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**NUCLEAR ENERGY AGENCY
COMMITTEE ON NUCLEAR REGULATORY ACTIVITIES**

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Working Group on Inspection Practices

The Effectiveness of Licensees in Inspecting the Management of Safety

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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;
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- to contribute to the expansion of world trade on a multilateral, non-discriminatory basis in accordance with international obligations.

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NUCLEAR ENERGY AGENCY

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

The mission of the NEA is:

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

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

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

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COMMITTEE ON NUCLEAR REGULATORY ACTIVITIES

The Committee on Nuclear Regulatory Activities (CNRA) of the OECD Nuclear Energy Agency (NEA) is an international committee made up primarily of senior nuclear regulators. It was set up in 1989 as a forum for the exchange of information and experience among regulatory organisations and for the review of developments which could affect regulatory requirements.

The Committee is responsible for the programme of the NEA, concerning the regulation, licensing and inspection of nuclear installations. The Committee reviews developments which could affect regulatory requirements with the objective of providing members with an understanding of the motivation for new regulatory requirements under consideration and an opportunity to offer suggestions that might improve them or avoid disparities among Member Countries. In particular, the Committee reviews current practices and operating experience.

The Committee focuses primarily on power reactors and other nuclear installations currently being built and operated. It also may consider the regulatory implications of new designs of power reactors and other types of nuclear installations.

In implementing its programme, CNRA establishes co-operative mechanisms with NEA's Committee on the Safety of Nuclear Installations (CSNI), responsible for co-ordinating the activities of the Agency concerning the technical aspects of design, construction and operation of nuclear installations insofar as they affect the safety of such installations. It also co-operates with NEA's Committee on Radiation Protection and Public Health (CRPPH) and NEA's Radioactive Waste Management Committee (RWMC) on matters of common interest.

NOTE TO THE READERS

As part of work performed by the Committee on Nuclear Regulatory Activities in the area of Measuring and Developing Regulatory Effectiveness, the Working Group on Inspection Practices was assigned the task of producing a report on Regulatory Inspection Effectiveness. The report is based on discussions held by the working group and special expert task group.

FOREWORD

The CNRA believes that safety inspections are a major element in the regulatory authority's efforts to ensure the safe operation of nuclear facilities. Considering the importance of these issues, the Committee has established a special Working Group on Inspection Practices (WGIP). The purpose of WGIP, is to facilitate the exchange of information and experience related to regulatory safety inspections between CNRA Member countries

In offering thanks to the members of WGIP who provided valuable time and considerable efforts towards the production of this report, the NEA Secretariat also wishes to acknowledge the special work of several key persons. Mr. Thomas Warren of the United Kingdom, former Chairman of WGIP, who undertook the lead role in producing the report and Dr. Hartmut Klonk of BfS in Germany and Mr. Lyn Summers of NII, United Kingdom who reviewed and edited the final report.

The members of the sub-group who developed the contents for the report were: J.J. van Binnebeek, AVN, Belgium, F. Rinfret, CNCS, Canada, P. Pittermann, SONS, Czech Republic and S. Forsberg, SKI, Sweden.

INTRODUCTION

During discussions at several meetings, the Working Group on Inspection Practices (WGIP) on management and safety culture issues, it was agreed: it was important that the management of a licensee needs to be effective in managing safety related issues; and that the regulatory authority is aware of the licensee's performance relating to this matter. Accordingly, members made presentations at the WGIP meeting, held in Budapest on 20-22 October 1998, on how they carried out inspections of licensees' management systems and practices related to safety at nuclear installations. The presentations showed that there was little commonality in approach.

With the approval of CNRA, WGIP set up a small sub-group to give further consideration to how a regulatory authority can assess the effectiveness of a licensee in managing safety.

This report outlines the work of the sub-group and the subsequent discussions and conclusions of WGIP.

SUB-GROUP DISCUSSIONS

Representatives of Belgium, Canada, Czech Republic, Sweden and UK formed the sub-group, which met in Liverpool, UK, on 16-18 February 1999.

The sub-group addressed a wide range of questions including whether regulatory authorities need to monitor the effectiveness of licensees' management related to safety and, if so, how and when such inspections should be carried out. Each question and associated answers are given below.

