Nuclear Regulation
2011

Improving Nuclear Regulation

NEA Regulatory Guidance Booklets

Volumes 1–14



NUCLEAR ENERGY AGENCY

Nuclear Regulation
NEA/CNRA/R(2011)10 ISBN 978-92-64-99162-0

Improving Nuclear Regulation

NEA Regulatory Guidance Booklets

Volumes 1-14

NEA No. 6905

NUCLEAR ENERGY AGENCY
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

The OECD is a unique forum where the governments of 34 democracies work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD member countries are: Australia, Austria, Belgium, Canada, Chile, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Republic of Korea, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The European Commission takes part in the work of the OECD.

OECD Publishing disseminates widely the results of the Organisation's statistics gathering and research on economic, social and environmental issues, as well as the conventions, guidelines and standards agreed by its members.

NUCLEAR ENERGY AGENCY

The OECD Nuclear Energy Agency (NEA) was established on 1 February 1958. Current NEA membership consists of 30 OECD member countries: Australia, Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Luxembourg, Mexico, the Netherlands, Norway, Poland, Portugal, the Republic of Korea, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The European Commission 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 the 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.

Corrigenda to OECD publications may be found online at: *www.oecd.org/publishing/corrigenda*.

Cover credits: Olkiluoto 3, TVO, Finland (*Hannu Huovila); Saint-Alban, France (EDF, Marc Morceau); Beznau NPP, Switzerland.*

Foreword

The Committee on Nuclear Regulatory Activities (CNRA) of the OECD Nuclear Energy Agency (NEA) is an international committee composed primarily of senior nuclear regulators. It was established 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 that part of the NEA programme concerning the regulation, licensing and inspection of nuclear installations. In particular, the Committee reviews current practices and operating experience.

Over the previous decade, the CNRA has produced a series of regulatory guidance reports known as the "green booklets". These reports are prepared and peer reviewed by senior regulators. They provide a unique resource on key contemporary nuclear regulatory issues.

The full series of these reports was brought together in one edition for the first time in 2009 and was widely found to be a useful resource. This second edition comprises 14 volumes, including the latest on *The Nuclear Regulator's Role in Assessing Licensee Oversight of Vendor and Other Contracted Services*. The reports address various challenges that could apply throughout the lifetime of a nuclear facility, including design, siting, manufacturing, construction, commissioning, operation, maintenance and decommissioning. The compilation is intended to serve as a knowledge management tool both for current regulators and the new nuclear professionals and organisations entering the regulatory field. While the primary audience for the publication is nuclear regulators, the information and concepts may also be of interest to nuclear operators, other nuclear organisations and the general public.

Acknowledgements

These reports have been developed by senior-level regulatory experts from the NEA Committee on Nuclear Regulatory Activities (CNRA) who are cited in each of the chapters. The work benefited from the guidance of the task group chairs and a number of expert consultants. In particular, Dr. Serge Prêtre, former Director-General of the Swiss Nuclear Safety Inspectorate (HSK), was instrumental as Chair for the first several task groups, including the booklets on safety culture, and setting a high standard for the final products. Dr. Ulrich Schmocker, HSK Director-General, provided skilful leadership as Chair for three booklets, including those on decision-making and assuring nuclear safety.

In addition to the task group chairs and CNRA senior-level experts, the production of these reports relied on expert consultants for the content and quality of the reports. These consultants provided clear insights into the objectives, much of the in-depth analysis throughout the reports, overall co-ordination of their completion (including moderating meetings and preparing drafts), as well as many hours in editing and compiling the final versions. Especially noteworthy are Dr. Thomas E. Murley, Dr. Samuel A. Harbison and Dr. Kurt Asmis.

Finally, the members of the NEA Nuclear Safety Division assisted the task groups and consultants. Dr. Gianni Frescura provided outstanding leadership in guiding the development of the initial series of booklets, followed by Secretariat members who provided guidance and support for the subsequent reports in the series.

Table of Contents

Executive Summary

Introduction

Over the past decade, the Committee on Nuclear Regulatory Activities (CNRA) has produced a series of guidance documents known as the "Green Booklets". These reports, prepared and peer reviewed by senior regulators, have provided unique source material primarily for nuclear safety regulators, but also of interest to government authorities, nuclear power plant operators and the general public. The focus of most of these reports has been on specific regulatory challenges although a few have been addressed to broader regulatory issues.

A common theme throughout the series of green booklets is the premise that the fundamental objective of all nuclear safety regulatory bodies is to ensure that nuclear facilities are operated at all times in an acceptably safe manner including the safe conduct of decommissioning activities. In meeting this objective, the regulator must keep in mind that it is the operator that has the responsibility for safely operating a nuclear facility, while it is the nuclear regulator's responsibility to oversee the operator's activities in order to assure that a plant is operated safely.

This publication, for the first time, presents all of these reports in one edition. As such, it is intended to serve as a knowledge management tool both for current regulators and the younger generation of nuclear experts entering the regulatory field. While the audience for this publication is primarily nuclear regulators, the information and ideas may also be of interest to nuclear operators, other nuclear industry organisations and the general public.

Each of the fourteen booklets in this series was overseen by a Task Group of senior regulators from a wide range of OECD countries, and each was prepared by experienced former regulators as consultants to the CNRA. As a result, the booklets in this compilation represent the collective experience and insights from a broad range of OECD nuclear regulatory experts.

Qualifications on the contents

The reports contained in this publication were produced starting in 1999. They are reproduced in this publication in their original form. While there have been evolutionary changes and advances in regulatory practice over the years, these reports continue to provide valuable guidance for regulators in their approach to nuclear regulation. As noted in many of the reports, the experts utilised international experience, such as IAEA Standards, in addition to their own national experience.

In selecting the issues and developing and preparing the individual reports, the senior regulators of the CNRA based their work on priorities in regulatory safety issues set forth in the CNRA report on Future Nuclear Regulatory Challenges[1] and the safety relevance determined by the CNRA. The reports have been rearranged in this publication to provide the reader a systematic and logical categorisation for reading and learning. The original order of the publication for the CNRA green booklets is provided in Annex A.

Outline

In order for the reader to have a systematic and structured understanding, the series has been divided into three categories: regulatory challenges, regulatory effectiveness and regulatory assessment.

The first section is divided into nine chapters and looks at regulatory challenges, including areas of human and organisational factors, socio-economic issues, use of operating experience to promote safety, nuclear plant decommissioning and licensee. The second section contains three chapters showing how regulators assess and measure their own performance, and the third section has the final two chapters which explain how regulators assess safety information and make judgments for their regulatory actions. Annex A provides the original publication order for the reports. Reference and additional reading material related to the various booklets are located in Annex B. Annex C contains the complete compilation of survey results used to produce the report on Licensee Safety Assessment.

The following paragraphs provide a short synopsis of each section and its chapters.

Regulatory Challenges

Chapters 1 and 2: The Role of the Nuclear Regulator in Promoting and Evaluating Safety Culture and Regulatory Response Strategies for Safety Culture Problems

Safety Culture is that assembly of characteristics and attitudes in organisations and individuals which establishes that, as an overriding priority, nuclear power plant safety issues receive the attention warranted by their significance.[2]

The first chapter looks at how the relationship between the regulator and operator can influence plant safety culture either negatively or positively and discusses how regulators can recognise early signs of declining performance. The second chapter explores regulatory responses strategies for dealing with declining performance and follow-up activities.

1. NEA (1998), *Future Nuclear Regulatory Challenges*, OECD, Paris. ISBN 92-64-16106-6.
2. IAEA (1991), Safety Series No. 75-INSAG-4, Safety Culture: a Report by the International Nuclear Safety Advisory Group, Vienna. Definition of Safety Culture from INSAG-4.

Chapter 3: Nuclear Regulatory Challenges Related to Human Performance

This chapter discusses how and why human performance is important in relation to nuclear safety and challenges faced by regulators in developing better tools for handling the complex nature of this issue.

Chapter 4: Regulatory Challenges in Using Nuclear Operating Experience

The primary focus of this chapter is on how regulatory bodies can assure that operating experience is used effectively to promote the safety of nuclear power plants.

Chapter 5: Nuclear Regulatory Review of Licensee Self-assessment (LSA)

Licensee Self-Assessment (LSA) by nuclear power plant operators is described as all the activities that a licensee performs in order to identify opportunities for improvements. This chapter provides an overview of regulatory philosophy on and approaches to self-assessment as performed by licensees.

Chapter 6: Nuclear Regulatory Challenges Arising from Competition in Electricity Markets

Over the past ten years, changes have taken place in electricity markets which has included more open competition (e.g., deregulation) both nationally and internationally. This chapter provides insights on the potential challenges and the safety implications and possible regulatory strategies for dealing with them.

Chapter 7: The Nuclear Regulatory Challenges in Judging Safety Backfits

Economic pressures have led nuclear power plant operators to seek ways to increase production and reduce operating costs. Corresponding pressures on the regulator includes operator demands to reduce regulatory burdens perceived as unnecessary and general resistance to consider safety backfits sought by the regulator. This chapter describes potential situations giving rise to safety backfit questions and discusses regulatory approaches for judging them.

Chapter 8: The Regulatory Challenges of Decommissioning Nuclear Reactors

Decommissioning in this chapter is defined in its broadest sense, that is, to cover all of the administrative and technical actions associated with early planning for cessation of operations through termination of all licenses and release of the site from nuclear regulatory control.

The chapter describes the broad set of safety, environmental, organisational, human factors and public policy issues that may arise during the decommissioning of nuclear reactors and that the regulatory body should be prepared to deal with in the framework of its national regulatory system.

Chapter 9: The Nuclear Regulator's Role in Assessing Licensee Oversight of Vendor and Other Contracted Services

Contracted services are an integral part of the design, construction and operation of a nuclear facility. The licensee must ensure that throughout any contracting process, the licensee must retain ultimate responsibility for the quality of work performed, whether by its staff or by contractors, and for maintaining the safety of the licensed facility. This chapter provides guidance to assist regulatory bodies in assessing their current practices on the oversight of the licensees' use of contractors, and in adapting their practices where necessary to meet the changing situation.

Regulatory Effectiveness

Chapters 10 and 11: Improving nuclear regulatory effectiveness and direct indicators of nuclear regulatory efficiency and effectiveness pilot project results

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 and strives for continuous improvements in its performance.

Chapter 10 covers the basic concepts underlying nuclear regulatory effectiveness, while Chapter 11 describes the results of a pilot project carried out to test a set of indicators for measuring and assessing regulatory efficiency and effectiveness.

Chapter 12: Improving versus maintaining nuclear safety

The concept of improving safety versus maintaining safety has been discussed at a number of meetings of nuclear regulators in recent years, and national reports have indicated that there are philosophical differences between NEA member countries about whether their regulatory approaches require licensees to continuously improve safety or to continuously maintain safety.

This chapter provides an overview of current regulatory philosophies and approaches as well as insights into a selection of public perception issues. It concludes that, while the actual level of safety achieved in all member countries is probably much the same, this is difficult to prove in a quantitative way. In practice, all regulatory approaches require improvements to be made to correct deficiencies and when otherwise warranted.

Regulatory Assessment

Chapter 13: Nuclear Regulatory Decision Making

The fundamental objective of all nuclear safety regulatory bodies is to ensure that nuclear utilities operate their plants at all times in an acceptably safe manner. In meeting this objective, the regulatory body should strive to ensure that its regulatory decisions are technically sound, consistent from case to case, and timely. In addition, the regulator must be aware that its decisions and the circumstances surrounding those decisions can affect how its stakeholders, such as government policy makers, the industry it regulates, and the public, view it as an effective and credible regulator. In order to maintain the confidence of those stakeholders, the regulator should make sure that its decisions are transparent, have a clear basis in law and regulations, and are seen by impartial observers to be fair to all parties

This chapter discusses some basic principles and criteria that a regulatory body should consider in making decisions and describes the elements of an integrated framework for making regulatory decisions.

Chapter 14: The Regulatory Goal of Assuring Nuclear Safety

There are currently many sources of information available to the regulator pertaining to safety at any nuclear facility, such as inspection reports, operating experience reports, research results, periodic safety reviews, probabilistic safety analysis (PSA) results, insights from IAEA reviews and other similar information. A major challenge for the regulator is to systematically collect and analyse this information in order to arrive at an integrated assessment of the level of safety of the particular facility and then to make a judgement about its acceptability.

The primary focus of this chapter is on how the regulatory body can systematically collect and make an integrated analysis of all the relevant safety information available to it and arrive at a sound judgement on the acceptability of the level of safety of the facilities that it regulates.

REGULATORY CHALLENGES

1. The Role of the Nuclear Regulator in Promoting and Evaluating Safety Culture

Foreword

The Committee on Nuclear Regulatory Activities (CNRA) of the OECD Nuclear Energy Agency (NEA) is an international body made up of senior representatives from nuclear regulatory bodies. The Committee guides the NEA programme concerning the regulation, licensing and inspection of nuclear installations with respect to safety. It acts as a forum for the exchange of information and experience, and for the review of developments which could affect regulatory requirements.

In 1998, following the publication of the CNRA report on Future Regulatory Challenges, the Committee established a Task Group to advance the discussion on how a regulatory organisation recognises and addresses safety performance problems that may stem from safety culture weaknesses. This report is the first in a series produced by the Task Group and focuses on early signs of declining safety performance, and the role of the regulator in promoting and evaluating safety culture. A follow-up paper, currently in preparation will amplify the discussion on the response strategies available to a regulatory organisation in dealing with safety culture problems.

The report was prepared by Thomas E. Murley, on the basis of discussion and input provided by the members of the Task Group listed below:

Serge Prêtre (Chairman, Switzerland), Samuel J. Collins (United States of America), Michael Cullingford (United States of America), Klaus Kotthoff (Germany), Philippe Saint-Raymond (France), Mike Taylor (Canada), Christer Viktorsson (Sweden), Christopher Willby (United Kingdom), Paul Woodhouse (United Kingdom), Roy Zimmerman (United States of America) and Gianni Frescura (NEA).

Introduction

The term "safety culture" was first introduced by the International Nuclear Safety Advisory Group (INSAG) in 1986 in its "Summary Report on the Post-Accident Review Meeting on the Chernobyl Accident." An early definition was given in the INSAG-4 report in 1991:

"Safety Culture is that assembly of characteristics and attitudes in organisations and individuals which establishes that, as an overriding priority, nuclear plant safety issues receive the attention warranted by their significance."

Thus it is understood that safety culture refers to an organisation's basic safety values, attitudes toward conservative operation, quality, professionalism, continuous learning and improvement processes as well as an environment in which workers are free to raise safety concerns without fear of retribution.

By now, there is an extensive body of literature on safety culture in many countries as well as international organisations such as the International Atomic Energy Agency (IAEA) and the NEA. The bulk of this literature is concerned with defining the attributes of a good safety culture and describing how nuclear plant operators can develop those attributes.

It has become clear that safety culture involves everyone whose attitude may influence nuclear safety, not only the utility operators but also the regulatory body. The aim of this document is to focus on the dual role of the regulatory body in both (a) promoting safety culture, through its own example and through encouragement given to operators, and (b) evaluating the safety culture of licensees through performance or process based inspections and other methods.

Defining and establishing an effective safety culture and recognising related trends is still a recent initiative, undergoing development and review within operator organisations and regulatory bodies. As more studies are performed and experience is gained in this area, the role of the regulator in promoting and evaluating safety culture will continue to evolve and mature.

The audience for this report, therefore, is primarily nuclear regulators, but the information and ideas may also be of interest to governmental authorities, operators, other industry organisations and the general public.

Importance of safety culture to nuclear safety

Our understanding of the essential aspects of nuclear safety has evolved and deepened over the four decades of commercial nuclear power experience. In the early years, the primary focus was on basic physics and engineering principles, safety system design features, codes and standards, and general design criteria governing such matters as redundancy and diversity of safety systems.

The accident at the TMI-2 plant in 1979 showed that more attention was required on the human factor aspects of safety such as operator qualifications and training, emergency operating procedures, accident mitigation, and emergency planning.

It was several years later, in the aftermath of the 1986 accident at Chernobyl, that the importance of safety culture came into clearer focus. That accident showed that lack of a safety culture can lead to operator behaviour which breaches multiple barriers of the entire defence-in-depth safety fabric. That is, when the basic safety values, norms and attitudes of an entire organisation are weak or missing, then one can have procedures ignored, operating limits exceeded and safety systems bypassed, no matter how well they have been designed and built.

We now know that a good safety culture is essential for overall nuclear safety. However, it does not represent the whole of safety – a robust design, competent management of the technology and work processes, and compliance with regulations are also required for safety.

Safety culture must permeate all levels of an operating organisation. At the top of the corporation, management commitment to safety has a profound influence on the safety culture of the entire organisation, and senior management must establish a set of values emphasizing safety and quality, making it clear that workers should not have a conflict in their daily tasks between safety and electrical production goals. The employees will keenly watch whether the senior management's actions match their words in this regard.

For the plant management it means, for example, establishing an organisation which facilitates openness, confidence between employees and managers, and control of quality in all activities. For the operating staff, safety culture means a feeling of personal accountability for safe operations, having a questioning attitude, effective communication between different departments, and following the rules and procedures.

At the time when in many countries, there is an increasing competitive pressure which leads operators to search for every means to lower production costs, a robust safety culture is more than ever necessary to sustain safe operation in the face of these economic pressures.

Role and attitude of regulator in promoting safety culture

In discussing the role of the regulator, we must keep in mind that the operator has the responsibility for safely operating the nuclear power plant. Nothing the regulator does should ever diminish or interfere with that basic principle of responsibility for safety.

There are differences among countries not only in national cultures but in the form of safety regulation, which may range from a highly prescriptive system to a more performance based system, depending on the laws and regulations of each country. But regardless of the system of regulation, the regulator has the responsibility for independently assuring that nuclear plants are operated safely.

The nature of the relationship between the regulator and the operator can influence the operator's safety culture at a plant either positively or negatively. In promoting safety culture, a regulatory body should set a good example in its own performance. This means, for example, the regulatory body should be technically competent, set high safety standards for itself, conduct its dealings with operators in a professional manner and show good judgement in its regulatory decisions. Some of the attributes of a good regulatory safety culture are the following:

- A clear organisational commitment to priority of safety matters.
- Clear lines of responsibility within the regulatory body.
- A programme of initial and continuing training to maintain regulatory staff competence.
- A personal commitment to safety from every staff member.

- Good communication and co-ordination between organisational units of the regulatory body.
- Clear guidelines for conducting safety reviews.
- Clear guidelines for conducting safety inspections.
- Clear regulatory acceptance criteria.
- A commitment to timely regulatory decisions.
- A commitment to regulatory intervention that is proportionate to the safety circumstances.
- The use of risk insights in decision making.

Although it is beyond the scope of this paper, one should note that the government can also play a key role in the safety culture of the regulatory body. In particular, it is important for the government to maintain a strong separation between safety regulation and energy policy.

In a sense, it is easy for regulators to emphasize safety culture within their own organisations. After all, safety is the primary purpose of the regulatory body. What is more difficult for the regulator is finding the right balance of firmness but fairness in dealing with the operator. In addition to enforcing safety regulations, the regulator should make sure he/she has a positive effect on the operator's safety culture.

The regulator can promote safety culture in the operator's organisation just through the mere fact of placing it on the agenda at the highest organisational levels. The operator's priorities are influenced by those matters regarded as important by the regulatory body. Thus, the regulator can stimulate the development of a safety culture by providing positive reinforcement for good performance and high quality in plant work processes, by encouraging good safety practices, by promoting the examples of operators having a good safety culture, and by recognising initiatives of industry organisations.

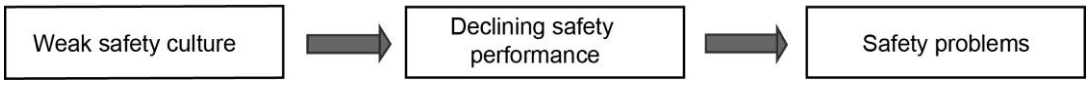
Role of regulator in evaluating safety culture

When discussing this concept with operators, the regulator should recognise that it is not really possible to quantitatively measure safety culture. Some operators have found it useful to conduct surveys evaluating safety culture attributes in order to provide management with insights regarding the underlying safety values and attitudes of the workforce at their nuclear plant. But this is a tool that is generally regarded as not yet appropriate for use by a regulatory body. Instead the regulator can evaluate the outward operational manifestations of safety culture as well as the quality of work processes, and not the safety culture itself. The role of safety culture performance indicators in such evaluations will be determined by each regulatory body.

One of the most difficult challenges in assessing the safety performance at a nuclear power plant is to recognise the early signs of declining safety performance, before conditions become so

serious that regulatory sanctions must be imposed or, worse, a serious incident or accident occurs. Most nuclear plants collect and publish a standard set of performance indicators such as automatic trips, safety system failures, forced outage rate and collective radiation exposure. Unfortunately, these are lagging indicators, and by the time negative trends in the performance indicators are evident, the plant is well into a stage of declining performance. Furthermore, the indicators are at such a high level that they give few clues regarding the underlying weaknesses causing the declining performance. For this reason, it is important that the safety regulator have the capability to inspect and recognise early signs of declining performance.

The regulatory evaluation strategy is based on the performance model shown below, where it is assumed that when a weak safety culture exists for a period of time, signs of declining safety performance will appear. If the root causes are not found and corrected, actual safety problems will eventually appear. Therefore, the regulator will have to look for signs of declining performance and subsequently evaluate whether there are signs of a weak safety culture, which may be the root cause of the declining performance.



In carrying out this role, the regulator may use new techniques in addition to the traditional regulatory tools and methods developed over the years to evaluate safety performance. Experience in several countries has shown that a good approach is to have senior on-site inspectors who can observe the day-to-day operations of the plant. These observations can be augmented by periodic specialist team inspections that include experienced inspectors who bring a fresh perspective to the site.

To facilitate the recognition of declining plant processes and performance, the regulator may perform periodic safety assessments of a facility. This should be a systematic assessment of performance based on co-ordinated discussions and reviews by the regulatory staff. The assessment may include the following:

- Observations by site inspectors and specialist inspectors.
- Reviews by regulatory safety specialists.
- Reviews of trends in event reports.
- Review of the effectiveness of operator's controls to identify, correct and prevent problems. These controls include: safety review committees, root cause analysis programmes, corrective action programmes, and self-assessment programmes.
- Review of work backlog and delays in implementing prescribed actions.
- Assessment of day-to-day incidents, which can reveal both organisational weaknesses and inadequate response by individuals.

- Review of operating events to look carefully for safety significant events or conditions that may be precursors to serious accidents. Often it requires an analysis using probabilistic safety assessment (PSA) methodology to fully understand the safety significance of a complex event.

When the outcome of a safety assessment suggests the onset of declining performance, the regulator may decide upon a special surveillance programme for the plant. This could include regulator meetings with plant management and staff to discuss the assessment findings and to better understand any special circumstances facing the plant (such as budget or personnel changes). The purpose of these meetings is not to place the operator on the defensive but to encourage improvements.

A key to having good inspection findings to make the safety assessment insightful and accurate is for regulatory management to give their inspectors guidance on what to look for. While it is not possible to present a complete list of performance weaknesses at a nuclear power plant, the following list gives a general idea of early signs for which the inspectors may look.

Early signs of declining performance

Management

- Inadequate capital investment in upgrading plant equipment.
- Inadequate resources for operations and maintenance.
- Frequent deferral of needed improvements.
- High number of operator work-around items.
- Poor oversight and control of contractors.

Operations

- Operator errors due to inattention to details.
- Loss of system configuration control (e.g., valve alignment errors).
- Misalignment of electrical and mechanical systems.
- Errors in reactivity manipulations.
- Operator errors due to training inadequacy.
- Failure to perform equipment checks and surveillances.
- Failure to follow operating procedures.
- Decision-making dominated by concern for production.
- Large number of employee grievances.
- Plant restart after an incident without full analysis.
- Failure to stay within allowed range of operating parameters.

Maintenance

- Large backlog of overdue maintenance work items.
- Large backlog of inoperable equipment.
- Inadequate control of maintenance work.
- Reactor trips caused by maintenance errors.
- Leaking valves.
- Poor housekeeping.
- Poor material condition of plant equipment.
- Failure to follow maintenance procedures.

Engineering design and safety analysis
• Inadequate qualification of equipment for accident conditions. • Inadequate fire protection design and equipment qualification. • Superficial evaluation of anomalous equipment behaviour. • Inadequate response to operating experience including other plants. • Inadequate support of operators with timely safety analyses. • Poor preparation of plant modifications.
Plant documentation
• Plant changes not incorporated into design basis documents. • Large backlog of design change modifications. • Large backlog of procedure changes. • Outdated safety analyses.
Radiological controls
• Poor planning of radiological protection for maintenance work. • Inadequate radiological posting of work areas. • Worker overexposures and contaminations. • Inadequate radiological training of workers. • Weak ALARA programme. • Upward trend in collective radiation exposure. • Upward trend in effluent discharges.
Outage activities
• Poor planning of work activities. • Poor control of work activities throughout the site. • Failure to maintain adequate shutdown cooling. • High collective radiation exposure. • Poor industrial health and safety record.
Event analysis
• Failure to recognise potential accident precursors. • No formal programme for analysing operating events.
Regulatory relations
• Long delays or failure to meet regulatory commitments. • Failure to maintain operation within current licensing basis. • Inadequate response to regulatory correspondence.

When several of these signs are present at a nuclear plant for some time, and seem to be correlated, careful evaluation of each situation is needed. In some cases, these signs of deep-seated problems can be masked for years by high plant capacity factors, while the problems continue to build up a growing backlog of corrective action work. Eventually the cumulative backlog becomes so large that the organisation cannot deal with it but is simply reduced to coping with day-to-day problems as they arise. Then a triggering event, which a healthy organisation might find easy to handle, causes a virtual functional collapse of the organisation. In other cases, a careful evaluation of the signs will show clearly that safety performance is declining.

In any case, without an outside influence to promote changes in the way of doing business (e.g., organisational structure, programmes and procedures, personnel, or backlog reduction) it is likely that performance will decline to the point that a serious safety concern is presented.

It is true that even a good operating plant may show signs of some of the problems listed above from time to time. But the fundamental strengths of their organisations will soon find, analyse and correct the problems. That is why they are good operating plants.

A key insight from periodic safety assessments may be for the regulator to recognise the signs of a weak safety culture as a root cause of declining performance. The change from good safety performance to poor performance is rarely, if ever, a sharp decline over a short period of time. The initial root causes are often subtle and may only be recognised in retrospect.

Thus, it is important for the regulator to also look for signs of a weak safety culture that may be the root cause for actual declining performance. All of the conditions described below have their nexus in ineffective management of nuclear plants. This may take the form of misguided policies, weak leadership, or inadequate standards to guide employees' conduct of work.

Signs of potentially weak safety culture

Management
- Lack of clear organisational commitment to safety.
- Lack of management awareness and involvement in plant activities.
- Lack of proactive approach to safety issues that arise.
- Lack of nuclear experience among top managers.
- Incomplete information reaching the top managers.
- Not receptive to outside views – isolated.
- Lack of depth in talented managers.
- Unwilling to face difficult problems and correct them.
- Lack of teamwork between functional organisations.

Programmes
- Ineffective work planning and scheduling.
- Ineffective corrective actions – recurring problems.
- Cumbersome work control processes.
- Quality assurance not an integral part of plant activities.
- Training not an integral part of management planning.
- No formal programme for analysing events including other plants.

Self-assessment
- Outside organisations regularly find problems first.
- Quality assurance audits are ineffective.
- Superficial reviews by safety organisations.
- Do not learn from the experience of others.
- Management does not want to hear bad news.
- Insufficient incident analysis – no experience feedback

Accountability
- Responsibility for fixing problems is not clearly assigned.
- Schedules not established or routinely missed.
- Decision-making is too slow.
- Poor work performance is tolerated.
- Ineffective internal inspection

Regulatory relations
- Management policy to dispute and defy the safety regulator.
- Policy of minimal compliance with regulations.
- Practice of delaying or deferring regulatory commitments.

Isolation
- Little participation on standards or other committees.
- No exchange of personnel or information with other plants.
- No participation in technical conferences.
- No awareness of safety research advances.

Attitudes
- Complacency.
- "The hypnosis of excessive self-confidence".
- Not receptive to outside suggestions.
- Technical arrogance in relations with regulator.
- Provincialism – no managers from outside.
- Self-satisfaction with current performance – no need to look for problems.

A nuclear plant that has several of the weak safety culture conditions listed above, in addition to signs of actual declining performance, indicates that further regulatory attention will probably be needed.

Regulatory response strategies

The regulator has to find the proper balance between intervening too early or too late when signs of either a weak safety culture or actual declining performance are observed. If intervention is too early, the operator may not agree on the nature and extent of the problems, or the regulator may pre-empt operator initiatives to improve. If intervention is too late, the declining performance may not be arrested before serious safety problems become evident.

How the regulator deals with declining safety performance depends, of course, upon the laws, regulations and customs of each nation. What is discussed here is a graduated approach of escalating regulatory attention that experience in several countries has shown to be effective in dealing with declining performance.

When a few early signs are observed, a graduated approach would be for the regulator to monitor the situation and document the inspection findings carefully so that trends can be seen. It is especially important that inspectors evaluate thoroughly all significant operating events at a plant. If the signs persist or new signs appear to be correlated, the regulator may decide to place the plant under special surveillance, which means special attention through focused inspections and requirements for periodic progress reports on technical and programmatic improvements. The regulator should meet with plant management to inform them of the reasons for the surveillance, areas where improvements are needed, and the need for regular progress reports on improvements.

If the special surveillance and enhanced inspection programme over a period of several months continues to find signs of declining performance, further regulatory action will probably be needed. These performance problems are rarely self-correcting without sustained outside intervention. A further action for the regulator might be for a meeting with the highest levels of the operator's management to stress the seriousness of the concerns and to describe the detailed basis for these concerns about declining performance. This meeting could be followed by an official letter describing the purpose of the meeting and its conclusions.

If performance continues to decline, the regulator will likely be faced with the need for enforcement sanctions. The precise form of such sanctions depends upon the laws and regulations of each regulatory authority. Clearly, however, a regulatory body must have the ability to take enforcement actions, including the authority to order a nuclear plant to be shut down if judged necessary to protect public health and safety.

2. Regulatory Response Strategies for Safety Culture Problems

Foreword

The Committee on Nuclear Regulatory Activities (CNRA) of the OECD Nuclear Energy Agency (NEA) is an international body made up of senior representatives from nuclear regulatory bodies. The Committee guides the NEA programme concerning the regulation, licensing and inspection of nuclear installations with respect to safety. It acts as a forum for the exchange of information and experience, and for the review of developments which could affect regulatory requirements.

In 1998, the Committee established a Task Group to advance the discussion on how a regulatory organisation recognises and addresses safety performance problems that may stem from safety culture weaknesses. In 1999, the Task Group published a report entitled "The Role of the Regulator in Promoting and Evaluating Safety Culture".

As a sequel to that report, this publication explores possible regulatory response strategies for dealing with declining safety performance when the outward manifestations of that performance suggest that there may be fundamental safety culture problems. It also discusses the resumption of normal surveillance after enhanced regulatory attention and intervention.

This publication was prepared by Thomas E. Murley, on the basis of discussion and input provided by the members of the Task Group listed below:
Serge Prêtre (Chairman, Switzerland), Samuel J. Collins (United States of America), Michael Cullingford (United States of America), Klaus Kotthoff (Germany), Philippe Saint-Raymond (France), Lynn Summers (United Kingdom), Mike Taylor (Canada), Christer Viktorsson (Sweden), Roy Zimmerman (United States of America) and Gianni Frescura (NEA).

Introduction

An earlier NEA report[1] discussed the role of the regulator in promoting and evaluating safety culture in an operator's organisation. It also discussed how the regulatory body can recognise early signs of declining performance. This report places emphasis upon those situations where there are signs of actual safety performance problems, which may or may not be reflected in declining operational performance.

1. NEA (1999), *The Role of the Nuclear Regulator in Promoting and Evaluating Safety Culture*, OECD, Paris.

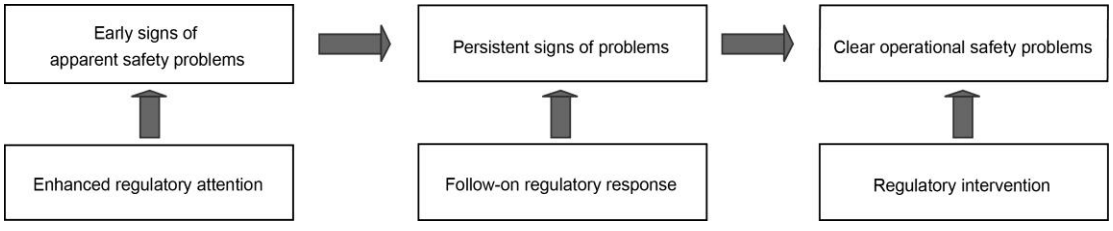
Thus, the purpose of this report is to explore possible regulatory response strategies for dealing with declining safety performance when the outward manifestations of that performance suggest that there may be fundamental safety culture problems. This report also discusses the resumption of normal surveillance after enhanced regulatory attention and intervention.

When a nuclear power plant begins to show signs of declining safety performance, a possible root cause may be that the operator's organisation has elements of a weak safety culture. This situation poses a difficult challenge for a regulatory body for several reasons. In the first place, it is not really possible to measure quantitatively the safety culture of an operating organisation, since safety culture refers to fundamentally unmeasurable characteristics of an organisation's basic safety values and attitudes. Secondly, not every regulatory body has the resources nor the intention to look into safety culture and the associated management issues. Some regulators may prefer to focus inspections and assessments on observable safety performance indicators while others may prefer to focus on directly observable safety management policies and processes. Finally, it is seldom clear from the early signs of safety performance problems just what the root causes may be, and operators may object to regulators probing into safety culture areas that may be emotionally sensitive for some operating organisations.

Thus, the regulator has to use careful judgement in diagnosing the root causes of apparent declining safety performance and in finding the appropriate threshold for regulatory intervention. If intervention is too early, the operator may not agree on the nature and extent of the problems, or the regulator may pre-empt operator initiatives to resolve their own problems. If intervention is too late, the declining performance may not be arrested before serious safety problems become evident.

Approach

The regulatory response strategy is based on the model shown below; where it is assumed that the early signs of safety problems may be ambiguous but nonetheless may justify enhanced regulatory attention. If the problems persist, perhaps growing more frequent and more risk significant, a follow-on response will be called for. Finally, if the root cause issues are not corrected, and clear operational safety problems are evident, the regulator will have to increase the level of intervention. Regulatory intervention in this context means action to require the operator to take steps to improve specific performance problems – steps that the operator probably would not take without intervention by the regulator.



The model above is not meant to suggest that all causes of declining safety performance will inevitably follow this pattern. Even good operating plants may show some of the early signs of

problems from time to time, but the fundamental strengths of their organisations will soon find, analyse and correct the problems. Other safety performance problems may be corrected easily by modest early regulatory attention. But these fortunate situations do not pose a safety challenge to the regulator, and for that reason the focus of this report is on those difficult situations where regulatory intervention is ultimately needed.

There may be other situations where a plant's operating organisation has a weak safety culture from the inception of operation, and the regulator may only recognise this weakness after an extended period of operational safety problems that become more risk significant over time. Even in these situations, the general regulatory response strategy described here would be applicable.

It should be stressed that the regulatory body need not wait for obvious signs of safety performance problems before giving attention to a nuclear power plant. The normal, everyday oversight and inspection activities may be able to detect safety culture weaknesses or deficient safety processes that are the precursors to declining performance. Some regulators find it important that the operating events at a power plant be analysed to look for trends in performance and for apparent common cause problems that may have collective significance as precursors. They further find that a synthesis of these routine assessments, for instance on a yearly basis, is a helpful diagnostic tool.

Enhanced regulatory attention

In the beginning stages of a plant's declining safety performance, it will generally not be clear whether the early signs are merely the type of everyday problems that all nuclear plants experience during their operation or that these signs may in fact be the early precursors of more deep-seated problems. Since the diagnosis is not known, the regulatory approach will have to be flexible but persistent in seeking the true state of affairs at the plant. The earlier referenced NEA report describes a number of early signs of declining safety performance that the regulatory inspector may look for when safety culture problems are suspected.

In many ways, the ultimate effectiveness of the regulatory response to safety culture problems depends upon the approach taken during these early stages. Therefore, the strategy can best be described as a graduated approach. The regulator's normal inspection and oversight activities will have provided a substantial baseline of information about the performance and even the past safety culture at the plant. In light of the early signs of problems, the regulator may decide to analyse the plant's performance indicators more closely and to develop focused inspections aimed at determining the nature of the problems and their underlying causes. The inspection team may include a member or members with expertise in organisational factors. Often these inspections may be inconclusive but it is nonetheless important to document the inspection findings so that trends can be seen. It is especially important that inspectors evaluate thoroughly all significant operating events at the plant.

During the planning for this enhanced oversight, it would be appropriate to discuss with senior plant managers the observations of safety performance problems and the reasons for

increased regulatory attention. The plant managers can provide their assessment of the situation and describe any initiatives they have underway or planned to improve performance. The regulator may suggest that the operator conduct a thorough self-assessment of the safety performance problems, but it is important that the enhanced regulatory oversight does not interfere with any ongoing self-assessment and corrective actions by the operator. Through the focused inspections, and periodic progress reports from the operator, it should become apparent in due course if the operator's corrective actions are being effective or not.

In some cases, this enhanced regulatory attention may be sufficient to promote corrective actions by the operator that correct any underlying safety culture problems. If so, this approach will have produced the desired safety result without undue intervention.

Follow-on regulatory response

In some cases, the early attention by the regulatory body may not be effective in getting the safety performance problems corrected. The early signs persist, perhaps growing more frequent and more risk significant. There may be several possible reasons for this, but a likely cause would be that the safety culture problems are deep-seated at the plant and the plant management's actions have simply not been adequate to address the root causes. In any case, the graduated approach will lead the regulator to enhance further the oversight activities. This will probably mean closer observation of activities at the plant and additional in-depth focused inspections.

But the major focus of the follow-on regulatory response is to have discussions with corporate management to be sure they understand the nature and seriousness of the regulator's concerns. Based upon the findings of the focused inspections and the interactions with the operator during the early response stage, the regulator will have reached a preliminary judgement on how the plant managers view the situation and why their actions have thus far been ineffective. The goal of the discussions with corporate management would be to reach a mutual understanding of the nature of the performance problems, their apparent root causes, and the outline of plans for improvement. The corporate management might not be well informed of the detailed regulatory concerns, and the regulator may wish to suggest an independent assessment of the situation, such as a peer review or a third party assessment of the safety culture at the plant. This phase of involvement with corporate management may last several months and entail several meetings, but the result will generally be an agreement on a course of action for improvement on the part of the operator. The regulator will have to use judgement in allowing the corporate management sufficient time and latitude to correct the problems as they see them, bearing in mind that requiring a comprehensive improvement plan at this stage could result in delaying improvements the corporate management judges to be more fundamental, for example changes in the organisation at the site. Throughout this period, of course, there will be frequent meetings and ongoing inspections to monitor the situation at the plant.

Concurrent with these discussions and oversight activities, the regulator will have to consider under what conditions it may be necessary to intervene and take further actions. This is not to prejudge that the operator's corrective actions will be unsuccessful, but rather to be in a position to

act promptly if the safety performance continues to decline. The general criteria for considering further intervention are along the following lines:

- Does the frequency of operating events and problems appear to be declining?
- Do the operator's corrective actions seem to be effective in producing real change?
- Does the safety culture at the site appear to be improving?

If the answers to these questions are mostly positive, it is reasonable to let the operator's actions continue to improve the situation, even if the pace of improvement is not what one would like. It is especially important for the regulator to remain objective in evaluating real progress at the plant and not get so distracted by promises of improvement that continuing decline is not recognised. If the answers to the questions above are objectively negative, it is likely that the threshold has been crossed where further regulatory intervention is necessary.

Regulatory intervention

Up to this point the graduated regulatory response strategy has led to a steadily escalating oversight programme and discussions with the operator concerning the nature and seriousness of the safety performance problems. The operator has been given opportunities to conduct self-assessments and to formulate corrective actions, but they have not been effective in improving performance. By this stage the regulator will know that there are deep-seated safety culture problems at the plant, which have resulted in operational safety problems.

The mere fact that the situation has deteriorated to this stage is evidence that the operator has experienced some degree of denial that the safety problems are as serious as the regulator believes. It may take some time for the operator to accept the nature and seriousness of the problems, to embrace the need for the improvement plan and to begin working through the often difficult changes needed to improve safety performance.

If the operator continues to deny the seriousness of the safety problems, the regulator will be faced with the need to intervene and take enforcement actions. The precise form of such actions will depend upon the laws and regulations of each country, and some regulatory bodies may wish to examine whether they have sufficient enforcement authority. In any event, the purpose of the next stage of the graduated approach is a regulatory intervention to require a comprehensive improvement programme that addresses and corrects the underlying problems. There can be no avoiding a discussion of the safety culture issues with senior corporate and plant management. There will be two major goals in these discussions. The first goal will be to have the operator's organisation recognise and accept its fundamental problems as seen by the regulatory body. One may suggest that the operator seek outside coaching from a peer group. The second goal is for the operator to agree to develop a comprehensive improvement plan that analyses and provides corrective actions for the fundamental problems seen by the regulator. The plan should include:

- A detailed list of actions, with scheduled milestones and deadlines.

- The nomination by the operator of a person responsible for implementing the plan, with commensurate authority.
- Assurance of adequate resources to implement the plan.

At this stage, the public should be informed of the overall problem if they have not been informed previously. The logical approach is for the regulator to send an official letter describing the previous meeting and confirming the need for an improvement plan. The plan itself may be made publicly available when the regulator and operator agree on its final contents.

Concurrent with these discussions, the regulator will have to face a fundamental decision concerning the plant. In some cases the regulator may conclude that the safety problems are so pervasive and deep-rooted that the plant is considered not safe to operate, or that it would be simply too difficult to produce the necessary changes while the plant is operating. That is, the comprehensive change actions needed would be too distracting for the operator to operate the plant safely. It would be best if there were mutual agreement with the operator on this point, but the regulator's judgement would have to prevail in this matter.

In either case, whether the plant is operating or shut down, the regulator will have to increase the oversight and inspection programme even further. If the plant is operating, the normal safety inspections will have to be enhanced to look for signs of human errors due to distraction or work overload, in addition to monitoring the problems that led to the current situation. Beyond this inspection programme, there will have to be regular meetings with the operator to monitor progress on the improvement plan.

Resumption of normal regulatory surveillance

By the time this stage has been reached, the regulator has had many months of enhanced oversight and dialogue with the operator concerning the reasons for the observed decline in performance. The operator has failed to correct the safety problems and the underlying safety culture weaknesses, the regulator has intervened, and the operator has developed an improvement plan and is implementing the actions in the plan.

The gradual resumption of normal regulatory oversight will be governed by the operator's pace of improvement. For those plants where the safety problems are less serious and the improvement actions are carried out while the plant is operating, the enhanced oversight and inspection programme can be gradually relaxed in step with the problem corrections and improving performance. In these cases, there will generally be no need for formal relaxation criteria, other than a finding at some point that the improvement plan has been satisfactorily implemented. This finding would normally be communicated to the operator and may be made public. Although the regulatory surveillance has returned to normal, the regulator will likely want to conduct follow-on focused inspections to confirm that the problems are not recurring.

In those cases where the safety problems are more serious and widespread, and the plant is shut down, the criteria for allowing resumed operation will be described in a general way in the

shutdown decision. That is, the criteria will state that the most safety significant problems must be addressed and resolved to the satisfaction of the regulator before operation can be resumed. As the detailed implementation plan is prepared by the operator and agreed upon, the regulator may publish more specific restart criteria for each of the significant problem areas. For instance, if one of the basic problems is a large backlog of maintenance work orders and engineering change requests, and the root cause is determined to be ineffective work practices, the improvement plan would include actions to revise the work planning and scheduling processes at the plant. The regulator in this instance would have to agree that the root cause has been addressed and that the changes appear to be effective. To give another example, if the root cause of radiological problems is found to be weak radiological protection training, the training programme will have to be revised and the workers retrained. When the regulator has observed a period of improved radiological performance, he will conclude that that specific restart criterion has been met.

In these more difficult cases, the enhanced regulatory surveillance would be maintained until all the restart criteria have been met and the plant resumes operation. The decision to permit restart would normally be communicated to the operator and be made public. Even after operation resumes, the regulator will have to maintain a level of enhanced oversight for a period to confirm that problems are not recurring. There may also be a need to monitor continuing actions on improvement plan actions that were judged not necessary to complete before restarting. As operation is observed to be satisfactory, the regulatory oversight and inspection programme can be gradually relaxed to the normal surveillance programme.

Improving regulatory performance

As a conclusion of this response strategy, and in the spirit of improving regulatory performance, the regulator should conduct a retrospective self-assessment. Some of the questions that such a self-assessment could address are:

- Could the normal oversight and inspection programme have detected the underlying safety culture problems sooner?
- Was the regulatory response to early signs of declining safety performance effective?
- Were the early communications with the operator as clear in describing the problems as they could have been?
- Were the interactions with the operator conducted professionally?
- Was the intervention timely?
- Was the intervention proportionate to the safety significance of the problems?
- Were communications with the public adequate?

3. Nuclear Regulatory Challenges Related to Human Performance

Foreword

The Committee on Nuclear Regulatory Activities (CNRA) of the OECD Nuclear Energy Agency (NEA) is an international body made up of senior representatives from nuclear regulatory bodies. The Committee guides the NEA programme concerning the regulation, licensing and inspection of nuclear installations with respect to safety. It acts as a forum for the exchange of information and experience, and for the review of developments which could affect regulatory requirements.

In 2001, the CNRA Bureau decided to organise a discussion on the importance of human performance with regard to nuclear safety. Aid was requested from three working groups of the NEA Committee on the Safety of Nuclear Installations (CSNI). Those groups were: the Special Expert Group on Human and Organisational Factors (SEGHOF), the Working Group on Operating Experience (WGOE) and the Working Group on Risk Assessment (WGRisk). The individual members of those groups and the NEA Secretariat prepared material to introduce the topic to the CNRA. The discussion itself took place during the CNRA meeting held in Paris in June 2003. On the same occasion, the CNRA decided that it would be beneficial to document the introductory presentations and the summary of the CNRA discussion in the form of a publication.

Albert Frischknecht (HSK) presented the input of the three CSNI working groups to the CNRA and provided the corresponding contribution to this report. Herbert Deutschmann (HSK) and Vinh Dang (PSI) also contributed to the present publication. Pekka Pyy, Barry Kaufer and Elisabeth Mauny from the NEA provided secretarial assistance and summarised the CNRA discussion.

Introduction

This publication is based on a discussion organised by the OECD Nuclear Energy Agency (NEA) Committee on Nuclear Regulatory Activities (CNRA) in June 2003. The aim of the discussion was to confirm the idea of the importance of human performance, and the factors influencing it, to nuclear safety by sharing knowledge from recent research and CNRA members' experience. Information was provided by three groups within the NEA Committee on Safety of Nuclear Installations. These groups were the Working Group on Operating Experience (WGOE), the Working Group on Risk (WGRisk) and the Special Expert Group on Human and Organisational factors (SEGHOF).

The introductory presentation was based on three questions as follows:

- Is human performance as important to safety of nuclear installations as many references seem to indicate?
- Has the importance of human performance increased during the past 5 to 10 years?
- What recommendations can be made on how to manage human performance challenges?

After the discussion, the members of the CNRA noted that it would be beneficial to both regulators and nuclear operators to prepare a booklet summarising the preparatory work and the conclusions of the discussion. Consequently, the intention of this publication is not to provide a complete picture of human performance and its contributing factors but rather to draw attention to some most challenging aspects of it.

The following sections of the report provide responses to the CNRA questions that were derived from studies on human performance and factors, operating experience and risk analysis. Suggestions have been included which may help in assessing and improving human and organisational performance. Finally, a summary and conclusions from the CNRA discussions are presented. It is believed that this short publication is useful to readers in both regulatory bodies and utilities.

Human performance depends directly and indirectly on task characteristics and the working environment of individual. The factors that influence human performance are known as "human and organisational factors". No commonly acknowledged definition of human and organisational factors exists nowadays. Sometimes, terms like operability, usability, maintainability have to be used instead in order to make it sure that all stakeholders correctly understand the subject of discussion. Consequently, many countries have established working definitions for the concept "human factors" in order to have a common basis for discussions and to complete the text in IAEA Safety Fundamentals (Safety Series No. 110) and other related documents. These definitions generally present human factors as task, individual and organisational characteristics influencing human performance.

Is human performance important to the safety of nuclear installations?

Recent operating experience shows that human performance plays an essential role in the safe operation of nuclear installations. Human performance is important in every phase of the plant lifecycle: design, commissioning, operation, maintenance, surveillance, modification, decommissioning/dismantling.

Failures in human actions, in the organisation or in the management of nuclear installations contribute to 48% of events reported in the IAEA/NEA Incident Reporting System (IRS). Only a few IRS events are due to pure technical causes or to new phenomena causing non-expected plant behaviour. About 63% of the events that were reported to the IRS, and included significant human contribution, occurred during power operation and 37% during shutdown. Also, international analyses of common cause failures show a very significant contribution from human actions.

To complete the picture with the gravity dimension, a quick review was carried out of events reported through International Nuclear Events Scale (INES) over the last ten years. It confirms that a large majority of events with INES level 2 and higher can be attributed to human performance related causes.

In Probabilistic Safety Assessments (PSAs), the quality of human performance has an important impact on the core damage frequency (CDF). Accident scenarios that include human actions represent 15-80% of the CDF. The contribution mainly depends on the plant design, scope of the PSA and the extent to which human actions have been analysed and modelled. PSA results have been systematically studied from this perspective only seldom. One survey of the human actions and of their treatment in a range of PSAs is, however, to be found in NEA/CSNI/R(98)1.

Despite the differences in PSAs, the results show that human actions on the whole are important to maintain a high level of safety. Improvements in the quality of human performance would have a significant decreasing impact on the level of risk as measured by the PSAs. The converse also applies. Finally, the PSA accident scenarios show that the plants are tolerant both to single human and hardware failures, and that there need to be common mode factors involved in scenarios leading to a high risk.

The contributions included in PSA mainly reflect two types of human performance: 1) maintenance and testing, and 2) personnel responses to initiating events, i.e. to events that could lead to an accident without a balancing action. Human and organisational factors support or degrade performing human actions and thus contribute to their success or failure probabilities.

Both operating experience and PSAs show that NPPs are socio-technical systems, also known as MTO (man-technology-organisation) systems. They represent a combination of the hardware of the plant and the humans that operate the installation in an organised manner. Technical problems have been treated with a very high professionalism since the very beginning of the nuclear era. However, for a long time human and organisational questions were mostly approached from technical point of view only.

This development has, in few cases, led to deficiencies in the design of human-system-interfaces (HSIs: alarm systems, process information systems, operator support systems, procedures, handling equipment etc.) as well as in weaknesses in work organisation, communication, teamwork, etc. Many of these shortcomings remained latent because the personnel generally are well-trained and supported by good procedures. Initiating events and special plant conditions, however, have in some cases unveiled gaps in overall MTO system design.

Furthermore, an analysis of a number of recent events with significant human contribution shows that, in most cases, the plant personnel has demonstrated their capability to cope with difficult situations in a very professional manner. However, this information is not evidently collected systematically, e.g. by identifying and recording good practices. This may mean missing a significant improvement potential.

Has the importance of human performance increased over the past 5 to 10 years?

Based on the reported events in IRS, the human causal contribution has increased slightly over the past 20 years, from approximately 45% in the 1980s to approximately 55% in more recent years. It can be further stated that the Chernobyl accident and some other earlier events contributed to focusing attention to safety culture and safety management. These events also triggered the use of in-depth reviews to improve management capability at installations and efficiency of the legal and regulatory oversight processes.

The main causes for recent events with human performance problems have been deficiencies in the safety awareness, management and organisational weaknesses and unclear legal and regulatory requirements. A common feature is that senior corporate management failed to appreciate the symptoms of weaknesses or their significance, and it also failed to take effective corrective action at an early stage. Many of the events have received considerable attention in the public and nuclear community, and they have led to considerable long shutdown periods which have been used for improving safety.

The salience of human and safety management aspects in recent events reported to IRS might lead to a conclusion that the importance of human performance as causal category would have increased in absolute terms. This is not the case. Human performance has been a very important factor from the very beginning of nuclear power generation. However, the perception of the importance of human performance has increased significantly during the past 10-20 years. Another fact is the significant number of improvements in nuclear technology throughout the years. Consequently, the relative contribution of technical causes to safety related events has decreased. This together with the increased perception may explain the fact that more details of human and organisational factors are reported in the recent IRS reports.

