IMPROVING NUCLEAR REGULATORY EFFECTIVENESS

NUCLEAR ENERGY AGENCY

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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

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

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

NUCLEAR ENERGY AGENCY

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

The mission of the NEA is:

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

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

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

FOREWORD

Among the recommendations made in the report by the NEA Committee on Nuclear Regulatory Activities (CNRA) on *Future Nuclear Regulatory Challenges*, the issue of regulatory effectiveness was considered of high importance. As a result, a CNRA special issues meeting on "Developing and Measuring Regulatory Effectiveness" was held in June 1999. Several specific aspects were considered, such as how regulatory effectiveness could be judged, how regulatory bodies justified their existence and resources to government authorities, how industry perceived the effectiveness of regulatory bodies, and how the public perceived regulatory effectiveness.

In follow-up to this meeting, a senior task group was established in order to exchange information on ongoing national and international initiatives and to devise an overall strategy for improving regulatory effectiveness. This report presents the results of these exchanges and provides several recommendations for future international collaboration.

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EXECUTIVE SUMMARY

Ensuring that nuclear installations are operated and maintained in such a way that their impact on public health and safety is as low as reasonably practicable has been and will continue to be the cornerstone of nuclear regulation. The organisations, structures and processes of regulatory authorities have evolved over the past 50 or so years. Major changes have been made following events such as Three Mile Island and Chernobyl. As in the past, events such as the recent criticality incident at Tokai-mura will provide impetus for further reviews and changes. However, factors other than events are beginning to have an impact on how regulatory authorities will need to function. Economic factors, deregulation, technological advancements, government oversight and the general requirements for openness and accountability are some of the main elements that are leading regulatory bodies to look at their effectiveness. Seeking to enhance the present level of safety by continuously improving the effectiveness of regulatory bodies is seen as one of the ways to strengthen public confidence in the regulatory systems.

Regardless of the reason, most regulatory authorities in the NEA Member countries have begun to realise that in the near future, they will need to be more effective. A CNRA task group reviewed the current efforts underway in individual Member countries as well as in international organisations, and attempted to deduce the common elements among them. Building on that analysis, the present report, prepared by a Group of Senior Level Experts, provides a regulatory perspective on the basic concepts of regulatory effectiveness and identifies some of the tasks which remain to be addressed.

The Group discussed and agreed a common definition of regulatory effectiveness and elaborated the difference between regulatory efficiency and regulatory effectiveness (Chapter 2). In Chapter 3 the Group considers the effectiveness models in use or being developed amongst Member countries and develops a model for assessing and measuring regulatory efficiency and effectiveness. This model includes conventional management wisdom as well as modern business practices adapted to governmental organisations. In Chapter 4 the Group discusses the Quality Management Models most commonly used by regulatory bodies and emphasises that it is not important which model is

used – simply that *some* model should be used. It also discusses the pros and cons of formal accreditation and concludes that decisions about whether to apply for such accreditation should be left to each individual regulatory authority.

In Chapter 5 the Group discusses the types of indicators that might be used to measure regulatory performance and concludes that the most appropriate classification is in terms of *direct performance indicators* (which measure the activities of the regulatory body itself) and *indirect performance indicators* (which depend on the performance indicators of the regulator's stakeholders, especially the licensees). The criteria for good performance indicators are discussed and a number of possible indicators of regulatory effectiveness and efficiency are proposed. However, the Group recognises that generating meaningful and measurable performance indicators for regulatory bodies is not straightforward and recommends that further work should be carried out in this area.

In Chapter 6 the Group considers the value that a regulatory body adds to the overall nuclear safety system and discusses methods by which this value might be quantified. This is recognised as a sensitive and difficult area, though one of great relevance to the position and authority of all regulatory bodies. The Group recommends that the CNRA should continue its activities in this area. Finally, the Group's conclusions and recommendations are given in Chapter 7.

1. INTRODUCTION

As part of the recommendations made in the CNRA report on Future Nuclear Regulatory Challenges, the issue of regulatory effectiveness was considered of high importance.

As a result of this report, a CNRA special issues meeting and workshop on Developing and Measuring Regulatory Effectiveness was held in June 1999. Several aspects needed to be considered: how regulatory effectiveness could be judged, how regulatory bodies justified their existence and resources to governmental authorities, how the nuclear industry and the public perceived the effectiveness of regulatory bodies.

Nuclear Regulators, Industry Representatives, Governmental and Public Experts participated in the workshop and discussed ways to develop and measure nuclear regulatory effectiveness. The main objective was to improve knowledge about regulatory effectiveness in relation to nuclear installations, to establish a better understanding of how regulatory effectiveness may be measured and to share experiences in enhancing regulatory effectiveness.

The speakers brought several important issues forward including the definition of regulatory effectiveness, its measurement, the need for clear and comprehensive regulations, ways in which to assess regulatory effectiveness, the resources required and the need for a regulator to be credible.

Discussion during the final panel session focused on communication issues and how the regulator could best communicate with the public. The need to be both credible and open and to maintain the necessary regulatory independence was stressed by many of the participants. The use of internal quality assurance was briefly discussed, but its importance was duly note by several speakers. Similarly, the need for international exchanges in which regulators can share ideas with each on this issue was considered essential. Other important elements such as whether regulatory effectiveness can actually be measured, and if so whether such measurements are meaningful, and the concept of regulatory independence were topics which were also regarded as significant.

The CNRA, at its follow-up meeting after the conclusion of the workshop, took several actions. The issue of communicating with the public was addressed through a separate CNRA workshop on Investing in Trust which was held between 29 November and 1 December 2000. It was decided that the best way of exploring the issue of regulatory effectiveness was to hold a series of strategy meetings. The purpose of these meetings was to exchange information on ongoing national and international initiatives in this area and devise strategies to advance the discussion. Main issues to be included were internal indicators (measurement of regulatory effectiveness) and internal Q/A and quality management systems. During its meetings the task group reviewed and discussed many of the issues, exchanged information on current initiatives and developed several recommendations as set out in this report.

2. DEFINING REGULATORY EFFECTIVENESS

The consensus of the Task Group was that the statement that evolved from recent IAEA discussions, which led to the publication of IAEA document, PDRP-4, "Assessment of Regulatory Effectiveness", 1999 was useful. It was noted that the need to maintain competence was a further important attribute, and participants agreed that this element should be added to a formal definition.

