Health and Safety Commission set up the Advisory Committee on the Safety of Nuclear Installations. This Committee was renamed the Nuclear Safety Advisory Committee on 11 July 1997. The Committee consists of a chairperson and twenty members appointed for a three-year term, drawn from academic, scientific, and industrial circles, advised by a number of expert assessors from the nuclear industry.

The Committee's mandate is to advise the Health and Safety Commission and make recommendations on major issues affecting the safety of nuclear installations, including their design, siting, operation, maintenance and decommissioning which are referred to them or which they consider require consideration.

c) Radioactive Waste Management Advisory Committee

In its Sixth Report to parliament, the Royal Commission on Environmental Pollution took the view that "the responsibility for developing the best strategy for dealing with radioactive wastes is one for the government, and specifically for a department concerned to protect the environment, not one concerned to promote nuclear power" and recommended that a Committee be established to advise the Secretary of State for the Environment on the management of radioactive wastes.

The Radioactive Waste Management Advisory Committee was set up as a non-statutory body to provide independent advice to government. Its members are drawn from a wide range of specialists, including radioactive waste management, earth sciences, nuclear medicine, radiological protection and the social sciences. Members are appointed by the Secretary of State for Environment, Food and Rural Affairs, with the agreement of Ministers in the Devolved Administrations for Scotland and Wales.

The Committee's mandate is to advise the relevant ministers on major issues relating to the development and implementation of an overall policy for all aspects of the management of civil radioactive waste, and on any matters referred to it by these ministers.

3. Public and Semi-Public Agencies

a) United Kingdom Atomic Energy Authority (UKAEA)

The United Kingdom Atomic Energy Authority (UKAEA) is a statutory corporation which, while remaining in the public sector, has moved progressively away from its original role as the research and development body responsible for taking forward the mission of developing nuclear power technology in the United Kingdom. Although the Authority is still the repository of very considerable nuclear expertise and research capability it is now entrusted with the task of dealing with the legacy of past nuclear research (including decommissioning of redundant nuclear installations, the responsibility for the land and property holdings of the Authority, and certain activities which are not appropriate to be carried out on a commercial basis, such as research into nuclear fusion and the operations of the UKAEA Constabulary).

i) Legal status

The UKAEA was set up as a statutory corporation by the Atomic Energy Authority Act 1954 [Section 1] in implementation of the government's policy that the mission of developing atomic power in the United Kingdom should be carried out by an autonomous organisation outside the scope of direct ministerial control and free from day to day involvement by government in its activities. During its existence the Authority has been under the general supervisory authority of a succession of government departments. The Secretary of State for Trade and Industry has the "sponsorship" role at present. The Secretary of State can give directions to the Authority, and they must comply, but in the same section of the 1954 Act [Section 3] it is expressly provided that he should not concern himself with the detail of operations. The UKAEA therefore enjoys a significant degree of autonomy. It has certain powers which are normally attached to government agencies, such as the power to acquire land compulsorily for the performance of its functions, but it has not exercised such powers for many years and has never had significant regulatory functions. As already mentioned, nuclear installations operated by the UKAEA were not previously subject to licensing. Since 1990, this exemption has been removed [the Nuclear Installations Act 1965 (Repeal and Modification) Regulations 1990].

ii) Responsibilities

The original functions of the Authority, in effect the activities which it has legal power to carry out (because there is no legal obligation to carry on all or any of these activities), and which it retains, are to produce, use, and dispose of atomic energy and to carry out research into related matters; to manufacture, buy or acquire, store and transport any articles which, in its opinion, may be required in connection with the production and use of atomic energy; to produce, treat, transport and dispose of radioactive substances; and to disseminate information relating to and train persons in matters concerned with atomic energy and radioactive substances [Atomic Energy Authority Act 1954, Section 2(2)].

This mandate was extended to include research and development in non-nuclear fields as required by the Secretary of State [Science and Technology Act 1965, Section 4]. There have been numerous such requirements. There has also been an extension to certain activities related to treatment and disposal of wastes [Control of Pollution Act 1974, Section 101].