Another reason for the increased attention may be the new challenges the nuclear industry is faced with, e.g. deregulation, use of contractors and changes in institutional ownership; ageing workforce and its turnover; perception of the nuclear by civil society; and finally emerging technologies and generally increased information demands of work itself. Such factors may challenge many cornerstones of nuclear safety work and simply cannot be left outside consideration nowadays.

PSAs confirm that human performance and human factors have been from the beginning important to safety, and that neither increasing nor decreasing importance trend is to be seen. When PSAs have identified human factor deficiencies in risk-significant scenarios, modifications to the plant hardware or improvements of the human-machine interface, procedures, and training have often taken place. In absolute terms, these measures have reduced both the overall CDF and the frequency of accident scenarios with human contributions. The relative contribution of such scenarios, when compared to scenarios due to the equipment failures, may in some cases have increased.

Significant efforts have been made during the past 5-10 years to improve and extend the treatment of human performance in PSAs by means of human reliability analysis (HRA). These

efforts are aimed at improving methods for the estimation of probabilities, as well as at identifying and accounting for a more comprehensive range of failure modes in human actions. An example of activities to extend the scope of PSAs is the inclusions of "errors of commission" i.e. wrong and spurious human actions. Attention is also being paid to accident management, outages and the organisational and human factors issues that have been highlighted in recent events.

What recommendations can be made on how to better manage human performance challenges?

The lessons derived from in-depth event analyses and from studies of operating experience lead to a number of suggestions. Firstly, operational experience feedback should be a standard component of any safety relevant process for operators and regulators. Secondly, enhanced event investigation including human and management point of views is needed in order to identify all contributors to the event and barriers broken. In the longer term, analysis of NPP databases is necessary in order to identify latent common cause failures of which many are caused by human acts. Those three actions should be taken by nuclear utilities and regulatory organisations. Finally, improvements in practices and tools used for dissemination, retrieval and analysis of operating experience information should be fostered. National technical support organisations, NEA, IAEA and WANO can play an important role in that process.

The PSA methodology provides an essential tool to analyze and to manage the safety of a NPP. While it has proven useful in its current state, the treatment of human performance in PSA has some known shortcomings. Firstly, systematic approaches for identification, modelling and quantification a more comprehensive range of human failure scenarios in PSAs should be further developed. Many of these scenarios involve human decision making, an area in which the available HRA quantification methods and databases currently are weak.

Secondly, continued efforts to collect and exchange human performance information for PSA and HRA data are needed to improve the empirical and plant specific operating experience basis. A systematic evaluation of events in simulator facilities and use of plant maintenance databases could increase the amount of available quantitative information about human performance in real environments. Finally, one should notice that qualitative information about human performance and factors affecting it is at least as useful as quantitative data and always required to accompany numerical estimates.

Conceptually, a term often manifested in PSAs and event analyses is human error. The view that "humans commit errors", "humans are the weak part of the system" or "human actions have to be replaced by automation" is too simplistic. Man is able to cope with unforeseen situations, to analyse and to create solutions for terminating or mitigating adverse event sequences. Without human actions many incidents would have led to accidents. Safe behaviour is not only the absence of errors but also positive human contributions to safety in the form of prevention, detection and mitigation. Therefore, it is recommended that the concept of human error should be used with utmost care.

Related to this, aiding the employees for being able to perform well and providing them with the necessary support (e.g. knowledge, information, tools) will most certainly contribute

significantly to improved safety of a nuclear installation. Consequently, collection, dissemination and application of good practices to detect latent failures, means for recovery, etc. should be fostered among the utilities and regulatory bodies.

A proactive tool that helps utilities to address most of the issues mentioned in this publication systematically is a robust safety management system. International organisations, many individual countries and different nuclear utilities have recognised the importance of safety management and have already taken initiatives to give guidance for implementing explicit safety management as a part existing management systems.

Finally, it is necessary to apply the same professionalism to human and organisational issues as to the technical systems. Only a comprehensive cross-cutting approach to MTO systems as a whole leads to considering all parts of them adequately. This implies to all organisations that play a role in nuclear safety (vendors, operators and regulators) and to all phases of the life cycle of a nuclear installation. Experts in psychological and social sciences having experience with nuclear power also need to be consulted in order to make the used competence genuinely interdisciplinary.

Summary and conclusions of the CNRA discussions

A number of important points were raised during the open CNRA discussion that followed the presentation. This section comprises of a summary of the discussion.

There was a general agreement that while many technical problems have been resolved in the past, human and organisational problems largely remain unresolved. Consequently, it is important to provide the proper working conditions to improve performance where required. For example, human performance in and after modifications is one important area requiring attention.

There has been an increased focus on human factors and performance during the past decades. Despite this fact, there is a need to better incorporate the human performance viewpoint into plant design. Also, the most important level is not the individual, but the organisation and the environment that he is operating within. After trained individuals have achieved a certain qualified performance, not much improvement can be reached on the task level only. Therefore, more work must be carried out to evaluate organisations and their support to workers in order to identify problems before they lead into events. Treating the employees that have the responsibility for safe NPP operation with care cannot be emphasised too much.

There have been many events with their roots in human and organisation, and such events will continue to take place. Consequently, more complete and detailed reporting of contributing factors is necessary. This should take place through international systems for exchange of operating experience, like the IRS. Reporting human and organisational performance problems should take place independently of their direct safety impact, since such problems have a high common cause potential for the whole plant. Also, commendable practices need to be exchanged as a part of event analysis, since human actions have a great potential in improving safety. Fostering such exchange of experience is a major challenge.

Special focus should be put on safety management issues by proactively analysing organisational performance to prevent incidents. Proactive safety management needs to be integrated into the overall management systems dealing with plant operational safety. Clear regulatory criteria are necessary in order to establish a balanced approach both to plant safety management and to human and organisational performance. These criteria should be imposed across plants equally. Developing and implementing such criteria is a challenge, since it should include adequate flexibility and, at the same time, maintain the ultimate accountability of the licensees for operational safety.

Training of inspectors, by especially providing tools and guidance to detect problems in declining human and organisational performance, is a vital part of regulatory oversight. While training is very important, it is also valuable to have experts in human and organisational performance issues involved due to the cross-cutting nature of the area. Expertise in human and organisational issues takes many forms and taking into account its interdisciplinary dimension is necessary in order to improve the safety of nuclear power plants.

The complex nature of human performance with the involved organisational issues and safety management dimension make the good collaboration both between NEA Committees and with international organisations like IAEA and WANO vital. Co-operation between these organisations in developing programmes has been successful over the years. In future, even more effort may be required in order to find means to understand and give guidance to deal with human and organisational performance to a sufficient extent.

4. Regulatory Challenges in Using Nuclear Operating Experience

Foreword

The Committee on Nuclear Regulatory Activities (CNRA) of the OECD Nuclear Energy Agency (NEA) is an international committee composed 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 NEA programme concerning the regulation, licensing and inspection of nuclear installations. In particular, the Committee reviews current practices and operating experience.

The NEA/CNRA Senior Level Expert Group was formed in 2004, based on the CNRA member consensus, to produce a report on *Regulatory Challenges in Using Nuclear Operational Experience.* The fundamental objective of all nuclear safety regulatory bodies is to ensure that nuclear utilities operate their plants in an acceptably safe manner at all times. In meeting this objective, learning from experience has been a key element throughout the history of nuclear power, and the CNRA has recognised that there is a continuing need to further enhance international exchanges in this area.

This report is not intended to be a handbook on collecting and analysing operating experience, and avoids duplicating information well-presented elsewhere. Its purpose is to serve as a guide for regulatory bodies to help ensure that operating experience is used to promote safety. While focused on nuclear power plants, the principles in this report may apply to other nuclear facilities as well. It therefore follows that the audience for this report is primarily nuclear regulators, although the information and ideas may also be of interest to nuclear operators, other nuclear industry organisations and interested members of the public.

The report was prepared by Thomas Murley on the basis of discussions with, and input provided by, the members of the Senior Level Expert Group listed below. Ulrich Schmocker (Switzerland) and Barry Kaufer (NEA) skilfully chaired the meetings and the work of the group.
André Vandewalle (Belgium), Petr Brandejs (Czech Republic), Timo Eurasto (Finland), Philippe Bordarier (France), Michael Herttrich (Germany), Eiji Hiraoka (Japan), Shunsuke Ogiya (Japan), Victor González Mercado (Mexico), Arend Rooseboom (the Netherlands), Pavel Bobaly (Slovak Republic), Maria Moracho Ramirez (Spain), Peter Flury (Switzerland), Paul Woodhouse (United Kingdom), Brian Sheron (United States), Xavier Bernard-Bruls (IAEA) and Gustavo Caruso (IAEA).

Introduction

As the nuclear programmes in OECD countries have matured over the four decades of commercial nuclear power operation, this maturation has brought steady improvements in the operational safety of nuclear power plants. This improvement is demonstrated by several performance indicators, but most notably by the reduced frequency and severity of accident precursor events relative to the events of, say, ten to twenty years ago.

One of the major reasons for this improved performance has been the extensive use of lessons from operating experience to backfit safety systems, improve operator training and emergency procedures, and to focus more attention on human factors, safety culture and nuclear quality management systems. Indeed, a prominent lesson from the TMI-2 accident in 1979 was the need for systematic evaluation of operating experience on an industry-wide basis, both by the nuclear industry, which has the greatest direct stake in safe operations, and by the nuclear regulator.[1]

The practice of collecting and analysing operating experience (OE) information has grown in depth and sophistication over the years, and by now there is an extensive literature on the methodology for collecting and analysing operating experience.[2, 3] In general, it can be stated that nuclear operators and regulators are familiar with these methods.

Now, however, questions are being raised about whether the lessons from operating experience are being used commensurate with their importance to safety. For example, recent concerns have been voiced that:

- Lessons may be learned but they are subsequently forgotten over time.
- Often nothing is done in response to information learned about others' experiences.
- There is a tendency to consider foreign operating experience as not relevant to one's own situation.
- More generally, operating experience reporting is not meaningful if it is not used to promote operational safety.

To give an example for these concerns, the NEA Working Group on Operating Experience (WGOE) has recently noted, "Almost all the recent significant events reported at the international meetings have occurred earlier in one form or another. Counter-actions are usually well known, but information does not always seem to reach end users or corrective action programmes are not always rigorously applied."[4] A separate concern that has been raised is that not all important operating experience is reported to established international reporting systems in a timely manner.

1. "Three Mile Island", USNRC Special Inquiry Group, Washington, USA, (1980).
2. IAEA (2005), *A System for the Feedback of Experience from Events in Nuclear Installations*, IAEA Safety Guide, Vienna.
3. IAEA (1998), *Joint IAEA/NEA Incident Reporting System Guidelines*, IAEA, Vienna.
4. "Lessons Drawn from Recent (2003-2004) Nuclear Power Plant Operating Experience", Technical Note, OECD/NEA, Paris (2005).

One reason given for this lack of timely reporting is the relatively large resources needed (both for the operator and the regulator) for the preparation and translation of the reports in the proper format. Another reason given is the concern for possibly providing incomplete or inaccurate information on operating events or conditions before they are fully analysed and understood.

Thus, it appears that a challenge to maintaining the recent good operational safety performance is to ensure that operating experience is promptly reported to established international reporting systems and that the lessons from operating experience are actually used to promote safety. It was for this reason that the CNRA has commissioned this report.

The primary focus of this report, therefore, is on how regulatory bodies can assure that operating experience is used effectively to promote the safety of nuclear power plants. One must keep in mind that the operator has the responsibility for safely operating a nuclear power plant, and hence it is important for the operator to have an active programme for collecting, analysing and acting on the lessons of operating experience that could affect the safety of his plant. It is the nuclear regulator's responsibility to oversee the operator's activities to assure the plant is operated safely. Therefore, a key topic for this report is the role of operating experience in the regulator's management system.

This report is not intended to be a handbook on collecting and analysing OE nor will it duplicate information better presented elsewhere. Rather, it is intended to be a guide for regulatory bodies to help in assuring that operating experience is used to promote safety. While focused on nuclear power plants, the principles in this report apply to other nuclear facilities as well. It follows, therefore, that the audience for this report is primarily nuclear regulators, although the information and ideas may also be of interest to nuclear operators, other nuclear industry organisations and the general public.

The importance of operating experience for safety

The fundamental logic supporting the need for a vigorous operating experience programme is that serious accidents are almost always preceded by less serious precursor events and that by taking actions to prevent recurrence of similar events, one is thereby reducing the probability of serious accidents. In this chapter, "precursor event" is an actual event or condition that has some of the characteristics of a serious accident but falls short of being a serious core damage accident. It implies that more serious events could follow in the future if no changes are made.

Nuclear power plants are highly complex installations, with several redundant and diverse mechanical, electrical and control systems. There are dozens of such systems and thousands of individual components in a typical plant. Experience over the years has shown that all plants experience individual component and system failures from time to time, almost always with no safety consequences. Many of these operating events at nuclear power plants include contributions from human and organisational factors. If no steps are taken to correct the root causes of these failures, they will recur and, accompanied by other failures or perhaps human errors, will lead to a more serious event or accident. Therefore, an effective OE programme must be understood as a key factor in maintaining the strength of the defence in depth concept. There is a need for a programme

at each nuclear power plant to collect and analyse this experience and take steps to reduce the likelihood of similar precursor events.

The IAEA Report (IAEA, 2005) provides an excellent rationale for the importance of a vigorous OE programme to promote nuclear safety:

- To identify and quantify events and conditions that are precursors to more serious events.
- To identify the root causes of these events and suggest corrective actions.
- To discover emerging trends or patterns of potential safety significance.
- To assess the seriousness of the events and conditions by analysing what could have happened.
- To assess the generic applicability of events.
- To recommend steps to prevent the recurrence of similar events.

In this chapter, we shall define operating experience as all events, conditions, observations or new information that could affect nuclear safety. This broad definition of operating experience includes the following categories under its umbrella:

1. Actual operating events, typically plant transients accompanied by equipment failures, human errors or other anomalous behaviour.
2. Actual failures of systems, structures or components, or human errors, that may or may not have caused a plant transient.
3. Adverse safety conditions such as design weaknesses, degraded safety equipment or aging effects that could lead to failures of systems, structures or components.
4. External challenges such as vulnerability to severe weather, flooding, high winds or security threats.
5. Organisational or human factor issues such as a degraded safety culture at a plant, high human error rates, weak quality assurance (QA) programmes, inadequate procedures, inadequate training or inadequate control of contractors at a plant site.
6. New information, such as research results or new safety analyses, showing a previously unknown weakness in a safety system or a fuel failure vulnerability.
7. Non-nuclear experience such as equipment flaws or seismic effects on non-nuclear structures and equipment.

It is self-evident that, in order to make use of this array of operating experience information to promote safety, one must have formal programmes for collecting and analysing this operating experience data. The responsibility for these programmes will be discussed in later chapters.

Regulatory approaches for assuring effective operating experience programme

The fundamental objective of all nuclear safety regulatory bodies is to assure that nuclear utilities operate their plants at all times in an acceptably safe manner. The main focus of this report is on how the regulatory bodies can assure that operators use operating experience effectively to support the objective of safe operation. While there are differences in the laws, regulations and customs among OECD countries, all regulatory bodies have the means to oversee the operators' system for collecting, analysing and acting on the lessons of operating experiences that could affect the safety of their plants. As discussed in Chapter 5, the regulatory body must have its own internal system for collecting and analysing operating experience, but this cannot substitute for the need for the operator to have an effective OE programme.

An essential foundation of an effective operating experience programme is the need for each operating organisation to report events and conditions that occur at its own plant. After many years of experience each regulatory body has developed requirements governing operating experience reporting requirements, and for the purposes of this report it is assumed that these requirements are satisfactory to meet the regulator's needs. The scope of reporting requirements should be broad enough that it includes reporting by design organisations, equipment suppliers, fuel suppliers and other nuclear service providers. The regulator may choose to request information on component and system failures having little or no safety consequences in order to analyse other events and conditions. In some countries regulatory authority extends to all companies that supply safety relevant material to nuclear power plants. Where this is not the case, the regulator will have to ensure that the operator reports safety significant operating experience information from its suppliers according to established procedures.

The elements of an effective programme are described in Reference 2 and they include (a) collecting all relevant operating experience information, (b) screening for safety significance, (c) analysis of significant events or conditions, (d) assigning actions to correct any problems or weaknesses found, (e) tracking of actions, and (f) follow-up to ensure the actions are completed satisfactorily. There are a number of methods and techniques that regulators can use to analyse and draw lessons from operating experience.[5] For example, some regulatory bodies have found that the Case Study method is a powerful tool for understanding complex events and for teaching new regulatory staff many of the nuances of nuclear safety. Some regulators have found it beneficial to encourage their licensees to consider human and organisational factors causes when analysing operating events and conditions. An especially effective tool for analysing and understanding complex events is PSA methodology. While not absolutely necessary for an effective OE programme, many regulatory bodies find it of benefit to require operators to have the capability for PSA analysis of their plants and for analysis of operating experience information.

In some countries having several nuclear power plants with different operating organisations or at different sites, they have found it beneficial to use probabilistic methods for analysis of precursor events. A reliable source of information for assessing the actual risks from nuclear plants

5. *Review of Methodologies for Analysis of Safety Incidents at NPPs*, IAEA-TECDOC-1278, Vienna (2002).

comes from a careful retrospective examination of the frequency and severity of actual operating events at those plants. This is done by using the accident sequence precursor (ASP) methodology. Accident sequence precursors are actual initiating events or conditions that, when coupled with other postulated subsequent events, could result in a core damage accident. PSA methods are used to estimate a conditional probability of core damage associated with each precursor event. This conditional core damage probability (CCDP) can be considered a measure of the residual protection against severe core damage during the actual precursor event. By adding the sum of all CCDPs for a year and comparing with the sum of yearly CCDPs for earlier years, one can deduce trends in the overall safety performance of the nuclear plants. There are limitations on the accuracy of ASP methodology, notably the limits of PSA methodology and data, the completeness of event reporting, and the absence of actual data on rare events such as earthquakes. Nevertheless, some regulatory bodies find ASP methods highly valuable for analysing operating experience for overall safety trends.

An operating experience programme cannot be maximally effective unless it includes worldwide operating experience. For many OECD countries, the majority of operating experience will come from foreign countries, and for that reason it is essential that both the regulator and operator have access to international information such as the IAEA/NEA Incident Reporting System. In addition, the World Association of Nuclear Operators (WANO) and the Institute of Nuclear Power Operations (INPO) conduct many analyses of operating events each year and make the results available to nuclear operators around the world. These reports and analyses are a supplement but not a substitute for individual operating plant OE programmes. The regulator should be aware of these analyses and those of other industry and government organisations.

Regulatory approach for assuring that operating experience is used to promote safety

In the introduction, it was noted that concerns have been raised recently that often nothing is done in response to information learned about others' experiences. That is, although an operator may have a process for collecting and analysing operating experience information, there is often no follow up with effective actions to prevent the same event or condition from occurring at the operator's own plant. This, then, is the fundamental challenge for the regulator. How can the regulatory body assure that operating experience is used effectively to promote safety?

The actual legal basis for requiring each operator to have an operating experience programme varies among OECD countries. But regardless of the precise regulatory basis, the regulator has the means for emphasizing the importance of operating experience within the operator's organisation just through the mere fact of placing it on the agenda of the highest level of plant management. The operator's priorities are influenced by those matters regarded as important by the regulatory body and, by including operating experience in the normal regulatory inspection programme and in meetings with senior plant managers, the regulator can ensure that the operating experience programme receives the operator's attention.

In assessing the adequacy and effectiveness of an operator's operating experience programme, the regulator can begin by using the IAEA Safety Guide (IAEA, 2005) as a template

to judge whether the programme includes the essential elements. Based on experience, it appears there are several key attributes of successful operating experience programmes:

1. A detailed OE procedure and adequate resources to implement the procedure.
2. A dedicated, conscientious operating experience co-ordinator who is responsible for assuring the programme is effective and is diligent in making the procedure work and in following up on corrective actions.
3. Ready access to a wide range of sources of operating experience, including international and non-nuclear experience.
4. A procedure that assures that important safety issues passing a significance screening test are placed in a tracking system until acted upon and closed out.
5. A staff that is competent in conducting event and causal analyses.
6. An attitude on the part of plant management that values operating experience, is receptive to all sources of operating experience (especially outside sources), and supports the need to take corrective actions based on operating experience lessons.
7. Periodic self-assessments and external assessments to check the effectiveness of their operating experience programme.

The regulatory body can focus attention on operating experience programmes by making it part of the regular inspection programme, especially part of reactive inspections the regulator would normally conduct following operating events. In addition to examining whether the programme includes the necessary elements, the inspection programme can look into questions such as the following:

- Does the operator have staff who are competent in root cause analysis and similar methodologies?
- Does the operating experience information reliably reach the end user in a form that can be acted upon?
- Does the operator include regular audits of operating experience in its QA oversight programme?
- Does the operator have an effective corrective action programme for capturing significant operating experience lessons, formulating corrective actions and tracking them to completion?
- Is operating experience information used in training control room operators and other plant staff?
- Is operating experience data used for plant system and component reliability trend analyses?
- Does senior plant management take an interest in and actively support the OE programme?

In conducting its inspections, the regulator must have complete access to proprietary and confidential information related to safety from its licensees, nuclear fuel and equipment suppliers, plant designers and other nuclear service providers.

The regulatory inspections should be especially sensitive to signs that the operating experience programme at a plant may be weak or ineffective. Some of these signs might be minimal staffing and a perfunctory implementation of the programme, few or no actions resulting from lessons learned, lack of support for operating experience from senior management, and a prevailing attitude among the staff at the site that operating experience feedback is not really important for nuclear safety.

After the results of the inspection are assimilated, the regulator will have to reach a preliminary judgment on the adequacy and effectiveness of a plant's operating experience programme. If weaknesses are found, they must, of course, be communicated to the operator, and the regulator may choose to schedule a follow-on inspection or a meeting with plant management, or both. Usually these actions will be sufficient to prompt corrective actions by the operator, but if serious weaknesses in the operating experience programme persist, the regulatory body may have to consider other enforcement actions.

The role of operating experience in a regulator's management system

One of the lessons from the TMI-2 accident in 1979 was the need for systematic evaluation of operating experience by the nuclear regulator (see Footnote 1). As part of its responsibility for assuring safety, the regulator must be confident that safety relevant operating experience, especially accident precursor events, are not overlooked by operators. This report further emphasises that the regulator has the duty to oversee the effectiveness of the operator's operating experience programme.

For purposes of this discussion, the term "regulatory body" refers not only to the regulatory authority itself, but also to its technical support contractors. Indeed, the regulatory authority may find it most effective to rely on contractors for the expertise needed to analyse complex events, for example using PSA methodology. The regulator may choose to have a unit of its organisation dedicated to collecting and analysing operating experience. Alternatively, the regulator may choose to have most of this work done by contractors. In any event, the regulatory body should have adequate resources to implement the OE programme, some staff trained in the skills of operating experience evaluations, and a conscientious OE coordinator as the key elements of a successful regulatory OE programme.

The regulator's operating experience programme should be guided by a detailed procedure and it should include all of the elements discussed in Chapter 3; namely, collection, screening, analysis, corrective actions, tracking and follow-up. The regulator's programme must be independent of operators' programmes, and there undoubtedly will be differences. For example, it is not likely that an operator's OE collection programme would include worldwide research results or extensive non-nuclear experience. In these cases, the challenge for the regulator is to assure that this relevant research and non-nuclear operating experience is collected, analysed and disseminated, either by

operators, industry organisations or through the regulator's own OE programme. The regulator should request a response from the operator concerning its analysis of each issue for its own plant and what actions it plans to take.

In general, the regulator's analysis of an operating event or condition need not be as detailed as the operator's analysis at the plant where the event occurred, in order to avoid unnecessary duplication. On the other hand, the regulator may decide that its own detailed analysis is needed if it judges that the operator's analysis is inadequate. In particular, the regulator should develop the capability for analysing human and organisational factor issues and industry-wide trending. The regulator's operating experience staff will have to stay in close touch with industry operating experience activities as well as with its international regulatory counterparts regarding operating experience.

The regulatory body can make a significant contribution to promoting safety by making the results of its operating experience collection and analysis activities widely available throughout the nuclear industry, both nationally and through international bodies such as IAEA and NEA. Of course, the regulator's OE procedure must provide for protection of proprietary, confidential and sensitive security information.

In addition to its notification responsibility, the regulator should review event analyses for safety insights that can be used to guide its inspection programme and licensing procedures. Another major objective of the regulator's OE programme is to determine the need for new or amended regulations, standards and regulatory guidance, including the need for additional safety research. Frequently the review of operating events will challenge the regulator to judge whether to require safety backfits for the plant that has experienced the event or condition.[6] In some cases, the analysis may point to a broader, generic safety issue that may require more widespread backfits and even a change in its regulatory requirements. This means that the OE analysis should carefully consider the generic applicability of its conclusions. Some regulators find it useful to categorise OE information according to its impact on specific safety functions and level of defence in depth, in order to make any gaps in safety information more obvious.

Yet another responsibility of the regulatory body is the need for careful trending of operating experience, for example equipment failure rates, system failure rates, aging effects such as stress corrosion cracking, and even safety culture and organisational issues. A regular review of this trend information should be a part of the regulator's operating experience procedure.

When new backfits are imposed, either on single plants or on a wider basis, the regulator must follow the progress of the operator's implementation of the backfits. This tracking responsibility should be included in the regulator's normal management system for tracking licensee commitments and requirements.

From this discussion, it is evident that the operating experience function plays a vital role in the nuclear regulator's safety oversight responsibilities, and therefore the regulator should assure

6. NEA (2002), *The Nuclear Regulatory Challenge of Judging Safety Backfits*, OECD, Paris.

that operating experience is a well defined component of the regulator's management system and that it is supported with adequate resources. In this regard it would be a good practice for the regulatory body to conduct periodic self-assessments or sponsor external assessments to ensure that its procedures and practices are meeting this responsibility.

Summary and conclusions

There can be no doubt that the systematic evaluation of operating experience by the operator and the regulator is essential for continued safe operation of nuclear power plants. Recent concerns have been voiced that the operating experience information and insights are not being used effectively to promote safety. If these concerns foreshadow a real trend in OECD countries toward complacency in reporting and analysing operating events and taking corrective actions, then past experience suggests that similar or even more serious events will recur.

This report discusses how the regulator can take actions to assure that operators have effective programmes to collect and analyse operating experience and, just as important, for taking steps to follow up with actions to prevent the events and conditions from recurring. These regulatory actions include special inspections of an operator's OE programme and discussion with senior plant managers to emphasize the importance of having an effective operating experience programme.

In addition to overseeing the operator's programmes, the regulator has the broader responsibility for assuring that industry-wide trends, both national and international are monitored. To meet these responsibilities, the regulatory body must have its own operating experience programme, and this report discusses the important attributes of such regulatory programmes. It is especially important for the regulator to have the capability for assessing the full scope of operating experience issues, including those that may not be included in an operator's operating experience programme, such as new research results, international operating experience, and broad industry trend information.

5. Nuclear Regulatory Review of Licensee Self-assessment (LSA)

Foreword

The Committee on Nuclear Regulatory Activities (CNRA) of the OECD Nuclear Energy Agency (NEA) is an international body made up of senior representatives from nuclear regulatory bodies. The Committee guides the NEA programme concerning the regulation, licensing and inspection of nuclear installations with respect to safety. It acts as a forum for the exchange of information and experience, and for the review of developments which could affect regulatory requirements.

This report was prepared based on input from the "Contact Network of Regulatory Experts" set up by the CNRA, with technical and secretarial assistance by Kurt Asmis, Barry Kaufer and Laure Geffroy. The Network mainly corresponded by e-mail, but also met on 19-20 September 2002 at NEA headquarters in Paris. Those attending the meeting were: Kurt Asmis, Bill Borchardt, Gerhard Feige, Rudolf Görtz, Barry Kaufer, Lyn Summers, Nobuo Tanaka and Jiri Vesely. The meeting proposed a draft report, which was circulated amongst all of the Network members. The other members of the Network included Albert Frischtnecht, Seija Suksi, András Tóth, Christer Viktorsson and Norio Watanabe.

The Network wishes to acknowledge the valuable contribution of Andrew Kadak, former President of Yankee Atomic and now Professor of Nuclear Engineering at the Massachusetts Institute of Technology, who provided a perspective from the licensee point of view.

Introduction

Licensee self-assessment (LSA) was discussed at a number of CNRA meetings. In the summer of 2001, the CNRA membership was a sent a questionnaire on the subject that resulted in a report that was presented to the CNRA at the December 2001 meeting.

At the December 2001 meeting, the CNRA requested the Secretariat to follow up on answers given in the questionnaire with the assistance of the "Contact Network of Regulatory Experts", nominated by CNRA members. Specifically, the CNRA requested a report on LSA that was to include:

- Definition of LSA.
- A recommendation for a general response strategy to LSA by regulators.

The report as prepared is a short "principles" document that is intended to close the current effort on LSA.

The Network also discussed the relationship of quality assurance (QA) and periodic safety review (PSR) to LSA, but decided not to include these discussions in the document. The main difficulty in this area is that regulators have very different perspectives of QA. Many define QA as being a process of assuring that processes are adequate and being followed, while others think of QA as being total quality management (TQM). For the former the statement that QA is part of LSA is correct while for the latter LSA is an integral part of TQM.

What is LSA?

Description

LSA is described as all the activities that a licensee performs in order to identify opportunities for improvements.

The following elements amplify the compact description above:

- Helps organisations to find potential plant improvements, as well as policies, procedures and practises, which may be improved.
- Is an on-going process expected from a high reliability organisation?
- Assesses safety, quality and related issue performance against regulations, internal rules, industry standards, etc.
- Includes activities on and off site (offsite would include such entities as: corporate offices, engineering services, laboratory services, etc. that may be situated external to the site but provide services to the site).
- Should be performed by each level of management including the top management and individual workers.
- Should be a systematic and complete evaluation by the licensee of its technical, organisational, personnel and administrative arrangements.
- Should address declining performance.
- Results in improvement actions.

It is evident from the above definition and the amplifying bullets that LSA is part of the organisation's holistic management system, which must include other process elements. Particularly important elements are: a process for choosing which identified potential improvements are to be taken forward for implementation and a process of project management for implementation of improvements.

LSA may be an integral part of a licensee's managed processes that is expected to bring an operating organisation to a higher level of performance in:

- Safety.
- Efficiency.
- Economics.

Nuclear Safety Regulators expect the licensee to run an effective LSA programme, which shows the licensee's "priority to safety", as required, for example, by the Convention on Nuclear Safety.

Regulatory approaches to LSA

Goal

An effective licensee self-assessment (LSA) programme should result in improved safety performance. In addition, the insights LSA produces and the potential for improvements in safety performance, commends it to regulators and offers to them the opportunity for increased regulatory effectiveness.

Strategy

In order to realise the goal, the regulatory body should seek evidence of:

- Management providing support and adequate funds.
- All the elements included under description in Section 2 are present.
- A formally defined and properly implemented process.
- The process operating on a written hierarchical basis and includes:
  - Policies.
  - Processes.
  - Procedures.
- Appropriate and timely notification to the regulatory body to enhance the opportunities for regulatory oversight.
- Appropriate communication of results (e.g., public, regulatory body, licensee's staff).
- Delivery and implementation of improvements.
- Programme being subject to independent review.

Fulfilling the above, including satisfactory results of regulatory oversight, LSA may offer the opportunity for adjusting regulatory oversight.

Recommendations

This report attempts to answer the questions asked by CNRA in recent meetings. If the CNRA wishes to further explore this area then the TG has developed the following options:

- Seek industry views and experience through dialog with licensees and other appropriate organisations.
- Obtain input from other CNRA groups (e.g. Effectiveness Group, Performance Indicators (PI) Group, WGIP).
- Obtain input from other CSNI groups (e.g. SEGHOF).
- Explore ways that the regulatory body may review the licensee's LSA activities and programmes and judge adequacy.

Survey[1]

Questionnaire

1. Licensee self-assessment (LSA) can be defined in many different terms. Please provide brief description of what licensee self-assessment means.
2. Do you have any requirements on licensees to perform self-assessment? If so please describe.
3. How does the regulatory body assess and inspect LSA programmes? Is it a systematic process?
4. How are the results from a licensee self-assessment evaluated and what steps are taken the regulatory body?
5. Does the regulator follow-up on corrective actions taken by the licensee as a result of LSA?
6. What "credit" if any is given to the licensee for performing an LSA (i.e., decreased inspections, etc.)?
7. Licensee self-assessment and periodic safety reviews:
   - If a periodic safety review (PSR) is performed in your country, are LSAs also performed?
   - What type of frequency is required for LSAs and how are they different from the PSR?
8. What other issues relating to licensee self-assessment would you like to see discussed by CNRA?

Summary of results

The results of the questionnaire proved a valuable basis for assessing member countries' views about licensee self-assessment. The preliminary analysis of the results clearly shows that while wide differences exist and there is basically no standard approaches taken. A majority of

1. Complete compilation of survey results is provided in Annex C.

countries would welcome more information exchange by the CNRA, especially for the following issues:

- Possibility of harmonisation of LSA programmes.
- Best practices.
- Value added (e.g., results achieved).
- Performance metrics.

Discussion on these issues may be beneficial towards determining whether further international collaboration will help advancing the topic as well as providing input to areas of regulatory challenges being reviewed by CNRA. Other areas CNRA may want to consider as further steps are:

- Identifying types of criteria useful to individual member countries.
- Establishing tools on implementing an LSA programme.
- Development of methods for assessing the effectiveness of LSA programmes.

The following sections provide a preliminary summary for each question. While it is difficult to attain exact commonalties by the responses received, it is possible to identify several major aspects from each area surveyed. It is important to note that in the following summaries, specific countries are referred to in many cases. These are used to provide examples and are not meant to be inclusive. Other countries responding may also have like or similar requirements. The summaries are not intended to provide an in-depth review of the responses, but rather an overall perspective of the issues

Definition

While the wording differed in each case, the overall definitions provided were basically along the same lines. One good perspective was provided by the Netherlands, which stated that "LSA is a systematic evaluation by the licensee of all its technical, organisational, personnel and administrative arrangements in order to improve safety." A more general definition was offered in the US response, which stated, "LSA is generally defined as those activities conducted by licensees to monitor and evaluate various aspects of organisational performance."

The responses in themselves showed many differences in what regulators expect of an LSA and in consequence raised several additional issues in how LSA is defined, including:

- Is LSA a continuous process that covers activities over the lifetime of the plant (e.g. Czech Republic and Sweden), part of the QA system (e.g. Germany, Hungary and Switzerland), a one-time process or dependent entirely on the licensee?
- What specific area does an LSA cover (e.g. technical, organisational, operations, etc.) and what aspects should be looked at (e.g. non-conformances, areas of improvement, declining performance, etc.).

- Is LSA performed as a voluntary process (e.g. Japan) or a mandatory process? Should it be carried out by the licensee or an independent party contracted by the licensee.

The question that remains for CNRA to answer is whether there should be an internationally accepted definition of licensee self-assessment. A more thorough review of the IAEA standards and guidelines as well as the work performed by INSAG may be helpful in this area.

LSA requirements

While not all countries have a specific legal requirement for LSA, the responses show that the most regulators have some type of standards, auditing system or process set-up, most commonly associated with QA, which obligates (not necessarily legally) the licensee to have a self-assessment process. It is important to note, as pointed out by the UK response, that "the self-assessment process should be regarded as something different from a pure QA programme in that one of its functions should be to check that at all times the plant is operated within the boundary conditions defined in its safety case."

Several countries (e.g. Sweden) have a continuous process supplemented by documenting and carrying out corrective actions. Other countries rely more on general requirements and pro-actively encourage licensees to conduct self-assessments.

Therefore some key elements are:

- While not all countries have a specific legal requirement for LSA, the responses show that the most regulators have some type of standards, auditing system or process set-up, most commonly associated with QA, which obligates (not necessarily legally) the licensee to have a self-assessment process.
- The responses show that while most countries do not have a legal requirement, *per se*, most expect the licensee to perform LSA and to monitor the results.
- Some countries require that LSAs plans be submitted for approval prior to implementing them.

Assessment and inspection of LSA programmes

A few countries (e.g. Australia, Czech Republic, Hungary) noted that they have programmes to assess LSAs while others (e.g. Finland, Hungary, Sweden, Switzerland, United States) regularly inspect specific aspects of licensees' assessments. Several countries (e.g. France, United States) pay special attention to ensure that corrective actions have been implemented.

Several mention the need for the regulator to remain completely independent in the LSA process. This is considered essential to allow the licensee to be able to fairly assess himself (e.g. it is noted that without this element the licensee may not be as thorough and frank and willing to make self-criticisms of his performance).

Evaluation and regulatory actions

Various timing (scheduling) and varying levels of degree are taken by regulatory bodies in evaluating LSAs. For example, Finland and the United Kingdom perform "spot" checks. Inspection results are used by Sweden (into the integrated safety assessment), Switzerland and as part of the US baseline inspection (selected) programme.

The Czech Republic, Japan and a few others receive results of LSAs performed. France receives a yearly report.

As noted above, results receive differing levels of review from. A few countries carry out checks to ensure that licensees have capability to perform LSA, but do perform detailed assessments of results. Several other countries evaluate the results as part of a larger assessment (e.g. Swedish integrated assessment programme, QM process in Switzerland, etc.).

Several countries (e.g. Netherlands, Japan, United States) note the need to ensure that appropriate corrective actions are implemented.

Corrective actions as a result of LSA

The use of inspections is most frequently quoted as how regulators follow-up on the implementation of corrective actions found as a result of LSA. A few countries (e.g. Japan, Switzerland) have formalised processes through the periodic safety review or quality management systems.

Regulatory credit for LSA

No country gives credit for LSA, with the exception that the US, under the revised Oversight programme, does recognise LSA during supplemental inspections (although this depends on the effectiveness of the LSA process) and Australia, which noted that satisfactory performance of LSA may lead to reduced regulatory surveillance.

Several countries note that a strong and effective LSA programme by the licensee does enhance co-operation with the regulator in the overall evaluation process. For example, SKI maintains sort of minimum inspection and assessment programme of all licensees. Strong confidence in a licensee's self-assessment process will mean less active activities in relation to that licensee.

Periodic safety review versus LSA

Most countries distinguish specific differences between PSR and LSA mainly that LSA is a continuous process and are performed more routinely while periodic safety reviews (PSRs) are 10-year overall assessments of the plant as to the current SOAR.

LSAs are also considered more or less to be a continuous process, although reporting is most often done at a fixed time (e.g. 1-year period). PSR are seen by some countries as a special case of LSA. Additionally LSA is perceived by some to be a more dynamic process continuously reactive to safety challenges.

6. Nuclear Regulatory Challenges Arising from Competition in Electricity Markets

Foreword

The Committee on Nuclear Regulatory Activities (CNRA) of the OECD Nuclear Energy Agency (NEA) is an international body made up of senior representatives from nuclear regulatory authorities. The Committee guides the NEA programme concerning the regulation, licensing and inspection of nuclear installations with respect to safety. It acts as a forum for the exchange of information and experience, and for the review of developments which could affect regulatory requirements.

In 1999, the Committee established a Task Group to consider the potential challenges which may have to be faced by nuclear regulators as a result of the introduction of competition in electricity markets. This report describes many of these challenges, their implications and possible regulatory response strategies.

The present report was prepared by Thomas E. Murley, on the basis of discussion and input provided by the members of the Task Group listed below:
Serge Prêtre (Chairman, Switzerland), Samuel J. Collins (United States of America), Michael Cullingford (United States of America), Klaus Kotthoff (Germany), Aníbal Martín Marquínez (Spain), Philippe Saint-Raymond (France), Lynn Summers (United Kingdom), Mike Taylor (Canada), Christer Viktorsson (Sweden), Roy Zimmerman (United States of America) and Gianni Frescura (NEA).

Introduction

In recent years, a world-wide trend has been developing to introduce competition in electricity markets (commonly referred to as economic deregulation). While not all countries or their various jurisdictions have fully introduced market competition, the trend is gathering momentum and virtually all nuclear operating companies are feeling competitive pressures to reduce operating costs and to increase electricity production. A recent report by the NEA[1] discusses the specific impacts of competitive electricity markets on the nuclear power industry and concludes that existing nuclear plants are expected to be economically competitive in such markets. It further concludes that nuclear safety, regulatory compliance and efficient economic performance are not in conflict, but in fact are complementary.

1. NEA (2000), *Nuclear Power in Competitive Electricity Markets*, OECD, Paris.

Those nuclear safety regulatory bodies that in the past, provided oversight of economic matters typically restricted their oversight to ensuring that utilities had a stable source of income to operate the plants safely, to decommission the plants upon their retirement, and to safely manage the spent nuclear fuel and radioactive waste. Now, however, as market competition unfolds, it is becoming clear that competitive pressures can produce a wide range of safety challenges for nuclear power plant operators and regulators. While the nuclear safety regulatory bodies are neutral regarding the introduction of competition in electricity markets, they must be aware of the safety challenges produced and should consider whether new regulatory response strategies are warranted.

Where electricity market competition has been introduced, it is causing many nuclear operators to request reductions in what they view as unnecessary regulatory burdens. In this respect, the regulatory body may decide to respond to the new competitive environment by examining how it may improve regulatory effectiveness and efficiency. Other changes are the consolidation of smaller nuclear operating companies into larger operating companies, as well as the purchase of nuclear plants by foreign companies. In the face of these challenges, the nuclear regulator must reaffirm that necessary levels of safety are not being reduced because of electricity market competition.

In some countries, the first step in introducing competition in electricity markets may be the transfer of ownership from the public sector into the private sector. Many of the features of market competition will come into being at the time of privatisation – for example, the need for decommissioning funds and the heightened public awareness of the nuclear safety regulatory system. Thus, the nuclear safety regulatory body can be proactive in considering the issues of market competition during the early stages of privatisation and can perhaps influence the subsequent course of developments.

It is the intersection of these competitive pressures with their potential impacts on the safety of nuclear power plants that is the focus of this report. Specifically, the purpose of this report is to describe many of the challenges facing nuclear regulatory bodies as a result of market competition and to discuss possible regulatory response strategies.

It follows that the audience for this report is primarily nuclear regulators, although the information and ideas may also be of interest to government authorities, nuclear operating organisations, other industry organisations and the general public.

Outline of electricity market competition

As the laws and rules governing market competition are promulgated in each country, the specific details will vary accordingly. For instance, a thorough presentation of the status of introducing competition in electricity markets in the United Kingdom is presented in a paper by Laurence Williams,[2] which also discusses some of the challenges facing the nuclear regulatory body in that country.

2. Laurence Williams, *Economic Deregulation in the Nuclear Industry: The Regulatory Challenge*, IAEA, Vienna, September 1999.

While the details will be different in each country, the essential features affecting nuclear power plants will be the same – namely, increased and persistent competitive pressures to reduce nuclear generation costs.

A characteristic of nuclear power plants is that they have low fuel costs and high fixed (non-fuel) costs relative to fossil fuel plants. In recent years the fuel costs of coal and natural gas plants have decreased substantially in several countries, and that has added to the competitive pressures on nuclear plants. This, in turn, has led nuclear operators to reduce costs in all areas, but especially to focus on reducing operating and maintenance (O&M) costs. In parallel with reducing costs, many nuclear operators have focused on increasing electricity production by upgrading plant generating capacity, increasing plant capacity factors, and seeking to extend the life of plants.

The nuclear operators' responses to competition may produce either safety benefits or safety challenges. For instance, there have been recent examples of more efficient work processes; better outage planning and better overall management of day-to-day operations at some plants. There are other examples of substantial staff reductions, greater use of less skilled contractors and increased use of on-line maintenance. Operating organisations that have a strong safety culture[3, 4] may find it easier to adapt to these circumstances. It is too early to judge how the safety balance will be struck, but what is clear is that market competition poses significant new challenges for the nuclear safety regulatory authorities. The following sections present a comprehensive listing of these challenges and a discussion of possible regulatory response strategies.

Regulatory challenges and response strategies

While the full impact of electricity market competition has not yet been felt in all countries, it is becoming clear that the changes are presenting the safety regulator with new issues to understand and deal with, and may even affect the nature of the established relationship between nuclear operators and the regulator. The wide scope and depth of the issues below illustrate the challenge to the safety regulator to understand and deal with the changes taking place in the nuclear industry under market competition. It is especially important for the regulator to develop an early understanding of these changes and the operator's approach to managing the challenges before they develop into actual safety problems. Merely by placing the issues on the agenda for discussion with the senior management of the operator organisations, the regulator may be effective in ensuring that management retains its focus on nuclear safety. In fact, it is quite possible that the operator's responses to market competition issues can lead to improved safety performance if there is an enlightened approach to improved planning, more efficient work practices and better overall management of day-to-day operations.

To illustrate the nature of these challenges for the regulator, several specific examples are listed below for each of four broad categories, followed by a discussion of regulatory response strategies.

3. NEA (1999), *The Role of the Nuclear Regulator in Promoting and Evaluating Safety Culture*, OECD, Paris.
4. NEA (2000), *Regulatory Response Strategies for Safety Culture Problems*, OECD, Paris.

Governance issues – ownership, financial and organisational

The most obvious changes arising from privatisation and competition are those affecting the governance structures of the operating organisations. Some of the possible challenges facing the regulator in this regard are discussed below. These issues are not predicted to become certain safety problems, but are discussed as potential challenges that the regulator should be aware of in order to shape the appropriate regulatory response.

- Dilution of responsibilities for safety (change in ownership, portions of nuclear site leased to other companies).
- Decoupling of owners and business managers at the top of the organisation from the technical managers operating the nuclear plants.
- Greater use of low-price contractors (perhaps less qualified).
- Financial qualification of licensees may be reduced.
- Less than adequate funds for decommissioning and spent fuel and radioactive waste management.

In some countries where the introduction of competition in electricity markets has begun, one sees the onset of a consolidation of the nuclear industry through corporate mergers, new generating companies formed and the sale of nuclear power plants. The general trend is towards fewer but larger nuclear operating organisations.

As this restructuring of the industry proceeds, it is important for the regulator to understand the ownership changes and to monitor the financial and organisational changes that follow in the wake of restructuring. For example, when there is a change in ownership of nuclear plants, the regulator should make it clear to the new owner's senior managers that they, as well as the plant managers, have responsibility for nuclear safety.

It is common for owners of nuclear power plants to reduce operating and maintenance costs by reducing the size of plant staff and by outsourcing some work to specialist contractor organisations. While these actions may be seen as normal business decisions in response to competitive pressures, the effect over time may be a loss of technical competence and resources within the operator's organisation. Contributing to the loss of actual technical capability might be a growing belief among the remaining workers that senior management places increasing priority on economics over safety. At the extreme, the operator could possibly lose the ability to effectively manage the safety of the plants.

The use of contractors is not inherently a safety challenge. Operators have used contractors for specialised tasks and general support for years. Where the safety challenge arises is when the use of contractors becomes so widespread that the operator's staff finds it difficult to control the contractor's work and thereby loses the understanding of that work and eventually loses the core capability in the operator organisation to manage the plant effectively. The regulator should hold the operator responsible for ensuring that contractors are technically competent and financially

sound, for specifying and overseeing the contractor's work products, and for maintaining sufficient technical staff within the operator organisation to manage effectively the safety of the plants.

To give another example of the effect of market competition, in a fully competitive electricity market the operator only receives income from the electricity that is generated and sold at the prevailing market prices. If the plants have low capacity factors and the generating costs are high, it is easy to imagine that a nuclear operating company could become unprofitable. If that situation were to persist, the regulator could be faced with the question whether the operator remained financially qualified to operate the nuclear plants safely and, in addition, whether the operator had adequate funds to meet its obligations for plant site decommissioning and long-term spent fuel and radioactive waste management.

The regulator may want to examine whether its authority is adequate to cover the situation where a nuclear operator encounters severe financial difficulty. In particular, the regulator should require third-party liability insurance and segregated funding arrangements, such as trust funds, to meet the operator's obligations for plant site decommissioning and long-term spent fuel and radioactive waste management.

These governance issues, while not entirely new for the regulator, are likely to be persistent, and they point to the need for the regulator to be prepared to deal with them as ongoing safety challenges. An essential step in preparing to deal with the governance issues is for the regulator to fully understand the economic conditions of the competitive electricity market and therefore the competitive pressures facing the operator. These conditions will be very different from the days of regulated markets. In addition to the steady pressure on costs and production, because of expected electricity price volatility there will be added pressure to keep the nuclear plants on line during those times when prices are highest.

The regulator may want to add members to its staff with special knowledge of market economics, finance, organisation issues and business management. But most important for the regulator is to stay in close communication with the operator's senior management to learn firsthand the operator's proposed actions in response to competitive pressures and how the operator intends to maintain safe operation of the plants.

In addition to discussions with the operator's senior management, the regulator will have to examine whether the current inspection programme is adequate to detect early signs of declining safety performance as the plants operate in the new economic conditions. Most likely the scope of the current inspection programme will be found to be adequate, but the regulator may decide to add some inspection depth in certain areas, for example, where the operator has outsourced work to contractors.

In parallel with these activities, the regulator will have to examine whether the regulations and regulatory guidance documents are adequate to deal with the challenges of market competition. In the United Kingdom, for instance, the regulatory body has found it necessary to introduce a new license condition (LC 36) requiring the operator to effectively manage changes to

its organisational structure and use of resources, and in some cases requiring the regulator's concurrence with the changes. The regulator may conclude that some controls over reductions in the operator's manpower are necessary. Another area that may be examined is whether regulatory guidance is needed to establish minimum standards on the use of contractors for conducting essential safety work associated with the plants.

Direct safety challenges

It is possible that some of the changes resulting from market competition can lead to direct safety challenges in the operation of nuclear plants. These challenges are largely the result of competitive pressures on the operators to increase electricity generation and reduce generation costs. Listed below are some potential direct safety challenges facing the regulator:

- Operator management focused on economics over safety.
- More pressure on workers, perhaps overstressing them.
- Excessive overtime causing worker fatigue.
- Lower quality of work (reduced expertise, lower quality equipment).
- Plant ageing problems (reduced maintenance and pressure for life extension).
- Reduced safety margins (power upgrades, increased fuel burn-up).
- Less investment for equipment upgrades and safety backfits.
- Reduced equipment reliability due to changed maintenance strategies (reduced preventive maintenance, increased on-line maintenance).
- Decreased electricity grid stability and reliability.

The types of issues presented by the economic pressure on operators to reduce costs and increase electricity production are similar to the traditional issues that have been of concern to regulators for years. However, under market competition, the pressures on the operators will be more intense and will be relentless, and may lead workers to suppress (or self-censor) the reporting of safety problems.

The collective impact of these direct safety challenges may be a decline in safety performance. The regulatory response to these challenges will generally be similar to the standard regulatory oversight programme of looking for early signs of declining performance. But the regulator may want to increase focus on safety culture issues, such as signs that plant worker morale is being negatively affected by job security concerns brought about by staff reductions. Likewise, the regulator may want to give increased attention to safety management processes, as the operator attempts to compensate for staffing reductions by work process improvements.

In most countries introducing competition in electricity markets, the generating companies may no longer have responsibility for grid stability and reliability. Instead, this responsibility will be held by an independent grid regulator. For nuclear power plants, grid reliability can be a safety

issue because it can affect the frequency of degraded grid conditions and offsite power losses to the plant. The response to this challenge is for the regulator to understand fully the new responsibilities for grid stability and reliability and to have discussions with the grid regulator. The safety regulator should ensure that the plant operator has adequate procedures to monitor grid stability and reliability changes and their effects on nuclear plant operations.

As discussed in the previous section, the regulator should stay in close communication with operator senior management to understand and ensure the adequacy of the operator's proposed actions in response to these challenges.

Nuclear technology infrastructure issues

The challenges of electricity market competition come at a time when a general consolidation and reduction in size of the nuclear industry is already under way in most OECD countries, partly in anticipation of competitive pressures. These changes in the nuclear technology infrastructure present yet another set of potential challenges for the regulator:

- Less expertise in operator organisations, at vendors and at contractors.
- Diffusion of design authority capability (loss of design basis knowledge).
- Less co-operation among operators.
- Less safety research by operators, with consequent less support for their safety positions.
- More pressure to reduce the regulatory safety research programmes.

The general challenge posed by the set of nuclear technology infrastructure issues is the potential for a gradual decrease in technical safety expertise in the nuclear operator organisations and in the broader nuclear industry, including vendors, contractors and universities. This challenge is especially difficult for the regulatory body because its regulatory authority generally extends only to the operator organisations.

The primary regulatory response to this challenge is to discuss with senior management the operator's plans for maintaining the essential skill sets needed among the plant staff to operate the plant safely. In particular, the regulator will have to ensure that the training programmes remain adequate for the plant workers. A related area for discussion is how the operator intends to maintain its design authority capability and thereby maintain the plant design basis.