The statement contained in the peer discussions on regulatory practices document PDRP-4 is:

The regulatory body is effective when it:

- Ensures that an acceptable level of safety is being maintained by the regulated operating organisations.
- Takes appropriate actions to prevent degradation of safety and to promote safety improvements.
- Performs its regulatory functions in a timely and cost-effective manner as well as in a manner that ensures the confidence of the operating organisations, the general public, and the government,
- Strives for continuous improvements in its performance.

given the necessary authority and resources as prerequisites.

The formal definition for regulatory effectiveness adopted by the task group builds on the IAEA statement to include the issue on maintaining competence and reads as follows:

Given the necessary authority and resources as prerequisites, the regulatory body is effective when it:

- *Ensures that an acceptable level of safety is being maintained by the regulated operating organisations.*

- *Develops and maintains an adequate level of competence.*
- *Takes appropriate actions to prevent degradation of safety and to promote safety improvements.*
- *Performs its regulatory functions in a timely and cost-effective manner as well as in a manner that ensures the confidence of the operating organisations, the general public, and the government.*
- *Strives for continuous improvements in its performance.*

Further discussions looked at how effectiveness and efficiency are defined in relative terms. It was noted that in many instances these terms are interchanged quite freely, but in essence have quite different meanings to the observer. Participants generally agreed that the following simple definitions are adequate:

Regulatory effectiveness means	*"to do the right work"*
whereas	
Regulatory efficiency means	*"to do the work right".*

This implies that one has to analyse effectiveness first, based on well-defined mission objectives of the regulatory body. Having done that, one can then work to improve efficiency. Setting goals that are possible to follow-up is very important.

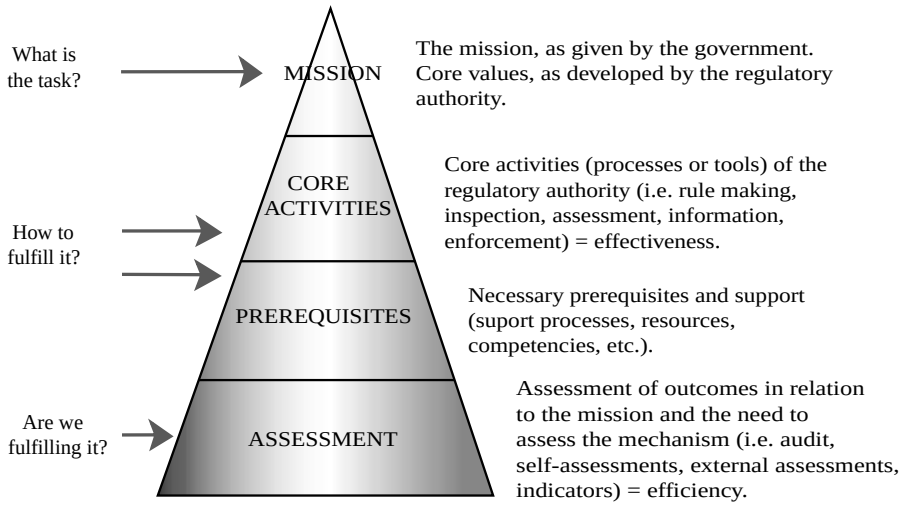
Ensuring that licensees maintain a high level of safety is the main objective of regulatory bodies. While philosophical differences exist within the Member countries about whether this obligates licensees to continuously improve safety or to continuously maintain safety, the end result in either case is that the importance of ensuring an adequate safety margin is maintained. Every time a plant safety case is amended or updated the regulatory body checks for compliance with the original design basis and the ALARA requirement. What is ALARA depends on the answer to the question "how safe is safe enough?" and this is ultimately for society to answer. However, regulatory bodies have to interpret what society requires in terms of technical requirements that are imposed on licensees' plants. How this interpretation is achieved varies from country to country (depending on legal traditions, regulatory procedures, etc.)

but, in reality, there is probably little difference in terms of the level of safety that is ultimately required. No country would tolerate any of its NPPs operating with clearly identified safety deficiencies and, beyond that, operators and regulators always have to react in a sensible and timely manner to society's changing perceptions of the acceptable level of risk from NPPs. The extent to which society considers that the regulatory body has correctly judged what it requires in terms of ALARA is a key element in establishing the effectiveness of the regulator.

3. MODELLING REGULATORY EFFECTIVENESS

Several countries have or are currently developing effectiveness models. Using the above logic, the participants agreed that it would be very useful to develop a model for assessing and measuring regulatory efficiency and effectiveness. This model, which is based on those primarily used for managing the safety of nuclear installations and the quality of the regulatory body, is depicted in Figure 1. It includes conventional management wisdom as well as modern business practices adapted to governmental organisations.

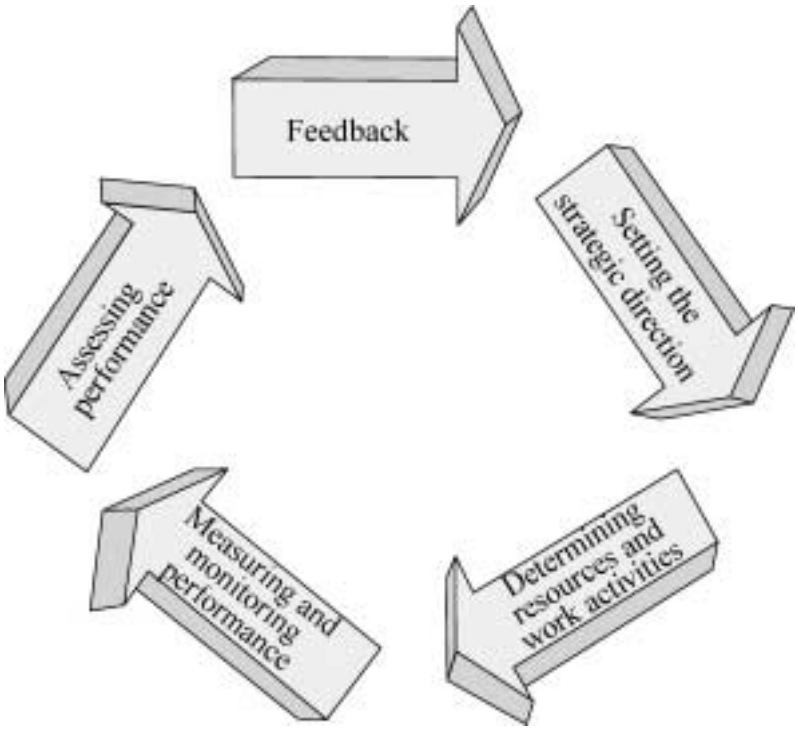
Figure 1. **Building a quality system for regulatory authority**



Several countries volunteered to perform a case study based on the model. Table 1, attached as Appendix to this report provides a summarised version of the results of these case studies.

