IAEA TECDOC SERIES

IAEA-TECDOC-1940

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Integrated Safety Assessment of Nuclear Installations by the Regulatory Body

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International Atomic Energy Agency

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INTEGRATED SAFETY ASSESSMENT OF NUCLEAR INSTALLATIONS BY THE REGULATORY BODY

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FOREWORD

IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety, establishes the requirement for the regulatory body to periodically perform integrated safety assessments of facilities or activities, in accordance with the graded approach, and to provide feedback to the authorized party. These assessments are to be based on the results of, and trends and conclusions identified from, inspections, reviews, assessments and the conduct of relevant activities. In this way, integrated safety assessment aims to ensure continuous safe operation of nuclear installations and to provide information to interested parties (e.g. the government, the public, the international community) within a specified time frame (e.g. quarterly, annually, as necessary).

The lessons identified from different IAEA peer review missions and training workshops have highlighted differences in Member States' understanding of the integrated safety assessment process, and thus the need for information on establishing an integrated safety assessment process consistent with the safety requirements established in GSR Part 1 (Rev. 1).

This TECDOC is intended to help address that need by providing practical information on the development of an integrated safety assessment mechanism by the regulatory bodies of nuclear installations. This mechanism can serve as a tool for performing an independent, holistic review of the safety performance of a nuclear installation by the regulatory body as well as for a broader preview to provide feedback to the authorized party on safety, optimization of its regulatory activities or initiation of a particular regulatory response, if needed. The mechanism proposed in this TECDOC comprises three steps: organizing the input data for integrated safety assessment from existing regulatory processes (e.g. inspections, reviews, assessments of operating facilities); trending and analysis; and development of overall results and conclusions.

This publication draws on the experience of experts from different regulatory bodies and provides a broader view of integrated safety assessment methodologies. The IAEA is grateful to all those involved in the development process. The IAEA officers responsible for this publication were Z.H. Shah and M. Shahzad of the Division of Nuclear Installation Safety.

EDITORIAL NOTE

CONTENTS

1. INTRODUCTION

1.1. BACKGROUND

The overall regulatory oversight and compliance verification with regulatory requirements are the important objectives of any nuclear regulatory system to ensure high standards of nuclear installation safety. These objectives are achieved through the systematic delivery of regulatory functions by means of established regulatory processes such as authorization, review and assessment, regulatory inspection and enforcement, to ensure that an adequate level of safety exists at nuclear installations. This verification and assessment for safety is conducted prior to granting authorization and is repeated over the entire lifetime of the installations. The need for a consistent and continuous assessment of safety was further highlighted as part of the IAEA Director General's report on lessons learned from the Fukushima Daichi accident [1]. The IAEA report on Strengthening Nuclear Regulatory Effectiveness in the Light of the Accident at the Fukushima Daiichi Nuclear Power Plant [2] further deliberated on some of the lessons learned, focusing on strengthening the nuclear regulatory system by recommending the following:

(a) "Regulatory review and assessment should be expanded to include a systematic reassessment of safety margins (robustness of the nuclear power plant design) for both existing and future nuclear power plants."
(b) "Regulatory bodies should be transparent and open to the public, and provide understandable and fact based information."
(c) "Regulatory bodies should enhance communication, transparency and sharing of regulatory knowledge and experience among themselves and with interested parties such as industry and the public."
(d) "Regulatory bodies should seek to adopt, adapt or reference IAEA safety standards in their legal or regulatory framework."

In respect of building up a comprehensive regulatory view regarding the overall safety status of nuclear installations, an integrated safety assessment is considered as a useful tool. In this regard, para. 4.46 of IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [3], requires the regulatory body to periodically conduct an integrated safety assessment (ISA). The ISA is a structured and systematic safety evaluation that looks at the overall safety of operating nuclear installations, in order to ensure continuous safe operation and to provide information to interested parties (such as the government, the public and the international community). The key inputs for the ISA include capturing the results from the regulatory oversight functions, e.g. inspections, review and assessment of operating facilities, and other relevant activities. The ISA process captures data, analyses trends and draw conclusions from these and other inputs to assess the overall safety of nuclear installations.

GSR Part 1 (Rev. 1) [3] requires regulatory bodies to have an effective oversight on the safety of facilities and activities in conducting their regulatory functions. Recommendations on how to fulfil these regulatory functions are provided by the associated IAEA Safety Guides. However, the Safety Guides supporting GSR Part 1 (Rev. 1) [3] do not currently contain practical information and guidance on the development of the ISA process to be used by the regulatory body. Moreover, the lessons from conferences, workshops, technical meetings and IAEA review missions, such as the Integrated Regulatory Review Service (IRRS), revealed that the understanding of the ISA process differs among States. There are also varying levels of understanding of the ISA among the IRRS international reviewers. This was identified by the nuclear regulatory bodies as a potential area of interest for the IAEA to develop a publication which is providing insights and practical information on establishing and implementing an ISA process, in accordance with GSR Part 1 (Rev. 1) [3], and which elaborates on some of the ISA practices being implemented in regulatory bodies of States experienced in regulating nuclear installations.

Considering the importance of the ISA process for assessing the overall safety of nuclear installations, there is a need to provide practical guidance on developing this process. Such guidance might take advantage of the expertise in States with well-established nuclear power programmes and the experience of States embarking on nuclear power programmes. The present publication provides practical guidance to the regulatory body for conducting an ISA of nuclear installations.

In this publication, the term ‘authorized party’ is used to indicate the person or organization responsible for any authorized facility that give rise to radiation risks who has been granted written permission by the regulatory body; the authorized party could be a licensee or an operating organization.

Specific terms used in this publication are to be understood as defined in the IAEA Safety Glossary [3] unless otherwise specified in the text.

1.2. OBJECTIVE

The objective of this publication is to provide practical guidance on conducting integrated safety assessments of nuclear installations by the regulatory body and their technical support organizations, where applicable, by describing:

(a) The importance and usefulness of ISA for assessment of the overall safety of nuclear installations;
(b) How the ISA process is established by regulatory bodies;
(c) Examples of ISA practices and processes in different States.

1.3. SCOPE

The ISA process and procedure described in the publication is developed for all types of nuclear installation in the operational phase. However, ISA can also be applied to other stages in the lifetime of nuclear installations, including design, construction, commissioning, and decommissioning.

1.4. STRUCTURE

This publication is structured into six sections and two annexes.

Section 1 includes the background, objective, scope and structure of the publication. Section 2 provides the basis and concept of the ISA. Section 3 describes the input to the ISA from various regulatory functions and activities. Section 4 describes the processes for the ISA by the regulatory body, and how to organize results and data from ISA inputs, trending analysis and development of overall results, as well as communication to the authorized party and other interested parties. Section 5 describes the output and outcomes of the ISA. The conclusions are summarized in Section 6. Annex I and Annex II describe practices of regulatory bodies in several States for the development and implementation of the ISA.

2. BASICS AND CONCEPT OF INTEGRATED SAFETY ASSESSMENT

2.1. DEFINITION OF INTEGRATED SAFETY ASSESSMENT

Integrated safety assessment is the independent, systematic and comprehensive assessment by the regulatory body of the safety performance of a regulated facility, resulting in conclusion of the overall safety performance and any necessary regulatory response.

2.2. OBJECTIVE OF INTEGRATED SAFETY ASSESSMENT

Integrated safety assessment is a tool for independent, holistic reviews of safety performance by the regulatory body, resulting in conclusion of overall safety performance and the potential for additional or reduced regulatory attention. Integration of the results of the regulatory core functions, and other relevant information, allows the regulatory body to step back and develop a higher level, comprehensive perspective on the safety of each facility. The integration is more than just a compilation of individual results, but rather a synergistic review to look for deeper understanding of performance drivers. Information from multiple processes and perspectives are looked at collectively for insights that is not usually apparent when looking at the information from an individual process from its own narrower perspective. States have different practices, which are presented in more detail in Annex I. It is beneficial for the regulatory body to conduct an ISA for the following reasons:

(a) This review process allows the regulatory body to make proactive judgements about performance trends. In case of declining performance, it allows for an earlier intervention by the regulatory body before the performance declines significantly. Accordingly, an ISA might be done periodically over the lifetime of the facility. Additionally, the ISA might be used for continuous improvement of safety by identifying additional actions that need to be taken to strengthen safety performance above what has been previously expected. Integrated safety assessment by the regulatory body does not relieve the authorized party from their prime responsibility for safety [4];

(b) ISA also supports the regulatory body in the implementation of defence in depth concept by its own independent and holistic assessment of safety justifications provided by the operating organization. This review is to check the consistency and the completeness of these justifications;

(c) Under Requirement 36 of GSR Part 1 (Rev. 1) [3], regulatory bodies are required to communicate to the public and other interested parties the basis for regulatory judgements and decisions. ISA is a beneficial tool to support this requirement, communicating the regulatory perspective of the safety performance of each regulated facility;

(d) The ISA might also serve as a tool for the regulatory body to plan and assess the effectiveness of their own regulatory programmes and processes. The ISA process also help to identify gaps or aspects in the regulatory oversight which are no longer necessary in the regulatory programmes allowing for enhancements to strengthen the regulatory body's processes.

2.3. SCOPE OF INTEGRATED SAFETY ASSESSMENT

ISA typically focuses on data and results which are collected for the operational phase of a nuclear power plant or other type of nuclear installation. However, the ISA process can also be applied to other stages in the lifetime of a nuclear installation. Furthermore, the ISA approach can also be used to provide, for example, a collective view of a fleet of nuclear power plants or a nuclear sector (e.g. nuclear power plants, nuclear fuel cycle, radioactive waste management).

2.4. BASIC CHARACTERISTICS OF INTEGRATED SAFETY ASSESSMENT

Paragraph 4.46 of GSR Part 1 (Rev. 1) [3] states:

"For an integrated safety assessment, the regulatory body shall first organize the results obtained in a systematic manner. It shall then identify trends and conclusions drawn from inspections, from reviews and assessments for operating facilities, and from the conduct of activities where relevant. Feedback information shall be provided to the authorized party. This integrated safety assessment shall be repeated periodically, with account taken of the radiation risks associated with the facility or activity, in accordance with a graded approach."

In general, the ISA embraces existing regulatory processes and does not necessarily constitute the creation of an entirely new set of processes. In addition, important generic inputs such as safety performance indicators, grading and rating of inspections and other regulatory functions, safety culture oversight, operating experience, international developments and the implementation of relevant safety improvements (e.g. new IAEA safety standards) might be considered for the ISA as appropriate.

There is sometimes confusion about the need of an ISA when a periodic safety review (PSR) is already being conducted. The concepts of ISA and PSR differ to an extent such that the authorized party conducts the PSR and the regulatory body conducts the ISA. The ISA also incorporates the results of the PSR, along with insights and input from other regulatory activities.

The frequency and scope of the ISA need to be determined depending on the risk involved and authorized party's performance by using a graded approach. The determination of this frequency can also consider other factors, such as whether the site is under enhanced regulatory oversight due to external events or other factors, or generic lessons learned from events in other facilities. Generally, the ISA is a longer term process compared to the frequency of assessments performed within the individual regulatory functions, which is providing input to the ISA process. Typically, an ISA might be conducted comprehensively within one to two years, based on the insights presented in this publication.

2.5. DEVELOPMENT OF THE INTEGRATED SAFETY ASSESSMENT PROCESS

Most of the information to be assessed in the ISA process is already available from the existing processes of the regulatory body. However, the overall time necessary to conduct the ISA process will depend on the availability and retrievability of relevant information and the organizational structure of the regulatory body. The way information is to be analyzed and evaluated might be established prior to attempting the review for a specific facility. It is recognized that some States might prefer alternative arrangements to an ISA. However, when an alternative approach is utilized, it is vital that it meets the objectives of the ISA as set out in Section 2.2. Such approaches can, if applied with appropriate scope, depth, frequency and rigour, achieve the same results as the process recommended in this publication. It is important that the process be developed in an open and transparent manner with authorized and interested parties. An assessment plan and subsequent procedures need to be prepared by the regulatory body for performing the ISA. The plan and procedure might state the topical areas of review, performance criteria to be used, and the source and availability of the technical experts who will perform this assessment.

Appropriate training and briefings of the team performing the ISA can be conducted to ensure that uniform criteria are applied, as well as to ensure the effective and efficient completion of the ISA.