To deal with the broader issue of loss of expertise across the nuclear industry, the regulator may choose to have a meeting with all operator organisations to determine their plans for collective support of the nuclear industry, such as owners groups, industry groups sponsoring nuclear research, and university nuclear engineering departments.

Of particular concern is the potential reduction in safety research, because it has the direct effect of loss of continuing safety knowledge as well as the consequent effect of loss of research facilities and expertise and the loss of academic interest in nuclear safety research. The regulator

will have to be firm in defining what research information is necessary to justify the operator's safety positions, for example, on higher fuel burn-ups. Further, the regulator will have to be firm in defining an adequate programme and seeking funds for a regulatory research programme.

Increased pressures on the regulatory body

Just as market competition will produce competitive pressures on nuclear operators, there will no doubt be corresponding pressures on the regulatory body that challenge the way the regulator has carried out its activities in the past. These pressures may include the demand to reduce perceived unnecessary regulatory burdens and a general resistance by operators to consider plant backfits and other safety improvements sought by the regulator. Listed below are some of the potential increased pressures foreseen for the regulatory body:

- New regulatory competencies needed.
- Less expertise available to the regulator.
- More aggressive relations between operator and regulator (more pushback, unwillingness to backfit).
- Information flow reduced because of sensitive market information.
- Legislative basis for enforcement may be inadequate.
- Pressure on regulator to avoid requiring shutdown (projected long shutdown may lead to decommissioning).
- Operators will demand more international consistency of regulations.
- Pressure to reduce regulatory impact costs (fees, research and size of regulatory body).
- Increased direct pressure on the regulator to reduce perceived unnecessary regulatory burdens.

All of these issues will combine to produce an increased workload for the regulatory body. In the face of these broad regulatory challenges and new pressures, the regulator may want to conduct a broad self-assessment to examine what changes in the regulatory body may be called for in light of the changes taking place in the nuclear industry.

A special area for the regulator to examine is what new skills and competencies may be needed by the regulatory staff, especially in the areas of market economics, finance, organisational issues and business management. Similarly, the regulator may want to examine how it intends to maintain the technical skills and historical safety knowledge among its own staff in the future.

Yet another challenge for the regulator is the pressure for international regulatory consistency where operators face the competitive pressures of selling electricity across national boundaries. In Western Europe, for instance, there is an initiative for safety regulators from several countries to work together to harmonise regulatory requirements, largely in response to these pressures brought about by market competition.

Earlier sections have discussed how the regulator will have to examine whether the current inspection programme is adequate to detect early signs of declining safety performance as the operator makes changes in response to new economic conditions.

Finally, the regulator may want to review the current body of regulations and guidance documents and to examine current enforcement authority to see if different requirements may be needed and, just as important, whether all of the regulations and other requirements are still necessary and effective.

Summary and implications

The regulatory challenges of electricity market competition represent a broad set of new issues for the safety regulator, and these issues are likely to be permanent. Thus the proposed regulatory responses discussed in this report are not one-time actions, but will have to be continued. In that sense, the responses represent a new regulatory approach to market competition.

Of course, the competitive climate of electricity markets has not changed the basic responsibility of the operators to safely operate the nuclear power plants. In independently ensuring that nuclear plants are operated safely amid the changes of market competition, the regulator must ensure that the operator maintains the staff expertise, design basis information, research data and resources to support safe operation.

The main elements of this new regulatory approach can be summarised in the following elements:

- The regulator must fully understand the economic conditions of the competitive electricity market and the range of competitive pressures facing the operator. It will be necessary to stay in close communication with senior management to learn firsthand the operator's proposed changes and how the operator intends to maintain safe operation of the plant.
- The regulator will have to consider how its existing technical skills will be maintained and what new skill sets and competencies must be added to the regulatory staff, particularly in areas such as market economics, finance, business management, safety culture and organisational issues.
- The regulatory inspection programme should be re-examined to ensure that it is adequate to detect early signs of declining safety performance.
- The regulator will have to define what research information is necessary to justify the operator's safety positions, and similarly will have to define an adequate regulatory research programme.
- The regulator will have to consider whether the current set of regulations and enforcement authority is adequate to cover the changing conditions brought about by market competition.

- Regulatory bodies should continue to share essential safety information with their international colleagues, particularly operating event experience, and will have to make special efforts to share their experiences as electricity market competition unfolds.

This new regulatory approach to the challenges arising from electricity market competition implies a larger workload for nuclear safety regulatory bodies in the future. The regulator may want to conduct a self-assessment of its current workload and priorities in order to plan how to accommodate the new regulatory approach within current regulatory resources.

7. The Nuclear Regulatory Challenge of Judging Safety Backfits

Foreword

The Committee on Nuclear Regulatory Activities (CNRA) of the OECD Nuclear Energy Agency (NEA) is an international body made up of senior representatives from nuclear regulatory bodies. The Committee guides the NEA programme concerning the regulation, licensing and inspection of nuclear installations with respect to safety. It acts as a forum for the exchange of information and experience, and for the review of developments which could affect regulatory requirements.

In 1999, the Committee established a Task Group to reflect and advance the discussion on specific issues of regulatory policy. Over the years the Task Group produced a series of short reports dealing with early signs of declining safety performance and regulatory response strategies for safety culture problems, as well as the regulatory challenges arising from competition in electricity markets.

Continuing in the series, this report describes potential situations giving rise to safety backfit questions and discusses regulatory approaches for judging the backfits. The growing pressure on regulators to reduce the number of safety backfits is a challenge that many regulators currently face.

The present report was prepared by Thomas E. Murley, on the basis of discussion and input provided by the members of the Task Group listed below:
Serge Prêtre (Chairman, Switzerland), Michael Cullingford (United States of America), Lars Gunsell (Sweden), Jon Johnson (United States of America), Klaus Kotthoff (Germany), Aníbal Martín Marquínez (Spain), Philippe Saint-Raymond (France), Lynn Summers (United Kingdom), Mike Taylor (Canada), Gianni Frescura and Miroslav Hrehor (NEA).

Introduction

It is now generally recognised that the nuclear power programmes of OECD countries have reached a high level of maturity. A great deal of information and lessons have been learned from the several thousand reactor-years of operating experience and supporting research in OECD countries, and these lessons have become institutionalised in various national laws, regulations, nuclear plant operating procedures and nuclear plant programmes such as training, security, quality assurance and emergency planning.

A significant result of this operating experience has been the steady improvement in operational safety performance of nuclear power plants in OECD countries in recent years. This improved performance is reflected in many published performance indicators.

A parallel development in OECD countries is the trend to introduce competition in electricity markets.[1] The economic pressures of electricity market competition have led nuclear power plant operators to seek ways to increase electricity production and to reduce operating costs at their plants. Just as market competition produces competitive pressures on nuclear operators, there will be corresponding pressures on the regulatory bodies that include the demand to reduce regulatory burdens perceived as unnecessary and a general resistance by operators to consider safety backfits sought by the regulator. A frequently voiced demand by nuclear operators is the need for regulatory stability – that is, a stable set of regulatory safety requirements that the operator must meet and that are not changed frequently by the regulator. In other words, there is a growing pressure on regulators to reduce the number of safety backfits. This pressure will present a challenge to the regulator, which is the topic of this report.

Some countries have adopted the concept of a periodic safety review (PSR) for each nuclear power plant. A PSR gives the operator the responsibility to review the overall safety of the plant against current standards and to evaluate and justify any deviations. Experience in those countries has shown that operators generally have embraced PSRs because it allows potential backfit issues to be addressed in an integrated fashion and gives the operator the opportunity to put his safety case in an overall safety perspective.

The term backfit for dealing with new safety issues is intended to include a range of regulatory approaches. In countries where the approach is less prescriptive, with only the objectives being set by regulations, a new backfit issue is resolved through a process that includes discussions between the regulator and the operator, without formal changes in the regulatory requirements. In countries with a more prescriptive approach, after discussions between the regulator and operator, a backfit means a new or changed requirement by the regulatory authority to modify the operating conditions of a plant, to modify the systems, structures or components of a plant, to modify the programmes or procedures used to support operation of a plant, to modify the organisation used to support operation of the plant, or to modify the qualifications or training of safety workers at a plant.

While there are differences in the laws and regulations of each OECD country, all regulatory bodies set a level of safety that must be achieved by nuclear power plants. In the past four decades of commercial power operation, regulators have often required safety backfits, for a number of reasons. Among the reasons for requiring backfits are:

a) To maintain the required level of safety of a plant or plants.

b) To require compliance with existing regulations.

1. NEA (2001), *Nuclear Regulatory Challenges Arising from Competition in Electricity Markets*, OECD, Paris.

c) To require substantial safety enhancements when new information or analyses show that such enhancements are necessary and practical to implement.

Of course, there have been many instances where the nuclear plant operators, on their own initiative, have implemented backfits for the same reasons above. Some operators have adopted a policy of continuous improvement, which can also lead to operator-initiated backfits for improving safety. This continuous improvement policy focuses on regular self-assessments of safety performance and includes programmes for corrective actions, operating experience evaluation, and benchmarking against best practices in the nuclear industry. In some cases, new information has shown that safety margins were greater than believed, and that information has been used to relax some safety requirements. While the focus of this report is on backfits (i.e. enhanced safety requirements), it should be kept in mind that the regulator may also consider requests for relaxation of safety requirements when new information or analyses justify such actions.

The large number of safety backfits over the years (as well as improved attention to safety management by operators) is believed to be a significant contributor to the improved safety performance of OECD plants over that period. However, neither operators nor regulators should allow improved performance to be a cause for complacency.

Regulatory bodies recognise that there are always arguments for and against backfitting, and they further recognise that operators wish to obtain regulatory stability. A stable regulatory environment does not mean, however, that there cannot be new safety backfits to nuclear plants. Clearly, when a new safety issue arises, whether from operating experience, new analyses, research programmes or other sources, the regulator has the responsibility to consider whether safety backfits may be required. A regulatory body should never stop looking for safety problems at nuclear power plants. Likewise, operators must acknowledge that they are responsible for operating their plants safely, and that includes the responsibility to consider safety backfits when new safety issues arise.

In view of the background above, the purpose of this report is to describe potential situations giving rise to safety backfit questions and to discuss regulatory approaches for judging safety backfits. It follows that the audience for this report is primarily nuclear regulators, although the information and ideas may also be of interest to nuclear operating organisations, other industry organisations and the general public.

Situations giving rise to safety backfit questions

Making decisions on the need for safety backfits is a normal activity for any regulatory body, and all regulators can point to actual backfit decisions in the past. This section of the report describes some hypothetical situations that could give rise to safety backfit questions. Not every regulatory body would consider the following situations as posing backfit questions. Some regulators might consider the situations as involving normal regulatory actions to maintain the plant or plants within the approved safe operating envelope or the current design basis. In any case, the hypothetical examples are given to set the stage for the discussion of regulatory approaches for judging safety backfits.

Operating events

A routine inspection inside containment during an outage reveals evidence of small leakage of primary coolant water from a section of small bore piping. The operator proposes to conduct non-destructive examination of the full length of the pipe and to repair any cracks with a weld overlay technique. The regulatory staff believes all similar piping should be inspected and all cracked piping should be replaced.

Operating experience (conditions)

A routine design review reveals that under some accident conditions (unlikely but possible), the emergency diesel generators (EDGs) would be overloaded and therefore rendered inoperable. Adding an additional safety-grade EDG would be quite expensive, and the operator does not believe it is necessary for such an unlikely event.

Evolution in plant operating conditions

Some operators are proposing to increase the fuel burn-up limits for their plants. In reviewing these proposals, the regulatory staff believes that changes in the fuel design may be needed, such as improvements in fuel assembly rigidity.

Evolution in nuclear plant technology

As nuclear plant component reliability increases, the relative weight of human factors in the residual risk increases. In reviewing this matter, the regulatory staff and the operator believe that safety can be improved by installing automated systems in place of relying on operator actions to cope with certain situations.

New insights from probabilistic safety analyses (PSA)

A plant-specific PSA shows that a large pipe rupture in the circulating water system could flood multiple rooms containing redundant safety system equipment. The regulatory staff acknowledges this is a new accident sequence not considered in the original safety licensing review but believes it should be corrected with new flood protection features. The operator believes that leak detection methods will allow actions to be taken to prevent a full pipe rupture.

Effects of plant ageing

A routine steam generator tube inspection finds indications of partial circumferential cracking. Comparison with previous tube inspection records shows the crack growth rate may be higher than expected. The regulator believes that another inspection should be conducted at the middle of the next operating cycle. The operator believes the inferred crack growth rate is an artefact of changed tube inspection methodology and that it is safe to wait until the next refuelling outage to do a tube inspection.

Inspection findings

During a comprehensive regulatory team inspection at an older plant it is found that the freeze protection system for the high pressure safety injection system is not single failure proof. Furthermore, the freeze protection system was not included in the original licensing basis as a safety-related system and is therefore not included in the technical specifications. The regulator is considering whether to require the addition of a redundant freeze protection system and whether to add regular inspection requirements in the technical specifications.

New research findings

In a research experiment aimed at determining the best method for conducting tests on qualifying electrical equipment for the harsh environment inside containment during a loss-of-coolant accident, the researchers find that certain types of electrical equipment fail in 30% of the tests. The equipment suppliers and the operators contend that the tests are not representative of actual accident conditions.

New information external to the plant

During excavation for a construction project 10 km from a nuclear plant, a previously unknown seismic fault is discovered. The extent and severity of the ground fault is not known. Using new ground motion assumptions in seismic structural analyses, believed to be bounding assumptions, the regulatory staff finds that important safety systems may fail to function in an earthquake. The regulator and the operator are discussing how to determine the extent and severity of the ground fault and how to conduct new, realistic seismic analyses of the plant. Separately, the owners of the plant have let it be known that they are considering whether to shut down and decommission the plant if major backfits are required.

New international safety consensus (or standards)

After several years of research studies and analyses, safety experts gather at an international conference and conclude that the addition of new post-accident mitigation systems in containment can significantly reduce the offsite radiological consequences for certain core melt accident sequences. Regulatory bodies are pondering how to deal with this new consensus information.

New insights from periodic safety reviews (PSR)

A PSR finds that under certain conditions (unlikely but possible) a single failure in an electrical system could disable both trains of an important safety system. Both the regulator and the operator agree that the design should be changed but disagree on the urgency of installing the new design.

Safety reviews for plant life extension

During a safety review for an application for plant life extension, a detailed review of fracture toughness data from archival samples of pressure vessel welds reveals that the vessel weld material may not meet current requirements for weld fracture toughness.

International consensus on good safety practices

An international consensus has developed concerning the safety benefits of using plant-specific performance indicators (PIs) to track operational safety trends at each nuclear power plant. The regulator believes that the operator should implement a more comprehensive programme for collecting and publishing plant-specific PIs in conformance with this international consensus.

Summary

It is not the intent of this report to discuss the merits of any particular course of action for the hypothetical situations above. Rather, these examples are used to show that new safety information can come from a wide range of sources; that the initial information on safety significance may be fragmentary and inconclusive; and that there may be technical disagreements between the regulator and the operator on the facts of the situation and on the safety significance of the facts.

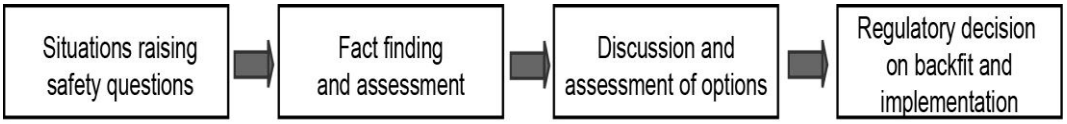
In situations like these, the regulator will be faced with the issues of whether to require a safety backfit and what should be an appropriate time period allowed to implement the backfit.

Regulatory approaches to judging safety backfits

When a situation arises like one of the examples above, where basic safety issues are apparent, both the regulator and the operator have a common interest in resolving the safety issues. While it is the responsibility of the operator to safely operate the nuclear power plant, the regulator has responsibility for independently assuring that all nuclear plants are operated safely. It is in the interest of safety that the regulator and the operator work together in a professional manner to establish the basic facts in the situation and to agree on a plan to develop the additional data and information that is needed.

The first question that must be asked in such situations is whether an immediate safety problem is present and whether urgent protective measures must be taken, such as the shutdown of the plant. This question of whether to take urgent protective measures may arise at any time during the backfit process. Experience has shown that most often the safety issues do not require urgent protective measures. If there is a difference of opinion on this matter, the regulator’s views must prevail.

Whether or not immediate protective actions are taken, the broader question remains whether a backfit is required to address the safety issue and, if so, what is the appropriate backfit. The regulatory approach to judging safety backfits is based on the model shown below.



After the new information raising a safety issue has come into clear focus and a decision has been made on immediate protective actions, a period of fact finding will be needed to assess the scope of the safety issue. Are the physical phenomena understood? Is more research or analysis needed? How many plants are affected? Do the plants meet the current regulations? Will new regulations, license conditions or regulatory guides be needed? Will safety be substantially improved by a backfit? Are there legal, regulatory credibility or other public policy issues that must be considered? The regulator may request the operator to perform special safety analyses, including probabilistic safety analyses (PSA). This phase of the process may take time, perhaps several months or a year or more, and of course there will be frequent discussions with plant management during this process.

As fact finding proceeds, the regulator and the operator will begin to form preliminary views on what is needed to resolve the safety issue. In some instances the operator may propose a voluntary backfit that is completely satisfactory to the regulator. In such cases, the regulator need do little more than formally document the backfit commitment and monitor its implementation through the regulatory inspection programme.

A more likely situation is that the regulator and operator do not initially have congruent views on the remedy for the safety issue. This situation will require discussions with plant management, and it is usually best for the regulator to request the operator to propose a remedy for the issue. If multiple options are under consideration, the operator may perform comparative analyses of the options.

After fully discussing the backfit options with plant management, the regulator must come to a decision on the type of safety backfit (if any) and the allowed time to implement the backfit. If the regulator concludes that a safety backfit is necessary to ensure the required level of safety, then the major remaining question is the time to implement the backfit. This judgment can usually be aided by insights from PSA as well as operating experience and an assessment of the robustness and effectiveness of the backfit.

In those cases where the required level of safety is not challenged, but where safety improvements are thought to be possible through a backfit, the regulator will balance the advantages and drawbacks of the proposed backfit. Some regulators may use a largely qualitative approach, considering such factors as the degree of improved safety, improved public confidence, or other factors. There may be considerations other than health and safety in deciding on backfits – for example, environmental protection, nuclear material security and compliance with international obligations such as non-proliferation objectives.

Other regulators may choose to use a more quantitative approach to judging backfits, such as the following two-part test: the backfit must provide a substantial increase in safety and the direct

and indirect costs of implementing the backfit must be justified in view of the substantial increase in safety.

In judging whether a proposed backfit provides substantial additional safety protection, the analysis should follow established regulatory guidelines. One may use PSA for insights into quantitative benefits, for example the incremental reduction in core damage frequency resulting from implementation of the backfit. If the proposed backfit meets the first test of substantial increase in safety, the regulator may request cost-benefit information from the operator or may develop its own cost-benefit analysis. In evaluating whether the backfit benefits outweigh the costs, the analysis should include all costs associated with implementing the backfit – for example design, procurement, installation, worker radiation exposure, procedure revision, training and costs for any plant shutdown time. Likewise, the benefits should include the reduced likelihood of accidents and their consequences (i.e. all averted costs including averted radiation exposure).

Whether the regulator uses a qualitative or quantitative approach, or some mixture of the two approaches, after reviewing the *pros* and *cons* of backfit options with the plant management the regulator must decide whether to impose the safety backfit.

If the decision is for a backfit, as mentioned above the regulator must also specify a time for completion of the backfit implementation, after discussions with the plant management. In some cases (e.g. steam generator tube inspections and tube plugging which are normally done during plant outages), the timing will be clear. In other cases involving design modifications and hardware changes, the practicalities of the design, procurement and installation processes will be major considerations in the implementation time, along with judgments of the safety importance of the backfit. A factor in the timing decision may be the use of compensatory actions while the backfit is being implemented.

After the decisions on the backfit and implementation time have been communicated to the operator, the regulator should maintain a dialogue with the operator as the planning for the backfit progresses. In some cases, the regulator may want to review and approve any design changes to be sure that there are no unintended systems interactions or negative safety effects of the backfit.

The operator must review the design changes and bring the safety analysis reports, operating and maintenance procedures, training programme and other programmes into conformance with the backfit before it is actually implemented. Likewise, the regulator should ensure that the relevant regulatory guidance is revised, if necessary, to conform with the backfit decision. The regulator should plan to inspect the actual backfit implementation through the regulatory inspection programme.

As a conclusion to this regulatory approach for judging safety backfits, and in the spirit of improving regulatory performance, the regulator should consider conducting a retrospective self-assessment. Some of the questions that such a self-assessment could address are:

- Could the process for identifying new safety problems be improved?

- Was the fact-finding process concerning the new safety problem thorough?
- Were the interactions with the operator conducted professionally?
- Were communications with the public adequate?

Summary and conclusions

While the operational safety performance of nuclear power plants in OECD countries has improved in recent years, neither operators nor regulators should allow that performance to be a cause for complacency. Regulatory authorities can still expect to be confronted with challenging safety backfit decisions from time to time. There will continue to be situations where operating experience or new information will give rise to safety issues and questions concerning the need for safety backfits. In this regard, regulatory bodies should continue to share essential safety information with their international colleagues.

This report discusses a general regulatory approach for judging safety backfits. The main features of this approach are the following:

- Regular analysis of plant operating experience, especially operational events, to determine whether new safety issues are presented.
- Regular review of the results of safety analyses (e.g. probabilistic safety analyses and periodic safety reviews) and research activities.
- A comprehensive fact-finding review of potential new safety issues.
- Frequent and thorough discussions with the operators on their view of the situation and on their proposals for addressing the safety issues.
- A careful analysis of the pros and cons of various backfit options.
- After the decision on a backfit and implementation time, monitoring the backfit implementation through the regulatory inspection programme.
- Revision of regulatory guidance, if necessary, to conform with the backfit decision.

A key principle of this approach is that the operators must maintain the responsibility for safely operating the nuclear power plants. In this regard, the regulator should preserve a dialogue with the operators to determine their views of the safety issues and their proposals for addressing them.

It is believed that the regulatory approach to judging safety backfits described in this report is consistent with the desire for a predictable and transparent regulatory process.

8. The Regulatory Challenges of Decommissioning Nuclear Reactors

Foreword

The Committee on Nuclear Regulatory Activities (CNRA) of the OECD Nuclear Energy Agency (NEA) is an international body made up of senior representatives from nuclear regulatory bodies. The Committee guides the NEA programme concerning the regulation, licensing and inspection of nuclear installations with respect to safety. It acts as a forum for the exchange of information and experience, and for the review of developments which could affect regulatory requirements.

In 1999, the Committee established a Task Group to reflect and advance the discussion on specific issues of regulatory policy. Over the years, the Task Group produced a series of short reports dealing with early signs of declining safety performance; regulatory response strategies for safety culture problems; the regulatory challenges arising from competition in electricity markets; and the regulatory challenge of judging safety backfits.

Continuing in the series, this report describes the broad set of safety, environmental, organisational, human factors and public policy issues that may arise during the decommissioning of nuclear reactors and that the regulatory body should be prepared to deal with in the framework of its national regulatory system.

The present report was prepared by Thomas E. Murley, on the basis of discussions with, and input provided by, the members of the Task Group listed below:
Serge Prêtre (Chairman, Switzerland), Michel Duthé (France), Bernd Rehs (Germany), José L. Revilla (Spain), Anna Lekberg (Sweden), Frances Taylor (United Kingdom), Jon Johnson (United States of America), Gianni Frescura and Mr. Miroslav Hrehor (NEA).

Introduction

Each nuclear power plant, fuel cycle facility and nuclear research and test facility that is operating today will eventually reach the end of its useful life and cease operation. Indeed, several such facilities have already ceased operation. At that time, the operator of the facility will undertake a series of decommissioning actions that will eventually lead to a satisfactorily safe condition of the facility and an environmentally acceptable condition of the site. It is important that the health and environmental hazards and physical protection measures of the shutdown facility be managed properly during this process to protect the health and safety of public and workers and to safeguard any nuclear materials. In this regard, the regulatory body has the responsibility for independently assuring that decommissioning activities are conducted safely,

that radioactive materials and spent nuclear fuel are disposed of properly and that the site is in an acceptable end state.

Although there are several uses of the term "decommissioning", in this report we shall use decommissioning in its broadest sense to cover all of the administrative and technical actions associated with early planning for cessation of operations through termination of all licenses and release of the site from nuclear regulatory control. These actions may include early strategic and financial planning, removal of spent or unused fuel to a reprocessing or storage site, decontamination of structures and equipment, dismantling of plant and equipment, shipping radioactive and other waste to offsite disposal sites, remediation of contaminated land and remaining structures, and other related that the site is in an acceptable end state.

The decommissioning process may take a few years or even several decades, and it may involve work being done in stages of activity separated by periods of relative inactivity. While substantial research and analysis regarding the technical aspects of decommissioning have been conducted in OECD countries in recent years, there is no preferred approach to decommissioning of nuclear facilities. Nonetheless, the techniques and institutional arrangements for decommissioning are sufficient for today's needs and, in fact, several nuclear that the site is in an acceptable end state.

The types of safety, security, environmental and public policy issues that arise in decommissioning are very different from those during operation, and often public interest and concern can be quite high. The population living near a nuclear facility may have become accustomed to its normal operation, but they are naturally concerned that a new activity like decommissioning be done safely, and they may be even more concerned about plans for the long-term condition of the site. These new safety, environmental, organisational, human factors and public policy issues will produce new challenges for the regulator.

Just as the approach for regulation of operating nuclear facilities varies widely among OECD countries, the regulation of decommissioning activities also shows widely varying approaches.[1] Some countries have, or are developing, general regulatory guidance and expectations that are applicable to both operating and decommissioning activities, while others have prescriptive regulations and guides that apply specifically to decommissioning. All regulators, however, share the same general regulatory objectives – namely that (a) the decommissioning activities be conducted safely, (b) good waste management principles are followed, and (c) the site is left in an acceptable end that the site is in an acceptable end state.

By now there is an extensive body of literature on the technical, safety, radiological, waste management and environmental aspects of decommissioning. Some of the discussions in this report draw from that extensive literature.[2, 3]

1. NEA (2000), *Regulatory Practices for Decommissioning of Nuclear Facilities with Special Regard of Regulatory Inspection Practices*, NEA/CNRA/R(99)4, February 2000, OECD/NEA, Paris.
2. IAEA (1999), IAEA Safety Guide WS-G-2.1 *Decommissioning of Nuclear Power Plants and Research Reactors*, Vienna.

This report is not intended to specify a preferred approach to regulate the decommissioning of nuclear facilities but rather to discuss the broad set of issues that may arise during decommissioning and which the regulatory body should be prepared to deal with in the framework of its regulatory system. The discussions in this report relate primarily to nuclear power plants, but the decommissioning principles and the regulatory challenges apply to other nuclear facilities as well.

It follows, therefore, that the audience for this report is primarily nuclear regulators, although the information and ideas may also be of interest to government authorities, environmental regulators, nuclear operating organisations, technical expert organisations and the general public.

Changes from operation to decommissioning

Experience has shown that decommissioning is not simply an extension of operations, like a new operating mode. While the early stages after shutdown may resemble the activities during a normal outage, the operator will soon begin taking actions that will render the facility permanently inoperable.

It is important that the management and staff of the facility understand the fundamental nature of the changes taking place during this phase. Actions will be taken that are effectively irreversible, and the operator's staff must cope with the emotional effects that come with the realisation that the facility will never operate again. New organisational and human factors issues are presented, such as the need to maintain key staff personnel and staff expertise and the need to maintain a safety focus during these changing times.

One of the biggest changes will be the change in mindset among the workers. Operational staff tends to view a complex nuclear facility in terms of **systems** that run throughout the plant, whereas decommissioning staff, especially during the dismantlement phase, tend to view the facility in terms of **areas** that must be taken down. The management of decommissioning has more of a project focus rather than a focus on teams supporting the operations staff. Also, since many of the structures and components are radioactive, this presents an added complication for the dismantlement procedures relative to those used during initial construction.

It is clear that the facility operator should not have to improvise with new plans in the weeks and months immediately after a facility ceases operation. There should be a strategic plan for decommissioning prepared while the plant is still operating. This plan should describe the overall decommissioning strategy chosen, such as moving directly to complete dismantlement and site restoration for unrestricted use, or placing the facility in a safe and secure condition to await final decommissioning at a later time. The strategic plan should be accompanied by more specific plans and safety analyses for the tasks immediately after shutdown. In some countries a specific decommissioning safety analysis report is required that analyses all significant risks expected during the entire decommissioning process.

3. NEA (2002), *The Decommissioning and Dismantling of Nuclear Facilities*, OECD, Paris.

The decommissioning plans should include financial information, including a cost estimate to complete decommissioning according to the strategy and schedule chosen by the operator and a clearly defined and reliable source of funding for these activities. This financial information is especially important for facilities operating in competitive electrical markets[4] where the facility likely will be generating little or no revenue after it has ceased operation.

There are some important policy issues that should be considered well before the facility is shut down and decommissioning begins. For example, planning for radioactive waste and other waste management and disposal should be done well in advance of shutdown. Some countries have a legal requirement that an environmental impact assessment, which considers alternative strategies, be conducted before decommissioning can begin. Insofar as practical, these matters should be included in the decommissioning plans.

The need for having decommissioning plans prepared during operation is especially important in cases where a facility is unexpectedly shut down before the end of its useful life, perhaps because of economic reasons or political decisions or even an abnormal event that has resulted in serious plant damage. Having plans in place could avoid a long (and costly) hiatus while senior management decides what to do next. The plans will give the staff a new work focus that will help them overcome any emotional effects associated with the early cessation of operation of the facility. This will be true even if the plans have to be modified due to the circumstances of the shutdown.

Among the first actions after shutdown will be to transfer hazardous material, such as reactor fuel and other removable core components, to a safe interim storage location. The decommissioning plans should include an analysis of which systems, procedures and programmes are needed to maintain the facility in a safe condition and which other systems and structures can begin the process of dismantlement. The plans may include new systems and procedures – for example, some shutdown facilities have constructed new, simpler spent fuel cooling systems, and even new control rooms with dedicated power supplies, in order to isolate the existing systems in preparation for dismantlement.

There may be special situations (for example, in Spain) where responsibility for decommissioning a nuclear facility is transferred from the operating organisation to a separate decommissioning organisation. In such situations the regulator is faced with the special challenge to assure that the new decommissioning organisation maintains operating records, facility design information and facility knowledge and experience during the decommissioning period. It will be especially important for the regulatory body to emphasise to the decommissioning organisation its responsibility for conducting all activities safely and to maintain careful oversight of contractors' qualifications and activities.

The change from operation to decommissioning will obviously present new challenges to the regulator as well. The regulator will want to have some early assurance that the decommissioning

4. NEA (2001), *Nuclear Regulatory Challenges Arising from Competition in Electricity Markets*, OECD, Paris.

strategy will result in an acceptable final end state and that there are adequate resources to accomplish it safely. Regarding its own organisation and procedures, the regulatory body will naturally have to review and revise its oversight plans for the facility to focus more on the new organisational, human factors and dismantlement issues, and it may augment staff expertise in those areas. These regulatory oversight matters are discussed more fully in Chapter 4 of this report.

Regulatory challenges

The decommissioning of a nuclear facility generally proceeds through the stages below. In some cases the work proceeds uninterrupted to the final end state, while in other cases there may be long periods of relative inactivity between stages. For instance, many nuclear power plants are located on multi-unit sites, and the other units continue to operate. In such cases the decommissioning activities may be limited to the first phase and portions of the second phase, whereafter the facility may rest in a safe storage state until all of the units are shut down and ready for full site decommissioning. The pace of activities may be dictated by the availability of funds or other strategic interests of the operator.

Immediate post shutdown activities:

- Placing the facility in a safe and secure condition.
- Removal of fuel and other materials to a safe interim storage location.
- Preparation of new procedures for shutdown activities, such as new radiation protection procedures.
- Measurement and documentation of the radioactive inventory and its distribution.

Preparation for dismantlement:

- Environmental impact assessment.
- New contractual arrangements with specialised contractors.
- Clearly distinguishing systems and components that may be de-powered from those that are needed for ongoing functions, such as spent fuel cooling.
- Separation of salvageable components and materials for asset recovery.
- Construction of special facilities such as a new control room, dedicated fuel pool cooling, new rail line, or sodium coolant treatment facility.
- Removal of hazardous materials such as asbestos.
- Decontamination of systems.

Dismantlement:

- Dismantlement of systems, structures, components and buildings.
- Shipping materials to a waste disposal site or a waste storage facility.

Site remediation:

- Removal of all residual radioactivity above acceptable levels for the chosen end state.
- Final site survey.

Acceptable end state:

- The end state does not necessarily have to be a "greenfield" condition. Some buildings or facilities like water supplies, roads, rail lines or electrical equipment may remain if the site is to be used for industrial or other purposes. There are many variations of an acceptable end state for a decommissioned facility site.

Most regulatory bodies have at least a minimum set of regulatory requirements or expectations regarding nuclear facility decommissioning:

- Strategic decommissioning plan – that is, the operator should describe his planned decommissioning activities and the regulator should review the plans and agree that the strategy will result in safe activities and an acceptable end state.
- Regulatory consent to begin decommissioning – that is, a judgment by the regulator that decommissioning activities can safely be started and that there are sufficient resources to carry out the plan.
- Conditions for terminating all facility licenses – the criteria for an acceptable end state.

Thus, the regulator will have an important decision making role at the onset of decommissioning and at the termination of all licenses. Once a nuclear facility ceases operation and regulatory approval for decommissioning is granted, the timing of site activities is largely controlled by the operator. During this period of actual decommissioning, which may be only a few years of heavy site activity or may be several decades of intermittent activity, the regulator will have continuing safety oversight activities. Many issues like those discussed in this report will require the regulator's attention and may require regulatory decisions.

The sections below describe a number of issues associated with decommissioning where the regulatory body needs to consider whether regulatory guidance may be necessary. Depending upon the regulatory approach in each country, the regulatory body may have specific requirements or only general expectations for the operator in dealing with these issues. Several specific examples of possible regulatory responses are discussed. These examples are merely illustrative and are not meant to imply that they are the preferred regulatory approaches nor do they imply that any specific regulatory guidance is necessary.

Organisation and human factors

The decision to permanently cease operation of a nuclear facility can have a profound impact on the operating organisation, especially if the shutdown is because of an accident, economic reasons or political decisions and if the facility is shut down before its expected end of life. Immediately upon shutdown the operator will be faced with many decisions of how to proceed

with decommissioning. Having an approved decommissioning plan in place will provide a road map for management to navigate through the changing circumstances and will give the operating staff a new work focus that will help them overcome the emotional effects associated with the shutdown.

Whether the shutdown is relatively sudden and unexpected, or the culmination of several years of planning, the immediate aftermath will almost certainly be a period of high uncertainty for workers accustomed to the routines of an operating facility. Some will recognise that their skills are no longer needed, and all will realise that long-term employment at the facility is not a realistic prospect. In these circumstances the facility management must have plans for retaining adequate staff competency, for maintaining the safety focus of the staff and for sustaining the overall safety culture of the site.[5, 6]

As the operator develops specific plans for hiring specialised contractors, the operator will have to consider hiring new workers and managers in his own organisation with the necessary skills for decommissioning and for overseeing contractors. It will be important that the operator retains an appropriate mixture of experienced workers with organisational and operational memory and new workers with decommissioning experience. It will be especially important to have procedures in place for maintaining facility records and for controlling changes to the facility. For instance, at a multi-unit site, the shutdown facility may share systems with operating facilities, and these systems cannot be altered without a careful analysis for unreviewed safety questions.

In view of these new challenges, which are quite different from those of normal operation, the regulator will have to consider new approaches for oversight of the operator's activities. For example, while the regulator will have reviewed the general strategic plans and the decommissioning safety analysis report, he will need to have frequent discussions with site management in the months after shutdown as more detailed decommissioning plans are prepared. The regulator will certainly want to know of the operator's plans for maintaining the safety focus of the staff and for management of contractors, and will also want to review the specific procedures for facility change control and for maintaining site records. In addition to frequent meetings with site management, the regulator will want to conduct regular inspections in the months after shutdown to look for possible adverse trends in the overall safety culture at the site.

Shutdown and preparation for dismantlement

Final shutdown of a nuclear facility will normally be followed by a formal notification to the regulatory body and a public announcement of the shutdown. The operator may have authority under the previous operating license to remove fuel, removable core components and other radioactive materials to a safe interim storage location, such as a spent fuel pool. Before substantive decommissioning activities can begin the operator will need regulatory approval, and the operator must confirm that the broad strategic plans are still valid and that adequate financial resources are

5. NEA (1999), *The Role of the Nuclear Regulator in Promoting and Evaluating Safety Culture*, OECD, Paris.
6. NEA (2000), *Regulatory Response Strategies for Safety Culture Problems*, OECD, Paris.

available for the immediate work ahead. The regulator will also want some reassurances regarding the operator's plans for dealing with the organisational and human factors issues discussed above.

Experience has shown that public interest and concern over decommissioning issues can be quite high. Typically the public concerns are centred on safety and radioactive releases during decommissioning and the residual risks of the site after all licenses have been terminated. The public is also naturally concerned if there are long-term plans for a spent fuel storage facility or an interim radioactive waste storage facility on the site. All of these issues should be addressed by the operator before decommissioning work begins. Some operators have found it of great benefit in communicating with the public to establish a committee of local political and civic leaders to have regular public discussions of decommissioning issues. Representatives of the regulatory body should plan on attending the public meetings to present the regulatory perspective on the issues, to describe the regulatory oversight activities, and listen to public concerns.

The early months of decommissioning will be devoted to preparation for the dismantlement of plant systems and structures. Many new procedures will have to be written, and the regulator may want to review these procedures. An early activity will be to conduct a comprehensive site survey for radioactive and hazardous material contamination in buildings, in the ground and in groundwater. The operator will no doubt begin to separate salvageable components and materials for asset recovery, and procedures must be in place for surveying and release of such materials.

A difficult policy issue for the regulator is that of defining acceptable clearance criteria for the release of waste material from nuclear regulatory control. Large volumes of waste will be handled, and much of the waste, like structural concrete debris with no detectable radioactivity above background levels, can be shipped offsite to normal landfills or used on the premises for filling the large ground cavities that dismantling may produce. Other material, such as concrete from the reactor pressure vessel cavity, will have surface contamination and must be surveyed and sent to a low level waste disposal site. Other material like steel piping and steam generator shells may have salvage value if surface contamination can be reduced to meet the material release criteria. There is currently no consensus within OECD countries on clearance criteria for the unrestricted release of waste material. For example, in some countries the release of radioactive material is not permitted at all, while in other countries nuclide-specific clearance levels are included in the legal framework.

Before undertaking substantive work on radioactive systems and components, it is a good practice, from a worker protection viewpoint, to remove other hazardous materials from the plant, such as asbestos and chemicals. In this regard the operator must co-ordinate its activities with the nuclear regulator as well as with the regulatory bodies having primary responsibility for regulating the hazardous materials being removed.

After the non-radioactive hazardous materials have been removed the operator can undertake the decontamination of systems, components and buildings in preparation for dismantlement. Before decontamination is started, however, the operator must carefully distinguish systems and components that may be depowered and drained from those which are still needed for ongoing functions such as spent fuel cooling. The choice of the method for decontamination should

consider the production of secondary waste arising from the decontamination activity itself, which may pose its own disposal challenges. All of these activities should be reviewed by the regulatory staff.

Before major dismantlement can begin it is likely that new, temporary facilities may need to be constructed. Some examples are a new control room, a new dedicated offsite electrical power supply, a new heat sink for the spent fuel pool, a new spent fuel pool cooling system, a new rail line, and facilities for waste treatment and material clearance measurements. Each of these new facilities will require new operating and maintenance procedures. Because these new facilities may present unreviewed safety questions, the regulator should review the new designs and procedures.

Since this initial period of decommissioning will be a very active time at the site, with many diverse activities happening in parallel, the regulator may find that its inspection and oversight are more intense than when the facility was operating. The planning and staffing implications for the regulator are discussed in earlier in this report.

Regulatory guidance on radiological and environmental controls

Nuclear safety regulators will typically have some shared responsibilities with the environmental regulators during decommissioning, but the basic radiological and environmental standards, especially effluent discharge and material release criteria, should be the same for decommissioning activities as for operations. Since each country's laws and practices are different, it is not practical in this report to discuss the division of responsibilities between the nuclear and the environmental regulatory authorities. Therefore, when the term "regulator" is used, it is understood that it may mean either the nuclear or the environmental regulator, depending upon national laws and practices.

Specific regulatory guidance will be needed on radiological and environmental controls for decommissioning. The form and content of the guidance will depend on the individual country's regulatory approach, but the following topics will need to be addressed:

- Acceptable duration of decommissioning period – some regulatory bodies place a limit on the length of time that a facility is allowed to complete decommissioning. There can be several reasons for such a time limit, but one important consideration is that the local public may find an indefinite delay to be unacceptable.
- Acceptable strategic options – many countries permit a choice of (a) immediate dismantlement, (b) temporary safe storage for a period of years, with eventual dismantlement, or (c) structures encased in concrete and maintained until radioactivity decays to a level permitting removal of regulatory controls, or some combination of these options.
- Scope of radiation surveillances – the regulator will want to ensure that the early site radiation survey covers all important buildings, ground locations, potential groundwater contamination and all effluent discharge pathways. Even if all effluent discharges have been within acceptable levels during the operating life of the facility, the cumulative

effect over the years could be great enough that remediation of effluent discharge pathways may be necessary. All offsite shipments of waste must be monitored and documented. It will be especially important for the operator to have controls for any gaseous and liquid wastes that may be different from those during normal operation.

- Interim storage facilities for radioactive waste, if needed.
- Requirements for the scope and duration of maintaining operational and decommissioning records, especially if there is contemplated a long period of safe storage of the facility.
- Acceptance criteria for termination of all licenses.

There are some unique challenges of decommissioning that the operator and regulator must recognise early. The radiological protection and physical safety of workers will be challenged by the decontamination, disassembly and removal of large radioactive components such as reactor pressure vessel, steam generators and pressuriser, large pipes, pumps and valves. Some workers will be sent into areas of the facility that have not been entered for a very long time and whose condition is uncertain. These activities will require careful planning and adherence to sound ALARA principles. Another unique challenge of decommissioning is the large quantity of waste containing only small concentrations of radioactivity, which must nevertheless be surveyed and monitored throughout its movement on the site and offsite to its ultimate disposal location.

Of course there is much other regulatory guidance on radiological and environmental controls during decommissioning activities, such as routine worker monitoring and effluent controls, but this guidance remains largely the same as it was during normal operation.

Safety and security challenges

Once a nuclear reactor has ceased operation and the fuel has been removed from the reactor vessel to a safe storage location, the radiological risks to the offsite public are greatly reduced. Nonetheless, the regulator will expect the operator to update the safety analysis report or prepare a specific decommissioning safety report to ensure that all decommissioning risks have been considered and analysed. There have been several generic studies of the risks of shutdown nuclear facilities, but the facility-specific risks must be carefully considered and analysed.

Perhaps the most immediate and pervasive safety challenge facing the operator upon shutdown will be the organisation and human factors issues discussed earlier, particularly the need to maintain the safety focus of the staff. The operator will have to develop plans for retention of essential workers, for retraining workers in new skills, hiring new workers and contractors and plans for oversight of contractors. The regulator will want to have discussions with operator management to assure these plans are satisfactory.

A key safety question concerns the plans for the spent fuel. The fuel may be transported offsite after a cooling period to a storage site or a reprocessing facility. Alternatively, the fuel may be stored in the spent fuel pool for a few years or even several decades under the temporary safe

storage option. Yet another possibility is for the fuel to be stored in special storage casks at a separate facility on the site. In any case, the regulator will have to assure that the safety systems for spent fuel storage are maintained during the decommissioning period as long as spent fuel is on site.

A major challenge for both the operator and regulator will be to decide which regulatory requirements that were in place for the operating facility can be modified for the decommissioning phase. Of course there will be new regulatory requirements and expectations for decommissioning, but just as clearly there are many requirements for an operating facility that can be modified, such as:

- Control room staffing.
- Worker training.
- Maintenance and surveillance testing of systems and components removed from service.
- Emergency planning.
- Insurance;
- Programmes such as fire protection and steam erosion protection.
- Quality assurance and oversight – the operator may decide to eliminate some operational oversight functions and replace them with a new oversight body that deals with special decommissioning issues.

The regulator can expect that each of these modifications to operational regulatory requirements will require review and discussion with operator management.

The security plans for the site will have to be revised to protect against diversion of nuclear materials to unauthorised uses and to protect against sabotage during decommissioning. If a special fuel storage facility is constructed, there will be security requirements associated with it as well.

There may be situations where the facility owner may request that parts of the site be removed from the nuclear license before decommissioning is complete. The regulator will want assurances that such portions of the site have been thoroughly surveyed, that they meet the site release criteria, and that any new activities do not adversely affect decommissioning. A special case would be where the owner or other organisation desires to use a portion of the site for a new, non-nuclear electrical generating facility (sometimes called repowering the site). In this case, the regulator will want assurances that any new construction will not interfere with decommissioning and that any stored materials such as chemicals or fossil fuel storage tanks will not present a hazard to the safe storage of nuclear fuel and materials on the site.

Waste management

A major factor affecting the successful completion of decommissioning a nuclear facility is the availability of a repository for disposing of low-level and intermediate-level radioactive waste. When no repository is available, the radioactive waste from decommissioning must be stored until a repository becomes available. The availability of disposal facilities greatly affects the degree of decontamination and dismantlement and thereby influences the operator's decommissioning strategy. If necessary, new interim waste storage capacity will have to be constructed. In some cases, *in situ* disposal may be considered, although this option must be discussed thoroughly with local officials since the local public may object strongly to the site becoming a waste disposal site. The question of waste treatment, waste storage and waste disposal is an important challenge of nuclear facility decommissioning and it requires regulatory guidance. It is important that requirements and responsibilities be defined clearly, particularly in the cases where intermediate storage is built to store waste until a final disposal site is available.

As decommissioning proceeds, large volumes of waste will be handled. Much of the waste, like structural concrete debris, will pose no health risks, and after monitoring it can be shipped offsite to normal landfills or remain on the site for filling operations there. Other waste that may have low levels of radioactive contamination will have to be monitored and sent to a low-level waste disposal site or a temporary storage site. There will be other materials having chemical or other environmental contaminants that will have to be treated and sent to special disposal sites.

Special plans and procedures will be needed for removing the large components such as the reactor pressure vessel, steam generators, pressuriser, piping, pumps and valves. The operator will usually have these components decontaminated to remove much of the surface radioactivity before removal and sent to a low-level waste disposal site. The reactor pressure vessel internal structures present a special challenge because they are intensely radioactive and may not be permitted to be disposed of in a low-level waste site. In that case, the operator will likely have the structures cut into segments that can be placed in special canisters and stored in the spent fuel pool or special storage facility on site. Ultimately the reactor vessel internal structural materials will have to be removed to a long-term disposal site. The debris that is generated during these decontamination and cutting process will also have to be packaged and sent to a low level waste disposal site or a temporary storage site.

License termination

The final regulatory decision associated with a nuclear facility at the end of decommissioning is the decision to terminate all licenses. Experience has shown that there can be high public interest in the conditions for terminating nuclear facility licenses and in the final end state of the site. In particular, there may be public concern that the delicensed site not be viewed as a nuclear waste site.

A particularly difficult challenge for the regulator is to establish a clear set of site release criteria for terminating the license. There is currently no consensus within OECD countries on a preferred set of site release criteria or even the form of such criteria. Whatever conditions or

criteria are chosen, it is important for openness and transparency, and ultimate public acceptance of the decommissioning process, for the operator to have public discussions of the site release criteria. These public discussions should include a description of any final site surveys that will lend a degree of assurance that the site meets the release criteria. The regulatory body should also plan on meeting with the public to present the regulatory perspective and listen to public concerns.

There are many variations of an acceptable end state for a decommissioned nuclear facility site. In particular the end state does not necessarily have to be a "greenfield" condition. Some buildings or facilities may remain on the site, as long as they meet the site release criteria. A portion of the site may remain under a new type of nuclear license for storage of spent fuel in special storage casks.

Some nuclear facility sites may have become so thoroughly contaminated during operation, either through spillage, ground disposal or accidents, that it is not economically practical to clean the site for unrestricted use. In these cases, the regulator will have to work with the operator in deciding what level of decommissioning and cleanup is practical and what restrictions must be placed on use of the site in the future. The regulatory body could require that the license remains in force or require that there be legally enforceable controls placed on future use of the site, for example, restrictions placed in the deed for the site property describing what the site can and cannot be used for.

The regulator should also have requirements or expectations on what records for the site should be maintained. Such records could include a description of decommissioning activities completed, a description of any waste stored on the site, the results of the final site survey, and the overall final condition of the site. The regulator will have to specify where these records are to be maintained and for how long.

Regulatory oversight during decommissioning

The broad range of safety, environmental and public policy issues that arise in decommissioning a nuclear facility are quite different from those during operation, and they produce corresponding new challenges for the regulator. In the weeks and months after a facility ceases operation, there will likely be intense regulatory activity as the operator makes decisions on how to proceed in light of his changing circumstances. Just as the operator should have prepared a strategic plan for decommissioning before shutdown, the regulator also should plan ahead for decommissioning. Many of the regulatory challenges discussed above involve substantive public policy issues and they may generate a good deal of local and even national public interest. In the interest of efficient regulation, it is best to have those public policy issues, such as site release criteria, settled before decisions must be made for individual facilities in the midst of decommissioning.

Because of the organisational and human factors issues that will inevitably arise in the wake of cessation of operation of a nuclear facility, the regulator should be prepared to conduct regular inspections to look for possible adverse trends in the overall safety culture at the site. The regulatory body will want to review its overall staffing and inspection plans for the facility to focus more on the

new organisational, human factors and dismantlement issues and may augment staff expertise in these areas.

It will be important for the regulator to have regular communications with the operator's corporate and site management prior to cessation of operation and throughout the period of active decommissioning. The regulator will want to review the operator's plans for decommissioning, the adequacy of funding for the proposed strategy, the plans for dealing with the organisational and human factors issues at the site, and other licensing issues. The regulator may request regular reports on the plans and status of decommissioning as work progresses.

Just as important for the regulator will be regular communications with the public. The shutdown and imminent decommissioning of a nuclear facility will present a new situation for the local population, and they will be concerned about safety and radioactive releases during decommissioning and about plans for the long-term condition of the site. The operator should be encouraged to have regular public discussions to explain his plans and activities and especially the long-term plans for the site. The regulatory body should also plan on meeting with the public to present the regulatory perspective on the issues, to describe the regulatory oversight activities, and listen to public concerns.

Since the public health risks posed by a shutdown facility are substantially reduced from those of an operating facility, the regulatory inspection programme should be tailored to address the new regulatory challenges. For example, many of the challenges involve regulatory policy questions rather than operator performance issues. Those regulatory bodies that utilise resident inspectors at operating facilities may want to replace the resident inspectors with periodic team inspections focused on special areas such as ALARA programme implementation, worker radiation protection, site security, operator's contractor oversight, and looking for signs of deteriorating safety culture. When special operations are planned, such as removing the pressure vessel, the regulator may want to review the procedures and have inspectors on site to observe the activities.

As decommissioning progresses, there may be periods of only routine activity on the site, and the regulatory inspections can be scaled back accordingly. If the operator chooses to place the facility in a safe storage mode for an extended period, there will be reduced need for inspections to observe that safety and security systems are not degrading. The regulator should continue to assure that the license conditions are maintained, including adequate funding for subsequent dismantlement.

The final regulatory oversight activity at a decommissioning site will be to review the plans for the final site survey and the results of the survey. When the regulatory body is satisfied that its site release criteria have been met, it can take actions to terminate all licenses.

Summary and conclusions

When a nuclear facility ceases operation and enters the decommissioning phase, both the operator and the regulator face a new set of challenges very different from those of an operating

facility. The operator should have in place a strategic plan for decommissioning, prepared well in advance of shutdown and reviewed by the regulatory body, to guide the facility managers and workers through the changed circumstances. An essential part of the strategic plan should be the operator's plan for securing adequate funds to complete the decommissioning activities. In fact, the regulator should ensure that the operator sets aside funds, perhaps in a trust fund, while the facility is still operating and generating revenues.

Both the operator and the regulator should expect a heightened public interest and concern about decommissioning. The public will naturally be concerned that a new activity like decommissioning be done safely and that the site will be returned to an acceptable end state. It will be important for both the operator and the regulatory body to have regular public discussions to explain the decommissioning plans and activities and the regulatory oversight activities, and listen to public concerns. Such public discussions will greatly enhance the transparency of the decommissioning process.