Participants felt that the dynamics of an organisation need to be stressed, in particular the need for continuous improvement in performance. The concept of "learning organisation" was also stressed and supported. Steps include: identify issues; set objectives to solve the issues; design solutions, implement these, evaluate their effectiveness, track success, identify issues, etc. repeating the process as an endless loop. Figure 2 showing the steps taken toward continuous improvement was adopted.

Figure 2. **Steps toward continuous improvement**



4. QUALITY SYSTEMS AS A BASIS TO IMPROVING REGULATORY EFFECTIVENESS

It was agreed that both of these models (Figures 1 and 2) provided a useful framework and indeed that both were compatible with a general approach to the adoption of quality assurance by nuclear regulators. The IAEA document, PDRP-4 “Assessment of regulatory effectiveness” 1999 includes the statement that the regulatory body is effective when inter alia it strives for continuous improvements to its performance. (This is necessary but not sufficient).

There was agreement that the adoption of quality assurance by the regulatory body has the potential to contribute both to regulatory effectiveness, i.e. doing the right work, and to regulatory efficiency, i.e. doing the work right. QA for the regulator implies having the right systems covering all aspects of regulatory work, applying those systems, checking their application through a feedback and review process, improving the systems over time and the adherence to them. This is consistent with the feedback model in Figure 2.

Introduction

There was broad consensus on the usefulness of both the triangle model, Figure 1, and the continuous feedback model, Figure 2, although there were some national differences on the extent to which regulatory bodies used formal auditing systems to check that procedures were being adhered to. Some countries, notably USA and Canada, use meetings which are open to members of the general public at which to take key decisions, and these act as a different form of check and balance on decisions which are reached. Again there were significant differences on the degree to which regulatory bodies specify the level or grade of staff authorised to agree the final text of letters or other documents which may go into the public domain. Some countries place high reliance on self audit and internal review systems by staff and their immediate line managers rather than formal audits by independent departments, but all use these as a means of identifying necessary improvements to procedures and the adherence of staff to them.

In general, it appeared that all of the regulatory bodies represented at the meeting were moving forward with the introduction of formal quality assurance systems as a significant contribution to the improvement of both regulatory efficiency and effectiveness.

Quality management models used by regulatory bodies

At least three of the *regulatory authorities* represented had chosen the **European Foundation for Quality Management's (EFQM) Business Excellence Model (BEM)** to use as a template in their drive for continuous improvement. This model has the advantage of addressing a wider range of business management *attributes* than simply quality assurance, and in the experience of some, has been successful in providing a framework for drawing together a range of different initiatives aimed at improving both business efficiency and business effectiveness. The BEM consists of 5 ***enablers*** (leadership; policy and strategy; people; partnership and resources; and processes) and 4 ***results*** (customer results; people results; society results; and key performance results). It can be used for a number of activities such as self-assessment, third party assessment, benchmarking and as a basis for applying for the European Quality Award. The EFQM provides two evaluation tools – the Pathfinder Card and the RADAR Scoring Matrix. Pathfinder is not a scoring tool, rather it is a series of questions designed to be answered quickly whilst undertaking a Self-assessment. The RADAR scoring matrix is the evaluation method used to score applications for the European Quality Award. It can also be used by organisations that wish to use a score for benchmarking or other purposes.

ISO 9000 is a series of five international standards published in 1987 by the International Organisation for Standardisation (ISO), Geneva, Switzerland. Companies can use the standards to help determine what is needed to maintain an efficient quality conformance system. For example, the standards describe the need for an effective quality system, for ensuring that measuring and testing equipment is calibrated regularly and for maintaining an adequate record-keeping system. ISO 9000 registration determines whether a company complies with its own quality system.

The **Malcolm Baldridge National Quality** award was created by the U.S. Congress in 1987 and has resulted in a public-private partnership. Principal support for the program comes from the Foundation for the Malcolm Baldridge National Quality Award, established in 1988. The purpose, content, and focus of the Baldridge Award and ISO 9000 are very different. The Baldridge Award was created by Congress in 1987 to enhance U.S. competitiveness. The award

program promotes quality awareness, recognises quality achievements of U.S. organisations, and provides a vehicle for sharing successful strategies. The Baldridge Award criteria focus on results and continuous improvement. They provide a framework for designing, implementing, and assessing a process for managing all business operations.

The **United States President's Quality Award Program**, managed by the office of Executive and Management Development, is designed to recognise federal organisations which have documented high-performance management systems and approaches. Each year, Award Criteria are updated to reflect the best approaches within the public and private sectors to systematically improve organisational performance. The President's Quality Award Program application and information package is produced annually to communicate the new Criteria and provide instructions and guidance to agencies interested in applying to the Program.

The Program's Performance Excellence Criteria are closely aligned with the Malcolm Baldridge National Quality Award Criteria (MBNQA), with several modifications to reflect the government environment. The close alignment with the MBNQA promotes co-operation and exchange of information between public and private sector organisations and sets the same high standards of excellence for both government and business.

The **Balanced Scorecard** approach complements traditional financial gauges with measurements taken from three additional perspectives: customers, internal business processes, and learning and growth. This gives management a clear, comprehensive picture of how the enterprise is really doing. The balanced scorecard concept says success is dependent on, and should be measured from, multiple business perspectives using a more appropriate and balanced set of measures. In addition to traditional financial measures, it is critical to monitor leading indicators of core competencies that drive financial performance. The balanced scorecard doesn't define corporate or departmental strategy, but it does help an organisation more effectively communicate the strategy to both internal and external stakeholders in terms of key performance indicators – metrics and numbers.

The IAEA has produced the document on **Quality Assurance within Regulatory Bodies, IAEA-TECDOC-1090,** which provides information and good practices in the development and application of quality assurance to regulatory activities for effectively and efficiently fulfilling the requirements of its mandate. Utilising a systematic approach to regulatory processes it proceeds to look at management aspects, performance activities and assessment issues.