In 1986, the UKAEA was empowered to exploit commercially the intellectual property which it acquired through the performance of its functions [Atomic Energy Authority Act 1986]. This was the basis for the UKAEA's expansion into consultancy and the provision of specialised services.

These commercial operations of the UKAEA were privatised in 1996 under a new company: AEA Technology plc. [Atomic Energy Authority Act 1995].

The Authority must submit to the Secretary of State for Trade and Industry a report on its activities as soon as possible after the end of each financial year [Atomic Energy Authority Act 1954, Section 3(5)].

iii) Structure

The Authority consists of a chairperson and from four to fifteen members; all are appointed by the Secretary of State for Trade and Industry on a full-time or part-time basis [Atomic Energy Authority Act 1995].

Historically the UKAEA has on several occasions been divested of parts of its undertaking which were capable of independent commercial existence. For example, in 1971 the major fuel cycle operations were devolved to form what is now British Nuclear Fuels plc. (public limited company) while the Authority's radiochemical centre became an independent company, now Amersham International plc. [Atomic Energy Authority Act 1971]. This was in line with the original conception of the UKAEA's development. The Authority Weapons Group was also transferred to the Ministry of Defence in 1973.

The UKAEA was reorganised in 1994 into two divisions: Government Division and AEA Technology. The former was to continue as a public sector organisation with responsibilities broadly as outlined above. In preparation for privatisation, the latter was to carry on the commercial science, engineering and consultancy work that had been developed in more recent years. AEA Technology was vested as a separate company at the end of March 1996 and privatised by flotation in September 1996 [Atomic Energy Authority Act 1995].

iv) Financing

For a large part of its existence the UKAEA has been financed by parliamentary grants to an amount determined by the Secretary of State, with the consent of the Treasury [Atomic Energy Authority Act 1954, Section 4]. In 1986 the Authority was placed on a trading fund basis [Atomic Energy Authority Act 1986]. This means that its assets were valued and capitalised to form a "commencing debt" on which the UKAEA is required to provide such financial return to the government as the Treasury may determine from time to time. The Authority was required to carry on business on a commercial basis, and was given appropriate borrowing and ancillary powers. The commencing capital debt and the capital of the outstanding loans borrowed from the National Loans Fund (NLF) were repaid in October 1996 from proceeds from the flotation of AEA Technology plc. [Atomic Energy Authority Act 1995, Section 10 and the UKAEA (Extinguishment of Liabilities) Order 1996, S.I. 1996, No. 2511]. The UKAEA has now reverted to being a predominantly grant funded body.

The Department of Trade and Industry remains a substantial customer for services provided by the Authority.

The Authority is required to transmit to the Controller and Auditor General statements of accounts for each financial year [Atomic Energy Authority Act 1954, Section 4(3)].

b) Health and Safety Commission and Executive (HSC/HSE)

i) Legal status

The Health and Safety Commission (HSC) and the Health and Safety Executive (HSE), the latter being the Commission's operational arm, originally were set up as bodies corporate under the general authority of the Secretary of State for Employment [Health and Safety at Work etc. Act 1974, Sections 10, 11 and 12]. Subsequently, the Secretary of State for Work and Pensions assumed responsibility for the administration of this act. Under an interdepartmental arrangement agreed in 1975, the Secretary of State for Trade and Industry is answerable to parliament for all aspects of safety concerning the UK civil nuclear power industry, including responsibility for ensuring the adequacy of measures for protecting the health and safety of the public and those employed in the industry. Responsibility for certain civil nuclear emergency issues relating to Scottish nuclear sites lies with the Scottish Executive. It is the Secretary of State for Trade and Industry who is accountable to parliament for nuclear safety in Scotland as well as in England and Wales. The functions of the Commission and the Executive are performed on behalf of the Crown [Section 1(7)].

ii) Responsibilities

The general functions of the Commission are to do such things and make such arrangements as it considers appropriate for securing the health, safety and welfare of persons at work and others who may be affected by work activities, and to control the keeping and use of dangerous substances [Section 11]. This general mandate extends to all aspects of health protection related to nuclear activities.