The regulatory response to the challenges of decommissioning will involve frequent communications with the operator management, revised inspection programmes and regular communication with the public and local authorities. In the interest of efficient regulation it is best to have the important public policy issues, such as material release criteria, site release criteria, and the availability of waste disposal or storage sites, settled well before decommissioning commences. In this regard, regulatory bodies should continue to share decommissioning information and experiences with their international colleagues.

Most of the decommissioning experience to date has been with research and test facilities and relatively small commercial nuclear facilities. As experience is gained with decommissioning large commercial facilities like nuclear power plants and fuel cycle facilities, regulators and operators should collect the lessons learned and propose design guidelines for future nuclear facilities that will facilitate their decommissioning.

9. The Nuclear Regulator's Role in Assessing Licensee Oversight of Vendor and Other Contracted Services

Foreword

The OECD Nuclear Energy Agency (NEA) Committee on Nuclear Regulatory Activities (CNRA) is an international committee consisting primarily of senior nuclear regulators. It was established in 1989 as a forum for the exchange of information and experience among regulatory organisations and for the review of developments which could affect nuclear regulatory requirements. The committee is responsible for the NEA programme which deals with the regulation, licensing and inspection of nuclear installations. In particular, it shares information on current regulatory practices and operating experience.

The CNRA has produced a series of reports, known as regulatory guidance booklets or "green booklets", which examine various regulatory challenges and address the major elements and contemporary issues of a nuclear safety regime. A compilation of the first thirteen booklets was issued in 2009 under the title *Improving Nuclear Regulation* [1]. Based on the consensus of CNRA members at their December 2008 meeting, a senior-level expert group was formed to produce a report on *The Nuclear Regulator's Role in Assessing Licensee Oversight of Vendor and Other Contracted Services*. In preparing its report, the group considered previously published proceedings and reports (see References) by the CNRA and the International Atomic Energy Agency (IAEA).

The current report focuses on nuclear power plants; however, the principles addressing the oversight of contractors have equal applicability to other types of nuclear installations. "Safety" is understood to incorporate the nuclear safety of systems, structures and components, the radiological protection of workers, the public and the environment, and the health and safety of those who might be affected by the facility throughout each phase of its lifetime. All references to contractors are intended to include the whole of the contracting and subcontracting chain, whether for the provision of goods or services to be supplied to the nuclear facility, or for the performance of activities partly or wholly at the nuclear facility. "Contractors" are thus understood to include designers, vendors, suppliers, manufacturers and any chains of subcontractors involved in the supply of items or services to the licensed site.

The audience for this report is primarily nuclear regulatory bodies, although the information and ideas are also expected to be of interest to licensees and nuclear industry organisations in general, as well as of special interest to countries looking to begin a nuclear energy programme but which have yet to develop well-established regulatory regimes. The challenges apply to all phases

throughout the lifetime of the nuclear facility, including design, siting, manufacturing, construction, commissioning, operation, maintenance and decommissioning.

This report is the result of contributions from all the members of the expert group. Glenn Tracy (United States) skilfully chaired the group, with technical and secretarial assistance from Diane Jackson and Jim Furness.

The senior-level expert group consisted of the following representatives:

Mr. Pierre Barras	Belgium
Mr. Ken Lafreniere	Canada
Mr. Jouko Mononen	Finland
Dr. Jean-Christophe Niel	France
Dr. Hartmut Klonk	Germany
Mr. Atsuhiko Kosaka	Japan
Mr. Shunsuke Ogiya	Japan
Dr. Albert Frischknecht	Switzerland
Mr. Jim Furness	United Kingdom
Mr. Glenn Tracy	United States
Ms. Diane Jackson	OECD Nuclear Energy Agency

Note: Dr. Frischknecht replaced Dr. Germerdonk as the Swiss delegate following the group's first meeting in 2009.

Executive summary

Contracted services are an integral part of the design, construction and operation of a nuclear facility. Changes in the nuclear industry sector, including the availability of nuclear expertise, the expansion of the international supply market and the introduction of new technologies have tended to increase the licensee's use of contracted services. These changes have created challenges for licensees and regulators related to the retention of nuclear expertise, the effective management of the interfaces between the licensees and contractors, and the oversight of contractor manufacturing quality in the context of greater multinational diversity. The regulatory body must address these challenges to provide assurance that the licensee maintains its responsibility for the safety of the facility, regardless of who provides goods and services for the facility or where the activities involved in the supply chain take place. This report is intended to assist regulatory bodies in assessing their current practices for the oversight of licensees' use of contractors, and to adapt them where necessary to meet the changing situation.

Throughout any contracting process, the licensee must retain ultimate responsibility for the quality of work performed, whether by its staff or by contractors, and for maintaining the safety of the licensed facility. Effective oversight by the licensee must ensure the quality of products and services from its contractors, and any chain of subcontractors, commensurate with their safety

significance. The licensee's oversight must ensure compliance with applicable codes, standards and regulatory requirements of the country in which the service or product will be used. Regulatory bodies should ensure that the licensee is retaining its core technical capabilities to be an "intelligent customer" in its contracting process and oversight; has a robust management system to ensure the required quality and to be the "controlling mind" for all activities; and maintains (or at the appropriate time takes ownership of) its safety case to be the "design authority" for the facility.

Contractor oversight challenges have equal applicability to operating facilities, as well as to new construction. The need to upgrade facilities for long-term operation and to replace components at existing facilities has led to an increased use of contractors who may be drawn from other countries. Additionally, for the construction of the new facilities being planned in a number of countries, there will be an increase in first-of-a-kind and turn-key projects, where the dependence on contractors will be substantially greater. As such, this report provides recommendations that apply to both mature and emergent regulatory bodies.

The regulatory body's assessment of the licensee's oversight of its contractors is based on a sample of activities that should be aimed primarily at ensuring that the licensee is meeting its overall responsibility for the safety of its nuclear installation. The regulatory body's activities for assessing the adequacy of the licensee's oversight of its contractors should not be seen as duplication of the oversight of contractors, which should be exercised by the licensee. It is clear that the potential for the regulatory body to have a presence at the contractors' premises adds to the robustness of the quality and safety assurance of safety-significant equipment and activities.

The report also includes a sample of guiding questions to consider when assessing the adequacy of the licensee's oversight of contractors. Depending on the nature of the contracted activity and the regulatory structure, the questions can be adapted as required to meet the particular circumstances faced by the regulatory body.

Introduction

Contractors have long been an integral part of the resources available to a licensee, particularly in relation to the design, construction, maintenance and modification of nuclear power plants. Indeed, contractors can be regarded as part of the licensee's team, bringing specialist skills and expertise, and additional manpower to particular tasks. To the regulatory body, whether work is performed by the licensee's employees or by contractors is immaterial in the assessment of safety. However, when a licensee chooses to use a contractor, the licensee's oversight of the contractor is of interest to the regulatory body. Regulatory oversight must extend to include the activities of those contractors whose work could affect safety at the licensed facility.

When assessing the licensee's oversight of contractors, the regulatory body must make rational judgements on the extent and the method of regulatory oversight that needs to be applied. The choice will depend on a range of factors including the safety significance of the goods or services being supplied, the previous experience of the licensee and the contractor in relation to the goods or services being procured, the presence of any novel or unusual features, the extent of

evidence available that the appropriate quality can be demonstrated, and the national legislation that governs the regulatory body. Much of the same considerations will apply to the degree to which the licensee should be involved in the contractor's activities. All of the parties will be aware of the different sanctions that are ultimately available to the licensee and the regulator, and this will affect the relationships that each has with the contractor.

Two fundamental principles which provide a foundation for the regulatory body's role in the assessment of the licensee's oversight of contractors are the following:

> *The licensee shall retain primary responsibility for the safety of its licensed facility, including responsibility for those activities of contractors and subcontractors which might affect safety.*
> *The regulatory body should, through its regulatory activities, provide assurance that the licensee meets its responsibilities for the safety of its facility. This includes assuring that the licensee provides the appropriate level of oversight of all contractors and subcontractors, commensurate with the safety significance of the activity.*

These fundamental principles are an extension of the requirements in the Convention on Nuclear Safety (CNS). Although the CNS contains no specific reference to contractors, it is clear that if the licensee holds the prime responsibility for safety, the licensee has the responsibility for the activities of any contractors that it uses and for the activities in the chain of subcontractors. This concept is reinforced by international organisations and has been documented in various reports such as the IAEA GS-R-3 [2] report on management systems, and its associated guides.

It is essential that the licensee retains the capability to be:

- The "controlling mind" of those core activities for which the licence has been granted. Ceding that control to other parties would not be consistent with the principle that the licensee retains primary responsibility for safety.
- The "design authority" [3] which understands the basis of the safety case, and the significance of ensuring that all activities are designed so as to keep the facility within the boundaries of the safety case.
- An "intelligent customer" or "smart buyer" for the goods and services being procured.

Challenges

The licensee's use of contractors presents challenges that are grouped under four categories. Important features under each of these headings are outlined in the following sections.

Challenges with the retention of nuclear expertise

The global interest in constructing nuclear facilities has led to the formation of some new licensees and contractors, not all of whom have had longstanding experience in the field of nuclear safety. The general trend, driven by economic, financial and societal influences is towards:

- The merging of companies and the formation of new partnerships and alliances between licensees and some contractors, which will bring a new mixture of employees, skills, and diversity, and potentially a new safety culture.
- The greater ability for skilled staff of licensees and contractors to move between companies, thus challenging the knowledge management of these companies.
- The increased use of contractors drawn from other countries, with whom a relationship must be established and built to work effectively at each stage of the contract.
- Licensees tending to concentrate increasingly on their core business as a means of controlling the costs of work formerly done in-house and contracting more work than in the past.

The last decade has led to some loss of skills within existing nuclear organisations. Some experienced people have retired without their knowledge being transferred to other workers. Written procedures and available documentation did not necessarily capture all the information needed to retain the lessons learned from operating history, to understand the nuances of the safety case and to train new recruits. Additionally, there was a reduction in the intake of new students interested in the nuclear field, which now makes it more difficult to recruit individuals with the necessary qualifications.

In some countries, existing nuclear plants are entering or preparing for the long-term operation. As such, it is even more important for licensees to retain sufficient knowledge of the technical details of the original safety case, as well as understanding the need for, and safety justification of, any plant upgrades or updating to modern standards that might be required. This is more difficult where there has previously been a heavy reliance on contractors for key activities.

These issues are compounded in the case of an organisation seeking to become a licensee for the first time, possibly in a country without previous experience of nuclear power generation. In some of these countries, the regulatory body may also be newly formed. The prospective new licensee faces the challenge of creating an entirely new nuclear operating organisation, hiring and training managers and staff, and making the initial choice of reactor design and contractors for the main design, key components and for construction. In this context, the prospect of using a "turn-key" approach can be an appealing and practical option, the objective being to utilise the experience of design, manufacturing and construction consortia with previous experience of constructing a similar design in other countries.

However, additional challenges may arise from this approach. Reactor designs, particularly at the start of a new design generation, are far from static. A licensee who chooses a previously

untried design must weigh the commercial risks. The regulatory body works to prevent such situations from having a detrimental effect on nuclear safety, but in these circumstances it should be expected that there will be major challenges for the regulatory body, and the strains in terms of the nuclear expertise available to both the licensee and the regulatory body can be very significant.

Challenges with the interfaces between the licensee and the contractors

A licensee's relationship to any contractor is primarily of a commercial nature, based on a purchased service or work in return for a negotiated payment, but it will also include carefully defined safety and quality requirements. All contracts between licensee and contractors are therefore expected to be governed primarily by commercial objectives. Challenges at the interface between licensee and contractors arise when the contract requirements for less tangible aspects such as quality assurance, quality management, quality of safety cases, ways in which regulatory requirements can be satisfied, the adequacy of the qualification of personnel have to be interpreted during the course of the contract.

Normally, contractors working at a licensed facility are under the direct supervision of the contractor's managerial personnel, but at the same time will have to comply with the relevant safety provisions and instructions set by the licensee. It is the licensee's responsibility to check the contractor's compliance with the relevant safety requirements at all stages of the supply chain and regardless of the location of the activity.

Licensees must take control of the drawings, design codes and documentation which describe the basis for licensing the construction, commissioning and operation of the nuclear facility in order to maintain design configuration control. Obtaining all of this detailed documentation from contractors can potentially give rise to tensions between the licensee's need to take over as the design authority, and the contractor's wish to retain what it sees as proprietary information. However, the licensee must have this information so that it can be preserved throughout the life of the facility, and in case the information is no longer available from its original source.

The regulatory body, through its programme of sampling inspection, tries to ensure that the licensee does not put into service any purchased component that does not meet the required specification. However, the regulatory body needs to make judgements on how far back up the procurement chain it is practicable to exercise its regulatory oversight. The general spirit of the IAEA GS-R-3 is to encourage regulators to examine the management systems of the licensee with the intention of reducing the precursor factors which could lead to a degradation of nuclear safety. In the case of contracting, the management systems for procurement form part of the licensee's overall management system, and weaknesses here could well have the potential to affect the nuclear safety of the facility. This report therefore recommends that regulatory bodies should consider the licensee's procurement arrangements within its list of candidate areas for regulatory oversight.

Challenges with multinational contracting and manufacturing

The variety of challenges that arise when dealing with projects involving multinational contracting and manufacturing range from differing levels of understanding among the participating organisations of the relevant regulatory requirements, to addressing the issues of cultural and linguistic diversity inherent in a global supply chain.

Licensees face the challenge of ensuring the quality of the thousands of parts and materials manufactured across the world that are used in their nuclear power plants. This challenge increases in complexity with more contractors and subcontractors within the supply chain, and differences in regulatory requirements, codes and standards in the various countries that may be involved. This expanded supply chain also increases the possibility, and challenges associated with preventing the entry of counterfeit, fraudulent or substandard parts.

Differences in regulatory requirements, nuclear codes, standards and safety goals among countries using nuclear power continue to be a challenge for regulators, licensees and the industry. The regulatory body and the licensee in the country where the components will be used might each impose requirements that differ from the specification that would be normal for the country in which the component is manufactured. It is important to ensure that the applicable regulatory requirements are known and understood by all those within the supply chain.

Contracts may be placed with contractors who are not completely familiar with the culture language and terminology of the country in which the equipment will be used. Licensees must ensure that contractors are familiar with the working practices and expectations regarding safety and security at the licensed site. Licensees also need to ensure that all of the information supplied by the design contractors is sufficiently clear and explicit to convey all the relevant requirements to the contractors chosen to manufacture, install and commission the equipment.

It is important that the safety culture and safety awareness of contractors along the whole of the supply chain is no less effective than that of the licensee in terms of assuring the future safety of the facility for which the component or service is being supplied. All contractors need to be fully aware of the safety significance of what they have been contracted to supply, and to demonstrate the same "questioning attitude" if any aspect of the work specified seems unusual or is not fully understood, or if any situation occurs during the course of the supply that could affect the quality of the finished component or service.

Translating technical drawings and construction-related documents into other languages can be a significant problem: some recent large construction sites have experienced workforce diversity resulting in more than five languages being spoken by contractors on site. The accurate translation of engineering documents requires the services of specialist translators with specific experience of the subject-matter if the licensee's quality and safety management expectations are to be communicated effectively to those carrying out the work.

In those cases where the design and safety case documents for the facility originate from a country that uses a different convention, such as for measurements, drawings or materials, the conversion from one system to another may be considerably more complicated than simply applying the appropriate conversion factors. Materials made to mathematically "converted" dimensions may not be available in the country where the manufacturing takes place, and the use of the nearest equivalent "standard" size may significantly alter the originally-designed properties of significant structures. An example of this kind of challenge would be the different sizes of steel reinforcing bars and rolled steel structural sections that are standard in different regions of the world. Licensees should ensure that designers take full account of these issues if the country of the licensee or of the key equipment manufacturers uses different systems for the measurement of dimensions, material properties, pressures, temperatures and other parameters relevant to the design, manufacturing, construction, commissioning and operating processes. Regulatory oversight should review the adequacy of the licensee's arrangements for dealing with the additional problems that can arise in such a situation.

Challenges with new technology and processes

Among the most notable changes related to nuclear power plants is the incorporation of modern technology into the design, including safety-related systems and components, and the implementation of innovative construction techniques for several recent designs. There have been several examples of design contractors from other countries proposing the use of novel design features with which the licensees and regulatory bodies have had no previous experience. New nuclear power plants, even though they share the same basic technical principles with their predecessors, make increasing use of new technologies, particularly in relation to software and digital instrumentation and control (I&C). Additionally, the increasing use of prefabrication, preassembly, and modularisation means an increase in the size and complexity of the modules being installed, from building elements or components to sub-systems or systems, ranging in some cases up to entire plant structures. This potentially increases project vulnerabilities in the event that regulatory requirements require changes to the design.

Some new approaches involve the pre-manufacture and storage of parts and components before specific customers have been identified. For example, to reduce costs and shorten delivery times, contractors may choose to manufacture a batch of components sufficient for several reactors, and store the batch, sometimes for a long time, for use in future projects. Some licensees have used components originally made for other plants (sometimes from a different country), and have faced problems in demonstrating that such components meet the specific quality requirements for their particular country, given what could have been a long time in storage.

The acceptance of innovative structural design and manufacturing techniques, such as steel concrete composites and self-consolidating concrete, poses new challenges that have not been fully analysed. Innovative techniques, whilst offering potential benefits, may raise new issues due to the limited experience and confidence in their use, the limited availability of relevant standards that provide specific requirements regarding structural strength, and the need for additional samples, tests and analysis to justify their use in safety-related applications.

The use of digital I&C technology for process and control systems is another challenge faced by regulatory authorities as well as licensees. Demonstrating how software design, architecture, qualification and testing meet the regulatory requirements for separation, redundancy, diversity and the separation of control and protection functions is a particular problem. The growing use of digital technologies also increases the need to protect both control and safety systems against malicious attacks. New technologies in the area of human system interfaces, e.g., computer controlled systems and touch screens, may need new regulatory requirements to be defined, as well as new and additional competences, e.g., human and organisational factors engineering skills on the part of the licensee.

For long-term operation, the need for plant upgrades in existing facilities may be driven by such factors as the obsolescence of the original components, the non-availability of nuclear grade replacements, or the developments in safety standards. The regulatory body may need to consider proposals by the licensee for significant modifications to the facility in these circumstances, with correspondingly significant revisions to the original safety case. Changes to the I&C systems because of obsolescence is a typical example.

Elements of regulatory assessment of the licensee's oversight

When assessing the licensee's method and extent of oversight needed for each product or service, the regulatory body must consider the safety significance of the product or service, and the evidence that will be needed to demonstrate that it meets the required quality. The licensee must provide appropriate oversight of contractors, especially those whose work is crucial to the safety of the facility, regardless if this work is performed at the licensee's facility, contractor's facility, or other locations.

The regulatory body should be able to make a judgement on the effectiveness of the licensee's programme for contract management to provide adequate assurance that the required quality levels have been achieved in the products or services from contractors.

The licensee's approach to the oversight of contractors

This section and the associated guidance questions highlight elements that a regulatory body should expect in a robust general contracting process. The regulatory body can structure its regulatory oversight based on some of the activities discussed here.

The licensee's oversight ensures that the expected product or service is delivered, and that the contractual requirements have been met, particularly with regard to safety and quality. Licensees should conduct all of their operations in accordance with suitable management systems that have a strong emphasis on safety and quality.

As part of its management system, each licensee should have a policy on the use of the contractors. The policy should include:

- the type of products and services that may be sourced from contractors, as well as when and how such sourcing may be performed;
- a definition of the core competencies and functions which must be retained within the licensee's organisation; and
- a logical justification for the subcontracting of any activity which is important to the safety of the plant.

All contracts between the licensee and any contractors, and through to any chains of subcontractors, should make it clear that the contractor's work will potentially be subject to oversight by the nuclear regulatory body of the country where the component or service will eventually be used, as well as by the licensee. Contract documents should therefore include the requirement for the regulatory body and the licensee to have rights of access for the purposes of oversight to the contractors' premises, which could be in another country and to any documents or information that might be relevant to quality or safety. Contractors and subcontractors will be expected to co-operate with the regulatory body and the licensee to facilitate this oversight in an effective and efficient manner. When the regulatory oversight takes place in another country, it is usual, as a matter of courtesy, to inform the regulatory body in that country so that it can observe the process if it wishes.

The licensee should have a process for the assessment or qualification of potential contractors, in which each contractor's capability to achieve the required levels of safety and quality is assessed prior to letting the contract. An assessment of the contractor's trustworthiness should be a part of the assessment process, and should include all staff within the contractor's organisation whose deliberate acts or omissions could affect the safety of the contracted work, or the licensed facility. The licensee's staff responsible for awarding qualifications to potential contractors must themselves possess the necessary competencies to make the assessment. Ongoing discussions with contractors enable the experience of contractors to be judged. The licensee may also use these discussions to advance its own knowledge in order to act as a better "intelligent customer" or "smart buyer". In some countries, the contractor assessment may result in the award of a formal qualification as a potential supplier for the items or services to be contracted, and only contractors holding the formal qualification might be invited to bid for the work.

The award of a formal qualification, or the decision to include a contractor on a list of potential contractors, should be based on the determination that the contractor can meet the technical, quality and safety requirements of the product or service to be supplied. The contractor's qualification should be granted for a specified time period. Feedback on the contractor's performance can be used as input to assess the contractor's continuing suitability to remain a qualified contractor. The award of a qualification may be conditional upon the contractor having addressed earlier comments or corrective actions which the licensee has identified. All concerns should either be resolved, or be part of an agreed programme for improvement, prior to (further) orders being placed with the contractor. The licensee should maintain and regularly update a database containing all relevant information regarding the list of qualified contractors, which may assist in demonstrating regulatory compliance.

Where subcontracting is allowed by the terms of the contract between the licensee and the contractor, the contract should be clear on what parts of the work may be subcontracted, and whether the prior agreement or notification of the licensee is required. Such notification would, for example, enable the licensee to judge the suitability of the proposed subcontractor and put in place arrangements for the appropriate oversight of the subcontractor's work. The contractor should provide oversight of the subcontractor and maintain appropriate records; however, the primary responsibility remains with the licensee.

Some licensees use independent inspection agencies to assist in the oversight of contractors. The use of an independent third party inspection agency can add further robustness to the oversight process. Such inspection agencies can also provide the specialised knowledge needed to verify that the appropriate quality levels have been achieved. However, independent inspection agencies are themselves contractors acting on behalf of the licensee. As such, the scope of any independent inspection oversight needs to be defined by the licensee just as carefully as the work that is being contracted, and the work of the inspection organisation should also be overseen by the licensee.

Some countries have had previous experience of "turn-key" projects for the design and construction of new reactors, and this looks likely to be an increasing trend, particularly as a way for countries with limited previous nuclear experience to start or to expand their nuclear programmes. There have been a number of different approaches to the licensing of these turn-key projects in their early phases, and experiences have been mixed. At some stage, the licensee who is to be the eventual operator of the nuclear plant needs to take over as the "design authority" for the facility. Regardless of the choice of timing for the handover of the design authority responsibility from the original reactor design organisation to the licensee, there are a number of advantages in the eventual licensee being closely involved in the construction and commissioning of their facilities, even if the initial design phase may have already been completed. The licensee can use this involvement as a means of gaining the experience needed to take over as the design authority. Regulatory bodies also need to think very carefully about the questions of who is the "controlling mind" through each of these early phases – whether this is the reactor designer or vendor, the organisation responsible for construction and/or commissioning, the eventual licensee who will operate the facility, or possibly combinations of these organisations which may change over time.

The following are considered key elements in the licensee's oversight of contractors:

Within the contract document, the licensee should:

- Make clear the importance to safety of the quality of the goods or services to be supplied.
- State the need for a proper quality plan and management system within any contractor or subcontractor to ensure that the quality requirements, on which the plant's safety case is based, can be achieved. The quality plan should summarise the planned manufacturing stages, the quality and inspection checks planned to be carried out by the contractor at each stage of the process and who will sign off each of these checks, and the records which are to be retained and provided to the licensee.

- Include the information from the safety case that is relevant to the performance of the component or service during its lifetime.
- Identify relevant regulatory requirements that apply in the country where the equipment will be used, and specify clearly whether any drawings and/or specifications will need to be modified to fully reflect the national regulatory requirements where the equipment will be used.
- Identify all relevant security-related information requirements.
- Specify the requirements for the security clearance of contractor's staff who may have access to sensitive equipment or locations, whether on or off the licensed facility.
- Explain the system that will be used to monitor the contract as it progresses, identifying any predefined hold-points and the possibility of random checks.
- Include terms of agreements and the definition of applicable personnel requirements, including any special qualifications or training for the contractor's staff, special measures (such as site induction training, personal protective equipment, and fitness for duty) that may be applicable, delivery schedule, documentation requirements, etc.
- Establish formal lines of communication between the licensee and the contractor, including any consortium of architect/engineers, nuclear designers, and balance of plant designers – along with a clear definition of roles and responsibilities.
- Identify access rights for the licensee and regulatory body to the contractor's and any subcontractor's premises, and to any documentation relevant to the quality or safety of the items or services being supplied.
- Identify the system that will be used to update or change the contract after it has been awarded.
- Ensure the orderly hand-over of all design and safety case information to the licensee.

The licensee's management of the contractor oversight process should include:

- A confirmatory check that any decision to contract a service is in accordance with the licensee's overall policy on the use of contractors.
- A verification that work is only placed with contractors who are fully qualified to perform the work. This means that the contractor should possess both the necessary technical capability and the appropriate quality assurance qualification for the work being contracted.
- The periodic re-assessment of the contractor's qualification for the work.
- An expectation that contractors will continue to assure the trustworthiness of their staff throughout the course of the work.

- A system to maintain records of all oversight activities, including records of any subsequent repairs, re-work or re-testing.
- A process for identifying any non-conformances from contractors and their resolution.
- A means to collect feedback on the contractor's performance in areas such as technical competency, safety culture, reporting of non-conformities, and resolution of issues.
- A process to assess the contractor's oversight of subcontractors.
- A means to inform the regulatory body of relevant information on its use of contractors and how this has, or might, affect the safety of the plant.
- A process to assess and ensure that contractors understand the relevant safety requirements and have a safety-conscious working environment.
- The assessment of the contractor's management system, especially those processes and control/surveillance steps that may have an influence on the quality and the future safety implications of the provided products/services. The contractor's quality system may have been recognised as meeting known national or international quality standards, in addition to other standards which are applicable to the activities being subcontracted.
- The contractor's safety culture as demonstrated through training, corrective action programmes, and its prior experience of supply to the nuclear sector or other safety critical applications.
- The contractor's policies related to occupational health safety, radiation protection and environment.
- Other commercial and socio-economical aspects. Given the potential adverse effect on safety, consideration should be given to the contractor's financial stability and human resource management policies.

Regulatory assessment of the licensee's oversight

The basic regulatory approach for assessing the use of contractors by the licensee is designed to provide assurance that:

- Contracts are fulfilled in a manner that will not adversely affect the safety of the facilities.
- The quality of work and services supplied is commensurate with the safety significance of the activities.
- The licensee has made and implemented procedures that will detect non-conformances in contracted activities and prevent them from affecting the safety of the facility.

The manner in which regulatory oversight is implemented will depend upon the legislative framework, status of the national nuclear programme and the culture in each country. Whether requirements for the regulatory oversight of licensee's contractors have been defined within the

national legislation or not, it is clear that the regulatory body should include within its regulatory system appropriate mechanisms that can provide assurance that the appropriate oversight of contractors is implemented by the licensee.

The regulatory approach should be based on the requirement that competence, quality standards and safety levels are never compromised. The regulatory body should verify that the competency for judging the quality of all safety-related work resides within the licensee's organisation, regardless of whether the work is carried out by the licensee's own staff or by contractors.

If the licensee uses an independent inspection agency to assist its oversight of contractors, the regulatory body should consider the suitability of the chosen agency, the scope of the oversight that the licensee has contracted the inspection agency to undertake on its behalf, and how the licensee is overseeing the work of the agency.

The regulatory body should verify that the licensee maintains processes in its management system for the use of contractors that provide oversight for the technical work and quality assurance systems of its contractors which is appropriate to the safety significance of the contracted work. The regulatory body should use its regulatory tools, such as inspections, audits and assessment to verify the licensee's oversight of contractors. These tools may need to be modified when the regulatory oversight involves locations other than licensed facilities, or takes place in other countries. The regulatory body can use the quality plan to identify points to witness an activity or perform an audit.

The regulatory body should assure that the licensee carries out the proper and comprehensive assessment of the work of its contractors, using documented procedures fit for this purpose. The regulatory assessment should include the licensee's oversight of the training, competence and experience of the contractor's staff, as well as the suitability of the contractor's facilities for the various stages involved in the manufacture, inspection and testing of the manufactured items. It is desirable for the regulatory body to produce guidance, providing the reasoning behind the regulatory requirements for the licensees' use of contractors.

The regulatory body needs to focus on the measures that will provide reasonable assurance that the specification for any goods or services, which forms a part of the basis of the plant's safety case, has been met. The regulatory body also needs to verify that the licensee ensures that contractors have sufficient training, particularly in the areas where the contracted service can affect the safety case, so that the contractor is fully aware of the importance and link to safety of the quality of the item being made. Regulatory bodies must also assure that licensees maintain full traceability of components, robust evidence of their quality and compliance with country-specific requirements.

The following are considered key elements in the regulatory body's role in assessing the licensee's oversight of vendors and other contracted services.

Regulatory management

- The regulatory body should have sufficient expertise on management systems (with special emphasis on quality and safety), as well as on contract and procurement management.
- The regulatory body should develop a strategy for the assessment of the licensee's use of contractors, which could take the form of rules, standards, requirements or other guidance, depending on the legislative regime. The regulatory body should make the strategy known to the licensees, and apply the strategy in a consistent manner.

Process for regulatory inspection/assessment

- The regulatory body should verify that the licensee establishes and implements a contracting process which provides reasonable assurance that all procured items and services meet the required levels of quality and safety.
- The regulatory body should consider whether the licensee's documented procurement processes include an effective evaluation and selection process for potential contractors, and whether the licensee effectively implements this process.
- The regulatory body should confirm that the licensee verifies the performance of the contractor's processes to assure quality and safety.
- The regulatory body should inspect/assess the licensee's arrangements for ensuring that it has sufficient human and technical resources to oversee the contractor's work.
- The regulatory body needs to be aware of circumstances when the licensee is likely to make increasing use of contractors. The regulatory body should also be aware if the licensee experiences increased difficulties in knowledge management as the result of an increased reliance of contractors.
- The regulatory body may review the licensee's analysis of the trend of the contractor's non-conformance reports in order to evaluate the impact on safety.
- The regulatory body should develop techniques to evaluate how safety and quality are achieved by the processes of both the licensee's and the contractor's management systems.
- The regulatory body should verify that the licensee authorises only suitably qualified and experienced staff to supervise the work of contractors.
- The regulatory body should check that the licensee, and where appropriate, the contractor's staff know how to contact the regulatory body in order to raise any safety concerns.
- The regulatory body should encourage the licensee to improve the awareness of contractors of their responsibility for safe working and effective management of their staff at all times, promoting a positive safety culture.

Information/knowledge and experience for the regulatory role

- The regulatory body should have access to all information and all places of work, including those of contractors, where it is relevant to the current and future safety of the licensed facility.
- The regulatory body should have access to procurement contracts and documents which may help the regulatory body to identify which activities to oversee. National policy in some countries may make it appropriate for price and cost information to be redacted prior to the copies of the documents being passed to the regulator. However, even in these countries, there may be particular circumstances in which it is necessary for the regulatory body to see the original non-redacted versions.
- The regulatory body should keep itself informed on the licensee's use of contractors and contractors' activities, and use this information in developing its regulatory strategy and in focusing inspections, audits or assessments.
- The regulatory body should encourage the licensee to share information and experience regarding contractors with others in the licensees' communities.
- The regulatory body should encourage the licensee and its contractors to share information, knowledge, and lessons learnt from safety-significant events which might, in part, be due to inadequacies in its oversight of contractors.
- The regulatory body should ensure that the licensee and contractors have an effective corrective action process so that they can understand and correct deficiencies in order to prevent re-occurrence of quality- or safety-significant events.
- The regulatory body should protect all proprietary information, as well as considering sensitive information in inspections and assessments, by establishing processes and procedures for the exchange of this information with any technical support organisations (TSOs) that it may use. When selecting TSOs, the regulatory body should ensure that any potential conflicts of interest are declared and understood.

Communication

- Depending on the regulatory regime in each country, the regulatory body should discuss its regulatory strategy with stakeholders, and explain the regulatory system and the safety goals using meetings, workshops or conferences to which licensees and contractors are invited.
- Routine senior level meetings should be held between the regulatory body and the licensees, at which the discussion should include any organisational changes proposed by the licensee, including an increased use of contractors.
- Regulatory bodies should share among themselves information, knowledge and lessons learnt from deficiencies in contractor performance which might, in part, be due to inadequacies in the licensee's oversight of contractors.

IMPROVING NUCLEAR REGULATION, ISBN 978-92-64-99162-0, © OECD 2011

Procurement oversight

- The regulatory body should be alert to the introduction by the licensee of cost management measures that could affect the safety of nuclear facilities. In relation to procurement, the regulatory body should make sure that the licensee recognises that the "best" tender does not necessarily mean the lowest price.
- The regulatory body should be aware that the mechanisms for placing contracts between suppliers and buyers have changed dramatically since the arrival of the Internet. The use of some procurement mechanisms, e.g., electronic reversed auctions (ERAs), may not be appropriate for the procurement of safety-significant equipment and services.
- The regulatory body should try to be alert to any practice that could distort the objectivity, fairness and transparency of the procurement process, as these may have an adverse effect on the nuclear safety of the facility. Because the nuclear regulatory body is likely to have a greater presence than any other government authority, if it has suspicions of any lack of integrity in the procurement process, it should draw these suspicions to the attention of the relevant government authority.

Conclusions

The regulatory approach for assessing the licensee's performance in its use of contractors is to provide reasonable assurance that contracts are fulfilled in a manner that will not adversely affect the safety of the facilities, and that the quality of work and services supplied is commensurate with the safety significance of the activities. The manner in which regulatory oversight is implemented will depend upon the legislative framework, the status of the national nuclear power programme and the culture in each country.

This report has described in detail some key elements for a regulatory body to consider when developing or verifying the effectiveness of its regulatory programme to meet the challenges of an environment in which licensees are making increasing use of contractors. Additionally, it has identified the important elements of a robust licensee oversight programme in order to help the regulatory body when planning its assessment of the effectiveness of the licensee's oversight programmes. The key elements include procurement and contract development, contract implementation throughout the supply chain, contractor quality management, access to documentation and facilities, communications and safety culture.

As contracted services change and licensees modify their oversight and procurement practices, regulatory bodies must also continually adapt to maintain their effectiveness in the assessment of the licensees' contracting practices in an increasingly international supply market. Such improvements in the oversight process will facilitate the ongoing multinational work to evaluate and eventually increase harmonisation in designs, regulations, standards and quality requirements that is now being supported by many of the regulatory bodies and by industry. Continued and increased international co-ordination and co-operation among regulatory bodies through the collection and dissemination of inspection findings, operating and construction

experience, lessons learnt, and information related to substandard contractor products and services, including the timely identification and communication of information on counterfeit, fraudulent and substandard parts, is paramount. These efforts enhance regulatory effectiveness and efficiency in all countries without diminishing regulatory independence.

Gaining insights from the rules and practices of regulatory authorities of other countries greatly strengthens the effectiveness of regulatory activities. Enhanced co-operative agreements among regulatory bodies around the world should be aimed at developing common approaches towards addressing safety-significant issues and harmonising safety approaches, codes and standards, and inspection practices. Greater harmonisation would enhance confidence in meeting regulatory requirements in all countries. Such efforts would also assist in the development of more consistent nuclear regulatory policies in emerging nuclear countries.

References

[1] *Improving Nuclear Regulation*, *Compilation of NEA Regulatory Guidance Booklets*, OECD/NEA CNRA Report, 2009, ISBN 978-92-64-99075-3. Available at: www.nea.fr/html/nsd/reports/2009/nea6275_Improving_ Nuclear_ Regulation.pdf.

[2] *The Management System for Facilities and Activities*, and its associated guides, IAEA GS-R-3, GS-G-3.1 and GS-G-3.5. These are available at: www-pub.iaea.org/MTCD/publications/PDF/Pub1252_web.pdf, www-pub; iaea.org/MTCD/publications/PDF/Pub1253_web.pdf; and www-pub.iaea /MTCD/publications/PDF/Pub1392_web.pdf respectively.

[3] *Maintaining the Design Integrity of Nuclear Installations throughout their Operating Life*, IAEA INSAG-19. Available at: www-pub.iaea.org/MTCD/publications/PDF/Pub1178_web.pdf.

Additional reading material related to the subject of this report:

NEA/CNRA/R(2007)1 WGIP: Proceedings of the 8th International Nuclear Regulatory Inspection Workshop on how international nuclear regulatory inspections can promote, or not promote, good safety culture, inspection of interactions between the licensee and its contractors and future challenges for inspectors (e.g. new techniques, developing competence, etc.), held on 1–3 May 2006 in Toronto, Canada.
Proceedings: www.nea.fr/nsd/docs/2007/cnra-r-2007-1.pdf.
Appendix: www.nea.fr/nsd/docs/2007/cnra-r-2007-2.pdf.

NEA/CNRA/R(2003)4 WGIP: "Nuclear Regulatory Inspection of Contracted Work Survey Results", www.nea.fr/nsd/docs/2003/cnra-r-2003-4.pdf.

IAEA Peer Discussion Report, "Regulatory Control of the Use of Contractors by Operating Organisations", PDRP-5, 2000, www-pub.iaea.org/MTCD/publications/PDF/pdrp_005_prn.pdf.

IAEA TECDOC-1232: "Assuring the Competence of Nuclear Power Plant Contractor Personnel", July 2001, www-pub.iaea.org/MTCD/publications/ PDF/te_1232_prn.pdf.

Appendix: Guidance Questions

These guidance questions are intended to be used as tools that the regulatory body can use when assessing the licensee's oversight of vendor and other contracted services. Depending on the nature of the contracted activity and regulatory structure, further questions can be added, as necessary by the particular circumstances. They should be taken as examples that can be adapted to fit into each country's legal framework and regulatory approach.

Section	Guidance questions
1.	**General process for contracting**
1.1	Does the licensee have a clear policy governing what activities or services may be contracted and what should remain in-house?
1.2	Does the licensee have formal processes and procedures for contracting?
1.3	Do the licensee's policies include the requirement to retain the core competencies needed to remain the "controlling mind" for the licensed facility?
1.4	Does the licensee's staff have the necessary qualifications to ensure it is an "intelligent customer" or "smart buyer" for the contracted goods or services? This includes the ability to: - draft an invitation to tender, including the accompanying technical specification for the work? - carry out the process of evaluating potential contractors, including their safety culture, know-how and previous experience? - judge between several tenders for work? - ensure effective oversight of the contract during its execution phase?
1.5	Does the licensee have a management system that ensures contracted goods or services conform to specified purchase requirements?
1.6	Does the licensee's management system include provisions that the type and level of oversight applied to the contractor and the procurement of goods and services recognises their related safety significance?
2.	**Procurement**
2.1	Does the licensee ensure that all relevant information for the safety case is included in the procurement documentation?
2.2	Does the licensee ensure that all relevant legislative and regulatory requirements are either included or referenced in the procurement documentation?
2.3	Does the licensee include within the procurement documentation the requirement for those contractor's staff who could, by their deliberate acts or omissions, degrade the safety of the licensed facility to hold a suitable security clearance?
2.4	Does the licensee have standard conditions of contract that provide rights of access for the staff of the licensee, and of the regulatory body which has jurisdiction in the licensee's country to the contractor's premises and to any subcontractors, and to documentation relevant to the contract? Do these rights include the ability to have unannounced access?
2.5	Does the licensee establish contractual requirements that the contractor notifies it of any product or service non-conformances and establish a system for the communication of these non-conformances?
2.6	Does the licensee define in the contract a means for resolving disputes between the licensee and the contractor, when these relate to the quality of work that affects safety?
2.7	Does the licensee have in mind that the "best" tender does not necessarily mean the lowest price? Does the licensee ensure that the contractor applies a similar approach to any subcontracts?
2.8	Does the licensee verify that potential contractors have the relevant quality assurance or quality management qualifications?

Section	Guidance questions
2.9	Does the licensee assess organisational matters, such as the financial stability of potential contractors, their industrial relations policies, and the pattern of staff turnover, as these pertain to safety?
2.10	Does the licensee maintain an up-to-date list of qualified and certified contractors?
2.11	Does the licensee's system ensure that the contractor delivers all relevant documentation to the required level of quality and in a timely manner?
3.	**Contract implementation and oversight**
3.1	Does the licensee include a requirement in the contract, when necessary, for the contractor to supply a quality plan? Does the quality plan include the checks that are necessary to demonstrate that the required quality will be delivered in the finished product or service?
3.2	Do contracts include a requirement for the relevant training and qualification of contractor's staff that will be involved in the contracted activity?
3.3	Does the licensee stipulate whether contractors may or may not use subcontractors?
3.4	Does the licensee's staff have the appropriate expertise to monitor the quality of the work during the contract?
3.5	Does the licensee adequately document its oversight activities, including the oversight by independent inspection agencies?
3.6	Does the licensee assess the contractor's performance, including any subcontractors, in accordance with the safety significance of the contracted service and use feedback from this assessment to refine its oversight of the contractor's work?
3.7	Does the licensee have defined hold points at which it formally inspects the delivered service?
3.8	Does the licensee have a system to effectively document and address non-conformances from the contractor in accordance with their safety significance?
3.9	Does the licensee's system ensure that any such non-conformance reports are raised to the appropriate level in the licensee's organisation, depending on their safety significance?
3.10	Is there a clear path and sufficient organisational freedom for licensee staff, contractors and subcontractors to raise and document safety and quality concerns and issues without fear of retaliation?
3.11	Does the licensee communicate the importance of a good safety culture to the contractor?
3.12	Does the licensee's management system include a means to address issues which can be caused by multinational contracting and workforce cultural and linguistic diversity?
3.13	Does the licensee communicate the final acceptance of the work to the regulatory body?

REGULATORY EFFECTIVENESS

10. Improving Nuclear Regulatory Effectiveness

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.

The report was prepared by S. A. Harbison, on the basis of discussions and input provided by the members of the task group listed below:
Christer Viktorsson (Chairman, Sweden), James Harvie (Canada), Sabyasachi Chakraborty (Switzerland), Marja-Leena Järvinen (Finland), Michael Cullingford (United States), Charles McDermott (Canada), Gerhard Feige (Germany), Lasse Reiman (Finland), James Furness (United Kingdom), Jacqueline Silber (United States), Jean Gauvain (France), Roy Zimmerman (United States), Antonio Gea Malpica (Spain) and Barry Kaufer (NEA).

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 (Section on defining regulatory effectiveness). In the section on modelling regulatory effectiveness, 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 the section on quality systems as a basis to improving regulatory effectiveness, 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 the section on regulatory performance indicators, 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 the section on added value of the regulator, 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 the last section.

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 QA 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.

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".

IMPROVING NUCLEAR REGULATION, ISBN 978-92-64-99162-0, © OECD 2011

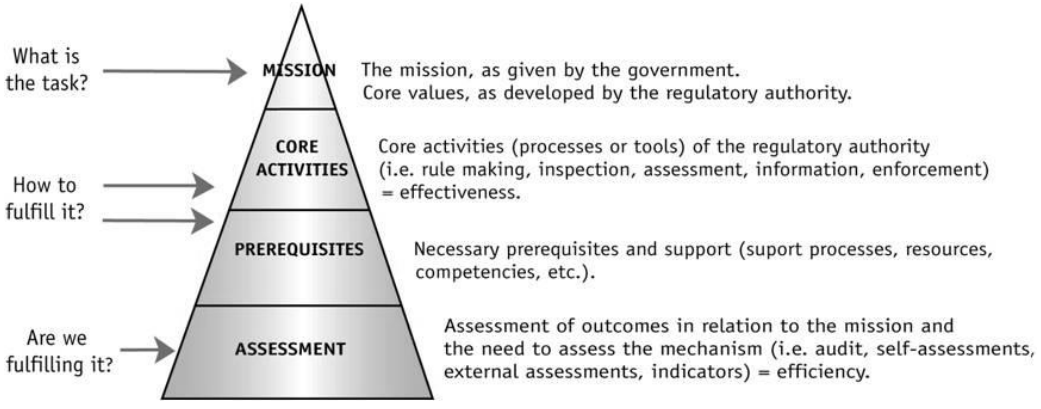
This implies that one has to analyse effectiveness first, based on well-defined mission objectives of the regulatory body. Having done that, one can then work to improve efficiency. Setting goals that are possible to follow-up is very important.

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.

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.

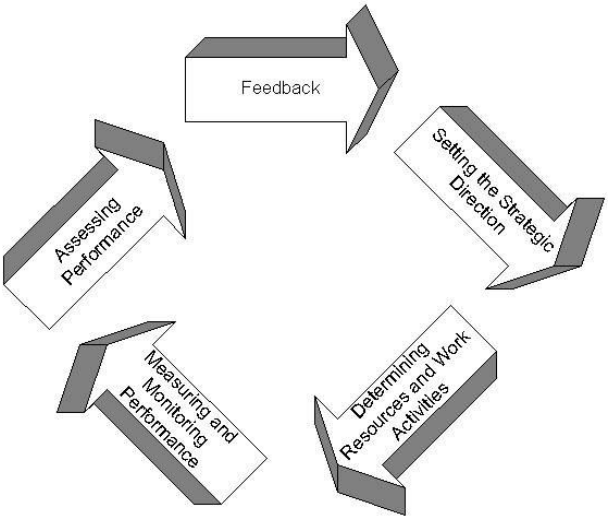
Figure 1. **Building a quality system for regulatory authority**



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 towards continuous improvement**



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 programme 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 does not 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.

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 section on added value of the regulator).

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 the section on the definition of the regulatory effectiveness, 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 section on the definition of the regulatory effectiveness), 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.

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.
- 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 the section on the regulatory performance indicators, the sub-section on "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 did not 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.

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 *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 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 chapter 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.
- 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. • 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.	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.
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.

Table 1. **Summary of case studies** *(Cont.)*

	Sweden	Finland	United States
Pre-requisites	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.

11. Direct Indicators of Nuclear Regulatory Efficiency and Effectiveness

Foreword

In 1998, the OECD/NEA Committee on Nuclear Regulatory Activities (CNRA) initiated an activity to advance the discussion on how to enhance and measure regulatory effectiveness in relation to nuclear installations. A task group reviewed the issue and drafted a report entitled *Improving Nuclear Regulatory Effectiveness*, published in 2001. The CNRA accepted the recommendations of the report and, in particular, decided that the task group should continue its activities with the aim of developing a set of direct performance indicators of regulatory efficiency and effectiveness.

To pursue this objective, the task group assembled a demonstration set of direct indicators and conducted a one-year pilot project. The present report describes the results of the pilot project, and makes some general observations about the usefulness of individual indicators as well as recommendations for future activities.

The report has been prepared on the basis of discussions and input from the Task Group on Regulatory Effectiveness (TGRE), with technical and secretarial assistance from Barry Kaufer, G.J. Kurt Asmis, S.A Harbison and Elisabeth Mauny. Members of the task group were: Sabyasachi Chalaborty, (Chairman, Switzerland), Jongile Majola (Canada), Kaisa Koskinen (Finland), Bruno Bensasson (France), Gerhard Feige (Germany), Jan Seredynski (Germany), Lajos Vöröss (Hungary), Nobuo Tanaka (Japan), Christer Viktorsson (Sweden), Lyn Summers (United Kingdom), Bill Borchardt (United States) and Gunter Giersch (IAEA).

Executive summary

A pilot project, conducted by a CNRA task group of regulators from nine NEA member countries, has proven the usefulness of direct performance indicators in helping to assess and communicate regulatory efficiency and effectiveness. Direct indicators are those which measure a regulator's own performance, as distinct from indirect indicators which infer a regulator's effectiveness from its licensee's safety performance. It has also identified potential limits and cautions related to the use of performance indicators. The pilot project was prompted by Recommendation 6 of the previous NEA report on *Improving Nuclear Regulatory Effectiveness*. The task group developed a set of trial indicators based on the definition of regulatory effectiveness given in this report.

The direct indicators were developed to be able to:

- Verify that regulatory work is performed in accordance with the regulator's mission, strategy and plans.
- Verify that work is done according to internal quality procedures and policy.
- Measure performance of work.
- Determine the perception of various stakeholders and staff towards regulatory processes.
- Promote the use of detailed work plans for regulatory activities.

The fundamental value of performance indicators for a nuclear regulatory body is to focus on its safety mission. Maximum benefit can be derived from the use of performance indicators if they are part of an established quality management model. Performance indicators may also be used to communicate with stakeholders, to monitor internal processes and budgeting, and when necessary to assist strategic development and to manage change. Their use should be part of a continuous improvement process involving all stakeholders, including regulatory staff.

After initial discussions to identify the sorts of direct performance indicators that could be usefully tested, the group developed a common template for performing the pilot. The pilot was carried out over a period of one year. At its conclusion, an international forum "Measuring, Assessing and Communicating Regulatory Effectiveness, (MACRE 2003)" was held, which validated the work of the task group and provided helpful insights. This report describes the results of the pilot project, gives some observations about the usefulness of individual indicators and makes recommendations for future activities. The complete results are contained in a separate project document. The two first sections discuss the background and framework for the set indicators developed and tested by the task group. The 3rd one lists the indicators and provides an assessment of their use and the lessons learned. The 4th section provides observations and general conclusions. The report concludes with recommendations in the fifth section. The last one provides the major references used by the task group.

It is recommended that regulatory bodies utilise direct performance indicators to the extent possible and remain active in the area to continue development of an integrated framework for regulatory efficiency and effectiveness.

The organisations from the nine countries that took part in the pilot project were:

- Canadian Nuclear Safety Commission (CNSC), Canada.
- STUK, Radiation and Nuclear Safety Authority, Finland.
- Direction générale de la sûreté nucléaire et de la radioprotection (DGSNR), France.
- Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU), Germany.
- Nuclear and Industrial Safety Agency (NISA), Japan.
- Swedish Nuclear Power Inspectorate (SKI), Sweden.

- Swiss Federal Nuclear Safety Inspectorate (HSK), Switzerland.
- Health and Safety Executive Nuclear Installations Inspectorate, (HSE/NII), United Kingdom.
- Nuclear Regulatory Commission (NRC), United States.

Introduction

In 1998, the OECD/NEA Committee on Nuclear Regulatory Activities (CNRA) initiated an activity with the objective of advancing the discussion on how to enhance and measure regulatory effectiveness in relation to nuclear installations. One of the outcomes of this activity was to establish a task group to advance the understanding of regulatory effectiveness. The discussions and deliberations of the task group resulted in the publication of the report *Improving Nuclear Regulatory Effectiveness*. The CNRA accepted the recommendations of the report and, in particular relating to recommendation 6, decided that the task group should continue its activities with the aim of developing a set of direct performance indicators of regulatory efficiency and effectiveness.

In the NEA report on *Improving Nuclear Regulatory Effectiveness*, the role of indicators in a regulatory process is defined. In order to identify meaningful and measurable performance indicators it is necessary for a regulatory body to engage all of its stakeholders. Once a regulatory body has established a suite of performance indicators, it can use them to evaluate and improve its level of regulatory efficiency and effectiveness.

As defined in the previous NEA report, 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 improvements in its performance.

A task group of regulators from nine (9) NEA member countries was established to continue the development and evaluation of potential direct performance indicators of regulatory efficiency and effectiveness, based on this definition. A set of direct performance indicators was evaluated during the one-year pilot project. At the conclusion of the pilot a workshop, MACRE 2003, was held which validated the usefulness of this approach and provided helpful insights that enhanced the value of this work.

Using nuclear regulatory performance indicators

The desired outcome of regulatory activities is the safe operation of nuclear facilities in a manner that protects public health and safety, and the environment. The operator has prime responsibility for safe operation; however, the actions of the regulator contribute to this objective.

The regulator's direct contribution to nuclear safety is difficult to demonstrate, but it should at least be possible to develop indicators that provide insights into the regulator's performance in meeting its overall mission and objectives. It is important to recognise that a set of performance indicators is only one element in a matrix of evidence to assist management/stakeholders in evaluating the performance of a regulatory body. Other elements include qualitative assessments of regulatory activities and stakeholder feedback, which give an indication of the quality of regulatory performance. Performance indicators can be used by regulators to measure progress towards achieving regulatory outcomes and strategic objectives, addressing stakeholders' issues, and to provide timely indication of problems.