Discussion and conclusions

Generally it was agreed that the greatest value to any regulatory body from using one of these models lies in the capability for self-assessment that it provides. However, all of them allow the possibility of benchmarking and outside evaluation, which can enhance the internal motivation of staff to work for quality. Members stressed that it is not really important which quality model is used: the important thing is that ***some*** appropriate model should be applied to a regulatory organisation to clarify who its stakeholders are, what processes it uses and what are its expected results. Once these are clear the regulator has a sound basis for improvement. All members recognised the importance of documented systems to ensure transparency and consistency of their processes, as well as enabling the necessary staff competencies and training requirements to be more easily assessed.

Members discussed the pros and cons of regulatory bodies applying for formal certification or accreditation of their management systems particularly to ISO standards. They recognised that the quality assurance model set out in ISO 9001 provides the framework for the quality assurance programme of a supplier, enabling the supplier to demonstrate the capability to produce a quality product. The specified requirements are aimed essentially at achieving customer satisfaction by preventing non-conformity at all stages from design to servicing. Thus ISO 9001 is a bottom-up approach focusing on satisfying the specific requirements of the immediate customer. While it has benefits in terms of visibility and understandability and may be a viable option, most Members were not prepared to recommend formal accreditation of regulatory bodies. There was agreement that where the responsibilities of the regulatory body include routine tasks for which quality standards can readily be established e.g., laboratory analysis of environmental samples, formal accreditation may be appropriate. Some Members felt that it might be more appropriate for regulatory bodies to seek accreditation or certification under a quality management model, such as the EFQM Business Excellence Model. The overall consensus was that regulatory bodies needed to be very clear about what they expected to achieve from formal accreditation or certification before they embarked upon the costly and possibly rather intrusive processes involved. Members agreed that such decisions should be left to each individual regulatory body, acting within the environment and expectations of its own country.

5. REGULATORY PERFORMANCE INDICATORS

Introduction

It is essential for any organisation working to a Quality System, such as the one illustrated in Figure 1, to have relevant indicators of its performance. In order to identify meaningful and measurable performance indicators (PIs) it is necessary for a Regulatory Authority to identify all of its stakeholders and the expectations that each stakeholder has about the interactions between them. Once a regulator has established such a suite of PIs it can use them to attempt to determine the added value that it contributes to the overall safety system (see Chapter 6).

A performance-based management approach applied to decision-making processes which also permeates its organisational culture and performance history enables the regulatory body:

- To have a clear, well-defined and predictable regulatory regime.
- To focus attention on the most important risk-significant safety related activities of utility organisations.
- To establish objective criteria for evaluating the performance of utility organisations.
- To provide a feedback mechanism for evaluation of direct and indirect influences of regulatory actions on maintaining and improving the safety of nuclear power plants.
- To identify utility organisational and cultural problems affecting safety.
- To identify factors that affect safety which may include utility organisational and cultural problems.

Therefore, it is desirable to attempt to develop a comprehensive indicator system that will contribute to fulfilling these objectives. A performance-based approach to management should ideally focus on the regulatory body's actual performance results (i.e. desired outcomes) and not just its products (i.e. outputs).

Categorisation of performance indicators

Performance indicators can be categorised in several ways. For regulatory bodies the most useful approach is to consider them under two headings: *direct* and *indirect* indicators.

- *Direct* performance indicators attempt to measure the regulator's own activities and tend to use data generated within the regulatory body itself, while

- *Indirect* performance indicators rely on the PIs of other stakeholders, principally the licensees, to deduce the performance of the regulatory body.

The advantage of direct PIs is that they can provide a relatively unambiguous measure of relevant aspects of the regulator's performance. The problem with most of them is that they do not provide insights into the regulatory body's fundamental mission and desired outcomes in terms of risk reduction or safety achievement amongst its licensees. On the other hand, while indirect PIs can shed light on such desired regulatory outcomes, they must be treated with great caution in order to isolate the contribution of the regulatory body to the achievement of the eventual outcome.

Identification of stakeholders

When regulators apply a Quality Management Model to their organisations they typically identify five or more bodies that have a legitimate interest (or stake) in their activities. Such stakeholders include:

- *The general public.* The licensing of nuclear installations, in all countries, is basically aimed at reassuring the public that nuclear activities will be handled and regulated in such a way that the probability of a severe accident is extremely small. The public and its elected representatives expect the regulatory body to provide evidence that it is doing everything it can to ensure that

such accidents, and indeed very much smaller accidents, will not occur. The public also expects the regulator to provide information and advice on nuclear regulatory matters through, for example, publication of its regulatory "standards"; publication of technical reports on a whole range of licensing and other decisions; appearances at public hearings and inquiries; responding to letters and so on.

- *Nuclear Licensees.* The interaction between regulators and licensees can be described by the general term "licence issue, maintenance and monitoring". There are many aspects of this which need to be clearly identified in terms of the modes of interaction (e.g. safety case submissions, assessments, clarification meetings and decisions; site inspection activities of various sorts; testing of emergency procedures; and so on) and the consequent decision making and recording procedures.

- *Government Departments*. Irrespective of the extent of their independence from Government as regards regulatory decisions which they make, all nuclear regulatory bodies have interactions with and responsibilities to one or more government departments. Thus the regulator must establish and maintain suitable procedures for carrying out such interactions with government departments and for providing them with unbiased, independent and technically expert advice about the safety of licensed nuclear installations.

- *Other national agencies and bodies concerned with nuclear power.* These can include other health and safety environmental regulators, technical support agencies, research organisations, radiation protection bodies, economic electricity regulators and so on. The frequency, type and level of interaction with each of these agencies and bodies may well be different and require unique processes to be developed.

- *Concerned Action groups*. This aspect of a regulatory body's activities is gaining increasing prominence in some countries at least and demands considerable resources and carefully developed procedures for dealing with it.

Criteria for good performance indicators

The overriding criterion for any good PI is that it should be suitable for the purpose for which it is intended (fit for purpose) and measurable. Other important criteria are that PIs should be:

- Used as part of a structured, formal process for communicating within the regulatory body and with its stakeholders.
- Capable of identifying undesirable trends to trigger actions by the regulatory body.
- Of value in helping to focus and prioritise the regulator's activities.
- A stimulus to the regulatory authority to improve its performance.

However, it is clearly difficult to achieve a fully representative and comprehensive set of PIs for regulatory bodies and so care must be taken in measuring them and using them to initiate action.

