

NUCLEAR
LAW
Bulletin
number 35

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June 1985

Nuclear Energy Agency
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 Signatories of the Convention on the OECD are Austria, Belgium, Canada Denmark France the Federal Republic of Germany, Greece, Iceland, Ireland, Italy Luxembourg the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, Turkey the United Kingdom and the United States The following countries acceded subsequently to this Convention (the dates are those on which the instruments of accession were deposited) Japan (28th April 1964), Finland (28th January, 1969), Australia (7th June, 1971) and New Zealand (29th May, 1973)

The Socialist Federal Republic of Yugoslavia takes part in certain work of the OECD (agreement of 28th October, 1961)

The OECD Nuclear Energy Agency (NEA) was established on 20th April 1972 replacing OECD's European Nuclear Energy Agency (ENEA) on the accession of Japan as a full Member

NEA now groups all the European Member countries of OECD and Australia Canada Japan, and the United States. The Commission of the European Communities takes part in the work of the Agency

The primary objectives of NEA are to promote co-operation between its Member governments on the safety and regulatory aspects of nuclear development and on assessing the future role of nuclear energy as a contributor to economic progress

This is achieved by

- *encouraging harmonisation of governments regulatory policies and practices in the nuclear field with particular reference to the safety of nuclear installations protection of man against ionising radiation and preservation of the environment radioactive waste management, and nuclear third party liability and insurance*
- *keeping under review the technical and economic characteristics of nuclear power growth and of the nuclear fuel cycle and assessing demand and supply for the different phases of the nuclear fuel cycle and the potential future contribution of nuclear power to overall energy demand*
- *developing exchanges of scientific and technical information on nuclear energy particularly through participation in common services*
- *setting up international research and development programmes and undertakings jointly organised and operated by OECD countries*

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

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FOREWORD

The first issue of the Nuclear Law Bulletin appeared in February 1968 and since then, its readership has continued to expand the world over. Understandably, and in step with the evolution of nuclear activities, information on nuclear laws and regulations as well as related case-law has increased in volume. This is why, to facilitate consultation of the texts in the Bulletin, an analytical Index covering all the Bulletins to date is published every five issues.

A new analytical Index accompanies this issue of the Nuclear Law Bulletin and supersedes previous Indexes, covering all thirty-five issues.

The NEA Secretariat wishes to take this opportunity to thank all those whose kind assistance has enabled it to continue publishing this Bulletin and to enrich its contents.

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LEGISLATIVE AND REGULATORY ACTIVITIES

• *Finland*

NUCLEAR LEGISLATION

Outline of Nuclear Energy Bill (1985)

1. SCOPE AND CONCEPTS

Scope

As compared to the 1957 Atomic Energy Act, the Nuclear Energy Act of 1985 is both more comprehensive and more detailed and covers the following

- mining carried out for the purpose of producing uranium or thorium,
- activities carried out for the purpose of obtaining uranium or thorium concentrates;
- mined uranium/thorium ores, prepared uranium/thorium concentrates and imports and exports of such substances;
- facilities producing nuclear fuels;
- nuclear fuels and other nuclear substances;
- nuclear power plants;
- nuclear waste;
- facilities for the handling, treatment or storage of nuclear waste,
- repositories for large-scale permanent storage of nuclear waste;
- certain substances, equipment and information having significance for preventing of the proliferation of nuclear weapons or involving obligations under international treaties,
- certain contracts concluded with foreigners.

Concepts

The general concept is that the Act should cover the use of nuclear energy and separate sections of the Act define the particular concepts, the main ones being nuclear substances, nuclear waste, nuclear waste management and nuclear facilities.

Exemptions

In certain cases it is possible and even considered advisable to grant exemptions from the scope of the Act. This would apply for example to insignificant amounts of nuclear substances acquired for research or similar purposes. Exemptions from licensing requirements may, in actual practice, come to be granted far more frequently.

2. GENERAL PRINCIPLES

The Act sets out the general principles to be complied with when engaging in nuclear activities

These principles include certain special prohibitions, namely it is forbidden to introduce nuclear devices on the national territory; it is also forbidden to fabricate, possess or explode such devices. Non-compliance with this principle is subject to severe penalties.

The other principles are . the safe use of nuclear energy; compatibility with the overall interest of society; the organisation of adequate physical protection, emergency preparedness and rescue services.

The extent to which the various principles are met is taken into account when granting a licence. These principles must be complied with throughout actual operations, otherwise the operations must cease.

3. THE "PRINCIPLES DECISION" PROCEDURE AND THE LICENSING PROCEDURE

The "Principles Decision" procedure

The actual licensing procedure to be followed in respect of facilities remains essentially unchanged as previously, a construction licence and subsequently, an operating licence are required. Prior to the construction licence, however, a so-called Principles Decision must be obtained showing that the project has been found compatible with the overall interest of the community. This Decision must generally be obtained before the construction licence can be issued.

A Principles Decision is not required for all projected facilities; however, it is mandatory for the following :

- every nuclear power plant (of 50 MW and above),
- every nuclear waste repository;

- every other nuclear facility comparable to both of the above, on account of the quantities of nuclear substances or waste contained simultaneously in the facility or on account of the radiation hazards involved.

The Principles Decision is taken at a fairly early stage, that is all the information relating to the final concept of the facility is available : at that stage, the information required covers such data as identity of the supplier of the facility, the basic options from which selection can be made and which sites are available. An application for Decision must therefore be made before tenders are invited.

Before the Decision is taken by the Council of State,

- various governmental bodies are heard and a preliminary estimate requested from the Radiation Protection Centre as to the safety aspects of the project;
- a statement of opinions is requested from the municipal committee the municipality in which the facility is to be situated as well as from the adjoining municipalities;
- an account of the outline of the project is released to the press;
- a public meeting is held at the place where the facility would be located; and
- the various opinions obtained are communicated to the Council of State.

The Council of State cannot take a Principles Decision if

- the municipality in which the facility would be located does not support the project, or
- circumstances have appeared showing that the safety requirements cannot be satisfied.

The next step is to decide on the compatibility aspect, i.e. whether the project is compatible with the overall interest of the community. In the affirmative, the Principles Decision is submitted to Parliament without delay for consideration. Parliament has two options : it may either reject or approve the Decision without modifications. The applicant is not authorised to proceed with any measures of economic significance prior to the Decision.

Licensing

The preconditions for a construction licence include an account of the points of view from which satisfaction of the general principles is to be considered. Attention is paid to :

- the plans relating to the nuclear facility and its main operation systems and various components. These plans must be adequate from

the point of view of safety, and the planning must take proper account of the labour protection aspects and safety of the population,

- the appropriateness of the site from the points of view of safety and environmental protection;
- plans relating to physical protection,
- regional planning;
- methods available for nuclear waste management;
- plans relating to nuclear fuel supply;
- the Radiation Protection Centre's possibilities of carrying out control; and
- the applicant's expertise, financial situation and other qualifications.

The licence is granted by the Council of State.

To obtain an operating licence the applicant is expected to have proceeded from plans to actual measures whenever these are required. Attention is now mainly paid to :

- arrangements guaranteeing safety of operation;
- nuclear waste management,
- the applicant's expertise (in particular the competence of personnel operating the facility) and the planned operational organisation;
- the applicant's various qualifications.

This licence, too, is issued by the Council of State.

The operation of a facility is subject to an inspection of operation to be performed after the operating licence has been issued. The inspection is carried out in accordance with measures laid down by the Radiation Protection centre and the Ministry of Trade and Industry.

In addition, the Act lists the conditions to be met for other forms of the use of nuclear energy which require a licence. They are, mutatis mutandis, the same as those already described above. These conditions are applicable to mining and concentration and any other activities not involving the construction or operation of a facility.

The licence is normally issued by the Ministry of Trade and Industry.

4. THE LICENCE : THE LICENSEE, PERIOD OF VALIDITY, COMPENSATION

The licensee

As a rule, licences can be granted only to citizens of Finland and Finnish organisations. Foreigners may obtain a licence only for :

- transports carried out within Finland;
- import and export in connection with transit; and
- temporary operation in Finland of a nuclear facility conveyed by means of transport in Finland.

In cases provided for in international treaties, a licence may also be issued to a body exercising supranational control, or to another state.

Period of validity of a licence

Unlike licences issued under the present Act, those to be issued under the new Act will be valid for a stated period only. The period of validity will depend in particular on safety guarantees and the expected duration of operations. For construction licences, however, no duration is fixed.

Licences are not permanent, even in the sense that their terms and conditions are subject to modification. A licence must, from the outset, include all those terms and conditions which are needed for satisfaction of the general principles. On similar grounds, they can be modified, especially with a view to

- guaranteeing safety;
- guaranteeing appropriate nuclear waste management;
- carrying out the arrangements relating to physical protection and emergency preparedness;
- meeting the requirements of international treaties binding on Finland,
- preventing the proliferation of nuclear weapons.

In an extreme case, a licence may even be withdrawn. This applies if satisfaction of the general principles is substantially jeopardized. This, in turn, may be due to a cause within the control of the licensee or because its activities are no longer deemed compatible with the overall interest of the community.

A licence is withdrawn by the authority which issued it.

Compensation

The provisions concerning withdrawal of a licence give the authorities considerable latitude. These provisions are counterbalanced by those relating to compensation for withdrawal, according to which compensation is paid if the

licence is withdrawn on the basis of the overall interest of society. Compensation is not necessarily "full", but it must be reasonable. The amount of such compensation should primarily be decided by mutual agreement.

5. OPERATOR'S OBLIGATIONS AND PUBLIC CONTROL

Operator's obligations

Whoever conducts nuclear operations (the "operator"), whether or not the holder of a licence, is responsible for

- ensuring the safe use of nuclear energy;
- ensuring that those arrangements relating to physical protection, emergency preparedness and rescue services for which he is responsible are appropriate,
- ensuring that all the measures involved in nuclear waste management are taken;
- making due preparation for such measures,
- bearing the cost of any measures in connection with nuclear waste management and preparations for such measures; and
- providing in advance for payment of these expenses as prescribed by the Act.

These obligations arise directly from commencement of operations and generally cease when operations cease; expiry of the validity of the licence does not automatically discharge the operator concerned from his obligations.

Public control

Under the new Act, as previously, ultimate public control in the field of nuclear energy is entrusted to the Ministry of Trade and Industry. In practice, the Radiation Protection Centre is responsible for exercising actual control, which covers the following :

- ensuring safety;
- checking the arrangements relating to physical protection and emergency preparedness, and
- preventing the proliferation of nuclear weapons.

To ensure the effectiveness of the Radiation Protection Centre's control, the Act lists the various powers vested in the Centre for carrying out its tasks, namely, it is entitled to :

- access to any premises where operations governed by the Act are carried out;

- inspect and supervise operations, take samples, perform measurements, obtain samples and install control devices;
- prescribe criteria for the fabrication of nuclear fuels, plant structures and components, and to check that such criteria are met,
- be informed of any data, plans and contracts as necessary;
- require reporting and accounting;
- prohibit certain measures.

The Centre may also provide that the person in charge of a facility should make certain necessary changes to its construction or operation. In addition, the Centre may require the licensee to eliminate any flaws and failures detected in the use of nuclear energy. As an extreme measure, the Centre is empowered to interrupt or restrict operations. To ensure compliance with the obligations imposed, the Centre may apply a wide range of sanctions, such as conditional charge of fines, commission an outsider to perform an act omitted, call upon police assistance, or make a seizure.

6. ADVANCE PROVISION FOR THE COST OF NUCLEAR WASTE MANAGEMENT

Waste producers are responsible for taking the measures involved in nuclear waste management. Under the new Act, advance provision for the expenses will be made through a governmental fund. Some of the main features of the system are the following :

- the term "nuclear waste" also applies to contaminated installations and components. An entity in charge of nuclear waste management will be responsible for storing the waste in a repository. Once this operation has been conducted in a satisfactory manner, the State assumes responsibility for monitoring and control of the repository as well as for the nuclear waste;
- an entity in charge of nuclear waste management must contribute annually to the fund and provide securities to the State in such a way that the payments and the securities together cover, at a given moment, the estimated amount of the expenses payable in future in respect of the nuclear waste produced (underlying assumptions price level to be that prevailing at the time or estimate; amount to be readjusted annually; in determining the payment due, account should be taken of the change in the volume of waste as well as the impact of inflation and technical progress).
- the system of securities applies only during the useful lifetime of the nuclear facility, and its purpose is to level down the incidence (in time) of the waste expenditure on the price of the commodity (e.g. electric power produced by the facility). The only acceptable securities are credit securities and bank guarantees, as well as other securities, as approved separately by the Council of State,
- an entity in charge of nuclear waste management as well as the owners of its shares are entitled to borrow back 75% of their

- payments into the fund against (other) securities. The balance remaining will be lent to the State. The rate of interest on these loans will be at least the same as that charged by way of a "basic interest" by the Central Bank of Finland plus 2 percentage units, but it may be increased, as appropriate, if the level of the consumer prices justify such an adjustment;
- the interest accruing on the loans made by the fund will be used for decreasing the rate of payments to be made by the entities in charge of nuclear waste management. (If the rate of interest and that of inflation are identical, their effects on the rate of payment neutralise each other);
- should the payments made by an entity in charge of nuclear waste management exceed the amount of money considered necessary for nuclear waste management operations still to be performed, the balance will be repaid to the entity. This may be the case especially when measures relating to nuclear waste management are taken;
- to provide for unforeseeable expenses in the field of nuclear waste management, the entities in charge shall furnish to the State extra securities covering up to 10% of the estimated expenses of nuclear waste management yet to be incurred;
- should the State have to take charge of nuclear waste on account of a gross omission by the entity in charge, there will be immediately formed in the fund a separate capital reserve deemed adequate for the payment of the expenses involved by the waste transferred. This capital will consist of the payments made by the entity in charge of nuclear waste management and by demanding sufficient payments from the entity or by realizing the securities provided. The capital will be invested in order to make it yield interest.

7. OTHER IMPORTANT PROVISIONS

The penalties applicable according to the proposed Act are more varied and specific than those under the existing law. Actually novel types of criminal cases are the following :

- "nuclear energy crime", amounting to terrorism and involving the use of a nuclear substance or nuclear waste thereby creating a hazard to people's life, health or property. There are three degrees in such a crime : grave, "middling" and moderate,
- "nuclear device crime", amounting to a breach of the ban on the introduction or explosion of a nuclear device;
- the act of threatening people with either of the above-mentioned crimes.

The Bill also contains provisions aimed at protecting licensees' professional and business secrets, physical protection arrangements or sensitive information material against disclosure.

The Bill authorises the Council of State to make regulations about certain aspects of the use of nuclear energy, namely, safety, the organisation of physical protection and emergency preparedness, and arrangement of rescue services.

The transitional provisions of the Bill are based on the principle that on the entry into force of the new Act any stipulations in existing licences not in harmony with the requirements of the Act should cease to apply. Licences conforming to existing law would be valid for a maximum of five years after the entry into force of the new Act.

ORGANISATION AND STRUCTURE

1983 Act setting up a Radiation Protection Centre

Act No. 1069/1983 of 22nd December 1983 sets up a Radiation Protection Centre and lays down its tasks; it furthermore repeals the Act of 20th June 1974 establishing the Institute for Radiation Protection (see Nuclear Law Bulletin No. 17).

The 1983 Act provides that the Radiation Protection Centre's main duties are to prevent and limit the harmful effects of radiation, to control the safe use of radiation and nuclear energy; and to undertake related research and training and provide information on the subject.

Finally, the Act lays down that further provisions regarding the Centre's tasks and operation are to be issued by Ordinance.

1984 Ordinance on the Radiation Protection Centre

Ordinance No. 190/1984 of 22nd February 1984 was made in implementation of the above Act and details the Radiation Protection Centre's responsibilities and organisation.

The Centre's main duties include supervising observance of the 1957 Radiation Protection Act as amended (see Nuclear Law Bulletin No. 7) and the 1957 Atomic Energy Act as amended (see Nuclear Law Bulletin No. 11) as well as regulations made in accordance with both Acts.

To this effect, the Centre is empowered to issue instructions on application of regulations and standards within its field of competence and may also take initiatives and make proposals. The Centre is responsible, inter alia, for performing research and development work on the safe use of nuclear energy and radiation and for analysing and monitoring radiation exposure doses to workers and the population as well as for monitoring the environment.

The Centre also carries out inspections for protection of the population against radiation and provides advice on the organisation of all aspects of radiation protection.

The Ordinance sets up the structure of the Radiation Protection Centre, which is made up of four divisions and one laboratory. The Centre is run by a Director and supervised by an Intergovernmental Board.

● *France*

ORGANISATION AND STRUCTURE

1985 Order setting up a Nuclear Engineering Terminology Commission

An Order of 27th February 1985 has set up a Nuclear Engineering Terminology Commission under the Ministry of Industrial Redeployment and Foreign Trade (published in the Official Gazette of 6th March 1985).

This Commission will draw up an inventory of the gaps in French nuclear engineering vocabulary, taking into account users' needs; it will also propose and revise the necessary terms in the light of present knowledge and contribute to collection and harmonisation of terminological and neological data.

Finally, the Commission will encourage dissemination of new terminology to users.

REGIME OF NUCLEAR INSTALLATIONS

1984 Order and Circular on design, quality, construction and operation of large nuclear installations

This Order of 10th August 1984 and the accompanying Circular issued on the same date have been reported in Nuclear Law Bulletin No. 35, December 1984. The texts of the Order and the Circular are reproduced in the "Texts" Chapter of this issue of the Bulletin.

TRANSPORT OF RADIOACTIVE MATERIALS

1985 Order on the transport and handling of dangerous goods

This Order of 4th January 1985 (revision of the Regulations of 15th April 1945 on the transport of dangerous goods, modification of Appendix 7, labelling of dangerous goods, 1985, No. 2) was published in the Official Gazette of 6th February 1985.

The amendments the Order has made regarding labelling and markings concern several classes of substances, including class 7 which covers radioactive materials.

• *Federal Republic of Germany*

RADIATION PROTECTION

1985 Ordinance to amend the Ordinance on medicaments treated with ionizing radiation

A Third Ordinance of 12th February 1985, to amend the Ordinance relating to the authorisation of medicaments treated with ionizing radiation or containing radioactive substances (see Nuclear Law Bulletin No. 8) has been published in Bundesgesetzblatt 1985, I, p. 368. The new Ordinance prescribes in particular that the ban on distribution provided by law does not apply to radioactive substances which have the status of medicine under that law.

THIRD PARTY LIABILITY

1985 Act to amend the nuclear third party liability provisions of the Atomic Energy Act

The Act of 22nd May 1985 (Bundesgesetzblatt 1985, I, p. 781) introduces in the Atomic Energy Act the concept of unlimited liability for the operator of a nuclear installation. It also provides for amendment of the Act in order to implement in national law the 1982 Protocols to amend the Paris Convention and the Brussels Supplementary Convention (see under "Multilateral Agreements" in this issue of the Bulletin). The Act will enter into force on 1st August 1985.

After Switzerland, which introduced unlimited liability in its 1983 Act on Nuclear Liability (see Nuclear Law Bulletin Nos. 32 and 33), the Federal Republic of Germany is the second Signatory of the Paris Convention to provide for the liability of a nuclear operator without a ceiling being fixed. The amended Section 31, paragraph 1 No. 1 of the Atomic Energy Act now reads as follows: "The liability of the operator of a nuclear installation according to the Paris Convention in connection with Section 25, paragraph 1, 2 and 4 is not limited in amount". Thus the claim of a victim will not only be covered by the mandatory financial security to be maintained by the operator, but also by the entire property of the operator, including for example, claims from property insurance. There is only one exception from the principle of unlimited liability: according to a reservation made by the Federal Republic of Germany to the Paris Convention, German nuclear liability law also provides for the operator's liability in the cases covered by Article 9 of the Paris Convention (armed conflict, grave natural disaster...). Such liability, however, is limited to 1,000 million Deutsche Mark per incident.

Though the amendment establishes an unlimited liability for the operator, he is not obliged to have and to maintain an unlimited financial security well. Mandatory private financial security is limited to 500 million

Deutsche Mark. In addition, the Act provides for State indemnification up to twice the amount of private security in cases where victims cannot be compensated from the private security. Therefore, the total financial security available amounts to 1,000 million Deutsche Mark, the property of the operator must be added to that amount. The maximum amount of mandatory financial security must be assessed every five years to ensure that the real value of the amount is still preserved; where there is a loss due to inflation the sum must be increased.

As regards nuclear incidents causing damage in other States, a provision has been drafted on the basis of reciprocity. The operator will only be held liable without limitation if the State concerned also provides for unlimited liability in relation to nationals of the Federal Republic of Germany. Different provision is made for States with limited liability: the operator is liable up to 300 million Special Drawing Rights (SDR) with regard to States which have ratified the Brussels Supplementary Convention, as amended by the 1982 Protocol; he is liable up to 120 million SDR if the State concerned has ratified the Brussels Supplementary Convention as amended only by the 1964 Additional Protocol. In all other cases his liability is limited to 15 million SDR.

• *Mexico*

NUCLEAR LEGISLATION

1984 Act on the administration and control of nuclear energy

This Act, published in the Official Gazette of 4th February 1985, was promulgated on 27th December 1984 under Section 27 of the Constitution relating to nuclear energy. It cancels the 1978 Act which had established a National Atomic Energy Commission responsible for supervising all nuclear activities, as well as a public body called Uranio Mexicano (URAMEX) which had been granted a state monopoly for the exploration and exploitation of radioactive ores (see Nuclear Law Bulletin No. 23). It maintains and enlarges the responsibilities of the National Nuclear Research Institute and the National Nuclear Safety and Safeguards Commission, also set up by the 1978 Act.

The application of the Act has been broadened to include the exploration, exploitation and use of radioactive ores, as well as the use of nuclear fuels, the application of nuclear energy, scientific and technical nuclear research, and the nuclear industry and all activities related thereto.

The Act stipulates that all uses of nuclear energy shall be for peaceful purposes and that the Federal Executive shall establish the

regulations to which the use, both energetic and non-energetic, of radioactive materials, shall be subject. The Ministry for Energy, Mines and Industry shall be responsible for its application.

The exploration, exploitation and use of radioactive ores

Radioactive ores are the property of the State and cannot be the subject of concessions or contracts.

As regards the exploration, exploitation and use of the radioactive ores as defined in the Act, the Ministry of Energy, Mines and Industry assigns the corresponding obligations to the following public bodies: the Board of Mineral Resources, a decentralised, federal public organisation is granted the exclusive and direct responsibility for all exploration activities under the control of the Ministry, which determines the conditions for carrying out these activities. Similarly, the Ministry assigns exploitation rights to another decentralised, federal public organisation, the Commission for Mineral Development which is the sole organism permitted to install and operate plants for the use of these ores.

The nuclear industry

Responsibility for implementation of the various stages of the fuel cycle previously reserved to URAMEX under the 1978 Act, is now granted to the Federal Executive acting through the Ministry of Energy, Mines and Industry. The activities of the nuclear industry for which the Ministry is responsible cover all stages of the fuel cycle, including enrichment of uranium, reprocessing and back-end activities; the design and manufacture of components and equipment, and the production and use of radioisotopes

The use of nuclear fuel for the generation of electricity is subject to authorisation by the Ministry. In particular, the Federal Executive, acting through the Ministry takes on the responsibilities for the co-ordination of the activities of the two decentralised public organisations mentioned above and for the importing and exporting of nuclear fuels and materials, responsibilities formerly attributed to the National Atomic Energy Commission and URAMEX respectively.

In addition, the Federal Executive is responsible for regulating nuclear security, radiological protection and health physics, as well as for safeguards. It shall implement the various stages of the fuel cycle and reprocessing, and shall regulate and supervise those stages which cannot be carried out in the country. The exportation of radioactive ores or materials shall take account of the country's self-sufficiency. When applicable, an export authorisation shall not exceed an annual five per cent of the proven reserves that the country will require under the National Development Plan provided for by the Constitution.