Performance indicators can be categorised in several ways. In the previous NEA report on *Improving Nuclear Regulatory Effectiveness*, they were considered 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 performance indicators of other stakeholders, principally the licensees, to deduce the performance of the regulatory body.

The focus of this pilot project was on direct indicators, recognising that other groups are dealing with indirect indicators. The objectives of this project were to:

- Obtain practical experience in gathering information and data related to regulatory efficiency and effectiveness.
- Assess the relevance and usefulness of the selected performance indicators.
- Assess the value of performance indicators in:
  - Promoting internal quality.
  - Providing information on regulatory efficiency and effectiveness.
  - Providing input to a continuous improvement process.
  - Helping to communicate with stakeholders.
- Disseminate lessons learned from the pilot.

The pilot project also identified a number of limitations and cautions related to the use of performance indicators.

Framework

For a regulatory body to make effective use of performance indicators, it should have a formal business or management model in place. This provides a framework for sustainable use and integration of performance information to improve regulatory efficiency and effectiveness. Other benefits include improved communication with stakeholders including regulatory staff, integration of budget and resource allocations, accountability, and linkage of performance results to desired outcomes. Even without a formal business model, however, it is beneficial to establish a set of performance indicators to help the regulatory body assess and improve its performance.

This pilot project adopted the definition of regulatory effectiveness in the previous NEA report and developed and grouped a set of direct indicators to demonstrate the extent to which the regulatory body:

- 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.

Desirable attributes of indicators

Previous NEA documents have identified the following attributes of good performance indicators:

- Suitable for the purpose intended and measurable.
- Useful for communicating within the regulatory body and with its stakeholders.
- Capable of identifying undesirable trends to trigger actions by the regulator.
- Helping to focus and prioritise the regulator's activities.
- Providing a stimulus to the regulatory body to improve its performance.

The task group had these attributes in mind when it developed the list of performance indicators presented in this report (see section on the results of the pilot project). Although the direct performance indicators chosen for this pilot satisfied the above attributes, it is also recognised that they provide a valuable though clearly incomplete assessment of regulatory performance. Within this framework, each regulatory body is naturally free to choose, modify, amend and supplement these indicators to suit its particular regulatory environment.

Limits and cautions when using performance indicators

Notwithstanding the significant potential benefits of using performance indicators, stakeholders should be aware of certain limits and cautions:

- Performance indicators (particularly direct indicators) cannot give the complete picture of the performance of a regulatory body.
- There may be a tendency to focus on areas where it is easy to develop indicators and to forget the importance of qualitative aspects.
- Resources may be diverted in an attempt to meet performance indicator targets at the expense of the overall mission of the regulatory body.
- As verified during the pilot project, it is easier to develop performance indicators on efficiency rather than on effectiveness.
- There is a temptation to compare regulators without an in-depth understanding of the subtle differences between indicators used by different national regulatory bodies and the differences in culture, laws and the style of regulation.
- Comparing performance against the targets does not give the complete picture; there needs to be an analysis of trends as well.
- Caution must be exercised to avoid sacrificing quality to meet numerical targets.

In spite of these limits and cautions, and the cost of establishing and maintaining a performance management system, the task group feels quite strongly that performance indicators, correctly used, will have such great benefits that it is worthwhile making significant efforts to work within these limitations.

Results of the pilot project

This section provides the definition given for each indicator, a specific example on how it was used and a general assessment of the results obtained in the pilot project.

Each of the nine countries participating in the pilot reviewed each of the indicators and the defined measurable attributes and selected a candidate number of indicators to track. A country's candidate indicator selection was completely voluntary, nominally based on their national experience, the availability of information in the required category and most importantly their interest in being able to address specific concerns. The participants were given the flexibility to adjust the indicators for their use.

To establish uniformity in reporting, a standard template (see Table 2) was developed. This template allowed the pilot country to identify and describe the specific indicator, establish specific targets and/or ranges, provide a discussion of how it was applied including benefits and limitations and explain the results obtained with supplemental information on related issues. The complete

results of the pilot project are contained in a separate project document. Members of the pilot project will use this material for further analysis in the future.

A particular finding of note was that for each attribute addressed by the indicators the maturity of a regulator's processes has to be considered. This was more evident in indicator sub-section on "Strives for continuous improvements in its performance", but the members of the study recognised that it applies throughout the pilot structure. And it explains, to some extent, a general finding that many of our indicators are of output rather than outcome.

Through the maturity process the indicators might become less subjective and more objective; less lagging and more leading; less output and more outcome.

For example, for the introduction of a regulatory management system the steps are: to develop a QM framework; then a strategy to implement it. The measure is simply whether there is a framework – yes or no? The next stage is to identify elements of the QM system and commence their implementation – the measure might be has each stage been delivered as planned? Once there is a process in operation there will be *outputs* that can be measured – e.g. non-conformance resolution. Beyond that, as the process becomes self-improving, *outcomes* may be measured. At each stage the measures are different and the early stage indicators need to be abandoned once processes have been delivered. For each regulator, each attribute of the pilot structure will be in a different stage of the process – some may not even have started. The recognition that a particular aspect is missing should in itself be an important driver for improvement.

The remainder of this chapter is devoted to providing an assessment of the indicators used in the pilot project.

Table 1. **Pilot project indicators**

#	Indicator Title	Page
1	**Ensures that an acceptable level of safety is being maintained by the regulated operating organisations.**	103
1.1	Regulations and Guides are published, up-to-date, clear and comprehensive.	103
1.2	Planned inspections are carried out.	104
1.3	Safety assessments are carried out.	104
1.4	Licensee events are recorded and analysed.	105
1.5	Emergency exercises are planned and carried out.	105
1.6	Emerging issues are responded to.	106
1.7	Integrated safety assessments of licensees' facilities are carried out.	106
1.8	Safety deficiencies are recorded and corrected.	106
2	**Develops and maintains an adequate level of competence**	107
2.1	Appropriate resources, financial and human, for the regulatory control of nuclear safety are identified and updated according to plan.	107
2.2	The training and professional development of regulatory staff is carried out.	107
2.3	Maintain requisite skills.	107
2.4	The workload of regulatory staff members is appropriate for a learning organisation.	108

Table 2. **Reporting template**

Performance Indicator	Title as it relates to Chapter 3 and any changes that may be required.
Description	Description to amplify the title as modified. May touch on frequency that the indicator area is sampled.
Target or Range	Target or range the indicator is supposed to be in (if not available then a note about how that target will be established).
Discussion	Discussion on whether or not this will be a leading/lagging indicator, what might be the challenges in collecting the data, what might be the challenges in transforming the data to meaningful information for decision makers. Focus comments on: • What was learned. • Limitations. • Improvements generated. • Initiatives or "investments" that are being tracked through performance indicators. • Anticipated benefits.
Results (optional)	The results already achieved (this applies to existing indicators and if no past history, perhaps a past history of like minded indicators in other industries or jurisdictions, or failing that similarity, a discussion on results that are hoped to be achieved).
Supplemental Information	Supplemental Information which might include related studies, how this indicator fits into say the hierarchy of indicators – some more detailed, others more global or indirect, etc.

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

1.1 Regulations and guides are published, up-to-date, clear and comprehensive.

- The proportion completed relative to the plan.

Specific example

Maintenance of regulations – Regulatory guides are updated according to annual plan.

Assessment

- All users were able to use the established indicator, but predetermined targets (e.g. predefined period for reviewing and updating) and results depended on differences in how the participating countries defined regulations and guides. (e.g. legally binding documents, non-binding guides, etc.).

- The qualitative aspects (relevance, comprehensiveness, proportionality, clearness, applicability, etc.) may not have been explicitly included in this indicator.
- This indicator can be extended to include other regulatory documents.

1.2 Planned inspections are carried out.

- The proportion of planned inspections made in a given year.
- The proportion of inspections leading to significant enforcement actions.

Specific example

The proportion completed relative to plan.

Assessment

- This indicator was found to be useful. Some of the benefits noted were: improved management and promotes holistic view; prompted the regulator to consider improvements to inspection planning and reporting system; showed obligation to perform certain inspections met; was useful for tracking a fundamental regulatory activity and that routine inspections are carried out according to plan; use of indicator led to programme improvements; and the use to focus inspection on high risk licensees and to lower effort on low risk licensed operations.
- The main limitation of this indicator is that by itself it does not reflect quality and added value of inspections carried out.
- Several new sub-indicators were identified such as the percent of reactors for which "baseline" inspections are completed per year.

1.3 Safety assessments are carried out.

- The proportion completed and on time relative to the plan.
- The proportion utilising risk informed technology.

Specific example

The proportion of safety assessments completed and on time relative to the plan.

Assessment

- This indicator was generally found to be useful in tracking the assessment work both internally within the regulator and with their Technical Support Organisations (TSOs). The second sub-indicator was found useful by those users that had already established a risk-informed approach for optimising resource allocation for their operations and for communicating safety issues with licensing management and stakeholders.
- Difficulties encountered were:
  - Challenges in compiling information due to lack of resources/staff shortages; challenges in establishing processing times for safety assessments.

  - Factoring in the delays that occur when licensees submit safety submissions are received that require questions to be asked and a dialogue to be undertaken.

- Some of the benefits quoted were: used in reactor oversight programme; used to track performance on different categories of safety assessments carried out by the regulator; used to track completion of safety assessments by Technical Support Organisations (TSOs).
- The indicator by itself it does not reflect quality and added value of safety assessments carried out.
- Implementation of an electronic documentation system was offered as one solution to getting the information more easily.

1.4 Licensee events are recorded and analysed.

- Time to completion of analysis based on plan.
- Time for regulatory response to emerging issues.

Specific example

Time to issue communications to industry regarding follow-up to licensee events.

Assessment

- This indicator was found useful because it highlights the intensity of resources used and the adequacy of resources assigned to this type of activity. Additionally the first sub-indicator was found useful to disseminate results of analysis within the regulatory authority and nuclear safety community.
- In order to better utilise the indicator, in addition to the time factor, completeness, screening, determination of safety significance, generic implications, immediate corrective action and release of generic communication should be addressed.
- Several new sub-indicators were identified. For example, the number of and proportion of licensee events categorised as significant, very significant or extremely significant and the number of incidents per risk level or type of response.

1.5 Emergency exercises are planned and carried out.

- The proportion completed relative to the plan.

Specific example

The proportion of emergency exercises relative to the plan in a given year.

Assessment

- In using this indicator, it was agreed that the definition should be interpreted such that it refers to the regulator's activities (e.g. the regulator's involvement in emergency exercises relative to the plan). The indicator was found useful; however there may be a need to define sub-indicators in order to reflect country specific situations.
- Use of this indicator provides strong evidence to authorities concerning the need to put more emphasis on emergency exercises.
- This indicator has a limitation of not being informative on the quality or adequacy of plans. Poor performance in terms of this, or any other indicator, should trigger an analysis of root causes, an identification of the trade-offs made, and whether these were justified in terms of risk.
- Consideration should be given to developing indicators or tools to evaluate the effectiveness of emergency exercises.

1.6 Emerging issues are responded to…

- Staff is provided with and aware of guidance and instructions.
- Number and proportion of emerging issues responded to.
- Stability of instructions as measured against changes to instructions following new issues.

Specific example

None.

Assessment

- This indicator was not evaluated in the pilot. However we recommend that it be retained for future evaluations. Some reasons that it may not have been used are: difficulty to identify an issue as an emerging issue and difficulty to determine at what time it emerged.

1.7 Integrated safety assessments of licensees' facilities are carried out.

- Comparative assessment of licensees' performance indicators – results achieved vs. planned performance.
- Proportion of planned activities reviewed relative to plan.

Specific example

Comparative assessment of licensees' performance in safety areas – results achieved.

Assessment

- This indicator is useful for monitoring regulatory performance.

- This indicator can be tied to the corporate strategic objective of ensuring that the regulatory regime is effective and efficient.
- This indicator focused on a process that can include an analysis of licensees performance indicators thereby allowing the integration of indirect indicators.

1.8 Safety deficiencies are recorded and corrected.

- Proportion and number of safety deficiencies still outstanding at end of year.

Specific example

Safety deficiencies or non-compliances are recorded and corrected within the stipulated time.

Assessment

- The indicator was found useful for tracking the resolution of issues, deficiencies or items of non-compliance raised in inspection and safety assessment reports and to reflect the ability of staff action to encourage licensees to address deficiencies or items of non-compliance.
- Difficulties or problems of data collection and tracking were encountered.
- To be useful and relevant this indicator should include "importance attributes". Care needs to be taken with this indicator to avoid taking away the licensees' responsibilities.

2. Develops and maintains an adequate level of competence.

2.1 Appropriate resources, financial and human, for the regulatory control of nuclear safety are identified and updated according to plan.

- Proportion of staff with particular core competencies (such as structural mechanics), compared with planned number.
- Competence analysis updated according to plan.
- Corporate memory is maintained according to plan.

Specific example

Proportion of staff with particular core competencies (such as structural mechanics), compared with planned number.

Assessment

- Participants used the first sub-indicator and found this one useful.
- This indicator is able to track strategic measures to ensure sustainability and availability of competencies of staff.

- The indicator could be used for human resource planning and to gauge how well the strategies for attracting and retaining excellent staff are working.
- Extension to the full intent of the indicator may be useful in the future.

2.2 The training and professional development of regulatory staff is carried out.

- Proportion of staff completing training/development activities, compared with planned number.

Specific example

Proportion of resources expended on training/development versus the budgeted number.

Assessment

- The exercise showed that this is an appropriate indicator.
- The Performance Indicator gives one point of view on training effort but it should be completed with figures concerning staff turnover and information on level of competencies at hiring time.
- An integrated information system to track training should make this indicator easier to use.
- Other sub-indicators were provided for example: training and professional development and time tracking.

2.3 Maintain requisite skills.

- Staff turnover measured by rate or other appropriate techniques.
- Corporate memory is maintained according to plan.

Specific example

Total and average years of experience of the technical staff.

Assessment

- The indicator was found to be useful but targets were difficult to fix.
- This can be used to track trends and analyse the impact on regulatory objectives.
- The Performance Indicator does not take into account competencies at hiring time.
- Personal development programs could be included as well as indicators to keep a proper balance in terms of experience, knowledge, and diversity of viewpoints.

2.4 The workload of regulatory staff members is appropriate for a learning organisation.

- Number of staff whose workload fell outside defined boundaries.

Specific example

Overtime greater than 15 hours per month (in per cent of nominal working hours).

Assessment

- Not enough exposure in this pilot to give a meaningful judgement on benefits or on limitations.
- This performance indicator needs to be developed further to include proper work mix, which takes into account: age, experience, background, new-emerging technologies, new ways of licensing, etc.

3. Takes appropriate actions to prevent degradation of safety and to promote safety improvements.

3.1 Regulatory responses to periodic safety reviews are carried out.

- Proportion of safety assessments/periodic safety reviews performed to time, according to plan.

Specific example

Average age of the last safety review.

Assessment

- This indicator was useful for tracking the completion of specific safety reviews, rather proactive or reactive. It enables timely resource allocation in order to accomplish the highest priority activities.
- This indicator doesn't address qualitative aspects of safety reviews regarding scope and depth of reviews.

3.2 Experience is gained from abnormal situations, plant failures and their repairs and then this experience is incorporated into the regulatory programme.

- Number of recommendation issued by experience feedback group.
- Proportion of recommendations issued actually implemented.

Specific example

Precursor reports are issued in timely fashion.

Assessment

- Targets are difficult to set for this indicator because of the emerging issue aspect. Value is derived from monitoring and analysing the trend of abnormal situations and following up on the resulting recommendations for improvement.
- There is a danger that putting too much importance on an absolute numerical target could influence the licensee and regulatory body (e.g. licensee not looking for or not declaring abnormal situations and regulatory body issuing recommendations regardless of their benefit or applicability) behaviours. The indicator does not track qualitative aspects of recommendations (significance of abnormal situations and added value of recommendations).

3.3 An active programme of safety-related research is developed and implemented in accordance with an agreed/published plan.

- Proportion of projects completed to plan.

Specific examples

Proportion of research projects progressing according to plan.

Proportion of projects completed to plan.

Assessment

- This indicator has benefits in monitoring the progress and completion of research activities against an established plan. In the case of joint research programs, the monitoring of the indicator can avoid undue duplication of efforts and help optimising resource allocation.
- However, the indicator does not evaluate the adequacy of the plan or the results of the research.

3.4 The safety management of regulated organisations is monitored.

- Proportion of regulated organisations evaluated for core competency staffing levels, to established standards.
- Proportion of regulated organisations planned changes (e.g. technologies, management systems, and organisational structures) evaluated, to established standards.

Specific example

Proportion of regulated organisations planned changes evaluated, to established standards.

Assessment

- This indicator simply monitors the review activities of the regulator, on a topic that is important but difficult to assess.
- This area does not have well-established standards for evaluation such as what to evaluate, how to evaluate it and who evaluates it.

4. 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 and all other stakeholders.

4.1 The regulatory outcome targets (e.g. mission and goals) are being adequately met.

- Proportion of outcome targets met.
- Proportion of licensing requirements that have been met by the operating organisations.
- Number of safety deficiencies identified by regulator that were not identified by operator.

Specific example

Proportion of planned compliance promotion activities carried out at the end of the year.

Assessment

- This indicator was found to be useful. It can be used to track and provide clear evidence on the extent to which the goals and mission of the regulatory body have been met.
- Generally, this indicator and the others in group 4 are designed to build stakeholder confidence and trust.
- The indicators in group 4 give insights on activities, outputs, and global outcomes.

4.2 Regulatory decision making is in accordance with criteria.

- Proportion of regulatory decisions meeting the criteria (e.g. number of safety cases cleared within 3 months of submission).

Specific example

Timely decision making – decisions should be distributed in two months. Indicator is number (and proportions) of decisions distribution: less than 1 month / 1-3 months / more than 3 months.

Assessment

- The indicator was found to be useful. It allows the regulatory body to structure its work and allocate its resources.

- A limitation is that this indicator by itself does not reflect quality and added value of regulatory decisions.

4.3 Timeliness, clarity and openness of regulatory processes and procedures criteria and goals are met.

- The compliance policy in terms of graded enforcement has been fairly administered.

Specific example

Ratio of number of jobs for which the time schedule is met to total number (without counting those occasions where schedule changes are beyond the regulator's control).

Assessment

- This indicator was found to be useful, but more specific sub-indicators were felt to be needed.
- There may be added value to the regulator in establishing more consistent outputs, evaluations that have some uniformity in terms of risk, penalties awarded, and sanctions towards the licensees.

4.4 The regulatory document control systems meet the established quality standards.

- Proportion of documents completed to quality and timeliness standards.
- Number of incidents of unavailability of information required to support regulatory activities.

Specific example

Ratio of number of times inspection reports are completed on schedule to total number.

Assessment

- There is not enough information at this point to assess the usefulness of this indicator. However, we recommend that this indicator be retained and put to trial use as it can be used for root cause analysis.

4.5 The initial regulatory response to any abnormal or accident situation on a licensed facility meets the agreed published plan.

- Proportion of situations responded to within specified criteria.
- Proportion of investigations responded to within specified criteria.
- Tools, guidance and training provided to responding staff meet expectations.

Specific example

None

Assessment

- There is no information at this point to assess the usefulness of this indicator. However, we recommend that this indicator be retained and put to trial use as it can be used for root cause analysis and incident reporting.

4.6 Enforcement actions taken by the regulator are in accordance with policy.

- Proportion of enforcement activities that meet criteria in plan.

Specific examples

Proportion of enforcement activities that meet criteria in plan.

The percent of enforcement activities that meet timeliness criteria.

Assessment

- This indicator was found to be useful, particularly for monitoring the effectiveness of a graded enforcement approach.
- The effectiveness of an enforcement policy can be checked using this performance indicator.
- The pilot project showed that a number of sub-indicators can be defined in this area.

4.7 Regulatory obligations with regard to informing/communicating with other stakeholders (e.g. Government, general public, etc.) are in accordance with policy.

- Number of surveys of stakeholder views.
- Stakeholder views fall within target bands.
- Number of questions responded to within criteria.

Specific examples

Regulatory obligations with regard to informing/communicating with other stakeholders (e.g. Government, general public, etc.) are in accordance with policy.

Number of surveys of stakeholder views.

Assessment

- The indicator was found to be useful.

- To get a complete picture of stakeholder views, the regulatory body has to consult a spectrum of stakeholders.
- To use this indicator, a regulatory body needs a clear policy on communication with its stakeholders.
- This indicator may require extensive resources to implement.
- Regulatory bodies should consider sub-indicators that measure accessibility of the regulator, particularly using technologies such as the Internet.

4.8 The regulator's international obligations are carried out in accordance with the agreed plan.

- Proportion of staff participating in meetings, working groups, peer review activities relative to plan.
- Standards changed and improved, regulations up-graded due to international involvement.

Specific examples

Volume of international activities.

Volume of exchange of personnel.

Assessment

- This indicator was found to be useful, but more work needs to be done to develop additional sub-indicators. For instance, sub-indicators that show that the regulator's participation in international activities has been effective would be useful. Also, sub-indicators that show how the aspects of a learning organisation can be addressed by participating in international activities would be useful.
- There is a danger in focusing on the volume of activity without looking at the quality of the international activity.
- There is value to extend this indicator to garner viewpoints from international and other sources of data and information.

4.9 The management of contracts is carried out in accordance with the agreed/published policy.

- Proportion of planned contracts issued on time.
- Proportion of results that met pre-established success criteria.

Specific example

Ratio of non-chargeable to total resources.

Assessment

- There is not enough information at this point to assess the usefulness of this indicator. However, we recommend that this indicator be retained and put to trial use as it can be used for checking if the contractor has provided quality work and value for the money.
- This indicator could provide management with a means of verifying that the right contractor has been awarded the right work.

4.10 Leadership is responsive and supports vision, mission and values of the organisation.

- Proportion of acceptance of staff proposals.

Specific example

Ratio of suggestions related to process improvement to total number submitted.

Assessment

- There is not enough information at this point to assess the usefulness of this indicator. However, we recommend that this indicator be retained and put to trial use as it can be useful for making improvements based on feedback from staff.
- A programme is needed for responding to staff proposals to effectively use this indicator.
- There is a need for more sub-indicators in this area (e.g., internal surveys to assess the quality of leadership).

5. Strives for continuous improvement in its performance

5.1 Feedback from all stakeholders and licensees in the regulatory process is obtained, analysed and utilised as appropriate on a regular basis.

- Proportion of meetings with licensees and stakeholders, compared with plan.
- Proportion of licensee and stakeholder views that indicate satisfaction with regulator.
- Number of analyses carried out and improvements instigated due to licensee and stakeholder feedback process .

Specific example

Number of analyses carried out and improvements instigated due to licensee and stakeholder feedback process.

Assessment

- This is a useful indicator to evaluate stakeholders feedback and could be used within the framework of a quality management system. It is also useful to align or to adjust your strategic goals and thereby can provide improvements.

- Use of this indicator requires not only solicitation of stakeholders by the regulator but also an active participation of the external stakeholders
- The appropriateness and adequacy of input for further analysis has to be carefully judged taking into account the various view-points of various stakeholders.

5.2 The efficacy of any action programme in response to licensee and stakeholder feedback is determined by reference to the criteria.

- Proportion of changes to strategic and corporate internal programmes that can be attributed to licensee and stakeholder feedback.

Specific example

None

Assessment

- This performance indicator was not evaluated during the pilot project as it is necessary to have a mature stakeholder engagement process in place before it can be used.
- Distinguishing which category of stakeholders provides specific input could enrich the indicator.

5.3 The results of regulatory processes are regularly reviewed and evaluated, against agreed/published criteria, and used to modify the strategic direction for the following year.

- Proportion of regulatory processes reviewed relative to plan.
- Timeliness of such reviews in relation to plans.
- Proportion of changes attributed to process reviews.
- Strategic plan for the year produced.
- Annual report produced.
- Values of the organisation discussed .

Specific example

Strategic plans for the year produced.

Assessment

- These performance indicators were easy to use and happened to be useful to review and monitor the functionality of regulatory processes and can thereby help initiate necessary improvements.
- These performance indicators do not track qualitative aspects of these products (effectiveness of the processes, pertinence of the plans or interest of the report).

5.4 Regulatory activities are assessed against the overall mission to ascertain the extent to which outcome targets have been met.

- Proportion of assessments of regulatory activities carried out compared with plan.
- Performance indicators reviewed.
- Results of external peer reviews.

Specific example

Proportion of internal audits carried out compared to plan.

Assessment

- Use of this Performance Indicator fosters an effective self-assessment programme and continuous improvement philosophy. It incorporates all contributing elements to the regulatory body's missions.
- It is not possible to use all sub-indicators if a regulator does not have a quality management system.

5.5 The regulatory Plan and its associated performance indicators are evaluated regularly in order to verify that outputs correspond to expected outcomes and that resources are being used efficiently and effectively.

- Number of evaluations of Performance Indicators carried out relative to plan.
- Number of Performance Indicators reworked and redesigned (measures stability of suite of Performance Indicators).
- Number of new Performance Indicators required to properly assign resources and to confirm achievement of mission and goals.

Specific example

This performance indicator was not evaluated during the pilot project.

Assessment

- Since this indicator evaluates the entire performance indicator system, there must be several years of experience before a thorough assessment can be performed.

5.6 Has a formal business and or quality management system.

- Uses a recognised methodology (such as ISO 9000 or EFQM).
- Includes a policy for its business management.
- Applies to the whole of the regulator's activities and at all levels.

- Regular reviews are planned, carried out and improvements and findings are implemented.
- External and internal audits and benchmarking is planned and carried out to plan (remark: ISO-definitions).

Specific example

Scores of internal/external assessments of the business excellence model of the European Foundation for Quality Management (EFQM).

Assessment

- This indicator requires redefinition and further elaboration to change the current wording of this Yes/No indicator with indicators that measure progress towards a formal business and or quality management system.

Observations and conclusions

Throughout the pilot project, participants provided feedback regarding their experiences in implementing the direct performance indicators, using a template designed for that purpose. The significant feedback is summarised below. The task group recognises that, during the course of one year, it is impossible to capture all of the positive and negative aspects of the use of performance indicators.

Use of direct performance indicators:

- Provided a better holistic picture of the work situation and allowed line management to get a better picture of the work situation of every individual.
- Allowed an increased focus on long term matters and provided a basis for adjusting priorities within the work plan and planning system.
- Allowed the identification of poor performance and triggered corrective actions.
- Allowed a more informed allocation of resources with appropriate adjustments in accordance with the mission.
- Demonstrated the difficulty of defining indicators that are not influenced by other indicators.
- Allowed more effective communication with internal and external stakeholders.
- Fostered an improved understanding of expectations by internal and external stakeholders.
- Promoted a better focus on regulatory outcomes.
- Should be part of a long term commitment to self-improvement.

- Can lead to staff frustration if the performance indicators are regarded as too many, unhelpful, or unfocused on the main mission of the regulatory body.
- Must be preceded by clear definitions, and followed by appropriate analysis, to avoid misinterpretation.
- Should be viewed in the context of a balanced quality management system.
- Needs to be supplemented with qualitative aspects, indirect indicators and other information in order to get a complete assessment of regulatory performance.
- Requires caution in order to avoid sacrificing quality to meet numerical targets.
- Tends to focus on efficiency rather than effectiveness performance indicators.

Recommendations

Based upon the experience gained during the course of this pilot project, the following recommendations are made:

- It is recommended that member countries utilise direct performance indicators, including those presented in this report, to the extent possible to assess and improve their regulatory efficiency and effectiveness. Maximum benefit can be derived from the use of performance indicators if they are part of an established quality management system.
- It is recommended that the CNRA remains active in this area and convene an annual status review to exchange lessons learned. A task group should be convened in 2006 to produce a progress report by 2007, taking into consideration other international activities in this area.
- The CNRA should examine methods of integrating all the various efforts and initiatives in the general area of regulatory efficiency and effectiveness.
- It is recommended that the NEA communicate the results of this pilot project to other interested stakeholders (e.g. member and non-member countries).
- It is recommended that the CNRA develop an integrated framework for regulatory efficiency and effectiveness, paying particular attention to qualitative aspects of regulatory performance and the value added by the regulatory body to nuclear safety.

Reference material

Numerous documents were used in the preparation of this report and several are directly referenced in this report. They are considered as both reference material and additional reading for those who plan to begin work on direct indicators. These documents include:

Direct references

- NEA (2001), Improving Nuclear Regulatory Effectiveness, CNRA Report 2001 (Note: This is sometimes referred to as the previous NEA report), OECD, Paris.
- Proceedings from the NEA International Forum on Measuring, Assessing and Communicating Regulatory Effectiveness (MACRE 2003), NEA/CNRA/R(2004)x, not yet published.
- CNRA Pilot Project on Direct Indicators for Nuclear Regulatory Efficiency and Effectiveness – Complete Results (for official use only), NEA/CNRA/R(2004)x, not yet published.
- TGRE Notebook – Compilation of information compiled by the TGRE Task Group, (for official use only), internal CNRA document.

Other useful references

- NEA (2002), Improving versus Maintaining Nuclear Safety, CNRA Report, OECD, Paris.
- Assessment of Regulatory Effectiveness, IAEA PDRP-4, 1999.

12. Improving Versus Maintaining Nuclear Safety

Foreword

The concept of improving nuclear safety versus maintaining it has been discussed at a number of meetings of the NEA Committee on Nuclear Regulatory Activities (CNRA) in recent years. In the summer of 2000, CNRA members were asked to submit their views on the concept in writing. These comments were reviewed and compiled in a paper that was discussed at the December 2000 CNRA meeting. The CNRA then requested two of its expert task groups on regulatory effectiveness and safety backfits to prepare an NEA publication.

The national submissions indicated that there are philosophical differences between member countries about whether their regulatory approaches require licensees to continuously improve nuclear safety or to continuously maintain it. It has been concluded that, while the actual level of safety achieved in all member countries is probably much the same, this is difficult to prove in a quantitative way. In practice, all regulatory approaches require improvements to be made to correct deficiencies and when otherwise warranted. However, the various descriptions of whether safety has to be maintained or improved may cause confusion for the regulator's stakeholders, particularly the licensees and the general public. The CNRA or national regulatory agencies may thus wish to consider what further steps may be taken to reduce such confusion.

This publication was prepared based on contributions from the CNRA members from Finland, France, Germany, Spain, Sweden, the United Kingdom and the United States as well as the work of the expert task groups on regulatory effectiveness and safety backfits. The initial paper written by Sam Harbison was used as a basis for drafting the publication, which was completed by G.J. Kurt Asmis.

Introduction

The fundamental objective of all nuclear safety regulatory bodies is to ensure that nuclear utilities operate their plants at all times in an acceptably safe way. The problem, of course, is that the timespan covered by a nuclear power plant, from its initial design stages to its eventual decommissioning and dismantling, can be as much as fifty years or more. Over such a long period of time there will certainly be major changes in the engineering and scientific knowledge that underpins the design, construction, operation and maintenance of the plant, as well as a better understanding of the threats that are posed by and to the plant from a variety of internal and external sources. Though improvements in testing and modelling help to reduce the margins of uncertainty in the behaviour of structural components and in the reliability of safety-significant parts of the plant, they also tend to reveal new threats and challenges to its safe operation. In other

words the state of the art in science and engineering is constantly changing and presenting new challenges to both the utility and the regulatory body.

An even greater challenge to the regulator is to determine what is the "acceptable" level of safety for a nuclear power plant. What is acceptable is a matter for society to decide by weighing the risks and benefits of any particular activity and judging where the balance lies. Clearly this balance is different for different countries and varies with time in any individual country. The challenge to any regulatory body is to interpret society's answer to the question "how safe is safe enough?" and to reflect it in the regulatory standards and enforcement strategy that it adopts.

These issues are fundamental to the debate about whether regulators should be requiring licensees to continuously **improve safety** or to continuously **maintain safety**, which is reflected, in the detailed submissions (see Appendix).

Licensing basis

The licensing basis of a nuclear power plant (NPP) is normally established before it goes into operation and consists of: a detailed description of the plant and site facilities; the design safety analysis; applicable codes and standards; operational procedures, rules and limits; emergency procedures, etc. When granting a licence the regulatory authority has to take account of society's views about what level of risk is "acceptable" as well as the current state of the art in science and technology. Once the licensing basis has been established, the regulatory authority requires the plant to remain in conformity with it throughout its operational life, i.e. the level of safety as defined in the licensing basis must be **maintained**.

However, although the licensing basis stays the same, the scientific and engineering understanding of the various components of it may well change. For example, many older plants were licensed on the basis of a "maximum credible accident" approach, with the design having to show that the plant could withstand such an event. The application of modern probabilistic safety assessment (PSA) procedures to such plants has shown that:

- The "maximum credible accident" is only one of many possible accidents that the plant safety systems might potentially have to cope with.
- Even for the "maximum credible accident" additional aspects are often identified that were not considered properly at the time the original design basis was agreed.

The question of how far older plants need to be upgraded to conform to the general insights from modern PSAs will be considered further. However, most regulators have experience of the second point above, which is often revealed when licensees have to upgrade their safety analysis following some unexpected event or when carrying out a major review, such as a Periodic Safety Review (PSR). As an example, the vulnerabilities of certain safety-significant structures and components of the UK's gas-cooled reactors to the effects of hot gas releases were revealed when PSA techniques were applied to them as part of their first long-term safety reviews. The original, deterministic safety analysis paid most attention to the events within the core and gave little

consideration to the potential damage that jets of hot gas, escaping from the pressure vessel or primary coolant pipes, might do to the boilers, control and instrumentation cables and so on. When these effects were fully appreciated the licensees had to make plant modifications and improvements to cope with them. However, such modifications and improvements were strictly to **maintain** the licensing basis and not to improve safety in line with any new expectations of society. Other examples, which fall into this category, are proper segregation of electrical cabling (after the Brown's Ferry fire); the change of insulation material following the Barsebäck incident in 1992; and the incorporation of steam generator level indicators after TMI.

Current state of the art in science and engineering

Some improvements in the state of the art in science and engineering have a direct impact on the understanding of the safety of the plant. The introduction and development of probabilistic safety assessment (PSA) has had a major impact on both the maintenance of the design basis (as discussed above) and on the whole question of what is acceptable in risk terms. Other improvements, however, are more problematical for the regulatory body in terms of whether or not they should be required on older NPPs. For example, many of the developments in instrumentation and control (I&C) that have occurred over the past few years give the potential for more accurate, reliable and "user friendly" monitoring of plant conditions. However, they can be costly to install, in both time and financial terms, and have their own reliability/compatibility problems if mixed with existing analogue systems. The regulator needs to consider carefully the value of requiring the installation of such "state-of-the-art" devices if the existing ones are clearly allowing the plant to operate reliably within its licensing basis.

Similar issues arise from the application of modern inspection techniques to structural components on older plants. The modern equipment often detects cracks and faults in components and welds that were undetectable by the equipment available when the plant was constructed. If the plant has operated safely and reliably for many years, and there is good evidence that the defect is not "growing", should the regulator require the defect to be repaired, especially if the repair might degrade other safety features of the plant? Such questions present a real challenge to the regulator when he has to decide how to react to such new information and he must be clear whether he is requiring the licensee to **maintain** safety or to **improve** safety. The costs involved can be very great and, in the present financial climate, utilities are likely to mount strong challenges to requirements which they perceive go beyond the original design basis.

As low as reasonably achievable

The various acronyms, such as ALARA, ALARP and SAHARA (safety as high as reasonably achievable), all express essentially the same concept – that the operators and regulators of NPPs should constantly ask themselves the question "how safe is safe enough?" The answer to this question is not fixed but varies with time and, to a certain extent, from country to country. It expresses concepts found in several of the national submissions, such as:

- "The risk from using nuclear power has to be low compared to other risks in society" (Sweden).

- "Improving safety is understood to mean reducing the relative risk share of using nuclear energy in relation to the overall risk in the society" (Finland).
- "Documented safety reviews [have to show that] all reasonably practicable improvements have been implemented" (UK).
- "An activity is deemed to be safe if the perceived risks are judged to be acceptable" (USA).
- "An acceptable level of risk can only result from a constant confrontation between what is desirable and what is possible" (France).

These last two perceptions give an excellent insight into the process that has to be gone through to answer the question "how safe is safe enough?" Fundamentally, it is for society to answer, on the basis of all the information (technical and otherwise) available to it. The regulatory authority then has to attempt to frame technical safety requirements that accurately reflect society's answer. In some countries, such as the USA, decisions about ALARA are made on a broad, industry-wide basis through the very wide-ranging and open consultation process that is used to obtain the views of all stakeholders (including the utilities) about where the balance lies between risk reduction and cost. The process results in an across-the-board decision about what is acceptably safe and this is normally reflected in a formal regulatory document. The advantage of this approach is that it provides clarity and consistency for both the utilities and the regulatory body though it can appear somewhat rigid (as in the re-licensing requirements).

In other countries, ALARA questions are decided largely between the regulator and the utility on a more ad-hoc, continuous basis. The advantage of this approach is that it is very flexible and can react more or less instantly to new technical information or perceptions of risk. The disadvantage is that there is less certainty for both the regulator and the utilities about where they stand in the ALARA continuum at any particular time. Some countries, such as the UK, have made efforts to restrict this area of uncertainty by attempting to generate public and scientific debates about the limits of acceptable risk, through documents such as the Tolerability of Risk and the associated NII Safety Assessment Principles. It seems that, after a slow start, this approach is gradually gaining a foothold in the public/media debate about risks.

Finally, there is the question of so-called "reverse ALARA". As the state of the art in science and technology improves, especially with the development of more realistic models, longer operating experience and the refinement of PSA, the levels of conservatism built into much of the design and operation of NPPs is becoming clearer. How should regulatory bodies react to such evidence? In the French submission it is stated that:

"The SAHARA principle (safety as high as reasonably achievable) is not paradoxical with the fact that it is possible to relax some regulatory constraints as a better knowledge of the risk is obtained and thus to apparently agree on an increase of the level of risk; but, as the margins are decreased in the same time as their uncertainty is reduced, the actual level of risk accepted by the regulatory body would be maintained."

The key to implementing this precept is how the regulatory body "confirms its acceptability" – is it just a matter for the regulatory body to decide or should it take note of (or consult) its other stakeholders, particularly the public, who may not be prepared to tolerate any increase in the apparent level of risk from NPPs?

In reality, of course, it is extremely difficult for any regulatory body to make an accurate assessment of the level of risk that is deemed to be acceptable by the society it represents. The most reliable indication is usually obtained from the Public Inquiries, parliamentary questions and media coverage that follow any untoward nuclear events – but these are too infrequent and the information comes too late to guide the normal precautionary regulatory approach that is required for nuclear power. It is recommended that further consideration should be given to the general issue of public acceptability as part of the CNRA's further consideration of regulatory effectiveness and regulatory performance indicators.

The human side of improve versus maintain

In a series of penetrating studies carried out by the High Reliability Group,[1] researchers concluded that within the organisations they examined –nuclear power, naval aviation, air traffic control – the one constant was that all were organised for continuous improvement. The warning given was that organising to maintain (rather than to improve) safety would be a difficult prospect. Organising to maintain runs the risk of a dominance of routine and a lapse of mindfulness. The staff at Diablo Canyon, that was the object of one of their studies, were observed to guard against what could be called "business as usual", that is, maintaining what has already been achieved. By a constant and relentless drive for safety improvements, the organisation kept itself mobilised in a fairly high state of energy and attention.

Independent of any industry or societal demands to build in new levels of safety, the actual level of safety of any given plant is a constantly shifting condition and never is a single state for any plant. This is so for two broad sets of reasons, the first is technical and the second is organisational:

Technical

- Physically the plant is not a constant over time. It is constantly ageing, which alters some components and performance characteristics. New and updated component parts enter the plant – e.g. valve and other manufacturers alter their products slightly over time as they seek manufacturing cost reductions or upgrades in performance.
- New knowledge changes the representation of the plant in analytic models and current "understanding". As we know more about failure probabilities, good practice or characteristics of ageing, the plant is not the same as in its prior analytical representations.

1. The High Reliability Group included social psychologist such as Todd LaPorte, Gene Rochlin, Karen Roberts of Berkeley, Paul Schulman of Mills College, Oakland and others. Paul Schulman spent a sabbatical working at Diablo Canyon where he formulated the conclusions reported here.

Organisational

- Organisationally there is no constant level of safety at a plant. Key organisational variables like worker attentiveness and inter-departmental trust can decay over time. Routines, worker turnover and ageing of the workforce can change the ability of the members to cope with surprise. There will be almost imperceptible shifts in standards enforcement as safety becomes taken for granted.

The **effort** to improve safety was seen as a necessary condition for maintaining some upward equilibrium level of safety – that is, it protected against a downward decay in the trend of cyclical safety fluctuations to which plants are subject. To put it another way, there probably is no zero-slope line or "resting point" for safety equilibria in a high reliability organisation. The aviation industry has data that supports this conclusion.

Changing the level of safety: an example from civil aviation

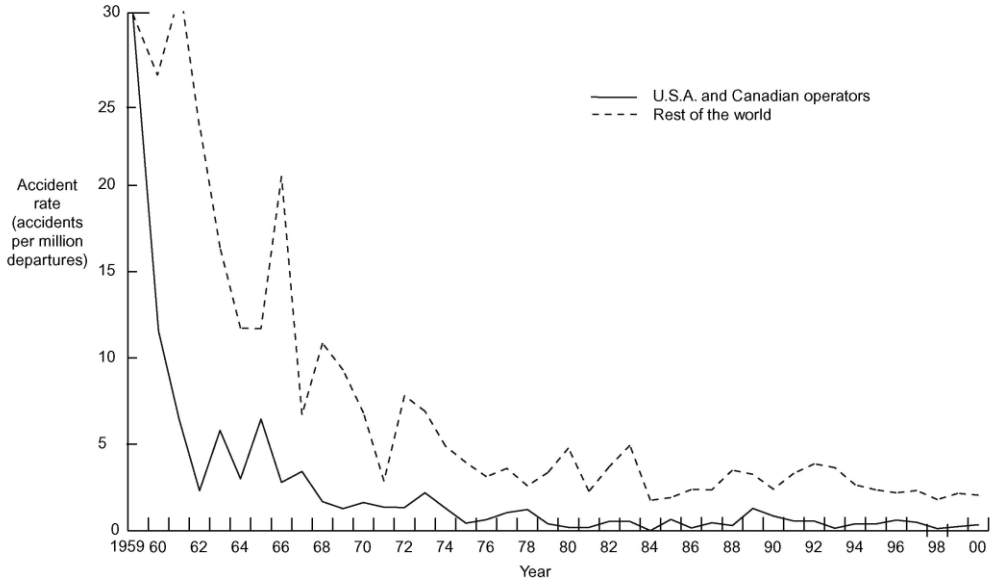
Commercial civil aviation has an exceptional safety record. For the last 20 years, a high level of safety has been maintained. The public has found this level of safety acceptable. The concern that the regulator and industry share is that the accident rate has stabilised over the last 20 years and the many improvements in technology and human factors that have been added over that time period have not made a significant change in the safety level achieved.

Air traffic is on the increase. The number of units flying are expected to double over the next few years. This means that the number of accidents will increase proportionally if the current safety levels are kept. The regulator and the industry fear that an increase of the number of accidents will not be accepted by society and are vigorously trying to improve and change the level of safety. National strategies[2] reflect that concern.

The relationship of civil aviation to the nuclear industry debate of improve or maintain is that the aviation industry has tried hard to improve safety over the last 20 years through constant vigilance, experience feedback, addition of new technology and research – particularly in human factors. The reality, however, is that all that improvement effort has only maintained the safety level. The lesson for nuclear safety here may very well be: *qui n'avance pas recule !*

2. Transport Canada, for example, in their current strategic plan are proactively trying to improve the safety levels by providing numerical targets which they hope will cut the accident rate in half within 5 years. See: www.tc.gc.ca/aviation .

Commercial jet fleet accident rate



Source: Airplane Safety, Boeing Commercial Airplane, *Summary of Commercial Jet Airplane Accidents, Worldwide Operations 1959-2000*, page 15, (www.boeing.com/techissues)

Conclusions

The national submissions indicate that there are differences in how member countries describe their responsibilities to ensure adequate nuclear safety and about whether their regulatory approaches require licensees to continuously improve safety or to continuously maintain safety. It is concluded that, while the actual level of safety achieved in all member countries is probably much the same, this is difficult to prove in a quantitative way. In practice, all regulatory approaches require improvements to be made to correct deficiencies and when otherwise warranted. However, the various descriptions of whether safety has to be **maintained** or **improved** may cause confusion for the regulator's stakeholders, particularly the licensees and the general public, and the CNRA or national regulatory agencies may wish to consider what further steps may be taken to reduce such confusion.

In practice, there is probably little difference between member countries with regard to the requirement for licensees to operate their plants at all times within the licensing basis. No regulatory authority would allow an NPP to continue to operate to its previous safety standards if some development in the state of the art in science or engineering (such as probabilistic safety assessment) showed clear deficiencies, either in the safety standards or in the extent to which the plant met the standards. However, licensees sometimes fail to appreciate that improvements in the understanding of the science and engineering that underpins the licensing basis may require plant improvements or modifications just to **maintain** the licensing basis. More difficult questions for the regulatory authority would concern the extent to which licensees should be required to

maintain or to **improve** safety with respect to new developments in the state of the art. In addition, the CNRA or national regulatory agencies may wish to discuss how this can be communicated to the licensees in a better way.

All regulatory authorities recognise that they have to react sensitively to the views of society about the level of acceptable risk from NPPs. Indeed, other safety regulators in civil aviation, food, health and the environment have similar concerns. This is a difficult issue that is tackled in different ways by different regulatory bodies, depending on the culture and traditions of their particular countries. Nevertheless, regulators need to have some techniques for gauging society's answer to the question "how safe is safe enough?" and for deciding, at any particular time and for any particular plant, whether it means that safety should be **improved**, **maintained** or even **reduced** (in line with a better knowledge of the inherent margins in the models and assumptions). Openness and clarity are important in order that the public can appreciate the technical arguments involved and the licensees can understand the grounds on which the regulator is basing his decision. The regulator must avoid giving the impression of either: allowing the operator carte blanche to run his plant unchanged for a fixed length of time irrespective of the public's view of what is acceptable; or constantly changing the regulatory "goal posts" in an attempt to reflect every swing in the perceived social attitudes to nuclear power.

Throughout the life of a nuclear power plant, changes occur both at the technical and human/organisational level. Regulatory authorities recognise that, in practice, it is very difficult to organise to maintain safety and that improvements to correct deficiencies and when otherwise warranted will continue to be made. Organising to maintain safety brings the risk of a dominance of routine and a lapse of mindfulness.

IMPROVING NUCLEAR REGULATION, ISBN 978-92-64-99162-0, © OECD 2011

Appendix: Compilation of Country Contributions

In developing its report on Improving Regulatory Effectiveness the CNRA special task group discussed the issue of improving safety versus maintaining safety. The CNRA member countries were asked to provide their definitions. The following responses were received.

Finland

What is safe enough?

The constitutional law of Finland stipulates that everyone shall have the right to life and personal liberty, physical integrity and security of person. Also it is stipulated, that the property of every person shall be protected and that public authorities shall strive to ensure for everyone the right to a healthy environment as well as the opportunity to influence the decision making concerning his living environment. Everyone shall be responsible for the natural world and for its diversity, for the environment and for the cultural heritage.

These fundamental rights and responsibilities are reflected in the Nuclear Energy Act defining as the main prerequisite for using nuclear energy, that the use of nuclear energy must be safe; it shall not cause injury to people, or damage to the environment or property. Safety is defined such a way that the activity does not endanger the citizens' health. The use of nuclear energy has to be in line with the overall good of society. This means that only a very low-level risk is considered tolerable. The goal is to keep the risk as low as possible, however, taking into account that the measures needed to meet this goal have to be reasonably achievable. Achievability can often be measured in terms of technical availability, reasonableness in terms of cost and inconvenience.

The safety records show that in reducing the risks of operations the nuclear industry has been a forerunner among the industrial community. That leads to the conclusion, that in order to be safe enough, the risk stemming from the use nuclear energy has to be low compared to the other risk factors of the society.

Maintaining safety

In modern societies there is a general trend to improve the safety of the society and to minimise all the risks caused by human activities (industry, traffic) as well as by natural hazards (fires, floods, and diseases). This overall risk reduction objective calls for continuous alertness for seeking opportunities to reduce the risks also in nuclear industry. Formal cost-benefit analysis is not used by the licensees nor required by the regulators in Finland.

In Finnish approach "to maintain the safety level achieved" is not considered to mean that the absolute value of risk would be maintained, but instead of that, that the share of the incremental risk from using nuclear power would be maintained unchanged following the overall safety development in the society. This requires constant active efforts to enhance the nuclear safety.

In legal terms, this principle has been manifested in Finnish safety regulations as follows: "Operating experience from nuclear power plants as well as results of safety research shall be systematically followed and assessed. For further safety enhancement, actions shall be taken which can be regarded as justified considering operating experience and the results of safety research as well as the advancement of science and technology". This principle can of course also lead to real safety improvements.

Improving safety

Real improving the safety is understood to mean reducing the relative risk share of using nuclear energy from the overall risk in the society. This interpretation requires that the nuclear industry has a role of a forerunner in safety work, not a role of a follower.

The legislative requirements for reducing the nuclear risk share are somewhat fuzzy and therefore, the driving force behind the safety improvements is more likely to be found in a well-developed safety culture of the licensee. One could say that where the requirements end, the culture begins. The difference of maintaining a safety level already achieved and of really improving it, could also be clarified by an old slogan: When you have done everything that was assigned you, you should say "We are undeserving slaves; we have simply done our duty".

France

Acceptable or accepted level of risk?

Determining whether a risk is acceptable is the result not only of a technical decision based on a scientific assessment of the level of risk but also of its acceptability by the society.

An acceptable level of risk can only result from a constant confrontation between what is desirable and what is possible. Consequently the acceptable level of risk can only be assessed by the yardstick of current knowledge and technical means. By definition, this level is changing with time.

At a given moment, and in a fixed technical and social context, it is possible to decide that a certain level of residual risk is acceptable. However it is not possible to decide that this very level of residual risk will remain acceptable later and that it will be enough to maintain it from now on.

A political choice

In France the (implicit) demand from citizens clearly appears as a request for the highest possible reduction of the level of risk. This demand is taken over (also implicitly) by the elected representatives and the government. The regulator must comply with this demand. Even if it is implicit, it really seems that a political consensus exists in France, which considers that the level of nuclear safety must be constantly improved.

As a consequence, despite the fact that regulators can always discuss such a subject, it will be anyway the political aspect that will decide.

A matter of culture

A good safety culture, based on a constant questioning attitude, constitutes a key point of the safety, whether to be improved or maintained. One can doubt whether it is really possible to keep intact such a questioning attitude without any prospect of progress. Without the willingness to seek for improved safety level, can we really hope to maintain the actual level of safety?

Good principles

The policy of constant safety improvement is absolutely similar to that which is followed as far as radiation protection and environment protection are concerned. The SAHARA (safety as high as reasonably achievable) principle is the "first cousin" of the ALARA principle used in radiation protection and the BATNEEC principle used in environment protection. These three principles, together, make a consistent whole, which by far exceeds the notion of preventing unfavourable consequences of nuclear activities on health and environment. The same concept is presented in some international fora with different and possibly excessive words but, in fact, with the same idea like the willingness to "strive for zero". (What is excessive is not the will to strive for zero, but the fixing of a deadline to that will: the asymptote of zero risk, zero dose or zero release will never be reached).

Periodic safety reviews

In France, the practice is now well established to regularly reassess (about every ten years) the safety reference of existing installations. For PWRs, the homogeneity of the plants and the evolutionary practice among reactor series allow, in fact, to review the safety of a standardised plant series by comparing to following series. This does not mean that the level of safety for a series is considered as insufficient, but as soon as an improvement has been implemented on the most recent reactors, it is necessary to wonder about the possibility to apply it to older ones.

The safety reassessment and the incident operating experience constitute the two driving forces for the policy of improving safety.

This is why the French Safety Authority considers as a key point, not only for the safety of future reactors but also for the safety of present ones, the work performed on new projects like the EPR.

Improving risk knowledge

"The SAHARA principle is not paradoxical with the fact that it is possible to relax some regulatory constraints as a better knowledge of the risk is obtained and thus to apparently agree on an increase of the level of risk; but, as the margins are decreased in the same time as their

uncertainty is reduced, the actual level of risk accepted by the regulatory body would be maintained."

For instance, the agreement given to a new fuel management cycle with a higher burn-up, based on more exhaustive studies showing that previously accepted criteria continue to be satisfied, can be accepted as far as the uncertainty in the risk assessment is itself reduced in order to insure that safety margins are still sufficient to cover "uncertainty". Improving risk acceptability, is also a matter of improving its knowledge.