Some PIs are capable of being "controlled" by the regulatory body (*direct* PIs) while others can only be "influenced" by it (*indirect* PIs). Clearly, since the responsibility for achieving and maintaining NPP safety lies with the licensee, any PIs that relate to engineering safety or management of safety fall within the latter category. Though these are undoubtedly of the greatest value in attempting to assess the extent to which a regulatory authority is fulfilling its fundamental *mission* (the top segment of the pyramid in Figure 1) they are the most difficult to interpret in terms of the "safety value" added by the regulator. Regulators also need to be careful not to allow PIs to constrain their activities too much; they have to be able to assess them carefully and use the results of inspections and reviews to help them to decide on taking action towards a licensee.

Nevertheless, a well thought-out and properly constructed set of indirect PIs, that describe the safety performance of utility organisations and their individual NPPs, is a valuable tool for the regulatory body, both in measuring its effectiveness and in directing its inspections and safety review activities. Properly chosen and defined indicators can provide an objective way for the regulator to assess nuclear safety and to evaluate its own priorities. Trends in safety performance or safety culture indicators can make possible an early detection of deteriorating safety.

On the other hand, it is fundamental for any organisation to be able to critically assess its own performance. This is particularly true when dealing with an industry that is strictly regulated and of concern to the public. Thus regulatory authorities need to be able to assess their effectiveness in meeting the legitimate expectations of all their stakeholders. This requires the development of a comprehensive set of "direct" PIs (that are under the control of the regulatory body) for determining the overall effectiveness of the regulatory structure and systems. Note that such direct PIs tend to concentrate on the second and third segments of the pyramid in Figure 1.

Most direct PIs characterise the efficiency of the regulatory activities, the outputs, although it may be possible to establish some direct PIs which also relate to the effectiveness of the regulatory body. They should be representative of the overall performance of the regulatory body and give information about all aspects of the regulatory work. Some objectives of direct PIs should be to:

- Verify that regulatory work is performed in accordance with the mission, strategic guidance and detailed plans.
- Verify that regulatory work is performed according to internal QA procedures.
- Measure the successful performance of work processes.
- Determine the perceptions of its various stakeholders and staff towards the regulatory process.

A prerequisite for this kind of direct indicator system is that the organisation has a functioning quality system with well-defined working processes. There is also a strong incentive for this from the Convention on Nuclear Safety.

The acceptability of the indicator system within the regulatory body can be improved by involving all staff in the definition of the indicators and the implementation of the system. The participation of the staff in the data collection and analysis improves commitment throughout the organisation.

Possible indicators of regulatory effectiveness

In Chapter 2 it was argued that a regulatory body is effective when it:

- Ensures that an acceptable level of safety is being maintained by the regulated operating organisations.

- Develops and maintains an adequate level of competence.
- Takes appropriate actions to prevent degradation of safety and to promote safety improvements.
- Performs its regulatory functions in a timely and cost-effective manner as well as in a manner that ensures the confidence of the operating organisations, the general public, and the government.
- Strives for continuous improvement in its performance.

As pointed out earlier, the effectiveness of a regulatory body in fulfilling its fundamental mission (to ensure a safe nuclear industry) can only be assessed indirectly, using PIs that derive from, and depend upon, the performance of the licensees. Such indicators should ideally show the impact of the regulatory body on:

- The predicted frequency of potential accidents (especially severe accidents).
- The levels of occupational and public radiation exposure.
- The number of significant events and near-misses on the plant.
- The "health" of the licensee's safety culture and safety management systems.
- The minimisation of radioactive waste generation and environmental impact of the licensee's plants.

Note that some of these indicators (particularly the last one) may depend not only on the performance of the licensees but also on the policies and activities of other regulatory agencies.

Some of the more important indicators of NPP safety performance that may be used by the regulatory authority as indirect indicators of effectiveness include:

- unplanned reactor scrams;
- unplanned power changes;
- unavailability of safety systems;
- breaches of technical specifications and operating rules/instructions;
- safety system failures;

- fuel cladding leakage (measured by radioactivity in the reactor coolant system);
- reactor coolant leak rate;
- emergency exercise training and performance;
- the effectiveness of occupational radiation exposure control;
- the monitoring and control of radioactive effluence;
- the completeness of the staff training records.

Other stakeholders may have additional or alternative expectations of the regulatory body, in line with the additional criteria of effectiveness quoted earlier. Issues such as developing and maintaining the competence of the regulatory body, operating in an appropriately open manner and responding promptly to signs of degrading safety are all capable of direct measurement, though with varying amounts of subjectivity. They also merge into issues related to the efficiency of the regulatory body.

Possible indicators of regulatory efficiency

Though it is useful, for organisational analysis, to define *effectiveness* and *efficiency* as two separate attributes of a regulatory organisation (see Chapter 2), there is no doubt that they merge together when one attempts to define possible direct indicators of regulatory effectiveness. Thus, for example, while Concerned Action groups may regard the publication of detailed technical reports in support of licensing decisions as part of the regulator's duty to keep them informed, other stakeholders (particularly the licensee concerned) may regard such reports as at best unnecessary and at worst, as intruding into their rightful domain. Such conflicts of interest are all bound up in the fourth criterion of regulatory effectiveness namely:

> "Performs its regulatory functions in a timely and cost effective manner as well as in a manner that ensures the confidence of the operating organisations, the general public and the government".

So the regulatory body needs to analyse very carefully what are its expected (and, if possible, agreed) outputs with regard to each of its stakeholders before attempting to set up performance measures related to them. It might then utilise indicators such as:

- The timely and efficient processing of the licensees' "safety business" (meeting deadlines, avoiding inefficient interactions with licensees, having the correct regulatory expertise available in a timely/ properly trained way, using proper prioritisation of safety issues, etc.).
- Creating an environment that makes it easier for licensees to get their safety submissions "right first time" (clarity of published regulatory standards and requirements, well-understood regulatory procedures, consistent and predictable regulatory decision-making and so on).
- Meeting internal standards of quality, cost and timeliness for producing technical reports, decision documents, public hearing documents and so on.
- Meeting internal standards of quality, cost and timeliness for informing/communicating with the public.
- Meeting internal standards of quality, cost and timeliness for necessary enforcement actions (working to an agreed enforcement strategy with pre-defined "success" criteria).
- Meeting agreed standards of quality, cost and timeliness for other activities such as assisting/advising other government departments, parliamentary select committees, international work, research activities, etc.
- Meeting agreed standards of quality, cost and timeliness for dealing with correspondence from members of the public, Concerned Action groups, etc.