The Commission is empowered to make agreements with any government department or person to perform on behalf of the Commission or the Executive any of their functions [Section 13]. It may also conclude agreements with any minister, government department or public authority to perform on

their behalf functions which are exercisable by them, if the Secretary of State considers it appropriate to do so. The Commission may appoint persons or committees to provide it with advice in connection with its functions [see Section 2, b) "Nuclear Safety Advisory Committee" above] and has power to direct investigations and inquiries [Section 13]. It may furthermore formally approve and issue codes of practice with the consent of the Secretary of State, following consultation with appropriate bodies and government departments.

The HSE is the authority responsible for the licensing of nuclear installations in the United Kingdom. Certain provisions of the Nuclear Installations Act 1965 relating to licensing are relevant statutory provisions for the purposes of the Health and Safety at Work etc. Act 1974. The HSE has a duty to make adequate arrangements for the enforcement of the relevant statutory provisions [Section 18]. The Executive is empowered to appoint inspectors to carry into effect the relevant statutory provisions within its field of responsibility [Section 19].

The Nuclear Installations Inspectorate (NII) (a branch of the Executive) ensures the compliance with all statutory requirements concerning the safety of the workforce and the public in relation to nuclear installations. The Inspectorate also regulates the safety aspects of design, construction and operation of nuclear installations. In this respect, the NII can subject the grant of a nuclear site licence to any conditions it deems necessary in the interest of safety. Its staff includes safety assessors whose principal task is to examine those facets of nuclear installations which are significant for safety and to recommend, where necessary, the improvements that should be made.

The Commission must submit to the Secretary of State as soon as possible after the end of each accounting year, a report on its activities [Schedule 2, paragraph 14].

iii) Structure

The Commission consists of a chairperson and not less than six members, all appointed by the Secretary of State for Work and Pensions. Before appointing the members of the Commission, other than the chairperson, the Secretary of State, as to three of them, consults organisations representing employers, as to three others, organisations representing employees, and as to any other members he may appoint, organisations representing local authorities, and all organisations the activities of whose members are pertinent to the purposes of the Health and Safety at Work etc. Act 1974 [Section 10(2) and (3)].

The Executive consists of a director-general and two other members. The Commission appoints the Director-General of the Executive with the approval of the Secretary of State; the other two are appointed by the Commission, also with his approval after consultation with the Director-General [Section 10(5)].

iv) Financing

The Secretary of State is empowered, with the consent of the Treasury, to pay the Commission such sums as he considers appropriate for the carrying out of its work [Section 43].

The Commission is required to prepare each year a statement of accounts for the Secretary of State and the Comptroller and Auditor General; the latter examines the statement, certifies it and lays a copy of it before parliament [Schedule 2, paragraph 14].

c) National Radiological Protection Board (NRPB)

The National Radiological Protection Board (NRPB) was established by the Radiological Protection Act 1970 [Section 1 as amended by the Health and Safety at Work Act etc. 1974, Section 77]. The functions of the Board are [Section 1]:

- by means of research and otherwise, to advance the acquisition of knowledge about the protection of mankind from radiation hazards; and

- to provide information and advice to persons (including government departments) with responsibilities in the United Kingdom in relation to protection from radiation hazards either of the community as a whole or of particular sections of the community.

The functions of the Board were extended by the National Radiation Protection Board (Extension of Functions) Order 1974 [S.I. 1974, No. 1230], which provided that the Board's existing functions mentioned above should also be exercised in respect of the dangers of radiation which is electromagnetic but not ionising. The Board has power to provide technical services to persons concerned with radiation hazards and to make charges for those services and for providing information and advice [Radiological Protection Act 1970, Section 1(2)].

The Health Ministers (the ministers respectively responsible for health in England, Scotland, Wales and Northern Ireland) gave two directions to the Board on 9 August 1977 under the Radiological Protection Act, requiring the Board to advise on radiation protection standards, to specify emergency reference levels of dose and guidance on their derivation, for those with responsibilities for the protection of the public in the event of an accident involving, or likely to involve, radiation doses to the public in excess of dose limits [Section 1(7)].