1. Does the regulatory authority need to monitor the effectiveness of the licensee's management related to safety?

Yes. The reason is that management directs all activities and can have an overriding effect on safety. Studies of major accidents show that management or organisational deficiencies are almost always factors.

How can the regulatory authority get insights of the effectiveness of the licensee's management?

The regulatory authority can get insights from:

- Routine Inspections covering plant condition, configuration control, cleanliness, compliance with the law and licence conditions and licensee documents;
- Meetings with the licensee which include assessment of whether the licensee delivers a timely outcome of what the regulator wants and of the licensee's responses to matters of regulatory concern;
- Reports to the regulator of events, plant deficiencies, unavailability, etc.;
- The number and types of incidents, the adequacy of the licensee's analyses of incidents and whether the licensee is a learning organisation; and
- Performance indicators e.g. trip rates, failure rates, radiation protection statistics etc.

The regulatory authority can also get insights when it finds that:

- Licensee's managers are not honest, transparent and open about safety issues with the regulatory authority;
- The licensee is over-reliant on other organisations e.g. contractors or architect engineers such that the licensee does not monitor and take responsibility for their work;
- The licensee does not have a systematic or structured approach to the management of safety and is unable to anticipate problems; and
- The licensee is losing his knowledge base.

2. Are inspections of the licensee's management practices related to safety necessary:

Yes. Because if there are more than a small number of insights (say over a year):

- the insights may be symptoms of bigger or common problems;
- the regulatory authority will need to see the 'big picture' before raising the overall problem with the licensee's senior management;
- the regulatory authority will probably only see the 'big picture' after a structured inspection of management to gather the facts about management deficiencies because without facts any approach to a sceptical licensee or a licensee in denial is likely to fail; and
- it may not be effective or efficient for the regulator to deal with insights one by one.

3. Are there different types of such inspections?

Yes. Inspections may be carried out proactively, i.e. inspections that are planned in an inspection programme, or reactively because of a large number of insights or because a licensee changes its organisational structure or resources in such a way that safety may be affected.

Inspections may also vary in scope ranging from inspections of the licensee's management practices for individual tasks (see paragraph 11), through groups of tasks, through the totality of tasks carried out at a site, to the totality of tasks related to safety which are carried out by the licensee both at site and elsewhere, including the interfaces for work carried out by contractors or architect engineers on behalf of the licensee.

Typical individual tasks related to safety and carried out by or for the licensee are:

- Design,
- Preparation of safety cases,
- Assessment of safety cases,
- Periodic safety review,
- Construction,
- Commissioning,
- Operation,
- Maintenance, examination and testing,
- Training,
- Incident reporting, analysis and learning from experience,
- Radiation protection,
- Conventional safety,
- Nuclear matter and radioactive waste,
- Decommissioning and demolition,
- Emergency arrangements,
- Quality assurance,
- Management of change including modifications to plant or methods of operation and changes to the licensee's organisational structure and staffing,
- Management of contractors.

4. When should proactive inspections be made of the licensee's management practices related to safety?

Full blown inspections of this type across a large number of tasks, across the whole site, including the licensee's other offices or the corporate level or contractors or architect engineers are very resource intensive and may therefore only be undertaken according to need (see question 5).

Planned inspections of a licensee's management practices on individual tasks that are carried out either by the licensee or of the interfaces for work carried out on behalf of the licensee give a top-down view to the regulatory authority rather than the bottom-up view that is usually obtained from traditional inspections carried out by the regulatory authority. It is recommended that planned top-down inspections are carried out on individual tasks at infrequent but regular intervals to cover most tasks over a 3 to 5 year periodicity. These inspections will augment the insights gained from the bottom-up inspections that are usually carried out by site inspectors.

All important tasks should be covered in a programme of inspections even if the tasks are partly or wholly carried out by the licensee or contractors or architect engineers at other locations. The aim should be to assess the licensee's management practices for the task being inspected and inspection other than at the site in question may be necessary.