The Federal Executive shall also establish the research and technical development policy as concerns the nuclear industry and is responsible for the storage, transport, and deposit of nuclear fuels and radioactive wastes irrespective of their origin, although it may delegate responsibility for the

temporary storage of nuclear fuels and radioactive wastes to the corresponding public organisations. The Act confers responsibility on the Federal Executive to ensure the observance of treaties and other international legal instruments entered into in the nuclear field.

Nuclear safety, radiological protection, health physics, and safeguards

The Act stipulates that nuclear safety considerations, including radiological protection of workers and physical security of the plant, be taken into consideration for all stages of a nuclear installation, up to and including dismantling. The purpose of the safeguards provisions of the Act is to organise and maintain a national system for the regulation and control of all nuclear materials in order to prevent their unauthorised diversion.

The Ministry of Energy, Mines and Industry is the licensing authority for the siting, design, construction and operation of nuclear installations. Licences for the construction and operation of a nuclear installation will only be granted when the applicant has demonstrated how he will comply with the safety requirements. He is also obliged to submit a radiological emergency plan at the same time. A licence is also required from the Ministry for the acquisition, import, export, possession, use, transfer, transport or storage of radioactive material and processes utilising ionizing radiations.

National Nuclear Research Institute

The Act maintains the National Nuclear Research Institute which, as mentioned above, was set up under the 1978 Act as a decentralised public organisation with the status of a juridical person and the right to own property. Its purpose, as in the 1978 Act, remains the implementation of research and development in the field of nuclear science and technology, the promotion of the peaceful uses of nuclear energy and the dissemination of the progress made in applying them to the country's economic, social, scientific and technological development.

Its most important functions include are to

- carry out and promote activities conducive to scientific and technological development in the field of nuclear energy, and to foster the transfer of technical knowledge in this area;
- provide technical assistance to public and private bodies which may require it, in the design, construction and operation of nuclear plants and, as appropriate, in contracting for such services;
- promote national technological development within the nuclear industry, encouraging innovation, the transfer and adaptation of technologies for the design, manufacture, and construction of components and equipment,

- implement research and development activities relating to the application and use of nuclear systems and radioactive materials for non-energy purposes necessary to national development and to promote the uses of radiation and radioisotopes in various fields,
- encourage the specific nuclear research and development activities underway at research institutes and higher educational establishments of the country;
- encourage, together with national and international organisations, joint research activities and the exchange of information upon authorisation of the Ministry of Energy, Mines and Industry,
- maintain a documentation centre, the aim of which shall be to acquire, analyse and disseminate information and developments in the nuclear field.

In addition to the Governing Council and the Directorate-General, the Institute will also be governed by a Supervisory Committee responsible for ensuring realisation of the programmes and proposals as well as efficient administration of the resources.

National Nuclear Safety and Safeguards Commission

In order to ensure the application of standards for nuclear safety, health physics and safeguards, the Act maintains the National Nuclear Safety and Safeguards Commission, set up in 1978, expanding its responsibilities as follows:

- in addition to overseeing and advising the Ministry on all phases of nuclear installation operations, including shut-down and dismantling, the Commission is responsible for all activities relating to the manufacture, use, storage, reprocessing, and transport of nuclear materials and fuels, radioactive materials as well as activities relating to radioactive waste management and disposal;
- the Commission is in charge of all permits and licences required by radioactive installations as well as the removal of any radioactive parts from these installations,
- prior to operation, the Commission examines emergency plans which should be established for nuclear and radioactive installations,
- it should also advise, prior to authorisation for the import or export of radioactive materials and nuclear materials and fuels, as regards safety, accounting and control; it should also propose

safety, accounting and control criteria for the regulation of the import and export of nuclear materials and fuels,

- the Commission shall propose standards and otherwise oversee all phases of the operation of installations for the extraction and treatment of radioactive materials; and
- it shall order and carry out inspections and verifications to determine if the provisions regarding nuclear safety, health physics
- and safeguards are complied with, as well as impose measures and administrative sanctions in accordance with the provisions of this Act.

The Federal Executive, acting through the Ministry, may also exercise the functions laid down in these provisions.

The Commission is administered by a Director General with the assistance of an Advisory Council. The Director General is appointed by the Minister of Energy, Mines and Property.

• *Norway*

NUCLEAR LEGISLATION

REGIME OF RADIOACTIVE MATERIALS

1984 Decree establishing Regulations for the Physical Protection of Nuclear Materials

A Royal Decree of 2nd May 1984, made in pursuance of the Act of 1972 concerning Nuclear Energy Activities (see Nuclear Law Bulletin No. 11), lays down Regulations for the Physical Protection of Nuclear Materials. The Regulations entered into force immediately.

The purpose of these Regulations on physical protection is to establish conditions which will minimize the possibilities of theft of nuclear materials and sabotage of nuclear plants, as well as facilitate recovery of stolen nuclear materials. To this effect, the Regulations lay down detailed provisions concerning the obligations of nuclear operators and specify the powers of the competent authorities regarding physical protection. A chart describing the functions of the relevant authorities in the theft of nuclear material and sabotage of nuclear facilities is appended to the Regulations.

Competent authorities

The Norwegian Nuclear Safety Authority (SAT), which is the supervisory authority in connection with the licensing of nuclear materials under the 1972 Act, is also competent for the physical protection of such materials, while the State Institute for Radiation Hygiene (SIS) is responsible for radiation protection aspects.

In addition, if theft or sabotage are reported, the Ministry of Petroleum and Energy which is the SAT's supervisory authority, acts as the co-ordinating body for the steps to be taken by the Ministry of Justice and Police and the Ministry of Foreign Affairs. The Ministry of Justice and Police is for its part responsible for initiating the operations to counteract such theft or sabotage, and the Ministry of Foreign Affairs is charged with providing information on the subject to other countries in accordance with Norway's obligations under the 1980 Convention on the Physical Protection of Nuclear Material.

Duties of operator

A person responsible for nuclear materials and facilities (the "operator" in accordance with 1972 Act on Nuclear Energy Activities) is required to establish and maintain a system for physical protection of the facilities, and of materials during storage, processing and transport. He must also prepare a safety report on physical protection for the approval of the Ministry of Petroleum and Energy, on the basis of a recommendation by SAT. The report must also take into account radiation protection aspects and criticality hazards and be kept up to date regarding new facilities, any changes or any acquisition of nuclear materials requiring stricter safety measures.

The operator must also appoint one or more persons to be responsible for the physical protection aspects of stored materials, as well as equipment and material being processed or shipped. In particular, for each individual shipment, he must appoint a transport co-ordinator responsible for preparing the shipment involved. Finally, he must check that the physical protection system is operative in accordance with guidelines on the subject established by SAT.

Emergency plan

The Regulations provide for the preparation of an emergency plan - also for transport operators, in consultation with the police. The plan must tally with the actual division of authority between the bodies involved and must include the protective and measuring equipment required which the operator can provide to the police. The plan, which should be based on the safety report prepared by the operator, must include training activities for emergencies.

In case of sabotage, theft or of threat thereof, the operator concerned must immediately inform the police, the Ministry of Petroleum and Energy, SAT and SIS which in turn will take the necessary action.

The Regulations lay down specific requirements for protecting nuclear materials in storage as well as for nuclear facilities and divide the materials into three categories (I, II, and III) according to their radioactivity and weight. The premises where they may be housed are divided into three areas: restricted, protected, and vital e.g., category I materials may only be used or stored in a vital area, and reactors with a power of 50MW(th) or more are classified as such an area, unless otherwise decided by SAT. Access to the three areas differs according to their classification and is limited to authorised persons for protected and vital areas. In addition, detailed instructions are given regarding the setting up of protection and alarm systems for each different area, apart from a general alarm system, connected with a continuously manned guard centre which has a direct connection to the police.

Transport operations

The Regulations also detail fundamental rules for physical protection of nuclear materials during transport by road and as appropriate, to other means of transport.

The physical protection of all shipments must be approved by SAT which must authorise them in advance. Such authorisation contains the conditions and requirements applying to each particular shipment. However, SAT may give a general permit only for shipment of categories II and III material, in which case no further notification is required for individual shipments.

An External Transport Control, established by the operator, maintains telephone/radio contact with the transport vehicle or the escorting vehicle and with the recipient of the material and will give instructions to the transport personnel, the police or the highway authorities if any irregularities occur during the transport operation.

The Regulations specifically provide that, to reduce any risks in connection with transport of nuclear materials, the operator must ensure that

shipments remain as short a time as possible in transit, that as few reloadings and temporary storage occur on the way and that shipments do not take place at regular, known times. Only authorised persons may proceed with shipments and the operator, together with the authorities concerned must be cautious in dealing with information which could jeopardise physical protection. Shipments of category I material must be treated as confidential in accordance with security instructions issued by Royal Decree of 17th March 1972.

Shipments of nuclear materials are subject to agreements being concluded prior to the shipment between the sender and the recipient on the one hand, and the sender and the transport firm on the other, also at least 24 hours' notice of the transport operation must be given to the recipient and the sender must keep the recipient informed of the estimated time of arrival. In case the shipment does not arrive at that time, the recipient must inform the External Transport Control accordingly. The transport route must be decided in advance, and an alternative route planned.

Special, more stringent, rules apply to the transport of category I materials as regards transport by road, rail, sea and air, e.g., road transport equipment must be designed and built to resist attack and the position of the vehicle on the road must be reported to the External Transport Control several times an hour, and shipments by rail must be placed in a goods train or a separate waggon in a passenger train and must have a police escort.

Finally, international shipments of nuclear materials must comply with the level of physical protection laid down by the Convention on the Physical Protection of Nuclear Material and be carried out on the basis of the IAEA Regulations on the Safe Transport of Radioactive Materials.

It is specified that these Regulations are additional to those already applying to the storage and transport of radioactive substances or dangerous goods.

• *South Africa*

NUCLEAR LEGISLATION

Nuclear Energy Act, 1982

The Nuclear Energy Act, 1982 (Act No. 92, published in the Government Gazette of 16th June 1982) provides the legal framework for nuclear activities in South Africa and repeals most previous legislation in the nuclear field (reported in Nuclear Law Bulletin Nos. 15, 17, 18, 20 and 22). It entered into force on the day it was published.

The purpose of the 1982 Act is to establish the Atomic Energy Corporation of South Africa, Limited and the Council for Nuclear Safety; it regulates the licensing of certain nuclear activities and their related security and liability. The Act also provides for the control of source material, special nuclear material, restricted material and radioactive nuclides as well as of patents relating to nuclear energy.

The Minister of Mineral and Energy Affairs is the competent authority for nuclear activities, which are controlled by the State.

Atomic Energy Corporation of South Africa, Ltd

The Corporation has legal personality, with a share capital owned by the State. All the assets and liabilities etc. of the Atomic Energy Board and the Uranium Enrichment Corporation, Ltd., and their personnel, have been transferred to the Corporation, which is run under the supervisory authority of the Minister of Mineral and Energy Affairs.

The purpose of the Corporation is to undertake research in the nuclear field, produce nuclear power, enrich, process and reprocess source material and special nuclear material, licence nuclear activities and exercise control over them. To this effect, and subject to the approval of the Minister of Mineral and Energy Affairs, in agreement with the Minister of Finance as the case may be, the Corporation has been vested with wide powers to carry through its work.

In particular, the Corporation may set up subsidiary companies and undertakings as well as finance them; conclude agreements with producers for the production and delivery of source material; prospect for and mine source material and restricted material, and enrich, process and reprocess such material as well as acquire, hold or dispose of it and import or export it. It is also authorised to produce nuclear power and may undertake and promote R and D activities in the nuclear field.

Finally, the Corporation may establish and control facilities for the collection of scientific and technical information within its scope and may apply for, buy or acquire patents, licences, etc. related to nuclear activities.

The Corporation is managed by a Board of Directors consisting of a Chairman appointed by the Minister of Mineral and Energy Affairs, two Directors-General (for Mineral and Energy Affairs and Foreign Affairs and Information respectively) and not more than six other Directors, also appointed by the Minister.

The Corporation is funded by share capital, by money appropriated by Parliament, and may receive money from any other source. It is authorised to raise money through loans.

Council for Nuclear Safety

The Council for Nuclear Safety's mission is essentially of an advisory nature. It advises the Minister for Mineral and Energy Affairs and the

Corporation, in particular regarding licensing questions. It also advises the Minister and the Corporation on any matter relating to safety and health in connection with nuclear installations or the production, use, storage, disposal or transport of nuclear material.

The Council consists of not more than fourteen independent members, appointed by the Minister, four of whom will be officers respectively in the Office of the Prime Minister, the Department of Health and Welfare, the Department of Transport and the Department of the Environment. Where necessary, the Council may set up committees to assist it with its work

The Council's activities are funded by Parliamentary appropriations

Licensing

No person except the Corporation or a subsidiary company may produce nuclear power, construct or operate a nuclear installation or use, produce, store, process, reprocess, transport or dispose of nuclear material without a licence granted by the Corporation. This also applies to nuclear installations for research purposes and to extraction of special nuclear material.

In addition, no nuclear vessel may enter the State's territorial water or call at any port without a licence granted by the Corporation.

Applications for licences (nuclear licences) for the above activities are made to the Corporation and are referred to the Council for Nuclear Safety for its recommendations. The Corporation acts on such recommendations and, in case of non-agreement between both bodies, the final decision rests with the Minister of Mineral and Energy Affairs.

Nuclear licences are only granted to a body corporate and are not transferable. They are subject to any conditions the Corporation may impose, in consultation with the Council, in the interest of health and safety. These conditions include, inter alia:

- maintenance of an efficient system to record radiation levels,
- proper design, siting, construction and modification of a nuclear installation;
- proper emergency planning;
- safe production, storage, processing and disposal of nuclear material and radioactive waste.

In addition, in case of a nuclear incident, licensees are required to report the occurrence immediately to the Corporation, which will take all the necessary steps in its respect.

Nuclear licences may be revoked at any time by the Corporation or surrendered by the licensees.

Inspectors, appointed by the Corporation, may at all reasonable times inspect any licenced premises or activities to check that the conditions of the relevant licence are being complied with.

Control of nuclear material and radioactive waste

It is forbidden to prospect for and mine source material without a prior permit from the Minister of Mineral and Energy Affairs, the Mining Rights Act, 1967 applies. The permit may be granted subject to the levying of fees by the State if the applicant owns the land or to the payment of a royalty to the landowner as the case may be.

The Minister may at any time withdraw a permit, in particular, if he considers that the security of the State is endangered or, if the permit holder does not comply with the conditions specified in the permit.

In addition, no person may possess, dispose of, enrich, reprocess or export source material, restricted material and special material without the written authority of the Minister. This also applies to radioactive nuclides, in particular as regards their import and export.

Finally, the Minister may, on behalf of the State, acquire any source material which has been mined or processed, and any special nuclear material.

Liability and compensation

Under the Act, holders of licences which relate to any nuclear installation or any site are absolutely liable for nuclear damage caused by anything present or any activity being carried out in the installation or on the site in question, or by any radioactive waste discharged, released or transported, or by any nuclear material in course of transport to or from the installation or site. This also applies to other holders of licences for nuclear material under their control.

Licensees are exempted from liability if the damage is attributable to any person present in the installation or on the site without their authorisation or to any person having deliberately caused the damage. Licensees also have a right of recourse against persons in cases where they have concluded contracts specifying such terms.

Licensees must supply security for their liability, the amount of which is determined by the Minister of Mineral and Energy Affairs, in concurrence with the Minister of Finance. If, in the event of a nuclear incident, the aggregate amount of any claims for compensation is likely to exceed the security provided, the licensee concerned must report accordingly to the Minister; he in turn submits a report to the House of Assembly if he is satisfied with the facts given, and recommends a Parliamentary appropriation to provide additional security. The final decision rests with the House of Assembly.

No action for compensation may be commenced thirty years after the date of the occurrence of the accident giving rise to the nuclear damage. However, if the claimant concerned knows, or ought reasonably to have known the

identity of the licensee in question the period is two years from the date of such occurrence.

The Act also makes provision for compensation of occupational injuries suffered by persons employed by the Corporation or subsidiary companies. The right to such payment and its amount is determined by the Workmen's Compensation Commissioner, in accordance with the Workmen's Compensation Act, 1941. The Corporation and subsidiary companies contribute regularly to the accident fund established by that Act.

In cases where employees suffer any other injury or disease during the course of their work which does not come within the scope of the Commissioner's determination, the Minister of Mineral and Energy Affairs, in consultation with the Minister of Finance and following the advice of an advisory committee, may authorise payment of compensation from the funds of the Corporation or the subsidiary company concerned.

Patents

The Act lays down a detailed procedure regarding the filing of applications for patents in the nuclear field. When filing an application for a patent, the applicants must provide the Corporation with a copy of the specifications of the invention and any other relevant information. The Corporation may withhold the granting of a patent and the decision cannot be appealed.

Only the Corporation can be granted patents relating to enrichment of source material or special nuclear material and it may also acquire rights to certain patents or licences by serving notice to the person concerned. The Corporation pays compensation when acquiring such rights and, when granting a patent it has acquired it charges a royalty fee.

Disclosure of information

Without the written consent of the Corporation, it is forbidden to disclose any information on ore reserves containing source material or any data regarding source material. In addition, the written permission of the Corporation is required to communicate or publish any information connected with negotiations to acquire a nuclear licence for an installation or any nuclear material.

The Corporation may make any arrangements it considers necessary for the proper protection, defence or security of property under its control

• *Spain*

RADIOACTIVE WASTE MANAGEMENT

1984 Decree concerning the nuclear fuel cycle

Royal Decree No. 1899 of 1st August 1984 (Official Gazette of 27th October 1984) amends Royal Decree No. 2967 of 7th December 1979 on the organisation of activities relating to the nuclear fuel cycle (see Nuclear Law Bulletin No. 25).

It should be recalled that the Nuclear Energy Act of 29th April 1964 lays down that nuclear and radioactive installations using radioactive substances must have appropriate equipment to ensure storage, handling and transport of radioactive waste resulting from the operation of such installations.

Under above-mentioned Decree No. 2967 of 1979 the "Empresa Nacional del Uranio SA" (National Uranium Enterprise-ENUSA) was responsible for spent fuel management while the Junta de Energia Nuclear (JEN) was responsible for the final storage of radioactive waste. However, these provisions do not cover waste resulting from activities outside the fuel cycle or the dismantling of nuclear and radioactive installations, nor do they provide a global solution to the different problems involved in organising the overall management of radioactive waste.

Therefore, this Decree authorises the National Enterprise for Radioactive Waste (ENRESA) (see Nuclear Law Bulletin No. 34) to perform the tasks prescribed in this field by the Nuclear Energy Act and the 1979 Decree.

Electricity-generating companies and, more generally, operators of nuclear and radioactive installations may henceforth and irrespective of their own storage methods, call upon duly authorised companies to undertake the handling, transport and final storage of their radioactive waste. The Decree expressly designates ENRESA to this effect.

The Ministry of Industry and Energy will set the economic and contractual conditions for such services. It is provided in particular that the duration of the contract will cover the lifetime of the installations, including their dismantling, the costs being calculated on that basis.

TRANSPORT OF RADIOACTIVE MATERIALS

1984 Regulations on the transport of dangerous goods by air

Royal Decree No. 1749 of 1st August 1984 (Official Gazettes of 2nd, 3rd, 9th, 10th, 11th, and 12th October 1984) approves the national Regulations on the safe transport of dangerous goods by air.

The Regulations as well as the attached detailed technical instructions are based on the 1981 revised text of the Annex concerning dangerous goods of the Chicago Convention on International Civil Aviation.

In Spain, the competent department for safe transport by air is the Ministry of Transport, Tourism and Communications, General Directorate for Civil Aviation. Radioactive substances are listed as Class 7 in the classification of dangerous goods under the Regulations. The technical conditions of the Regulations apply concurrently with the provisions of the 1964 Nuclear Energy Act.

• *Switzerland*

RADIOACTIVE WASTE MANAGEMENT

"GARANTIE" Project on radioactive waste management (1985)

Having acknowledged that great importance should be attached to the disposal of radioactive waste, Switzerland revised its nuclear legislation in 1978: new nuclear power plants will not be licensed unless the management and final storage of waste produced by the plant are guaranteed (see Nuclear Law Bulletin Nos. 23, 28, 29 and 31). In parallel, a new provision was added to licences to operate existing nuclear power plants: "The validity of this licence expires if no project has been established by 31st December 1985 to guarantee the safe management and final storage of radioactive waste from the power plant...".

Since then, the National Corporation for the Disposal of Radioactive Waste (CEDRA), commissioned by the Swiss nuclear power plant licensees, has been at work to demonstrate the feasibility of management. In January 1985, CEDRA submitted a "Garantie" Project which, according to the Corporation and its mandators, should provide the data for such a demonstration. The Project includes eight volumes and 150 reference reports. It describes the construction technique, the barrier system and the safety analysis applying to two types of final storage repositories: the first repository, for low and medium-level radioactive waste, uses data from a model referring to marly alpine formations; the second, which would contain highly-active waste,

corresponds to a model in crystalline rock in the north of Switzerland and is based in particular on deep borings made by CEDRA in recent years.

The Swiss safety authorities have begun an assessment of the Project which will probably last for one year. Once they have communicated their conclusions, the Federal Council (the Government) will take a decision on maintaining licences to operate nuclear power plants.

• *Tunisia*

ORGANISATION AND STRUCTURE

1982 Decree creating the National Centre for Radiation Protection

Decree N° 82-1389 of 27th October 1982 creating a National Centre for Radiation Protection was published in the Official Gazette of 2nd November 1982.

The Decree defines the Centre as an administrative, public institution, with civil personality and financial autonomy. It is placed under the responsibility of the Ministry of Public Health.

The Centre is charged with promoting national measures and methods against the dangers of ionizing radiation through the promulgation of regulations and through training and research activities.

In particular, the Centre is responsible for the codification of preventive measures and measures for treatment applicable to all establishments utilising ionizing radiation. It must also supervise the quality of radiation protection measures and inspect all establishments where ionizing radiations are used.

The Centre should participate in the training of medical and technical personnel to ensure that the establishments concerned are adequately staffed. The Centre should also take part in national public health campaigns and is responsible for centralizing all statistical data and documentation concerning ionizing radiation in order to promote research in this field.

The Centre is headed by a Medical Director, proposed by the Minister of Public Health, responsible for the overall functioning of the Centre and is assisted by the Head of the Administrative and Financial Service, nominated by Decree.

The budget for the Centre is part of the State budget and is therefore prepared, approved and regulated by the provisions applicable to the State budget.

In case of loss of civil personality, the property of the Centre will revert to the Ministry of Public Health.

• *United Kingdom*

RADIOACTIVE WASTE MANAGEMENT

The Control of Pollution (Radioactive Waste) Regulations 1984 and 1985

These Regulations (Statutory Instruments 1984 No.863 and 1985 No. 708) were made on 22nd June 1984 and 2nd May 1985 and came into operation on 26th July 1984 and 6th June 1985 respectively.

The regulations provide that radioactive waste is to be treated as any other waste for pollution control purposes as opposed to special radioactive control purposes. In the former respect, radioactive waste is subject to Part II of the Control of Pollution Act 1974, but in the latter, it remains subject to the Radioactive Substances Act 1960. S.I. 1985 No. 708 amends Schedule 2 of S.I. 1984 No. 863.

• *United States*

REGIME OF NUCLEAR INSTALLATIONS

Publication by NRC of policy statements regarding power plant personnel (1985)

The Commission plans to publish shortly three final policy statements designed to further improve safety in nuclear power plants. The statements concern requirements for plant personnel and are summarised below.

Final policy statement on engineering expertise on shift at nuclear power plants. It will present the Commission policy on ensuring that the operating staff at a nuclear power plant possess adequate engineering and

accident assessment expertise. The policy statement offers licensees two options in this respect.