The Board is a body corporate, consisting of a chairperson and not less than seven nor more than twelve other members; the chairperson and members of the Board are appointed jointly by the Health Ministers [Section 2, as amended by S.I. 1980, No. 970]. In practice, by arrangements between the Health Ministers, appointments are made by the Secretary of State for Health after consultation with the Medical Research Council (MRC) and the UKAEA [Sections 1(4), 1(8) and 2(1)].

To avoid duplication of activities, the Board has assumed responsibility for the Radiological Protection Service of the MRC and carries on in place of the UKAEA activities related to the effect of radiation hazards in relation to health and safety. Section 77 of the Health and Safety at Work etc. Act 1974 amends Section 1 of the 1970 Act by requiring the Board, when carrying out tasks which relate to those of the Health and Safety Commission, to act in consultation with the Commission and to have regard to its policies. It empowers the Board, on the direction of the Health Ministers, to enter into an agreement with the Commission to carry out its functions relating to ionising or other radiation.

The Board is financed from receipts from charges it makes for the provision of services and from funds provided by parliament through the Secretary of State for Health [1970 Act, Sections 1(2)(b) and 3]. The Scottish Executive also contributes separately a grant to the Board.

The Board must prepare each year a statement of accounts and other records for submission to the Secretary of State for Health, who in turn lays them before parliament with his own report, after the statement has been examined and certified by the Comptroller and Auditor General [Section 3(4)]. A copy of the accounts of the Board is also laid before the Scottish parliament.

The Board carries out pilot studies and research on its own volition in addition to undertaking such work under contract. In 1974, the MRC and the Board established a Joint Committee on Radiological Protection to improve liaison between the two bodies with regard to research on radiobiology.

d) Environment Agencies

The Environment Agency, a non-departmental public body, was set up under the Environment Act of 1995. The Environment Agency is vested with extensive powers and has statutory duties to protect and improve the environment across England and Wales with principal functions of pollution prevention and control, water resources, flood defence, fisheries, recreation, conservation and navigation. Its Environmental Protection Directorate has responsibility for radioactive substances, integrated pollution control, waste regulation and quality and water quality functions.

The Scottish Environment Protection Agency (SEPA) has similar, but not identical, powers to the Environment Agency in the fields of pollution prevention and control. SEPA also has functions in other fields such as conservation, including water and flood monitoring advice.

In Northern Ireland, the Environment and Heritage Service became an agency within the Department of the Environment, Northern Ireland on 1 April 1996. Its role is to build on the work of its predecessor, the Environment Service, which brought together Countryside and Wildlife, Environmental Protection and Historic Monuments and Buildings.

The Service is responsible for implementing environmental policy in Northern Ireland within the framework of Northern Ireland legislation and EC Directives and other provisions. It protects wildlife sites, habitats and species, and protects and promotes the countryside. The Service maintains water quality, regulates pollution, promotes environmental quality, oversees waste management and is responsible for the control of radioactive materials. Historic monuments, buildings and shipwrecks are identified, recorded and protected, and sites in state care are conserved and preserved for the public.

Since April 1996, the power to grant authorisations to discharge radioactive waste has been exercisable by the Environment Agency alone, after consulting the Food Standards Agency or the Secretary of State for Wales and the Health and Safety Executive (HSE).

In England, the Secretary of State for Environment, Food and Rural Affairs and the Secretary of State for Health acting jointly, in Wales the National Assembly for Wales, and in Scotland the Scottish Ministers have the power to call in applications for the disposal of radioactive waste for their own determination and the power to direct the relevant Agency (in England and Wales, the Environment Agency, and in Scotland, the Scottish Environment Protection Agency). In Northern Ireland, the Department for the Environment for Northern Ireland has the power to call in applications and make regulations with respect to the Industrial Pollution and Radiochemical Inspectorate.

