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

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Working Group on Inspection Practices

The Effectiveness of Nuclear Regulatory Inspection

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- 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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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.

ABSTRACT

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. Dr. Hartmut Klonk of BfS in Germany and Mr. Lyn Summers of NII, United Kingdom who reviewed and edited the final report.

1. INTRODUCTION

In late 1998 the Committee on Nuclear Regulatory Activities agreed that the Working Group on Inspection Practices [WGIP] should discuss the subject of effectiveness of regulatory inspections and produce a report. This work would augment the work that it and the International Atomic Agency (reference 1) were doing on the subject of regulatory effectiveness.

Accordingly, WGIP discussed the subject at a meeting in Den Haag held on 4-6 May 1999. Because there was no obvious consensus at the meeting on the subject, a sub-group was formed to brainstorm the issue.

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

2. SUB-GROUP DISCUSSIONS

Representatives of Belgium, Sweden and the UK formed the sub-group which met in Liverpool, UK on 30 June and 1 July 1999.

Although WGIP particularly asked the sub-group to determine the objectives of inspection programmes and to determine a definition of the effectiveness of regulatory inspection, the sub-group started its work by considering the following questions:

1. What are the major elements that make regulatory inspections effective?
2. In what areas should effectiveness be assessed and how?
3. What kind of operating organisations' performance can be used to evaluate effectiveness and how?
4. What indicators are there of effectiveness?
5. How can effectiveness be enhanced?

Although each question was discussed in turn by the sub-group, there was much overlap in the answers to the questions. For simplicity, therefore, the output from the sub-group discussions are reported in the following sections:

- major elements that make regulatory inspections effective;
- possible indicators of effective regulatory inspection; and
- the enhancement of regulatory effectiveness related to inspection.

3. MAJOR ELEMENTS THAT MAKE REGULATORY INSPECTIONS EFFECTIVE

3.1 Policies, Objectives and Strategies

Although most of the elements that enable a regulatory authority to be effective when carrying out regulatory inspections are provided by the regulatory authority itself, there are a few which have to be provided by government or the law makers of the country in which it operates. These are the legal basis for the regulatory authority to inspect, to regulate and enforce, a legal right of entry of its inspectors to enter nuclear sites and installations to carry out inspections and sufficient resources for the regulatory authority to enable it to carry out its inspection function.

Of the elements provided by the regulatory authority for inspection, the most important are its policies, objectives and strategies. An example of a policy related to inspection is a statement which states that it is the policy of the regulatory authority to secure compliance by licensees of their legal obligations related to safety by means of the regulatory authority carrying out inspections of the licensable activities for which the licensee is responsible in a manner which is transparent and consistent.

An example of an associated objective is that a regulatory authority has a relevant, comprehensive and systematic inspection programme for each class of installation which it inspects with inspections being targeted according to perceived risk or where hazards are not well controlled.

Examples of associated strategies are those which state the minimum frequency with which installations are visited, the target inspection time per installation each year and an inspection planning system which enables inspection programmes to be delivered in practice.

3.2 Organisation, Structure, Competence and General Functions

Another group of elements relates to the people resources that are allocated by the regulatory authority to carry out its inspection function. The number of inspectors needs to be sufficient to carry out the task of:

- sampling the activities carried out by licensees taking account of the size of the risks or hazards to be inspected;
- the regulatory authority's confidence in the licensee to operate safely;
- the need to complete inspection programmes to time; and
- the need to have sufficient resource available to follow up significant events>

But the regulatory authority needs to organise and structure this group of inspectors so as to carry out this task.

In addition, the inspectors need to be competent with adequate skills, knowledge and experience so as to be able to carry out inspections in a consistent manner and in a manner which is proportionate to the risk, hazard or situation which is encountered during an inspection.

Sufficient regulatory and internal guidance related to inspection needs to exist, particularly to give guidance to inspectors and licensees about circumstances which are not acceptable, and on enforcement activities which may be appropriate.