3. INPUTS TO INTEGRATED SAFETY ASSESSMENT

3.1. CORE REGULATORY FUNCTIONS AND PROCESS

The core regulatory processes used to verify and fulfill regulatory functions are the following:

(a) Authorization;
(b) Review and assessment;
(c) Regulatory inspections;
(d) Enforcement;
(e) Development of regulations and guides;
(f) Emergency preparedness and response.

The objective of regulatory functions is the verification and assessment of safety in compliance with regulatory requirements. The regulatory processes provide a high degree of confidence for ensuring safety of the public and the environment throughout the lifetime of nuclear installations, until the release of facilities and activities from the regulatory control. The core regulatory functions interact with one another; for example, regulations and guides set out the regulatory requirements to be used in review and assessment, in the authorization process, in carrying out inspections, and when determining enforcement action. Similarly, the findings of review and assessment might identify important inspection areas and guide through the approach to inspections, and inspections provide areas for review and assessment. All the regulatory processes interact with each other by providing the basis for regulatory decision making and contributing in application and improvement to each process [5]. Since the authorization is based on of regulatory review and assessment as well as regulatory inspections, ISA inputs from authorization may be considered under Sections 3.1.1 and 3.1.2.

3.1.1. Regulatory review and assessment

The review and assessment process is a critical appraisal, performed by the regulatory body, of the information submitted by the authorized party or information that comes from inspection, information from events/accidents, feedback on operating experience at national and international levels or other specified reports (e.g. records, comprehensive safety reviews, dose records) relevant to the safety of the facility or activity. Review and assessment is undertaken in order to enable the regulatory body to make a decision or a series of decisions on the acceptability of the facility or activity by complying with regulatory requirements and conditions specified in authorization, as stated in Requirement 25 of GSR Part 1 (Rev. 1) [3]. The process consists of examining the authorized party's submissions, and other information as described above, on all aspects relating to the safety of the facility or activity.

For operation of the facility or conduct of the activity, the regulatory body requires that the authorized party reports regularly on adherence to safety objectives and compliance with specified regulatory requirements, and on efforts made to enhance safety. Accordingly, the regulatory body reviews and assesses the reports and performs inspections to confirm compliance with regulatory requirements and to confirm that the facility can continue safe operation.

It may be necessary for the authorized party to perform a reassessment for safety of its facility and for the regulatory body to review and reassess its results. For example, an experience relevant to safety has been gained at the facility or similar facilities, information from relevant tests or from research and development (R&D) programmes and new knowledge of technical matters, proposed modifications to the facility, or changes in the regulations and guides. Further recommendations on conducting review and assessment are provided in IAEA Safety Standards Series No. GSG-13, Functions and Processes of the Regulatory Body for Safety [6].

With regards to PSR, para. 2.18 of IAEA Safety Standards Series No. SSG-25, Periodic Safety Review for Nuclear Power Plants [7], states:

"The regulatory body should review the PSR report prepared by the operating organization and the proposed safety improvements, should identify any issues it wishes to raise (for example, whether further safety improvements need to be considered), should review the proposed integrated implementation plan and should determine whether the licensing basis for the nuclear power plant remains valid."

Results from regulatory review and assessment are a key input to the ISA and can include:

(a) The overall hazard and risk posed by the facility and any anticipated changes over the period of time;
(b) Short/long term resolution issues in the Safety Evaluation Reports during the licensing period;
(c) Technical adequacy of authorized party's submissions;
(d) Safety improvements arising e.g. from the review of results of the PSRs, insights from probabilistic safety assessments, stress tests and major design modifications;
(e) Safety issues identified e.g. from the assessment of incidents, new research findings or technological advancements.

There are various examples of different practices in States regarding consideration of review and assessment as an input to ISA. More details are provided in Annex I. As a typical example, in Pakistan regulatory review and assessment is considered one of the important pillars of ISA.

3.1.2. Regulatory inspections

The primary purpose of regulatory inspections is to independently provide a high level of assurance that activities performed by the authorized party are complying to applicable laws, regulations and conditions of authorization. The regulatory body performs inspections on a sample of the authorized party’s activities. These sample activities are selected using a graded approach, consistent with the magnitude of hazard and risk associated with the activity.

Paragraph 4.50 of GSR Part 1 (Rev. 1) [3] states:

“The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization.”

The regulatory body verifies the contents of the documents submitted by the applicant by means of inspection of the facility or activity where radiation sources are to be installed or used. Such inspections will also allow the regulatory body to supplement the information and data necessary for review and assessment. Recommendations on types, performance and records of the regulatory inspection are provided in GSG 13 [8].

In addition to verifying compliance with regulatory requirements, the regulatory body’s inspection programme needs to be able to obtain a general indication of safety performance at the facility or activity. Common performance indicators for safety include the following:

(a) Housekeeping;
(b) Financial stability;
(c) Staffing, including turnover of staff;
(d) Record keeping and retrieval systems;
(e) Investigation levels set by the authorized party and the procedures to be followed in the event that investigation levels are exceeded;
(f) Training, including arrangements for retraining of staff;
(g) Occupational exposures for the type of facility or activity;
(h) Recurring failures of structures, systems and components (SSCs) important to safety;
(i) Unavailability of SSCs;
(j) Compliance with operating rules and technical specifications.

In Germany, in addition to safety performance indicator described by the authorized party, the regulatory body has developed its own set of performance indicators to form a comprehensive impression of safety performance of the plant. Further details of this supervision instrument are given in Annex I.

Inspection findings and observations from planned and reactive inspections are important inputs into the assessment of overall safety performance of the authorized party. Independent insights into strengths and weaknesses of operations, event response, equipment functionality, material condition, corrective actions, safety improvements, management oversight, safety cultures, etc. can be input into the ISA. Prior to commencing the review of the various inspection findings during ISA, a method to assess, categorize, rank and prioritize findings needs to be established and documented, for example in the review reports. One criterion to categorize the findings is the impact of non-conformances on the concept of defence in depth and the fundamental safety functions of a nuclear power plant (reactivity control, core cooling and the confinement of radioactive material). The adequacy of the plant’s defence in depth with reference to the five levels is further explained in INSAG-10 [9].

3.1.3. Enforcement

Requirement 30 of GSR Part 1 (Rev. 1) [3] states:

"The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized party with regulatory requirements or with any conditions specified in the authorization."

The main purpose of enforcement is to ensure safety by deterring non-compliance, encouraging prompt identification of non-compliances by the authorized party, and ensuring that appropriate corrective actions are taken in a timely manner. Regulatory enforcement actions are taken by the regulatory body to address non-compliance by the authorized party with applicable requirements specified conditions of authorizations. Such actions are taken to ensure that the authorized party promptly modifies or corrects aspects of its procedures, practices, conditions of a facility's SSCs important to safety.

The severity and level of enforcement actions arising from regulatory response provide a measure of the authorized party's safety performance. Furthermore, the process of gathering evidence and investigations in support of potential enforcement activity provide unique insights into the effectiveness of the authorized party's management system, leadership and safety culture. In addition, numbers and kinds of enforcement cases (e.g. only a small number of enforcement actions of severe nature are expected against an effective regulatory regime) and time of issuing enforcement decisions after finding of non-compliance might be reviewed as part of the ISA process.

3.1.4. Revision and updating regulatory requirements

Regulations and guides need to be reviewed and revised by the regulatory body as necessary to keep them effective and up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience. Technological advances, research and development work, relevant operational lessons learned, and institutional knowledge is valuable and be used as appropriate in reviewing and revising the regulations and guides. After the Fukushima Daiichi accident and in line with the Vienna Declaration on Nuclear Safety [10], many States reviewed and updated their regulatory framework to incorporate the lessons learned from the accident. Specific examples on reviewing and revising regulations, provided by States, are given in Annex I.

The revised or updated regulatory requirements might necessitate reassessment of facilities or activities of the authorized party, followed by regulatory review and assessment and inspection. The PSR safety factor 1, Plant Design (see SSG-25 [11]), provides valuable input for the ISA as review of this safety factor is conducted by the authorized party for all SSCs important to safety. The deviation between the plant design and current safety requirements, as well as their safety significance, are identified during the review of PSR safety factor 1. In addition, the regulatory body can also collect the records of all letters and/or notifications in which the authorized party needs to take necessary actions and/or reassessment on the basis of revised or updated regulatory requirements and their current status of implementation. The results will serve as an input for the ISA.

3.1.5. Emergency preparedness and response

Paragraph 4.13 of IAEA Safety Standards Series No. GSR Part 7, Preparedness and Response for a Nuclear or Radiological Emergency [12], states:

"The regulatory body shall require that arrangements for preparedness and response for a nuclear or radiological emergency be in place for the on-site area for any regulated facility or activity that could necessitate emergency response actions."

Some countries have identified nuclear emergency preparedness and response as one of the important areas subject to evaluation in their regulatory oversight report for national nuclear power generating sites. Further details regarding the evaluation of this important input are provided in Annex I and Annex II.

Results from the regulatory oversight of the authorized party's emergency preparedness and response function are a key input to the ISA and can include the following:

(a) Review and assessment of the on-site emergency arrangements developed by the authorized party, to verify compliance with regulatory requirements. Review and assessment ensure that the on-site emergency arrangements provide, to the extent practicable, assurance of an effective response to the full range of postulated nuclear or radiological emergencies, including those of very low probability;
(b) Results from emergency prepardness inspection and evaluation of the on-site emergency arrangements against predetermined criteria and regulatory requirements;
(c) Findings and observations from emergency exercises, drills and training;
(d) Evaluation of the national emergency exercises to assess the interface and coordination between the authorized party, off-site response organizations and regulatory body itself.

3.2. OTHER REGULATORY ACTIVITIES

3.2.1. Insights from safety culture

Lessons learned from the accidents at Chernobyl and Fukushima Daiichi concluded that the lack of a strong safety culture was one of the factors that have significantly contributed to the accidents. Safety culture is defined as the set of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance [13, 14]. The publications INSAG-4 [15] and INSAG-15 [16] were originally written for operating organizations but the concepts apply equally well to regulatory bodies, although their roles are different.

IAEA Safety Standards Series No. GSR Part 2, Leadership and Management for Safety [17], requires an authorized party to have in place an effective management system, a strong leadership and safety culture, and robust self-assessment systems for ensuring the safety of the facility or activity. These features impact all aspects of operation and performance and as such are an important input to the ISA process.

To assess the performance of work and the improvement of safety, self-assessment is performed by the senior management and management at all levels of the authorized party. The regulatory body reviews and evaluates these assessment results. Self-assessment includes, for example, the effectiveness of the processes, strategies, plans and objectives, the organization's safety culture, the adequacy of work performance and leadership. The authorized parties' assessment results also include outputs from all other forms of assessment, objectives realized by the organization and its processes, results delivered, non-conformances and their associated corrective and preventive actions.

Assessing safety culture can identify vulnerabilities in attitudes, beliefs, values, behaviors and shared understandings across the facility that could directly impact its level of safety. Safety culture assessments can identify blind spots, lack of management commitment, communication issues, acceptance of poor conditions and poor compliance with standards and procedures. Many States, for example Canada, the Republic of Korea, the United Kingdom, and the United States of America, have developed guidelines for regulatory oversight of safety culture, and regularly conducted inspections of nuclear installations to verify the compliance with these guidelines. Further insights from safety culture assessment are provided in Annex I.

Inputs to the ISA process to verify effectiveness of safety culture can include safety culture self-assessments performed by the authorized party, relevant observations from planned and reactive inspections, third party assessments and outcomes of other regulatory activities.

3.2.2. Operating experience feedback

Requirement 15 of GSR Part 1 (Rev. 1) [3] states:

"The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities."

The operating experience programme, as described in IAEA Safety Standards Series No. SSG-50, Operating Experience Feedback for Nuclear Installations [18], consists of reporting, collecting, screening, analyzing, trending, documenting and communicating operating experience at nuclear installations in a systematic way. Events having significant implications for safety need to be investigated in order to identify their direct and root causes, including causes relating to equipment design, operation and maintenance, or to human and organizational factors.

The regulatory body ensures that the authorized party's operating experience programme is effective and consistent with the regulatory requirements and is monitored by appropriate means to determine its effectiveness as well as to identify and implement necessary improvements, in accordance with paras 3.29 and 3.30 of SSG-50 [19]. As an example, in the Republic of Korea, the authorized party needs to establish and implement a programme for operating experience feedback (OEF) and submit its report to the Nuclear Safety and Security Commission (NSSC). The Korean Institute of Nuclear Safety (KINS) reviews this report and organizes an annual meeting/workshop with the authorized party to discuss and share information on the implementation of OEF. Further details of different practices in States regarding OEF are given in Annex I.