Final policy statement on fitness for duty of nuclear power plant personnel. Pursuant to this policy statement, licensees and applicants will develop and implement fitness for duty programmes, in accordance with guidelines developed by the nuclear industry. These programmes will provide reasonable assurance that nuclear power plant personnel working in vital areas at operating nuclear power plants are not under the influence of alcohol or drugs and are not otherwise unfit for duty as a result of emotional stress problems.

Final policy statement on training and qualifications of nuclear power plant personnel, including operators, supervisors, technicians and other operating personnel. This policy statement provides regulatory guidance called for by the 1982 Nuclear Waste Policy Act. The Commission considers the following five elements as essential to acceptable training programmes: (1) systematic analysis of jobs to be performed; (2) learning objectives derived from this analysis which describe desired performance after training, (3) training design and implementation based on the learning objectives; (4) evaluation of trainee mastery of the objectives during training; and (5) evaluation and revision of the training based on the performance of trained personnel in the job setting.

REGIME OF RADIOACTIVE MATERIALS

Amendment of NRC import/export rules (1985)

The Nuclear Regulatory Commission has amended its regulations which govern the export and import of nuclear equipment and materials (see Nuclear Law Bulletin No. 33).

Adoption of the amendments will incorporate, for the first time in the Commission's regulations, a policy of facilitating nuclear co-operation with countries which share U.S. non-proliferation goals - one of the objectives of the Nuclear Non-Proliferation Act of 1978 (NNPA).

Among other things, the amendments will:

- 1) Exempt from case-by-case licensing reviews and permit the export under general licence of reactor components to specified countries. These countries share U.S. goals and are working with the U.S. to prevent the proliferation of nuclear weapons and, in addition, have provided written assurance that the exported components will meet certain U.S. legal requirements - application of International Atomic Energy Agency (IAEA) safeguards, no retransfer without U.S. approval and no nuclear explosives use.
- 2) Exempt from case-by-case licensing requirements and permit the export under general licence of specified minor quantities of nuclear material to a broad category of countries which (with the exception of the People's Republic of China and France, which are

nuclear weapons states, and Spain, which applies safeguards to all its nuclear facilities) have all signed the Treaty on the Non-Proliferation of Nuclear Weapons (NPT).

In adopting these and other less significant changes to its regulations, the Commission is also noting its concern about the nuclear intentions of certain countries which will receive more favourable treatment as a result of the new amendments. In particular, the Commission is concerned about the further spread of sensitive nuclear activities - isotope separation, chemical reprocessing, heavy water production and plutonium, fuel fabrication. Should any countries, which would be eligible for more favourable treatment, make significant moves that are inconsistent with U.S. law and policy (such as the design or acquisition of such facilities), the Commission will initiate immediate steps to revoke eligibility of such countries for favourable general licence treatment.

The amendments to the Commission's regulations (10 CFR, Part 110) became effective on 2nd January 1985.

RADIOACTIVE WASTE MANAGEMENT

Disposal of high-level radioactive waste under the 1982 Nuclear Waste Policy Act (1985)

The Nuclear Waste Policy Act of 1982 requires the Department of Energy (DOE) to site, construct, and operate by 31st January 1998, a mined geologic repository for the disposal of high-level radioactive waste and spent nuclear fuel (see Nuclear Law Bulletin Nos. 31 and 32). In addition, the Act requires the Department to consider monitored retrievable storage as an option for management of nuclear waste.

The initial steps in implementing the Act have been completed. In February 1983, the Secretary of Energy identified nine potentially acceptable sites for the first repository in the states of Louisiana, Mississippi, Nevada, Texas, Utah, and Washington, and provided notifications, as required by the Act, to relevant state governments and Indian tribes. The Secretary also issued general guidelines for the recommendation of sites for nuclear waste repositories, required by Section 112(a) of the Act on 6th December 1984. The guidelines were agreed to by the Nuclear Regulatory Commission (NRC) in July 1984 and address the entire DOE siting process, including (1) screening (2) site designation, (3) site recommendation for characterisation, (4) site characterisation, and (5) site selection (recommendation for development as a repository).

On 20th December 1984, draft environmental assessments (EA's) for each of the nine sites under consideration for the first repository were published for a 90-day public comment period. The draft EA's contain, inter alia, a proposed evaluation as to whether each site is suitable under the siting guidelines for further detailed study. Public hearings on the draft EA's are currently being held. The Act requires EA's to accompany the designation of at least five sites that the Secretary determines are suitable for further detailed study. Following designation the Secretary is to recommend three of

the designated sites to the President for the initiation of further detailed onsite study.

In the draft EA's, the Department proposed to designate sites in Texas, Nevada, Washington, Utah and Mississippi as suitable for further study and to recommend sites in Texas, Nevada, and Washington to the President for further study. Final EA's are expected to be issued, and site nominations and recommendations to be made in late summer 1985.

Disposal of low-level radioactive waste under the 1980 Low-Level Radioactive Waste Policy Act (1985)

The Low-Level Radioactive Waste Policy Act (see Nuclear Law Bulletin No. 27) sets forth as the policy of the Federal Government that each State is responsible for providing for the availability of capacity either within or outside the State for the disposal of low-level radioactive waste generated within its borders, except for wastes generated by certain activities of the Secretary of Energy or federal research and development activities. The Act which encourages formation of interstate compacts to provide for the establishment and operation of regional disposal facilities, requires congressional consent to such compacts, and authorises, after 1st January 1986, any such compact to restrict the use of regional disposal facilities under the compact to the disposal of low-level radioactive waste generated within the region. Several compacts have been formed but none have received congressional consent.

Thirty-nine States have enacted legislation relating to low-level radioactive waste disposal since enactment of the Low-Level Radioactive Waste Policy Act in December 1980. But no new disposal sites have been established. There are presently three commercially-operated open sites in Washington, Nevada, and South Carolina.

• *Yugoslavia*

NUCLEAR LEGISLATION

1984 Act on Radiation Protection and the Safe Use of Nuclear Energy

On 21st November 1984 the Federal Parliament of the Socialist Federative Republic of Yugoslavia approved a new Act on Radiation Protection and the Safe Use of Nuclear Energy. The new Federal Act was published in the Federal Official Gazette of the SFRY (Sluzbeni list SFRJ) No. 62/84 and entered into force on 1st December 1984. It repeals the 1976 Act on Protection against Ionizing Radiation (see Nuclear Law Bulletin No. 23).

During the period of validity and application of the former 1976 Act the first facilities dealing with the commercial use of nuclear energy in

Yugoslavia were built and started operating (namely, the Krsko nuclear power plant, the uranium mine Zirovski Vrh, both in the Socialist Republic of Slovenia). During this period, Yugoslavia also accepted or ratified a number of international agreements on the peaceful use of nuclear energy. These developments, together with the experience gained, required a reorganisation of the basic national nuclear legislation.

Following preparation of two separate bills, dealing with radiation protection and the peaceful use of nuclear energy, it was decided in 1983 to merge both texts into one common Act.

The 1984 Act covers the major portion of nuclear activities. The remaining areas, third party liability, food irradiation, patents, transport of radioactive materials, are governed by special legislation. As already mentioned, the new Act is a federal law and therefore provides a basic framework for the legislation of the six Yugoslav Republics (Bosnia and Herzegovina, Croatia, Macedonia, Montenegro, Serbia, Slovenia) and the two Autonomous Provinces (Kosovo, Voivodina) which will have to be amended on account of the new federal law.

The new provisions in the 1984 Act include a change in the procedure for the licensing of nuclear facilities. The modifications concern an addition to the existing licensing authorities. The procedure itself is still subject to the General Administrative Procedure Act (Federal Official Gazette No. 32/78) and the main licensing authorities remain the bodies of those Republics or Autonomous Provinces where a facility is located. The 1984 Act sets up a Federal Commission for the Safety of Nuclear Facilities. This Commission, made up of experts appointed by the Federal Committee of Energy and Industry, makes a prior assessment of each planned facility to ascertain whether certain conditions prescribed for licensing have been met. This assessment, confirming satisfaction of the conditions prescribed, is a precondition for a licence being granted by the competent bodies in the Republic or Autonomous Province. In this way the Act ensures a co-ordinated and uniform assessment of the basic questions related to the safety of nuclear facilities for the entire country, although the remainder of the licensing procedure is continued in the Republic or Province concerned.

Safety-related questions are also dealt with in connection with the use of standards, technical criteria and quality norms when designing, constructing, using or maintaining a nuclear facility. The 1984 Act prescribes that, under certain conditions, foreign technical regulations and standards are also applicable in Yugoslavia. These provisions reproduce to a great extent the corresponding provisions accepted on the subject in the Standardization Act (Federal Official Gazette of the SFRY Nos. 38/77, 11/80, 38/80).

From an international point of view, the 1984 Act takes into account several areas regulated at international level. In connection with new experience in international relations concerning transfrontier pollution, the obligation to inform neighbouring countries is foreseen if a risk of radioactive contamination is identified. A special section covers accounting and control of nuclear materials. These provisions result in part from international agreements ratified by Yugoslavia, in particular the Agreement between Yugoslavia and the IAEA for the application of safeguards in connection with the Treaty on the Non-Proliferation of Nuclear Weapons

(published in the Federal Official Gazette of the SFRY No. 67/73). The provisions on physical protection of nuclear facilities etc., have been established in accordance with the Convention on the Physical Protection of Nuclear Material, which was signed by Yugoslavia and is now in the process of being ratified.

Finally, the 1984 Act will be fully implemented when several additional regulations are made under the Act, which provides that the Federal Committee of Labour, Health and Social Welfare and the Federal Committee of Energy and Industry must make detailed regulations on fourteen topics. Their preparation and enactment, also proceeding from international experience and recommendations (e.g. the IAEA NUSS programme, the Basic Safety Standards for Radiation Protection etc.) will represent another important step in revising Yugoslav legislation in the field of radiation protection and the peaceful use of nuclear energy.

An unofficial translation of the full text of the 1984 Act will be reproduced in a forthcoming issue of the Nuclear Law Bulletin.

FOOD IRRADIATION

1984 Regulation on the conditions for marketing foods and articles of general use treated by irradiation

This Regulation was issued by the Federal Committee of Labour, Health and Social Welfare and is published in the Federal Official Gazette No. 68/84. It is based on the 1978 Act on the hygienically acceptable condition of foods and articles of general use (Federal Official Gazette No. 55/78), and also follows international recommendations in the field of food irradiation such as for example the International General Standards for Irradiated Foods.

The 1984 Regulation enumerates several food items (e.g. corn, onions, spices, fresh chicken, meat etc.) and two groups of articles of general use (packaging of food, cosmetics), that may be treated by irradiation for purposes of preservation. The general condition for such processing is that the nutritional value and the physical, chemical and organoleptic properties of the treated product remain unchanged. The Regulation permits the use of gamma rays (its most common sources cobalt-60 and cesium-137), X-rays (5 MeV maximum energy) and electrons (10 MeV maximum energy). The collective average absorbed dose for foods must not exceed 10 kilogray and for articles of general use 50 kilogray. Finally, the new Regulation lays down a number of labelling conditions for packaged irradiated products, in particular regarding the date of their irradiation and the name of the company concerned.

CASE LAW

• *Japan*

HIGH COURT DISMISSES SUIT AGAINST INSTALLATION OF IKATA NUCLEAR POWER STATION*

After some five years of hearings on the intermediate appeal on the legality of the permission for installation of the Ikata nuclear power station Unit-1, Ikatacho, Ehime Prefecture (Shikoku Electric Power Co.) issued under Section 23 of the Law for the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors, on 14th December 1984, the Takamatsu High Court decided against the plaintiffs and dismissed the case on the grounds that the government's permission for the installation of the nuclear reactor was legal, upholding the decision of the Matsuyama District Court, although the plaintiffs' competence in bringing the lawsuit was acknowledged (see Nuclear Law Bulletin No. 22).

The case was originally brought to the Matsuyama District Court on 27th August 1973 by a group of plaintiffs, people living around the proposed site of the nuclear power station. The defendant was the Prime Minister of Japan, who was asked to withdraw permission to install the nuclear reactor. It was the first administrative litigation on a nuclear power station in Japan.

After some four years of hearings (thirty-six sessions of oral proceedings, ten plaintiff witnesses, nine defense witnesses, and two on-site verifications), on 25th April 1975, the court dismissed the case against the plaintiffs. The plaintiffs then appealed to the Takamatsu High Court on 30th April. The hearings ended on 4th March 1983 (twenty-two sessions of oral proceedings, three plaintiff witnesses and one defence witness). The role of defendant was changed to the Minister of International Trade and Industry in January 1979, as a result of the modification of the administrative system on nuclear energy.

Major issues in the hearing were principally the same as on the original occasion. 1) Are plaintiffs qualified to institute the lawsuit? (plaintiff's competence), 2) Is permission for the installation of the nuclear reactor a discretionary disposition? (nature of the administrative disposition), 3) Is there any defect in the procedure for permission to install the nuclear reactor? (procedural legality), and 4) Was the safety

* This note is reproduced from "Atoms in Japan", December 1984, by kind permission of the Editor.

review on the nuclear reactor facilities done legally? (substantial legality). Another issue was added in this hearing: Is the rationale for the safety review materially affected by the accident at the Three Mile Island nuclear power station in March 1979 (assessment of TMI accident).

Court agreed plaintiffs' competence

In the judgment, the Court agreed that the plaintiffs were within their rights in suing for nullification of the administrative disposition in question. The Court reasoned that the plaintiffs were entitled to legal protection in so far as their interests were threatened by an administrative disposition, regardless of whether the administrative body had direct legal control over them.

As to the legality of the government's procedure in granting permission, the Court ruled that no fault or negligence was evident in the safety review, because "the procedure for granting permission is deemed to comply with the applicable provisions of the Law for the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors, as well as the Enforcement Ordinance for the Law."

The court was not in a position to judge scientific issues

As to the legality of the permission itself, the Court ruled that "permission for installation of a nuclear reactor is granted by the administrative authorities only after careful evaluation with regard to safety through scientific, professional and technical evaluations, as well as due consideration of atomic energy policy."

However, the Court also ruled that it was not in a position to make a final judgment on such scientific and technical issues. Henceforth, judicial judgments on administrative decisions regarding the safety of a nuclear reactor will be limited, in contrast with ordinary administrative litigation. The Court also stated that "permission for installation of a nuclear reactor is at the discretion of the administrative authorities." Thus, the Court defined the scope of judicial judgment as "limited to whether the administrative evaluation was substantially irrational when it decided on necessary safety measures for safety of a nuclear reactor."

As to the legality of the safety review, the Court decided that "the safety review was carried out in accordance with specified standards for review and evaluation, in terms of measures to reduce exposure during normal operation, and accident prevention and control measures, and thus was not at fault or negligent in defining the nuclear reactor's safety requirements. Therefore, it was not irrational for the defendant to agree with the result of the safety review, which determined that the said nuclear reactor facilities had adequate accident prevention measures.

Finally, in response to the plaintiffs' allegation that the radiological leak accident which occurred at the Three Mile Island nuclear power station in the U.S.A., revealed the irrationality of the safety review of the nuclear reactor, the Court overruled any association between the two nuclear reactors, stating that "that accident was primarily caused by improper operation, and

does not in any way affect the effectiveness of the safety review in question, under which the safety of the basic design of the nuclear reactor was evaluated."

In conclusion, the Court ruled that "although the plaintiffs were within their rights in instituting the lawsuit, the permission granted was legal in all respects. Therefore, the original decision which dismissed the plaintiffs' request to nullify the permission should be sustained, and the appeal must be dismissed due to the absence of judicial grounds."

Five nuclear administrative litigations have been instituted

To date, five administrative litigations on nuclear power stations have been instituted, including the Ikata case. A case on Ikata nuclear power station Unit-2 (Shikoku Electric Power Co.) is being heard at the Matsuyama District court, and a case on Kashiwazaki-Kariwa nuclear power station Unit-1 (Tokyo Electric Power Co.) is being heard at the Niigata District Court. A case on Fukushima II nuclear power station Unit-1 (TEPCO), brought to the Fukushima District Court, was dismissed against the plaintiffs on 23rd July 1984 (see Nuclear Law Bulletin No. 34). On 6th August, the case was appealed to the Sendai High Court, and the hearing is soon to be held. Finally, a case on Tokai nuclear power station Unit-2 (Japan Atomic Power Co.) ended on 25th September 1984 at the Mito District Court after some eleven years of hearings with the decision now pending

In addition to the above five cases, a case on Sendai-1 (Kyushu Electric Power Co.) was brought to the Kagoshima District Court in April 1980, and dropped in October 1981.

TABLE

MAJOR ISSUES IN TRIAL ON IKATA NUCLEAR POWER STATION UNIT 1

<u>Plaintiffs' assertion</u>	<u>Defendant's (government) assertion</u>
<u>Legal Issues:</u>	
<u>Plaintiff's competence</u>	
The plaintiffs have competence to institute a lawsuit on the case, since a primary objective of "The Law for the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors" is to preserve public safety by assuring the life and health of every individual in Japan, including the plaintiffs, as constitutional rights, and the plaintiffs will be directly affected by accidents which may occur at the time of construction and operation of the nuclear power station, which are a consequence of permission issued through illegal procedures.	The plaintiffs have no competence to institute the lawsuit since. the said Law is not intended to protect individual interests, and the plaintiffs' interests are not or will not be disturbed by the permission

Plaintiffs' assertion

Defendant's (government) assertion

Nature of permission

Permission for installation of a nuclear reactor is not a discretionary disposition since it will directly affect plaintiffs' fundamental human rights on life and health.

The permission is a discretionary disposition since it requires evaluation and judgment on public policy and specialised technology.

Procedural legality of permission

The permission procedure set forth in "The Law for the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors" violates the Atomic Energy Basic Law, which establishes three principles of democracy, independence and opening to the public on nuclear energy, and Article 31 of the Constitution, which warrants legal procedures, since it lacks public participation and information disclosure.

Evaluation criteria (guidelines) violate The Law for the Regulation of Nuclear Source Material, Nuclear Fuel Material Reactors, since they are not based on the Law and are insufficient to meet requirements.

The Law cannot be considered as violating the Constitution only on the ground that public participation and other procedures are not provided for, and three principles on nuclear energy are not a normative law to directly control administrative procedures. There are no substantiated grounds that require the evaluation criteria to be based on the Law, and contents of the evaluation criteria do not violate the said law.

Subjects of evaluation before permission

Effect of thermal effluent, final disposal of solid radioactive waste reprocessing and transportation of nuclear fuel, which should be subject to evaluation before permission, has not been carried out.

In accordance with the organisation of the Law for the Regulations of Nuclear Source Material, Nuclear Fuel Material and Reactors, among phenomena peculiar to nuclear reactor facilities, only the safety of its fundamental design and design policies are subject to evaluation. Effect of thermal effluent, final disposal of solid radioactive waste, and reprocessing and transportation of nuclear fuel are not for evaluation.

Technical Issues:

Safety in normal operation (effects of radiation)

Exposure to radiation, no matter how low the amount, will cause a certain degree of radiation hazards, and thus the permissible dose specified in the law does not constitute a safety standard.

Assessment of dose by radioactive materials during normal operation is irrational in assumptions and calculation methods, and as a result the dose is underestimated.

Although accurate data have not been obtained for the relationship between exposure at low dose and radiation hazards, "permissible dose" was established in accordance with values recommended by ICRP (International Commission on Radiological Protection) under the strict assumption that the minimum dose may cause radiation hazard, to be sufficiently acceptable to the public.

Preconditions for assessment of dose are established on the safe side (strict assessment), and thus the assessment is on a fully rational basis.

Accident prevention measures

The nuclear fuel, pressure vessel and steam generator have been found defective, and ECCS (Energy Core Cooling System) to be activated in accidents has not proved its effectiveness, and there is a risk of serious accidents.

Nuclear fuel, pressure vessel and steam generator are designed to have sufficient safety in normal operation as well as in accident or trouble. Effectiveness of ECCS is verified by analysis and experiments.

Disaster assessment (isolation from public)

Accidents for disaster assessment are arbitrarily set and underestimated. Disaster assessment should be done by assuming most serious accidents (core melt) which can be considered theoretically.

Disaster assessment on safety review is to judge the suitability of nuclear reactor's location in relation to isolation between nuclear reactor and public in accordance with a location evaluation guideline, and the plaintiffs' assertion ignores roles of disaster assessment in safety review and is considered unjust

Location

The nuclear reactor is located on very soft ground, and it is considered highly probable that the Medial Line, the largest active fault in Japan, exists a few hundred meters off the coast in front of the site. The site is located in an earthquake zone, with a high probability of a major earthquake in the future. However, seismic force is underestimated in the aseismic design for the nuclear reactor, and the risk of earthquakes related to the Medial Line was not evaluated during the permission procedure.

The ground beneath the site is proven to have sufficiently bearing capacity to support the nuclear reactor, and the Medial Line is far enough from the site, 5 - 8 km off the coast at least. The plaintiff's assertion that the site is located in an earthquake zone or will be subject to a major earthquake in the near future cannot be substantiated, and sufficient aseismic design was made for the nuclear reactor. Furthermore, there is no concrete evidence to prove association between activities in the Medial Line and earthquakes. Even if earthquakes occur in relation to the Medial Line off the coast of the site, its intensity is considered in the aseismic design.

Issues Related to TMI Accident:

Causes of the accident

The accident itself originated from a cause which is not considered in conventional design of nuclear reactors, which was further aggravated by defective alarm/indication and operation manuals. Thus, false judgment and operation by operators are not major causes of the accident.

False judgment and resultant false operation by operators were determining factors in expanding and developing a minor trouble, loss of main water supply, to damage the reactor core. This stems from insufficient education and training, and many other inadequate operation and maintenance practices.

Rationale for safety review on the nuclear reactor

The TMI accident was caused by defective fundamental design, to clearly demonstrate impropriety in the safety review of the nuclear reactor in this case. This is also substantiated by phenomena in excess of conventional safety standards which actually occurred during the TMI accident.

The TMI accident was primarily caused by wrong operation and maintenance practices, and will not in any way affect the rationale for safety review through fundamental design and design policy on nuclear reactor facilities.

• *United States*

TERMINATION OF CLINCH RIVER BREEDER REACTOR PROJECT (1985)

Nuclear Law Bulletin No. 31 (June 1983) reported on proceedings concerning site preparation activities for the Clinch River Breeder Reactor Project. The action by the Nuclear Regulatory Commission authorising site preparation was followed by court actions seeking to prevent such activities, in particular, the Natural Resources Defense Council (NRDC) had challenged this programme on the basis of alleged deficiencies in the Department of Energy's environmental impact statement.

This case is now closed since by Order dated 11th March 1985, the Atomic Safety and Licensing Board of the NRC granted applicants' motion to dismiss the licensing proceeding. Applicants will redress the site to make it suitable for industrial use.

INTERNATIONAL ORGANISATIONS AND AGREEMENTS

INTERNATIONAL ORGANISATIONS

• *The OECD Nuclear Energy Agency*

STATUS OF RATIFICATIONS OF THE 1982 PROTOCOLS TO AMEND THE PARIS CONVENTION AND THE BRUSSELS SUPPLEMENTARY CONVENTION (1985)

At its session of 29th April 1985, the OECD Steering Committee for Nuclear Energy reviewed the present status of ratifications of the 1982 Protocols to amend the Paris Convention and the Brussels Supplementary Convention respectively. Members of the Committee noted that since the adoption of these Protocols on 16th November 1982, only Sweden (Paris and Brussels) and Portugal (Paris only) have ratified the Protocols (see Nuclear Law Bulletin Nos. 31 and 33). In addition, Turkey has passed an Act authorising ratification of the Protocol to amend the Paris Convention (see Nuclear Law Bulletin No. 34). Recently, the Federal Republic of Germany and Italy have likewise taken similar steps for both Protocols (see under Multilateral Agreements in this issue of the Bulletin). Despite these encouraging developments, the Committee noted however, that most other countries have made no significant progress to date in this direction.