The regulatory authority also needs to ensure that its inspection processes are documented and the inspection outcomes are recorded in accordance with an internal quality assurance system.

In addition, the regulatory authority needs to adopt good communication practices in respect of its inspection function. It is very important that inspectors communicate well internally with specialist inspectors and assessors; there is also a need to communicate well with other regulatory authorities where there are matters of common interest and with the licensee in respect of inspection findings. In addition, there needs to be adequate communication with the regulatory authority's other stakeholders, for example by means of a published annual report.

The regulatory authority also needs to be a learning organisation in respect of its inspection function. A systematic review process of its inspection outcomes is necessary but inspection programmes, policies, objectives and strategies should also be regularly reviewed for adequacy. In addition, the regulatory authority needs to participate in international exchanges such as the IAEA/NEA Incident Reporting System and the CNRA Working Group on Inspection Practices so as to be aware of developments and good practice relating to inspection.

3.3 Inspection Programmes, Inspection Plans, Inspection Preparation, Inspection Reports and Review of Inspection Findings

This group of elements relates to the inspection function provided by the regulatory authority with the main element being the provision by the regulatory authority of an inspection programme for each class of installation which it inspects which is relevant, comprehensive and systematic. For example, an inspection programme for power reactors in the operational phase might cover a cycle of several years. This may include inspections for each power plant with the programme specifying the types of inspection of plant, buildings and processes, including the management processes of the licensee related to safety, and assessments of safety culture, according to national practice. The programme will also specify frequencies for each type of inspection which preferentially targets the most serious risks or the hazards that are likely to be least well controlled. Although there may be common elements in the inspection programmes for power plants that are either under construction, being commissioned or being decommissioned or for nuclear chemical plants, there will be differences. It is therefore likely that the regulatory authority will need to create an inspection programme for each class of installation which it inspects.

The regulatory authority will need to set up an inspection planning system which enables the inspection programme to be met to time in accordance with the relevant policies, objectives and strategies related to inspection. The planning system will need to take account of the need to target resources at areas of immediate safety need as well as to allow relevant reactive inspections to offset inspection requirements specified in inspection programmes.

Planned inspections in inspection programmes will need to target the licensee's hardware and processes related to safety. Such inspections over a period of time will target the licensee's staff, its organisation and competence, documentation and check that the licensee and its staff and contractors are actually meeting legal obligations related to safety.

Any inspections carried out by inspectors are only likely to be effective and efficient if sufficient preparation is made by inspectors beforehand. Such preparation is likely to include examination of relevant licensee's documentation, examination of relevant laws, regulatory guides and internal guidance, research

into previous history including previous inspection findings and the making of appointments to speak with licensee's staff members or other duty holders unless the inspection is unannounced.

The results of inspections need to be written up by inspectors making the inspections. The inspection reports need to be factual and record both positive and negative inspection findings, inspector's judgements, conclusions and actions at the time and recommendations for further work at a later date. The inspection reports need to be issued quickly, say within 2 weeks of the inspection for routine or reactive inspections, in order to provide prompt information to the regulatory authority's management that is responsible for inspection and, according to national practice, the licensee so as to augment the verbal report of key inspection findings given by the inspector to the site management at the time of the inspection.

The inspection reports will also provide source material for regular standback reviews of inspection and other technical findings which a regulatory authority needs to carry out at a typical frequency of between 6 and 12 months for a particular site. These reviews may lead to changes to inspection priorities and inspection plans, establish a possible need for special team inspections or other regulatory responses, establish a need for special inspections across a class of installations and lead to changes to inspection programmes. The results of the reviews will usually need to be discussed with the licensee.

4. POSSIBLE INDICATORS OF EFFECTIVE REGULATORY INSPECTION

A regulatory authority will be effective when it discharges its legal duties and delivers its mission, policies and objectives, including inspection programmes. It will know whether it is being effective when its management receives the results of any audits or peer reviews, such as audits by internal or external auditors, such as an IRRT mission, of the regulatory authority's inspection process or internal peer reviews which sample the delivery of consistency, proportionality, targeting and transparency relating to inspection.