Regulatory inspections and the review and assessment of the OEF programme can reveal significant learning opportunities arising from events at the nuclear installation as well as applicable regulatory learning, and serve as an input to the ISA.

3.3. OTHER INPUTS TO INTEGRATED SAFETY ASSESSMENT

3.3.1. Performance indicators

The authorized party has indicators of operational performance and the effectiveness of corrective actions taken in response to identified deficiencies. Most operating nuclear power plants collect and publish a standard set of performance indicators such as radiation exposure, number of unplanned reactor trips, forced outage rates, plant availability, human performance, ratio between number of low level events and total number of events, number of corrective actions delayed and so forth. Numerical indicators to monitor operational performance are used by authorized parties and regulatory bodies worldwide. Performance indicators are quantitative measures of attribute of authorized party’s performance that shows how well a plant is performing when measured against established thresholds. The authorized party might collect hundreds of performance indicators for their own use, but the regulatory body often selects a subset of performance indicators of interest to them. Regulatory bodies in the Republic of Korea, Pakistan, the United Kingdom, and the United States of America use performance indicators as an input to ISA. Further information in this regard is given in Section 3.1.2. This data is useful input into the ISA process. Performance indicators can be evaluated through another regulatory programme, such as inspections, so that the inspection conclusions are the ISA input, or they can be evaluated initially as part of the ISA process. In either way, the performance indicators can show performance relative to a threshold as well as trends over time.

3.3.2. Further inputs

There might be further inputs to the ISA, such as the following:

(a) New legal requirements or policy statements in case of emerging significant safety issues. If the authorized party allocates sufficient resources and funding to implement new legislative requirements subsequent to a significant safety issue, then it can be considered as a good practice and an input to the ISA;
(b) Implementation of generic safety issues and generic issues raised by the regulatory body. If the authorized party is voluntarily implementing general safety issues raised by the regulatory body, then it can be attributed to leadership commitments towards safety and strong safety culture and an important input to the ISA;
(c) Allegations or concerns raised by workers or other entities (e.g. contractors, media, the public, neighboring States). For example, a large number of allegations or concerns from workers could be an indicator of a poor safety culture and an input to the ISA;
(d) Results of third-party peer reviews, for example those performed by the IAEA and/or other parties. The IAEA offers different peer review services for their Member States; these services play a key role for the global nuclear safety and security regime, enabling States to benefit from the independent insights of leading international experts, based on IAEA safety standards and security guidance publications. If the authorized party is regularly inviting peer reviews and has also

established a system to ensure the implementation of findings from peer review, then this can be considered as a good practice and an input to the ISA.

4. PROCESSES FOR INTEGRATED SAFETY ASSESSMENT BY THE REGULATORY BODY

The ISA model proposed in this publication comprises three different processes:

(a) Organizing input data for the ISA (see Section 4.1);
(b) Trending and analysis (see Section 4.2);
(c) Development of overall results of the ISA (see Section 4.3).

The first process involves the acquisition of results from individual regulatory activities and data obtained from other sources. Results are organized into suitable categories to facilitate subsequent trending and analysis. To improve overall efficiency and consistency, a common set of strategic safety attributes and safety areas can be developed to link with each regulatory activity. These common set of attributes might be linked with regulatory review and assessment, regulatory inspections, enforcement and other regulatory activities. However, it is not always possible to establish link between these common safety attributers with all regulated activities.

Trending and analysis can be performed by an interdisciplinary team, with appropriate expertise in operation, design and safety of the plant, review and assessment, inspection, enforcement, safety culture, emergency planning and preparedness. Trending and analysis of results and data is performed to identify precursors and adverse trends in the safety performance of authorized party so that proactive measures can be taken before serious conditions arise. Positive trends and indications are also noted. The total effect of the negative findings, safety improvements and positive findings (strengths) identified in the ISA can be analysed to ensure that the overall level of plant safety is adequate. Finally, individual trends and indications are evaluated and integrated to derive the overall results of the ISA providing an overarching cohesive assessment of authorized party safety performance.

The inputs to the ISA model are described in Section 3 of this publication. Outputs and intended outcomes are described in Section 5.

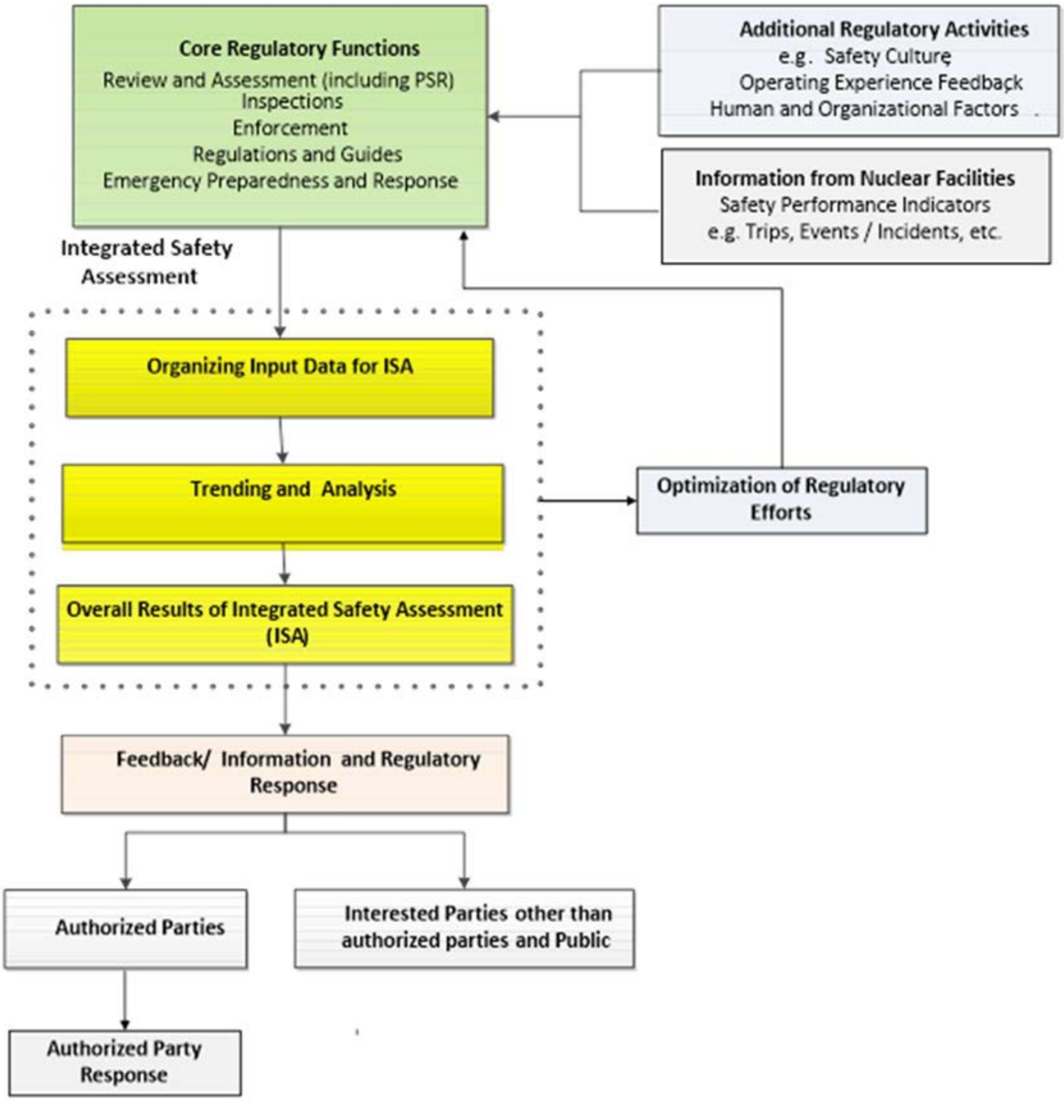

FIG. 1. Scheme of the process for ISA.

Figure 1 illustrates how these processes fit within the regulatory planning and execution cycle to drive continuous improvement in regulatory effectiveness and efficiency. The frequency with which this cycle is applied will vary depending on requirements of the regulatory body's management system. General practice within those States contributing to the development of this publication is to undertake an ISA with a frequency from one to two years.

4.1. ORGANIZING INPUT DATA

In order to apply a pragmatic approach to the ISA, a hierarchy might be established identifying the attributes on which the ISA is to focus. The identification of these attributes facilitates screening and organisation of results and data arising from regulatory activities and other sources for efficient and effective trending and analysis.

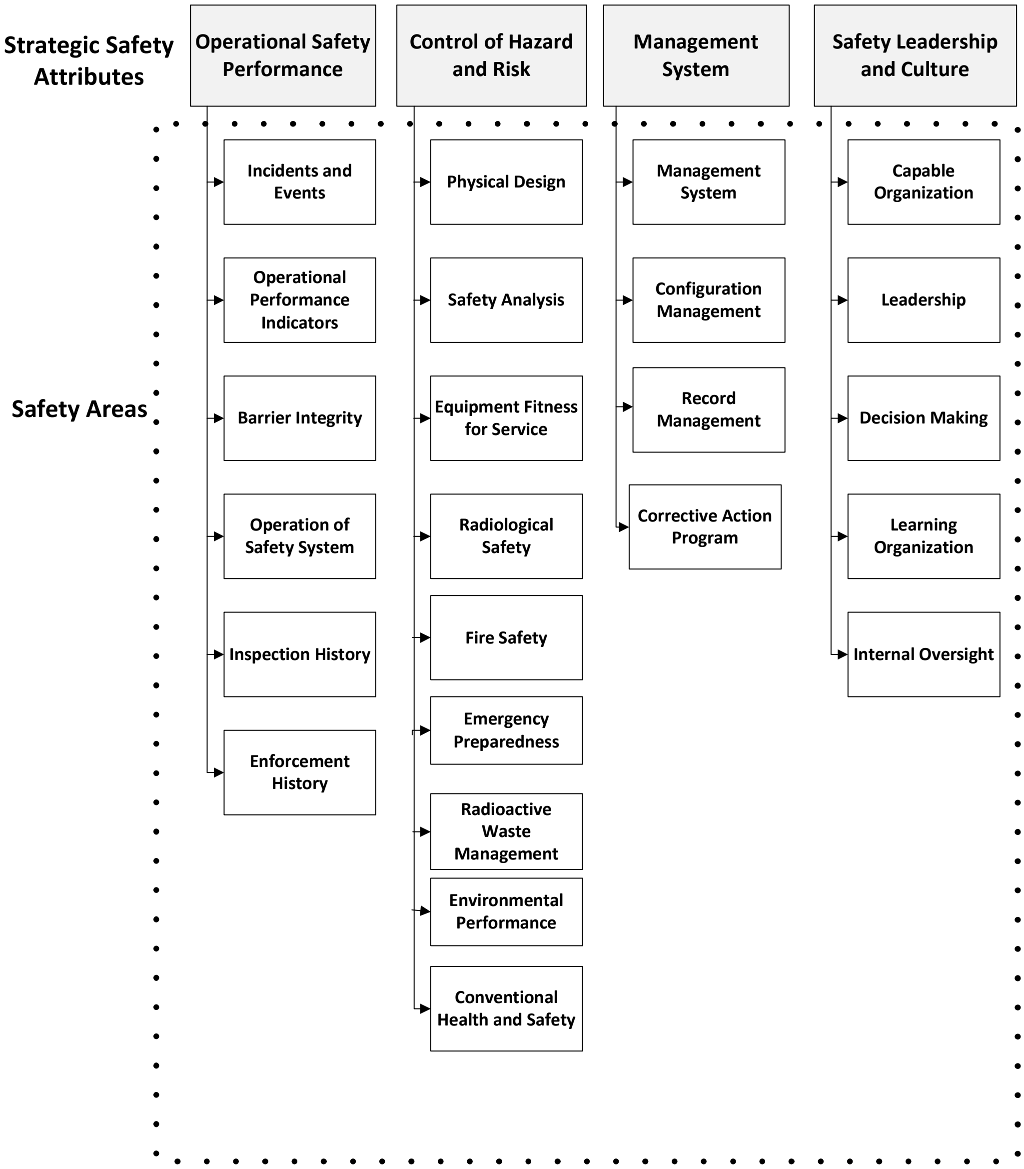

FIG. 2. Example of strategic safety attributes and safety areas which may be considered within ISA.