A well-recognised problem with any system of performance indicators is the tendency to devote too much attention to *quantity* of work, rather to its *quality*. The indicator system needs to specify how quality will be assessed and the overriding importance of quality must be made clear to the staff. But, perhaps most important of all, the regulatory staff should feel convinced that the adoption of a Quality Management System, with an appropriate set of performance indicators, will help to demonstrate the value that they add to the overall nuclear safety system of the country – as discussed in the following Chapter.

6. ADDED VALUE OF THE REGULATOR

Introduction

In very general terms, the two main outcomes of the activities of any nuclear safety regulatory body should be:

- safe nuclear installations; and
- stakeholder confidence in the regulatory authority.

These outcomes need to be achieved in an efficient manner with high quality and without unnecessary costs to licensees and society in general.

However, as discussed in Chapter 5, it is difficult to devise performance indicators that show the extent to which a regulatory body has achieved these desirable outcomes. The outcome "safe nuclear installations" depends largely on the activities of the licensees and it is not straightforward to quantify the impact of the regulatory body in achieving it. On the other hand, the outcome "stakeholder confidence in the regulatory authority" comprises a number of potentially conflicting outcomes which depend on the expectations of the various stakeholders, including the licensees. For each stakeholder, the value added by the regulatory body also depends directly on the expectations it has concerning the role and activities of the regulator.

In Chapter 5 "Identification of stakeholders", we identified the five most important stakeholders in the activities of a nuclear regulatory body, namely: the general public; nuclear licensees; Government Departments; other national agencies and bodies concerned with nuclear power; Concerned Action groups. By analysing the role that each of these stakeholders assigns to the regulatory body it is possible to deduce the added value that each one expects from the regulator – and how it might potentially be quantified. Added value can only be measured on the basis of an agreed set of performance indicators.

Valuing the services delivered by the regulatory body

Ensuring licensees operate safely

Clearly the most important "service" delivered by any regulatory body is ensuring that licensees operate their plants safely. However, this is also the most difficult to value since, by law, licensees have complete and undivided responsibility for the safety of their plants, workers and affected members of the public, as well as their impact on the environment. Given this, one could well ask, "what safety value does the regulator add?". There are a number of ways in which this question can potentially be addressed.

- *Making the frequency of potential nuclear accidents smaller than they would have been under the licensee's own internal safety procedures.*
  This is the objective of much of the technical assessment work carried out by, or on behalf of, regulatory authorities. Typically, quantitative risk assessments are received which have passed the licensee's internal peer review mechanisms and which therefore represent the level of safety that the licensee considers appropriate and would presumably pursue if the regulatory authority didn't exist. Sometimes the regulator accepts that the case has demonstrated that the risks have been made as low as reasonably practicable (ALARP) but, more often, the subsequent interactions with the licensee result in a lower level of risk. The difference between what the licensee offers and what the regulator finally accepts is a measure of regulatory effectiveness. Of course, such regulatory risk reduction activities must take place within the context of published regulatory goals and standards. (*Caution: this sort of indicator needs very careful consideration to ensure that it does not either encourage the licensee to attempt to transfer some of his responsibility for making ALARP judgements to the regulator or discourage regulatory staff from accepting cases where ALARP has clearly been demonstrated. Its greatest value may be in convincing government and the general public of the global value of the regulator's efforts).*

- *Ensuring that the operational safety of licensee's NPPs is acceptable.*
  This is the objective of the day-to-day inspection and monitoring activities of regulatory authorities. Licensees use a wide range of

performance indicators to check on the adequacy of the safety being achieved on the various NPPs. Regulators can attempt to use these indicators to assess the impact that they are having on the safety of the plants but the difficulty is how to identify the contribution that they make. For example, if the number of inadvertent scrams on a plant reduces in a particular year, is that a result of the attention of the regulator or simply a consequence of careful operation, good maintenance, etc., on the part of the operator? The same sort of uncertainty attaches to all the licensee's operational PIs when regulators attempt to use them to judge their own performance. It is very difficult, if not impossible to deduce the regulator's impact on any individual operational PI. So regulatory bodies should: a) work on comprehensive suites of operational PIs (based on, but probably not identical to, the ones used by the licensees); b) select the PIs that are most likely to show up the effect of the regulator (but be consistent and avoid "cherry picking"); c) not attempt to get an absolute quantification of the regulator's added value but concentrate on relative outputs from year to year. Such PIs are most useful for setting inspection priorities and for giving early indications of deterioration in licensee's safety performance. Other stakeholders will be interested in "regulatory outputs" such as: number of inspections carried out; number of licence instruments processed; number of emergency exercises witnessed, and so on.

- *Licence maintenance/safety case peer review.*
  While a lot of this activity is related to the previous two regulatory activities, some of it is relevant to the licensee's longer-term strategic or commercial interests. The regulatory body may decide that such activities are not central to its main mission (to ensure nuclear safety) and may accord them a lower priority. However, it needs to devise suitable PIs to measure such activities and discriminate between those that it regards as "core" and those it regards as "discretionary". It is clear that regulators need to have, in-house or readily available, sufficient nuclear expertise to meet the "core" demands in a timely way. "Discretionary" work for licensees would take a lower priority but should still meet agreed performance criteria. Clearly a basis exists for estimating the regulator's added value in both areas of work, provided suitable PIs exist.

- *Helping licensees to get their safety cases "right first time".* Irrespective of the degree of prescription in the regulatory

traditions of different countries, there is clear evidence to show how easy it is for licensees to misinterpret a regulator's requirements and produce incomplete or unsatisfactory safety cases. This is costly in terms of time and money for both the licensee and the regulator, and can be avoided by closer and better interactions between the two bodies to help the licensee get his case "right first time". Naturally there are pitfalls to be avoided, in terms of loss of regulatory independence and potential transfer of safety responsibilities. However, provided these can be avoided and suitable PIs constructed, it should be possible to assess the value that such regulatory activity adds to achieving adequate safety in an economic fashion.

Ensuring stakeholder confidence in the regulatory authority

Each of the stakeholders needs to have confidence in the regulatory authority and value the services that it delivers. In the previous section the value added by the regulator to the licensee's duty to operate safe nuclear installations was discussed. Part of that value relates to the confidence of the licensees in the impartiality, competence and consistency of the regulatory authority and will not be discussed further here. In this section we shall deal with regulatory activities on behalf of other stakeholders.