4.1 Possible indicators relating to elements provided by Government or Law Makers

Possible indicators are:

- A legal basis exists for the regulatory authority to inspect, to regulate and enforce.
- A legal basis exists for inspectors to have a right to enter nuclear sites and installations to carry out inspections, to regulate and enforce according to national practice.
- Sufficient resource is provided for the regulatory authority to enable it to recruit, train and retain inspectors who have sufficient competence, skills, knowledge and experience. The level of resource should be such that the regulatory authority is able to deliver its inspection programme to time and still have sufficient resource to follow up significant events and deficiencies found during previous inspections.

4.2 Possible indicators relating to inspection policy, objectives and strategies

A possible indicator is:

- The regulatory authority has inspection policies, objectives and strategies which are understood and followed and which are regularly reviewed and amended as necessary.

4.3 Possible indicators of organisation, structure and competence relating to inspection

Possible indicators are:

- The regulatory authority's inspection function is structured to enable the inspection policies and objectives, including inspection programmes to be delivered in a consistent, timely and proportionate manner. The structure should be such that there is good communication amongst inspectors and between inspectors and specialist assessors of the regulatory authority. The ability to mentor less experienced inspectors should also exist.
- Inspectors have the right knowledge, skills and experience to carry out inspections. They receive initial training and refresher training at the appropriate frequency.
- Sufficient regulatory and internal guidance related to inspection exists, is regularly reviewed and revised according to need.

- An internal quality assurance system exists for the inspection function covering guidance, inspection programmes and planning systems and the delivery of inspections and associated reports and records. The aim of the system should be to ensure that a quality inspection process exists in practice with minimal bureaucracy.
- Good communication exists between the regulatory authority and the licensee about inspection findings as well as the inspection policies and objectives of the regulatory authority.
- Good communication exists between the regulatory authority and its stakeholders in respect of its inspection function so as to maintain public confidence in the regulatory authority. Although there may be national variations depending on governmental policies relating to freedom of information, the regulatory authority can communicate effectively to workers, the public, Ministers and the Government by publishing an annual report and its response to incidents and licensees periodic safety reviews etc.
- The regulatory authority acts as a learning organisation for example by using the IAEA/NEA IRS information and USNRC generic letters, by participating in international committees and working groups such as CNRA/WGIP, participating in bilateral exchanges with regulatory authorities from other countries.

4.4 Possible indicators relating to inspection programmes and plans, inspection reports and reviews of inspection findings

Possible indicators are:

- The regulatory authority creates an inspection programme that is appropriate for the plant state of each type of plant which it regulates ensuring that all plant, buildings and processes are inspected at a frequency which is appropriate to the hazard or risk created by the licensed plant or processes. These inspection programmes are completed satisfactorily as scheduled.
- The ratio of time spent on reactive inspections to the time spent on planned inspections is low.
- Inspectors carry out some un-announced inspections as part of the inspection programme.
- Inspectors use the full range of techniques such as interviewing staff, examining documentation and inspecting plant and processes when inspecting so that balanced judgements can be made about a licensee's safety performance.
- An inspection planning system exists which ensures that the most serious risks and the hazards which are least likely to be well controlled receive the most attention by the regulatory authority. The planning system will also take account of the regulatory authorities priorities and campaigns, be sufficiently flexible to allow for reactive work, enforcement and new requirements, allow for re-inspection of previous activities found to be deficient, and allow for the appropriate use of preplanned team or specialist inspections.
- Appropriate use is made of reactive inspections for significant complaints, events or incidents. These inspections should be made without delay so as to establish the facts before evidence disappears or memories fade and completed with despatch.
- Inspection findings are communicated quickly to the licensee and, in the case of inspection findings where there are matters of serious or urgent concern relating to worker safety, are communicated urgently to workers.