One approach to establishing such a hierarchy is to establish top level, strategic safety attributes on which the authorized party's safety performance can be assessed. Below each strategic safety attribute, a range of lower tier measures (or safety areas) can be identified. The approach is illustrated in Fig. 2. The attributes identified in Fig. 2 are just for guidance; States may identify their own attributes and safety areas depending upon their national regulatory practices and type of nuclear installation. States can further consult the specific examples of Canada, Pakistan, the United Kingdom and the United States of America, regarding organizing results and data given in Annex I.

Irrespective of what approach is used, the regulatory body might wish, in the interests of openness and transparency, to communicate the proposed strategic safety attributes and safety areas on which the ISA is to focus to the authorized party and other interested parties. The safety areas of interest to the regulatory body can change with the stage in the lifetime of the plant (design, construction, operation, decommissioning). In any case, the set of safety areas considered in the ISA need to be reassessed from time to time.

4.2. TRENDING AND ANALYSIS

The results from different ISA input to the approach adopted in Section 4.1 need to be aligned and linked. For example, one of the core regulatory functions is regulatory inspections. The input of regulatory inspection needs to be aligned with the lower tier measures (safety areas) identified in Section 4.1. This can be elaborated with the following example. If during the assessment process it is found that one of the significant trends in regulatory inspection is increased in reactor coolant leakage rate, then this trend needs to be linked with 'Barrier Integrity' (safety area) defined under Operational Safety Performance (strategic safety attributes). For each of the safety areas considered in the ISA, performance criteria need to be set against which trending and analysis is then performed. The results and data from ISA inputs – after having been organized (see Section 4.1) – need to be analysed and evaluated.

These performance criteria can be defined as a general objective; for example, 'plant operation is safe and secure, with adequate regard for health, safety, security, radiation and environmental protection, and international obligations.' Alternatively, more specific criteria can be adopted as a measure of safety performance; for example, safety areas such as 'Operating performance' criteria, 'Number of automatic reactor shutdowns' and 'Number of technical specification violations' can be identified for review. Both quantitative and qualitative criteria are likely to be necessary. States' specific practices regarding performance criteria can be found in Annex I and Annex II.

Trending and analysis be performed to allow recognition of developing or emerging problems and to assess the significance of those observations so that early proactive action can be taken before performance declines significantly. The methodology for the trending and analysis generally depends on the safety area which is considered; however, such work is usually be performed by a multi-disciplinary team. The following types of trend can be identified:

(a) Reoccurring issues or causes of incidents;
(b) Incidents arising in certain modes of operation;
(c) Reoccurring failures or degradation modes;
(d) Adverse trends in human and organizational performance;
(e) Characteristics and indications of authorized party's safety culture;
(f) Positive trends;
(g) Changes in frequencies of events, incidents, findings, non-compliances, human errors etc;
(h) Significant number of enforcement actions and slow response to regulatory issues.

The results of the analysis might be a rating on a discrete or continuous scale and/or conclusions and insights (e.g. identified trends or weaknesses). The methodology for evaluating the results obtained typically cannot be purely numerical but will also necessitate the exercise of judgment by competent staff. Different States have adopted different approaches for rating; further details are provided in Annex I.

4.3. DEVELOPMENT OF OVERALL RESULTS

Depending on the intended use, the regulatory body can make judgement on the authorized party's performance in individual safety areas. Ratings for individual safety areas can be further aggregated to achieve combined judgement for each safety attribute and thereafter, each plant, site or fleet.

During the ISA process, the regulatory body and/or its technical support staff can communicate with the operating organization as well as its on-site inspectors to clarify issues, including discussion of any supplementary issues identified by the evaluator, and to obtain any essential additional information. The outcome of these communications needs to be recorded for future reference.

In case that the ISA identifies an issue that warranty an immediate and significant risk to the health and/or safety of workers or the general public or to the environment, the regulatory body needs to ensure that the authorized party takes urgent and appropriate action and does not wait until the completion of the ISA before taking corrective action or implementing safety improvements.

5. OUTPUT AND OUTCOMES OF INTEGRATED SAFETY ASSESSMENT

5.1. REPORTING THE RESULTS TO THE AUTHORIZED PARTY

The ISA contributes towards fulfilling the intent of requirements of para. 4.46 of GSR Part 1 (Rev. 1) [3]. The results obtained from the ISA (see Section 4.3) need to be compiled and reported to the authorized parties party periodically.

Paragraph 4.46 of GSR Part 1 (Rev. 1) [3] states that the regulatory body "shall … identify trends and conclusions drawn from inspections, from reviews and assessments for operating facilities, and from the conduct of activities where relevant. Feedback information shall be provided to the authorized party." Further, para. 4.46 states that the ISA "shall be repeated periodically, with account taken of the radiation risks associated with the facility or activity, in accordance with a graded approach." The results obtained from the ISA (see Section 4.3) can be reported through formal or informal meetings between the regulatory body and the authorized party or through issuance of formal documents such as reports or letters. These meetings or documents could be specific to a plant, a site or a fleet. If warranted, these communications could include some action on the part of the authorized party to make enhancements or take corrective actions to meet regulatory expectations within the identified or stipulated time frame.

Irrespective of the form in which reporting is made, all relevant results from ISA need to be provided. This might include the following:

(a) Description of the inputs used for the ISA;
(b) Safety areas considered in the ISA;
(c) Overall conclusions derived from the ISA;
(d) Actions required or expected from the authorized party;
(e) Future areas of regulatory focus.

The authorized party can consider the results from the ISA and use them for continuous safety improvement. The authorized party’s actions can be verified by the regulatory body through implementation of regulatory processes, i.e. review and assessment, inspection of facilities and activities, and enforcement.

5.2. INFORMATION TO INTERESTED PARTIES

Paragraph 2.14 of IAEA Safety Standards Series No. GSG-6, Communication and Consultation with Interested Parties by the Regulatory Body [20], states:

“The regulatory body should establish and implement appropriate arrangements for communication and consultation in order to provide interested parties with timely, reliable, comprehensive, understandable and easily accessible information on safety, radiation risks and regulatory issues.”

The ISA contribute towards fulfilling the intent of requirements regarding establishing, maintaining and retrieving information regarding safety of the facilities by following a systematic approach and its subsequent sharing with the public and other interested parties. The results of the ISA can be communicated to the public and other interested parties through various methods, including the following:

(a) Issuing a document such as a report (ISA can either be part of the annual report of the regulatory body or a dedicated ISA report);
(b) Posting on web page and/or social media;
(c) Holding a public meeting;
(d) Issuing a press release.

5.3. IMPROVEMENTS IN REGULATORY PROGRAMMES

Paragraph 5.60 of IAEA Safety Standards Series No. GSG-12, Organization, Management and Staffing of the Regulatory Body for Safety [21], states:

“In accordance with the concept of a learning organization, a strategic objective of the regulatory body should be the continuous improvement of its performance. The regulatory body should systematically seek and analyses information on its own performance, including the effectiveness and efficiency of its integrated management system and its processes.”

The results of the ISA might be used to improve the efficiency and effectiveness of regulatory programmes and processes. The outcome of the ISA highlights areas of strong safety performance and those areas where efforts are needed to improve the safety performance. This information will help the regulatory body to focus its regulatory oversight activities on those areas that have weak safety performance.

Enhanced or optimized regulatory attention might be one of the outcomes of the ISA findings requiring changes to the regulatory strategy and programme for a sector, installation or on authorized party. In addition, the regulatory body could also initiate improvements to its own processes and practices to enhance regulatory efficiency and effectiveness.

6. CONCLUSION

Integrated safety assessment (ISA) is an important tool for the regulator body to ensure that an authorized party is fulfilling its responsibilities for ensuring protection and safety of people and the environment from the harmful effects of ionizing radiation.

The Fukushima Daiichi accident showed that it is difficult to identify the vulnerabilities in systems which include, among others, the complex interaction between people and organization and technologies without having a consolidated assessment tool and process. The ISA provides a systematic approach which is necessary to examine the complex interactions and detect the weaknesses early, allowing corrective actions to be taken prior to significant degradation in performance.

Benefits of the ISA include a holistic view of safety performance, identification of needed safety enhancements, strengthening of regulatory programmes and communications with interested parties. However, the ISA by the regulatory body does not relieve the authorized party from their primary responsibility for safety, in accordance with Principle 1 of SF-1 [22].

The ISA process needs to be developed in consultation with authorized parties as well as other interested parties, to ensure robustness and a common understanding. The result of an ISA is a comprehensive review to ensure safety and wide communication of the regulatory body's safety conclusions, providing confidence in the regulation of nuclear installations in an open and transparent manner.

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ANNEX I. NATIONAL PRACTICES OF REGULATORY BODIES FOR INTEGRATED SAFETY ASSESSMENT

I-1. INTRODUCTION

The accumulated worldwide experience in regulating nuclear power programmes is substantial. It is recognized that every State has its unique characteristic of describing ISA and there is also variation in its application, keeping in view respective national polices, requirements and methodology. The experience of any specific State might not be directly applied; however, it does offer relevant information which, if duly analyzed and evaluated, may provide useful guidance for other States. Annex I provides an overall picture of the prevailing practices regarding development and implementation of ISA for the safety of nuclear power plants.

I-2. CANADA

The CNSC (Canadian Nuclear Safety Commission) evaluates the safety performance of nuclear power plant (NPP) licensees and prepares an annual report on their safety performance referred to as the Regulatory Oversight Report, which is presented to the Commission and is subsequently published on the CNSC web page. Prior to 2017, the report was referred to as the Regulatory Oversight Report for Canadian NPPs. However, in 2017, the report was expanded to include the safety performance evaluation of waste management facilities located at NPP sites. The report has been renamed as the Regulatory Oversight Report for Canadian Nuclear Power Generating Sites.

The CNSC evaluates how well licensees meet regulatory requirements and CNSC expectations for the performance of programmes in 14 safety and control areas (SCAs) that are grouped in accordance with their functional areas of management, facility and equipment, or core control processes.

These SCAs are further divided into 71 specific areas that define the key components of the SCA. The functional areas, SCAs and the specific areas that are used in CNSC's safety performance evaluation are presented in Table I-1.

An example of safety performance ratings for Canadian NPPs is given in Table I-2. An example of a conclusion of a CNSC Regulatory Oversight Report for Canadian Nuclear Power Generating Sites is as follows:

The evaluations of all findings for the SCAs show that, overall, NPP licensees made adequate provisions for the protection of health, safety and security of Canadians and the environment from the use of nuclear energy, and took the necessary measures to implement Canada's international obligations. The following observations support the conclusion of safe operation:

(a) There were no serious process failures at the NPPs;
(b) No member of the public received a radiation dose that exceeded the regulatory limit ;
(c) No workers at any NPP received a radiation dose that exceeded the regulatory limits;
(d) The frequency and severity of non-radiological injuries to workers was minimal;
(e) No radiological releases from the stations exceeded the regulatory limits;
(f) Licensees complied with their licence conditions concerning Canada's international obligations.

TABLE I-1. THE CNSC'S FUNCTIONAL AREAS, SAFETY AND CONTROL AREAS AND SPECIFIC AREAS FOR ASSESSING LICENSEES' SAFETY PERFORMANCE

Functional area	**Safety and control area (SCA)**	**Specific area**
Management	Management system	Management system
		Organization
		Change management
		Safety culture
		Configuration management
		Record management
		Management of contractors
		Business continuity
		Problem identification and operating experience
		Performance assessment, improvement and management review
	Human performance management	Human performance programme
		Personnel training
		Personnel certification
		Initial certification examinations and requalification tests
		Work organization and job design
		Fitness for duty
	Operating performance	Conduct of licensed activity
		Procedures
		Reporting and trending
		Outage management performance
		Safe operating envelope
		Severe accident management and recovery
		Accident management and recovery
Facility and equipment	Safety analysis	Deterministic safety analysis
		Probabilistic safety analysis
		Criticality safety

TABLE I-1. THE CNSC'S FUNCTIONAL AREAS, SAFETY AND CONTROL AREAS AND SPECIFIC AREAS FOR ASSESSING LICENSEES' SAFETY PERFORMANCE (cont.)