This situation causes concern since the entry into force of the amendments to the Brussels Supplementary Convention is subject to their being ratified by all the Contracting Parties. Given the de facto interdependence between Contracting Parties, the entire process leading to the implementation of the Brussels Protocol could be blocked indefinitely by a single country not ratifying that Protocol. Although not quite identical, the situation regarding the Paris Convention, which requires ratification by two-thirds of the Contracting Parties, would also be delicate if several of the countries concerned did not ratify the Paris Protocol.

In view of the importance they attach to a speedy implementation of the modifications to the nuclear third party liability regime - in particular to

the increase of the amounts for indemnifying the possible victims of a nuclear incident - the members of the NEA Group of Governmental Experts on Third Party Liability in the Field of Nuclear Energy drew the attention of the Steering Committee to the need to prevent the 1982 revision from being jeopardised. In this respect, the Steering Committee urged national authorities which had not yet done so to speed up the ratification process of the 1982 Protocols

STEERING COMMITTEE RECOMMENDATION FOLLOWING A COLLECTIVE EXPERT OPINION ON RADIOACTIVE WASTE MANAGEMENT (1985)

In a report published in January 1985, the NEA Radioactive Waste Management Committee (RWMC) presented a technical appraisal of the current situation and its collective view on the main issues, particularly from the point of view of radioactive waste disposal and associated long-term aspects

The summary and conclusions of the report read as follows

"Industrial activities are regarded as safe even though a small risk always exists. The philosophy of radiation protection accepts this and recognises that some level of risk will also be associated with safe radioactive waste management. Therefore the objective of radioactive waste management is to look for a strategy which, taken as a whole, is considered safe and provides an acceptable balance of all the radiological, technical, social, political and economic considerations. The RWMC's appraisal underlines the need for such a balance while concentrating on radiological and technical factors particularly on the long term safety aspects of radioactive waste management.

The fundamental conclusion is that detailed short and long-term safety assessments can now be made which give confidence that radiation protection objectives can be met with currently available technology for most waste types, and at a cost which is only a small fraction of the overall cost of nuclear-generated power. The other main conclusions on both the short and long-term aspects of radioactive waste management are as follows:

On the short term aspects, which cover the operational life of waste management facilities and any period of institutional control

- radiological protection objectives can be consistently met during the operation of a facility and for as long afterwards as controls are maintained for all currently used or envisaged radioactive waste management concepts;
- storage can be relied upon for all waste types as an interim measure, as long as appropriate surveillance and monitoring are provided;
- while high priority is currently given to the full development and early demonstration of disposal concepts, there is no urgency to dispose of the small volumes of high-level radioactive waste and spent fuel currently accumulated, as they can continue to be stored safely until disposal is judged appropriate.

On the long term aspects, which cover the post-institutional control period:

- specific long term radiation protection objectives for radioactive waste disposal have been developed to provide a basis for judging the radiological acceptability of disposal practices or developing specific criteria for individual waste types;
- predictive risk assessment methodologies have been developed for the assessment of the long-term safety of disposal systems;
- there is a high degree of confidence in the ability to design and operate disposal systems in deep geological structures which will assure long term isolation for high-level waste or spent fuel and meet the relevant long-term safety objectives,
- while the short term aspects of uranium mine and mill tailings can be safely managed, there remains some concern in the long term about human intrusion into tailings or their possible misuse, and long term requirements need to be established.

An overall impression of optimism and confidence prevails from the RWMC's appraisal. It results from the substantial body of scientific and technical evidence from past and ongoing studies and R-D activities as well as from the experience already available. At the same time, it is recognised that:

- R-D will have to continue, notably to fill remaining gaps for particular options, to collect site-specific data and to refine safety studies;
- periodic reassessments of waste management practices and policies will have to be made to take account of evolving knowledge; and
- quality control at all stages is an essential nuclear safety requirement and it will have to be applied throughout the whole sequence of waste management activities.

In this situation, the Radioactive Waste Management Committee considers that a step by step approach to the application of waste management technologies as they become viable on an industrial scale, is both justifiable and safe."

At its session of 29th April 1985, the OECD Steering Committee for Nuclear Energy agreed on the value and timeliness of this report and adopted the following recommendation

- 1) The Steering Committee for Nuclear Energy recalls that the safe and economically viable management of radioactive waste resulting from the production of nuclear energy is an essential requirement for the development of nuclear energy programmes. The Committee is therefore of the opinion that the clear consensus by experts from Member countries regarding the safety and feasibility of technologies for the management of radioactive waste should be of considerable interest to national decision-makers;

- 2) The Steering Committee warmly welcomes the technical appraisal developed collectively by the NEA Radioactive Waste Management Committee, as a successful attempt to take stock of the growing scientific understanding and technical progress at national and international levels in the field of radioactive waste management,
- 3) The Steering Committee notes in particular that short and long term safety assessments confirm that radiation protection objectives can be met with currently available technology when managing most types of waste, and at a cost which is only a small fraction of the overall cost of nuclear-generated power;
- 4) The Committee appreciates the high degree of confidence among experts in the ability to design and operate disposal systems in deep geological structures, which will assure long term isolation for high level waste or spent fuel and meet the relevant long term safety objectives;
- 5) While high priority is currently being given to the full development and early demonstration of disposal concepts in some Member countries, the Committee notes that there is no technical urgency to dispose of the relatively small volumes of high level radioactive waste and spent fuel currently accumulated, as they can continue to be stored safely and at reasonable cost until disposal is judged appropriate;
- 6) At the same time, the Steering Committee strongly emphasizes the experts' view that R&D studies need to be continued in order to supply additional data to refine safety assessments, adapt engineering designs and, in general, optimize already developed disposal solutions. Such confirmatory data, along with economic analyses, regulatory actions and government policy statements, should help to establish the necessary level of public confidence in waste management approaches; also further international co-operation can be useful in this respect;
- 7) Finally, the Steering Committee supports the conclusion of the Radioactive Waste Management Committee that a step-by-step approach to the implementation of radioactive waste management techniques, as they become viable on an industrial scale, is both justifiable and safe,
- 8) In conclusion, the Steering Committee RECOMMENDS that relevant national authorities take fully into account the conclusions of the Radioactive Waste Management Committee in the continuing development of their national nuclear energy policies; in so doing, they should take full advantage of the confidence evidenced by the NEA radioactive waste management experts.

GUIDE FOR CONTROLLING CONSUMER PRODUCTS CONTAINING RADIOACTIVE SUBSTANCES
(1985)

The first edition of the Guide on the radiation protection aspects of the use of consumer products containing radioactive materials was published by NEA in 1970. In 1979, it became clear that there was a need for revising the Guide, in particular, in the light of the publication by the International Commission on Radiological Protection (ICRP) of a major revision of radiological protection principles in 1977. Although the revision essentially endorsed the previous recommendations, it contains some substantial refinements. Also, several new products appeared on the market since publication of the first Guide and a new factor had emerged: a change in the awareness and perception of the public towards radiation, which in turn reflects upon public acceptance of consumer products containing radionuclides.

The Guide is concerned mainly with the exposure arising from consumer products of those persons who are not subject to any regulatory controls for purposes of radiation protection in normal circumstances. Its purpose is to provide national authorities with a set of recommendations defining the policy and basic radiation protection principles to be followed when controlling such consumer products.

The preparatory work for the revision was undertaken with the help of the United Kingdom Radiological Protection Board in co-operation with experts from a number of NEA Member countries. Subsequently, the revised Guide was prepared by a Working Group composed of representatives of Member countries, the Commission of the European Communities, the International Atomic Energy Agency and the World Health Organisation.

The Guide was approved by the OECD Steering Committee for Nuclear Energy at its session of 29th April 1985.

INAUGURAL MEETING OF THE EUROPEAN NUCLEAR ENERGY TRIBUNAL

The European Nuclear Energy Tribunal, whose judges had been appointed by OECD Council Resolution of 7th June 1984 (see Nuclear Law Bulletin No. 33), held its inaugural meeting in Paris on 7th June 1985.

The Tribunal elected as its President Mr. Paul Reuter (France). Mr. Reuter is now Professor Emeritus at the Faculty of Law in Paris where he teaches international law. Since 1948, he has been Legal Adviser to the Ministry of Foreign Affairs. Mr. Reuter has represented the French Government before the International Court of Justice and is a member of the International Law Commission, the International Narcotics Control Board and the Permanent Court of Arbitration at The Hague. He is also a member of the International Law Institute. In addition, the Tribunal appointed a Registrar and adopted its Rules of Procedure but agreed to undertake a review of these Rules with a view to any necessary modifications or clarifications.

• *International Atomic Energy Agency*

COMMUNICATIONS RECEIVED FROM CERTAIN MEMBER STATES REGARDING GUIDELINES FOR THE EXPORT OF NUCLEAR MATERIAL, EQUIPMENT OR TECHNOLOGY

Guidelines for nuclear transfers were issued by the IAEA in 1978 as document INFCIRC/254 (see Nuclear Law Bulletin No. 21) and contain fundamental principles for safeguards and export controls applicable to nuclear transfers to any non-nuclear weapons State for peaceful purposes. In this connection, suppliers have defined an export trigger list and agreed on common criteria for technology transfers.

The IAEA received communications in this respect from several Member States notifying their compliance with the above-mentioned Guidelines and principles. The States are: Denmark (13th August 1984), Greece (19th September 1984), Luxembourg (13th November 1984), Ireland (14th November 1984) and the People's Republic of Bulgaria (14th December 1984).

In addition, on 27th March 1985 the IAEA received a communication from the resident Representative of Italy on behalf of the European Community transmitting the text of a common policy declaration concerning the Guidelines adopted by the ten Member States of the Community on 20th November 1984

The text of this declaration is reproduced in the "Texts" Chapter of this issue of the Bulletin.

REGIONAL SEMINAR ON NUCLEAR LAW AND SAFETY REGULATIONS

At the invitation of and in co-operation with the Egyptian Atomic Energy Authority, the IAEA organised in Cairo, from 6th to 11th May 1985, a Regional Seminar on Nuclear Law and Safety Regulations for Developing Countries in Africa. The purpose of the Seminar was to provide an opportunity for national regulatory authorities, various ministries, public institutions and specialised organisations involved in peaceful nuclear applications to get an overview of the philosophy and scope of nuclear legislation and regulation, and of practices, experience and current developments in this area in different countries, including relevant standards and recommendations of worldwide applicability.

The Egyptian Minister of Electricity and Energy presided over the opening of the Seminar which was attended by more than forty participants from Egypt and ten other countries within and outside Africa: France, Federal Republic of Germany, Ghana, Kenya, Morocco, Spain, Sudan, Tanzania, United Kingdom and United States of America.

The programme of the Seminar included lectures presented by invited speakers and IAEA staff members on the purview of nuclear legislation and on regulatory and implementing aspects of radiation protection, nuclear safety, nuclear installations licensing, transport and physical protection of nuclear materials, nuclear materials accounting and safeguards, nuclear export control, nuclear liability and insurance. Discussions centered on optimum use of available standards, guidelines and recommendations of international significance for the framing of legislation and regulations for peaceful nuclear applications, and emphasis was laid on the related need for manpower training and development for regulatory and safety purposes.

The holding of the Seminar was of special interest to Egypt in connection with the implementation of its nuclear power programme to meet the country's increasing energy demand by the turn of the century.

• *Euratom*

1985 COUNCIL DECISIONS CONCERNING RESEARCH PROGRAMMES IN THE NUCLEAR FIELD

On 12th March 1985, the Council of the European Communities adopted a series of research programmes (published in the Official Journal of the European Communities No. L83 of 25th March 1985). The following programmes concern Euratom and, in accordance with Article 7 of the Euratom Treaty the Commission is responsible for implementing the programmes, assisted by the appropriate Advisory Committee for each programme:

- 1) Research and development programme on the management and storage of radioactive waste. This programme covers the period 1985-1989 and the funds estimated as necessary amount to 62 million ECU. This programme is aimed at perfecting and demonstrating a system for managing the radioactive waste produced by the nuclear industry, ensuring at the various stages, the best possible protection of man and the environment.
- 2) Research and training programme in the field of radiation protection. This programme covers the period 1985-1989 and the funds estimated as necessary amount to 58 million ECU.

The objective of this programme is to improve the conditions of life with respect to safety of work and protection of man and his environment and to assure a safe production of energy from atomic fission and, later, fusion.

- 3) Research and training programme in the field of controlled thermonuclear fusion. This programme covers the period 1985-1989 and the funds estimated as necessary amount to 690 million ECU.

The programme will cover in particular:

- a) plasma physics;
- b) research into the confinement, in closed configurations, of plasma of widely varying density and temperature;
- c) research into light-matter interactions and transport phenomena and the development of high-power lasers;
- d) improvement of diagnostic methods;
- e) definition and predesign of NET (Next European Torus) and technological developments necessary to its design and construction and those needed in the longer term for the fusion reactor;
- f) extension of the JET device to full performance; operation and exploitation of JET.

• *INLA*

NUCLEAR INTER JURA '85

As reported in the previous issue of the Nuclear Law Bulletin (No. 35, December 1984), the International Nuclear Law Association (INLA) will be holding its Seventh Congress - Nuclear Inter Jura '85 from 29th September to 2nd October 1985 in Constance, Federal Republic of Germany.

The Congress is organised by the German section of INLA and information on the programme may be obtained from Dr. G. Stucken, c/o GRS, Schwertnergasse 1, D-5000 Köln, 1, Federal Republic of Germany.

AGREEMENTS

• *France - Australia*

1985 DECREE PUBLISHING AN AGREEMENT BETWEEN FRANCE AND AUSTRALIA CONCERNING NUCLEAR TRANSFERS FOR PEACEFUL PURPOSES

Decree N° 85-296 of 1st March 1985 which appeared in the French Official Gazette of 5th March 1985, published an Agreement entered into by France and Australia concerning the transfer of nuclear materials, equipment and technology for peaceful purposes. The Agreement was signed on 7th January 1981 and entered into effect on 12th September 1981.

The Agreement applies to nuclear material and non-nuclear material set out in the Annex to be used in reactors, and to equipment and technology transferred between the two Parties, whether directly or through a third party. The transfer of such material to a party, other than the recipient party, except in the case of France to European Community countries, cannot take place without the prior written authorisation of the supplier party.

The materials referred to in the Agreement remain subject to its provisions until they are no longer usable for any nuclear activity relevant from the point of view of the safeguards mentioned therein or until they have been transferred beyond the jurisdiction of the recipient party in accordance with the Agreement.

The Agreement prohibits the use or diversion of such materials for the production of nuclear arms or other nuclear explosive devices, or for research on or development of nuclear weapons or other nuclear explosive devices, or for use for any military purpose.

In the case where Australia is the recipient party, the respect of the above provision is assured by the Safeguards System of the International Atomic Energy Agency (IAEA) pursuant to 1974 Agreement between Australia and the IAEA for the application of IAEA safeguards in Australia. Where France is the recipient party, the safeguard system of Euratom and of the IAEA pursuant to an Agreement concluded among the three Parties in 1978, is applicable.

The Parties also agree to take adequate measures for the physical protection of such material.

Nuclear material subject to the Agreement shall be reprocessed in accordance with conditions agreed to in writing by the Parties and shall not be enriched to more than 20 per cent in uranium 235 as agreed to also in writing by the Parties.

In considering a request for the transfer of material beyond the jurisdiction of the recipient country or for the reprocessing or enrichment of such materials, the supplier party will take into account non-proliferation considerations and the energy requirements of the recipient party.

In the case of non-compliance by a recipient party with the provisions of the Agreement or in the case of non-compliance or repudiation of the applicable safeguards, the supplier party shall have the right to suspend or cancel further transfer of the materials and to demand corrective measures. If such measures are not taken within a reasonable time, the supplier party shall have the right to demand the return of such material.

• *F.R. of Germany-France*

CO-OPERATION IN THE FIELD OF SAFETY RESEARCH ON LIGHT WATER REACTORS (1985)

The Federal Ministry of Research and Technology of the Federal Republic of Germany and the Commissariat à l'Energie Atomique of France signed, on 28th September 1983, in Marcoule (France) an Additional Agreement to the Agreement of 28th September 1978, on exchange and co-operation in the field of light water reactor safety research (see Nuclear Law Bulletin No. 23). The Additional Agreement extended the period of validity of the original agreement by five years and amended the Annex containing the list of fields in which co-operation is envisaged. The Agreement entered into force on the day of its signature and is published in Bundesgesetzblatt 1984, II, p. 944.

• *Switzerland-Egypt*

AGREEMENT ON CO-OPERATION IN THE PEACEFUL USES OF NUCLEAR ENERGY (1984)

The Agreement between Switzerland and Egypt, signed on 13th November 1984 in Bern, covers the following fields:

- the Parties express their willingness to expand co-operation in the nuclear field between public and private undertakings in both States,
- the conditions of collaboration constitute the major part of the Agreement and are included in the international non-proliferation

system. They were negotiated in the framework of the Non-Proliferation Treaty and within the London Club*. They contain the commitment by both Parties to use the nuclear materials and articles transferred exclusively for peaceful purposes, to submit them to control by the International Atomic Energy Agency, to re-export them to a third country under those same conditions and finally, to guarantee the physical protection of such materials and articles.

In addition to these conditions, the Agreement contains provisions providing for their implementation as well as the usual clauses on the settlement of disputes, the annulment and duration of the Agreement.

• *United States-Australia*

CO-OPERATION IN THE PEACEFUL USES OF NUCLEAR ENERGY (1985)

The United States and Australia concluded Administrative Arrangements in February 1985 as required by the U.S.-Australia Agreement for Co-operation in the Peaceful Uses of Nuclear Energy, in force since 1957. The Administrative Arrangements set forth specifics on matters of commerce which will take place under the Agreement.

• *International Atomic Energy Agency*

SAFEGUARDS AGREEMENT BETWEEN THE IAEA AND THE USSR

Following the announcement made by the Minister of Foreign Affairs of the Union of Soviet Socialist Republics at the Second Special Session of the United Nations General Assembly on Disarmament in July 1982, and the ensuing negotiations between the Soviet Union and the IAEA, an agreement for the application of safeguards in the Soviet Union was signed in Vienna on 21st February 1985.

*Guidelines for nuclear transfers.

The Agreement was ratified by the Soviet Union on 17th April 1985. In accordance with its provisions, the IAEA will apply safeguards to all nuclear material contained in the facilities which the IAEA will select from a list of peaceful nuclear installations designated by the Soviet Union.

This agreement is similar to the safeguards agreements concluded by France, the United Kingdom and the United States with the IAEA, on 12th September 1981, 14th August 1978 and 9th December 1980 respectively, on the basis of the voluntary offers made by these nuclear-weapon States to the IAEA.

MULTILATERAL AGREEMENTS

• *Federal Republic of Germany*

RATIFICATION OF THE 1982 PROTOCOLS TO AMEND THE PARIS CONVENTION AND THE BRUSSELS SUPPLEMENTARY CONVENTION (1985)

The Act of 21st May 1985 authorises ratification of the Protocols of 16th November 1982 to amend the Paris Convention on Third Party Liability in the Field of Nuclear Energy and the Brussels Supplementary Convention (see Nuclear Law Bulletin Nos. 24, 30 and 34). It has been published in Bundesgesetzblatt 1985, II, p. 690 and entered into force on 1st June 1985. The Protocols shall apply as domestic law in the Federal Republic of Germany irrespective of their binding force under public international law, unless such application is conditional upon reciprocity effective on their entry into force.

ORDINANCE TO IMPLEMENT THE CONVENTION ON THE PROTECTION OF THE MARINE ENVIRONMENT OF THE BALTIC SEA AREA (1985)

The Ordinance of 11th February 1985 (Bundesgesetzblatt 1985, I, p. 321) implements the above Convention, named the Helsinki Convention, providing for measures to prevent contamination of the Baltic Sea by ships flying the flag of the Federal Republic of Germany, ships crossing German territorial or inland waters, and submarine devices within the territorial sea and inland waters.

• *Italy*

RATIFICATION OF THE 1982 PROTOCOLS TO AMEND THE PARIS CONVENTION AND THE BRUSSELS SUPPLEMENTARY CONVENTION (1985)

Act No. 131 was adopted on 5th March 1985; it authorises the President of the Republic to ratify the Protocols of 16th November 1982 amending the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy and the 1963 Brussels Supplementary respectively (see Nuclear Law Bulletin Nos. 31, 33, and 34). The Act was published in the Ordinary Supplement to the Italian Official Gazette No. 89 of 15th April 1985.

• *International Atomic Energy Agency*

CONVENTION ON THE PHYSICAL PROTECTION OF NUCLEAR MATERIAL

Niger signed the Convention on the Physical Protection of Nuclear Material at the IAEA Headquarters in Vienna on 7th January 1985, Paraguay, Turkey and Guatemala deposited instruments of ratification of the Convention on 6th February 1985, 27th February 1985 and 23rd April 1985 respectively.

The Convention has thus been signed by thirty-nine States and the European Atomic Energy Community (EURATOM) and ratified by thirteen States.

Pursuant to Article 19.1, the Convention still requires eight ratifications or accessions for its entry into force (see Nuclear Law Bulletin No. 24). The following Table gives the status of signatures and ratifications of the Convention.

CONVENTION ON THE PHYSICAL PROTECTION OF NUCLEAR MATERIAL

Status of signatures and ratifications

Name of State/Organisation	Date of Signing	Place of Signing
1. United States of America	03.03.1980	New York, Vienna <u>ratified</u> 13.12.1982
2. Austria	03.03.1980	Vienna
3. Greece	03.03.1980	Vienna
4. Dominican Republic	03.03.1980	New York
5. Guatemala	12.03.1980	Vienna <u>ratified 23.04.1985</u>
6. Panama	18.03.1980	Vienna
7. Haiti	09.04.1980	New York
8. Philippines	19.05.1980	Vienna <u>ratified 22.09.1981</u>
9. German Democratic Republic	21.05.1980	Vienna <u>ratified 05.02.1981</u>
10. Paraguay	21.05.1980	New York <u>ratified 06.02.1985</u>
11. USSR	22.05.1980	Vienna <u>ratified 25.05.1983</u>
12. Italy	13.06.1980	Vienna - signed as Member State of Euratom
13. Luxembourg	"	" "
14. Netherlands	"	" "
15. United Kingdom	"	" "
16. Belgium	"	" "
17. Denmark	"	" "
18. Germany, Federal Republic of	"	" "
19. France	"	" "
20. Ireland	"	" "
21. Euratom	"	" "
22. Hungary	17.06.1980	Vienna <u>ratified 04.05.1984</u>
23. Sweden	02.07.1980	Vienna <u>ratified 01.08.1980</u>
24. Yugoslavia	15.07.1980	Vienna
25. Morocco	25.07.1980	New York
26. Poland	06.08.1980	Vienna <u>ratified 05.10.1983</u>
27. Canada	23.09.1980	Vienna
28. Romania	15.01.1981	Vienna
29. Brazil	15.05.1981	Vienna
30. South Africa	18.05.1981	Vienna
31. Bulgaria	23.06.1981	Vienna <u>ratified 10.04.1984</u>
32. Finland	25.06.1981	Vienna
33. Czechoslovakia	14.09.1981	Vienna <u>ratified 23.04.1982</u>
34. Korea (Republic of)	29.12.1981	Vienna <u>ratified 07.04.1982</u>
35. Norway	26.01.1983	Vienna
36. Israel	17.06.1983	Vienna
37. Turkey	23.08.1983	Vienna <u>ratified 27.02.1985</u>
38. Australia	22.02.1984	Vienna
39. Portugal	19.09.1984	Vienna
40. Niger	07.01.1985	Vienna

TEXTS

• *France*

ORDER OF 10TH AUGUST 1984 ON DESIGN, QUALITY, CONSTRUCTION AND OPERATION OF LARGE NUCLEAR INSTALLATIONS*

Ministry of Industrial Redeployment and Foreign Trade

Considering Decree 63-1228 of 11th December 1963 relative to nuclear installations, as amended by Decree 73-405 of 27th March 1973, especially Section 10A thereof;

Considering amended Decree 73-278 of 13th March 1973 relative in particular to the establishment of a Service Central de Sûreté des Installations Nucléaires (SCSIN)**;

Considering the opinion expressed by the Commission Interministérielle des Installations Nucléaires de Base*** at its meeting on 2nd July 1984,

On recommendation of the General Director of Industry,

Orders:

Part I - General Provisions

Section 1

The owner (operating organisation) of a large nuclear installation shall see to it that a quality consistent with the importance of its functions

*Translation communicated by French authorities.