- Dialogue takes place between inspectors and the site manager to ensure that issues are understood and acted upon.
- Inspection findings are comprehensively written up as inspection reports that are issued quickly after each inspection visit.
- Inspection findings and other regulatory insights are regularly reviewed on an annual basis for each site, each licensee and across all licensees to determine inspection priorities for the next period and to identify changes to inspection programmes and internal inspection guidance.

4.5 Possible indicators of inspection effectiveness from consideration of the performance of licensees

There are a number of truisms about effectiveness when considering indicators of the performance of licensees. These are:

- If a licensee's safety performance is good, the regulatory authority may still be ineffective;
- If a licensee's safety performance is consistently bad over a period of time, the regulatory authority is almost certainly ineffective; and
- If a licensee's safety performance improves as a result of persuasion, enforcement or other action by the regulatory authority, the regulatory authority is being effective.

Possible indicators of inspection effectiveness from consideration of the performance of licensees are:

- the extent to which licensees comply with legal requirements and other regulatory standards and guides
- the number of safety issues not discovered by a licensee and discovered by the regulatory authority
- whether occupational radiation exposures at a site are under constant review and the licensee aspires to reduce them to a level which is as low as is reasonably achievable
- whether the number of significant events each year continues to fall.

5. THE ENHANCEMENT OF REGULATORY EFFECTIVENESS RELATED TO INSPECTION

A regulatory authority can enhance the effectiveness of its inspection process by:

- being a learning and questioning organisation which is committed to improvement
- having staff who are competent, trained, capable of forming judgements and who concentrate on safety issues
- performing systematic inspections to established inspection programmes using appropriate planning techniques and a prioritisation system
- keeping inspection findings and processes under review and making subsequent improvements
- operating an appropriate quality assurance system for the inspection process (including the writing of reports and reviews of inspection findings) and the regulatory guidance and internal guidance such that these are documented, clear, complete, up to date, regularly reviewed and reissued as necessary
- good communication with licensees
- observation of the results of R&D in nuclear safety technology and appropriate technology
- appropriate interaction with stakeholders such as the advisory bodies, international agencies etc., and
- encouraging licensees to be self improving.

6. WGIP DISCUSSIONS

WGIP considered the outcome of the sub-group discussions at the WGIP meeting held in Lyon on 5-6 October 1999.

WGIP recognised that there are different cultures in countries as well as different regulatory practices which had evolved over time and continue to evolve.

WGIP also recognised that the use of indicators to measure effectiveness was difficult, particularly if they are numerical.

WGIP also recognised that it was now important for regulatory authorities to inspect systems of work as well as hardware.

7. CONCLUSIONS

WGIP concluded that the key aspects that lead to an effective inspection process are:

1. a proactive approach to inspection involving inspection programmes and a planning system which takes account of priorities that are linked to risk and hazard;
2. competent staff to perform inspections;
3. a questioning approach involving reviews of inspection findings and processes, research and development, the views of stakeholders and a willingness to make changes to the way the regulatory authority carries out and programmes inspections;
4. an internal quality assurance system for the inspection function of the regulatory authority.

WGIP concluded (as stated in NEA/SEN/NRA/WGIP(99)4) that the following definition (from Ref.1) of the effectiveness of regulatory inspection was appropriate:

A regulatory authority is effective in its work relation to inspection when it:

- strives for continuous improvements to its work relating to inspection;
- adopts a proactive approach to inspection using such tools as inspection programmes and planning systems which take account of priorities that are linked to risk and hazard and achieves an inspection regime which is timely, transparent and consistent;
- checks that licensees comply with their legal obligations; and
- encourages licensees to constantly seek to improve its safety performance and to make safety improvements which are reasonably practicable.

7. REFERENCES

1. PDRP-4, Assessment of Regulatory Effectiveness, International Atomic Energy Agency, 1999.
2. NEA/SEN/NRA/WGIP(99)4, Summary Record of the Eighteenth Meeting - Lyon 5-7 October 1999.