In discharging its functions, the principal aim of the Environment Agency as expressed in the Environment Act 1995 is to protect or enhance the environment taken as a whole so as to contribute towards attaining the objective of achieving sustainable development. SEPA has a similar aim, although not directly enshrined in statute, that is, “to provide an efficient and integrated environmental protection system for Scotland which will both improve the environment and contribute to the government’s goal of sustainable development”.

The Environment Agency's legal powers are vested in its board; members of the board are appointed by the Secretaries of State for Environment, Transport and the Regions and for Wales, and by the Minister of Agriculture, Fisheries and Food. SEPA's legal powers are also vested in its board members who are appointed by Scottish ministers.

The Environment Agency is responsible for enforcing, among other things, the provisions of the Radioactive Substances Act 1993, the Transfrontier Shipment of Radioactive Waste Regulations 1993 and Council Regulation (Euratom) No. 1493/93 of 8 June 1993 on Shipments of Radioactive Substances between Member States. SEPA is responsible for enforcing the same legislation in Scotland and the Industrial Pollution and Radiochemical Inspectorate (IPRI) in Northern Ireland.

Most of the Environment Agency staff is located in eight regions across England and Wales. Its head office is located in Bristol. In each region there is a statutory Regional Environmental Protection Advisory Committee which is consulted on major policies. SEPA staff is located in three regions across Scotland, each with a headquarters within the region. Its head office is located in Stirling.

The Agencies consult widely in exercising their function under the Radioactive Substances Act 1993, particularly for determination of applications for disposal of radioactive waste. Documents are made available for public scrutiny at Agency and at local authority offices.

Government policy for radioactive waste management is taken into account by the Agencies. The most recent statement of policy was in the 1995 White Paper Cm. 2919. The UK Strategy for Radioactive Discharges for the period 2001-2020 was published by the Department for Environment, Food and Rural Affairs in July 2002. This Strategy shows how the UK government proposes to implement the OSPAR Strategy with regard to Radioactive Substances agreed in Sintra in 1998. Work is underway to develop statutory guidance to the Agencies on the regulation of radioactive discharges into the environment.

The Agencies' role and responsibilities and those of the HSE impinge on each other. Memoranda of Understanding between the organisations have been agreed to ensure effective co-ordination so that the possibility of conflicting requirements being placed on licensees and others is eliminated, and to minimise duplication.

e) British Nuclear Fuels plc. (BNFL)

i) Legal status

In 1971, as part of the reorganisation of the UKAEA, British Nuclear Fuels Ltd. was set up as a private limited company and subsequently transformed into a public limited company. The fuel cycle operations previously undertaken by the UKAEA were transferred to BNFL, together with the related property, rights and obligations [Atomic Energy Authority Act 1971]. BNFL is responsible to the Secretary of State for Trade and Industry. Originally, shares in BNFL were issued to the UKAEA, but with effect from 3 August 1981 were transferred to the Secretary of State by the British Nuclear Fuels Ltd. (Transfer of Shares) Order 1981 [S.I. 1981, No. 868] made under Section 11 of the 1971 Act.

The Secretary of State has power to dispose of shares held by him in any nuclear company (including BNFL, but in this case no more than a minority stake) whether or not the disposal is consistent with promoting or controlling the development of atomic energy [Atomic Energy (Miscellaneous Provisions) Act 1981].

ii) Responsibilities

BNFL provides the full range of nuclear fuel cycle services to the United Kingdom and international markets, including enrichment (through its associated company, Urenco Ltd.), uranium hexafluoride production, fuel manufacture, reprocessing and waste management. BNFL also provides world-wide nuclear fuel transport services, runs a successful power generation business and has a thriving engineering business. BNFL is also committed to research and development in order to support and develop its business.

iii) Structure

BNFL is managed by a board of eleven directors, (including non-executive directors) appointed in accordance with the Company's Articles of Association, one of whom is the chairperson and another the chief executive. The Company Secretary convenes the annual general meeting at the direction of the board.