Germany

Priority to safety

In Germany, the main safety principle for the peaceful utilisation of nuclear energy is the protection of life, health and property against the hazards of nuclear energy and the detrimental effects of ionising radiation. This principle is established in the Atomic Energy Act and it governs the design and safety concept of the nuclear power plants. These must be equipped with an effective safety system that will protect the plant personnel and the public as well as the environment from the radioactivity related to the operation of the nuclear installation.

Accordingly, nuclear safety has always been considered as the primary objective of the Atomic Energy Act and must at all times be considered in its application. As early as 1972, the supreme administrative court of Germany decreed that nuclear safety has priority over any of the other objectives of the Atomic Energy Act. This decree has always been upheld in later court decisions. The principle of "safety first" has been the guiding theme in any administrative action in the field of nuclear energy. This principle has been concretised with respect to the individual license by the following licensing prerequisite: *"A license may only be granted if the necessary precautions have been taken in the light of the state of the art in science and technology to prevent damage resulting from the construction and operation of the installation."*

An important basis for implementing the safety-first principle is the independent full responsibility of the licensee as the party ultimately responsible for safety (see responsibility of the licensee). The willingness of the licensee to employ an all-encompassing safety management is of crucial importance. This must comprise all measures required for ensuring the achievement of a sufficient safety level.

Assessment of safety

The safety assessment during construction, commissioning and essential modifications of a nuclear power plant is performed within the licensing process, continuous safety evaluation during operation is performed within the scope of regulatory supervision.

After the respective license has been granted the safety assessment during construction, commissioning and subsequent power operation of the nuclear power plant is performed in accordance the Atomic Energy Act by the nuclear supervisory authority. This authority verifies

that the conditions and prerequisites on which the license was based continue to be maintained during the entire lifetime of a nuclear power plant.

Verification of safety

Within his independent full responsibility for plant safety each licensee adjusts the safety level of the nuclear power plant to be in correspondence with the state of the art in science and technology over the entire operating life of the plant. If new safety relevant findings come to light, the need for and appropriateness of improvements is evaluated. In addition safety assessments are continuously performed as part of the regulatory supervisory procedure, and discontinuously or periodically as a specific safety review (e.g. probabilistic safety reviews) or risk studies.

Routine verification of safety by the licensee

The licensee submits safety verifications for the first time with the application for construction of a nuclear power plant. These must show that the plant will be in conformity with the valid nuclear safety regulations and will have the necessary safety characteristics.

During operation a regularly repeated verification is required to show that the system functions important to plant safety are executed properly and, also, that the quality characteristics have not deteriorated below acceptable levels (e.g. by in-service inspections, periodical functional tests, and preventive maintenance).

Inspections under governmental supervision

The supervisory activities of the Länder under nuclear legislation include the performance of safety assessments on a continuous as well as discontinuous and periodic basis, both as specific safety reviews and probabilistic safety analyses. They lead to remedial measures wherever appropriate. These continuous supervisory activities assure an intensive assessment of plant safety. Federal supervision is engaged in the analysis of more general safety aspects. The safety reviews performed so far did not reveal the need for any immediate action. However, the plant-specific inspections during operation and the analysis of national and international operating experience have resulted in manifold improvements that have affected specific components and maintenance measures.

Backfitting and safety improvements

The findings of the safety evaluations and the resultant backfitting and safety improvements show that the licensed safety status of the plants have at least been successfully maintained but, also, that newer safety findings were given appropriate consideration during the time of licensed operation.

Conclusions

In Germany, licensees have full responsibility for plant safety. Each licensee adjusts the safety level of the nuclear power plant to be in correspondence with the state of the art in science and technology as long as the plant is in operation.

Accordingly, licensees are required to continuously analyse the safety performance of their NPPs and have to take action (under the supervision of the regulators) if deficiencies are discovered.

Thus, maintaining nuclear safety does not mean to just measure up with the once determined (or required) safety level in a sense of a "steady state" over the lifetime of the plant, but it means to support an ongoing manifold process, in order to achieve the highest possible reduction of risk (in an absolute sense) by improving both, knowledge and technical means.

Sweden

The Act on nuclear activities states that safety shall be **maintained** by the taking of those measures required to:

- Prevent errors in or malfunction of equipment, incorrect handling or anything else that may result in a radiological accidents.
- Prevent unlawful dealings with nuclear material or nuclear waste.

It is important to note that the law also says that the licensee of nuclear activities has to ensure that all measures are taken that are needed for maintaining safety.

Looking at the underlying documents to the law one can see that safety is seen in a wide sense, and one can conclude that the SKI cannot easily require a reactor of early design to be upgraded to modern standards just as such. On the contrary, SKI can require a licensee to correct deficiencies in safety, which have been discovered through improved analysis or new knowledge. If the SKI, following the application of such improved analysis of new knowledge sees that a reactor belonging to an earlier design does not meet the licensing conditions, safety has to be improved as a condition for further operation. This means technically improved safety but formally safety is maintained.

SKI also has a duty to "*Initiate safety improvements whenever justified by operating experience, or research and development".* Therefore the SKI requires the licensees to conduct an active safety work including the carrying out of safety analysis using modern analytical tools. Deviations discovered in such analysis have to be assessed and a programme for safety upgrading established.

This is taken care of in SKI regulations where we say "licensee has to maintain and develop safety". In the word "develop" we include a continuous work to "hunt" for safety deficiencies in

the reactor design and the quality of the safety work and to take actions if deficiencies are discovered.

In summary we can say that we require licensees to continuously analyse safety and take actions if deficiencies are discovered, not to continuously improve safety in an absolute sense. Also, we believe that the risks from using nuclear power has to be low compared to other risks in society. When risks in general are reduced the risks from nuclear power has to be reduced. Finally, it should be said that the licensees themselves have established safety goals, including probabilistic ones. These goals are rather ambitious and push the owners to modernise their reactors of earlier design. This is according to the SKI part of the responsibility for safety that the licensee has.

Spain

Requirements related to the required safety level for operating nuclear installations in Spain are established in the operation permit. Attached to the permit a set of conditions on Nuclear Safety and Radiation Protection are established. Among these conditions one related to approved Official Documents is included. In this condition are identified revisions of Final Safety Analysis Report (FSAR), Technical Specifications (TS), Emergency Plan and Organisation Manual, used by Regulatory Body to perform safety assessments necessary to release the operation permit. The format and content of both FSAR and TS is based on standards from US Nuclear Regulatory Commission. Emergency Plan and Organisation Manual follow Spanish approach based on national regulations.

From the content of the above mentioned documents the required safety level for the facility is well established as they include Safety analysis, applicable codes and standards and operational limits, so building the licensing base of the plants. Any doubt about which, based in the operating experience of the plant or similar plants, arises on the strict compliance of the licensing base is addressed by the CSN, in the framework of the license, as a regulatory control activity. The CSN is empowered to set direct requirements, as complementary instructions, to ascertain and restore the licensed safety level.

Also in the operating permit provision for safety improvements are included. All nuclear facilities permits in Spain include a condition requiring licensees to perform an analysis of new regulatory requirements released by the regulatory authority from the country of origin of the technology of Spanish plants (mainly USA and Germany). This analysis should consider both applicability of new requirements to the Spanish plant and provisions for licensee to implement it when found applicable.

The CSN perform assessment of licensee's year report related to new requirements. When a new requirement is to be implemented entailing an increase in the plant required safety level, an amendment to the operating permit is released by Ministry of Industry and Energy, following the CSN report.

In recent years a new condition has been included in Spanish nuclear power plants, requiring licensees to perform a ten-year based Periodic Safety Review (PSR). The CSN assessment of PSR results has become a main input for operating permit renewal. Derived from RPS assessment,

safety improvements to be implemented by licensees are identified. Depending on the scope and nature of the improvements, their implementation is required as conditions to permit renewal or as CSN complementary instructions.

Finally other ways for safety improvement, on a continuous basis, are the so called as "safety improvement programs". These are required directly from the CSN to licensees and they do not entail an increase in the licensed safety level, even when from the results of such programs design modifications are implemented in the plants to improve safety. This is the case of programmes, now under way of implementation or close to completion, related to Probabilistic Safety Assessment and its applications, man-machine interface, dose reduction programmes, radwaste management and fire protection.

An economically deregulated electricity market is now in place in Spain. This fact, as recognised in the CSN Strategic Guidance Plan (February 1998), poses a challenge on the CSN to increase its regulatory control specially on potential resource shortages and, at the same time perform an effective regulatory control addressing its activities to the most safety beneficial measures and to perform cost-benefit analysis of the regulatory requirements.

United Kingdom

There is a fundamental duty enshrined in UK safety law (the Health & Safety at Work, etc., Act 1974) for all employers to reduce the risks to their workers and the public "so far as is reasonably practicable". This duty applies to all employers, whether engaged in nuclear operations or, for example oil extraction, construction or agriculture. Combined with the requirement under standard nuclear site licence condition 15 for periodic safety reviews, this places a requirement on licensees periodically (every 10 years) to submit documented safety reviews to the Nuclear Installations Inspectorate (NII) in which it is demonstrated not only that the plant still meets the original design standards, but also that a comparison with modern standards has been made, possible improvements to reduce the gap between these and the original standards have been considered, and all reasonably practicable improvements have been implemented. There is consequently a continuing pressure upon licensees not only to maintain but also to improve safety. This pressure is maintained between the major Periodic Safety Reviews by NII's routine site inspection and technical assessment activities, which include 'minor' safety reviews prior to consent to reactor start-up being granted and assessments of licensees' proposals for plant modifications against the modern standards set out in NII's published Safety Assessment Principles (SAPs). These SAPs are themselves currently under review.

United States

The U.S. Atomic Energy Act of 1954 and Energy Reorganisation Act of 1974 establish the basic regulatory mission of the NRC. This mission is to regulate the civilian use of by-product, source, and special nuclear material to ensure adequate protection of public health and safety, to promote the common defence and security, and to protect the environment. As indicated, "adequate protection" is the standard of safety on which NRC regulation is based. As commonly understood, safety means freedom from exposure to danger, or protection from harm. In a practical

sense, an activity is deemed to be safe if the perceived risks are judged to be acceptable. The NRC recognises the risks to the public from nuclear power plant operation. As such, in 1986, it promulgated the Safety Goal Policy, which expresses an acceptable level of the risk from nuclear power plant operation by comparison with other societal risks.

The collective efforts of the NRC and the nuclear industry are needed to maintain safety. NRC licensees have the responsibility to safely design, construct, and operate reactors. Regulatory oversight of licensee safety is the responsibility of the NRC. Thus, safe performance reflects the results of the collective efforts of the NRC and the nuclear power industry.

The safety performance of the U.S. nuclear power industry has improved substantially over the past ten years, and nuclear reactors, collectively are operating above acceptable safety levels consistent with the agency's Safety Goal Policy. The NRC believes this level should be maintained. If substantial safety improvements are identified, additional regulatory requirements should only be imposed consistent with the Commission's Backfit Rule (10 CFR 50.109). Allowing small-risk increases may be acceptable when there is sufficient conservatism and reasonable assurance that sufficient defence-in-depth and safety margins are present. Small-risk changes that reduce unnecessary burden will allow more efficient use of licensee and the NRC resources as well as bring into focus those areas that are more critical to the safety of the public and the environment. We use the body of domestic and international knowledge, experience, and research to determine when changes that could affect risk are acceptable.

NRC licensees will continue to have the primary role in maintaining safety and are expected to identify, through mechanisms such as operating experience feedback and integrated risk assessments, the design and operational aspects of their plants that should be enhanced to maintain acceptable safety performance levels. For nuclear power plants to continue operating, safety performance must be at or above acceptable levels. The NRC will take action to improve safety performance before it falls below acceptable levels and will require the shutdown of plants when their safety performance is identified as unacceptable. In addition, circumstances may arise, where new information reveals, for example, that an unforeseen hazard exists or that there is a substantially greater potential for a know hazard to occur. In such situations, the NRC has the statutory authority to require licensee action above and beyond existing regulations to maintain the level of protection necessary to avoid undue risk to public health and safety.

Where requirements exist that the NRC concludes have no safety benefit, the NRC can and should take action, as appropriate, to modify or remove such requirements from the regulations or licences. Requirements that are duplicative, unnecessary, or unnecessarily burdensome can actually have a negative safety impact. They also can tend to create an inappropriate NRC and licensee focus on "safety versus compliance" debates. As the NRC has stated in its Principles of Good Regulation, "there should be a clear nexus between regulations and agency goals and objectives, whether explicitly or implicitly stated".

As some requirements are more important to safety than others, the NRC will use a risk-informed approach, whenever possible when adding, removing, or modifying NRC regulations, as well as when applying NRC resources to the oversight of license activities. Based on the

accumulation of operating experience and the increasing sophistication of risk analysis, the NRC will continue to refine its regulatory approach in a manner that enhances and reaffirms our fundamental safety objective. In addition, the NRC recognises that to be a successful regulator we must consider the effects of our decisions on the public and the industries we regulate. Therefore in addition to maintaining safety, our performance goals also include a focus on making our activities and decisions more effective and efficient, reducing unnecessary regulatory burden, and enhancing public confidence.

REGULATORY ASSESSMENT

13. Nuclear Regulatory Decision Making

Foreword

The Committee on Nuclear Regulatory Activities (CNRA) of the OECD Nuclear Energy Agency (NEA) is an international body made up of senior representatives from nuclear regulatory bodies. The Committee guides the work of the Agency concerning the regulation, licensing and inspection of nuclear installations with respect to safety. It acts as a forum for the exchange of information and experience, and for the review of developments which could affect regulatory requirements.

Following the Joint* Workshop on Regulatory Decision-making Processes held in October 2002 in Switzerland, the CNRA undertook the production of a definitive report providing an international consensus on the integrated decision-making process for nuclear regulation. To pursue this objective, similar to the work done in recent years on nuclear regulatory challenges and other nuclear safety issues, an expert group was formed with senior-level regulators.

This report discusses some of the basic principles and criteria that a regulatory body should consider in making decisions and describes the elements of an integrated framework for regulatory decision making. It is not, however, a handbook or guide on how to make regulatory decisions. In preparing the report, the task group reviewed and incorporated information from a wide array of documents produced by the NEA, its member countries and other international organisations, such as the International Atomic Energy Agency (IAEA) Safety Series reports.

The report was prepared by Thomas Murley, on the basis of discussions with, and input provided by, the members of the Task Group listed below. Ulrich Schmocker (Switzerland) skilfully chaired the meetings and the work of the group.
André Vandewalle (Belgium), Jim Blyth (Canada), Chuck McDermott (Canada), Petr Brandejs (Czech Republic), Marja-Leena Jarvinen (Finland), Lasse Reiman (Finland), Bruno Bensasson (France), Lajos Vöröss (Hungary), Ejii Hiraoka (Japan), Shunsuke Ogiya (Japan), Victor Gonzales Mercado (Mexico), Alexander Gutsalov (Russian Federation), Steve Lewis (United Kingdom), Lynn Summers (United Kingdom), Bill Borchardt (United States), Mamdouh El-Shanawany (IAEA) and Barry Kaufer (NEA).

* The joint organisers were: the Swiss Federal Nuclear Safety Inspectorate (HSK), the International Atomic Energy Agency (IAEA) and the OECD Nuclear Energy Agency (NEA).

Introduction

As the nuclear programmes in OECD countries have matured over the four decades of commercial nuclear power operation, this maturation has brought many improvements in safety through backfits in technology and programmes and improvements in operational performance of nuclear power plants generally. In parallel with these changes in nuclear plants' performance, there has been a maturation in the safety regulation of nuclear power plants, most notably in the use of new safety analysis methods like probabilistic safety analysis (PSA), in the regulatory responses to new information and insights from operating experience, especially from the accidents at Three Mile Island and Chernobyl, in the consideration of human factor and organisational impacts upon nuclear safety, and in an increased emphasis on nuclear quality management systems.

It has been recognised for some years that the nature of the relationship between the regulatory body and the operator can influence the operator's safety culture at a plant, either positively or negatively.[1, 2] An important factor affecting the relationship between the regulator and the operator is the nature of the regulator's decision-making process. In light of these insights, the CNRA has judged that it is an appropriate time to examine the broad issue of regulatory decision making. That judgement is the basis for preparing this report.

This report is not a handbook or guide on how to make regulatory decisions. Each nation's laws, customs and administrative processes are unique, and the range of circumstances potentially facing a regulatory body is so great that a handbook approach is simply not practical. Instead, this report attempts to discuss some basic principles and criteria that a regulatory body should consider when approaching the wide range of decisions faced in the course of its daily responsibilities.

The fundamental objective of all nuclear safety regulatory bodies is to ensure that nuclear utilities operate their plants at all times in an acceptably safe manner.[3] In meeting this objective, the regulatory body should strive to ensure that its regulatory decisions are technically sound, consistent from case to case, and timely. In addition, the regulator must be aware that its decisions and the circumstances surrounding those decisions can affect how its stakeholders, such as government policy makers, the industry it regulates, and the public, view it as an effective and credible regulator. In order to maintain the confidence of those stakeholders, the regulator should make sure that its decisions are transparent, have a clear basis in law and regulations, and are seen by impartial observers to be fair to all parties.

In meeting these goals, the regulator should be guided by an integrated framework for making regulatory decisions. The framework can be adapted to different types of decision-making processes but it must be consistent with national laws, customs, international treaties, regulations and internal policies of the regulator. The basic elements of such an approach to decision making are to: (a) clearly define the issue, (b) assess the safety significance, (c) determine the laws,

1. NEA (1999), *The Role of the Nuclear Regulator in Promoting and Evaluating Safety Culture*, OECD, Paris.
2. NEA (2000), *Regulatory Response Strategies for Safety Culture Problems*, OECD, Paris.
3. NEA (2002), *Improving Versus Maintaining Nuclear Safety*, OECD, Paris.

regulations or criteria to be applied, (d) collect the relevant information and data, (e) judge the expertise and the resources needed, (f) agree on the analyses to be performed, (g) assign priority to the issue among the other workload of the agency, (h) make a well-informed decision, and, finally (i) write a clear decision and its basis and publish the decision when needed.

Not every issue facing a regulator can be addressed in such a structured manner. There will be unexpected events, urgent situations, lack of information, uncertain information, difficult cases with strong differing opinions, and other challenges. Nonetheless, having recourse to a decision-making framework will benefit the regulator by fostering consistency and efficiency. By now all regulatory bodies have large case histories of past decisions and can rely on those precedents for handling similar issues. The nuclear plant operators will also see the benefits from a stable and consistent regulatory decision-making framework. Other stakeholders may see the benefits and thereby have enhanced confidence in the regulator's decision-making process by knowing that it has a structured framework.

A prime example of decision making facing a nuclear regulator is whether to require a safety backfit. This subject has been discussed extensively in a previous NEA report.[4]

In view of the background above, the purpose of this report is to describe the basic principles, criteria and elements of nuclear regulatory decision making.

While focused on the regulation of nuclear power plants, the principles in this report apply to the regulation of other nuclear facilities as well, and the principles can be considered by each regulatory body when structuring its unique decision-making framework. It follows, therefore, that the audience for this report is primarily nuclear regulators, although the information and ideas may also be of interest to nuclear operating organisations, other industry organisations and the general public.

Although this report stresses the importance of the regulatory body having a structured decision-making process, we must keep in mind that it cannot substitute for the experience and judgement of the senior managers in a regulatory body gained over many years in facing diverse situations and making regulatory decisions. Likewise, the decision-making framework should not be so rigid that it does not allow room for individual judgement and discretion on the part of inspectors and managers in making regulatory decisions.

Types of regulatory decisions

A nuclear safety regulator may be faced with making a decision for any number of reasons. Some of these may be made on the regulator's own initiative, for example a regulation on new reporting requirements, but the large majority of decisions are made in response to stimuli from outside the organisation. The regulatory decision-making framework discussed in this report is meant to apply to the full range of decisions that a nuclear regulator faces.

4. NEA (2002), *The Regulatory Challenge of Judging Safety Backfits*, OECD, Paris.

Examples of the types of decision issues facing a regulator are the following:

- Setting regulatory requirements including consensus standards.
- Granting licenses and permits.
- Reviewing plant modifications in response to operator requests.
- Reviewing fuel design changes and fuel operating limits.
- Reviewing calculation methods.
- Taking enforcement actions in response to inspection findings.
- Responding to stakeholder requests for regulatory action.
- Reviewing decommissioning plans.
- Reviewing new plant designs.
- Responding to serious operating events or accidents.
- Making recommendations for action during emergencies.
- Taking action to deal with perceived adverse operating trends.
- Dealing with perceived safety culture problems at a plant.
- Dealing with safety issues raised by new information.
- Dealing with generic safety issues affecting several plants.
- Deciding on the need for additional safety research.
- Dealing with legal changes to the regulatory framework.
- Dealing with disagreeing opinions within the regulatory staff or its technical safety advisors.
- Dealing with disagreements with the operator or other outside organisations.

Perhaps the bulk of the decision cases that come before a regulator are straightforward issues, but that does not mean they are unimportant or that the regulator does not need to consider them carefully. Rather, it simply means that there are substantial precedents of case histories and adequate time for the regulator to define the issues clearly, to analyse alternative actions and to involve the appropriate stakeholders. In other words, for such issues there is ample opportunity for the regulator to implement its deliberative, structured decision-making process.

Some of these decision issues will be more challenging for the regulator. They are frequently characterised by unexpected circumstances, lack of complete information, uncertain or contradictory information, disagreement among the safety experts, a real or perceived urgency to make a decision, an incomplete understanding of the consequences of a decision, or all of the above. Adding to these difficulties is often the concern in the mind of the regulator that its decision-making actions may have

profound effects not only on public safety but on the public's perception and confidence in the regulatory body itself.

Whether a decision issue is straightforward or difficult, a nuclear regulator will benefit by having a structured decision-making framework and by having experience in following its procedures.

Basic principles for regulatory decision making

A fundamental tenet of nuclear safety is that the operator has the responsibility for safely operating a nuclear power plant. It is the nuclear regulator's responsibility to oversee the operator's activities in order to assure that the plant is operated safely. Nothing the regulator does should ever diminish that fundamental distinction in roles between the operator and regulator.

To meet its responsibility, the regulatory body will have in place a set of regulations that the operator must follow in order to operate the plant safely, to assure the security of nuclear materials, to manage safely radioactive waste and spent nuclear fuel, and to protect the environment. The regulatory body will make regular inspections at a plant site to assure that plant activities are conducted in a safe manner and, in case they are not, will act to see that the operator takes corrective actions to bring the plant into compliance with regulations and the plant's safety envelope. In the course of its normal activities, the regulatory body will be faced with the need to make frequent decisions of the types discussed in the previous section. In making these decisions, the regulator should be guided by the basic principles embodied in an integrated framework for making regulatory decisions. Having such a structural process will foster consistency and efficiency as well as provide enhanced stakeholder confidence in the decisions.

A regulator's decisions must be grounded in the nation's laws and the regulations and standards that implement those laws. But even further, the regulatory body should promote safety by setting a good example in its own performance. This means, for example, the regulatory body should be technically competent, set high safety standards for itself, conduct its dealings with operators in a professional manner, have clear guidelines for its safety reviews and inspections, have clear acceptance criteria, and show good judgement in its regulatory decisions. In the spirit of improving regulatory performance, the regulatory body may consider conducting periodic self-assessments or requesting external assessments of its performance.

When approaching regulatory decisions, the regulator must make an early assessment of the safety significance of the issues. This action is necessary to give priority attention to the most serious risks and to guide the proportionality of the regulatory action to be commensurate to the risks involved.[5] Most regulators find that assessing the safety significance of an issue can be improved through the use of PSA insights. This topic will be discussed later in this report.

Once a judgement has been reached on the safety significance of an issue, the regulator should gather sufficient information to make an informed decision. This activity may be limited by

5. HSE (2001), *Reducing Risks, Protecting People* – HSE's decision-making process, United Kingdom.

the time available. In some cases, regulatory decisions must be made urgently with little time for extensive data gathering, for instance when making protective action recommendations to local authorities during emergencies at a nuclear plant. In most cases, however, there will be sufficient time to collect adequate information on the issue. The regulatory body should not let itself be rushed into a premature decision by pressures from interests that may conflict with safety.

A regulator may find it useful to have internal policy guidelines on when to seek input from outside stakeholders. The operator's input should be sought on decisions affecting the operator's plant, if it has not already been volunteered, and in many cases it may be appropriate to seek public input as well. On broader generic issues, like changes to radiation protection requirements, the regulator should obtain the views of other government agencies and national and international experts, in addition to the interested public. When the regulator is seen to consider a broad range of views, the regulator's ultimate decision will generally have enhanced credibility and acceptance by its stakeholders.

The regulator should be particularly sensitive to the need to maintain consistency in its decisions. That is, when faced with similar safety issues and similar circumstances, the regulator should render similar decisions or clearly explain why a different decision was made. If operators consistently see that they are treated differently on similar issues, they may view the regulator as arbitrary and may lose respect for the professionalism of the regulatory body. A good way to promote consistency is to maintain transparency in decision making – that is, being open in how decisions were arrived at and what their implications are. This can best be done by promptly producing a clear written basis for the decision.

The credibility of the regulator in the eyes of the public depends, in part, upon the independence of the regulator to make decisions without pressure from interests that may conflict with safety. Within the government, the regulatory body should have a clear separation of responsibilities from those organisations responsible for generating electricity and for developing nuclear technologies. That is, the regulatory body should be seen by the public as a competent, professional, independent body that makes regulatory decisions on the basis of protecting safety, security and the environment.

In making a decision on a difficult issue, the regulator will have to consider how the decision will appear in retrospect if it turns out to be wrong or not to have the desired outcome. In difficult cases there will frequently be pressures on the regulator from many sources, so the regulatory body should ask itself some questions before rendering a final decision.

- Is there a clear safety basis for the decision?
- Is there a clear legal basis for the decision?
- Were normal procedures followed?
- Were all stakeholder views considered?
- Was there due diligence used in gathering the necessary information?

- Is the decision consistent with earlier precedents?
- Has the regulator assured that it was not hurried into bypassing some regulatory requirements to satisfy the operational needs of the plant operator?

This questioning is not meant to suggest that the regulator should allow itself to become paralysed by concerns that a decision may not turn out well. Rather, it is a reminder that the regulatory body should assure itself that it has approached the decision following its procedures in a structured manner, has considered all relevant input, has used sound safety principles and has not appeared to be unduly pressured in making the decision.

Criteria for regulatory decisions

It is axiomatic that the decisions of a nuclear safety regulator must be grounded in its national laws, regulations, codes, standards and policies. Current, comprehensive and clear regulations are essential for a good decision-making process, but these cannot cover all aspects of the issues that a regulator will face. There will always be questions of completeness, differing interpretations and unexpected situations. For these reasons a regulatory body will usually be guided by broad criteria that form the foundation of its safety philosophy.

One of these criteria is the level of safety and environmental protection to be required by the regulator. There are various statements of the basic level of protection criterion among OECD countries, but they all acknowledge that it is not possible to achieve zero risk in nuclear activities. Some of these criteria for basic level of protection in OECD countries are:

- "No unreasonable risk".
- "Adequate protection of public health and safety".
- "Risk as low as reasonably practicable".
- "Safety as high as reasonably achievable".
- "Limit risk by use of best technologies at acceptable economic costs".

A related question is what criterion should be used for the level of assurance that the required safety criteria are met? Here again there are various formulations of the criterion for level of assurance among OECD countries, but they all recognise that absolute assurance cannot be achieved. Most countries have some variation of a "reasonable assurance" criterion.

These are seen to be qualitative aspirational criteria rather than quantitative safety requirements that must be met. In practice these criteria are what some may call "revealed standards". That is, the sum of perhaps hundreds of case history decisions and case law over several years will yield a working definition of what these criteria mean.

Beyond these qualitative aspirational criteria a regulatory body may adopt quantitative safety goals – for example, numerical goals for protection of the health and safety of people living near

nuclear power plants. In order to be more useful in practical decision making, the health goals are often supplemented by numerical goals for core damage frequency (CDF) and large early radioactive release frequency (LERF). Clearly the use of these latter safety goals requires the production and maintenance of high quality plant specific PSAs as well as operator and regulatory staffs proficient in PSA methodology. Although the promulgation and use of quantitative safety goals is fairly common among OECD regulatory bodies, these criteria are generally regarded as not appropriate for use as the sole basis for making regulatory decisions. Rather, the quantitative safety goals are best used as guidelines by the regulator to supplement other regulatory criteria.

A fundamental principle for safety regulators is the practice of conservative decision making. This is exemplified by the traditional defence in depth safety philosophy. Since the earliest days of commercial nuclear power, regulators have embraced defence in depth to require multiple layers of protection to prevent accidents and to mitigate their consequences. The use of defence in depth principles and safety margins have been, and continue to be, effective ways to account for uncertainties in equipment and human performance. As more operating experience and improved safety analysis methods give us a deeper understanding of nuclear plant safety, safety margins, and their uncertainties, it may be possible to reduce overly conservative margins or to add margins where needed.

Nuclear safety regulators generally require that their basic level of protection criterion (e.g., "no unreasonable risk") must be met regardless of cost or other considerations. When considering safety improvements beyond that level, there may come a point where a safety improvement may not be rationally justified after evaluating offsetting factors such as costs, worker radiation exposure, worker safety and equipment degradation through excessive testing. For this reason, the regulatory body's integrated framework for decision making may include provision for considering these types of trade-offs. Whether this provision includes a formal quantitative cost-benefit methodology or a qualitative consideration of trade-offs is a policy matter for each regulatory body.

Elements of regulatory decision-making process

The basic principles and criteria for regulatory decision making discussed in the previous chapters should be embodied in a practical integrated framework that regulators can use in their daily activities. The framework need not be rigid but must be consistent with national laws, customs, international treaties, regulations and internal policies of the regulator. The basic elements of an integrated framework are discussed below.

Cleary define the issue

In most cases, the regulatory issue will be straightforward, but in some difficult cases the issue will be more complicated. An example might be to determine which governmental agency has jurisdiction when an operator proposes to dispose of mixed waste containing both radioactive and chemically toxic materials. In such cases, it is important that the issues are clearly defined before making a decision that may be inappropriate.

Assess the safety significance

In most cases, the regulator's experience will tell it the safety significance of the issue, but in some cases further analyses will have to be done. An example might be an operator's request to delay the repair of service water pipe corrosion until the next refuelling outage. In such a case, the regulator would have to decide whether the risk is serious enough to require an early shutdown or whether the plant can safely continue operating until the next refuelling outage to repair the service water pipe. Clearly the most safety significant issues should receive the regulator's priority attention.

Determine the laws, regulations, or criteria to be applied

An experienced regulator will generally know which criteria will govern the issue being faced. There may be situations, such as an apparent weak safety culture at a plant that is affecting performance, where the criteria do not explicitly cover the circumstances being considered. In these cases the regulator may need legal advice to be sure it is on a sound legal footing before taking regulatory action. In all cases the regulator should review past case histories on similar issues and use these precedents to ensure consistent decision making. There may be instances where the regulator may deviate from its current criteria where new criteria based on new information are in preparation. In such cases, the regulator should follow its established procedures for granting deviations.

Collect data and information

An early activity for the regulator is to assemble all of the relevant information pertaining to the decision. This may, for example, involve the operating history of the plant, recent event reports, and case histories of similar situations it has faced at other plants it regulates. The regulator might also want to contact other regulatory bodies for information and consider international sources and other industry organisations that may have relevant information. The regulator will have to judge the adequacy of the information available and, if there is an information gap, how best to proceed toward a regulatory decision. One possible conclusion by the regulator could be that more safety research is needed.

Judge the expertise and resources needed

For most of the decision cases that come before a regulator, the expertise and resources needed will be well known from past experience. There may be more complex issues from time to time, for example an operator's request for approval to install a modern digital instrumentation and control system to replace an older analogue system. If the regulator has not faced a similar situation before, it will be necessary to analyse carefully the skills and resources needed for the review, including expert resources outside the regulatory staff. It is important that such complex reviews be carefully planned in order to avoid disruptions to other regulatory decision schedules.

Agree on the analyses to be performed

After the safety issue and the regulatory criteria have been defined, the regulator must agree on the analyses to be performed. An example would be an operator's request to extend the fuel

burnup limits. In such cases the regulator must be in agreement with the validity of the computer codes, the data, the acceptance criteria to be used in the analyses, and the operator's quality programmes. The regulator may choose to conduct an independent analysis, particularly in first of a kind situations.

Assign priority to the issue among the other workload of the agency

It can be expected that there will be many competing interests for a regulator's decision-making attention. A good regulatory practice would be to have an established set of work priority categories that may be publicly available for all stakeholders to see. Obviously, the most safety significant issues should have the regulator's highest priority. But all issues, particularly requests for action from outside organisations, deserve a timely decision. If the regulatory body finds that it has a chronic and growing work backlog, it may find it necessary to approach the government authorities and the legislature for additional resources.

Make the decision

Prior to reaching a final decision on an issue the regulator should be sure that it has sought appropriate stakeholder input. These stakeholders may include nuclear plant operators, nuclear organisations, national and local government authorities, public interest groups and the general public. In some urgent or highly technical situations it may not be practical to obtain broad stakeholder input, but it is a good regulatory practice to seek as broad an input to the decision-making process as practical. After reviewing the stakeholder input and analysing the facts against the relevant criteria the regulator must reach a decision. Clearly, where the issue involves safety, the regulator must assure that its basic protection criteria are met, above all other considerations. When considering safety improvement beyond the basic level of safety criteria, there may come a point where a safety improvement may not be rationally justified by the costs involved. The regulatory body's decision-making framework may include provisions for considering these types of trade-offs. Whether this provision includes a formal cost-benefit methodology or a qualitative consideration of trade-offs is a policy matter for each regulatory body.

Write a clear decision and publish it

In the interest of assuring transparency and future consistency in its decision-making process, the regulator should write a clear description of its final decision and its basis and may make it publicly available.

The elements above are not meant to be followed in sequential order; in fact, several of them can be conducted in parallel and some could even be omitted. The rigor and depth with which the elements are followed should generally be proportionate to the safety and regulatory significance of the issue being considered.

The regulator's responsibility does not end with the decision and its publication. Clearly, there are follow-up actions a regulator should take to ensure that its decision is implemented. Likewise, the decision and its basis must be stored in the regulatory body's established document

control system. This will enable effective follow-up actions and will facilitate retrieval of the information to assist in future decision making.

In the spirit of continuous regulatory improvement the regulator may want to add an element on lessons learned to its decision-making process. For issues of high regulatory significance, the regulator could conduct a self-assessment to consider the quality of how the decision-making process was conducted, the effect of the decision on safety, and the impact of the decision on stakeholders.

Implementing the elements of decision-making process

The regulatory body can use the elements above to develop a regulatory decision-making framework and integrate it into its overall management system, similar to its planning and budgeting processes, taking into account the national laws, customs and internal policies of the regulator. In this way the decision-making process will over time become part of the culture of the regulatory body's organisation.

The integrated decision-making framework will cover the great majority of decisions faced by a regulatory body. But every regulator will encounter special situations that are unique or that do not fit neatly into the framework outlined above. The following discussions focus on some of those difficult decision-making situation that regulators may face from time to time.

Decision making in the face of uncertainties

Some of the most challenging decision-making situations for a regulator are when it is faced with an issue that is surrounded by uncertainties or lack of data or time pressures. A characteristic of these situations is that one may not be able to rely on a detailed safety analysis for the decision, and that is what makes them so difficult. There may be a number of reasons for these situations, for example:

- Operating experience leads to discovery of a new phenomenon that is not well studied but that appears to pose a serious safety problem.
- Analyses uncover a completely new issue where there are no governing regulatory criteria.
- Technical issues may arise that pose questions beyond normal engineering experience and where data is sparse.
- There may be signs of potential degradation of plant equipment or components that are difficult to inspect.
- Emergency situations may arise that pose time pressure for a regulatory decision and where information may be lacking or not reliable or contradictory.

When faced with situations like these, the regulator must first do its best to collect and assess the available information. Since the plant operators are usually the ones closest to the issue, the regulator should request their information and their assessment of the issue. There may be other sources of information and data as well. After gathering and assessing the information, the next step for the regulator is to assess where there are information gaps and what are the implications of proceeding

without filling those gaps. It may be possible to use conservative bounding analyses to cover data uncertainties until better data are available. The regulator may also decide that additional research is needed.

In parallel with the information gathering effort, the regulator may begin to consider alternate resolutions of the issue. If there are time pressures, this effort to evaluate alternatives may be constrained, but generally there will be time to evaluate the pros and cons of alternate resolutions. An early step is to request the operator's recommended solution to the issue. The regulator may develop its own approach to resolution, perhaps with advice and consultation with outside experts. The regulator may consider requiring compensatory measures at the plant while more data is gathered and a permanent resolution can be found.

Sooner or later the regulator will have to make a decision on the issue, even in light of continuing uncertainties and lack of full information. This is where the regulatory body's conservative tradition of using the defence in depth principle and safety margins will be an important guide. Of equal importance will be the experience and judgement of the experts and senior members of the regulatory staff.

As in other significant regulatory decisions, the regulator should consider carefully how the decision is communicated to its stakeholders and the public. Special attention should be given to any discussion of how conservative decision making was used to compensate for uncertainties or lack of data.

Safety culture issues

When assessing the operational safety of a nuclear power plant it is important for the regulator to consider all the information concerning the plant that could affect its safe operation. A special challenge for the regulator is how to assess and evaluate conditions at a plant that may not be covered by specific regulations such as safety culture problems. By now there can be no doubt that safety culture problems at a nuclear plant can lead to safety risks that a regulator must be prepared to recognise and deal with. An earlier OECD report[6] discussed how a regulatory body can assess and recognise early signs of declining performance caused by safety culture problems.

When a nuclear power plant shows signs of declining performance, a possible root cause may be that the operator's organisation has elements of a weak safety culture. This situation poses a difficult challenge for a regulator because it is not really possible to measure quantitatively the safety culture of an operating organisation and it is seldom clear from the early signs of declining safety performance just what the root causes may be. Nonetheless, the regulatory body should be alert to potential safety culture problems at a nuclear plant and should include that information in the framework for making regulatory decisions concerning that plant. A follow-on OECD report[7] discussed a graduated regulatory strategy for assessing possible safety culture problems. This

6. NEA (1999), *The Role of the Nuclear Regulator in Promoting and Evaluating Safety Culture*, OECD, Paris.
7. NEA (2000), *Regulatory Response Strategies for Safety Culture Problems*, OECD, Paris.

strategy includes enhanced inspection oversight, regular meetings with operator management, and systematic assessments of all aspects of the plant's performance.

The specific conditions at a plant with safety culture problems are certain to be unique to that plant. This difficulty should not deter the regulator from facing the issue and taking the necessary actions, because safety culture problems are likely to recur from time to time. With experience in dealing with safety culture issues, the regulatory body can use those case history precedents to include some general guidelines in its integrated decision-making framework. There are experts in several countries working to understand the influence of safety culture on a plant's safety performance. As these efforts bear fruit over time, the regulatory body may choose to include this information in its decision-making process. In this regard, it would be a special benefit for OECD regulatory bodies to share their experiences in dealing with specific safety culture issues.

Differing opinions

It is not uncommon for a regulatory body to be faced with strong differing opinions when considering complex safety issues. In fact, it may be expected that plant operators and nuclear industry organisations will view issues differently from the regulator simply because of their different responsibilities and perspectives. These types of differences can be handled in the normal interactions associated with regulatory decision making. From time to time, the nuclear regulatory body may encounter disagreements with other government agencies. Insofar as possible, these disagreements should be reduced to a set of technical questions that can be resolved through additional data, analysis and perhaps compromise. When the disagreements with other government agencies are philosophical or political, the resolution is much more difficult and in any case is beyond the scope of this report.

Particularly challenging are those cases of differing professional opinions within the regulatory body itself. Senior regulatory managers should pay careful attention to differing professional opinions within the regulatory staff because of the potential to harm the credibility of the regulatory body if not handled properly. If a differing view has not been considered seriously or has been peremptorily dismissed, it can lead to lingering animosity within the staff or even a source of public controversy. Thus, it is clearly important for the regulatory body to respectfully consider dissenting views within its own organisation. To a large degree, this issue is a function of management style of individual managers. Some regulatory bodies have found that they can deal with these situations by having a procedure for resolving differing professional opinions within the decision-making framework. The elements of a procedure for resolving differing professional opinions might include: (a) having the differing professional clearly state the issue at stake and the areas of disagreement, (b) having an independent technical review of the issue, (c) having the decision made by a senior manager in the regulatory body, and (d) perhaps allowing for an appeal process. Clearly the resolution of a differing professional view should be done in an expeditious manner.

The regulatory decision maker might not always know that there are differing opinions among the staff when preparing to make a decision. Therefore, the decision maker may want to

make it a practice in complicated or difficult issues to find out if there are differing opinions among the staff.

In all cases of differing opinions, whether from inside or outside the regulatory body, the regulator should observe some basic principles in dealing with them. First and foremost is a serious, respectful consideration of the differing opinions. A second principle is to deal with the differing opinion promptly according to established procedures, once it becomes clear that the issue is not coming to closure through the regular management processes. Finally, there should be a clear record of the decision and its basis.

Safety advisory bodies

Many nuclear regulatory bodies have established advisory bodies to give advice on technical safety matters. These bodies are generally composed of independent, outside experts in various technical disciplines of relevance to nuclear engineering and safety. Although the functions of safety advisory bodies are unique to each country where they have been established, the safety advisory bodies should generally be viewed as a part of the regulatory decision-making process. The views of advisory bodies must be seriously considered (and may sometimes be adopted), but it should always be clear that the regulatory body is the decision maker. It should be a basic regulatory principle that the role of advisory bodies is to provide the regulator with technical information and insights that may be used for regulatory decisions but not to propose decisions.

Using risk information in regulatory decisions

Most of the safety regulations of OECD regulatory bodies were established before the methods of probabilistic safety analysis was well developed. The regulations were developed using engineering judgement and analyses to specify rules about design features, operations and quality assurance. This deterministic approach, using conservative assumptions in analyses and supplemented by following the defence in depth safety philosophy, has generally resulted in substantial safety margins that have served the interests of safety well over the years.

To some extent, safety regulations have always been risk informed, in the sense that there was an attempt from the earliest times to design a plant's safety systems and accident mitigation systems with capabilities commensurate with the risk significance of design basis accidents thought to pose the most risk to public health and safety. These qualitative risk insights were sometimes augmented by quantitative risk analyses, for example in the requirements for safety train redundancy.

Since the introduction of a complete probabilistic safety assessment framework in 1975, PSA methodology has matured and found widespread usage in OECD countries. By now there is a vast literature on the technology and uses of PSA, and it is generally accepted among OECD regulatory bodies that PSA methods can be used to augment the traditional deterministic methods for regulatory decision making. In many cases, PSA provides deeper insights and a more balanced picture of the actual risks posed by operation of nuclear plants than the largely conservative deterministic analyses. At the same time, it is recognised that a PSA, like all other methodologies,

has limitations in portraying the total risk at a plant. For example, a PSA cannot model safety culture and is therefore unable to quantify the risk impact of a poor safety culture at the plant. For this reason, regulators are generally cautious in using PSA bottom line estimates of risk (such as core damage frequency) as the sole basis for making regulatory safety decisions for a plant. But a PSA does not have to be perfect to be of value to the regulator and the operator. Therefore, recognising the strengths and weaknesses of probabilistic safety analyses, the regulator is faced with the question of how extensively to use risk information in its regulatory decision-making process.

In some countries the regulatory body has the explicit policy to use PSA wherever practical in its decision-making process as a complement to deterministic approaches. Other regulatory bodies rely largely on deterministic regulations and methods, with only a limited use of PSA information. Within this spectrum among OECD countries there is nonetheless a general consensus that PSA, if properly used, can be an effective tool for supporting the regulatory decision-making process. Some of the areas where it is generally agreed that PSA can be most useful are:

- Identification of plant vulnerabilities.
- Ranking accident sequences according to their relative contribution to risk.
- Ranking the relative risk importance of different systems, components, and operator actions.
- Specifying equipment allowed outage times and surveillance intervals.
- Scheduling maintenance and outage activities.
- Analysing operating events for lessons learned.

In the final analysis there is no single approach to using risk information in decision making that is correct for all regulatory bodies. Each regulator must judge for itself how much weight should be given to risk information and at what pace to introduce risk informed judgements into its decision-making process. There are some basic guidelines that the regulator can use to assist in its judgements on the use of risk information:

- The regulator needs to ensure that a PSA used to generate risk information for decision making is of high quality.
- The operator’s staff should have a depth of competence and experience in using PSA methodology.
- The regulatory staff itself should be knowledgeable of PSA methodology and its limitations.
- The risk information from PSAs should not be used to replace the defence in depth safety philosophy.
- PSA results should be judiciously interpreted and used with consideration of their limitations and uncertainties.

Communicating regulatory decisions

In any discussion of the basic principles and criteria that a safety regulatory body should consider when making a decision that can affect a wide range of stakeholders, it is necessary to keep in mind how those stakeholders might view the decision and its rationale. In this regard, it is important for the regulatory body to consider how its decisions are communicated to its stakeholders.

For most decisions of the type discussed in Section 2, the regulator will have procedures, such as a letter to the operator or a press release that will be sufficient communication of the decision. For the more difficult issues, particularly those that are complicated or publicly contentious, the regulator should consider a careful written explanation of its decision. After all, the published decision by the regulatory body is the major product of the decision-making process that the general public will see. For this reason, the regulator should strive to make sure its written decisions are transparent and will be seen by impartial observers to be fair to all parties.

There are some special circumstances, such as during emergencies, where a regulator may have special communication policies to be followed. For important public policy decision of special interest to the public the regulator may augment its regular communication procedures with meetings with local government authorities and the public to discuss the decision and its basis.

In preparing the written decision, the regulator should consider some of the questions from Section 3.

- Were normal procedures followed?
- Is there a clear legal basis for the decision?
- Is there a clear safety basis for the decision?
- Were all stakeholder views considered?
- Was there due diligence used in gathering the necessary information?
- Is the decision consistent with earlier precedents?

For many of the difficult issues facing the regulator, the outside party most directly affected will be the plant operator. In some complex or contentious cases, the regulator may want to explain the written decision in a meeting with the operator, perhaps in a meeting open to the public.

Summary

This report has described some basic principles and criteria that a regulatory body should consider when approaching the wide range of decisions faced in the course of its daily responsibilities. In addition to these basic principles and criteria, it was emphasised that the regulatory body should have internal procedures for an integrated framework for making regulatory decisions. The basic elements of such an integrated framework were outlined in this report.

There is no guide or handbook that will tell a regulator how to make a proper decision, especially for difficult cases where the issues may be contentious and the circumstances unique. That is the value of having a decision-making framework to fall back on. Beyond that, the regulator will have to rely on its experience and good judgement, keeping in mind that safety, and, to some degree at least, the credibility of the regulatory body may be at stake in the regulatory decision and the way it is made.

14. The Regulatory Goal of Assuring Nuclear Safety

Foreword

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. In particular, the Committee reviews current practices and operating experience.

Over the past decade the CNRA has produced a series of twelve reports, known as the "green booklets", which look at a number of regulatory challenges. These booklets form part of a mosaic which, when put together, provide most of the major elements of a nuclear safety regime. The objective of this booklet was to bring together these elements and others to show how regulators can develop an overall process for integrated safety assessment. Based on the consensus of the CNRA members at their June 2006 meeting, a Senior-level Expert Group was formed to produce a report on *The Regulatory Goal of Assuring Nuclear Safety*.

The report was prepared by Thomas Murley and Samuel Harbison on the basis of discussions with, and input provided by, the members of the Senior-level Expert Group listed below. Ulrich Schmocker (HSK, Switzerland) skilfully chaired the meetings and the work of the group.
John Loy (Australia), Ken Lafreniere (Canada), Petr Brandejs (Czech Republic), Marja-Leena Jarvinen (Finland), Guillaume Wack (France), Michael Herttrich (Germany), Lamberto Matteocci (Italy), Eiji Hiraoka (Japan), Shunsuke Ogiya (Japan), Woong Sik Kim (Korea), Marli Vogels (The Netherlands), Andrej Stritar (Slovenia), Lennart Carlsson (Sweden), Peter Flury (Switzerland), Colin Potter (United Kingdom), Jim Dyer (United States), James Wiggins (United States), Adriana Nicic (IAEA) and Barry Kaufer (NEA).

Introduction

The fundamental objective of all nuclear safety regulatory bodies is to ensure that nuclear facilities are operated at all times in an acceptably safe manner including the safe conduct of decommissioning activities.[1] In meeting this objective the regulator must keep in mind that it is the operator that has the responsibility for safely operating a nuclear facility. The nuclear regulator's

1. NEA (2002), *Improving versus Maintaining Safety*, OECD, Paris.

responsibility is to oversee the operator's activities in order to assure that the facility is operated safely. Nothing the regulator does should ever diminish that fundamental distinction in roles between the operator and regulator.

Of comparable importance to the regulator's effectiveness in assuring nuclear safety is the need for stakeholder confidence in its technical competence, integrity and sound judgement. Thus, a regulator's decisions must be technically sound, transparent, and consistent from case to case, and seen by impartial observers to be fair to all parties.

To meet its responsibility to proactively promote safety, the regulator will have in place a set of requirements that the operator must follow in order to operate the facility safely, to assure the security of nuclear materials, to protect the environment, and to manage safely radioactive waste and spent nuclear fuel. The regulator conducts oversight activities at facilities to gain assurance that activities are being conducted in a safe manner and, in case they are not, acts to see that the operator takes corrective actions to bring the facility into compliance with requirements and the facility's safety envelope. In the course of its routine activities, the regulator makes ongoing judgements on the acceptability of the level of safety of the facilities it regulates. For any regulator one of the most important questions is "How can I judge whether my actions are actually assuring an acceptable level of safety at nuclear facilities?" but this is never a simple or straightforward question to answer.

For example, in the weeks and months leading up to the accidents at TMI-2 and Chernobyl, there was no unequivocal evidence that the reactors were skirting on the edge of disastrous accidents. To be sure, in retrospect it was possible to discern several signs of design weaknesses, operator training deficiencies and safety culture problems at both facilities but these did not alert either the operators or the regulators to the impending accidents. A major lesson from both accidents is the need for the regulator to be sensitive to such early signs of weaknesses and problems and to take pre-emptive actions to require improvements before severe accidents can occur.

There are today, many sources of information available to the regulator pertaining to safety at any nuclear facility, such as inspection reports, operating experience reports, research results, periodic safety reviews, probabilistic safety analysis (PSA) results, insights from IAEA reviews and other similar information. A major challenge for the regulator is to systematically collect and analyse this information in order to arrive at an integrated assessment of the level of safety of the particular facility and then to make a judgement about its acceptability.

Clearly, regulatory bodies around the world have been making such judgements for the past five decades, relying mainly on the competence, experience and impartiality of their staff. During that time they have developed criteria and regulations to guide their inspectors in reaching safety judgements. The excellent safety record of the nuclear industry indicates that this process has been generally satisfactory.

More recently, a number of regulatory bodies have started to develop more systematic ways of measuring, recording and analysing safety information in order to arrive at a more quantitative

and transparent assessment of the safety level achieved. They recognise the benefits of using a systematic approach but also recognise that, while it is desirable, it is not necessary to have a formal systematic assessment system in order to have an efficient and effective regulatory organisation.

The principal advantages of using such a systematic approach are that it gives an objective, transparent and reproducible snapshot of the safety performance of a facility or a licensee, it provides a basis for trending safety performance at individual facilities, and it assists the regulator in setting safety priorities for future regulatory actions. In addition, it should improve the efficiency of the regulator and, if applied correctly, it should also make the regulator more effective.

The challenge for any regulatory body is to identify an approach that is systematic, comprehensive, has well-defined safety acceptability guidelines and is of practical help in reaching sound, transparent and timely decisions within the laws and regulatory culture of the country in question. In order to assist member countries to address this challenging question, the CNRA has sponsored this report.

While this report focuses on the benefits of having an integrated safety assessment system, one must keep in mind that there is no single, right way of carrying out such an integration. This report provides advice on the necessary attributes and basic components of any systematic method, with examples of how the safety components can be integrated and suggestions about the subsequent decision-making process. Clearly, no integrated safety assessment system should be so rigid that it precludes the possibility of individual safety judgements by experienced experts and senior managers in the regulatory body, especially if a facility has been showing an unusual number of events or regulatory non-conformances. Furthermore, it must always be remembered that the safety information available to any regulatory body can only ever be a sample of the total safety picture. Therefore, when using an integrated safety assessment system, regulatory bodies need to beware of assuming, or of giving the impression that the outcome provides an absolute determination of the safety of the facility in question.