- *The general public.* The regulatory activities associated with ensuring safe nuclear installations are all carried out on behalf of the general public and it is important that regulators develop skills and techniques for informing and communicating with the public about them. This can be done by:

  - Developing, publishing and updating as necessary the technical standards that the regulatory authority applies to NPPs to ensure that they operate safely.
  - Publishing discussion documents about the regulator's general approach to risk, enforcement, etc., and more detailed standards as appropriate.
  - Publishing documents explaining the basis of various licensing decisions e.g. licence approval/renewal, periodic safety review findings, incident investigations and so on.
  - Publishing general information bulletins on the organisation, staffing, training etc. of the regulatory body.

- Participating in local liaison committee meetings at NPP sites.
- Participating in public hearings and public inquiries.
- Meeting groups of concerned citizens.

It is relatively straightforward to generate PIs to measure these activities, though their actual added value may be much more difficult to determine. There are two possible approaches to valuing them: either attempt to assess their intrinsic value in convincing the public that the regulatory authority is sensible, impartial and competent, or assume that a regulatory authority, like any other business, should spend some percentage of the value of its other main activities in such public communication. The latter approach is, of course, quite straightforward though its basis may be open to question by, for example, government officials! The former is difficult and requires the regulator to determine what the relevant sections of the general public thought of its attempts to communicate with them. This is an area where further discussion and research are needed, especially in the light of on-going developments on openness. It might be possible, for example, to formulate PIs relating to the scores achieved in independent statistical surveys of public attitudes towards nuclear power, and towards the regulatory body.

- *Government Departments.* Although most countries have specific arrangements to ensure that day-to-day regulatory decisions are free from political interference, regulatory authorities must account for their budgets, staff levels, planning arrangements, outputs, etc. to their governments, which either fund them directly or permit them to levy fees on their licensees. So regulatory authorities need appropriate PIs for reporting to government and these should be recognisable and comprehensible to government officials and politicians! Undoubtedly the greatest value of a regulatory authority to government comes from the contribution it makes to preventing nuclear accidents. Even a very approximate estimate of this is very useful in convincing Ministers, parliamentary select committees and individual MPs of the need for a properly staffed and equipped organisation. Government departments also rely on the technical competence and independence of the regulatory authority to help convince other stakeholders, both national and international, of the safety of their NPPs. They also call on the technical competence of their nuclear regulators in various international discussions and assistance activities. PIs can readily

be generated to measure this sort of activity and its added value can be assessed by calculating what it would cost to set up contracts with outside organisations to provide the same support. In making such estimations of cost it is important to define clearly the experience, competence and independence that are embodied in the regulator and which may be very difficult, or even impossible, to replicate.

- *Other national agencies and bodies concerned with nuclear power.* The nature and extent of the regulatory body's interaction with such agencies/bodies depends on the legal and industrial structure of each individual country. In most countries the nuclear regulatory authority is an integral part of a network which includes: other industrial and financial regulators; technical support organisations; research bodies; national advisory bodies; and so on. Many of these bodies depend on the regulator to set acceptable levels of risk from NPPs, as well as defining the more detailed standards and procedures that are required to be met on licensed nuclear plants. Without such guidance they would, for instance, be much less effective in carrying out meaningful nuclear safety research, developing new or replacement items of plant, helping to prepare safety cases, defining the operating envelope of NPPs in the commercial electricity market, and so on. A clear understanding of the regulator's interactions with each of these agencies/bodies should help to define the PIs that are needed to measure and evaluate them. As above, one approach to assessing the regulator's added value for these stakeholders would be to calculate the costs of providing the equivalent "services" using a separate organisation – with the same caveats!

- *Concerned Action groups.* The extent of any regulatory body's interaction with such groups depends on national circumstances but, for most countries, it is growing rapidly. Some of these groups are capable of preparing extremely detailed technical reports which they expect the regulatory authority to treat in the same way as material supplied by the licensees. They can also consume a lot of regulatory resources by attempting to gain access to the licensees' technical information through the regulator. There are a number of other ways in which they make demands on the regulator's time and expertise. At the outset, the regulatory authority should establish some ground rules with its other stakeholders, particularly the government and the licensees,

about the extent and funding of these interactions. For instance, it may be wise for the government to arrange separate funding for such interactions (rather than relying on licensees' fees, for instance) to avoid possible conflicts of interest. Once these ground rules have been agreed, it should be relatively straightforward to devise appropriate PIs to measure the amount of regulatory effort expended – and to assess its value on the basis of what it would cost to purchase it from outside the regulatory body.

Conclusion

The above list of stakeholders and "services" is probably not complete but it does serve to illustrate the wide range of activities that any regulatory authority carries out. It shows that, in principle, the added safety value of each of these activities can be estimated, provided that suitable PIs are available. Naturally much work remains to be done to achieve reliable results and regulators need to be careful about how they are used. However, the *process* of attempting such quantification is potentially very valuable in elucidating why regulatory bodies do things in certain ways, what improvements are possible, how they can demonstrate the quality of what they do and how they can better prioritise the calls on their resources.

7. CONCLUSIONS AND RECOMMENDATIONS

CNRA members have noted that one common theme emerging from many recent national and international meetings on such issues as de-regulation, maintaining industry and regulatory competence, and communicating with the public is the importance of achieving, measuring and demonstrating regulatory effectiveness. Although independent regulatory authorities are required by the atomic laws of each Member State this, of itself, is no longer sufficient. In the new climate of openness and accountability it is important, for both nuclear safety and public confidence, that the regulatory authority should be as effective and efficient as possible and should be clear about the value that it adds to the overall nuclear safety system.

Recommendation 1: CNRA should remain active in the area of exchanging information on regulatory effectiveness. The issue has a high priority in many countries and there is a need to maintain a high level of international exchange.

Members agreed that, assuming the necessary authority and resources are available, a regulatory body can be considered to be e*ffective* when it:

- Ensures that an acceptable level of safety is being maintained by the regulated operating organisations.
- Develops and maintains an adequate level of competence.
- Takes appropriate actions to prevent degradation of safety and to provide safety improvements.
- Performs its regulatory functions in a timely and cost-effective manner as well as in a manner that ensures the confidence of the operating organisations, the general public and the government.
- Strives for continuous improvement in its performance.

Recommendation 2: CNRA members should adopt this definition of regulatory effectiveness.