5. When should reactive or demand led inspections be made of the licensee's management practices related to safety?

Reactive or demand led inspections are likely to be necessary:

- As a result of a review by the regulatory authority of recent insights. Insights that are more than 12 months old are likely to be of questionable value in reaching a decision about carrying out an inspection of management practice if it is felt that the licensee's management system is fairly dynamic in the affected task areas;
- when there has been a major incident. In this case the inspection will take place after any investigation by the regulatory authority into the causes of the incident and any decision to apportion blame and to take enforcement action; or
- when a licensee is setting up a new organisation, is changing its organisational structure, is undertaking a major reduction in staff numbers or staff with great experience or specialist knowledge, or is undertaking major contractorisation of safety related tasks.

6. Are there any other ways of reaching a view about the effectiveness of a licensee's management related to safety?

Another way of obtaining a view of the effectiveness of a licensee's management of safety is to have an annual discussion with the licensee's senior management about their policies, strategies and out-turns from previous discussions. Although this technique may be useful, it will not on its own reveal what is actually taking place on the site.

7. What are the various phases for an inspection?

The various phases are:

- Policy. It is important to identify the purpose and scope of the inspection at a very early stage.
- Planning. The timing for the inspection and the resources to be used need to be established. It is also important to understand the licensee's processes for the topic to be inspected prior to going to the site so as to be able to conduct the inspection efficiently. It is also desirable to establish question sets for the people who are to be interviewed. It is also essential to explain to the group being inspected what is to happen.
- Gathering of information. Information will be gathered from interviews with staff members, examination of documents and from direct observation of activities in order to see the reality of what happens.
- Forming judgements. This phase is where the inspection team draws conclusions from the gathered information and decides what are the important issues.
- Writing the report.
- Follow up action. This phase will start with the regulatory authority supplying a copy of the report to the licensee, followed by some discussion to agree the programme of any necessary follow up work and the monitoring of such a programme.

8. How should inspections be made of a licensee's management practices related to safety?

The main aspects to be considered are summarised in the following statements:

- Inspections by the regulatory authority of a licensee's management practices related to safety should ideally not be confrontational or used at the outset to gather formal evidence for use in enforcement action. Rather the aim should be to assist the licensee to improve, to get in better control of his safety related activities and to encourage him to have or develop a learning organisation.
- The inspections will consist of a combination of interviews with staff and managers at all levels, examination of relevant documentation and physical checks of the processes being examined. All three elements will normally be covered in each inspection.
- Inspections should typically be arranged in several teams each of two inspectors for a given topic. The ability of the inspectors for the work is more important than their status or grade. Each team should complete its inspection task for reasons of continuity rather than the inspection task being fragmented.
- Typically an inspection will start with an interview with the senior manager for the task being inspected to establish the policies, strategies and organisation that relate to the task. The inspection will continue with sample interviews at a lower level in a deep vertical slice to confirm understandings and implementation of policies, convergence of ideas etc. and to

assess the effectiveness of upward and downward communication and management processes etc. The inspection will also include an examination of relevant documentation and direct observation of the task being carried out. It will also be necessary to return to the senior manager to discuss apparent anomalies in order to clarify potential misunderstandings by the inspectors. Plans should not be too well developed as the teams will want the flexibility to follow trails as concerns are revealed.

- If it is evident that the senior manager is unclear on safety related issues then the inspection team should explore upwards and/or laterally in order to complete the inspection.
- On completion of the inspection, preliminary findings should be shared with the licensee and a report should be written, a copy of which should be sent to the licensee and subsequently discussed with him.
- The licensee should be encouraged to accept the findings and to prepare and implement a plan of remedial actions, which should be monitored by the regulatory authority.

9. Should a licensee have a safety management system and, if so, what should it cover?

It is unlikely that a licensee will be consistently effective in managing safety unless he has a systematic and structured approach to the management of safety. Such a management system is likely to include policies, organisation, planning and implementation, measuring auditing and review as follows:

Policy:

Policies will express vision, mission and values as a written reference point and include statements about goals, strategies and standards. Policies will apply to people, plant, safety cases, plant history and support services, including the need to retain knowledge over a period of time. The policies should identify protected work and overall should express a high commitment to safety.