Functional area	**Safety and control area (SCA)**	**Specific area**
		Severe accident analysis
		Management of safety issues (including R&D programmes)
	Physical design	Design governance
		Site characterization
		Facility design
		Structure design
		System design
		Component design
	Fitness for service	Equipment fitness for service/equipment performance
		Maintenance
		Structural integrity
		Aging management
		Chemistry control
		Periodic inspection and testing
Core Controls and Processes	Radiation protection	Application of as low as reasonably achievable (ALARA)
		Worker dose control
		Radiation protection programme performance
		Radiological hazard control
		Estimated dose to public
	Conventional health and safety	Performance
		Practices
		Awareness
	Environmental protection	Effluent and emissions control (releases)
		Environmental management system
		Assessment and monitoring
		Protection of the public
		Environmental risk assessment

TABLE I-1. THE CNSC’S FUNCTIONAL AREAS, SAFETY AND CONTROL AREAS AND SPECIFIC AREAS FOR ASSESSING LICENSEES’ SAFETY PERFORMANCE (cont.)

Functional area	**Safety and control area (SCA)**	**Specific area**
	Emergency management and fire protection	Conventional emergency preparedness and response
		Nuclear emergency preparedness and response
		Fire emergency preparedness and response
	Waste management	Waste characterization
		Waste minimization
		Waste management practices
		Decommissioning plans
	Security	Facilities and equipment
		Response arrangements
		Security practices
		Drills and exercises
	Safeguards and non-proliferation	Nuclear material accountancy and control
		Access and assistance to the International Atomic Energy Agency
		Operational and design information
		Safeguards equipment, containment and surveillance
	Packaging and transport	Package design and maintenance
		Packaging and transport
		Registration for use

TABLE I-2. EXAMPLE OF SAFETY PERFORMANCE RATINGS FOR CANADIAN NUCLEAR POWER PLANTS

Canadian nuclear power plant safety performance ratings for Safety and control area	**NPP1**	**NPP2**	**NPP3**	**NPP4**	**NPP5**
Management system	SA	SA	SA	SA	SA
Human performance management	SA	SA	SA	SA	SA
Operating performance	FS	FS	FS	FS	FS
Safety analysis	FS	FS	FS	FS	SA
Physical design	SA	SA	SA	SA	SA
Fitness for service	SA	FS	SA	SA	SA
Radiation protection	FS	FS	FS	SA	SA
Conventional health and safety	FS	SA	SA	FS	FS
Environmental protection	SA	SA	SA	SA	SA
Emergency management and fire protection	SA	SA	SA	SA	SA
Waste management	FS	FS	FS	FS	SA
Security	SA	SA	SA	SA	SA
Safeguards and non-proliferation	SA	SA	SA	SA	SA
Packaging and transport	SA	SA	SA	SA	SA

SA: Satisfactory, FS: Full satisfactory.

I-3. GERMANY

In Germany, after the necessary licence has been granted, nuclear installations are subject to continuous regulatory supervision, in accordance with the Atomic Energy Act and associated ordinances, over their entire lifetime from the start of construction to the end of decommissioning. This supervision is performed by the nuclear licensing and supervisory authorities of the Länder (federal states) on behalf of the Federation. As in licensing, the supreme objective of regulatory supervision of nuclear installations is to protect the public and the people working in these installations against the risks associated with the operation of the installations.

Example from the Länder (federal states) level

In the following, examples are taken from the regulatory supervision of nuclear power plants in the Land Baden-Württemberg to illustrate practiced aspects of integrated safety assessment (systematic and periodically repeated organization of results from regulatory functions with feedback information provided to the authorized party). The processes are described in a supervision manual.

(a) Evaluation of the results from supervision and monitoring

In accordance with the process for supervision, monitoring, and licensing, the entirety of the supervision and monitoring results referring to one nuclear installation or facility is evaluated on an annual basis. The evaluation is aimed at whether the supervision and monitoring measures provided for in the annual programme were performed, and if weak spots could be identified. The results of the evaluation are communicated within the section, to the operator and used for the preparation of the following work programme. Findings of superordinate significance are communicated within the division and evaluated with regard to future objectives and measures. If the evaluation yields suggestions for improvements of the management system, these are integrated in the improvement process. Specific processes underlying the process for supervision, monitoring, and licensing with relevance to such an integrated safety assessment are described exemplarily below.

(b) On-site inspections and annual inspection programme

In accordance with the process for on-site inspections, at the beginning of the year, an annual inspection programme is developed for each installation on the basis of findings gained during supervision activities. Based on the findings from current on-site inspections and other areas of supervision (e.g. the reports on the safety management system or the event analysis), the current annual inspection programme is being reviewed during the respective period and updated where necessary. To this end, this information is to be evaluated as to whether the annual inspection programme has to be modified until the end of the first quarter of each year. At the end of the year, the plant related section in charge evaluates the on-site inspections in a report. In doing so, the days of inspection performed are specified in table form for each area of inspection. Significant deviations from the reference values mentioned in the supervision manual or the annual inspection programme for the areas of inspection are annotated. Priorities and irregularities (e.g. special reportable events) of the supervision activity have to be mentioned and assessed in the report.

(c) Assessment of the personnel-organisational area (human and organizational factors) within the scope of on-site inspections

Going beyond the consideration of individual safety indicators described in operator reports, the regulatory authority attempts to form a comprehensive impression of the safety performance of the nuclear power plants by using its own set of indicators. To this end, quantitative indicators are explored and evaluated with a view to identifying emerging trends. The quantitative variables which are already communicated to the regulatory authorities in periodic reports are complemented by, and combined with, additional indicators to form a set of valid indicators.

The supervision instrument KOMFORT (catalogue for recording organisational and human factors during on-site inspections) serves the assessment of indicators of the personnel-organisational area within the scope of on-site inspections. The continuous collection of information in the personnel-organisational area serves the long term monitoring and helps to detect negative developments in this area at an early stage, similar to an early-warning system. Through an annual meeting with the operator, personnel-organisational improvements can be initiated.

KOMFORT comprises the following indicators:

(a) Quality of written documents;
(b) Adherence to obligations;

(c) Qualification and competencies;
(d) Work climate;
(e) Work load;
(f) Seizing of leadership functions;
(g) Cleanliness, tidiness and housekeeping of the plant; and
(h) Interaction with the authority.

The regulatory officer uses KOMFORT during subject related visits on-site. In doing so, data are collected on those indicators that may be integrated into the subject of the visit. The regulatory officer assesses the information acquired by means of his or her technical competence and experience in supervision in accordance with a four level assessment scale (ideal, alright, not alright, inadequate). In case of uncertainties or doubts as to the level on the scale the information has to be assigned to, an assessment aid for the respective indicator helps the regulatory officer. For every level of the assessment scale, it lists typical examples occurring in practice, each of them sorted in accordance with the assessment aspects. The assessment aid serves as a guideline only; the examples listed are not exhaustive. The operator is to receive feedback on the results of the annual evaluation of the KOMFORT indicators for each site every year. That way, noticeable results or possible negative developments can be addressed, and the causes can be clarified. The feedback to the operator is given within the scope of the annual meeting on safety management.

Management level meetings

The process for management level meetings describes that, regardless of a certain reason, the division head of the authority conducts discussions with the senior management of the nuclear power plants on a quarterly basis. These discussions are informal in order to promote the exchange of opinions and evaluations. The discussions serve the exchange of information on the basic issues and evaluations related to the following topics:

(a) The safety of the plants;
(b) Safety culture at the plants and the operator's safety culture promoting activities;
(c) Trends and the assessment thereof performed by both the operator and the authority;
(d) Findings gained from and the handling of events;
(e) Company strategy;
(f) Resources in respect of personnel, equipment/retrofits, and finances;
(g) Economic and political influences on both the operation of the plant and the supervision activities;
(h) The authority's influence on safety and safety culture;
(i) Working atmosphere including motivation, satisfaction, identification, and communication;
(j) The cooperation of regulatory authority and operator (perhaps the initiation of a discussion between the authority's head of the house and the operator's board); and
(k) Current issues of super ordinate or fundamental relevance.

The strategic dialogue also serves the purposes of mutual constructive and target oriented criticism, and the reciprocal evaluation of each other's behaviour.

Example from the federal level

Processes concerning the cooperation between the Federation and the Länder (federal states) within the Atomic Energy Act and associated ordinances are also described in a specific supervision manual. An example from this framework for a process involving aspects of an integrated safety assessment is the generic evaluation of national and international operating experience. This is performed by the federal supervisory authority BMUB (Federal Ministry for the Environment, Nature Conservation, and Nuclear Safety) and its technical support organization GRS, in addition to the event evaluation by the Länder (federal states) supervisory authorities. Different sources of operating experience are screened, including all events reported within Germany or via the International Reporting System for Operating Experience (IRS). In case a generic issue (considering safety significance and applicability to other German plants) is identified, a German Information Notice (GIN) containing recommendations to avoid equivalent or similar events is prepared and submitted to Länder (federal states) authorities, expert organizations, licensees, manufacturers, and other specialised institutions. Licensees have to react to GINs. GRS, on behalf of BMUB, systematically and comprehensively evaluates this feedback and regularly reports the results of this evaluation to BMUB and the national recipients of GINs. In case of important generic insights, the original GIN will be updated.

I-4. REPUBLIC OF KOREA

There is no specific guidance or predefined process on the ISA for nuclear facilities in Republic of Korea. Examples for basic elements of the ISA are review and assessment (including PSR), inspections, and OEF. The following list provides examples which are related to the ISA:

(a) Comprehensive Plan for Nuclear Safety;
(b) Annual Safety Reports;
(c) ‘Risk Informed Periodic Inspection’ focused on the risk significant systems in addition to current periodic inspection;
(d) Other activities.

Comprehensive Plan for Nuclear Safety

The government implements long term and systematic policies and strategies related to nuclear safety in accordance with the Nuclear Safety Act. For effective implementation of nuclear safety laws and various policies for safety regulation, a comprehensive mid term and long term nuclear safety plan is established and implemented every five years, along with a detailed implementation plan being established every year. The NSSC checks the implementation status every year in order to ensure its practical implementation. The Comprehensive Plan for Nuclear Safety is at the pinnacle of the national nuclear safety plan and establishes the mid term and long term policy direction for nuclear safety.

The Comprehensive Plan for Nuclear Safety states that the basic direction of its establishment is to “Achieve Nuclear Safety at the Highest Possible Level”. Some strategies were set out as follows:

(a) Strengthen Nuclear Safety with Feedback of Lessons Learned from the Fukushima Daiichi Accident;
(b) Promote Safety Culture and Strengthen Public Communication;
(c) Build an Integrated Radiation Safety Management System;
(d) Establish a System for Nuclear Nonproliferation and Nuclear Security;
(e) Upgrade Nuclear Regulatory Capabilities through Active Investment in R&D and Human Resources;
(f) Expand Contributions to Global Nuclear Safety Regime;
(g) Innovate National Laws and Systems for Nuclear Safety.

Annual safety reports

Korea Institute of Nuclear Safety (KINS) produces an annual report of the operating NPPs which contains, for example, information on evaluation of events/incidents, performance indicators, the OEF, and safety issues of the operating NPPs. The Nuclear Safety and Security Commission (NSSC) publishes a comprehensive annual safety report which describes, for example, overall regulatory activities related to nuclear facilities such as review and assessment, inspections, R&D, safety issues including nuclear safety policy, development of regulations and guides, emergency preparedness and exercises.

Risk Informed Periodic Inspection (RIPI)

Besides the periodic regulatory inspection, KINS performs the RIPI to enhance inspection effectiveness by focusing on the risk significant systems and to enhance regulatory efficiency by allocating regulatory resources to risk significant systems. For example, events contributing to the core damage frequency higher than 1.3×10^{-7} per year were selected and accordingly 19 inspection items were determined. The RIPI is not a legal regulatory inspection, but an activity to improve current inspection practice. The RIPI could provide broader insight to monitor safety level of the operating NPPs by considering risk significant systems rather than hardware oriented inspection practice.

Other activities

Other activities to ensure the safety level of the nuclear facilities are: (a) implementation of the OEF; (b) safety culture inspection to NPP sites as well as to the headquarter of the utility; (c) safety performance indicators (SPIs); and (d) human performance based inspection.

It is required to perform the OEF by the licensee and to report to the NSSC by the regulation. KINS reviews the licensee's report and organizes an annual meeting/workshop with the licensee to discuss and share information on the implementation of the OEF.

KINS developed safety culture oversight guidelines and has conducted inspections to the NPPs as well as to the headquarter of the utilities for several years. The safety culture oversight by the NSSC was a driver for all licensees to establish and maintain a positive safety culture commensurate with the safety significance of their activities.