Members agreed that it was helpful to differentiate between regulatory effectiveness (meaning "to do the right work") and regulatory efficiency (meaning "to do the work right") when carrying out a process analysis of a regulatory body. It was noted that process management is used by several regulatory bodies as a tool for managing their core activities and identifying their necessary prerequisites and other support activities. Several countries have developed quite similar effectiveness models. The model developed in this report uses conventional management wisdom as well as modern business practices adapted to governmental organisations. It has been successfully used in a case study performed by several countries.

Recommendation 3: CNRA members should adopt the effectiveness model developed in this report, modified as necessary for their own individual circumstances.

Members agreed that modern Quality Management Systems can provide a vehicle for the continuous improvement of the efficiency and effectiveness of regulatory bodies. Such quality systems can contribute to both regulatory effectiveness and efficiency. Almost every country is applying some type of quality system and the report identifies the main ones.

Recommendation 4: Regulatory authorities should consider the positive benefits of applying a quality management system to their activities; the choice of which system to use should be a matter for each regulatory authority to decide

The question of third party accreditation or certification is a matter for each individual regulatory authority to decide. The advantages of accreditation or certification , such as clear visibility and conformity to a widely-recognised standard, have to be weighed against the disadvantages, such as the cost, involvement of outsiders in regulatory affairs and the possibility of focusing regulatory staff on the wrong target. Members agreed that the fundamentally-important thing is that the regulatory authority should go through the process of applying a quality management model.

Recommendation 5: Formal accreditation should only be pursued if the regulatory authority is convinced that it will bring some extra significant benefits. Certification may be more appropriate for regulatory bodies, particularly if they include activities for which quality standards can readily be established. However, the ultimate decisions should be left to each individual regulatory authority.

Members agreed that regulatory performance indicators can provide a useful vehicle for assessing the performance of the regulatory body as well as helping it to manage its "business" better. Regulatory authorities need to be clear about the totality of the "business" in which they are involved, who their stakeholders are and what expectations these stakeholders have. Once these aspects have been identified, it is feasible to develop performance indicators which measure either regulatory outcomes or regulatory outputs. Members agreed that the most useful approach is to consider regulatory performance indicators in terms of:

- direct performance indicators which attempt to measure the regulator's own activities and tend to use data generated within the regulatory body itself; and
- indirect performance indicators which rely on the performance indicators of other stakeholders, principally the licensees, to deduce the performance of the regulatory body.

Some criteria for good performance indicators are elaborated in the report together with a number of possible indicators of regulatory effectiveness and efficiency. However, there is a clear need to further advance this work internationally.

Recommendation 6: This is one of the highest priority issues being undertaken by Member countries. It is an opportune time to attempt to reach international consensus on the types of indicators that can best be applied to measure regulatory efficiency and effectiveness. It is recommended that a task group be set up to develop specific performance indicators for measuring regulatory efficiency and effectiveness.

Members agreed that the application of an appropriate quality management model to a regulatory body, when taken in conjunction with suitable performance indicators, can provide a basis for assessing the value that the regulatory body adds to the overall nuclear safety system. They recognised

that this is very new work and that they should proceed with caution. However, they agreed that it has considerable potential for reassuring stakeholders and the regulator's own staff of the value of the organisation and the appropriateness of its processes and outputs.

Recommendation 7: It is recommended that CNRA should continue to explore how the added value of a regulatory body can be deduced from the available indicators of performance. Additional research may be beneficial for establishing the correlations that exist between performance indicators and regulatory added value.

Table 1. **Summary of Case Studies**

	Sweden	Finland	United States
Mission	SKI exists, because the Swedish society wants to: • prevent accidents with radiological consequences; • prevent nuclear materials and technology of Swedish origin to end up in nuclear weapons use; • fulfil the responsibility to future generations as concerns spent nuclear fuel and waste; • be well informed about nuclear risks and safety. SKI focuses its activities to: • provide a clear definition of safety requirements; • control compliance with requirements by supervision focusing on licensee's processes for safety; • initiate safety improvements whenever justified by operating experience, or research and development;	The mission of STUK is to limit and prevent harmful effects arising from radiation. The mission of the Nuclear Regulator Regulation Department is to ensure that: • the Finnish nuclear power plants are designed and operated according to the regulations; • the operation of plants does not cause radiation hazards to the plant personnel or to the public; • the operation does not damage environment or property. For personnel involved in regulatory operations values such as professional knowledge, honesty, openness and courage and ethical rules such as legality, openness, independence, equality, relativity, verifiability and intention-boundness are practised.	To regulate the Nation's civilian use of by-product, source, and special nuclear materials to ensure adequate protection of public health and safety, to promote the common defence and security, and to protect the environment.

	Sweden	Finland	United States
Mission	• maintain and develop competence at SKI, licensees and nationally; • report and inform stakeholders; • implement quality assurance of SKI regulatory activities. Maintain preparedness at SKI to give advice to relevant authorities in charge of rescue operations in case of emergency.		
Core Activities	• preparation of regulations; • conduct of safety reviews (including licensing); • carrying out of inspections; • control of nuclear material; • assessment of operating experience feedback; • conduct of safety evaluations; • conduct of international work; • carrying out research; • provision of information (to external world).	• preparation of proposals for higher level regulations; • preparation of regulatory guides; • safety assessment for the main licensing processes; • regulatory control of nuclear facilities; • response to emergency situations • public information; • duties due to international and bilateral agreements.	• licensing; • rulemaking; • allegations; • inspections; • event response and assessment control of nuclear materials.

	Sweden	Finland	United States
Prerequisites	SKI Quality System developed and documented to support processes which includes mission and tasks, regulatory strategy and principles and description of processes, core values, etc.	• management; • maintaining and development of internal QA system; • maintaining and developing the core knowledge and skills; • nuclear safety research; • information management.	• programme development • project management • regulatory licensing improvement • process improvement • management • administrative
Assessment	• continuous follow-up of work activities; • comprehensive self-assessment each year; • international peer reviews; • monitoring public confidence; • assessing internal work climate; • feedback from licensees; • international co-operation and benchmarking.	• yearly self-assessments; • organisational studies and seminars; • yearly audits; • safety indicator system; • external assessments (IRRT, etc.).	Planning, Budgeting and Performance Management (PBPM) as a continuing and ongoing process composed of: • setting strategic direction; • determining programmes and resources; • measuring and monitoring performance; • assessing performance.

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