The Company is organised into a head office at Risley which provides, via a small central team, overall strategy direction and control to four business groups and six Function/Process Owners. Central services, such as Corporate Strategy and Legal, provide certain services to the rest of the company. The four Business Groups are: Fuel, Magnox Generation, Thorp, and Waste Management and Decommissioning. The six Functions are: Technology and Operations, Safety, Health and Environment (SHE), Commercial, Finance, Public Affairs and Human Resources.

BNFL's UK operations span five sites in North West England and Southern Scotland. BNFL also has a number of overseas offices. Export success is strengthened through its wholly-owned subsidiary, BNFL Inc., based in North America, and its offices in Japan, China, South Korea, South Africa, Germany, Belgium and France.

iv) Financing

The initial capital was subscribed by the Secretary of State with the consent of the Treasury [Atomic Energy Authority Act 1971, Section 11(4)]. The Secretary of State may, with the approval of the Treasury, make loans to the Company [Section 12(1)]. Under the Nuclear Industry (Finance) Act of 1977, the Secretary of State is empowered, with the consent of the Treasury, to guarantee any loans made to BNFL, including the loan interest. The 1977 Act imposed new limits on the amount of public finance that may be committed to BNFL under the 1971 and 1977 Acts. The limit initially set by the 1977 Act was British pounds (GBP) 300 million. The initial limit of GBP 300 million was raised to GBP 1 000 million by order under Section 2(1)(a) of the 1977 Act [S.I. 1987, No. 875]; and to date, the limit has been increased from GBP 1 500 million to GBP 2 000 million by the Atomic Energy Act 1989 [Section 1].

The board submits an annual report and a statement of accounts, audited by independent auditors, to its shareholders at the end of each financial year.

f) Amersham International plc.

Also as part of the reorganisation of the UKAEA [Atomic Energy Authority Act 1971], Amersham International Ltd. was set up as the Radiochemical Centre Ltd., a private limited company,

at the same time as BNFL. With effect from 1 April 1971, the Radiochemical Centre Ltd. took over the UKAEA's activities in connection with the production and marketing of radioactive materials [Atomic Energy Authority Act 1971, Section 2, and S.I. 1971, No. 478]. The company, which has been transformed into a public limited company, has subsidiaries in a number of countries, including Australia, France, Germany, Japan and the United States. On 1 October 1981, the shares held by the UKAEA in Amersham International Ltd. were transferred to the Secretary of State [The Amersham International Ltd. (Transfer of Shares) Order 1981, S.I. 1981, No. 850]. The Secretary of State then divested himself of the ownership of the company, whose shares are now wholly owned by the private sector. [The Atomic Energy (Miscellaneous Provisions) Act 1981, Section 1(3), provides that the Secretary of State's power to dispose of shares is exercisable whether or not the disposal is consistent with promoting or controlling the development of atomic energy].

g) The National Nuclear Corporation Ltd. (NNC)

The National Nuclear Corporation Ltd. (NNC) was set up in 1973 as a private limited company whose shareholders were the UKAEA, General Electric Company plc. (GEC) and British Nuclear Associates Ltd. (representing companies engaged in the nuclear construction industry). The NNC was responsible for the design, instruction and marketing of nuclear power plants.

In 1977, the Secretary of State was empowered to incur, with the consent of the Treasury, out of money provided by parliament, any expenditure necessary for the acquisition of shares in the NNC or any of its subsidiaries [Nuclear Industry (Finance) Act 1977].

In 1988 the NNC became a wholly owned subsidiary of GEC, and is now a major project management and technical consultancy company operating in both the nuclear and non-nuclear sectors. It has an issued share capital of GBP 10 million.

h) United Kingdom Nirex Ltd.