The primary focus of this report is on how the regulatory body can systematically collect and make an integrated analysis of all the relevant safety information available to it and arrive at a sound judgement on the acceptability of the level of safety of the facilities that it regulates. It follows, therefore, that the audience for this report is primarily nuclear regulators, although the information and ideas may also be of interest to nuclear operators, other nuclear industry organisations and the general public.

The elements of nuclear safety

"The fundamental safety objective is to protect people and the environment from harmful effects of ionizing radiation."[2] Nuclear safety therefore means the achievement of proper operating conditions, prevention of accidents or mitigation of accident consequences, resulting in protection

2. IAEA (2006), *Fundamental Safety Principles,* IAEA, Vienna.

of workers, the public and the environment from undue radiation hazards. This definition includes the common understanding of nuclear safety as freedom from physical harm, meaning both acute and latent health effects from exposure to radiation. But the regulator must recognise that the general public also expects to be protected against frequent, potentially dangerous events (near misses), and therefore the definition of nuclear safety must include freedom from danger, or unreasonable risk. Furthermore, all stakeholders expect to be protected from environmental damage such as radiological contamination of land, water supplies, buildings and livestock. Therefore, in this report a broader understanding of nuclear safety is used, namely "freedom from physical harm, unreasonable risk and environmental damage due to the operation of nuclear facilities."

Here, operation includes not only facility operation but also the handling and disposal of spent fuel and radioactive waste and the transport of radioactive materials. In principle, safety at nuclear facilities includes protection from harm due to non-radiological accidents (such as falls or chemical spills) but in this report we shall focus solely on radiological protection of workers, the general public and the affected environment. Finally, the term freedom from unreasonable risk is understood to include freedom from security breaches at the facility and from diversion of nuclear materials to unauthorised persons.

Having established this broad understanding of safety, one must examine the elements of the detailed framework of safety. The international nuclear community has developed the fundamentals of nuclear safety in great depth and breadth over five decades of nuclear facility experience. In the early years of nuclear technology, the primary focus was on development of basic physics and engineering principles, safety system design features, codes and standards, and general design criteria governing such matters as redundancy and diversity of safety systems. From the mid-1970s the development of probabilistic safety assessment (PSA) brought important insights into the initiation and progression of potential accident scenarios and the contribution that different systems and components make to the overall safety of a facility. It led to risk-based insights into the operation and maintenance of facilities and gave the possibility of comparing achieved safety against numerical safety goals. As operating experience was gained, it showed the importance of human performance aspects of safety, including operator qualification and training, emergency operating procedures, accident mitigation measures, and emergency planning. In more recent years the importance of operational safety culture has come into clearer focus.[3] A strong safety culture is important to ensure the integrity of the multiple barriers of the entire defence in depth safety fabric. That is, the safety values, norms and attitudes of an entire operating organisation are just as important as the design and construction of the facility.

The defence in depth safety concept has long been recognised as a key element in ensuring safety.[4] After being refined and strengthened through years of application, the concept can best be described as multiple, independent levels of protection (or barriers) that would have to fail before harmful effects from radiation could be caused to the public or the environment. The concept of

3. NEA (1999), *The Role of the Nuclear Regulator in Promoting and Evaluating Safety Culture*, OECD, Paris.
4. IAEA (1996), *Defence in Depth in Nuclear Safety, INSAG-10*, IAEA, Vienna.

defence in depth has served safety well over the years and continues to be an effective method of accounting for uncertainties in equipment and human performance. As noted above, it applies not only to barriers and safety functions but also to human factors and organisational aspects.

There is no unique way of grouping the elements of nuclear safety. For the purposes of this report, they are grouped under the following three general headings:

- Technical.
- Human factors and organisational.
- Programmatic and cross-cutting.

Each of these safety elements is made up of a number of safety components, examples of which are listed below. The grouping of these safety components is not unique but the sum of the components is believed to be comprehensive.

Components of technical safety

- A solid foundation of knowledge of the basic physics, chemistry and engineering of nuclear technology.
- A robust facility design which uses established codes and standards that embody design margins, qualified materials, redundant and diverse safety systems, and which protects against the full range of nuclear, conventional and external hazards.
- A robust and properly resourced programme for ensuring that the facilities are designed, constructed, operated, maintained and tested in accordance with the design specifications and safety analyses.
- A strong engineering function that maintains plant, systems and equipment in accordance with the facility design basis, analyses technical and facility ageing issues as they arise, and provides support to operations and maintenance.
- Safety assessments of all changes and backfits made during the life of the facility.
- A radiological protection programme that ensures all personnel is adequately protected against the harmful effects of the ionizing radiations emitted from the nuclear facility and its fuel cycle.
- A programme for utilising the probabilistically-developed risk insights derived from systems analysis and operational experience.

Components of human factors and organisational safety

- Sufficient properly qualified, trained, and fit-for-duty personnel to operate the facility, maintain the equipment, implement the radiation protection programme, and who demonstrate a questioning attitude toward all aspects of operation of the facility.

- An operating staff that follows conservative decision-making principles and has a profound respect for the reactor core and radioactive materials, keeping them under absolute control at all times.
- A comprehensive set of operating, maintenance, and accident management procedures, including severe accident management guide-lines that have been developed and tested using established man-machine interaction principles.
- A strong corporate management organisation with a leadership that establishes a set of values emphasising the priority of nuclear safety, making it clear that workers should not have a conflict in their daily tasks between safety and other business goals, and that provides adequate resources to ensure that the facility is operated safely.
- A facility management organisation that has clear lines of authority and responsibility for safety and that facilitates openness, a questioning attitude, confidence between employees and managers, control of quality in all activities, and strict adherence to safety procedures.
- A programme and procedures for the management oversight of all safety-related work done by contract workers for or at the facility.

Components of programmatic and cross-cutting safety

- Operational limits and conditions (or technical specifications) that define and govern the safe operating envelope of the facility and ensure that radiation exposures are kept as low as reasonably achievable.
- Programmes such as fire protection and surveillance testing that are critical components of the defence in depth safety philosophy of maintaining multiple barriers, both physical and procedural, against severe accidents.
- A programme of operating experience analysis, trending analysis and feedback to operations.
- A programme of initial and continuing training to ensure an operating staff of qualified workers.
- A configuration management programme that maintains the safety design basis of the facility as approved by the regulatory body.
- An ageing management programme that monitors the potential deleterious effects of ageing on systems, structures and components and requires proactive steps to maintain the safety design basis.
- A change management programme that ensures that organisational changes do not inadvertently diminish operational safety.
- Effective integrated management systems (including quality assurance, self-assessment and corrective action programmes).

- A safety culture that has been instilled throughout the operating organisation based on the highest safety values and that fosters an attitude of conservative decision making.
- Emergency plans, which have been thoroughly reviewed and tested, to enable actions to protect both onsite workers and offsite populations in the event of a nuclear accident.
- Access to a continuing programme of nuclear safety research that is designed to add to the basic knowledge of safety fundamentals.
- Facility siting and environmental policies that promote offsite protection.
- Security plans that are tested and kept current to prevent threats to the facility and to prevent unauthorised use of nuclear materials.

In addition to these safety elements that apply to operation of a nuclear facility, there must be a safety regulatory body that has the legal authority, technical competence and adequate resources to independently assure that nuclear facilities are designed, built, operated and decommissioned safely.

Safety criteria

Regulatory bodies have the legal duty and authority to make final safety judgements on all nuclear activities under their responsibility. In a practical sense a nuclear activity is deemed to be safe if the perceived risks are judged to be acceptable. But the regulator can never have a certain quantitative assessment of the risks involved. Therefore, in arriving at its safety judgements, the regulatory body must be guided by the basic safety criteria embedded in its national laws, regulations and policies. One of these criteria is the level of safety protection required by the regulator. There are various statements of the basic level of safety required by OECD/NEA countries, but they all acknowledge that it is not possible to achieve absolute safety (i.e., zero risk) in nuclear activities. Some of these criteria are:

- No unreasonable risk.
- Adequate protection of public health and safety.
- Risk as low as reasonably practicable.
- Safety as high as reasonably achievable.
- Limit risk by use of best technologies at acceptable economic costs.

A related safety criterion is the degree of assurance needed by the regulator that the basic level of safety protection is being met. Here again, there are various formulations of this criterion among OECD/NEA countries, but they all recognise that absolute assurance cannot be achieved. Most countries have some variation of a "reasonable assurance" criterion.

These basic safety criteria are seen to be qualitative, aspirational criteria rather than quantitative safety requirements that must be demonstrated to the regulator. In practice these criteria are what some may call "revealed standards". That is, the cumulative experience of a

regulatory body's safety judgements over many years will yield a working definition of what these criteria mean.

It is recognised that nuclear facilities generally operate well above the minimally acceptable levels of safety implied by these qualitative safety criteria. Therefore, much of the regulator's oversight actions are directed toward judging compliance with regulations, assessing safety margins and looking for negative or positive safety trends.

Changing level of safety

As a practical matter, the actual level of safety of any given facility is constantly changing, for a number of reasons.

a. Physically the facility is not constant over time. Redundant safety systems are occasionally taken out of service for on-line maintenance during operation, thereby altering the risk profile of the facility in the short term. Over the longer term, as the facility ages and new and updated component parts are introduced, its performance characteristics change.

b. New knowledge about facility performance, such as equipment failure rates or newly discovered and unexpected accident sequences, changes the representation of the facility in analytical safety models and therefore changes the current understanding of the level of safety.

c. Many operators strive to improve the economic performance of their facilities by means of longer fuel cycles, new fuel designs, higher fuel burn-ups and power uprates, all of which have safety significance.

d. Organisationally there is no constant level of safety performance at a facility. Key organisational variables like interdepartmental co-operation and worker attention to quality can decay or improve over time. Ageing of the workforce and its consequent potential for complacency can change the ability of the workers to cope with unexpected events. Conversely, new managers with fresh ideas can improve operational safety performance.

e. The environment in which the facility operates may change over time. This could be due to nearby industrial, farming or housing developments or because new information emerges about the potential magnitude and frequency of environmental hazards, such as seismic events or severe weather.

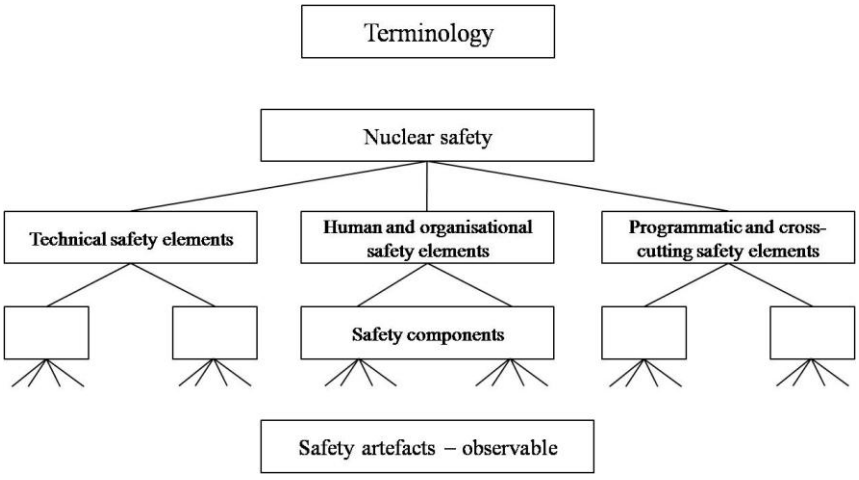
This constantly changing level of safety at nuclear facilities presents an obvious challenge to the regulator in reaching its safety judgements. Nonetheless, the consensus among international safety experts is that, if the safety elements and components above are rigorously followed, nuclear facilities can and will be operated safely.[5, 6] It is the responsibility of the regulator to continually monitor and assure that the safety elements and components are followed.

5. IAEA (2006), *Fundamental Safety Principles,* IAEA, Vienna.

Measuring safety

One of the fundamental challenges that any regulator faces is deciding how to measure[7] the safety elements in order to be satisfied that any particular facility is being operated safely. In meeting this challenge, the regulator must recognise that there is no direct means of measuring the current level of safety at a given facility, nor are there reliable indicators to predict future safety performance. Regulators generally rely on a combination of past experience, sound engineering judgement and risk-based insights to identify a number of safety artefacts which can be used to obtain information about each of the safety elements. This information is then collated and analysed to gauge the integrated safety performance of the facility. The relationship between safety elements, safety components and safety artefacts is shown in Figure 1.

Figure 1. **Relationship between safety elements, safety components and safety artefacts**



The important point is that safety artefacts are the directly observable aspects of the various safety elements and components. They include such things as:

- Safety performance indicators.
- Inspection findings and observations.
- Event findings.
- Test results and findings.
- Assessment results and findings.
- Maintenance results and findings.
- Training results, quality and programmes.

6. American Nuclear Society (2000), *ANS Position Statement on Reactor Safety*, ANS, USA.
7. In this report, the term "measure" includes qualitative as well as quantitative assessments.

- Documentation quality and completeness.
- Human resources and qualification.
- Organisational commitment to safety.
- Prompt and accurate responses to regulator's requests.

Some of these artefacts are more quantifiable than others but they all give valuable information to the trained regulator.

Each regulator has to develop its own suite of safety elements, components and artefacts, depending on national circumstances and safety approaches. Clearly it must have a sufficiently competent and experienced staff to be able to comprehend the significance of each piece of safety information and reach a judgement about its implications for the overall safety of the facility. In addition to the normal sources of safety information described above, the regulator's assessment systems should be able to integrate outside information as well. Examples of outside information include foreign operating experience, relevant non-nuclear experience, seismic and severe weather experience, and even anonymously provided information. The regulator's internal systems must be integrated properly so that information passes quickly and accurately between different parts of the organisation and the inputs of all relevant inspectors and technical specialists are taken into account in reaching safety judgements.

Traditionally, regulators have monitored a wide spectrum of safety artefacts to gain assurance about the safe operation of any nuclear facility but they have generally relied on the competence and experience of their staff to make qualitative, engineering judgements about the adequacy of the safety being achieved at the facility. Over the past few years, some regulators have started to devise systems for measuring and recording safety artefacts in a more systematic way in order to provide a more quantitative and transparent assessment of the level being achieved for each of the elements of safety. The aim is to allow the regulator's safety judgements to be made in a traceable way that stakeholders, especially the licensees and the public, can understand.

It has to be recognised that devising and implementing such a systematic approach to safety assurance has significant resource implications for the regulator. The extent of this additional resource commitment should be analysed and evaluated within the regulator's business plan before any final commitments are made. It may be useful for the regulator to begin with a small pilot programme for one or a few facilities, using the resources at hand, while it develops its methodology and internal processes. After perhaps a year's experience using the pilot programme the regulator can decide whether to expand the programme and perhaps request more resources.

Establishing the safety framework

Regulators do not achieve safety. Their responsibility is to observe the level of safety being achieved by the operators, make a judgement about its adequacy and then take any necessary regulatory action. The information available to them can never be fully comprehensive or complete and so an element of regulatory judgement is always necessary. In order to ensure that this judgement is as objective and reproducible as possible, the regulator should set a framework

of safety norms and requirements which, if properly implemented, should ensure an adequate level of safety. Some of the techniques for establishing such a framework are:

- Setting standards and issuing regulatory guides

  Most regulators have processes for setting nuclear safety standards which guide both the operators and the regulators on the level of safety that should be regarded as the best that is reasonably achievable. The level of detail varies from regulator to regulator, depending on the regulatory approach and national situation. Irrespective, however, of the level of detail in the standards, most regulators recognise the value and importance of issuing regulatory guides to explain fully the expectations for different facilities, phases of operation, etc. The status of such regulatory guides and the extent to which they will be used to measure safety achievements should be made clear to all stakeholders, especially the operators.

- Promulgating regulations

  Some regulators promulgate detailed regulations concerning the practical safety requirements for various systems and processes. In most cases these regulations are generic in the sense that they are applicable to all relevant nuclear facilities but sometimes a regulation is issued to deal with a particular safety issue on a specific cadre of facilities.

- Issuing licences and amendments

  The ultimate control of any civil nuclear facility is exercised via a licence which normally contains a number of conditions, with which the facility must comply. The licence and its conditions may be amended from time to time to reflect changing safety knowledge or regulatory requirements, or different phases of the facility's life.

Having established the safety framework that the operator is expected to comply with the next step for the regulator is to measure the extent to which the required safety elements are being adequately met within that framework. This is achieved by observing safety artefacts that give information about the components of each safety element. Safety artefacts are observed during:

- Inspections (including audits)

  Central to any regulator's attempts to gain assurance that a facility is being operated safely is the need to "go and see". This requires that the regulator must have complete and unfettered access to all nuclear facilities that it regulates. Actual observation of the performance of the facility and the safety attitudes of its staff by trained, critical, professional regulators is vitally important. Inspections are carried out to verify compliance with licence conditions and other regulatory requirements. There are various types of inspections, including:

  – The programme of routine inspections.

  – Team inspections or audits targeted at specific parts of the facility or specific technical or human issues.

- Inspections related to changes in the facility's status, such as commissioning inspections, re-start inspections, etc.
- Observation of emergency exercise drills.
- Non-routine (or special) inspections aimed at finding the root causes of apparent declining performance, for instance due to safety culture weaknesses.

Experience has shown that the benefits of any inspection are significantly enhanced by detailed pre-planning to establish clearly the safety artefacts to be measured and the success criteria for each such artefact.

- Regulatory reviews

  Regulators carry out a number of safety reviews throughout the life of a facility. Initial safety reviews help to identify the safety significant systems, components and procedures that the regulator will expect to monitor during the commissioning and operation of the facility. During the construction, commissioning and operation of any facility there are usually a considerable number of design changes which the regulator will review to ensure that they do not reduce the overall safety of the facility and that their implementation is properly reflected in operating rules or technical specifications. Proper implementation of the original design requirements and all subsequent design modifications on the facility and in the operating rules is an important safety indicator for the regulator. In addition, most regulators now require periodic safety reviews to give an across-the-board assessment of the safety of the facility and its components compared to the design basis. Such reviews provide the operator and regulator with detailed information about any ageing degradation of structures and components, and inform decisions about replacing obsolete equipment. They also give the regulator a wealth of information about how well the facility has fulfilled the safety expectations built into the original design.

- Enforcing regulatory requirements

  Operators are legally obliged to comply with all relevant regulations and regulators are responsible for enforcing such regulations. This requires that the quality of safety information provided by the operator to the regulator must be complete, accurate and timely. When a regulation is breached the regulator normally investigates the reasons for the breach and the extent of any deviation from the required level of safety before deciding what enforcement action to take. Such investigations can provide valuable information on both the technical safety of the facility (e.g. what facility defects or deficiencies allowed the breach to occur?) and the safety culture of the operator's staff (e.g. did they recognise and report the breach themselves or did they wait until the inspector discovered it?). Regulators can get significant insights from an analysis of the frequency and types of any breaches of regulations that occur at any facility.

- Reviewing operating experience

  Operating experience is one of the most reliable indicators of the safety of a facility. One of the most important means for a regulator to assess the level of safety at a facility or a group of facilities should be an evaluation of the frequency and severity of actual past operating events that may be precursors of severe accidents. Inspectors use information on such things as number of scrams, unplanned releases of radioactivity and excessive radiation exposures to give them an ongoing indication of the safety of a facility. They may even carry out their own independent review of a facility's operating experience. They also look closely at how well the operator analyses and reacts to his own operating experience and the operating experience feedback (OEF) from other facilities around the world. The accuracy, completeness and timeliness of statutory reporting of abnormal events by the operator are also important indicators of the overall safety of a facility and its operators.

- Observing attitudes to safety

  Safety is achieved on a nuclear facility through a combination of engineering excellence in the design, commissioning and operation of the facility, and a positive safety culture that pervades all members of the staff. The latter aspect is at least as important as the former but it is much more difficult to assess. Inspectors may rely on observation of the operator's attitudes to safety and safety information obtained during meetings with licensee's staff, as well as specific periodic surveys of the overall safety culture.

The following activities are essential and effective supports for the regulator in defining and measuring safety artefacts.

- Carrying out independent safety analyses

  In some situations regulators may perform or obtain an independent safety analysis of some critical safety indicator. This allows them to confirm or question the licensee's analysis and helps to establish the criteria for judging what the acceptable level of safety is.

- Sponsoring safety research

  Regulators cannot rely solely on the research sponsored by the licensee. They need to have access to independent research in order to:

  a. Have an adequate background to ensure that their safety standards are well-founded and correct.

  b. Keep their technical competence up-to-date.

  c. Be in a position to challenge the licensee's safety arguments.

  d. Be able to make informed judgements about the best indicators of safety performance.

Using a combination of the techniques discussed before to measure safety artefacts the regulator accumulates a considerable variety of measurements related to the safety of any facility.

Some will be quantitative, such as the number of unplanned scrams in a particular period, while others will be almost completely qualitative, such as the degree of conservatism demonstrated by the operators. Most will have implications for more than one safety element. For all of them the regulator must have access to all relevant information from the licence holder. Any reluctance on the part of the license holder, or the provision of incomplete or inaccurate information, are additional indicators of a poor attitude to safety. Having obtained all available measurements of safety artefacts, the regulatory challenge is then to arrive at an integrated safety judgement from them.

Making integrated safety assessments

In Chapter 2 the safety elements were grouped under three headings: technical; human factors and organisational; programmatic and cross-cutting. Using the techniques outlined in Chapter 3, regulators measure a wide range of safety artefacts related to the components of each of these elements. The challenge is then to find a consistent way of arriving at an integrated safety judgement from all this information. There are a number of factors the regulator needs to consider in developing a framework for integrated safety assessments. These factors include:

- The extent to which the different components of each element of safety are amenable to quantification

  The most straightforward aspects for the regulator to assess are the components of the technical safety element. For these there will generally be pre-determined levels of acceptability which can be applied immediately to the measured safety artefacts. The levels of acceptable safety are generally defined in the operating limits, technical specifications requirements, etc., that are derived from the facility's overall safety case, and the extent of any failure to meet one of them is immediately obvious when measured information is available. Next come those safety artefacts where it is possible to set minimum requirements in quantitative terms but where there is at least some subjective judgement in assessing the quality of the safety performance. For example, the necessary components of an acceptable emergency plan can be defined quite closely, as well as the numbers of trained staff that are needed to carry it out. While the regulator can readily check whether these are being complied with, the actual state of emergency preparedness of any facility or site can only be deduced from observations of the behaviour and interaction of staff during emergency exercises. Such observations are essentially subjective and provide qualitative safety information. Finally, there are those safety artefacts which are almost impossible to assess in a quantitative way. These generally relate to human behaviour and include conservative decision making and safety culture.

- The timeframe over which safety information is obtained

  The regulator obtains some safety information continuously (from information provided by the operators, from its inspectors, etc.), some on a frequent basis (from the inspector's regular meetings with site management, from facility modification proposals, from emergency drills, etc.) and other information on an irregular, infrequent basis (such as abnormal events, major facility outages or modifications, surveys of staff attitudes/safety

culture, etc.). It can be difficult to keep all such information in mind when making a judgement about the level of safety being achieved at any particular time or when attempting to generate meaningful information about safety trends. Clearly a system that records and organises all the relevant information should be of great help in giving the regulator an accurate overall picture of instantaneous and time-trended safety performance.

- The importance that should be given to each piece of safety information

  It is evident that different safety artefacts have different levels of importance when it comes to assessing the overall safety of a facility. For example, if a scram occurred because inadequately trained operators went outside the proper start-up envelope it would probably be of much greater concern than the fact that the licensee had cumbersome work control processes. From their technical competence and regulatory experience regulators attach different importances to different types of safety information and this needs to be reflected in any systematic method for collating and assessing safety.

Bringing the different elements together

At any one time, there will typically be thousands of safety artefacts available to the regulator. Some will be historical, relating to the original design, commissioning, construction and previous operation of the facility. Other information will come from:

- Current inspections, including audits.
- Licensee reports.
- Facility modifications and their close outs.
- Analysis of operating experience on the facility in question and elsewhere.
- The licensee's record of compliance with the license and relevant regulations.
- The results of regulatory reviews.
- Training records and the maintenance of the necessary cadre of suitably qualified and experienced personnel.
- The safety attitudes of the licensee's staff and contractors.
- Emergency exercises.

As noted previously, the regulator's integrated safety assessment system should be capable of combining both quantitative and qualitative information in order to provide a basis for the decision-making process.

In some situations the regulator's judgement about the acceptability of safety at a particular facility will be reached quite quickly on the basis of one or a few pieces of safety information. Consider, for example, the situation where, during a periodic inspection on a PWR, a licensee's NDE

(non-destructive examination) discovers cracks in the letdown line upstream of the isolation valves where the cracks are greater than the critical size and have grown significantly since the last inspection. In such a situation the regulator is likely to judge that the situation is unsafe and take immediate regulatory action, without waiting for an analysis of all the other available safety information.

In many situations, however, the regulator will have no specific safety information that demands immediate regulatory action but rather will have information on a number of different safety artefacts that do not individually or collectively yield a clear or complete picture of the safety of a facility. For such situations it is important to have an objective way of organising, integrating and assessing all the safety information for a facility (both good and bad) in order to avoid "cherry picking" those artefacts that, for whatever reason, readily attract inspectors' attention. This helps to avoid biased or arbitrary regulatory decisions and also helps with deciding the extent of any required regulatory actions and the priority areas for future regulatory efforts.

A number of regulatory bodies have recently started to develop systematic ways of measuring, recording and analysing safety elements in order to provide a more integrated, complete and transparent assessment of the safety level being achieved. In the Appendix, there are descriptions of five systems that have been developed by national regulatory bodies, plus an illustrative model which uses a "traffic light" system to indicate safety performance.

The desirable attributes of all such systems are:

- They should be *systematic*. This means that they should be able to include all observations in a pre-determined system which assigns each observation to a defined and reproducible safety "box".
- They should be *comprehensive.* The models should be capable of encompassing the entire spectrum of safety observations obtained within the three groups of safety elements identified in Chapter 2, namely technical, human factors and organisational, and programmatic and cross-cutting.
- They should be *consistent.* This means that they should ensure that reproducible and predictable results are generated from any one set of data, irrespective of which staff member enters the data or the circumstances (e.g. time) under which the analysis is carried out. Their treatment of quantitative and qualitative information should be compatible and logical. The results should be coherent in terms of the types of facilities involved and the safety trends predicted.
- As far as possible, they should contain pre-determined *acceptability guidelines* for safety artefacts which should be based on the regulator's requirements and expectations for safety performance. This is an important though difficult and time-consuming aspect of setting up such systems. The basic framework for acceptability derives from the concepts of defence in depth, safety goals and barriers. The five levels of defence in depth have been defined in INSAG-10 (see Footnote 4). Most regulatory bodies have regulations or criteria which attempt to establish acceptability guidelines, while recognising the challenges of dealing

with difficult topics such as human errors and events with only a remote probability of occurrence. For certain types of safety information the acceptability guidelines are immediately defined from the safety case in terms of technical specifications or operating rules. For many others, however, the acceptability guidelines can only be arrived at on the basis of the professional judgement of experienced inspectors with a deep knowledge of the facility in question, taking due account of the relevant regulations or criteria. This implies a requirement for significant involvement of inspectors during the setting up of such systems and their continuing involvement to assess the safety significance of inspection observations and to help judge acceptability guidelines. Defining such acceptability guidelines often entails a regulatory discussion about the necessary margin of safety above some minimum level, as well as what the regulatory expectations should be based on previous industry performance.

- It is very useful for the system to be able to generate information about the *trend* of safety performance with time to enable a graded regulatory response.
- Finally, the system should generate information in a form that helps the regulator to reach *decisions*. It should provide a methodology for analysing the overall safety significance to a degree sufficient for taking graded regulatory actions before an unacceptable level of safety performance is reached.

There are clearly some challenges involved in setting up and operating such an integrated safety assessment system. To begin with, the regulatory body needs to devote significant time and resources to analysing the many different types of safety information that are available to it and the means by which it is obtained. It then needs to identify the criteria of acceptability (where they exist) for each safety artefact and, if possible, the relative importance of each artefact. A special challenge for the regulator is how to assess the non-technical safety elements, particularly safety culture and organisational safety elements. Earlier NEA reports have described methods for the regulator to recognise early signs of declining safety performance and signs of a weak safety culture.[8, 9] Finally, the regulatory staff need to reach a consensus on the criteria for applying the system.

After the initial, resource-intensive set-up phase there will be a continuing commitment on all relevant regulatory staff to report their safety information in a way that allows the system to be operated efficiently and effectively. It seems likely that most regulatory bodies would find it appropriate to have a dedicated resource to input the data and prepare the necessary tables. The information in such tables would then help the regulator to take action and set inspection priorities as discussed in the next chapter.

8. NEA (1999), *The Role of the Nuclear Regulator in Promoting and Evaluating Safety Culture*, OECD, Paris.
9. NEA (2000), *Regulatory Response Strategies for Safety Culture Problems*, OECD, Paris.

Implementing and communicating integrated safety assessments

In a previous booklet on nuclear regulatory decision making it is stated that, in meeting the goals of technical soundness, consistency and timeliness, the regulator should be guided by an integrated framework for making decisions.[10] Most regulatory decisions relate to or flow from the regulator's fundamental goal of assuring nuclear safety and should be based on a systematic and comprehensive assessment of all the safety elements.

Chapter 4 discussed the main attributes of any systematic method for handling the many safety artefacts that the regulator needs to consider when reaching an integrated safety judgement. The major benefits of using such a system are that it allows the regulator to have a comprehensive, balanced and transparent picture of the state of safety of a facility and facilitates an instant comparison with previous assessments.

The results of any systematic method will normally be presented in a tabular form which identifies where the weak areas of safety performance lie and shows whether safety performance has improved, deteriorated or remained constant since the last assessment. Where the table(s) point to some general area of weakness, such as human factors, the regulator will normally go back to the more detailed tables to identify which particular safety components had been assessed as less than satisfactory. Discussions amongst regulatory staff, supplemented by reference to the relevant safety artefacts, then assist management to determine what actions need to be taken and on what timescales.

There will, of course, be situations where very rapid regulatory action is called for, e.g. where one or more of the safety elements is clearly unacceptable. Consider, for example, the integrated safety assessment that might be generated for a facility that had suffered a significant, uncontrolled leakage from its secondary coolant system due to a long-standing corrosion problem that had been missed by the in-service inspection programme and the negligence of the operators. Clearly this would call for immediate regulatory action, especially if the facility had other signs of a poor safety culture or other unsatisfactory organisational factors. It might also result in the regulator reviewing its own systems to see whether lessons needed to be learned about the efficiency and effectiveness of its procedures. Nevertheless, even in those situations where immediate action is needed a systematic decision-making framework will benefit the regulator by fostering consistency and efficiency.

All regulatory decisions should be based on the accumulation of systematic, recorded evidence. Normally, the regulator would generate an integrated safety assessment table for each nuclear facility showing, where relevant, the trend of different safety elements with time. In evaluating the significance of this integrated assessment the regulator will ask itself questions such as, "Do we understand the basic reasons why a safety element assessment has changed from satisfactory to marginal or even unsatisfactory?" and "Do we understand why an assessment continues to show marginal or unsatisfactory – that is, why do the operator's corrective actions appear not to be effective?".

10. NEA (2005), *Nuclear Regulatory Decision Making*, OECD, Paris.

The outcome of the systematic analysis helps to inform the regulator's decisions on such things as:

- The need for enforcement action to ensure compliance.
- The assessment and inspection priorities for the facility in the next time frame.
- Any industry-wide regulatory initiatives to deal with emerging safety issues or to set an example for all licensees of the consequences of becoming complacent and allowing operational safety to slip below acceptable levels.
- The need for additional research and safety studies.
- The need to transmit safety improvement lessons to other facilities and other regulators.
- The need to transmit lessons to the wider international regulatory community.

Whatever actions the regulator decides to take should be recorded properly and communicated to the operators and other stakeholders, as appropriate. This is an important step in ensuring that the stakeholders have confidence and trust in the regulator's technical competence, integrity and sound judgement.[11]

The stakeholders with a legitimate interest in nuclear regulatory activities are discussed in the NEA booklet on improving nuclear regulatory effectiveness[12] and include: the general public, nuclear licensees, Government departments and agencies, national and international bodies concerned with nuclear power, and concerned action groups.

There is a wide variation among these stakeholders in their level of technical sophistication and understanding of the technical details underlying the regulator's safety judgements. As a consequence the regulator must give careful thought to the challenges of communicating complex safety issues. A special challenge is how to deal with issues that may be of low public health risk but that are of high public concern, such as tritium leakage to groundwater or other small radioactivity releases to the environment.

Some principles the regulator should follow in communicating its safety judgements are the following:

- Strive for openness, completeness and transparency in giving the full story of the safety issues involved, the basis for the regulatory judgement about them, and what is being done to resolve them. Often it is useful to give a plain language summary that is stripped of technical jargon that may not be intelligible to a general audience.
- Explain the regulator's conservative safety philosophy, in particular the defence in depth philosophy that requires multiple barriers to protect the public against radiological harm.

11. NEA (2006), *Building, Measuring and Improving Public Confidence in the Nuclear Regulator*, OECD, Paris.
12. NEA (2001), *Improving Nuclear Regulatory Effectiveness*, OECD, Paris.

- Give a straightforward, objective technical assessment of the nuclear safety issues involved, trying to achieve a balance which avoids either minimising the safety problems or being unduly alarmist in describing them. If relevant, refer to regulatory acceptability criteria for the elements of safety involved and explain the extent of any deviations from them.
- Invite licence holders to give their assessments of their own safety performance.
- Discuss and, if possible, reconcile any differences in perception of performance but, in any case, do not make excuses for weaknesses or misconduct on the part of the licensees.
- Explain clearly how the regulator and the licensee are separately taking actions to resolve any safety issues.
- Acknowledge where the regulatory body itself has learned lessons on how it can handle safety issues better in the future.

There are various means for communicating the regulator's safety judgements. The fundamental document is the regulator's record of its safety decision and its basis, produced according to the regulator's standard procedures. This may be made public and may be accompanied by a press release summarising the decision in plain language for a broad audience.

In preparing the written decision on its final safety judgement, the regulator should consider and answer the following questions in order to reassure stakeholders:

- Were normal procedures followed?
- Is there a clear legal basis for the decision?
- Is there a clear safety basis for the decision?
- Were all relevant stakeholders' views considered?
- Was due diligence used in gathering necessary information?
- Is the decision consistent with earlier precedents?

The advantage of having the available information organised in a systematic way, as discussed in the previous chapter, is that it not only allows a balanced, reproducible regulatory decision to be reached but it also gives a sound basis for providing answers to the above questions which are fundamental to reassuring stakeholders.

Summary and conclusions

This report addresses the fundamental question facing all nuclear regulatory bodies, "How can the regulator judge whether its actions are actually assuring an acceptable level of safety at nuclear facilities?"

After establishing the broad understanding of nuclear safety to be used in this report, the synthesis of worldwide experience regarding the elements of safety was presented in three broad

categories: technical; human factors and organisational; and programmatic and cross-cutting. This was followed by a description of the activities a regulatory body undertakes to measure the detailed components of the various safety elements.

The necessary attributes of any systematic method for organising and evaluating the large amount of safety information available to the regulator are described in detail, followed by a discussion on how a regulator might use this comprehensive assessment information to arrive at the integrated safety judgements that are of vital importance in deciding regulatory actions and setting priorities for future regulatory activities.

Finally, the report discusses the importance of openly communicating the regulator's safety judgements and suggests some principles for doing so.

The ideas and suggestions in this report cannot be viewed as a rigid formula for all regulators to follow. Indeed it is clear that, while a formal systematic approach is desirable, it is not a necessity for achieving effective and efficient regulation. It has to be recognised that the output of any systematic approach is only as good as the data fed into it and regulators should avoid giving the impression to their staff or stakeholders that it provides a magic formula for assessing safety. Sound safety decisions will continue to rely heavily on the experience, wisdom and good judgement of the regulator's staff.

However, experience shows that there are clear benefits in having in place a systematic process for collecting and analysing safety information. Not only does it help the regulator to make integrated judgements about the acceptability of safety at the nuclear facilities it regulates but it also gives a sound basis for communicating and defending its decisions in a transparent way, thereby improving stakeholder confidence. Additionally, it informs future regulatory priorities, facilitates feedback to inspectors, helps promote regulatory consistency and assists knowledge management and knowledge transfer to new inspectors.

When a regulatory body decides to develop such a systematic approach to assist its decision making, it will need to tailor the methodology to be consistent with its national laws, requirements and procedural traditions. Establishing a workable approach will involve a considerable initial resource commitment, followed by a lower-level, but still significant, continuing resource commitment to ensure the system functions effectively and efficiently.

Appendix: Descriptions of Some Integrated Safety Assessment Systems

A. Introduction

This appendix gives a brief description of the main features of five different national integrated safety assessment (ISA) systems. The five ISA systems are broadly consistent with the principles and attributes discussed in this report, but the details of how the systems work are, of course, very different. There is no single right answer for how an ISA system should be developed and implemented. Each regulatory body has to develop its own system based on its national laws, regulations and safety practices. In order to assist regulators, an illustrative system has been developed, based on the three groupings of safety elements defined in Chapter 2, which uses a "traffic light" system to indicate the acceptability of different pieces of safety information. This illustrative system is described at the end of the Appendix, though it has to be recognised that much more development and analysis would be needed before it could be applied in practical situations.

B. National integrated safety assessment systems

1) The system of the Swiss Federal Nuclear Safety Inspectorate (HSK)

Additional information can be obtained by going to: www.hsk.ch

HSK has implemented an integrated safety assessment system for nuclear power plants (called an integrated oversight process) that generally meets the attributes described in this report. The sources of information used in this assessment are inspections, operator licensing data and event analysis data. In the future they plan to include information from licensee reports, safety indicators (i.e. PIs) and insights from plant modification authorisations.

The basic idea behind this system is to assess the design, the operational requirements and operational experience. The assessment of the requirements includes a thorough check to see if the applied design requirements are still valid in the light of the latest information from research and worldwide operational experience. Another purpose of the assessment is to check if the operational requirements (technical specifications, check lists, operational handbook, emergency guidelines, etc.) correctly reflect the allowed operational regime; if test procedures are complete and steps in the procedures are safe and in the correct order; and if the emergency guidelines are safety goal oriented. Operational experience is assessed by comparing it with operational requirements. Technical aspects are distinguished from human/organisational aspects to recognise that safety is not only dependent on the correct technical design and its implementation but also relies on the correct work of operational and maintenance staff.

To judge the safety importance of the requirements and the operational experience, each aspect is assigned to the corresponding levels of the defence in depth concept, to the corresponding barriers and to the corresponding safety functions. This systematic approach results in a two-

 IMPROVING NUCLEAR REGULATION, ISBN 978-92-64-99162-0, © OECD 2011

dimensional matrix as shown in Table 1. For each NPP, each data point which is based on inspection or assessment findings, on event analysis, etc. is assigned to one of the cells of this table.

The causes of each finding have to be carefully analysed. Experience shows that very often an observation or finding is caused by a number of different contributing factors. Quite often, both technical and human/organisational aspects play a role. In addition, a technical or human/organisational aspect can affect more than one level of the defence in depth or more than one barrier or safety function at the same time. Therefore each observation or finding can be assigned to one or several cells in the safety matrix.

The systematic safety assessment system is not only a process that defines how each data point contributes to plant safety; the structure also defines what kind of information has to be gathered to get a complete picture.

Findings are rated on a scale that is based upon the international nuclear event scale (INES). The goal of the scale is to assess all levels of safety performance from good practice to severe accidents on one single scale. The categories are defined as follows:

- **Category G: Good practice**

  All requirements are fulfilled and the practice of other NPPs is clearly exceeded.

- **Category N: Normality**

  All requirements are fulfilled.

- **Category V: Need for improvement**

  Deviations from requirements in documents that do not need formal authorisation by the Swiss Federal Nuclear Safety Inspectorate fall into this category.

- **Category A: Deviation**

  Deviations from normal operation within operational limits and conditions.

- **Categories 1 to 7**

  Rating according to the INES-Manual.

Categories V and A correspond to INES 0. Findings from inspections falling into categories A or higher will be treated as events. Any finding V and higher requires action.

The overall evaluation of the ratings is a resource intensive process whereby each rating (particularly negative ratings) are cross-validated by independent staff and qualitative judgements are made for the sum of the results for design requirements, operational requirements, plant

behaviour and human and organisational behaviour. Senior regulatory managers review these quantitative and qualitative ratings and arrive at an overall judgement on the safety performance of the plant being assessed. HSK produces an ISA for each reactor plant annually, and the results are used as a basis for annual reports to the national legislative body as well as for a guide for future inspection plans.

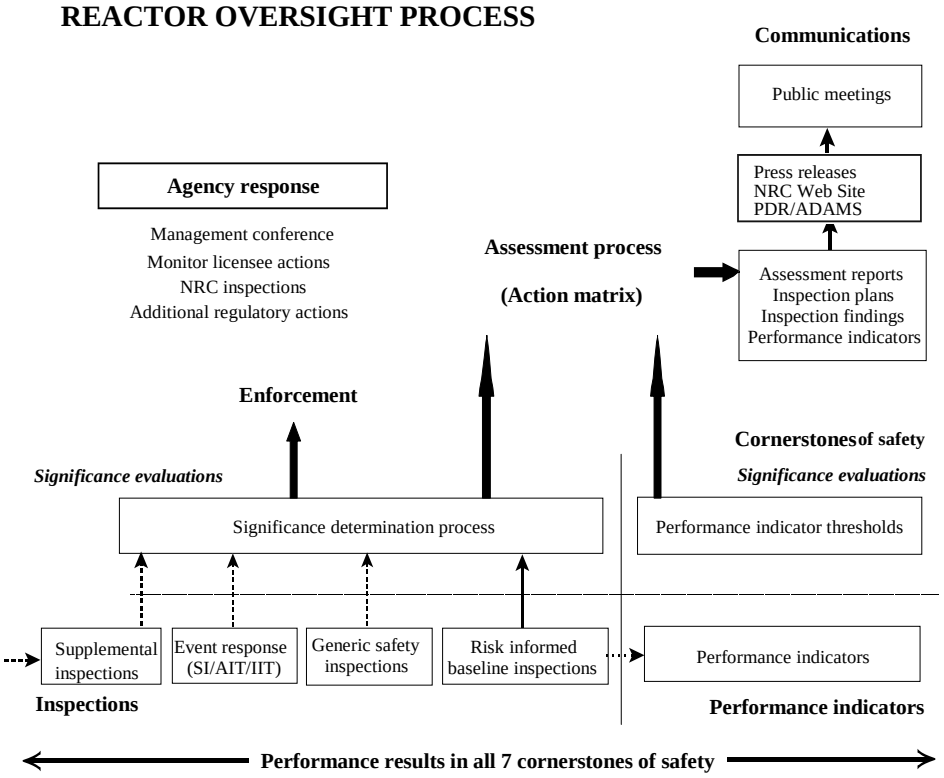
The following table shows the safety matrix used for safety assessment.

Goals \ Subject		Requirements		Operational experience	
		Design requirements	Operational requirements	State and behaviour of the plant	State and behaviour of man and organisation
Safety functions	Controlling reactivity				
	Cooling the fuel				
	Confining radioactive materials				
	Limiting exposure to radiation				
Levels of defence in depth	Level 1 Prevention of abnormal operation and failures				
	Level 2 Control of abnormal operation				
	Level 3 Control of accidents within the design basis				
	Level 4 Control of severe plant conditions				
	Level 5 Mitigation of the radiological consequences of significant external releases				
Barrier integrity	Fuel integrity				
	Integrity of the primary cooling system boundary				
	Containment integrity				
Overall safety	Multiple level aspects				

IMPROVING NUCLEAR REGULATION, ISBN 978-92-64-99162-0, © OECD 2011

2) The system of the United States Nuclear Regulatory Commission (reactor oversight process)

Additional information can be obtained by going to: www.nrc.gov



US NRC's reactor oversight process (ROP) for nuclear power plants is an integrated safety assessment process that generally meets the attributes described in this report. It is a risk informed and performance based system founded on the premise that NRC's safety mission is composed of three strategic performance areas – reactor safety, radiation safety and safeguards. These qualitative strategic performance areas are made up of seven measurable safety cornerstones: (1) initiating events, (2) mitigating systems, (3) barrier integrity, (4) emergency preparedness, (5) occupational radiation safety, (6) public radiation safety, and (7) physical protection. These safety cornerstones are not congruent with the safety elements and components in this report but are consistent with them.

Each of the cornerstones has associated objective performance indicators (PIs) such as unplanned reactor shutdowns, safety system failures, effluent releases, etc. The PIs, which are compiled and reported regularly by the operators, use a colour-coded system to display safety performance, and they are fed into an action matrix as inputs to NRC's semi-annual plant assessment process.

A parallel source of information for the plant assessments is the findings from regulatory inspections. There are two basic paths for evaluating inspection findings. The first path is for the inspection staff to assign safety significance to each inspection finding. There is formal guidance to enable the inspectors to determine if the finding is greater than minor. If so, the finding is screened through a significance determination process and the resultant findings are assigned a colour-coded rating. Those findings initially given a safety significance rating greater than green are subjected to a separate review by a Significance and Enforcement Review Panel. In a second path the NRC staff looks for cross-cutting issues, so named because they affect, and are therefore part of, each of the cornerstones. The three ROP cross-cutting issues are human performance, management attention to safety and workers' ability to raise safety issues (safety-conscious work environment), and finding and fixing problems (problem identification and resolution). In addition to these three cross-cutting issues and their associated cross-cutting aspects, the NRC believes accountability, continuous learning environment, organisational change management, and safety policies make up the final components of a licensee's safety culture.

All of this information, namely the objective performance indicators, cross-cutting safety trends, risk informed inspection findings and results from other complementary plant evaluation processes such as operating experience evaluations and accident sequence precursor evaluations, is fed into NRC's assessment process, the action matrix.

The action matrix describes a graded approach in addressing performance issues, such that NRC becomes more engaged as licensee performance declines. At lower levels of safety concern the licensee is encouraged to address its problems through its corrective action programme. At higher levels of safety significance of inspection findings or longer duration of substantive cross-cutting issues, NRC actions become more intrusive. These actions could include additional inspections, a demand for information, a confirmatory action letter or issuance of an order modifying the licence, which could include a plant shutdown.

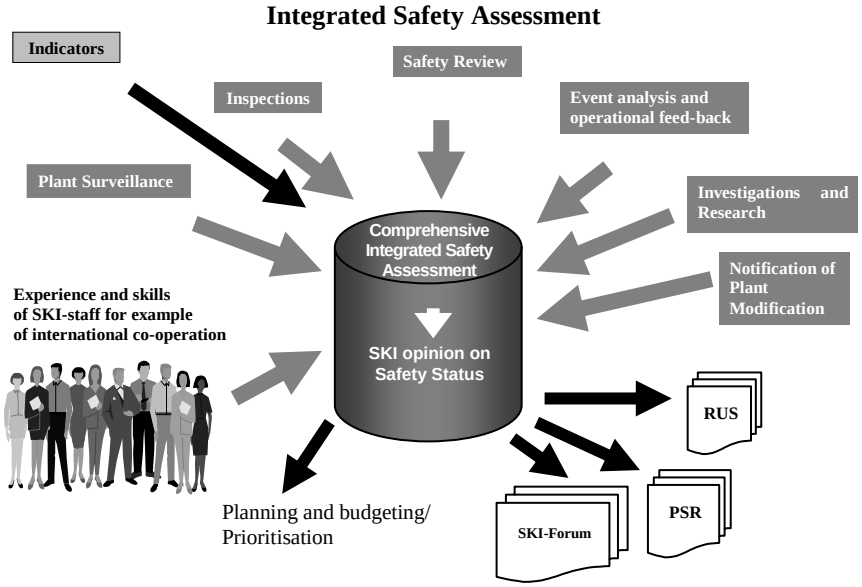
NRC's reactor oversight process is characterised by highly formalised procedures for collecting and evaluating safety information. In particular, the action matrix assessment process has procedures and guidelines outlining what regulatory actions are to be taken under a given set of circumstances. Nonetheless, the process is not so rigid that it eliminates the judgement of experienced senior regulatory staff and managers in deciding what regulatory actions are appropriate for each licensee.

3) The system of the Swedish Nuclear Power Inspectorate (SKI)

Additional information can be obtained by going to: www.ski.se

SKI conducts an annual integrated safety assessment (called SKI-Forum) for reactor plants it regulates using a process that generally meets the attributes described in this report. The sources of information used in this assessment are plant surveillances, inspections, performance indicators, safety reviews, operating experience evaluations, research results and special investigations. These are supplemented by input from experienced SKI staff. In addition, SKI requires a 10-year

periodic safety review for each plant that addresses a broad range of safety issues, including detailed safety analyses of structures, systems and components, such as pressure vessel integrity.



RUS: Annual Safety Report – PSR: Periodic Safety Review – SKI-Forum: Annual Safety Evaluation

SKI uses these sources of safety information to evaluate performance in the following 15 areas:

- design and construction;
- management and organisation;
- competence and staffing;
- operation and deviations in barrier and defence in depth standards;
- core and fuel issues;
- emergency preparedness;
- maintenance and material control;
- safety review;
- experience feedback;
- physical protection;
- safety analyses and documentation;
- safety programme;
- plant documentation procedure;

- fuel and waste handling;
- safeguards.

These 15 safety areas are not congruent with the safety elements and components in this report but are consistent with them, except for the areas of radiation safety and environmental protection for which SKI does not have regulatory responsibility.

SKI analyses the sources of safety information for safety significance using both physical barrier safety standards (fuel, cladding, primary systems, containment and buildings) and defence in depth safety standards. A document covering the 15 safety areas is prepared by the inspection staff and is reviewed by expert regulatory staff and managers. The final assessment is approved by senior regulatory managers and is discussed with the respective plant management shortly after each SKI-Forum.

The results of the integrated safety assessment are used as a basis for SKI's annual report to its national legislative body as well as for SKI's internal planning, budgeting and prioritisation process.

Based on recent experience SKI is continuing to refine and improve the integrated safety assessment process.

4) The system of the Canadian Nuclear Safety Commission (CNSC)

Additional information can be obtained by contacting: info@cnsc-ccsn.gc.ca

The Canadian Nuclear Safety Commission (CNSC) has implemented a licensee oversight process for the evaluation of licensee safety performance and the allocation of regulatory resources based on risk. The philosophy behind this process assigns the prime responsibility for safety to the licensee and the oversight function, which ensures that the licensee adequately discharges this responsibility, to CNSC staff. In order for the Commission Tribunal to issue a licence, proponents must demonstrate in their application that they have in place a standard set of programmes and processes which will provide adequate protection to the environment, and the health and safety of workers and the public.

CNSC staff assesses overall licensee performance using a comprehensive set of safety areas, programmes, and review factors and assigns grades (from A through E) to rate each safety area and programme. The Report Card requires integration of information from all activities related to the licensed activity. Supplemental information from ongoing regulatory compliance activities is used to update the ratings.

Evaluation of licensee performance in the safety areas and programmes is integral to the CNSC planning process. This involves linking of licensee performance to regulatory work plans for each facility on an annual basis.

The CNSC rating system consists of five categories: A-"Exceeds requirements", B-"Meets requirements", C-"Below requirements", D-"Significantly below requirements", and

E-"Unacceptable". The assessment process collects information from the compliance programme, the licensing and authorisation activities, event analysis and performance indicators such that a comprehensive picture of safety performance can be obtained. The safety areas and corresponding programmes are:

Safety Areas	Programmes
1. Operating performance	1.1 Organisation and plant management.
	1.2 Operations.
	1.3 Occupational health and safety (non-radiological).
2. Performance assurance	2.1 Quality management.
	2.2 Human factors.
	2.3 Training, examination, certification.
3. Design and analysis	3.1 Safety analysis.
	3.2 Safety issues.
	3.3 Design.
4. Equipment fitness for service	4.1 Maintenance.
	4.2 Structural integrity.
	4.3 Reliability.
	4.4 Equipment qualification.
5. Emergency preparedness	5.1 Emergency preparedness.
6. Environmental performance	6.1 Environmental management systems.
	6.2 Effluent and environmental monitoring.
7. Radiation protection	7.1 Radiation protection.
8. Site security	8.1 Site security.
9. Safeguards	9.1 Safeguards.

Permanent CNSC site inspectors perform system inspections and audits according to the preplanned annual inspection programme derived from the compliance programme. This programme includes both baseline and augmented inspections for areas of licensee performance which have been identified as not meeting regulatory requirements. Results are transmitted formally to the licensee and if necessary, corrective actions with target dates are followed up through the CNSC enforcement programme.

The CNSC has developed a set of 17 safety related performance indicators. These indicators are used to benchmark acceptable levels of operational safety. The indicators allow tracking of operational trends important to safety and performance comparisons between stations. These indicators are also used to identify potential problem areas where CNSC staff can redirect regulatory resources to determine whether a safety issue exists.