The human performance based inspection is conducted to minimize the likelihood of occurrence of human factors by intensifying on human behaviours associated with testing, repair, calibration or surveillance. Major factors which influence the human performance are education and training, fitness for duty, workplace environment, operating procedures, and human-system interfaces.

(a) Safety Performance Indicator (SPI)

SPI is a means to show the operational safety of a nuclear power plant and its radiological impacts, so that a trend analysis of safety performance can be performed.

The safety performance of each NPP is evaluated by 15 SPIs, related to safety management, safety system reliability, physical barriers, on-site and off-site radiation safety, with four colour coded ratings every year.

Development of SPIs

As the interest of the public in nuclear safety matters is increasing, a useful measure to show and easily perceive how the NPPs are being safely operated needs to be developed. Accordingly, several international organizations (such as IAEA and WANO) and national regulatory bodies (such as the U.S. NRC) began to develop a system of performance indicators to oversee the safety performance of NPPs.

Domestically, the SPI system was introduced in 1995 and applied to the operating PWRs for the performance trend analysis using 10 performance indicators. This SPI system was used to monitor the long term safety status of the NPPs' operation, to allocate regulatory resources and to facilitate international cooperation.

The SPI system given in Table I-3 was revised in the second quarter of 2005 and in the fourth quarter of 2015. The current SPI system is composed of 2 safety areas, 5 categories, and 15 indicators. Each indicator is colour coded to represent its safety performance grade. The four colours representing the grades are green, cyan, yellow, and orange, each of which stands for excellent, good, normal, and warning grade, respectively.

The evaluation of SPIs serves the following purposes:

- Confirmation of NPP safety, with quantitative operational performance;
- Efficient regulation through trend analysis of indicators;
- Enhancement of public confidence in the operational safety of NPPs.

(b) Feedback of Operating Experience

It is required to perform the OEF by the licensee and to report to the NSSC by the regulation. KINS reviews the licensee's report and organizes an annual meeting/workshop with the licensee to discuss and share information on the implementation of the OEF.

Domestic and foreign operating experiences related to safety, cases of incidents, and the results of safety related research are to be reflected in the operation and construction of nuclear installations through an administrative order of the NSSC, or through recommendations made during regulatory inspections by resident inspectors or inspectors of KINS. The Korea Nuclear and Hydro Power (KHNP), an authorized party in the Republic of Korea, is required to submit a report of the results on the implementation of the administrative orders and of the recommendations to the NSSC for review of its suitability. Typical examples are the action items following the Three Mile Island accident (1979), lessons learned from the damages at the reactor pressure vessel (RPV) head of the Davis-Besse nuclear power plant (2002), a loss of feedwater accident at the Mihama nuclear power plant in Japan (2004), and the loss of off-site power at the Forsmark nuclear power plant in Sweden (2006), all of which have been ordered to be reflected in all domestic nuclear power plants.

In cases where it is found necessary to modify nuclear installations or to change organizations or administrative matters on the basis of the results of self-assessments of domestic and foreign operating experiences, the KHNP files with the NSSC a safety assessment report related to the modifications and changes. Entrusted by the NSSC, KINS reviews the report. All procedures necessary for the operation of nuclear installations have to be deliberated by the plant nuclear safety committee and approved by the plant manager. To incorporate new technology, operating experiences and necessary information, the procedures are examined and supplemented at least every two years.

TABLE I-3. STRUCTURE OF THE SPI SYSTEM

Area	Category	Specific Performance Indicator	Remark
Reactor Safety	Operational Safety	Unplanned Reactor Scram	URS
		Unplanned Power Reduction	UPR
		Unplanned Reactor Scram with Complications	USwC
	Safety System	SI System Unavailability	SI
		EDG System Unavailability	EDG
		AFW System Unavailability	AFWS
		RHR System Unavailability	RHR
		CW System Unavailability	CW
		Safety System Functional Failures	SSFF
	Multiple Barrier	Fuel Reliability	FR
		Reactor Coolant Leakage	RCL
		Containment Reliability	CR
		Emergency Preparedness	EP
Radiation Safety	On-site Radiation Safety	Radiation Collective Dose	RCD
	Off-site Radiation Safety	Public Dose/Environmental Radiation	PD/ER

Grade of SPI:

- G **Excellent:** Safety margin is more than sufficient
- C **Good:** Safety margin is sufficient
- Y **Normal:** Safety margin is within expected norms
- O **Warning:** Safety margin is below norms while technically safe

The Nuclear Power Plant Event Scale Evaluation Committee was organized by the NSSC and it has been in operation for systematic assessment and feedback of safety related assessment of incidents and accidents and operating experiences. In addition, the KINS developed the Operational Performance Information System for Nuclear Power Plants (OIPS) to synthetically manage the data related to the incidents and accidents in operating nuclear facilities, event evaluation results and safety performance indicators. The OPIS can provide the foundation and means to give feedback to the operating experience. The information in OPIS (http://opis.kins.re.kr) is composed of the date, title, power level of reactor and turbine generator before shutdown, outline, watch code and field report, which are the input items for the IRS.

KHNP also formulates and implements the “Procedures for Utilization and Control of Technological Information”, to efficiently utilize the operating experience of foreign nuclear installations.

KHNP joined the Institute of Nuclear Power Operations (INPO) and the World Association of Nuclear Operators (WANO) to promote information exchange and cooperation among operators of nuclear installations. The KHNP also became a member of the PWR Owner’s Group, the Framatome Owner’s Group, and the CANDU Owner’s Group. The KHNP concluded technical agreements with foreign electric power companies to exchange relevant technologies and experience.

KINS continuously improves the e-FAST (electronic Functional Analysis and Simulation Tool) the nuclear plant analyzer which permits the qualitative and quantitative analysis of operating events collected to establish and enforce the nuclear plant operating experience feedback system on a national scale. The e-FAST, a tool of analyzing the status and operational progress of any nuclear power plant under normal operation, abnormal operation, transients and accidental circumstances, is the nuclear plant simulator designed to make the interactive manipulation of equipment possible through the Graphic User Interface. The e-FAST was developed from 2001 to 2005 and has regularly been improved for the five types of reactor operating in the Republic of Korea (i.e. OPR-1000, CANDU, Framatome, W/H 3 Loop, and W/H 2 Loop).

To share and spread the information on foreign and domestic operating experiences, a workshop on operating experiences feedback has been annually held at KINS with the government and other organizations since 2003.

(c) Safety Culture

KINS developed safety culture oversight guidelines and has conducted inspections to the NPPs as well as to the headquarter of the utilities for several years. The safety culture oversight by the NSSC was a driver for all licensees to establish and maintain a positive safety culture commensurate with the safety significance of their activities.

The government reaffirms that nuclear safety takes a top priority in the development of nuclear energy and that it is of foremost concern for organizations and individuals engaged in nuclear activities. The government also requires to develops safety culture by all organizations involved in the implementation and regulating nuclear energy in line with IAEA safety standards by recognizing that nuclear safety issues are more closely related to human factors rather than to technical ones, as demonstrated by two nuclear accidents (namely, Three Mile Island in 1979 and Chernobyl in 1986).

The safety of nuclear facilities can be ensured through dedication to common goals for nuclear safety by operating organizations and individuals at all levels, by giving a high priority to safety through sound thought, full knowledge and a proper sense of safety responsibility. The government recognizes that nuclear safety is achieved not only by safety systems and strict regulations throughout the whole stages of design, construction, operation and maintenance of nuclear power plants, but also by the spread of safety culture. In meeting this commitment, the government strives for strict regulations through the development of clear safety goals and regulatory policies. It will actively encourage safety related research and technical development to achieve technical expertise of regulatory activities and will ensure regulatory independence and fairness by minimizing any undue pressure and interference.

Nuclear utilities establish management policies, giving a high priority to nuclear safety, and foster a working climate in which attention to safety is a matter of everyday concern. Managers encourage, praise and provide tangible rewards to employees for commendable attitudes and good practices concerning safety matters. On the contrary, when errors are committed, individuals are encouraged to report them without any concealment and to correct them to avert future problems. For repeated deficiencies in or negligent attitudes toward nuclear safety, managers take firm measures in such a way to prevent the same errors from occurring again. In this way, safety culture will be achieved through sound safety policies and full understanding of safety culture by the senior management and through proper practices and implementation by individuals engaged in the nuclear industry.

Licensee's activities

In order to reflect the lesson learned from the Kori Unit 1 station blackout in February 2012 and subsequent cover-up, which occurred due to the lack of safety culture, KHNP created in 2012 a division dedicated to safety culture and has established and implemented measures to improve nuclear safety culture every year to help safety culture to take firm root and spread further.

Through research on ways to promote safety culture, KHNP developed an objective safety culture evaluation indicator and first applied it to the workers at NPP sites in 2006. Since then, the staff in operating NPPs has been subject to evaluation every two years. In addition, by applying international standards in June 2014, licensees set the specific definition of safety culture and spread eight principles and 32 characteristics, in order to encourage its workers to internalize safety culture. In 2011, the KHNP developed a new assessment method for nuclear safety culture and conducted a pilot evaluation in November 2011 to verify the practicality of the evaluation method. The evaluation has been continuously conducted in 2012 (four NPP units), 2013 (six NPP units), 2014 (six NPP units) and 2015 (six including Hanbit Unit 2). The yearly safety culture evaluation is expected to continue with the objectives to monitor the safety culture awareness of nuclear workers and to identify issues for improvements, thereby improving safety culture continuously.

Regulatory activities

Regarding the Kori Unit 1 station blackout in February 2012 and subsequent cover-up, the NSSC and KINS have set new policy directions for the licensees' safety culture. Before the case, the regulatory body had concentrated its efforts on campaigns to raise the safety awareness of workers at NPPs, rather than on intervening in the licensees' safety culture. However, the event was considered by the regulatory body as a typical case of compromised integrity of defence in depth barriers caused by organizational and cultural factors, and so it was taken as an opportunity to reconsider the regulatory supervision of safety culture.

Hence, the NSSC conducted a special inspection of licensees, and the NSSC and KINS have set new policy directions on safety culture. In addition, the nuclear safety analysis was revised in 2014 to establish a firm institutional basis for safety culture regulation by adding safety culture items to be checked during PSR.

Starting in 2013, KINS has conducted a research project on the development of a regulatory infrastructure for the oversight of safety culture to lay a firm foundation for the regulatory body to perform regulatory oversight of safety culture and to develop a system to implement the regulation. KINS defines nuclear safety culture as "the assembly of behavior patterns, core values, and basic beliefs shared by individuals in organization with regard to the importance of safety” and developed 16 safety performance indicators that constitute five areas for implementation of nuclear safety (human performance management, management for improvement, safety conscious work environment, leadership and organizational control, and safety culture management system) for safety culture regulation against licensees.

I-5. PAKISTAN

Integrated safety assessment for operating NPPs is performed by the Pakistan Nuclear Regulatory Authority (PNRA) biennially and its results are documented in the form of a report. The objective of ISA is to determine the safety level of operating NPPs considering risk.

ISA process utilizes outcomes emerging from various pillars of PNRA’s regulatory oversight process as input. These pillars include safety performance indicators, regulatory inspections, and review and assessment of routine submissions as illustrated in Fig. I-1.

For safety performance indicators (SPIs), NEI-99-02 (Regulatory Assessment Performance Indicators Guideline) is used as reference document, with necessary modifications to make it suitable considering national regulatory requirements and circumstances, and also to improve its flexibility for application to different technologies of NPPs, e.g. PWRs and PHWRs.

PNRA carries out different types of regulatory inspection at operating NPPs. These include periodic, announced, unannounced and reactive inspections, as well as general surveillance. Regulatory findings are made from these inspections, which are categorized considering their safety significance.

Routine submissions regarding operational performance, ensuring compliance with regulatory requirements (including technical specifications), event investigations, etc. are submitted to PNRA in accordance with a defined frequency. Review and assessment of these submissions are conducted and regulatory issues are highlighted. These regulatory issues are grouped or categorized considering their safety significance.