**Central Service for the Safety of Nuclear Installations.

***Interministerial Committee for Large Nuclear Installations

for safety, in the sense of the aforesaid Decree of 13th March 1973, is defined, achieved and maintained for the following items:

- structures and equipment;
- assemblies thereof,
- operating conditions of the facility.

To this end, the owner shall see that a system is implemented to define, achieve and maintain the quality of these items, to control its achievement and maintenance and to analyse and correct any deviations.

Such a system involves a controlled set of planned and systematic programme of actions based on written procedures and entailing the preparation of filed documents.

It shall provide the objective evidence that the required quality is achieved and maintained for the involved items.

It shall be implemented since the beginning of the design phase throughout the life of the large nuclear installation.

Section 2

2.1 Taking into account the specificity of this large nuclear installation, the owner shall identify the activities performed by himself or by suppliers which affect the quality of the safety-relevant items mentioned in Section 1.

Such activities are called "quality-relevant activities" in this Order.

2.2 The provisions of Sections 6 to 10.1, 11.2, 12, 13.1, 13.3, 14 and 15.1 of this Order apply to the quality-relevant activities. The steps to apply such provisions are determined and taken by the owner or his suppliers.

Section 3

For purposes of this Order, any person covered by Section 1 of the above-mentioned Decree of 11th December 1963 or any natural person or legal entity filing an application for authorisation to construct a large nuclear installation is an "owner".

For purposes of this Order, the holder of a contract with the owner or another supplier is a "supplier" when such a contract provides for the supply of goods or services constituting one or more quality-relevant activities.

Part II - Owner's Overall Responsibility

Section 4

Being responsible for the safety of the facility, the owner shall be thereby responsible for enforcement of this Order's provisions relative to quality-relevant activities.

In regard to quality-relevant activities of suppliers, the owner shall see to it that the contracts include notice to such suppliers of the provisions for enforcement of this Order.

The owner shall supervise all the suppliers or shall have them supervised in order to make sure that they apply the provisions so notified. In particular, he shall see that the items or services supplied are subject to control to ensure conformity with the procurement documents.

Section 5

The owner shall prepare and shall keep up to date a file summarising the measures and means planned for complying with this Order, including in particular the principles for the surveillance of suppliers. He shall transmit this file and its subsequent revisions to the SCSIN except for the temporary provisions of Section 17 below. In the case of a large nuclear installation to be constructed, this file shall be transmitted when applying for the authorisation of construction.

The owner shall keep all data evidencing enforcement of this Order or shall have them kept available to the Head of the SCSIN and his large nuclear installation inspectors.

The owner shall be able to report to the Head of the SCSIN on the compliance with this Order and particularly on the identification of the quality-relevant activities. He shall supply the Head of that Service, on request, with all data and evidence on those scores. Depending thereon, the Minister in charge of industry may require the owner to take all measures deemed necessary for compliance with this Order.

Part III - General Principles

Section 6

The requirements necessary to achieve and maintain the quality mentioned in Section 1 shall be defined for each quality-relevant activity taking into account its importance for safety.

Such requirements are called "definite requirements" in this Order

Section 7

The human and technical resources and the organisation implemented for a quality-relevant activity shall be tailored to this activity and enable the definite requirements to be met.

In particular, only individuals having the required proficiency may be assigned to a quality-relevant activity; such individual proficiency is determined, inter alia, on the basis of their training and experience.

The quality-relevant activities, for which individuals shall be qualified or cleared in advance or for which technical resources shall be qualified, shall be identified, with account taken of their nature and their importance for safety.

The organisational structure shall enable the responsibilities and duties of the individuals or organisations concerned and the relations between them to be identified for each quality-relevant activity.

Section 8

An organisational structure is defined and implemented for an appropriate technical control of each quality-relevant activity. It shall enable a determination to be made that.

- each quality-relevant activity has been executed according to the definite requirements;
- the result meets the definite quality;
- appropriate corrective and preventive action relative to any anomalies and incidents mentioned in Section 12 below has been defined and implemented.

The individuals responsible for technical control of a quality-relevant activity shall be different from the individuals who have executed it.

Section 9

An organisation in charge of verifying the satisfactory compliance with Sections 6, 7 and 8 of this Order shall be defined and implemented.

The individuals and organisations performing verification functions shall:

- have adequate technical qualifications;
- be independent of the individuals performing the quality-relevant activity;
- report directly to an individual having authority in regard to the achievement of the quality-relevant activity.

They shall evaluate periodically the effectiveness and adequacy of the measures taken to comply with this Order, inter alia, by means of appropriate investigations and, insofar as need be, programmed spot checks, such an evaluation covers the organisation established and the technical aspect of the quality-relevant activity.

This organisation shall see to it that steps are taken to evaluate abnormal situations and to implement the necessary corrective actions.

Part IV - Documenting Quality-Relevant Activities

Section 10

10.1 For each quality-relevant activity the following documents are prepared and appropriately updated and used:

- a) before initiation of this activity, description of the general measures taken to comply with this Order. This document may cover several quality-relevant activities;
- b) preliminary description of the definite requirements, conditions of performance and control, and conditions of handling any possible anomalies or incidents;
- c) record of the progress of this activity providing with sufficient details information as to, and for evaluation of, its performance, control and results;
- d) action plan of verification including audits provided for in Section 9;
- e) documents providing evidence that planned verification actions have been carried out and showing the results thereof, and reporting on the periodic audits;
- f) documents providing evidence of the surveillance programme under Section 4 in regard to each supplier and containing any comments.

10.2 The owner shall prepare a synthesis document which is an overall evaluation of the quality achieved before commissioning of the installation. Thereafter, he shall evaluate periodically the achievement and maintenance of the quality of the items important for safety mentioned in Section 1.

Section 11

11.1 The owner shall take, or shall see to the taking of, all requisite measures so that the documents necessary for quality assessment, including those describing the facility itself, are:

- stored for an appropriate duration,
- protected,
- properly preserved,
- readily accessible.

11.2 All the measures taken for storing the documents relative to a quality-relevant activity are described in an updated written document.

Part V - Anomalies and Incidents

Section 12

Any deviation from a definite requirement for the accomplishment or result of a quality-relevant activity, any situation liable to interfere with the definite quality or any situation calling for a corrective action in regard to safety, are called an "anomaly or incident" in this Order.

A corrective action of an anomaly or incident is a quality-relevant activity.

A list of anomalies and incidents is kept up to date.

Section 13

13.1 Anomalies or incidents which are particularly important for safety shall be identified. Such anomalies or incidents are called "significant anomalies or incidents" in this Order.

To this end, for each quality-relevant activity, a procedure shall provide a determination of the anomalies or incidents which are considered as significant, determination based on established criteria insofar as possible. The procedure shall specify the functions of the individuals in charge of this identification.

13.2 The owner shall report the significant anomalies and incidents to the SCSIN as promptly as possible. He shall take appropriate measures for that purpose with his suppliers.

The report describes the measures taken or planned to limit the extension of the anomaly or incident and, if need be, to attenuate the effects thereof. If the installation is in operation, the report specifies the measures taken or planned for continuation or resumption of operations under satisfactory safety conditions.

13.3 In-depth analysis is made of significant anomalies and incidents

- to determine precisely their causes and their direct or potential effects on safety,

- to draw a useful lesson for the quality-relevant activity involved and, if need be, for other quality-relevant activities.

A file is established and kept up to date for each significant anomaly or incident containing, inter alia, the data from such an analysis.

13.4 The owner shall periodically report to the Head of the SCSIN on the status of this file.

Part VI - Special Provisions

Section 14

The result of thought leading up to elaborate one or more technical documents required for a quality-relevant activity is called "study" in this Order.

A study is a quality-relevant activity.

Without prejudice to compliance with the other provisions of this , studies are subject to the following provisions.

14.1 For a study, the document mentioned in paragraph (a) of Section 10.1 shall include appropriate rules for:

- identification and consultation of the individuals and organisations concerned;
- taking the comments made into account;
- preparation of further revision of the documents relative to this study.

These rules shall also ensure that the organisations or individuals concerned with a study are familiar with the other studies or documents, such as design bases, codes, standards and regulatory provisions, which are helpful for this study.

14.2 Subject to justified exceptions, each study shall be subjected to control as required by Section 8. The nature of such control depends on the importance of the study for safety; such control is performed by means of reviews conducted by individuals who did not directly participate in the study

14.3 Subject to justified exceptions, the individuals and organisations in charge of verifications required by Section 9 shall be informed of the progress of the studies and the relevant documents are kept at their disposal

14.4 Critical examinations relative to the design of the whole facility or of major sub-assemblies are made in order to verify the consistency of the relevant studies.

Section 15

15.1 The provisions of this Order also apply to those activities initiated before filing of the application for authorisation to construct a large nuclear installation and which, when such application is filed, are identified as quality-relevant activities.

15.2 With his application for construction authorisation, the owner shall transmit to the SCSIN a report on the initiation of such quality-relevant activities and the measures he has taken for compliance with the provisions of this Order.

Section 16

Research and development or training activities carried out in a large nuclear installation for research and training purposes are not subject to the provisions of Section 2.2 and Sections 4 to 15. In any event, the owner shall be able to report to the Head of the SCSIN on the measures taken pursuant to Section 1.

Part VII - Enforcement

Section 17

Temporarily, every owner and everyone becoming an owner within one year of publication of this Order in the French Official Journal shall have not more than one year after such publication to submit the file prescribed in Section 5 and to comply with this Order subject to the following provisions.

For construction and operating activities already initiated or to be initiated within one year of such publication, the owner may, within 10 months of the publication date, apply to the Minister of Industrial Redeployment and Foreign Trade (SCSIN) for extension of the one-year period, which application shall include a proposed schedule for and a description of the measures to be taken for compliance with this Order. The Minister of Industrial Redeployment and Foreign Trade may allow longer time on terms he may prescribe, provided that the time from said publication may not exceed three years, subject to Section 18.

Section 18

Waivers of this Order are granted by the Minister of Industrial Redeployment and Foreign Trade on terms he may prescribe.

Section 19

The Head of the SCSIN is responsible for enforcing this Order, which shall be published in the French Official Journal.

**TRADE CIRCULAR OF 10TH AUGUST 1984
RELATIVE TO ENFORCEMENT OF THE LARGE NUCLEAR INSTALLATION
DESIGN, CONSTRUCTION AND OPERATING QUALITY REGULATIONS**

The purpose of this Circular is to clarify the prescriptions of an Order dated this day relative to the quality of design, construction and operation of large nuclear installations.

This regulation defines the scope of measures the owner* of any large nuclear installation shall take in order to achieve and maintain the quality of his installation and of the operating conditions, as necessary to ensure safety.

The required quality of an activity is achieved and maintained on the one hand by the efforts of those to whom the activity is assigned and, on the other hand, through appropriate organisation and control measures.

Most of the technical provisions of the Order are codifications, in a summary form, of the nuclear industry practice. Notice thereof had already been given to certain large nuclear installation owners in the form of "Basic Safety Rules" (BSR)**, which are documents published by the Service Central de Sécurité des Installations Nucléaires (SCSIN)*** to explain French regulatory practice on certain subjects as it appears from the preliminary technical examinations of applications for authorisation to construct or commission large nuclear installations.

Similar regulations have been enforced in other countries, particularly - the United States of America in the "Code of Federal Regulations", Title 10, Part 50, Appendix B, applying to nuclear and reprocessing plants, and in the Federal Republic of Germany in the form of a "Kerntechnischer Ausschuss" guide ref. KTA 1401 applying to nuclear power plants. Moreover, to facilitate dissemination of the practice to be adopted in nuclear plant design, construction and operation, the International Atomic Energy Agency has published Code of Practice 50-C-QA relative to "quality assurance for safety in nuclear power plants", which contributes to enforcement of the Order in the field thereof.

Finally, it should be noted that two French Standardisation Association quality standards - NFX 50-111 and NFX 50-112 - have been registered

*Owner: operating organisation.

**"Règles Fondamentales de Sécurité" (RFS).

***Central Service for the Safety of Nuclear Installations.

The technical provisions of the Order were developed by a working group of engineers specialised in design, construction and operating quality of large nuclear installations. They were reviewed by the standing groups of experts responsible for studying the technical aspects of the safety of large nuclear installations. Moreover, they were submitted to the Commission Interministérielle des Installations Nucléaires de Base (CIINB) pursuant to Section 8 of the amended decree of 11th December 1963.

The scope of the Order should be emphasized: it is designed to ensure quality of all of the items listed in Section 1 consistent with their importance for safety, by no means may it obviate enforcement of the other applicable regulations, including specific ones such as the regulation relative to the main primary system of nuclear water boilers.

As a rule, the quality of any industrial project is necessary to ensure adequate safety thereof. In the case of large nuclear installations, the required quality shall be suited to the special nuclear safety needs.

The Order requires large nuclear installation owners to adopt a system suited to the required quality for accomplishment of all the quality-relevant activities and for the controls and verifications of such activities, or to have it adopted; the system shall provide assurance that the necessary action has been taken to achieve the required quality and provide useful information to rectify, if need be, an activity or its result.

The quality of a large nuclear installation involves special problems justifying specific regulations. This specificity shall not lead to a misunderstanding as to the scope of the Order: the authorities, in prescribing a consistent but not necessarily sufficient set of measures relative, inter alia, to the quality organisation to be established, do not intend to supersede the owner or to assume his responsibilities.

The Sections of the Order are commented below, in their proper order, as needed.

Section 1

The quality of an item important to safety is its fitness to fulfil its function satisfactorily from the standpoint of the installation's safety.

Achievement of an appropriate quality is obviously essential for a large nuclear installation. Of course, this requirement is extended to the maintenance of such a quality throughout the installation's life.

The importance to safety mentioned in this Section is assessed, inter alia, by means of studies and evaluations of the installation's safety in the light of the direct or potential consequences of one or more failures of the items concerned by this Section. The installation's safety is evaluated in particular in the course of the regulatory procedures under the amended Decree of 11th December 1963.

A system, for purposes of this Section, is a co-ordinated set of practices leading to a result.

Section 2

The scope of the Order defined in this Section includes all the quality-relevant activities which the owner identifies as his responsibility, subject to possible additional provisions prescribed by the Head of the SCSIN. A methodology may be used to identify them.

In the case of a large nuclear installation which is a complex unit, the owner may assign certain quality-relevant activities to other natural persons or legal entities called suppliers.

In such a case obviously, while the owner is responsible for identifying the quality-relevant activities, such activities may be identifiable only after a dialogue and studies with one or more suppliers in the light of their experience and their knowledge of their own activities. In some cases, especially if principal suppliers are involved, such a dialogue may lead the latter to develop a methodology for identifying quality-relevant activities.

A quality-relevant activity may itself consist of several quality-relevant activities subject to the Order.

There are cases in which the quality of the result of a partial activity in a quality-relevant activity may form the subject of assurance equivalent to that of the systems mentioned in the Order. The decree need not be fully applied to this type of partial activity, provided that the owner can, at the request of the Head of the SCSIN, provide evidence relative to specification of and compliance with the Section 6 requirements and subject to proper controls of the end quality of the result of this partial activity (as an example, acceptance tests on raw materials or certain semi-manufactured products). These provisions relative to such partial activities enable the chain of suppliers mentioned in the comment on Section 3 to be cut

Certain control operations not directly relating to a production or repair quality-relevant activity can be treated themselves as quality-relevant activities.

Hereinafter the terms "activity" and "quality-relevant activity" are used with the same meaning.

Section 3

The suppliers, to which an owner contracts an activity, may in turn sub-contract part of such an activity. The sub-contractor in turn is a supplier, regardless of his position in the chain of suppliers. The chain of suppliers for an activity may be limited as regards the implementation of the provisions of the Order as a whole as outlined in the comments on Section 2

The word contract is used in the general sense of a written agreement between the supplier and his customer.

Section 4

The measures that the owner or a supplier notifies to his suppliers are, if necessary, detailed in order to be adapted to the activity in question.

The surveillance consists of operations enabling the owner or a supplier to make sure that his suppliers are applying to an activity provisions appropriate to the required quality.

Under this Section and the definition of supplier given in Section 3, the owner shall supervise the suppliers at all points of the chain of suppliers, or have them supervised.

The Order does not require surveillance by suppliers of their own suppliers, but only control of conformity of their supplies with the contract. Conformity with the contract means conformity with the technical contractual provisions between the owner or a supplier and his supplier. It is however desirable for suppliers to supervise their own suppliers in the way described below in connection with the owner's surveillance of his suppliers. In this case, the owner may rely on the effectiveness of such surveillance for purposes of his own surveillance.

This Section authorises the owner to sub-contract his surveillance. The contractor may be a specialist or a supplier responsible for an activity. The owner shall then make sure of the efficiency of the supplier's surveillance.

The surveillance of the suppliers shall start as soon as they are selected. This selection is made on the basis, inter alia, of an evaluation of ability to supply items or services meeting the requirements of the customer, whether this is an owner himself or another supplier, pursuant to the Order's provisions.

Such an evaluation is based on:

- the supplier's technical capability,
- the organisation set up to achieve and maintain the quality of his services;
- plus, if possible:
 - a) data relative to the quality obtained in past similar services;
 - b) product samples.

As a rule, the selected supplier should be in a position to carry out an activity in compliance with the provisions of the Order. The owner or a supplier may however contract all or part of a quality-relevant activity to a supplier unable to comply with the Order; the owner must then take the place of the supplier in respect of the provisions with which the latter cannot comply. Aside from application of the provisions relative to partial activities, which enable the chain of suppliers to be cut according to the comment on Section 2, such situations are permissible only in special cases

and only if evidence concerning compliance with the Order in such circumstances can be provided on request by the Head of the SCSIN

Surveillance shall extend, inter alia, to the supplier's compliance with the contract and to the existence of the document mentioned in paragraph (a) of Section 10.1 and of a system designed to meet the requirements of Sections 6 and 9 of the Order. The Section 10.1 documents are kept available to the persons responsible for such surveillance. In such surveillance, special attention shall be paid to the handling of anomalies and incidents.

The surveillance performed on all suppliers by or on behalf of the owner is based on programmed verifications, at random, which cover both the organisation set up and the technical aspect of the activity involved, it includes, insofar as need be, the specification of stages or operations for which the information or the presence of his representatives is necessary. In such cases, the owner specifies the responsibilities, duties and authority of these representatives.

In such surveillance, the owner makes or contracts for appropriate general investigations and draws all useful conclusions.

The term "surveillance" is used in reference to two entirely different : on the one hand, surveillance of the owner by the authorities under 11 of the amended Decree of 11th December 1963 and, on the other, surveillance of the suppliers by the owner under this Section. The Order uses term in the latter sense except when it refers to the amended Decree of 6th December 1963.

Section 5

The document mentioned in this Section applies to the activities to be accomplished. For new large nuclear installations, the owner's first document can be included in the preliminary safety report. It summarises the measures and means planned to comply with the Order during design, construction and first tests.

The updated document can be included, as the case may be, either in the provisional safety report, in the definitive safety report, in the supplemental files prescribed by the construction authorisation decrees or in the general operating rules. The document then summarises the measures and means planned pursuant to the Order in the commissioning tests, the maintenance, repair and modification operations and the actual operation. The owner also mentions in the definitive safety report the changes planned to be made during operation, in the initially planned measures and means

The owner shall, of course, be able to make the suppliers agree to keep available to the Head of the SCSIN the documents concerned by this Section and to make the suppliers report on their compliance with the Order.

This Section provides that the Head of the SCSIN may request information and evidence of the owner and that the Minister may lay down requirements to him. Such requests and requirements may result, inter alia, from the surveillance prescribed in Section 11 of the amended Decree of

11th December 1963, and from the technical safety reviews which the Head of the SCSIN shall make under the regulations.

Section 6

The importance of the thought given to the determination of the requirements should be emphasized; the choice of requirements based on such thought essentially conditions the achievement and maintenance of the required quality. The requirements must be revised in the light of acquired experience and take account of the measures resulting from examination of anomalies or incidents. The importance of an activity for safety, which importance conditions the relevant requirements, is assessed as mentioned in the comment on Section 1 on the basis of the direct or potential effects of inappropriate performance of the activity.

The supplier responsible for the activity may specify the requirements mentioned in this Section, if necessary by reference to pre-established rules. The definition of such requirements shall then be appropriately supervised.

The requirements may concern the organisation of the activity.

Section 7

The quality of an activity results, inter alia, from the work of the people assigned to it, taking into account the technical resources placed at their disposal and the organisation of the activity.

As a matter of fact, the quality objectives are attained first by those who have been assigned responsibility for a task; the performance of a task begins with a phase of definition and organisation. Each activity is performed with appropriate human and technical resources; this may include examination of the work done by individuals performing the task.

Human resources

It is essential that the personnel assigned to a quality-relevant activity should be aware of the importance of their tasks to safety.

In case of qualification or clearance of personnel, the conditions of recognition of the qualification or of issuance and renewal of the clearance are adapted to the tasks the personnel are to accomplish.

Clearance of an individual for an activity is granted by the owner for the activities he accomplishes himself or by the supplier for the activities concerning him, which clearance attests to a person's qualification for specified tasks and responsibilities.

These provisions shall apply without prejudice to those of the current regulations, including the amended Order of 21st March 1978 regulating welding in construction and repair of pressure vessels.

Technical resources

The technical resources corresponding to an activity consist of equipment, processes and documents used and of the conditions under which the activity is accomplished.

The technical resources corresponding to quality-relevant activities shall be adapted to such activities and, inter alia, enable the personnel to perform their work within the scope of their skills.

If equipment and processes need to be qualified, the owner shall make sure in particular that the qualification means and conditions are specified.

Organisation

If an activity or set of activities simultaneously or successively involve several organisations or units of the owner or of one or more suppliers, the specification of the responsibilities and duties of each, of the boundaries of their actions and of the co-ordination between these organisations shall be part of the requirements.

Section 8

The technical control consists of operations carried out according to a systematic method, in order to ensure that each activity has been performed according to the definite requirements, that the quality of the result has been achieved and, if necessary, that corrective and preventive measures have been defined and implemented in case of anomalies or incidents

The nature and methods of these controls and, if need be, the associated rates and criteria shall be defined. The controls may be made by individuals from the organisation responsible for the activity, but not by those who accomplish it. However, it is important that they should be made by qualified personnel familiar with quality problems using appropriate technical resources. If abnormalities are found, the control report is sent to people with sufficient authority to have such an activity or any other activity likely to be affected by the abnormality rectified or suspended at any time.

Section 9

The verifications consist of actions performed to ensure that the system established to achieve and maintain the quality of an activity according to Sections 6, 7 and 8 is effectively and permanently implemented to assess the effectiveness and adequacy of this system.

The individuals in charge of these verifications shall be clearly identified; their responsibilities and duties shall be clearly defined, and the technical and human resources shall be made available to them.

An investigation, as contemplated by the Order, is an operation making it possible to check the adequacy and the effectiveness of the measures taken pursuant to the Order, inter alia, by evaluation of the documents relative to quality-relevant activities.

Such investigation must be performed by individuals having no direct responsibility for the tasks to be investigated. The reports or investigations shall be sent through direct hierarchical channels within the organisation prescribed by this Section to the person specified in the same section. The number and scope of these investigations depend on the importance of the activity concerned from the safety viewpoint; the scheduling of investigations shall be consistent with the actual time schedule of these activities.

The organisational structure set up shall enable the individuals or organisations responsible for controls or verifications under Sections 8 or 9 to act under conditions respecting their independence of action and judgment when they perform their task.