Organise:

Documentation will state how policies are to be delivered in respect of the control of people, plant and processes. Resource allocation should be covered to identify the people needed for each task with sufficient in-built slack to provide a contingency for the unexpected. Roles, responsibilities, accountabilities and management structure will also be identified as well as the training, knowledge, skills and experience that are needed for each person. Permissible contractorisation of tasks will also be included, including how the contracts are to be managed and supervised.

Planning and implementation:

Documentation will identify the planning systems and implementation programmes and practices which are to be followed.

Measuring:

Documentation will identify the quality control and work measuring practices that are to be followed.

Auditing:

Documentation will identify the auditing regime for the process.

Review:

Documentation will identify how the management system for the task in question is regularly reviewed to seek relevant improvements.

10. What are the guidance or training needs for inspectors carrying out inspections?

The main aspects are as follows:

- All inspectors that carry out inspections of the effectiveness of a licensee's management related to safety should have relevant skills, experience and knowledge. It is likely that an experienced resident or site inspector will already have sufficient skills to interview staff at all levels in a licensee's organisation, examine documents and to observe the licensee's tasks being carried out, but they are unlikely to have background knowledge of organisational structure, management styles and management systems. Overall, the training needs of inspectors for this work should concentrate on these topics together with people skills (interviewing senior and junior staff etc.) and how to inspect (see question 8). The inclusion of less-skilled inspectors in an experienced team of inspectors is a powerful way of widening their skill base.
- Guidance to inspectors carrying out inspections should highlight important issues such as the policy and objectives for such inspections (e.g. what to look at and when) and what an inspector needs to consider in making a judgement about the effectiveness of a licensee's management related to safety.

11. How can a regime of inspections be introduced?

The first step for a regulatory authority is for it to recognise that management of safety problems exist at a site to such an extent that further investigation is needed. The next step is for the regulatory authority to decide on the structured approach it will use to assess the licensee's management system (e.g. the system stated in question 9). Following this the regulatory authority can tell the licensee's senior management of its intention to inspect the effectiveness of its management practices related to safety and to explain to them how the inspection will be conducted.

WGIP DISCUSSIONS

WGIP considered the outcome of the sub-group discussions at the WGIP meeting held in Den Haag, The Netherlands, on 4-6 May 1999.

WGIP recognised that there is a spectrum of approaches that may be appropriate for use by a regulatory authority when it assesses the effectiveness of a licensee in managing safety related issues. The selection of the appropriate approach will be dependent upon such factors as:

- The need for a regulatory authority to have a legal basis for carrying out inspections of licensees' management systems and practices related to safety wherever the licensees carry out such work.
- The need for a regulatory authority to have very experienced and properly trained inspectors to look at these types of issues.
- The extent to which prescriptive regulatory processes make it less necessary to inspect management systems and practices related to safety.
- The extent to which meetings or other contacts between the regulatory authority and licensees at management level make it less necessary to inspect the licensees' management systems and practices related to safety.
- The perceived performance history of the licensee.

CONCLUSIONS

WGIP concluded that:

- A regulatory authority needs to monitor the effectiveness of licensees' management systems and practices related to safety.
- It is unlikely that a regulatory authority will be able to identify deep rooted deficiencies in licensees' management practices without a systematic process, which includes structured and comprehensive inspections.
- Inspections of a licensee's management practices related to safety can range in scope from inspections of individual tasks e.g. maintenance, to full blown inspections at site, at the licensee's corporate level and at the licensee's contractor's or architect engineer's premises. The inspections can also be carried out in response to a change in the licensee's structure, staffing level or contractorisation policy or in response to a review by the regulatory authority of recent insights.
- Periodic top-down inspections of a licensee's management of individual tasks to augment the often fragmented approach of bottom-up inspections are desirable because different insights may emerge. Both types of inspection are complementary.
- Planned proactive inspections of a licensee's management of safety related tasks across a whole site, or a group of sites, or the relevant interfaces with all other parts of the licensee's organisation, or corporate level of the interface with contractors is resource intensive. It has the potential to be wasteful of the regulatory body's inspection resource unless a specific need for such large scale inspections has been established.
- Inspections of management practices carried out by regulatory authorities should ideally not be confrontational. The aims should be to assist the licensee to improve, to get in better control of his safety related activities and to encourage the licensee to have a learning organisation.