i) Legal status

The United Kingdom Nuclear Industry Radioactive Waste Executive (NIREX) was set up in 1982. It was incorporated in 1985 as United Kingdom Nirex Ltd., a private limited company with shares held by the UKAEA, BNFL, the Central Electricity Generating Board (CEGB) and the South of Scotland Electricity Board (SSEB). The Secretary of State for Energy held a special share which gave it ultimate control over land on which waste disposal facilities are sited if need be in perpetuity. In 1990 the CEGB and SSEB shares were transferred to Nuclear Electric plc. and British Energy Generation Ltd. respectively. In April 1992, the special share was transferred to the Secretary of State for Trade and Industry. On 31 March 1996 the ordinary shareholdings were further redistributed. Current shareholders are BNFL, British Energy Generation Ltd., British Energy Generation (UK) Ltd., Magnox Electric plc. and the UKAEA.

ii) Responsibilities

The Company's principal activity is to carry out research, development and design with a view to developing and managing commercial facilities for radioactive waste disposal.

The government has overall responsibility for radioactive waste strategy. The role of the Company, working within that strategy, is to provide disposal services for solid intermediate and low-level radioactive waste to its shareholders and other UK users of radioactive materials, such as hospitals, industries, etc. The ordinary shareholders are expected to be the majority users of the Company's services. High-level waste is managed by its producers, BNFL and the UKAEA.

iii) Structure

Nirex is based at Harwell and is managed by a board of directors. The board comprises two directors nominated by each shareholder (although for the time being shareholders have agreed to nominate only one director) together with such external directors as the shareholders may from time to time agree. As at 1 April 1999, three such external directors were in post, including the chairperson and the managing director.

iv) Financing

Nirex is funded by loans from its shareholders who have agreed to provide, by way of such loans, all funds in excess of the sums from time to time paid up on the issued share capital of the Company which may be necessary for the conduct of the business of the Company.

The directors submit a report on the Company's activities and a statement of accounts, audited by independent auditors, to its shareholders at the end of each financial year.

Note on the restructuring of the electricity industry

On 31 March 1990, the electricity industry in England and Wales and Scotland was completely restructured in accordance with the provisions of the Electricity Act 1989. The Central Electricity Generating Board (CEGB) which had until then been responsible for generating all electricity and its transmission and distribution throughout England and Wales was divided into four companies, National Power, PowerGen, both fossil-fuel generators, National Grid plc., for the transmission of electricity, and Nuclear Electric plc. The first three were privatised in 1990/91, while Nuclear Electric plc. remains in public ownership having been renamed Magnox Electric plc. in 1996 (see below). At the same time, the two public utilities responsible for generating, transmitting and distributing electricity in Scotland, North of Scotland Hydro-Electric Board and South of Scotland Electricity Board (SSEB) were also reorganised for purposes of privatisation. Two separate companies were created, Scottish Power plc. and Hydro-Electric plc., to take over the non-nuclear business of the previous bodies, and these were privatised in 1991. British Energy Generation (UK) Ltd. (formerly called Scottish Nuclear Ltd.), set up in parallel, took over the nuclear power plants in Scotland and remained in public ownership until the restructuring and privatisation programme in 1996 (see below).

In May 1995, a government review concluded that the early privatisation of the United Kingdom's advanced gas cooled reactor (AGR) stations and pressurised water reactor (PWR) stations was feasible. A reorganisation took place with effect from 31 March 1996, whereby Nuclear Electric plc. transferred the business of its five AGR stations and its PWR station to British Energy Generation Ltd. (formerly called Nuclear Electric Ltd.), a newly incorporated company, while retaining its Magnox stations. At the same time, British Energy Generation (UK) Ltd., while retaining its two AGR stations, transferred its Magnox station to Magnox Electric plc. A newly incorporated company, British Energy plc., was created as the parent company of British Energy Generation Ltd. and British

Energy Generation (UK) Ltd. On 26 June 1996, a prospectus was published offering shares of British Energy plc. for sale by way of public flotation. The sale took place on 15 July 1996 when the shares were listed on the London Stock Exchange. Lastly, the most recent development is the merge of BNFL with Magnox Electric plc. on 30 January 1998.

i) Magnox Electric plc.

i) Legal status

Magnox Electric plc. (formerly Nuclear Electric plc.) was set up as a public limited company in 1990 and is state-owned, with its shares held by the Secretary of State for Trade and Industry. Since 30 January 1998, the company has been a wholly-owned subsidiary of BNFL.