For a given activity, the actions taken under Sections 6 to 9 are generally carried out by individuals belonging to the same organisation. In special cases, some of these actions may be performed by individuals outside the organisation, particularly when a supplier cannot perform an activity according to the Order (see comment on Section 4).

Section 10

10.1 For all quality-relevant activities, objective evidence shall be provided that the required quality has been appropriately specified, that these activities have been accomplished satisfactorily and that a quality consistent with the required quality has been achieved.

The documents mentioned in this Section on one hand constitute a record of the reflections which shall precede every activity and, on the other hand, provide assurance that the activities have been accomplished satisfactorily. To enable the documents to be used properly, their conditions of distribution shall be carefully defined in each case and form part of the requirements.

The document mentioned in paragraph (a) shall specify the structure of the organisation and clearly delineate the responsibilities and duties of the individuals and organisations involved in one or more quality-relevant activities.

If the owner uses a supplier or if a supplier sub-contracts to another supplier, the documents prepared by the former shall provide measures to ensure that.

- the regulatory provisions, including especially those of the Order,
- the design bases and the standards,
- the definite requirements for achievement of the required quality,
- the measures providing access to the facilities and files of the production units for purposes of the actions mentioned in Section 4,

are taken up or referenced in the appropriate documents relative to the services; and that these measures are implemented by the supplier.

The adequacy of the document required in paragraph (a) to perform the activity shall be evaluated and the document updated periodically.

If an activity itself consists of a set of activities, a document shall verify the co-ordination of these activities and, if need be, of the control and verification procedures and actions.

All the measures established pursuant to Section 7 relative to human and technical resources necessary to perform an activity and to the qualifications and clearances concerning them are described in principle and in functioning in the documents prescribed by this Section.

In the preliminary descriptions mentioned in paragraph (b), account shall be taken, inter alia, of the stages of an activity which essentially determine its result.

The report documents mentioned in paragraphs (c) and (e) are prepared in accordance with the corresponding actions progress by the persons who actually accomplish

In the case of an activity relative to equipment, these documents, usually including the preliminary descriptions mentioned under paragraph (b), shall, if need be, further identification of activities which may have been affected by generic anomalies. They may provide aid in repeating the activity (e.g. maintenance of spare equipment for instance).

Documents containing trade secrets may not be subject to the access measures provided for above and to the storage measures recommended in the text of Section 11, provided that special measures are agreed on by all the persons involved.

The recapitulative document mentioned in this Section shall refer to the main anomalies or significant incidents which occurred prior to the commissioning of the installation and to the corrective actions taken. It shall describe the special measures to be taken in operation in the light of the assessment of the quality actually achieved.

The periodic evaluations mentioned in this Section shall refer to the main anomalies or significant incidents which have occurred since the commissioning or the preceding periodic evaluation and to the corrective actions taken. They include an assessment of the trend in quality of the installation. The periodic evaluations should take into account advances in technology.

Section 11

The documents mentioned in this Section include the descriptive files and the plans, the test and operating reports, the documents relative to the controls such as reports, and X-rays, magnetic or graphic recordings, original photographs and macrographs.

The retention time shall be appropriate to the potential use of the documents mentioned in Section 10 of the Order. For instance, the documents mentioned in paragraphs (b) and (c) of Section 10.1, in view of their direct

connection with the activity, shall be kept at least, and without prejudice to any other regulations, as long as the document might have to be consulted for example to maintain the installation or to repair or replace deficient parts under good conditions. The other documents such as revisions of the document mentioned in paragraph (a) of Section 10.1, periodic audit reports, schedules of verifications and audits may be kept for a shorter time - say five years - depending on the importance of the activities to safety.

To ensure proper preservation of the documents involved, it is advisable to have them stored by the owner himself. If an activity is accomplished by a foreign supplier, such documents should be kept in France to remain easily accessible.

If the nature of a large nuclear installation changes, certain documents may have to be included in records of the new large nuclear installation.

These provisions shall be applied without prejudice to those provided for, in particular, by the amended Order of 26th February 1974 extending the pressure vessel regulations to nuclear water boilers and the amended Order of 21st March 1978 regulating welding in pressure vessel manufacture and maintenance.

The protection prescribed by this Section includes appropriate protection against fire, theft and floods. Appropriate storage conditions include protection against ageing due to temperature, humidity and light.

Section 12

Each deviation mentioned in this Section may be an anomaly or an incident, the distinction between the two concepts being defined by each owner or supplier. It did not seem necessary to draw a distinction between the two concepts for the purpose of the Order, as Sections 12 and 13 apply to both.

Appropriate measures shall be taken to note and demonstrate the existence of anomalies or incidents, to take all the necessary steps for safety and thus to prevent the use or installation of the items concerned or inadvertent continuation of the activity concerned.

It is important that all the useful inferences should be drawn from such anomalies or incidents so as to improve, if need be, the quality of the activities concerned.

If anomalies or incidents are so noted and demonstrated, the items or actions involved shall be examined in order to determine and implement the preventive and corrective actions mentioned in Section 8. The individuals responsible for the examination and those authorised to deal with the anomalies or incidents shall be specified.

All general measures established pursuant to Sections 12 and 13 are described in the document mentioned in paragraph (a) of Section 10.1 and their actual implementation is mentioned in the other documents provided for in Section 10.1.

Section 13

Some of the anomalies or incidents mentioned in Section 12 require special attention in view of their importance to safety. Examination of such anomalies or incidents is an essential factor in the assessment of the safety of the large nuclear installations involved. The file relative to each significant anomaly or incident containing the results of such an analysis consists, inter alia, of:

- the detailed description of the anomaly or incident;
- the analysis of the cause of the anomaly or incident and the investigation of lessons that can be drawn therefrom in regard to the activity and, as the case may be, to other activities,
- the evaluation of the possible harmfulness of the anomaly or incident;
- the description and justification of any measures which may be necessary: additional control, repair or modification of operating conditions;
- the description and justification of the additional inspection resources that may be necessary in operation of the installation,
- the examination, in connection with the considered anomaly or incident, of the adequacy and implementation of the general measures taken pursuant to the Order and the lessons drawn, insofar as need be, reconsideration of the qualification of the technical and human resources involved.

This file is prepared on a schedule consistent on the one hand with the programme for construction or operation of the installations and, on the other hand, with the importance to safety of the anomaly or incident.

The first report on the file status shall be made to the SCSIN about one month after the report of the anomaly or incident, due cause for delay accepted. This report shall also list the available documents and the places where the surveillance provided for in Section 11 of the amended decree of 11th December 1963 can be performed in order to ensure that the aforesaid documents have been properly prepared, that they are valid and that the corresponding actions progress satisfactorily.

The report to the Head of the SCSIN is without prejudice to the other information supplied by the owner to the locally relevant Commissioner of the Republic, inter alia, in connection with incidents or accidents, pursuant to the Prime Minister's directives.

Section 14

It seemed advisable to adopt special provisions in regard to the studies which essentially condition other subsequent activities; only persons capable of making all or part of a study may supervise it.

The studies mentioned in this Section lead to technical documents which may be themselves documents leading to other studies or execution documents.

The studies cover activities performed in all phases of a large nuclear installation's lifetime.

The Section 14.1 rules, pursuant to Section 7, shall ensure a correct identification of the persons who participate in each study. If related studies are carried out by different persons or organisations, appropriate rules provide for the coherence of the jurisdiction boundaries of each of these persons or organisations pursuant to the comments on Section 7.

The control measures provided for in Section 14.2 include critical examinations relative, inter alia, to the validity of the basic documents used, the conformity with the definite requirements and the adequacy of the study. To confirm the results of the calculations, a different or simplified method can be used. The control measures may also be based on timely appropriate tests. Partial implementation of these measures is possible only in the following cases.

- other experience (operating experience of large nuclear installations, "standard practice") has enabled the processes or codes used to be validated, in such an event, it shall be systematically determined that the assumptions are correct and fall within the scope of such processes or codes,
- insofar as it is possible to make any necessary changes properly, the installation commissioning tests may be sufficient to confirm the achieved results; the number of cases in this category shall remain sufficiently limited so that possible changes necessary at an advanced stage of construction remain limited,
- the studies for which there are no technical control means independent of those used and a list of which is included as such with all necessary support in the safety report.

In these three cases, the procedures for the follow up of the studies provide evidence, with all necessary support, of the extent of the areas in which the special control measures are not implemented.

Finally, studies aiming only at improving assessment of the available tolerances with respect to situations not allowed for in the design are subject to adapted procedures; in such event, the use of simplified confirmation calculations is no longer required but they shall be used insofar as possible.

Section 15

For certain activities initiated before filing of the large nuclear installation construction permit application, and in particular for preliminary plan activities, the Order's provisions may be adapted or not applied entirely insofar as no action difficult to reverse under the decisions made for the safety of the future installation can result therefrom.

Section 16

(Mentioned as a reminder.)

Section 17

This Section takes into account the diversity of nuclear installations (power reactors, research reactors, fuel enrichment, manufacturing and reprocessing plants, waste storage centres, accelerators, irradiators, laboratories, etc.), the diversity of the phases in which they now stand and the time necessary for the establishment, if need be, of new measures.

The Order is obviously not applicable to activities completed on the date of publication of the Order in the Official Journal. It applies however as provided in this Section to future and continuing activities

Requests for waiver of the Order will be handled by the Head of the who will consult, insofar as need be, the competent experts or groups of us, in particular the standing groups responsible for studying the ical aspects of the safety of nuclear installations.

- 19

Like the other provisions of the regulations covering large nuclear installations, the Order applies in the strict sense only to the large nuclear installations operated or to be operated in France.

However, a supplier may happen to perform, or make others perform, in France, a significant part of the activities devoted to design or construction of a nuclear installation located or to be located abroad. If the involved supplier so requests, measures will be taken to enable provisions of the Order enforceable in France to be applied under the same conditions as if the nuclear facility were to be installed in France, considering the supplier as owner, as defined in the Order, during the design and construction period - Head of the SCSIN shall then be instructed to enforce the Order

• *Euratom*

DECLARATION OF COMMON POLICY BY THE MEMBER STATES OF THE EUROPEAN COMMUNITY*

The Ten (hereinafter called "the Member States"), united within the framework of European political co-operation:

- a) recalling the rights and obligations deriving from their membership of the European Atomic Energy Community,
 - b) emphasising their support for the objective of non-proliferation of nuclear weapons,
 - c) referring to the various undertakings relating to the peaceful utilisation of nuclear energy and the safeguarding thereof to which they have respectively subscribed, in particular the Treaty on the Non-Proliferation of Nuclear Weapons and the agreements concluded between the Member States, the European Atomic Energy Community and the International Atomic Energy Agency for the application of safeguards within the Community, and
 - d) taking note of the adoption by all the Member States of the Guidelines for the Export of Nuclear Material, Equipment or Technology set forth in document INFCIRC/254 of the International Atomic Energy Agency (hereinafter called "the Guidelines"),
1. State that the principles contained in the Guidelines constitute a common, fundamental set of rules for all the Member States in relation to their nuclear exports,
 2. Declare that, provided the provisions of the Treaties of Rome and the competence of the Member States are respected, transfers of nuclear material, equipment and technology may be made without restriction between the Member States, subject to the following additional arrangements:
 - 2.1 Until such time as they are used, separated plutonium and uranium enriched to more than 20% will be stored by the Member States at the place of separation or enrichment to more than 20% or at the places of fabrication of fuels containing plutonium or uranium enriched to more than 20%, or in a store established and administered by a Member State, or in a place to be determined by common agreement between the Member States concerned.
 - 2.1.1 Plutonium and uranium enriched to more than 20% will be transferred by the Member States upon receipt of a certificate from the consignee (see the model form annexed hereto) specifying the final destination, the quantities, the approximate date of delivery, the timetable for utilisation, the form in which delivery is to take place and the allocation of the material to one or other of the following uses.

*20th November 1984

- fuel supply for any power or research reactor in operation or under construction on the territory of a Member State or under its jurisdiction;
- fabrication on the territory of a Member State or under its jurisdiction for purposes of fuel supply to the reactors specified above or, subject to the terms of paragraph 2.1.3, for purposes of fuel supply to any reactor situated on the territory of a third-party State,
- research and development in any laboratory situated on the territory of a Member State or under its jurisdiction. Subject to the terms of paragraph 2.1.2, the materials may also be transferred to a third-party state under a co-operation agreement relating to research and development;
- utilisation in any other installation connected with an energy programme or a research and development programme and situated on the territory of a Member State or subject to its jurisdiction, including any intermediate storage required for satisfactory implementation of the above-mentioned operations.

The Government of the Member State to which the consignee belongs will confirm the correctness of the information given in the certificate referred to in paragraph 2.1.1 above.

3 Plutonium and uranium enriched to more than 20% will not be retransferred to a third State without mutual agreement between the Member State that has separated the plutonium or enriched the uranium to more than 20% and the Member State desiring to effect the retransfer, without prejudice to any other rights of prior consent that may exist.

1.4. Paragraphs 2.1.1, 2.1.2 and 2.1.3 above do not apply to:

- plutonium having an isotopic concentration of plutonium-238 above 80%,
- special fissile materials used in quantities of the order of a gramme or less as a component of sensitive measuring instruments,
- transfers to a given Member State not exceeding 50 effective grammes in the course of a year;
- retransfers to a given third State not exceeding 50 grammes in the course of a year, without prejudice to any other rights of prior consent that may exist.

5. The above arrangements will be reconsidered by the Member States in the event that an international plutonium store is set up under the aegis of the International Atomic Energy Agency.

- 2.2 Installations and technology relating to reprocessing, enrichment and the production of heavy water, or other installations created on the basis of such technology, may be transferred in the light of the nature and the degree of development of the nuclear programmes in the recipient Member States.
- 2.3 No enrichment facility transferred from a Member State nor any installation created on the basis of the technology derived from such a facility may be designed or operated for the production of uranium enriched to more than 20% without the agreement of the Member State supplying the facility.
- 2.4 In making transfers of sensitive equipment or technology, the Member States will observe the provisions relating to the protection of secret information.
- 2.5 The prior agreement of the supplying State will be required for any retransfer of installations, principal components of crucial importance, reprocessing or enrichment technology or the technology of heavy water production, as well as for any transfer of installations or principal components of crucial importance derived therefrom.

Such retransfers and transfers between Member States may take place in consultation with the originating Member State in the light of the nature and the degree of development of the nuclear programme of the receiving Member State;

3. State that the Member States will apply to the nuclear materials under their jurisdiction measures of physical protection at least equal to the levels established in the Guidelines; and

4. State finally that, in the above-mentioned conditions, transfers between the Member States of nuclear materials, equipment and technology will be carried out in a manner compatible with the requirements of non-proliferation and free movement of goods.

MODEL FORM

Request for Transfer of Plutonium or Uranium Enriched to More Than 20%

1. Enrichment or reprocessing facility
 - 1.1 Name or trade name of firm
 - 1.2 Address
2. Consignee
 - 2.1 Name or trade name or firm
 - 2.2 Address

2.3 Principal activity

3. Description of shipment

3.1 Total weight of material

3.2 Weight of fissile plutonium (or uranium enriched to more than 20%)

3.3 Form of material

3.4 Approximate date of delivery

4. Use of the material

- Fuel fabrication

.1 Nature of fabrication

4.1.2 Name, trade name and address of fabrication plant

4.1.3 Timetable for fuel fabrication

4.2 Other uses

4.2.1 Nature of the use

4.2.2 Name, trade name and address of the user

4.2.3 Timetable for use

4.3 Final destination

4.3.1 Nature of final use

4.3.2 Designation of facility

4.3.3 Name, trade name and address of final user

4.3.4 Timetable for final use

I the undersigned certify that the information given in this form is
identical and truthful.

Date and place of signature

Signature

Name and office of signer

STUDIES AND ARTICLES

STUDIES

THE REGULATION OF FOOD IRRADIATION

Diane Neff*

PART ONE: STATUS AND PROSPECTS

I. Introduction

The utilisation of ionizing radiation for purposes of food preservation and processing is one of the truly peaceful uses of nuclear energy. Since the early 1950s, extensive research on both national and international levels has demonstrated that certain applications of irradiation to foodstuffs not only are technically feasible but that food so treated is suitable for human consumption. The potential benefits of this process on world food supplies and health are enormous.

Nevertheless, before use of irradiated food can become widespread, certain impediments to its acceptability must be overcome. The purpose of Part One of this study is to examine the uses of irradiation and its effects on world food production as well as the impediments to its widescale use and the methods which are or can be used to surmount these obstacles. In this latter respect, particular emphasis will be placed on the role of international co-operation in encouraging acceptability of irradiated foodstuffs. Part Two provides an outline of national legislation in this field.

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II. Uses and Effects of Food Irradiation

Generally, foodstuffs are treated with irradiation¹ for one of the following reasons. inhibition of sprouting, retardation of the ripening process, control of insect infestation or destruction of pathogenic micro-organisms. The potential effects of these food preservation and processing treatments on world food supplies are fourfold.

First, by reducing post-harvest storage losses, preserving quickly perishable food and extending storage life at both normal and refrigerated temperatures, irradiation can increase existing food supplies significantly, thereby meeting the world's growing need for food. Second, prolongation of storage life can facilitate a wider distribution of foodstuffs by enabling export to those countries where transportation time previously made such distribution impossible. In this way, a more varied and nutritionally superior diet can be made available. Third, irradiation can reduce the incidence of food-poisoning and transmittal of parasitic disease by eliminating pathogenic organisms and controlling microbial contamination during food preparation. Fourth, the possibility of utilising cheaper methods of transportation and storage, particularly where expensive, energy-consuming refrigeration can be avoided, may result in lowering the cost of food to consumers.

Some advantages accruing from food irradiation are especially most urgently needed in those developing countries characterised by problems of undernourishment, tropical or sub-tropical climates and alternative food preservation methods. Not only are the climatic conditions in these countries conducive to rapid food spoilage but any increase in production resulting from the use of high yield potential crops is hampered by grossly inadequate storage and preservation practices. A further factor affecting the food trade in such countries is that of health hazards caused by food-borne micro-organisms and parasites. The use of irradiation to improve food hygiene is thus especially important in these areas.

Apart from its potential effects on world food supplies, the actual process of irradiation offers several advantages over more conventional preservation and processing techniques. Irradiation is a physical process for the treatment of foods and, as such, is comparable to heating or freezing food for preservation purposes. Unlike heating, however, irradiation leads to little, if any, rise in the temperature of treated food, thus making possible the distribution of frozen food and distribution of foods in their fresh or near-fresh state. The technique may be used in combination with more conventional methods but also can achieve effects unattainable by these processes, such as disinfection and decontamination of large volumes of food. Finally, and in line with current world

Irradiation is accomplished by exposing foodstuffs to ionizing radiations from gamma or X-rays, beams of electrons or negative beta particles until the required dose has been absorbed. The proper dosage, required radiation treatment and type of packaging material will depend upon the particular foodstuff treated and the purpose of the treatment. To ensure compliance with these specifications, the irradiation process must be strictly controlled in accordance with government regulations. See section IV.C.

concerns, irradiation is an environmentally clean and energy saving process that offers an alternative to the use of chemical treatments and other food additives which have become a matter of concern for health authorities.

III. Impediments to Commercialisation

Despite the many advantages of food irradiation and the scientific evidence on its feasibility and on the wholesomeness of food so treated, widespread use of the process has not been realised. The difficulty lies in the existence of two major, and inter-related, obstacles: public acceptance and general lack of trust in foreign irradiated products on the part of national competent authorities. Full commercialisation depends on the success with which these obstacles can be overcome.

The problem of public acceptance arises from the fear of radioactivity and irradiation that exists among the general public. Clearly, the potential advantages of food preservation will have little effect if no one will purchase the goods. The public, therefore, needs assurance that irradiated foodstuffs are nutritionally wholesome and safe for consumption over long periods of time. To do so, however, more than scientific evaluations of the nutritional, toxicological and microbiological aspects of such foodstuffs must be put forward. Irradiation must also be shown to have been performed in an approved and acceptable manner. Government control of the process at both national and international levels, with the concomitant knowledge that irradiation is strictly regulated, that only methods acceptable to the competent authorities are permitted and that irradiation is carried out by competent personnel, would provide the necessary assurance.

Similar assurance is needed to overcome governmental resistance to international trade in irradiated foodstuffs. Because it is technically extremely difficult to determine whether or to what extent food has been irradiated, the usual method of sampling to ensure that imported foods meet the required standards is ineffective. The development of international trust in the irradiation procedures utilised in foreign countries would ease import restrictions and encourage international trade in irradiated foodstuffs.

The means of promoting this trust have the added advantage of providing the assurance needed to attain public acceptance. For instance, because the only possible place to guarantee that irradiation is properly carried out is the facility itself, an effective regulatory system established at this level would ensure compliance with relevant standards. It then follows that harmonization of this legislation should be achieved in order to establish internationally accepted standards of wholesomeness and treatment. The combination of these two methods would not only facilitate international trade by ensuring that irradiated foodstuffs are of comparable quality regardless of source country, thereby promoting mutual acceptance of goods, but would also increase public confidence by guaranteeing proper regulation and commonly acceptable standards.

Because the preservation of foodstuffs through irradiation can have valuable and far-reaching effects on world food supplies and health, this field is a prime example of the use that can be made of international

operation in the peaceful uses of nuclear energy. The establishment of international guidelines as a means of harmonizing national legislation, as we stated, is one feature of this co-operation.

In addition, the international exchange of information and the coordination of or co-operation in food irradiation research is of utmost importance in enabling governments to dispel distrust of irradiated stuffs. Addressing the issue in an international context should remove grounds for refusing acceptance of the process.

Widespread use of irradiation as a food preservation technique thus depends upon the ability of these three measures - international co-operation, harmonization of legislation and national regulatory control - to achieve the dual goals of public assurance and international trust. The status of these three techniques is examined in the following section.

IV. Achieving Acceptability and Health Protection

A. International Co-operation

International co-operation is particularly advantageous in the field of food irradiation. Exchange of information on this level not only encourages governmental acceptance of scientific evidence and safety assessments obtained in other countries but also avoids wasteful duplication of effort among national food irradiation programmes. That an active interest exists in such matters is demonstrated by the numerous meetings and conferences which have taken place on the topic of food irradiation since the 1950s². Evidence is provided by the success of such joint undertakings as follows:

the International Programme on Irradiation of Fruit and Fruit Juices at the Austrian Nuclear Research Centre (Österreichische Studiengesellschaft für Atomenergie GmbH) at Seibersdorf, Austria. The so-called Seibersdorf Project was established by an Agreement on 16th September 1964 between the then OECD European Nuclear Energy Agency, the International Atomic Energy Agency and the Austrian Nuclear Research Centre; it covered the period 1st January 1965 to 30th June 1968;

- the International Project in the Field of Food Irradiation, sponsored by the OECD Nuclear Energy Agency (NEA) with the

These meetings include, inter alia: the 1980 Sri Lanka IAEA Special Committee on Legislative Aspects of Food Irradiation; the 1969, 1976 and 1980 meetings of Joint FAO/IAEA/World Health Organisation (WHO) Expert Committees on the Wholesomeness of Irradiated Food; the 1972 Vienna Consultation Group on Legal Aspects of Food Irradiation; meetings of the FAO/WHO Codex Alimentarius Commission and its Committee on Food Additives, and the congresses held at Karlsruhe (1966), Rome (1964), Brussels (1961) and Harwell (1958).

collaboration of the Food and Agricultural Organisation (FAO) and the International Atomic Energy Agency (IAEA) administered by NEA with its scientific direction at Karlsruhe, Federal Republic of Germany, to investigate the wholesomeness of irradiated foodstuffs and to assist authorities in considering acceptance of irradiated foodstuffs; this Project was set up by an Agreement concluded on 14th October 1970 by organisations from 19 countries and was terminated on 31st December 1981 when its objective of securing an international recommendation for the unconditional acceptance of all foods irradiated up to an average overall dose of 10KGy (a level which meets all practical commercial requirements) had been achieved. During its lifetime, organisations from 26 countries³ participated in the Project's activities;

- the International Facility for Food Irradiation Technology, established in 1978 by the FAO/IAEA and hosted by the Netherlands at Wageningen; it offers training programmes in the technology, economics and commercial aspects of food irradiation;
- the FAO/IAEA Co-ordinated Research Programme on Technology and Wholesomeness of Food Irradiation, set up in 1974 to establish the technical feasibility of irradiation and to demonstrate the wholesomeness of individual food items;
- the Asian Regional Co-operative Project on Food Irradiation established by an Agreement which entered into force on 28th August 1980; the Project conducts research and development to achieve commercialisation of irradiated foodstuffs of interest to the region. The Agreement establishing the Project was extended twice; the Second Extension Agreement entered into force on 28th August 1984 for a further period of three years;
- the FAO/IAEA/WHO International Consultative Group on Food Irradiation which held its first meeting in 1984, the main objectives of which are to further the development and commercialisation of food irradiation and to assist Member States, in particular developing countries, in the promotion of wholesome food supplies and proper nutrition.