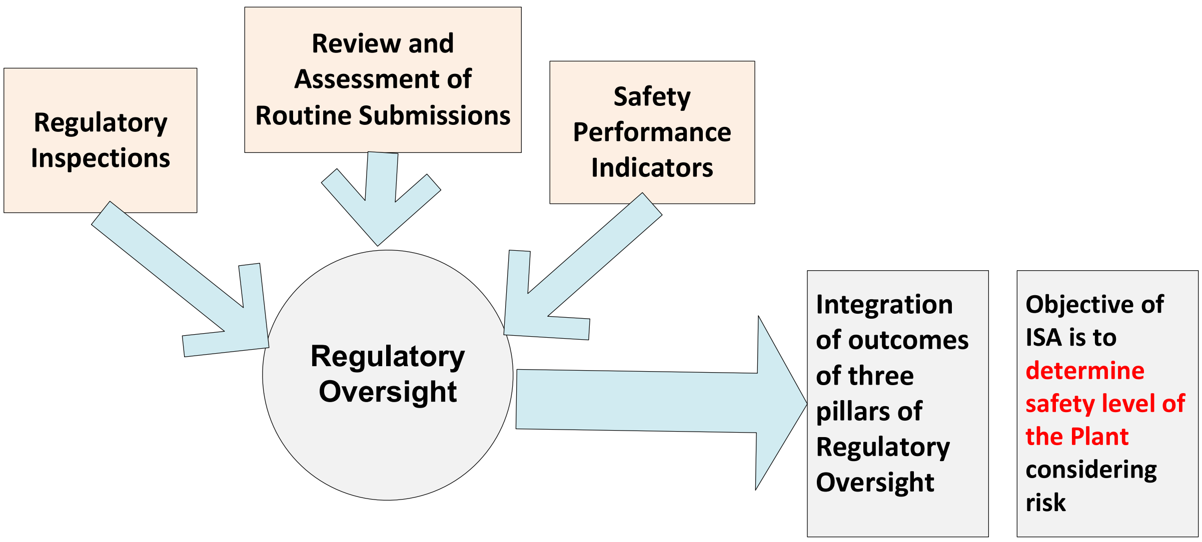


FIG. I-1. PNRA process for utilization of operating experience feedback.

For each of the pillars of regulatory oversight process providing input to ISA, a safety level is derived from each of the three pillars and is reflected in the form of colour coding, i.e. Green, White, Yellow, Red and Pink.

Utilization of Operating Experience Feedback at PNRA

The importance of utilization of experience feedback is widely acknowledged and reflected in processes at PNRA to learn from experiences of others and to avoid similar problems.

PNRA has established regulatory requirements for licensees in its "Regulations on the Safety of Nuclear Power Plant Operation" (PAK/913), to formulate formal process for utilizing operating experience feedback. PNRA also evaluates international and national operating experience in a systematic way to:

(a) Improve regulatory processes, e.g. inspections, review and assessment, licensing;
(b) Recommend actions to licensees in order to enhance nuclear safety;
(c) Convey feedback of regulatory concerns raised during operation of NPPs to the NPP projects (i.e. under construction, commissioning etc.) so that problems could be resolved by consideration in design improvements rather than retrofitting in design after bringing that plant into operation.

Utilization of Operating Experience Feedback in Improving Regulatory Processes

Licensing of NPPs

Utilization of OEF is specially focused during review of applications submitted by licensee for authorization at different stages of NPPs (e.g. construction license, permission for introduction of nuclear material into the nuclear installation). Initially, the PNRA process for review and assessment of licensing submissions was composed of two phases: (a) review of format and contents, and (b) detailed review phase. The detailed review phase was augmented in 2005 with audit calculations (i.e. limited scope) of safety assessment presented by the licensee in its submissions, learning from experiences of other regulatory authorities in the world.

In order to further utilize experience feedback in the review and assessment process, in addition to said phases, a third phase was introduced in 2005: review in the light of operating experience feedback. The purpose of addition of a third phase was to review the licensing application to ensure that appropriate measures have been taken into account in the design of NPPs and in the practices that will be followed at NPPs to avoid recurrence of similar events in Pakistan.

Development / Revision of Regulatory Framework

In line with PNRA's management system, the process for revision and development of regulatory framework considers input of experience feedback received internationally on regulatory requirements e.g. revision of IAEA safety standards, practices of other regulatory authorities, major accidents in nuclear industry for improving PNRA regulations.

As an example, PNRA reviewed regulatory framework for licensing of operating personnel in the light of experience feedback and practices followed at other regulatory authorities. Currently, annual renewal of operating personnel license at NPPs is required as per in accordance with the national regulatory framework. For this renewal, licensee has to submit the evidence of re-training, completion of minimum shift duties and medical fitness certificate. It has been learned through experience that, in a few cases, knowledge level of operators degrade with the passage of time for those areas that are not regularly in use by the operators but are still essential for their activities as reactor operator, shift engineer or shift supervisor, respectively.

Learning from this experience, the need for revalidation of operating personnel license after a certain period of time has been felt which is currently not included in PNRA's regulatory framework. Such practice for revalidation of license of operating personnel is also followed in some other States. PNRA is including the step of revalidation of operating personnel's license (i.e. after a specific period of time) in the authorization process for ensuring that the necessary level of knowledge is being maintained by the operating personnel in all areas relevant for carrying out safety related activities.

PNRA also reviewed its regulatory framework to incorporate lessons learned from the Fukushima Daiichi accident. PNRA's "Regulations on the Safety of Nuclear Power Plant Operation" (PAK/913) and "Regulations on the Safety of Nuclear Power Plant Design" (PAK/911) are being revised, based upon latest IAEA safety standards, i.e. SSR-2/1 (Rev. 1) and SSR-2/2 (Rev. 1), respectively.

Regulatory Inspection Process

The number of events reported in the nuclear industry is also relevant to equipment manufacturing, therefore, PNRA focused inspection process during manufacturing of safety significant equipment. In this process, PNRA made improvements on the following two fronts:

(a) Scope of Selection of Inspection Points and Preparations for Regulatory Inspections

Safety issues such as the flaw detection in the RPV of an NPP in Belgium during in-service inspection necessitate a pro-active approach by the regulatory body. Given that the RPV is non-replaceable and determines the design life of the NPP, the scope of regulatory inspection during manufacturing needs to be enhanced so that such failures can be avoided. In order to utilize this feedback, PNRA revisited its selection process for inspection during equipment manufacturing. Accordingly, the following steps have been taken:

- As a first step, PNRA requires from the licensee to submit the quality plans of the forgings and test coupons of long lead equipment, e.g. RPV and steam generator, for selection of inspection points. PNRA mainly selected inspection points as "record point" for regulatory inspections considering the graded approach.
- As a second step, PNRA extended the reporting requirements by including the submission of lists of non-conformance reports of all categories related to nuclear safety class equipment on a quarterly basis. This list enabled PNRA to further probe into the disposition of significant non-conformance reports and also helps PNRA to further inquire and/or verify the record of relevant non-conformance reports in subsequent manufacturing inspection.
- As a third step, basis for preparation of checklist for the manufacturing inspection has been broadened by including the feedback of previous regulatory inspections, briefing session among the pool of experts involved in the previous/similar inspections (i.e. for extraction of tacit knowledge), events reported at international level (e.g. IRS, INES) and list of non-conformances submitted in the second step.

(b) Chain Verification of Certificates

Learning from experiences of other States, like the Republic of Korea regarding submission of forged documents to the regulatory body, PNRA is considering including chain verification of certificates submitted by the licensee or applicant on sampling basis. Accordingly, chain verification step will be added in regulatory processes (e.g. regulatory inspections). This will further augment the layers established by PNRA for ensuring safety.

PNRA Experience Feedback Utilization Process for Enhancing Nuclear Safety

PNRA has been receiving feedback on operating experience through different sources (such as IRS and INES) and from the channels of regulatory bodies of other States. In recent years, PNRA has evolved a structured mechanism for collection and evaluation of international operating experience feedback for suggesting recommendation to licensees (i.e. operational NPPs, equipment manufacturers, NPPs under construction and commissioning phase, research reactors) and also for PNRA in order to ensure and further enhance safety. The methodology for evaluation of operating experience feedback was developed on the basis of practices being applied internationally.

Formulation of Evaluation Team

A dedicated team having experience of licensing and inspections of NPPs is formulated for evaluation of operating experience feedback being received at PNRA. In case of specialized areas, additional expert opinion is also obtained from within PNRA on case to case bases.

Collection of all Relevant Operating Experience Information through Identified Sources

For evaluating the international operating experience feedback, first step is to collect the relevant information from identified sources. These may include IRS reports, INES reports, useful information from the channels of regulatory bodies of other countries and information received from previous accidents at nuclear installations. This information is distributed among all the team members for further processing and evaluation.

Screening of Information

The available information is screened on the basis of three criteria: "safety significance", "technical applicability" and "generic applicability". Safety significance is determined by assessing the potential and real impact of the event on safety of the plant and potential consequences. Technical applicability is determined by the type of plant on which the event has occurred. If the plant is of similar type to that of Pakistan's NPPs (i.e. PWR or PHWR), then the event is evaluated to extract any specific lessons to avoid occurrence of such event at Pakistan's NPPs. There may be a few events occurring at plants of different types but providing generic safety oriented information which may be applicable at Pakistan's NPPs. Such events are evaluated to extract lessons of generic nature.

Analysis of Information and Recommendations and/or Actions

The information screened out in the previous step is evaluated and analyzed thoroughly to extract lessons applicable to nuclear installations in Pakistan and also to regulatory processes followed by PNRA. This analysis also includes physical verification at NPPs to verify the relevance of experience feedback and practical arrangements at NPPs in Pakistan in the light of OEF under consideration. After evaluation, recommendations and/or actions are proposed with actions assigned for the relevant licensees and PNRA. This evaluation is in the form of traceable records, e.g. letters or directives.

Communication of Recommendations and/or Actions to the Licensee and within PNRA

The recommendations and/or actions set forth may be communicated to the licensee with the view that these recommendations and/or actions may be considered to avoid occurrence of similar events at Pakistan's nuclear installations. Recommendations for improvement in PNRA processes are also circulated to directorates responsible for that specific activity (e.g. inspections, review and assessment) so that proposals for necessary improvements in regulatory processes may be developed to enhance regulatory effectiveness.

Follow up

After communicating the recommendations and/or actions, they are followed up to ensure that they have been implemented for enhancing nuclear safety and improving regulatory processes.

I-6. UNITED KINGDOM

Purpose

The section describes the approach developed by the Office for Nuclear Regulation (ONR) to the ISA of dutyholder's performance. It explains how ONR utilises the approach to inform its regulatory strategy and optimise deployment of its resources to influence improvements in safety, security and safeguards across the nuclear sector.

Overview

Set up by the Energy Act 2013 as a stand-alone public corporation, ONR independently regulates safety and security at 37 licensed nuclear sites in the UK. These include the existing fleet of operating reactors, fuel cycle facilities, waste management and decommissioning sites and the defence nuclear sector. ONR also regulates the design and construction of new nuclear facilities and the transport of nuclear and radioactive materials. ONR works with the international inspectorates to ensure that nuclear material safeguards obligations for the UK are met.

The responsibility for delivering a safe and secure nuclear industry rests with the nuclear industry itself. ONR's mission statement is 'To provide efficient and effective regulation of the nuclear industry, holding it to account on behalf of the public'. ONR uses a wide range of regulatory tools and processes (such as inspection, permissioning and enforcement) to influence those it regulates, and to encourage the achievement of sustained excellence and continuous improvement in nuclear safety, security and safeguards performance.

The integrated assessment of dutyholder's performance is an important element of ONR's management system, particularly in respect to processes for regulatory planning, delivery and reporting. The process involves an analysis of the performance of each of its licensees, normally on an annual basis. The results of this analysis are used to inform and continuously improve the effectiveness of regulatory strategies and plans. The overall process is summarised in Fig. I-2.