Analysis of safety significant events is the third component used in evaluating the safety performance. CNSC staff reviews all unplanned events and inputs the information from event reviews into a central tracking database. In addition, CNSC staff carries out detailed independent reviews of the most significant events to ensure that licensee root-cause analysis processes are robust.

An annual report on the industry safety performance presents the integration of information gathered through CNSC staff assessment activities. The annual report also presents the report card which gives the graded performance of each licensee in the aforementioned safety areas and

programmes. The annual report makes comparisons where possible, shows trends and averages and highlights significant issues that pertain to the industry at large.

5) The system of the Finnish Radiation and Nuclear Safety Authority (STUK)

Additional information can be obtained by going to: www.stuk.fi

STUK produces an annual integrated safety assessment for all operating nuclear power plants and plants under construction that it regulates using a process that generally meets the attributes described in this report. The five broad sources of information used in this assessment are (a) oversight of construction and modifications, (b) safety assessments and analyses, (c) oversight of operations, (d) oversight of management, and (e) nuclear safety indicators (PIs). In addition, STUK requires a 10-year periodic safety review that presumably includes more detailed safety analyses of structures, systems and components, such as pressure vessel integrity. The figure below shows that the observations and findings from these sources of information are used in preparing the integrated assessments.

Oversight of Finnish nuclear power plants

STUK analyses the sources of information and tests the results against radiation protection standards, defence in depth standards, barrier protection standards, and organisational factors. The ISA does not include analyses of emergency preparedness, waste management or nuclear material issues.

The process owners on the STUK staff are responsible for preparing and reporting the results of the assessment of their area of responsibility. The results of the ISA are used as a basis for STUK's annual report to the government.

STUK is continuing to develop its method for making integrated safety assessments in the areas of (a) breadth of coverage of the assessments and (b) methods for handling the safety observations and findings.

STUK functions for the oversight of nuclear power plants

Oversight of new plant projects and plant modifications 1. Changes at the nuclear facility
Safety assessments and analysis 2. Deterministic safety analysis 3. Probabilistic safety analysis (PSA) 4. Safety performance indicators; analysis and feedback
Oversight of operations 5. Compliance with technical specifications 6. Incidents 7. Oversight of outage management 8. Maintenance and ageing management 9. Fire protection 10. Radiation protection 11. Emergency preparedness 12. Physical protection
Oversight of management in regulated organisations 13. Safety management 14. Management systems and quality management (QM) 15. Training and qualification of staff 16. Use of operational experiences 17. Event investigation 18. Nuclear liability 19. Inspection and testing organisations
Oversight of nuclear waste management and nuclear materials 20. Safeguards of nuclear materials 21. Nuclear waste management 22. Control of radioactive materials transport 23. Licensees for the nuclear materials and nuclear waste

C. An illustrative ISA system

One possible approach to making an integrated safety assessment for nuclear power plants would be to use the three groups of safety elements identified in Chapter 2, assigning each safety artefact to one or more of these 3 groups. Each safety artefact could be given one of three possible colours: green, if the result is completely acceptable; amber, if it is questionable or on the margins of acceptability; and red, if it is clearly unacceptable.

This illustrative ISA system is based on the premise that the safety elements are comprehensive, and therefore every piece of safety information (or safety artefact) must fit somewhere in the matrix of safety element components. Frequently, a safety artefact will be relevant to two or even three of the broad safety elements – technical; human factors and organisational; programmatic and cross-cutting.

For example, if an unplanned scram were the result of a maintenance technician's error during a surveillance test, there would likely be no assessment for the technical safety element, but there could be assessments relative to worker qualifications, maintenance procedures and management oversight in the human factors and organisation safety element. Similarly, there may be assessments relative to training, safety culture and quality assurance in the programmatic and cross cutting safety element.

If, on the other hand, the scram resulted from failure of an electronic component, a careful analysis may find contributions from one or more of the following: design weaknesses, poor engineering analysis of replacement parts, inadequate maintenance procedures, inadequate management guidelines on preventive maintenance, inadequate surveillance testing procedures, inadequate analysis of operating experience with similar components, inadequate ageing management programme, safety culture issues and quality assurance (QA) programme weaknesses. Thus, this single safety artefact could have implications that affect all safety elements. This discussion holds true for every safety artefact that the operator or regulator must consider in this integrated safety analysis system.

Clearly, the effectiveness of this ISA system depends strongly on the quality and thoroughness of the analyses of each safety artefact. A strength of this ISA system is that it forces the operator and regulatory safety analysts to think broadly in terms of the root causes and contributing causes of the safety artefact and how these causes may be related to the entire range of safety elements and components. It is through this broad thinking that hidden (or secondary) safety weaknesses may be revealed.

Table 1 illustrates the approach for the technical safety element. It includes a column allowing the regulator to give each safety component an importance weighting. There is then a column in which the requirements for an acceptable level of safety are specified. For some aspects there would be pre-determined performance indicators to compare against while others might have acceptability guidelines derived by the regulator from past experience and technical judgement. This is followed by a column in which the actual safety performance is given. After that there is a column which shows the status in the "traffic light" system. It would also be useful to have one or more further columns, indicating the status of the safety components at the time of the last and earlier assessments in order to display performance trend information.

The overall status of each component of the technical safety elements would be arrived at by a synthesis of the information from all the relevant safety artefacts. This would nearly always be a matter of judgement for the regulator and would involve the relative importance of each safety artefact as well as its status colour. Naturally, the occurrence of one or more "red" boxes would warrant immediate regulatory action. Having arrived at a status colour for each of the safety components there would then a further synthesis, involving regulatory discussion of the relative importance of each safety component, to generate an overall status for the technical safety elements.

The same procedure would then be applied to each of the other two safety element areas, arriving at an overall safety status for each. The three groups would then be grouped together, as shown in Table 2, to give the regulator an integrated safety assessment of the facility.

Table 1. **Technical safety elements**

Safety component	Relative importance	Acceptability criteria	Operational achievement	Status	Previous status
Number of unplanned scrams					
Primary coolant chemistry within specification					
Compliance with technical specifications					
Availability of safety equipment					
Test results					
Plant modification procedures closed out					
Etc.					
Overall status				Red, amber or green	Red, amber or green

Table 2. **Integrated safety assessment for facility X**

Safety element	Previous status	Current status
Technical	Green	Green
Human factors and organisational	Amber	Amber
Programmatic and cross-cutting	Green	Amber
Overall	Green	Amber

The overview table should help the regulator to establish safety trends and set priorities while the information in the subsidiary tables should assist in identifying individual safety issues that require regulatory attention. The major benefits of such a system are that it allows the regulator to have a simple visual picture of the state of safety of a facility and facilitates an instant comparison with previous assessments.

For example, the first thing the information in the above table tells the regulator is that the overall safety of the facility has deteriorated since the previous assessment. It identifies that the technical safety element is satisfactory but the human factors and organisational safety elements has not improved since the previous assessment while the programmatic and cross-cutting one has deteriorated. At this point the regulator would go back to the detailed tables to identify which particular safety components are assessed as less than satisfactory. Discussions amongst relevant regulatory staff would then assist management to determine (preferably by means of a formal decision-making process) what actions needed to be taken and on what timescales. These proposed actions would then be recorded and transmitted to the operators and other stakeholders, as appropriate.

References

1. "Three Mile Island", USNRC Special Inquiry Group, Washington, USA, (1980).
2. A System for the Feedback of Experience from Events in Nuclear Installations, IAEA Safety Guide, Vienna (2005).
3. Joint IAEA/NEA Incident Reporting System Guidelines, IAEA, Vienna, (1998).
4. "Lessons Drawn from Recent (2003-2004) Nuclear Power Plant Operating Experience", Technical Note, OECD/NEA, Paris (2005).
5. Review of Methodologies for Analysis of Safety Incidents at NPPs, IAEA-TECDOC-1278, Vienna (2002).
6. *The Nuclear Regulatory Challenge of Judging Safety Backfits*, OECD/NEA, Paris (2002).

ANNEXES

Annex A

Original Publication Order of Booklets

1	1999	The Role of the Regulator in Promoting and Evaluating Safety Culture
2	2000	Regulatory Response Strategies for Safety Culture Problems
3	2001	Nuclear Regulatory Challenges Arising from Competition in Electricity Markets
4	2001	Improving Nuclear Regulatory Effectiveness
5	2002	The Nuclear Regulatory Challenges in Judging Safety Backfits
6	2002	Improving versus Maintaining Nuclear Safety
7	2003	The Regulatory Challenges of Decommissioning Nuclear Reactors
8	2003	Nuclear Regulatory Review of Licensee Self-assessment (LSA)
9	2004	Nuclear Regulatory Challenges Related to Human Performance
10	2004	Direct Indicators of Nuclear Regulatory Efficiency and Effectiveness Pilot Project Results
11	2005	Nuclear Regulatory Decision Making
12	2006	Regulatory Challenges in Using Nuclear Operating Experience
13	2008	The Regulatory Goal of Assuring Nuclear Safety
14	2011	The Nuclear Regulator's Role in Assessing Licensee Oversight of Vendor and Other Contracted Services

Annex B

References and Readings

Chapter 3: Nuclear Regulatory Challenges Related to Human Performance

Numerous documents were used in the preparation of this report and several are directly referenced in this report. They are considered as both reference material and additional reading for those who plan to begin work on direct indicators. These documents include:

Publications

NEA (2000), *Regulatory Response Strategies for Safety Culture Problems*, ISBN: 92-64-07672-7, OECD, Paris, 25 pages.

NEA (2001), *Nuclear Regulatory Challenges Arising from Competition in Electricity Markets*, ISBN: 92-64-08460-6, OECD, Paris, 34 pages.

NEA (2002), *The Nuclear Regulatory Challenge of Judging Safety Backfits*, ISBN: 92-64-18484-8, OECD, Paris, 24 pages.

NEA (2003), *Nuclear Regulatory Review of Licensee Self-assessment* (LSA), ISBN: 92-64-02132-9, OECD, Paris, 52 pages.

NEA (2003), *Recurring Events*, CSNI Technical Opinion Papers, No. 3, ISBN: 92-64-02155-8, OECD, Paris, 20 pages.

NEA (2004), *Direct Indicators of Nuclear Regulatory Efficiency and Effectiveness – Pilot Project Results*, ISBN: 92-64-02061-6, OECD, Paris, 48 pages.

NEA (2004), *Human Reliability Analysis in Probabilistic Safety Assessment for Nuclear Power Plants*, CSNI Technical Opinion Paper, No. 4, ISBN: 92-64-02157-4, OECD, Paris, 20 pages.

IAEA (2003), *Nuclear Power Plant Operating Experiences from the IAEA/NEA Incident Reporting System 1999 – 2002*, IAEA, Vienna, 29 pages.

CNRA Reports

NEA/CNRA/R(1998)1, "Comparison of the Inspection Practices in Relation to Control Room Operator and Shift Supervisor Licenses", Working Group on Inspection Practices, April 1998.

NEA/CNRA/R(1998)3, "Performance Indicators and Combining Assessments to Evaluate the Safety Performance of Licensees", Working Group on Inspection Practices, April 1998.

NEA/CNRA/R(2001)9, "The Effectiveness of Licensees in Inspecting the Management of Safety", Working Group on Inspection Practices, November 2001.

NEA/CNRA/R(2003)4, "CNRA – Nuclear Regulatory Inspection of Contracted Work Survey Results", Working Group on Inspection Practices, October 2003.

CSNI Reports

Studies of human and organisational factors

NEA/CSNI(1984)89, "Identifying Significant Human Actions in Reactor Accidents", December 1984.

NEA/CSNI(1987)137, "Analysis of Incidents Involving Human Factors", June 1987.

NEA/CSNI(1990)180, "Analysis of Incidents Involving Cognitive Error and Erroneous Human Actions", December 1990.

NEA/CSNI/R(1993)18, Task 3: "New Man-machine Interfaces in Nuclear Power Plants", Part 1: Executive Summary and Summary of Reports, November 1993.

NEA/CSNI/R(1994)17, "Management of Maintenance Outages and Shutdowns: Summary of Reports", 1994.

NEA/CSNI/R(1995)10/Part1, "Human Factor Related Common Cause Failure Part 1", November 1995.

NEA/CSNI/R(1997)13/1, "Task 5: Role of Simulators in Operator Training", Volume 1, PWG1, Extended Task Force on Human Factors, 1997.

NEA/CSNI/R(1997)15/Part2, "Compilations of National Contributions to a CSNI/PWG1 Task on Improving Reporting and Coding of Human and Organisational Factors in Event Reports", July 1998.

NEA/CSNI/R(1999)17, "Report on the CSNI Workshop on Nuclear Power Plant Transition from Operation into Decommissioning: Human Factors and Organisation Considerations", 17-18 May 1999, Rome, Italy.

NEA/CSNI/R(1999)21/Vol.1, "Identification and Assessment of Organisational Factors Related to the Safety of NPPs", State-of-the-art Report, September 1999.

NEA/CSNI/R(2002)9, "Approaches for the Integration of Human Factors into the Upgrading and Refurbishment of Control Rooms", Summary and Conclusions, held in Halden, Norway, 23-25 August 1999, Principal Working Group 1 on Operating Experience and Human Factors, July 2002.

NEA/CSNI/R(2002)20, "Regulatory Aspects of the Management of Change", Summary and Conclusions, Workshop held on the 10-12 September 2001, Chester, UK.

NEA/CSNI/R(2003)14, "Scientific Approaches to Safety Management", Proceedings of the Workshop, 8-10 April 2003, Paris.

Operating experience

NEA/CSNI/R(1997)5, "Latent Failures of Safety Systems", Vols 1&2, 1997.

NEA/CSNI/R(1999)2, "ICDE Project Report on Collection & Analysis of Common-cause Failures of Centrifugal Pumps", September 1999.

NEA/CSNI/R(1999)19, "Recurring Events", September 1999.

NEA/CSNI/R(2000)20, "ICDE Project Report: Collection and Analysis of Common-cause Failures of Emergency Diesel Generators", Idaho National Engineering and Environmental Laboratory, Idaho Falls, USA, May 2000.

NEA/CSNI/R(2001)10, "ICDE Project Report: Collection and Analysis of Common-cause Failures of Motor Operated Valves", February 2001.

NEA/CSNI/R(2001)12, "Requalification Problems of Safety Related Equipments Following Outages", Principal Working Group 1, July 2001.

NEA/CSNI/R(2002)19, "ICDE Project Report: Collection and Analysis of the Common-cause Failure of Safety Valves and Relief Valves".

NEA/CSNI/R(2002)24, "Conclusions Drawn from Recent (2001-2002) Events in Nuclear Power Plants", Technical Note, December 2002.

NEA/CSNI/R(2003)13, "Recurring Events", Volume 2, April 2003. Also referenced as: NEA/CSNI/R(99)19.

NEA/CSNI/R(2003)15, "ICDE Project Report: Collection and Analysis of Common-cause Failure of Check Valves", May 2003.

Risk Analysis

NEA/CSNI/R(1998)1. "Critical Operator Actions: Human Reliability Modelling and Data Issues: Final Task Report", 1998.

Chapter 4: Regulatory Challenges in Using Nuclear Operating Experience

Numerous documents were used in the preparation of this report and several are directly referenced in this report. They are considered as both reference material and additional reading for those who plan to begin work on direct indicators. These documents include:

"Three Mile Island", USNRC Special Inquiry Group, Washington, USA, (1980).

A System for the Feedback of Experience from Events in Nuclear Installations, IAEA Safety Guide, Vienna (2005).

Joint IAEA/NEA Incident Reporting System Guidelines, IAEA, Vienna, (1998).

"Lessons Drawn from Recent (2003-2004) Nuclear Power Plant Operating Experience", Technical Note, OECD/NEA, Paris (2005).

Review of Methodologies for Analysis of Safety Incidents at NPPs, IAEA-TECDOC-1278, Vienna (2002).

The Nuclear Regulatory Challenge of Judging Safety Backfits, OECD/NEA, Paris (2002).

Chapter 11: Direct Indicators of Nuclear Regulatory Efficiency and Effectiveness

Numerous documents were used in the preparation of this report and several are directly referenced in this report. They are considered as both reference material and additional reading for those who plan to begin work on direct indicators. These documents include:

Direct references

NEA (2001), *Improving Nuclear Regulatory Effectiveness*, CNRA Report 2001 (Note: This is sometimes referred to as the previous NEA report), OECD, Paris.

Proceedings from the NEA International Forum on Measuring, Assessing and Communicating Regulatory Effectiveness (MACRE 2003), NEA/CNRA/R(2004)x, not yet published.

CNRA Pilot Project on Direct Indicators for Nuclear Regulatory Efficiency and Effectiveness – Complete Results (for official use only), NEA/CNRA/R(2004)x, not yet published.

TGRE Notebook – Compilation of information compiled by the TGRE Task Group (for official use only), internal CNRA document.

Other useful references

NEA (2002), *Improving versus Maintaining Nuclear Safety*, CNRA Report, OECD, Paris.

Assessment of Regulatory Effectiveness, IAEA PDRP-4, 1999.

Annex C

Nuclear Regulatory Review of Licensee Self-Assessment (2001)

Compilation of Responses to Survey

1. Licensee self-assessment can be defined in many different terms. Please provide a brief description of what licensee self-assessment means.

Australia

Licensee self-assessment is the process by which the responsible safety approval body of the licensee satisfies itself that the particular conduct with any radiation or nuclear safety implications meets applicable safety and regulatory requirements. The *Responsible Safety Approval Body* means the licence holder's committee, group or individual with responsibility for ensuring the adequate safety review of an operation, procedure or experiment, and with the authority to approve the safe conduct of the reviewed modification, operation, procedure or experiment. See the ANSTO Licence Conditions Handbook available at www.arpansa.gov.au/pubs/ansto_hndbk.pdf.

Czech Republic

Licensee self-assessment covers all their activities during lifetime of NPP. It consists in assessment of operational and safety indicators:

- Annual report with results of all activities.
- Regular evaluation of all events.
- "Living" SAR (annually updated).
- Internal questionnaire.

Finland

In the STUK's regulatory guides a reference is made to the IAEA Safety Series document Nn 50-C/S/SG-Q (Code and Safety Guide 5). This document gives a detailed view on "management self-assessment". ISO 9000 defines management review etc. which are, as well, elements of self-assessment.

According to this self-assessment means all assessments carried out by licensee according to some criteria. These criteria can be either made by licensee itself (focus usually on improving quality

of single processes) or it can be made by some external organisation for example EFQM or MB criteria (focus usually on improving total quality of the organisation). Self-assessment helps organisation to find sectors and procedures, which need to be improved.

France

Self-assessment means an assessment by a special division of the corporate (EdF) which is distinct from the power plant staff, i.e. not in charge of its operation.

This assessment is dedicated to assess the performance with respect to safety, quality and related issues, based on regulation and internal rules. This assessment is mainly use for management purposes.

Utility self-assessment is conducted by EDF at three different levels:

- at the site level by the safety quality team which is independent from the operation team;
- at the corporate nuclear division level by inspection and reports;
- at the headquarter corporate level by the general safety inspectorate.

Germany

German regulations demand that licensees have to maintain an encompassing QA system. The scope of this QA system is outlined in KTA standard No. 1401. Accordingly, the licensee is to maintain a hierarchically independent quality management structure which is charged – amongst other duties – with internal and external (i.e. supplier) quality audits. Complementary to this "licensee-internal" self-assessment, the German licensees in 1998 initiated a national peer review programme of external assessments. The former as well as the latter can both be regarded as licensee self-assessments, as there is no direct involvement of the regulatory body. Should the peer review lead to insights that trigger the licensees' notification obligations the regulatory body would be involved.

Hungary

LSA according to regulatory code: "QA rules for NPPs" consists of management self-assessment and independent internal or external assessment.

Management self-assessment should be performed regularly on each level of the management including the top management to evaluate management processes, identify and eliminate their weaknesses and obstacles in achieving safety goals.

Independent self-assessment can be performed either by an internal organisation, independent of the assessed line organisation, or by an external organisation (e.g. QA-expert organisations, IAEA or WANO missions or the regulatory body itself).

The scope of independent self-assessment should cover every activity important for the safety.

Self-assessment of the subcontractors (persons and organisations) is not included in the regulatory code, but it is supposed to be performed according to internal QA-requirements of the utility.

Japan

Licensee self-assessment (LSA) can be defined as voluntary-based safety evaluation and action carried out by licensees that are authorised by the regulatory body. In Japan, typical examples are the executions of periodic safety reviews (PSR) and the implementation of accident management plans (AM).

Netherlands

A systematic evaluation by the licensee of all its technical, organisational, personnel and administrative arrangements in order to improve safety.

The evaluation may be initiated by the licensee himself or be a result of a requirement in the licence or a request of the RB.

Norway

LSA means the licensee's own assessment of the safety of the installations. It can be a part of the system for internal control or quality assurance of health, environment and safety.

Sweden

Licensee self-assessment or self-inspection that we prefer to call it in Sweden means for us all the activities that the licensee undertakes to establish goals and objectives as well as control and evaluate its actions to ensure safety is maintained and that all safety requirements are fulfilled.

Licensee self-assessment should be seen as a continuous process where each aspect of safe operation is continually evaluated to identify compliance and also where opportunities for improvement are taken into account. In the rest of the document the expression self-assessment is used in the sense mentioned above.

Switzerland

We are using the INSAG 12 Chapter 3.3.3 Self-Assessment: Self-assessment for all important activities at a nuclear plant ensures the involvement of personnel performing line functions in detecting problems concerning safety and performance and solving them.

Concerning the QA-Process, Management Self-assessment is described in IAEA Safety Series No. 50-C/G-Q "Quality Assurance" Guide 5: "Assessment of the Implementation of the Quality Assurance Programme". Other IAEA guidelines e.g. PROSPER exist (should replace the former ASSET self-assessment).

HSK relies heavily on the definitions mentioned in the above documents.

United Kingdom

Licensee self-assessment from the UK standpoint means that the licensee has an effective process for uncovering both non-compliances and potential areas for improvement which it operates on its own behalf, and without dependence on the external regulator. Implicit in this is that having discovered non-compliances and areas for improvement, the licensee has effective means for rectifying the situation, both in relation to the particular non-compliance which has been discovered, and also in order to reduce the chances of non-compliance in this and related areas in the future.

United States

In the United States, licensee self-assessment is generally defined as those activities conducted by licensees to monitor and evaluate various aspects of organisational performance. In a broad sense, self-assessment activities include those required by NRC regulations, such as periodic quality assurance audits, as well as those that are voluntary, such as those directed at improving safety or economic performance. Self-assessments may also be performed to address declining performance trends or as necessary to assess the extent of condition of identified issues. Self-assessment can take many forms and be performed by various levels throughout the organisation from top management through line management and down to individual workers.

2. Do you have any requirements on licensees to perform self-assessment? If so please describe.

Australia

The Standard Licence Conditions for Particular Conducts at Controlled Facilities (research reactor, spent fuel storage facilities) operated by ANSTO, Section 4.1.1 specifies the following condition: *12 Safety Approval.* The licence holder must maintain current approvals by the licence holder's responsible safety approval body for all dealings and conducts authorised under a facility licence. See Internet document (question 1) for further details.

Czech Republic

General requirements for assessment of licensee activities are in Atomic Act No.:18/97 Coll. which requires in *Article 17* "General Obligations of Licensees" to "assess in a systematic and comprehensive manner the fulfilment of conditions set in Article 4, from the aspect of the current level of science and technology, and ensure that the assessment results are put into practice" and in

*Article 18 "*Obligations from the Aspect of Nuclear Safety, Radiation Protection, Physical Protection and Emergency Preparedness" to "monitor, measure, **evaluate**, verify and record values, parameters and facts with an impact on nuclear safety, radiation protection, physical protection and emergency preparedness, to the extent laid down in an implementing regulations". Concrete requirements (see question No.1) are done by the SÚJB Letters and decisions.

Finland

The Decision of the State Council sets the general criteria of quality management. The YVL-guides issued by STUK supplement these criteria's. In our YVL-guides (rules) there are some requirements for licensees quality assurance. In YVL 1.4 (Quality Assurance for Nuclear Power Plants 20.9.1991) there are requirements for licensees quality assurance programs and in YVL 1.9 (Quality assurance during operation of nuclear power plant 13.11.1991) there are requirements for QA during operation, LSA can be an element in licensees quality assurance programme.

France

The French "quality" order (August 1984) requires, in its Article 9, a continuous surveillance action supplemented by corrective actions. Self-assessment shall also be performed when specifics problems arise.

Germany

LSA is not explicitly called for in the German regulations. However, the German nuclear (KTA) standard No. 1401 explicitly stipulates that "... the licensee is responsible for planning, conducting and auditing the effectiveness of QA measures..." And further: "The licensee has to assure that all companies involved in QA matters – which means the licensee proper, his contractors and subcontractors – plan and realise QA according to the rules laid down in this standard". Further: "...persons charged with installation and auditing of the QA system must be empowered to ... control adherence to predefined QA measures. These persons must not belong to the personnel named under subtitle a) [i.e. personnel charged with planning, design, procurement, production, and installation of items, erection of buildings, start-up of plant, and operation of plant]."

Based on this requirement, the regulatory authorities demand that the licensee submit QM documents – i.e. QM handbook and, to the authorities' discretion, yearly schedules for the audits.

Hungary

The regulatory code: "QA-rules for NPP-s" requires performing LSA according to IAEA safety code: 50-C-Q (1996). The "QA-rules" are actually an adopted version of the IAEA code.

Japan

Basically, yes. The requirements are not legal ones but are to be followed by licensees. Licensees submit their plans on the self-assessment and then, the Nuclear and Industrial Safety Agency (NISA) of METI approves the plans. If licensees change the plans, they need to re-submit the revised plans and NISA reviews them.

Netherlands

Yes, stated in the licence (see introduction).

Norway

The NRPA requires that the system for internal control is kept updated. This should be a continuous process.

Sweden

According to SKI's regulation SKIFS 98:1 (available on www.ski.se):

- The licensee shall maintain an efficient and effective self-assessment programme including a two-step safety review system, a primary and an independent as well as a clear safety strategy, total quality management system encompassing all activities important to safety and a solid decision-making system.
- The safety of nuclear facility shall be continuously analysed and assessed in a systematic manner. Any need for safety improvement measures, engineering as well as organisational, which arise as a result of such analyses and assessment, shall be documented in a safety programme. The programme shall be updated on an annual basis.

Thus, self-assessment is not seen as some isolated effort by the licensee such as PSR or internal or external peer-reviews. Such efforts are done in Sweden also, but for us self-assessment means the continuous process referred to above.

Switzerland

HSK required the compliance of the Licensees QA-Programmes with 50-C/G-Q. In this context Management Self Assessment of the Licensees is part of it, Safety Performance Indicators and other operating results have to be considered. The IAEA PROSPER Guideline may also be used in the special area of operating experience feedback.

In regular Management Meetings HSK discusses the NPPs annual goals and their achievement. Deviations from goals are also part of the discussions.

A regular formal self-assessment process is not established yet at Swiss NPPs.

United Kingdom

For many years, the United Kingdom has sought to persuade licensees to have their own departments, separate from the operational management at licensed sites, and in general reporting to a headquarters department, which could carry out surveillance and compliance checking activities on any matters affecting safety. There is, however no legal requirement for such a department except in general terms by virtue of a licence condition which requires the licensee to have adequate quality assurance arrangements. The self-assessment process should be regarded as something different from a pure quality assurance programme in that one of its functions should be to check that at all times the plant is operated within the boundary conditions defined in its safety case. In its pure sense, quality assurance can amount to merely a process of checking compliance with documented procedures, which may themselves be incomplete, inadequate or unsafe.

United States

Criterion XVIII of Appendix B to 10 CFR Part 50, requires licensees to establish a comprehensive system of audits to verify compliance with all aspects of the quality assurance programme and to verify the programme's effectiveness for safety-related equipment. Other NRC regulations are more specific to the plant support areas of emergency preparedness, security, and radiation protection. For example, Criterion IV to Appendix E of 10 CFR Part 50 requires licensees to conduct periodic drills and critiques of the emergency response plans. Also, 10CFR20.11.1 requires that licensees periodically review the radiation protection programme and its implementation. Requirements regarding the conduct of security audits are contained in 10CFR Part 73.55.

The NRC has also encouraged licensees to conduct self-assessments to determine the extent of performance problems once risk significant performance issues have been identified. The NRC's revised reactor oversight process assumes that licensees will perform such self-assessments, which will then be reviewed by NRC inspectors. The depth and breadth. of the safety assessments should correspond to the risk significance and complexity of the identified performance issues.

3. How does the regulatory body assess and inspect LSA programmes? Is it a systematic process?

Australia

A systematic process for regulatory assessment of the LSA programmes has been introduced via the ANSTO Licence Conditions Handbook Section 4.1.1 Standard Licence Conditions for Particular Conducts at Controlled Facilities. These include requirements for periodic and annual reporting by the licensee to the regulator (conditions 22, 23), licensee safety management arrangements (conditions 10 to 15), assessment and reporting of abnormal occurrences, incidents and accidents (18, 19) and modifications and relevant changes (24 to 29, particularly condition 25 requiring adequate review). The ARPANS Act and Regulations (available at www.arpansa.gov.au/reg_fun.htm#acts) establish an inspection system by which the regulatory

body may conduct inspections to ascertain compliance with the conditions related to the LSA programmes.

Czech Republic

The Regulatory Body (SÚJB) regularly assess LSA programme in this process:

- Annually – during the common meeting with licensee – the operational indicators are:
  - Annual report of licensee.
  - The "Living" SAR.
- Monthly – evaluation of events on common event commission meeting – it is ever subject of regular inspection with conclusions in monthly protocols.

Finland

STUK does not have any separate assessment or inspection specified for LSA-programmes, but these are assessed and inspected as a part of assessment or inspection of licensees QA.

LSAs are also inspected in our periodic inspection programme. It contains 16 different inspections and one of those is Safety Management. This is a regular inspection and it is carried out once in two years.

France

French regulator does not systematically assess and inspect LSA programmes.

Regulatory body checks that all necessary corrective actions are implemented.

The regulator remains independent and does not interfere with LSA in order not to disturb the internal process of the operator.

Germany

As stated before, regulatory authorities have the licensees submit their QM handbooks and pertaining documentation. And as LSA procedures (i.e., internal audits and supplier audits) are integral part of the QM system, they are assessed by the regulatory authorities. The national peer review programme being a complementary and voluntary effort of the German licensees, it is not assessed or supervised by the authorities.

Hungary

Assessment and inspection of LSA by the RB is a systematic process. According to inspection procedure of HAEA NSD: No. 3.2.1 – "Inspection of QA-system of the Licensee" an inspection of the top management's self-assessment should be performed by the head of NSD once a year. The performance of independent LSA (including follow-up of the corrective actions) should be performed by the inspection department permanently and evaluated once a year.

Japan

As mentioned above, NISA reviews and approves the LSA programmes submitted by licensees in consideration of the necessity of changes in design and/or operating procedures. When doing that, if necessary, the advisory committee of NISA is consulted. Also, NISA reports the review results to the Nuclear Safety Commission (NSC). The assessment of the LSA programmes is conducted in the systematic process through the review by the standing committee of NISA.

Netherlands

NPP Borssele has developed and described a system of "main-processes" in which all organisational aspects, communications and responsibilities are described to perform a "main-process" in an adequate manner.

At the 2-yearly assessment, this scheme is used. Before starting the assessment the set-up, including special subjects must be approved by the RB.

At the 10-yearly assessment it is very important that at the start of the real evaluation there is agreement between licensee and RB on the inventory of issues to be addressed as well as on the current licensing basis in which the current requirements and knowledge on nuclear safety are collected.

Norway

The LSA programmes are reviewed during the licensing process and followed up at ordinary inspections.

Sweden

One of the main components in SKI's regulatory strategy is the requirement of the licensee to maintain a self-assessment programme to control compliance with regulations. SKI oversight focuses mainly on the activities of the licensees in this respect, and SKI shall convince itself that the licensees have full control with regard to safety of plant processes as well as of organisational processes. Moreover, SKI shall supervise that the licensee's self-assessment:

- Is organised in an effective manner with sufficient staff and competence and that there are clear responsibilities and delegation/authorisation.
- Is conducted with sufficient quality supported by well-suited procedures, methods and tools.

The detailed content of SKI's oversight programme is decided in an annual budget and planning process. In many of the SKI oversight efforts and especially in the inspection activities, the quality of the licensees' self-assessment programme is reviewed and thus constitutes an important factor. Also, SKI reviews a sample of those notified modifications that SKI considers

are of special importance to safety. This concerns technical as well as organisational modifications.

Switzerland

HSK regularly inspects the QA processes of the Licensees. The Self-Assessment Process will be part of these inspections. Reportable events or other Non-conformances may also trigger an inspection on self-assessment.

United Kingdom

The NII does carry out checks to ensure that the licensee has both adequate staff and systems for performing the licensee self-assessment process described in answers 1 and 2 above. There is however a general policy of not looking closely at the detailed results of specific self-assessment checks and investigations. The same applies to QA audits carried out by the licensee. The reasons for this are to allow the licensee to be absolutely frank in making self criticisms. If these were examined too closely by the NII, the general view is that the thoroughness and frankness of these reports would quickly become degraded: they would become sanitised and would lose their value.

United States

The NRC evaluates licensee self-assessments as part of its baseline inspection programme that is implemented at all facilities and during supplemental inspections performed in response to risk significant performance issues. In the baseline programme, selected licensee self-assessments are reviewed during periodic inspections of licensee problem identification and corrective action programmes.[1] The focus of these inspections is to verify that when safety issues are identified during self-assessments, they are appropriately evaluated, prioritised, and corrected. The results of the licensee's self-assessments are also compared against NRC inspection findings to see whether the licensee and the NRC have a common understanding of problem areas. In the emergency preparedness area, licensee critiques of emergency drills are reviewed in an annual baseline inspection.[2]

NRC supplemental inspections are focused on a licensee's assessment of specific performance issues. Specific supplemental inspection procedures have been developed that are implemented based upon the safety significance and nature of the identified issue.[3] The supplemental inspection procedures are listed in the NRC's Assessment Action Matrix.[4]

1. NRC Inspection Procedure 71152, "Identification and Resolution of Problems".
2. NRC Inspection Procedure 71114.01, "Exercise Evaluation" and 71114.06, "Drill Evaluation".
3. NRC Inspection Procedures 95001, "Inspection for One or Two White Inputs in a Strategic Performance Area"; Ip 95002, "Inspection for One Degraded Cornerstone or Any Three White Inputs in a Strategic Performance Area"; and Ip 95003, "Supplemental Inspection for Repetitive Degraded Cornerstone, Multiple Degraded Cornerstone, Multiple Yellow Inputs, or One Red Input".
4. NRC Inspection Manual Chapter 0305, "Operating Reactor Assessment Program." Exhibit 5.

The ability of a licensee to perform effective self-assessments is also a criteria that is used in determining what, if any, additional regulatory actions are necessary should a significant safety issue be identified. These additional actions could range from additional inspections, orders, or ultimately, shutdown of the facility.

4. How are the results from a licensee self-assessment evaluated and what steps are taken the regulatory body?

Australia

Results of the LSA are routinely reviewed against the relevant licence conditions, regulatory assessment principles (www.arpansa.gov.au/ass_info.-htm#RAPs), and codes and standards, and the results notified to the Licensee. For assessment of modifications that will have significant implications for safety (defined as a "relevant change" for which ARPANS Regulation 51 applies), prior approval of the CEO of ARPANSA is required before the modification is undertaken; that is, the LSA in such cases requires formal approval of the regulator.

Czech Republic

The results from LSA are compared with results and conclusions of the Regulatory Body.

The "Living" SAR is evaluated and the Regulatory Body requires to correct identified discrepancies (scope of modifications, their impact on nuclear safety etc.).

As regards evaluation of events the SÚJB assesses the root causes analyses and accepted remedial measures. Requirements of the SÚJB are set in month protocols (legal document in accordance with Atomic Act) from common event commissioning meetings.

Finland

The results of LSAs are assessed as spot-check – licensees deliver partially their self-assessment documents for information to STUK.

France

The utility provides information excerpts from its LSA in its yearly reports but does not provide extensive LSA results reports. The regulatory body takes into account the conclusions of the operators in addition to the observations made during its own inspections when elaborating the final judgement of the ASN on each NPP.

Germany

See answer to question 1.

Hungary

The managers' self-assessment shall be documented and the documents are to be presented during the inspection. A broad set of questions is elaborated for evaluation of management self-assessment.

The independent assessment results are to be submitted to RB in quarterly and in yearly reports according to safety guide 1.24 – "Periodical reporting requirements of NPPs". The Licensees' safety performance evaluation programme, which shall include the LSA evaluation criteria, is under preparation.

Japan

The documents describing the results of LSA are submitted to the regulatory body. NISA carries out the comprehensive review of the results, focusing on the implementation of adequate preventive/corrective actions, the incorporation of the state-of-the-art technologies, etc., to ensure that the plant safety has been improved.

Netherlands

A final concept of the 2-yearly assessment (must be ready within 4 months after assessment period) is evaluated by several experts within the RB. The presented subjects, conclusions and actions to be taken are analysed in order to check that:

- All relevant subjects are dealt with.
- The right conclusions are reached.
- The proposed actions will be effective.

During a meeting with the licensee the comments on the final concept are presented and discussed. After corrections the final report is presented and a formal reaction of the RB will be given.

Norway

The licensee is obliged to take the evaluation into account and implement necessary.

Sweden

Results from the licensees' self-assessment activities are fed into SKI's integrated safety assessment of the licensees and will thus influence the oversight plan.

Switzerland

In the same manner as other inspection results, deviations to expected results will become an open issue. Details are formulated in the regulatory QM process.

United Kingdom

See the answer to 3 above.

United States

As stated above, the NRC reviews selected licensee self-assessments as part of the baseline inspection programme to ensure that issues identified during the self-assessments are entered into the licensee's corrective action programme, prioritised, and that appropriate corrective actions are taken to prevent recurrence and restore compliance with NRC regulations. The results of these NRC inspection reports are documented and made publicly available. Should significant weaknesses be identified during an NRC inspection of a licensee self-assessment, the NRC may decide to take additional enforcement actions or conduct additional inspections as necessary to ensure that the corrective actions are taken to prevent recurrence. Weaknesses identified during supplemental inspections are similarly followed up to ensure that appropriate corrective actions are taken.

5. Does the regulator follow-up on corrective actions taken by the licensee as a result of LSA?

Australia

Corrective actions are expected to be reported by the licensee under the periodic reporting requirements of the Licence Conditions Handbook. If ARPANSA is not satisfied with the actions undertaken, then follow-up action, inspection or audits are conducted.

Czech Republic

The SÚJB follows-up the corrective actions that have impact on nuclear safety or radiation protection mainly their fulfilment in prescribed terms by protocols.

Finland

STUK does not take prescriptive role if the licensee has found deficiencies in its LSA and it is apparent that the licensee will take the corrective actions. On the other hand, if the issue is significant or STUK has made some inspection remarks on the same things, are the corrective actions naturally followed up by STUK.

France

The follow-up by the regulator of operator's corrective actions is mainly performed through inspection by spot-checking.

Germany

The regulatory authorities are obliged to oversee any corrective actions taken by the licensee, provided this action is in any way safety-relevant.

Hungary

See Point 3.

Japan

Yes. NISA carries out follow-up activities on corrective actions taken by the licensees within the review of the results of licensees' PSR and on-site inspection, and requests licensees to take relevant measures if necessary.

Netherlands

Twice a year a special inspection takes place to check the progress of the corrective actions and to verify that a corrective action is completed.

Norway

If corrective actions are substantial, they are followed up by the NRPA.

Sweden

The corrective action programmes of the licensees are important and form a part of the basis for SKI assessment of the safety work at the plants. In relation to incidents and discovered plant deficiencies, for example, SKI reviews carefully the corrective actions proposed by the licensees and the corresponding internal safety review of these actions.

Switzerland

There are formalised ways how open issues have to be closed in the regulatory QM process. Normally it requires a written confirmation of the licensee that the deviation is solved, sometimes a regulatory inspection will also be performed.

United Kingdom

As stated above, the NII does not scrutinise the follow up on specific corrective actions undertaken by the licensee. The exception to this might be if the NII carried out an inspection or audit of its own, revealing a substantial degree of non-compliance. In such a case, the NII inspectors might well ask to examine the results of the licensee's self-assessment process on the same topic to understand why the licensee had not uncovered and rectified the non-compliances before these were discovered by the NII.

United States

During the baseline inspection of problem identification and corrective action programmes, selected issues are reviewed to ensure that the licensee has implemented planned corrective

actions. The issues reviewed included a sample taken from licensee self-assessment activities. During supplemental inspections conducted for risk significant issues, the NRC ensures that the licensee has established a method for evaluating the effectiveness of the corrective actions.

6. What "credit" if any is given to the licensee for performing an LSA (i.e., decreased inspections, etc.)?

Australia

ARPANSA sees the satisfactory performance of LSA as an indicator of good safety culture and good safety management arrangements. This is likely to lead to the reduction of regulatory surveillance activities (such as inspections).

Czech Republic

The regulatory body does not give any "credit". The inspection activities are planned among others mainly based on results and conclusions of previous SÚJB inspections.

Finland

STUK does not give the licensee any credit for performing an LSA.

France

There is currently no use of LSA to modify the French regulatory supervision programme.

Germany

Inspections and also the PSRs are scheduled subject to the plant license (and possible amendments thereto) or subject to general legal or regulatory requirements. These schedules are legally binding and are not subject to trade-offs due to LSAs.

Hungary

There is no direct credit for performing LSA, but LSA is one of 12-15 topics of integrated team-inspections. These inspections are performed 4 times a year. It means LSA can be inspected once in 3-4 years, but the frequency of each topic's inspection depends on satisfaction of the RB in that area.

Japan

No such credit is given to the licensee at present.

Netherlands

No credit is given when the licensee has drawn up a self-assessment.

Norway

No special credit is given for performing an LSA.

Sweden

SKI maintains sort of minimum inspection and assessment programme of all licensees. Strong confidence in a licensee's self-assessment process will mean less active activities in relation to that licensee. Less resources will be directed to supervision and inspection and a smaller sample of all the technical and organisational modifications that the licensee notifies will be reviewed by SKI.

Switzerland

Not yet defined. But it seems clear that such important activities have to be taken into account in the regulatory inspection strategy.

United Kingdom

There is a degree of co-operation between the self-assessment programmes run by the licensee and the inspection and audit programmes conducted by the NII. The objective of such co-operation is to try to cover different topics on team inspections and audits, rather than have a situation where the licensee uses its own self-assessment resources to "clean up" the topic area which the NII has said it intends to check, before the regulator makes those checks. It is however not easy to persuade the licensee to co-operate in this idealised fashion and to work properly it depends on the general confidence of the licensee's staff and the pressures they are under to avoid the regulator discovering non-compliances.

United States

In the past, the NRC has given "credit" to licensees for self-assessment activities and has decreased inspection accordingly.[5] The NRC's revised reactor oversight process now in effect does not allow substitution of licensee self-assessments for baseline inspections as the baseline inspection programme was developed with the assumption that it would be implemented equally at all facilities. The revised oversight process does however recognise licensee self-assessments during supplemental inspections, and emphasises that if licensee's do not do effective self-assessments, the NRC may do additional inspections as necessary to determine the cause and prevent recurrence of risk significant performance issues. As a future action, the NRC has committed to explore the possibility of using licensee self-assessments in lieu of NRC inspections in selected areas.

5. NRC Inspection Procedure 40501, "Licensee Self-assessments Related to Team Inspections" provides guidance for evaluating a licensee's self-assessment in lieu of an NRC team inspection.

7. Licensee self-assessment and periodic safety reviews

- **If a periodic safety review (PSR) is performed in your country, are LSAs also performed?**
- **What type of frequency is required for LSAs and how are they different from the PSR?**

Australia

LSAs are performed routinely. Safety reviews have recently been undertaken as part of the initial licensing of ANSTO facilities under the ARPANS Act 1999. See, for example, the safety evaluation report for ANSTO's HIFAR research reactor, available at www.arpansa.gov.au/hifar_lic_app.htm#ser.

Czech Republic

The periodic safety reviews are performed in ten years period. The requirement for periodicity of PSR is done as condition in permission for operation of NPP.

The LSA is performed (see above) some parts of LSA are given by SÚJB (see question No. 2).

The LSA frequency is not required but practically the LSA frequency is month (events evaluation) and annual (Living SAR, annual report). The LSA is continual process with conclusions for the nearest future (with fix terms of fulfilling), PSR evaluates and analyses impact on nuclear safety and radiation protection in ten year periodicity without concrete conclusions for future.

Finland

PSR is performed in Finland. In PSR there is a part dealing with the quality management at licensees, but self assessment is not specially mentioned in the review.

We do not have any rules about the frequency of LSA. Licensees in Finland do self assessment on a regular basis and in most cases the frequency is once a year.

France

Yes both PSR and LSA are performed in France.

What type of frequency is required for LSAs and how are they different from the PSR?

PSR is generic and concerns all of the plants from the same series.

As mentioned in answer to question 3, the utility uses different processes for the safety assessment of its NPPs:

- A continuous assessment process is performed on each NPP by the Safety Quality Team which reports to the plant manager.
- Annual reports from the General Inspectorate and the safety inspectorate of the power division synthesizing the main findings of their inspections.
- Global Safety Assessments which are extensive assessments lasting two weeks performed on each NPP every three years.

Germany

In Germany, PSRs have been performed in the 1990s and are to be repeated every ten years. PSRs are conducted complementary to continuous plant supervision to get an entire view of the plants safety including the results of deterministic and probabilistic analyses and operational experience. LSAs are not part of PSR but the information collected in a PSR by the licensee provides insights to him on his own performance. LSAs in the form of internal and supplier audits are scheduled according to the licensee's QM system (which is submitted to the regulatory authorities, as explained under No. 3); LSAs in the form of national peer reviews are a voluntary effort of the licensees and are, presently, rather in some test phase.

Hungary

LSA and PSR: the PSR is itself a LSA in a broader sense, the RB reviews it only. The scope of a PSR is in accordance with the safety guide No. 50-SG-D12 of IAEA. It does not include an explicit form of LSA as defined in point No. 1, though, some elements of LSA are mentioned there. The most important difference appears in frequency of both processes: PSRs are performed once in 10 years, LSA is to be performed at least once a year. The organisational structure of the utility changes relatively often and the safety performance requirements increase permanently that's why the frequency of the PSR seems to be too low for the LSA.

Japan

As mentioned above, PSR is being performed within LSAs.

What type of frequency is required for LSAs and how are they different from PSR?

NISA requests licensees to perform Periodic Safety Reviews for their respective nuclear power plants at fixed intervals (approximately every ten years). In the PSRs, the core damage frequency (CDF) for power operation is updated according to the current status of the plant system configurations. Also, the importance of safety equipment and/or postulated initiating events is examined based on the updated CDF.

Netherlands

In the opinion of the KFD the PSR is a very important part of the LSA. However other self-assessments e.g. initiated by the licensee himself, exist. In the LSA also the assessment of efficiency and cost reduction are taken into account.

In the Netherlands we have two types of LSA; one with a frequency of 2 years (reference: the existing licence) and another with a frequency of 10 years (reference "new insights"; see also the introduction).

Other self-assessments than PSR are mainly not bound to a prescribed frequency or follow frequencies that are specified in the licensee's QA system.

Norway

Yes, the licensee has to submit a report on the status of the installations every third year. This is quite close to a PSR and contains the licensee's assessment of the installations.

Sweden

Both periodic safety reviews, PSRs and licensee self-assessments are performed in Sweden. PSRs are performed every 10-years. Licensee self-assessments, however, are seen as the basis for safety at the nuclear installations and constitute the continuous day to day safety work of the licensee under the supervision toe SKI, as said above.

Switzerland

LSA is a short term problem solving or performance enhancement process, to maintain safety in reaction on operating results as deviations, new operating experience or changing external impacts.

PSR is a periodically self-assessment of the plant against the state of the art and how to close the gaps. Switzerland requires a 10 years period for PSRs.

What type of frequency is required for LSAs and how are they different from the PSR?

On PSR See above.

LSAs in the context of QM are expected to be done periodically or in reaction to internal or external triggers (e.g. declining of performance indicators, etc.).

United Kingdom

Under the definitions described in answers 1 and 2 above, it will be clear that the licensee's self-assessment process is quite distinct from the periodic safety review process. In the UK, periodic safety reviews are required every ten years whereas the self-assessment process is seen as a continuous process undertaken by a department within the licensee, which is permanently dedicated to this task.

United States

Periodic safety reviews are not performed in the U.S.

8. What other issues relating to Licensee Self-assessment would you like to see discussed by the CNRA?

Australia

None at this time

Czech Republic

- Tools for implementing of regular LSA and requirements for LSA range.
- Ways for enforcement of LSA results.

Finland

It might be useful to have a common position on LSAs – what things should be included in it and should there be a standard for LSAs. It might also be interesting to discuss if there is need or possibility to harmonise LSAs.

France

None at this time.

Germany

An in-depth discussion of experiences gained so far in the field of "LSA and de-regulation" might be interesting provided countries requiring LSA can offer input. Furthermore, it might be interesting whether countries have reduced plant inspections and introduced LSA instead and what are the experiences.

Hungary

It seems to be important to discuss about criteria of LSA in comparison with regulatory requirements. (To what extent can the RB encourage or motivate utilities to aim at results, higher than prescribed in legal or regulatory requirements? A typical example: the utilities obviously are in a position to have much lower radioactive emission than prescribed in regulatory requirements.)

Another opened question: Is it worth for the utilities to establish and maintain a QA or quality excellence system, which could be certified according to requirements of an internationally approved, independent of the nuclear industry standard? (It could be useful to have a certificate of utility's QA-system from an independent expert organisation outside of the nuclear society when discussing with anti-nuclear organisations or with people who just doubt of declarations from the "nuclear lobby".)

Japan

There is no particular item at present.

Sweden

It would be good to get an international definition/understanding of the term licensee self-assessment in order to facilitate communication inter-nationally and foster mutual understanding. Once this is done, CNRA could discuss pros and cons with various ways to inspect these programmes. It could also be discussed in what way and extent direct regulatory control could be replaced with regulatory requirements on licensee self-assessment.

United States

We would like to discuss whether any countries have experience with regard to the development of performance metrics for assessing the effectiveness of licensee self-assessment programmes.

NEA PUBLICATIONS AND INFORMATION

Printed material

The NEA produces a large selection of printed material, part of which is on sale, and part of which is distributed free of charge. The full catalogue of publications is available online at www.oecd-nea.org/pub.

Internet and electronic products

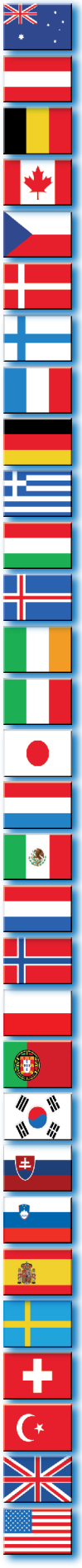
In addition to basic information on the Agency and its work programme, the **NEA website** offers free downloads of hundreds of technical and policy-oriented reports.

For full access to all print and electronic products, see the OECD/NEA **Nuclear Energy iLibrary** at www.oecd.org/bookshop?16121s1.

An **NEA monthly electronic bulletin** is distributed free of charge to subscribers, providing updates of new results, events and publications. Sign up at www.oecd-nea.org/bulletin/.

You can also visit us on **Facebook** at www.facebook.com/OECDNuclearEnergyAgency.

OECD PUBLISHING, 2 rue André-Pascal, 75775 PARIS CEDEX 16
ISBN 978-92-64-99162-0



Improving Nuclear Regulation

A common theme throughout the series of NEA regulatory guidance reports, or "green booklets", is the premise that the fundamental objective of all nuclear safety regulatory bodies is to ensure that nuclear facilities are continuously maintained and operated in an acceptably safe manner. In meeting this objective the regulator must bear in mind that it is the operator that has responsibility for safely operating the nuclear facility; the role of the regulator is to assess and to provide assurance regarding the operator's activities in terms of assuming that responsibility.

The full series of these reports was brought together in one edition for the first time in 2009 and was widely found to be a useful resource. This second edition comprises 14 volumes, including the latest on *The Nuclear Regulator's Role in Assessing Licensee Oversight of Vendor and Other Contracted Services*. The reports address various challenges that could apply throughout the lifetime of a nuclear facility, including design, siting, manufacturing, construction, commissioning, operation, maintenance and decommissioning. The compilation is intended to serve as a knowledge management tool both for current regulators and the new nuclear professionals and organisations entering the regulatory field.

OECD Nuclear Energy Agency
12, boulevard des Îles
92130 Issy-les-Moulineaux, France
Tel.: +33 (0)1 45 24 10 15
nea@oecd-nea.org **www.oecd-nea.org**

ISBN 978-92-64-99162-0