These and numerous other activities demonstrate the world-wide interest in food irradiation technology. But international information exchange alone will not guarantee widespread acceptance of irradiated foodstuffs. As discussed below, mutually dependent methods of international harmonization of legislation and strict regulatory control are needed as well.

B. Harmonization of Legislation

The need to establish a legal framework that would serve as a basis for harmonization of national legislation was recognised at those meetings

³. Australia, Austria, Belgium, Brazil, Canada, Denmark, Finland, France, Federal Republic of Germany, Ghana, Hungary, India, Iraq, Israel, Italy, Japan, the Netherlands, Norway, Portugal, South Africa, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States.

mentioned in Part IV.A as well as in the European Economic Community's 1972 Protocol for harmonization of legislation regarding irradiated foodstuffs and the Advisory Group Meeting on International Acceptance of Irradiated Food. As a result of several of these meetings, draft guidelines for legislation on irradiated foodstuffs were drawn up reflecting the commonly felt needs to be met by such regulations.

The similarities among the proposed guidelines allow certain realisations to be made. Foremost is the fact that the purpose of any food irradiation legislation is to ensure that food and its ingredients do not pose a hazard to public health. With this objective in mind, the guidelines address the major areas that legislation should involve: 1) specific authorisations to irradiate certain foodstuffs given by a competent authority, 2) regulation of the irradiation process itself; 3) establishment of enforcement procedures to ensure compliance with processing regulations; and 4) regulation in the processing areas of storage, trade, import and export.

In 1983, the FAO/WHO Codex Alimentarius Commission, which establishes the international standards to govern international trade in food commodities, adopted a Code of Practice for Irradiated Foods and a Code of Practice for the Operation of Irradiation Facilities Used for the Treatment of Foods. Because many, if not most, of the guidelines recommended by the above groups find a counterpart in the Codex Standard or Code, a brief review of the salient features of these documents may be useful.

As is common with all of the guidelines, the General Standard establishes a general prohibition against irradiation. Two types of exemption from this prohibition exist: a specific exemption granted by a competent authority for designated foods and purposes and a general exemption for any food exposed to a dose of 50 rad or less. A thorough evaluation of the irradiated food by the competent authority is required from the toxicological, nutritional and microbiological points of view to determine its safety and wholesomeness. At the international level, this authority would be a Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Foods. Only foods so evaluated and approved would be deemed acceptable.

Regarding regulation of the irradiation process itself, the Standard sets forth the specific radiation sources, energy level and dose range to be used for each food type. The treatment is to be carried out only in facilities licensed and registered for this purpose by the competent national authority and staffed by "adequately trained and competent personnel." Other regulations regarding the irradiation process are provided in the Code of Practice, which covers such topics as operating parameters, dosimetry, separation of irradiated products and source movement in different types of facilities. To ensure compliance with these procedures, the Standard also establishes record-keeping and inspection practices.

Concern that foodstuffs meet general requirements for food processing in addition to those laid down specifically for irradiation is demonstrated by the provision that the treatment take into consideration "requirements of safety and efficacy of food processing." Moreover, the food to be irradiated, along with its packaging material, must be of suitable quality and acceptable hygienic condition.

In the area of post-processing regulations, the Standard is less complete than that of other guidelines. Thus, while the Standard mandates that labels be used for the information of consumers, for trade and for further purposes of control, the actual labelling requirements are vague. The Standard also fails to establish import-export regulations or to provide specific guarantees to importers of proper processing and wholesomeness.

Although the Codex Standard and Code fail to cover other areas addressed by the guidelines, such as regulation of storage practices and prohibition of induced radioactivity, they do provide an overview of the type and extent of regulation needed in this field. How well national legislation accords with these principles will next be examined.

C. National Legislation

1. General Overview

As previously indicated, one reason that widespread use of irradiation has not been realised is the public's misconception that food so treated may have become radioactive. Research has shown, however, that irradiation with certain sources and at certain levels will not induce radioactivity⁴. Rather, foods properly treated present no health hazard nor is their wholesomeness or nutritional value impaired. The aim of national legislation, therefore, is to ensure that irradiation is properly carried out.

To accomplish this purpose, a dual regulatory scheme is used. The need for such a scheme arises because of the fact that an irradiated foodstuff is not a radioactive item and, consequently, falls outside the scope of current nuclear energy acts, which cover the use of ionizing radiations. Thus, one regime of nuclear legislation to protect the public and workers against the dangers of radiation is established for approval of the facility and operation of the plant while a second regime of general food legislation, covering manufacturing and trade in food, is utilised to ensure the safety and wholesomeness of such foodstuffs for the public.

Those countries that have promulgated food irradiation legislation within this second regime have invariably done so by imposing a general prohibition on the process with the possibility of obtaining exemptions from a competent authority, usually a government department responsible for food standards. All such legislation similarly specifies the level of radiation permitted and the authorised irradiation source or provides that the exemption order so provide, with the clear aim of preventing induced radioactivity. These general provisions rest on the basic assumption that protection of the public can best be achieved by subjecting food irradiation to authorisation and control before allowing foodstuffs on the market. A corollary principle is that any authorisation so granted must be based on scientific evidence establishing the safety of irradiated foods for human consumption.

4. It is now generally accepted that irradiation with cobalt-60 or cesium-137 or beta energies below 10 MeV presents no danger of inducing radioactivity in foodstuffs.

2. Legislative Summary

Apart from these basic principles and underlying assumptions, national legislation varies considerably in its treatment of the irradiation process, its rules on trade and its clearance of foodstuffs. These differences can be seen in the overview of existing national legislation provided in Part Two.

As demonstrated in the overview, the competent authority for granting requested exemptions is generally the state health authority; however, authorisations in several countries additionally require joint action with other governmental bodies, action only upon the advice or consultation of one or more health care or scientific bodies and, in one instance, parliamentary approval. The authorisations that are granted may be in the form of amendments to acts, regulations, decrees or ministerial orders. Distinctions in some legislative measures between the use of irradiation for measurement and control and for purposes of preservation. Other address this question. Similarly, several countries provide for irradiation below a specified energy level, others do other technicalities of the irradiation process, as well as the that have been cleared for irradiation, differ greatly among the legislative measures.

In addition to the disparities in national provisions, current legislation is marked by several shortcomings. For instance, either through provision or by overall context, irradiation is usually treated as a preservative. As previously noted, however, irradiation is a physical method of preservation and therefore differs fundamentally from the use of preservatives. This situation arose when irradiation first became practicable and of regulation was needed. The obvious solution was to utilise preservative procedures, which generally were designed to regulate processing with preservatives. Current legislation should recognise that differences between these methods so that use of irradiation will not be further regulated by a regulatory system designed to accomplish a different purpose.

A second shortcoming concerns measures to protect against induced radioactivity. While source and energy levels are generally designated either in legislation or relevant authorisations, few regulatory measures include provisions to ensure compliance with these, or other, processing requirements. Record-keeping, surveillance and inspection procedures are covered and labelling requirements are notably vague. In this latter area while most legislation does require some form of labelling, specific labels are seldom required to be designated. Labels must indicate that irradiation has taken place but inclusion of such information as source, dose, energy level, date and place of irradiation and similar technicalities of the irradiation process are rarely addressed. If re-irradiation, with the associated risk of induced radioactivity, is to be prevented, detailed provisions should be established. Similarly, if public and consumer assurance in the efficacy of irradiated foodstuffs is to be maintained, strict compliance with the rules and labelling procedures are of great importance.

Other areas infrequently covered concern such matters as the quality of foodstuffs prior to processing, the type of packaging to be used, methods of irradiation of foodstuffs intended for animal consumption and general provisions for foods irradiated below set dosages. Likewise, legislation

fails to distinguish between fixed and mobile irradiation installations or between irradiation used as the sole method of preservation and in combination with other methods.

Perhaps the area least regulated is that of international trade. Of the laws and regulations surveyed, only those of Belgium, Brazil and France have specific rules concerning exports while only those of France, the Federal Republic of Germany, Israel, Switzerland and Thailand specifically regulate import. As noted in Part III, failure to promote international trade in irradiated foodstuffs is one of the primary barriers to full commercialisation of such products.

Finally, it should be noted that in those developing countries where the benefits of food irradiation would be most greatly felt and are most urgently needed, the legislation is either totally inadequate or non-existent. Unless this situation changes, the advantages of the irradiation process will not reach their full potential.

IV. Conclusion

As of 1980, twenty-two countries had authorised, unconditionally or provisionally, the treatment of one or more foodstuffs for marketing. The total number of foods so authorised was thirty-nine. According to a 1980 FAO/IAEA survey of twelve of these foods, 134,225 tons of irradiated foodstuffs had been produced and marketed in fourteen countries⁵. This same survey indicates that in at least twenty nations private industry alone or in conjunction with governmental institutions, is developing commercial irradiators for use as food treatment or multipurpose units while pilot facilities have been established in several developing countries.

Given the fact that experience with irradiation has existed for nearly three decades, these figures represent very slow progress in the development of the process as a viable food preservation technique. Nevertheless, the degree of international co-operation evidenced in this area demonstrates worldwide interest in food irradiation. The report of the 1980 Joint Expert Committee, which for the first time, made a general recommendation on the acceptability of irradiation as a preservation process for all foods, marked the beginning of a new era for food irradiation processing and an upsurge of interest is becoming increasingly apparent. Continuation of such co-operation is particularly necessary given the current state of national legislation, which generally regulates the many areas involved in greatly varied or inadequate ways. Moreover, many developing nations that could benefit most by the process have not yet begun to legislate in this field. Complete control through national regulation with a concomitant harmonisation of legislation

5. The surveyed foods included potatoes, wheat flour, onions, mushrooms, spices, mangoes, papaya, strawberries, fish filets, frozen seafood and frogs legs, and predigested liquid animal protein, treated in Australia, Canada, Chile, France, the Federal Republic of Germany, Hungary, Israel, Italy, Japan, the Netherlands, South Africa, Thailand, Uruguay and the United States. See Food Irradiation Newsletter, Vol. 4, No. 3, October 1980 of the Joint FAO/IAEA Division of Isotope and Radiation Applications of Atomic Energy for Food and Agriculture Development.

the public acceptance and international trust needed to bring commercialisation of the food irradiation process and a realisation of accompanying benefits.

PART TWO: NATIONAL REGULATIONS⁶

2.1 - New South Wales

Only the State of New South Wales has legislation specifically dealing with food irradiation. Although there is no specific federal or other act or regulation in this area, the States of South Australia, Western Australia, Australian Capital Territory and Northern Territory do prohibit the manufacture and sale of irradiated foods with exemptions provided by specific orders of the Health and Medical Research Councils after consultation with the Food Irradiation Sub-committee of the Food Additives Committee. Irradiation is controlled under general provisions of food legislation as a food additive.

The Food Act of 1976 of New South Wales.

2.1.1 Areas

General Purpose

Prohibition without exemption of the manufacture, production packaging and sale for human consumption of foods that have been accidentally irradiated.

There is a general prohibition with the possibility of obtaining exemptions by special authorisation for the manufacture, production and sale of food for human consumption that has been intentionally exposed to irradiation.

Competent Authority

The Director General of the Health Commission is responsible for issuing specific authorisations.

The following survey which is not exhaustive is based on information currently available to the OECD Nuclear Energy Agency.

AUSTRIA

Relevant Legislation

Food Law of 1975 (Lebensmittelgesetz 1975).

Regulated Areas

A. General Purpose

Prohibition with exemption of the treatment or marketing of designated irradiated foodstuffs, consumption products or additives.

B. Processing

No specific procedures are established in the Law; however, the decree authorising the exemption is to set forth the particular requirements of the irradiation procedure, safety precautions and labelling.

Competent Authority

Exemptions are granted by the Federal Minister for Health and Environmental Protection after review of an application that includes all information allowing an evaluation of the irradiation procedure and the irradiated goods. The exemption is in the form of a decree whose period of validity cannot exceed three years.

BELGIUM

Relevant Legislation

The Order of 16th July 1980 on treatment by ionizing radiation of foodstuffs destined for human or animal consumption and its amending Orders of 16th October 1980 and 29th September 1983; the 1963 Royal Order laying down general regulations for the protection of the population and of workers against the hazards of ionizing radiation, as amended.

Regulated Areas

A. General Purpose

General prohibition with exemption of treatment for sale of designated irradiated foodstuffs for human and animal consumption. Exemptions are provided only for those foods listed in the annex to the Orders.

B. Processing

The Annex to each Order sets forth, with regard to each designated food item, the purpose for which irradiation is allowed, the specific irradiation source and dosage and the duration of the exemption. Mention is also made of product packaging but no specific requirements are set forth.

time foodstuffs are to be irradiated, prior notice must be given to the Director of foodstuffs for the relevant jurisdiction.

Following items have been listed in the Annexes as cleared for export:

Potatoes - Inhibition of germination (authorised duration of 10 years).

Onions, garlic and shallots - Inhibition of germination (provisional authorisation).

Strawberries - Destruction of microorganisms to prolong storage life (authorised duration of 10 years).

Paprika, pepper and other designated spices and aromatics, certain dehydrated and dried vegetables - Decontamination of micro-organisms (provisional authorisation).

Certain laboratory animals - Radicidation and radappertization⁷ (authorised duration of 3 years).

Export of foods other than those listed in the Annexes is permitted to countries which have authorised their importation, provided the accompanying documents and labelling clearly state that the foodstuffs are intended for export.

Specific labelling requirements for each foodstuff are set forth and must include the name of the irradiation facility, the date of irradiation, the identification code for the lot and the wording to be used. All commercial labels must state that the foodstuffs have been irradiated.

Authority

Orders granting exemptions are issued by the Minister of Public Health and the Environment upon receiving a favourable opinion from the Supreme Council of Public Health.

Radappertization refers to the process of irradiating foodstuffs for the purpose of eliminating pathogenic micro-organisms. Radappertization refers to sterilization by means of radiation.

BRAZIL

Relevant Legislation

1973 Decree (N°72.718) laying down general standards for irradiated foodstuffs.

Regulated Areas

A. General Purpose

Prohibition with exemption of the distribution, sale, storage, transport, import and export for human consumption of irradiated foodstuffs.

B. Processing

The competent authority establishes lists of foodstuffs whose irradiation is permitted setting forth, for each item, the specific source, dose, energy level and purpose of the irradiation together with other required treatments. Provision is also made for the quality of products prior and subsequent to irradiation. Only facilities licensed by the competent authority and authorised by the National Nuclear Energy Commission may carry out irradiation of foodstuffs.

C. Trade

Export is permitted and, in such case, the foodstuffs need not be processed as above but may be treated in accordance with the standards of the importing country.

There are specific labelling requirements.

Competent Authority

Permitted foodstuffs lists are drawn up by the Standards Commission for Foodstuffs of the Health Ministry on the proposal of the National Nuclear Energy Commission and after review of scientific and technical data on the innocuousness of irradiated foodstuffs, the effects of irradiation on nutritional value and wholesomeness and the efficiency of the operation.

CANADA

Relevant Legislation

Food and Drug Regulation, as amended 1966. Under this Regulation, irradiation is defined as a food additive and therefore comes under general federal legislation. Irradiation is contained in the list of permitted additives.

Areas

General Purpose

prohibition with exemption by special authorisation for treatment of irradiation.

Processing

Requirements for irradiation source and dosage are specified as well as those of the treatment and the type of clearance granted.

The following items have been listed in the regulations as cleared for sale:

Potatoes and onions - Anti-sprouting (unlimited clearance).

Wheat, whole wheat flour and flour - Disinfestation (unlimited clearance).

Poultry - Radicidation (marketing test).

Cod and haddock fillets - Radurization⁸ (marketing test).

Provision is made for inspection and control of the irradiation under the joint responsibility of the Food and Drug Directorate and the Radiation Protection Division of the Department of National Health and Welfare.

Trade

All food additives must be declared on a label. No specific requirements are set forth as to the type of statement required on potato, cod, haddock or onion packaging but mandatory wording is provided for each.

Authority

Authorisation is granted in the form of amendments to the Regulation by Order-in-Council on the recommendation of the Department of National Health and Welfare after receipt of information on food safety and on the

radiation refers to elimination by irradiation of micro-organisms to prevent food spoilage.

DENMARK

Relevant Legislation

Order No. 413 (1967) concerning treatment of foodstuffs by means of ionizing radiation pursuant to the Foodstuffs Act No. 174 (1950).

Regulated Areas

A. General Purpose

Prohibition with exemption by special permission for treatment and import.

Prohibition with exemption for purposes of control and measurement at specified dosage and energy level.

B. Processing

Specific dosages and radiation levels are set for individual commodities.

Unlimited clearance has been given for the irradiation of potatoes to inhibit sprouting.

Inspections are carried out by the Ministry of the Interior.

C. Trade

Import of irradiated foodstuffs is permitted subject to certain restrictions.

Labelling is required with mandatory wording.

Competent Authority

Authorisations are granted by the Ministry of the Interior upon the recommendation of the Board of Public Health.

FRANCE

Relevant Legislation

Decree No. 70-392 (1970) and Decree of 12th February 1973, both enacted pursuant to the 1905 Act concerning prevention of fraudulent practices in respect of trade in merchandise to be used as food for human and animal consumption; two Orders of 8th November 1972 implementing the 1970 Decree with regard to general exemptions and trade in potatoes; Order of 6th August 1974 concerning laboratory co-operation in implementing the

1975 Order regarding trade in compound irradiated foodstuffs
bulbs; and the 1984 Order on trade in garlic, onions and
by ionizing radiation.

1 Purpose

ion with exemption for treatment or sale of foodstuffs or
materials and objects that come into contact with foodstuffs for

of imports unless the exporter has equivalent provisions

exemption for foods irradiated below a specified dose rate

2 Sing

ations regarding source, dosage, energy level, criteria of
for consumer protection and enforcement procedures are set
authorisation order.

ion procedures that would induce radioactivity are prohibited.

ation has been given for irradiation of the following items:

garlic and shallot bulbs - to inhibit germination. The
ion Order further requires the separation of irradiated and
irradiated bulbs and forbids the use of chemical preservatives
before or after irradiation.

potatoes - to prevent sprouting. The exemption Order also sets
the specifications for the potatoes to be irradiated and
regulations for packaging, distribution and operation supervision
(authorised for 5 year period).

and foods for laboratory animals with specific regulations
concerning use of such foods in animal experiments, packaging of the
foodstuffs, and record-keeping and surveillance practices
(authorised for 3 year period).

ion Order also sets forth requirements for labelling both
before sale. Information from the label is also to be included on
label of sale and all other accompanying documentation.

is permitted if the laws of the exporting country are equivalent
regulations and if the foodstuffs are accompanied by a
statement indicating that they have been irradiated according to these

Competent Authority

Irradiation exemptions and conditions are established by a joint order of the Minister of Agriculture, the Minister of Public Health and Social Security and the Minister of Economics and Finance after consultation with the Superior Council of Public Hygiene, the National Academy of Medicine and the Interministerial Commission for Artificial Radioelements.

The Service for Repression of Fraudulent Practices and Quality Control is responsible for overseeing compliance with the regulatory provisions.

FEDERAL REPUBLIC OF GERMANY

Relevant Legislation

1936 Food Act, as amended (1958) and the Regulation on the Irradiation of Food (1959).

Regulated Areas

A. General Purpose

Prohibition with exemption by special authorisation for treatment for measurement and control.

General exemption for purposes of quality and quantity control of foods irradiated below a specified dosage level.

Prohibition of import unless the product was irradiated in conformance with German law.

Export is not restricted.

B. Processing

Authorisation has been granted by specified source and dose for purposes of testing and measurement and for sterilisation of water and the surfaces of fruit, vegetable preparations and hard cheese.

Authorisation has been given to irradiate potatoes in experimental batches for sprout inhibition and to sterilise deep frozen meals intended for consumption by hospital patients.

C. Trade

Labels are required but exemptions from this requirement may be granted.

Competent Authority

Authorisations are granted in the form of regulations issued by the Federal Minister of the Interior in collaboration with the Federal Minister of

Ministry of Agriculture and Forest, the Minister of Economics and the Minister of Scientific Research on approval of the Bundesrat.

Legislation

Public Health (Preservation of Foodstuffs by Radiation) Regulations
as amended, issued pursuant to the Public Health (Rules as to Food)

Areas

... specific exemption for treatment and sale.

... import unless the goods meet the required standards for

Regulations

... foodstuff, class of radiation, source and dose are
Regulations. Instructions on the method of irradiation are
an accompanying permit.

... has been granted for the following items:

... and onions - prevention of sprouting (unrestricted
...).

... is required with mandatory wording prescribed.

... must submit the following documents to the Israeli customs
a declaration from the authorities in charge of food
... exporting country indicating the type and method of
... 2) a certificate that the irradiation was carried out in
... Israeli regulations.

-General, Ministry of Health is responsible for issuing the

ITALY

Relevant Legislation

Ministerial Decree regarding preservation of potatoes, onions and garlic by gamma radiation treatment (1973) issued pursuant to the Public Health Act 1962 regarding trade in foodstuffs and beverages that have undergone special treatment.

Regulated Areas

A. General Purpose

Prohibition with exemption for treatment, trade and sale.

B. Processing

Authorisation has been given for possession and trade of potatoes, onions and garlic to inhibit sprouting (unlimited clearance).

C. Trade

Labelling may, but need not, be prescribed in the authorisation.

Competent Authority

Authorisation is in the form of a ministerial decree issued by the Minister of Public Health after consultation with the High Council of Health.

JAPAN

Relevant Legislation

Food Sanitation Law (1947), as amended, and the 1972 Special Regulations for Control of Irradiated Potatoes.

Regulated Areas

A. General Purpose

Prohibition with exemption for processing and sale.

Prohibition of imports with the exception of potatoes.

Prohibition with exemption for the control of machinery at food processing plants within a specified dose range or when a specified processing standard is used for each food.

licensing for the irradiation facility must be granted and a supervisor assigned.

The Governor establishes standards for the facility and for records, including record-keeping procedures. The Governor is also responsible for food inspections and for food sanitation administration.

There has been given to irradiate potatoes to inhibit sprouting. Licensing regulation establishes such processing conditions and specifically prohibits re-irradiation. The facility has received unconditional acceptance for human consumption. Licensing has also been given to irradiate onions.

is required.

For exemption is granted by regulation of the Minister of Health after determination by the Food Sanitation Investigation Commission that irradiated foodstuff is not harmful to human health. The license to operate the facility itself is granted by the

Energy Act, as amended; Radioactive Materials Decree

Purpose

Under the Radioactive Materials Decree, a license is required to use a radioactive source. If that source is used for food irradiation, specific regulations provide that food cannot be irradiated without a license in one of three categories: testing, limited public distribution, or general distribution.