ii) Responsibilities

Magnox Electric owns nine nuclear power stations in the United Kingdom – six operating Magnox stations and three Magnox stations (including the Magnox station transferred from Scottish Nuclear Ltd. under the 1996 restructuring) which are being decommissioned. Most of the electricity produced by Magnox Electric is sold under contract to the Regional Electricity Companies (RECs) in England and Wales.

iii) Structure

The Company is headed by a board of directors, whose appointments must be approved by the Secretary of State for Trade and Industry. The board consists of five executive directors, one of whom is the chairperson, and four non-executive directors. The day to day management of the Company is the responsibility of the chief executive in consultation where appropriate with the chairperson and the directors. The government expects Magnox Electric to act in a commercial manner.

iv) Financing

Magnox Electric derives its income primarily from sales of electricity. It may obtain grants from the Secretary of State for Trade and Industry.

The directors publish a report on the Company's activities and a statement of accounts, audited by independent auditors in September each year relating to the previous 1 April to 31 March financial year.

j) British Energy Generation Ltd.

Under the 1996 restructuring and privatisation programme the five AGR stations and the PWR station, previously under the control of Nuclear Electric plc. (renamed Magnox Electric plc.), were transferred to British Energy Generation Ltd.

British Energy Generation Ltd., along with British Energy Generation (UK) Ltd., has as its parent company British Energy plc., whose shares were sold and listed on the London Stock Exchange in July 1996, privatising all the AGR and PWR stations in the United Kingdom.

k) Scottish Electricity Generator Companies

In accordance with the Electricity Act 1989 [Section 67(4)], the property, rights and liabilities of the Scottish Boards were, with effect from 31 March 1990, transferred by order to three companies nominated by the Secretary of State [The Electricity Act 1989 (Transfer Date) (Scotland) Order 1990, Section 24, S.I. 1990, No. 197]. The companies nominated for this purpose were two Scottish electricity generator companies (Scottish Power and Hydro Electric) and a Scottish nuclear generator company (Scottish Nuclear) [The Electricity Act 1989 (Nominated Companies) (Scotland) Order 1989, S.I. 1989, No. 2448].

l) British Energy Generation (UK) Ltd.

i) Legal status

British Energy Generation (UK) Ltd. (previously Scottish Nuclear Ltd.) was set up as a limited company in 1990 and was state-owned under the authority of the Secretary of State for Scotland. In 1996, as part of the restructuring and privatisation programme, it transferred its Magnox station to Magnox Electric plc., while retaining its two AGR stations. It was made a subsidiary of British Energy plc., which was sold by way of public flotation and its shares listed on the London Stock Exchange in July 1996.

ii) Responsibilities

British Energy Generation (UK) Ltd. operates the two nuclear power plants in Scotland, but does not supply electricity directly to customers. It sells all the nuclear electricity produced under contract to Scottish Power and Hydro Electric. It was also responsible for the decommissioning of Hunterston A nuclear power plant, but under the 1996 restructuring programme this Magnox station was transferred to Magnox Electric plc. [formerly Nuclear Electric plc., see *supra*, Section i)].

m) Regional Electricity Companies in England and Wales

In accordance with the Electricity Act 1989 [Section 65], the property, rights and liabilities of the twelve Area Boards, previously responsible for acquiring bulk supplies of electricity from the electricity producers and for distributing such supplies to the customers in their respective areas, were, with effect from 31 March 1990, transferred by order to twelve Regional Electricity companies in England and Wales, set up for that purpose [The Electricity Act 1989 (Commencement No. 1) Order 1989, S.I. 1989, No. 1369, and the Electricity Act 1989 (Transfer Date) (England and Wales) Order 1990, S.I. 1990, No. 225].

OECD PUBLICATIONS, 2, rue André-Pascal, 75775 PARIS CEDEX 16
PRINTED IN FRANCE
(66 2004 14 1 P) ISBN 92-64-01814-X No. 53757 2004