A license has been granted for the following items:

Small batches

Irradiation of asparagus, strawberries, shrimp, and eviscerated (in plastic bags) and endive

- . disinfection of cocoa beans
- . radication of spices, condiments, vegetable fillings and powdered batter mix.
- Unlimited clearance
 - . radappertization of deep frozen meals and fresh, tinned or liquid foodstuffs for hospital patients
 - . radurization and radication of chicken
 - . inhibition of sprouting in potatoes and onions
 - . inhibition of growth in mushrooms
- Provisional acceptance has also been given to irradiation of soup greens, fish, frozen frogs legs and rice.

C. Trade

Labelling is required.

Competent Authority

Permits are issued by the Minister of Public Health and the Environment upon the advice of the Public Health Council, the Food Directorate and the Radiation Directorate. The opinion of the Directorates is based largely upon their examination of documents supplied by the applicant containing data on wholesomeness and on the method of processing.

SOUTH AFRICA

Relevant Legislation

Foodstuffs, Cosmetics and Disinfectants Act (1972); Government Notice No. R.172 (1974); Regulation on Irradiated Foodstuffs (1974).

Regulated Areas

A. General Purpose

Prohibition with exemption for sale by special authorisation.

B. Processing

Unlimited clearance has been granted to irradiate potatoes for inhibition of sprouting and mangoes to control ripening. Unconditional acceptance has also been granted to irradiate onions, garlic, chicken, papaya and strawberries; provisional acceptance has been granted for dried bananas and avocados.

Authority

Orders are granted by the Minister of Health.

Regulation

No. 2725 regulating the procedure for approval of preservation of foodstuffs intended for human consumption (1966).

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Regulatory Purpose

Prohibition with exemption for treatment, sale, trade, import and foodstuffs, components and packaging materials.

Licence designates the type of food, the manner of use, energy level and packaging criteria and the and control.

of the Interior conducts inspections to ensure compliance while the Nuclear Energy Board supervises the irradiation

and clearance has been granted for potatoes and onions to inhibit

contains labelling requirements.

y

Orders are granted by the Minister of the Interior and also, for sale or trade in irradiated foodstuffs, by the Minister of Consultation with the Consultative Group on Food Irradiation in the Department of Health of the Ministry of the Interior.

or

Act on Radiation Protection; 1960 amendment to the Marketing of Foods and Commodities issued pursuant to the 1905 Act of Foods and Commodities.

Regulated Areas

A. General Purpose

Prohibition with exemption by specific authorisation for treatment, sale and import.

B. Processing

The authorisation prescribes the irradiation source and dose, the exact packaging to be used, and the gaseous environment during the process. Periodic controls of the process and performance of tests are also established.

C. Trade

Labelling is not required.

Requests for an authorisation to import must be accompanied by all the evidence submitted to the authorities of the exporting country.

Competent Authority

Authorisations are granted by the Federal Service of Public Hygiene upon proof that irradiation does not cause dangerous alterations in food characteristics.

THAILAND

Relevant Legislation

Food Control Act (1979), Notification of the Minister of Public Health No. 10 (B.E. 2522).

Regulated Areas

A. General Purpose

Licence required for production, distribution, sale, import and export.

B. Processing

Unlimited clearance has been given for the irradiation of onions to inhibit growth. The authorisation notice specifies the irradiation source and dose.

C. Trade

The authorisation notice requires labelling. For imports, especially detailed labelling instructions are set forth, including the requirement that the label be in Thai and that it indicate the type of treatment, the name and number of the food registration, the name and address of the manufacturer, the date of irradiation and the net weight.

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ing and regulatory authority is the Food and Drug
Ministry of Public Health.

tion

Control of Irradiation) Regulation (1967) and Food (Control of
(~~Control~~) Regulations (1972), both issued pursuant to the Food
1965).

al Purpose

tion with general exemption for foods irradiated with less than
energy level not exceeding 5 million electron volts.

tion with exemption only for irradiation of food for patients
requiring a sterile diet as an essential factor in their
provided the person irradiating the food notifies the Department
Social Security and keeps records.

ity

isations are provided jointly by the Minister of Agriculture,
Food and the Minister of Health and Social Security on the
Advisory Committee on the Irradiation of Food.

islation

Drug and Cosmetic Act (US Code Title 21) and its 1958 Food
~~Act~~, 1976 amendment and 1977 Regulations. Under this
the term "food additive" is defined to include any source of
Food is deemed to be adulterated if it is intentionally subjected
in accordance with the relevant regulation.

as

al Purpose

'bition with exemption for treatment, trade, import and export of
additives and packaging materials.

General exemption for inspection and control of food processing with irradiation from a specified source and below a maximum dose.

B. Processing

Regulations establish the energy level, source and dose for each foodstuff or packaging material.

Inspection and record-keeping procedures are set forth.

Authorisation has been granted for the following items:

- Wheat and wheat flour - disinfestation (unlimited clearance).
- White potatoes - inhibition of sprouting (unlimited clearance).

Authorisation has also been granted to irradiate certain packaging materials as well as food and food products for surface micro-organism control and to sterilise potable water used in food production.

C. Trade

Labelling is required with mandatory wording set forth.

Competent Authority

Authorisations are granted in the form of regulations issued by the Secretary of Health and Human Services. The Food and Drug Administration, under authorisation by the Secretary, is responsible for carrying out inspections. Information on the toxicological, nutritional and microbiological aspects of food irradiation is provided by numerous bodies: Division of Food Standards and Additives, Division of Toxicological Evaluation, Division on Nutrition, Division of Food Chemistry, Division of Microbiology and the Public Health Service's Office of Radiological Health.

YUGOSLAVIA

Relevant Legislation

1984 Regulation on conditions under which foods and articles of general use, preserved by irradiation, may be commercialised (Federal Official Gazette No. 68/84).

Regulated Areas

A. General Purpose

The Regulation is based on the 1978 Act on the hygienically acceptable condition of foods and articles of general use (Federal Official Gazette No. 55/78), and in line with international recommendations in the field of food irradiation, namely the FAO/WHO International General Standard for Irradiated Foods (see Part One IV.B for details on the General Standard).

B. Processing

The Regulation lists the foodstuffs which may be treated by irradiation e.g. corn, onions, spices, chicken and meat.

The collective average absorbed dose for foodstuffs must not exceed 10 kilogray and the general condition for irradiation is that the nutritional value and the physical, chemical and organoleptic properties of the irradiated products must remain unchanged.

C. Trade

The irradiated foodstuffs must bear labels giving, inter alia, the date of irradiation and the name of the company having processed the products.

Competent Authority

The 1984 Regulation on food irradiation was issued by the Federal Committee of Labour, Health and Social Welfare.

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On the basis of limited information, food irradiation legislation in the following countries may be summarised as below:

ARGENTINA

Under the 1971 Argentina Food Code, treatment of foods by irradiation may be authorised by the National Health Organisation upon proof by internationally recognised methods that there is no hazard to the consumer.

INDIA

Although there is no specific legislation concerning food irradiation, clearances have been sought from the Minister of Health through the Central Committee on Food Standards.

KOREA

Recommendations of the FAO/WHO have been accepted. Evaluation and regulation of irradiated foodstuffs is the responsibility of the Minister of Health and Social Affairs after consultation with the National Health Institute and the Committee of Food Deliberation.

LUXEMBOURG

Under the 1967 Regulations issued pursuant to the 1963 Act concerning protection of the public against the hazards of ionizing radiation, food

irradiation is prohibited with exemptions granted by the Minister of Public Health for purposes of treatment and import.

MALAYSIA

Although there is no specific legislation on food irradiation, import of irradiated foodstuffs is prohibited.

PHILIPPINES

There is no formal food irradiation legislation as yet; however, the Food and Drug Administration, the authority for public health clearance, temporarily accepted low dose irradiation of onions and potatoes to inhibit sprouting. The Codex Standard is used as a reference for clearance. Additionally, the Atomic Energy Commission, under the 1959 Rules and Regulations on the Acquisition, Possession and Use of Radioactive Materials, is responsible for licensing irradiation facilities.

SINGAPORE

There is no specific legislation although the laws on food and radiation control may be applied generally. These laws include the Sale of Food Act (1973), the Food Regulations (1974), the Radiation Protection Act (1973) and the Radiation Protection Regulations (1974).

SRI LANKA

Although there is no specific legislation, the 1949 Food and Drugs Act prohibits adding substances that would render food injurious to the public health and, therefore, implicitly covers food irradiation.

SWEDEN

Under the Food Decree (1971), irradiation of foodstuffs is prohibited unless an authorisation has been granted by the National Swedish Food Administration for purposes of treatment.

Summary Bibliography

1. **The Technical Basis for Legislation on Irradiated Food, Report of a Joint FAO/IAEA/WHO Expert Committee, Rome, 21st-28th April 1964; published by FAO and WHO, FAO Atomic Energy Series No. 6, WHO Technical Report Series No. 316, Rome, 1965.**
2. **Analysis of the International Legal and Administrative Regulations on Food Irradiation with regard to the Public Health Aspects, by J. Cornelis, EUR 4466e, 1970.**
3. **Report of a Consultation Group on the Legal Aspects of Food Irradiation, organised by FAO, IAEA, WHO, Vienna, 20th-24th March 1972; published by IAEA, Vienna, 1973.**
4. **Wholesomeness of Irradiated Food, Report of the Joint FAO/IAEA/WHO Expert Committee, Geneva, 31st August-7th September 1976; published by FAO and WHO, FAO Food and Nutrition Series No. 6, WHO Technical Report Series No. 604, Rome, 1977.**
5. **Joint FAO/WHO Food Standards Programme, Codex Committee on Food Additives, Eleventh Session, the Hague, 31st May-6th June 1977.**
6. **Food Irradiation Newsletter, FAO/IAEA, Vol. 4, No. 3, 1980.**
7. **Report of the 1980 Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Foods; IAEA Technical Series No. 231.**

ARTICLES

THE PHYSICAL PROTECTION OF NUCLEAR MATERIAL*

Ha-Vinh Phuong

International Atomic Energy Agency

I. INTRODUCTION

The transport of nuclear material is probably the operation most vulnerable to a threat of, or an attempt at, unauthorised removal or sabotage. Therefore, physical protection against theft or unauthorised diversion of such material is a matter of serious concern among nations.

As the issue may affect public order and security, the responsibility for physical protection of nuclear material and installations within a State or under its control rests entirely with the Government of that State. However, it is not a matter of indifference to other States whether and to which extent that responsibility is being fulfilled. Physical protection has thus become a matter of international concern that requires international co-operation and concerted action. The need for international co-operation becomes evident in situations where the effectiveness of physical protection in one State depends on the taking of adequate measures by other States as well to deter or defeat hostile acts directed against nuclear facilities or material, in particular during transport of such material across national boundaries.

*Lecture given in French at the IAEA Training Course on "Uranium from Mining to the Fabrication of Fuel Elements", held from 15th October to 16th November 1984, at the "Institut National des Sciences et Techniques Nucléaires de Saclay", France. The ideas expressed and the facts given are on the responsibility of the author.

The objectives of the State's physical protection system should be

- a) to establish conditions which would minimize the possibilities for unauthorised removal of nuclear material or for sabotage, and
- b) to provide information and technical support for prompt, co-ordinated and comprehensive measures by the competent authorities to locate and recover missing nuclear material, or to defeat any deliberate action against a nuclear installation, nuclear material or a means of transporting such material that could endanger public health and safety by exposure to radiation.

II. THE IAEA ROLE

In the area of physical protection, the International Atomic Energy Agency (IAEA) has no statutory responsibility - except with respect to nuclear material provided to it and kept in its custody. The IAEA is not vested with any specific function regarding the establishment of physical protection measures or the control of their implementation which are matters entirely within national jurisdictions. Nonetheless, as hostile acts against nuclear material or installations in one country may adversely affect other countries as well, a concerted approach to physical protection at worldwide level has increasingly been considered necessary to ensure adequate security of nuclear facilities and material wherever they may be.

Within this purview, Member States have encouraged the IAEA to play an advisory role in promoting the physical protection of nuclear material and installations. In the early 1970's, the IAEA accordingly convened expert groups, whose work resulted in the publication in 1972 of "Recommendations for the Physical Protection of Nuclear Material", subsequently revised in 1975 and published in document INFCIRC/225 (Corrected).

At its nineteenth regular session in 1975, the IAEA General Conference by a resolution endorsed such publication in noting that it contains "recommendations and explanations as to what can be done by Member States to establish their national systems for the physical protection of nuclear facilities and materials or to improve the quality and effectiveness of such systems". The General Conference also welcomed the intention of the Director General "to review and bring up to date those recommendations regularly to reflect advances made in the state of the art or in the introduction of new types of facilities".

The recommendations in question were further revised in 1977 and published in document INFCIRC/225/Rev.1 to provide guidance to national authorities in the establishment of physical protection measures for nuclear material in use, transit and storage. Many States have based their national systems of physical protection on such recommendations. Through incorporation by reference as guidelines or minimum standards in various nuclear co-operation agreements, safeguards agreements and supply agreements, concluded within the IAEA framework or between States, the IAEA recommendations have become legal norms applying to activities covered by such instruments.

The basic concept of these recommendations is the categorisation of nuclear material, based on its potential hazard which, in turn, depends upon its type, form and quantity. Such categorisation determines the levels of physical protection required. Detailed requirements are specified for each category of nuclear material in use and storage, and during transport.

With respect to nuclear material in use or storage, physical protection is based on a designed mixture of hardware (security devices), procedures for access and surveillance, and facility design and layout. For each facility, the physical protection system should take into account the geographical location and an appropriate assessment of potential threats.

To reduce and prevent possibilities for unauthorised removal of, or deliberate damage to, nuclear material in transport, special attention is to be paid to such measures as:

- minimizing the total time during which the material remains in transit;
- minimizing the number and duration of material transfers;
- avoiding regular movement schedules;
- pre-determination of the trustworthiness of all persons involved in transport operations.

III. CONVENTION ON THE PHYSICAL PROTECTION OF NUCLEAR MATERIAL

Though physical protection is matter entirely within the domestic jurisdiction of States as pointed out earlier, there are issues which could only be effectively coped with through multilateral co-operation and concerted action - in particular, when involving nuclear material during international transport. The need for an international convention on the subject matter was thus recognised long ago, notably in a resolution adopted on 30th May 1975 by the first Review Conference of the Parties to the Treaty on the Non-Proliferation of Nuclear Weapons, held in Geneva. The importance of this question was also mentioned by the IAEA General Conference in its resolution of September 1975 (Resolution GC (XIX)/RES/328) relating to the IAEA recommendations on physical protection, and in the context of these recommendations as well.

In response to these resolutions, the Director General of the IAEA in June 1977 circulated to all Member States a "Draft Convention on Physical Protection of Nuclear Facilities, Material and Transports", elaborated by the United States Government. In September 1977, the IAEA endorsed the Director General's invitation to Member States "to consider the drafting" of such a convention at a meeting of governmental representatives in Vienna (Resolution GC (XXI)/RES/350). In October 1977, 36 States were represented at the first meeting. The negotiations were concluded two years later by the adoption of a Convention on 26th October 1979, 58 States and the European Atomic Energy Community (EURATOM) had participated in the discussions.

The Convention on the Physical Protection of Nuclear Material (reproduced in document INFCIRC/274/Rev. 1), for which the IAEA is the depository, was opened for signature on 3rd March 1980 at the IAEA Headquarters in Vienna and at the United Nations in New York. As at November 1984, 38 States and EURATOM had signed the Convention, and 10 States had ratified it. Though the Convention is not yet in force (21 ratifications are required for its becoming binding), it constitutes a landmark in international co-operation to facilitate the peaceful uses of nuclear energy (for status of signatures and ratifications of the Convention, updated to April 1985, see under "International Atomic Energy Agency" in this issue of the Bulletin)

A. Scope of the Convention

The Convention focuses primarily on the protection of nuclear material during international transport - though several of its provisions also apply to nuclear material in domestic use, storage and transport. The Convention does not apply to nuclear material used for military purposes; its Preamble merely stresses the importance of effective physical protection of such material.

The levels of physical protection to be applied in international transport of nuclear material and the categorisation of nuclear material for determination of the required levels are respectively provided in Annexes I and II, which constitute an integral part of the Convention. Their contents are taken from the IAEA recommendations.

For the purposes of the Convention, "international nuclear transport" is stated to mean "the carriage of a consignment of nuclear material by any means of transportation intended to go beyond the territory of the State where the shipment originates, beginning with the departure from a facility of the shipper in that State and ending with the arrival at a facility of the receiver within the State of ultimate destination". The term "facility" appears in the Convention only in this definition. This term is not defined deliberately, and its interpretation is thus left to the Parties to the Convention. This was a compromise reached after extensive discussions in connection with the scope of the Convention.

Other compromises in this respect are reflected in the somewhat convoluted formulation of Article 2 and the review process established by Article 16. The latter makes it possible to extend the scope of the Convention through review and amendment of its provisions, five years after its entry into force. This corresponded to the views of proponents of a "wide-scope" Convention which would apply comprehensively to nuclear material within the jurisdiction of a State Party.

The question of possible application of the Convention to nuclear material in military use was another controversial issue until late in the negotiations. It was finally agreed to limit the scope of the Convention to nuclear materials used in peaceful activities.

A further item of disagreement until the ultimate stage of negotiation was the participation in the Convention of international and regional organisations. In the end, it was agreed as is provided in Article 18 of the Convention that such organisations may sign or accede to it, provided that

they are constituted by sovereign States and are vested with the competence to negotiate, conclude and apply international agreements in matters covered by the Convention.

B. Undertakings by State Parties

Under the Convention, each Party must take steps to ensure that, during the international transport, nuclear material is protected at the agreed level as long as the material is within its territory or on board a ship or aircraft under its jurisdiction. Each Party also agrees not to export or import nuclear material, or allow its transit through its territory, unless it has received assurances that the nuclear material will be protected during international transport according to the levels based upon the categorisation of nuclear material, as set out respectively in Annexes I and II of the Convention.

A Party must also apply such levels of protection to material which, during transit from one part of its territory to another, will pass through international waters or airspace. The Party responsible for receiving the requisite assurances must provide advance notice of the transfer to the States through whose territory the nuclear material will pass.

In the event of theft or robbery, or any threat of them, the Parties undertake to provide co-operation and assistance to any requesting State in the protection and recovery of the nuclear material involved.

Thus, even States not Parties to the Convention may invoke the benefit of this undertaking - and this is quite an innovation in international law that reflects the objective of facilitating the widest possible international co-operation, irrespective of adherence to the Convention.

The Parties further undertake to consult and co-operate with each other, directly or through international organisations, on matters relating to the design, maintenance, and improvement of physical protection systems for the international transport of nuclear material.

Of particular importance is the strategy against hostile acts involving nuclear material, based on several provisions of the Convention (Articles 7 to 11 and 13). Each party must make such acts serious criminal offences under its legislation, taking into account their grave nature, and subject offenders to prosecution or extradition. These offences include theft or robbery, embezzlement, extortion, and sabotage - that is, any unlawful act that causes or is likely to cause death or serious injury to persons, or substantial damage to properties.

The Convention sets out conditions under which a State must take measures to establish jurisdiction over these offences. Thus a State must establish jurisdiction:

- 1) when an offence is committed within its territory or on board a ship or aircraft registered in that State,
- 2) when the alleged offender is a national of that State; or

- 3) where the alleged offender is present within that State's territory and is not extradited.

In addition, a State may establish jurisdiction over these offences when involved in international nuclear transport as the exporting or importing State. Accordingly, appropriate penalties will apply to criminal acts involving nuclear material, irrespective of whether the material involved is in domestic use, storage, transit, or international transport. The Convention has thus adopted the strategy of "no sanctuary" to cope with criminal acts committed in those circumstances - as have some earlier conventions, in particular those relating to the safety of air transport*.

C. Role of the IAEA under the Convention

The IAEA is not a party to the Convention. In addition to performing the functions of depositary, it has been entrusted with the responsibility of serving as intermediary in informing States of national laws and regulations which give effect to the Convention, of national authorities responsible for physical protection and for co-ordinating recovery and response operations, and of the outcome of the proceedings related to the prosecution of an alleged offender.

Under the Convention, the IAEA has also an important role to play in facilitating international co-operation and in advising and assisting States in the development, maintenance and improvement of physical protection of nuclear material in international transport.

D. Significance of the Convention

It is evident that the improvement of physical protection measures, the uniform application of adequate physical protection to nuclear material, international co-operation and mutual assistance in the event of unlawful acts involving such material, and the establishment of a standardised range of criminal offences to cope with such acts as provided for under the Convention will contribute to ensuring the security of nuclear shipments.

In reducing the risk of, and in deterring and defeating, wilful hostile acts directed at nuclear material in transport, effective physical protection measures and their implementation in a concerted approach among the States involved will also contribute to public and governmental acceptance of peaceful nuclear undertakings by allaying legitimate concerns about the potential effects of any such criminal acts on public health and security.

*See the Multilateral Convention for the Suppression of Unlawful Seizure of Aircraft, The Hague, 16th December 1970, and the Convention for the Suppression of Unlawful Acts against the Safety of Civil Aviation, Montreal, 23rd September 1971. A similar approach also was followed by the Convention on the Prevention and Punishment of Crimes against Internationally Protected Persons, including Diplomatic Agents, adopted by Resolution 3166 of the 28th Session of the United Nations General Assembly and opened for signature in New York, 14th December 1973.

Moreover, an effective physical protection convention may facilitate arrangements for nuclear supplies among States as there would no longer be a need for negotiation of related provisions on a case-by-case basis. The levels of physical protection recommended by the IAEA and further embodied in the Convention may be more easily accepted in the context of such arrangements, even by States non-Party to the Convention.

IV. CONCLUSION

Physical protection measures for nuclear material and facilities do not substitute themselves for, but usefully complement, other requirements aimed at ensuring radiation and environmental protection, nuclear safety, and nuclear material accounting and control. Their interface is thus an important element of the regulatory structure and implementing scheme that need to be closely co-ordinated.

Indeed, it is of paramount importance for the effective and efficient discharge of respective responsibilities in these connected areas that, from the design of a physical protection system throughout its implementation, due account be taken of other equally important requirements for public protection and in the national interest.

BIBLIOGRAPHY

• *Italy*

Rassegna Giuridica dell'energia elettrica, I, No. 1 January-March 1984, I No. 2, April-June 1984, I, No. 3, July-September 1984, Giuffrè Editore, Milan, 857 pages

This new periodical, which had a forerunner whose publication ceased in 1983, is issued on a quarterly basis. It contains topical reports covering doctrine and case law in the energy field as well as meetings and conferences dealing with nuclear activities and their relevant laws and regulations, both at national and international levels.

The volumes reviewed here contain, inter alia, reviews of the Congress of the International Nuclear Law Association (INLA) held in San Francisco in September 1983, and the Symposium on Nuclear Third Party Liability and Insurance, organised jointly by the OECD Nuclear Energy Agency and the International Atomic Energy Agency, in Munich, in September 1984. They also contain reports on decisions in the energy field by Italian courts.

This periodical is available on subscription.

• *United Kingdom*

Disposal Facilities on Land for Low and Intermediate-Level Radioactive Wastes: Principles for the Protection of the Human Environment, HMSO, 1985, 25 pages

This document contains the principles which the relevant Departments propose to apply in considering whether they should give a general authorisation for any proposed disposal facility for low and intermediate-level radioactive wastes under the Radioactive Substances Act 1960. It also defines the contents of the environmental assessment which a developer proposing such a facility will be required to compile and publish.

To place the principles in context, reference is also made to the main features of the procedures that will need to be followed by a developer in

obtaining approval for a land disposal facility, both under the Radioactive Substances Act 1960 and under other legislation.

In England the authorising Department under the Radioactive Substances Act 1960 is the Department of the Environment, acting jointly with the Ministry of Agriculture, Fisheries and Food for disposals of wastes on or from sites licensed under the Nuclear Installations Act 1965 or operated by the United Kingdom Atomic Energy Authority. The Scottish Office, the Welsh Office, and the Department of the Environment for Northern Ireland are the authorising Departments in their respective countries.

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