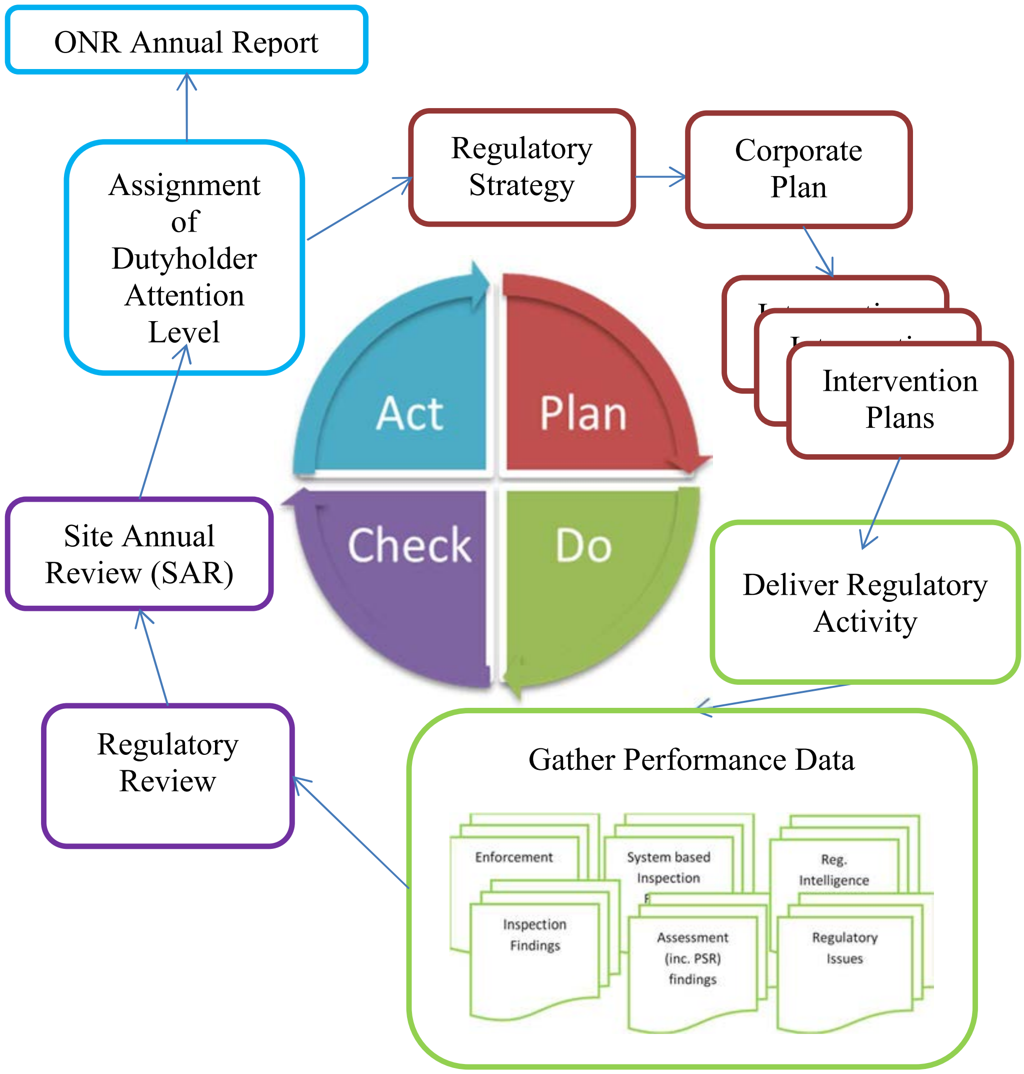


FIG. I-2. Integrated assessment within ONR's regulatory planning and delivery process.

Regulatory Review

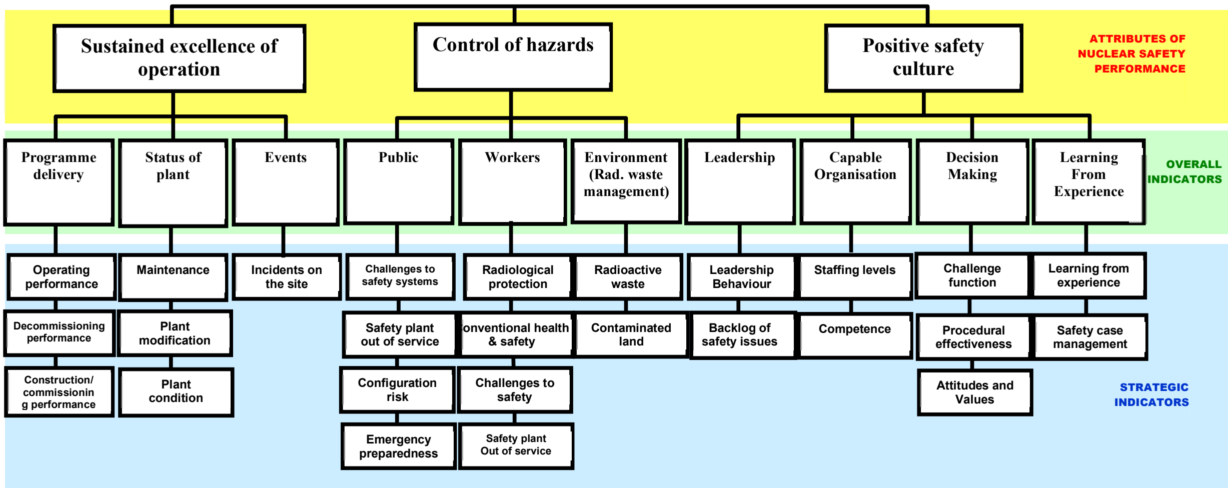
A regulatory review is conducted for each licensee with the objective of evaluating licensee performance across ONR's regulatory purposes. The regulatory review also considers whether ONR's regulatory strategy and plans are being effective in securing and influencing sustained compliance with the law.

While regulatory reviews are normally performed annually, a graded approach is taken with the frequency and depth of each regulatory review proportionate to site hazard and risk profiles. This means that for high hazard sites, such as operational nuclear power plants, a series of topical reviews take place during the year feeding into an overarching annual regulatory review. Topical reviews may include: Leadership and Management for Safety; Emergency Arrangements; Regulatory Intelligence; and Regulatory Effectiveness. Reviews are conducted on the basis of qualitative and quantitative analysis of data derived from:

- Regulatory Issues;
- Compliance Inspections;
- Systems Inspections;

- Themed Inspections;
- Permissioning and Assessment Activities;
- Operational Experience Feedback;
- Regulatory Intelligence;
- Dutyholder Safety Performance Indicators and data (see Fig. I-3).

ONR’s procedure and guidance for conducting regulatory review is contained in the guidance document NS-INSP-GD-059. ONR’s procedure for conducting leadership and management for safety reviews is contained within the guidance document NS-TAST-GD-093.



* Extract from ONR-OPEX-IN-002

FIG. I-3. ONR’s nuclear safety performance indicator framework.

Site Annual Review Meeting (SARM)

The SARM is a means for ONR and its licensees to:

(a) Review compliance and safety, security and safeguards performance over the preceding period;
(b) Review the extent to which the licensee has delivered on commitments made at the previous SARM have been met;
(c) Provide a strategic forward look over the next year, including what the licensee is committing to achieve, what needs to be accelerated and how.

During the engagement, the overall results from the regulatory review processes are fed back and discussed with the licensee, with notable successes in safety, security or safeguards performance acknowledged by the regulator. Instances of declining performance are discussed and commitments sought where necessary to address such trends. ONR also sets out its strategic regulatory focus over the coming period and highlights areas where improvements are expected from the licensee.

The SARM is normally conducted for each licensee on an annual basis, with the extent of the review commensurate with the magnitude of the hazard and risks presented by the site and the complexity of its operations. For lower hazard sites owned or managed by a single company, combined SARMs covering multiple sites may be undertaken.

Assignment of Dutyholder Attention Levels

Each year, ONR assigns an attention level for each licensed site, based on an overall judgment across nuclear safety, conventional health and safety, security[1] and transport purposes, informed by the regulatory review process. There are three levels of regulatory attention:

(a) Significantly enhanced;
(b) Enhanced;
(c) Routine.

Attention levels are assigned on the basis of judgment, underpinned by qualitative and quantitative assessments against a range of safety and security indicators. These broadly align with ONR's Nuclear Safety Performance Indicator framework but with greater regulatory emphasis, as outlined below:

Safety Attributes

- **Safety Performance** as a product of dutyholders' compliance recorded across the various safety purposes, incidents on the site and delivery against agreed or required safety enhancements.
- **Control of Hazard and Risk** as a product of the level of hazard and risk posed by the licensee's undertakings and the adequacy with which the licensee demonstrates that risks are controlled so far as is reasonably practicable in accordance with an adequate and live safety case.
- **Safety Leadership and Culture** relating to a framework adopted by ONR's human and organisational capability specialism for assessing licensee performance against Leadership and Management for Safety themes.

Security Attributes

- **Development of the Security Assessment Principles Plan**. The industry is currently in the process of developing nuclear site security plans for ONR to assess against ONR's Security Assessment Principles.
- **Security Strategic Enablers**. This relates directly to Fundamental Security Principles 1 to 5, measured by how appropriate the arrangements are in meeting the associated outcomes.
- **Security Operations**. This relates directly to Fundamental Security Principles 6 to 10, in terms of how appropriate the dutyholders' security operations are in meeting the associated outcomes.
- **Security Delivery**. This relates to dutyholders' performance as it relates to compliance and inspection ratings, the ability to complete improvements to schedule, reportable events and the outcomes from annual security response exercises.

ONR expects that licensees allocated to enhanced (or significantly enhanced) attention levels will develop structured improvement plans to deliver the performance improvements necessary to transition to routine levels of attention in a timely fashion. An intervention strategy is subsequently developed by ONR to monitor the licensee's progress against this plan, overseen by a Deputy Chief Inspector. This strategy may require additional regulatory resources allocated to a site to support an enhanced inspection programme or undertake additional

[1] Excluding defence nuclear licensed sites.

specialist assessment. However, enhanced attention may manifest in other ways judged by divisions to be necessary to secure, where practicable, a return to routine attention.

ONR's procedure and guidance for assignment of dutyholder attention levels is contained in the guidance document ONR-GEN-GD-013.

ONR Annual Report

Each year, the Chief Nuclear Inspector's report is published, providing a comprehensive analysis of ONR's view of the performance of the nuclear industry. Underpinned by the annual assessment of dutyholders' safety and security performance, the report provides transparency to interested parties in relation to:

(a) ONR's performance against its regulatory plan and overview of regulatory activity;
(b) ONR's judgments on the level of regulatory attention necessary for each licensed site;
(c) ONR's judgement on the progress of those dutyholders in enhanced (or significantly enhanced) attention, towards routine levels;
(d) Significant findings from regulatory interventions;
(e) ONR's response to events occurring on dutyholders' sites.

This is an example of providing feedback from ISA to interested parties.

Strategy and Plan Development

Although the scope of ONR's regulatory activities and priorities is informed by a number of factors, the attention levels assigned to dutyholders are an important tool to ensuring regulatory resources are appropriately targeted. Attention levels are considered by the ONR Board and Senior Leaders to establish the strategic intent for the organisation.

Attention levels and the findings from the regulatory review process inform development of ONR Corporate, Directorate and individual site plans, with interventions developed to influence sustained improvement in the authorized party's performance. For authorized parties in enhanced (or significantly enhanced) attention, interventions are developed to secure the improvements necessary to transition to routine levels of regulatory attention in a timely manner.

Conclusion

ONR regularly undertakes an integrated, systematic and comprehensive assessment of the safety, security and safeguards performance of its dutyholders. It considers that the assessment is an important component of ONR's management system, enabling senior leaders to direct and optimise the deployment of regulatory resources to achieve desired outcomes. Specifically, to influence and encourage those it regulates to achieve sustained excellence and continuous improvement.

Significant findings from this assessment are reported to dutyholders and other interested parties in accordance with ONR's commitment to openness and transparency in its activities.

I-7. UNITED STATES OF AMERICA

Regulatory Framework

The U.S. Nuclear Regulatory Commission's (NRC's) regulatory framework for reactor oversight, presented in Fig. I-4, is a risk informed, tiered approach for ensuring plant safety as described in the NRC Inspection Manual, Chapter 0305 "Operating Reactor Assessment Program", available on the NRC web page. There are three key strategic performance areas: reactor safety, radiation safety, and safeguards. Within each strategic performance area, there are cornerstones that reflect the essential safety aspects of facility operation.

Within this framework, the NRC's reactor oversight process (ROP) provides a means to collect information about licensees' performance, assess the information for its safety significance, and provide for appropriate response by licensees and NRC.

The ROP is intended to fulfill the following four goals established by the Commission:

- Maintain safety by establishing a regulatory oversight framework that provides assurance that plants continue to be operated safely by plant operators. Maintaining safety is the NRC's overarching mission;
- Enhance public confidence in the NRC's regulatory programme by increasing the predictability, consistency, objectivity and transparency of the oversight process so that all parties will be well served by the changes taking place;
- Improve the effectiveness, efficiency, and realism of the oversight process by focusing both NRC resources and utility resources on those issues with the highest significance for safety;
- Reduce unnecessary regulatory burden by using a more efficient and effective process.

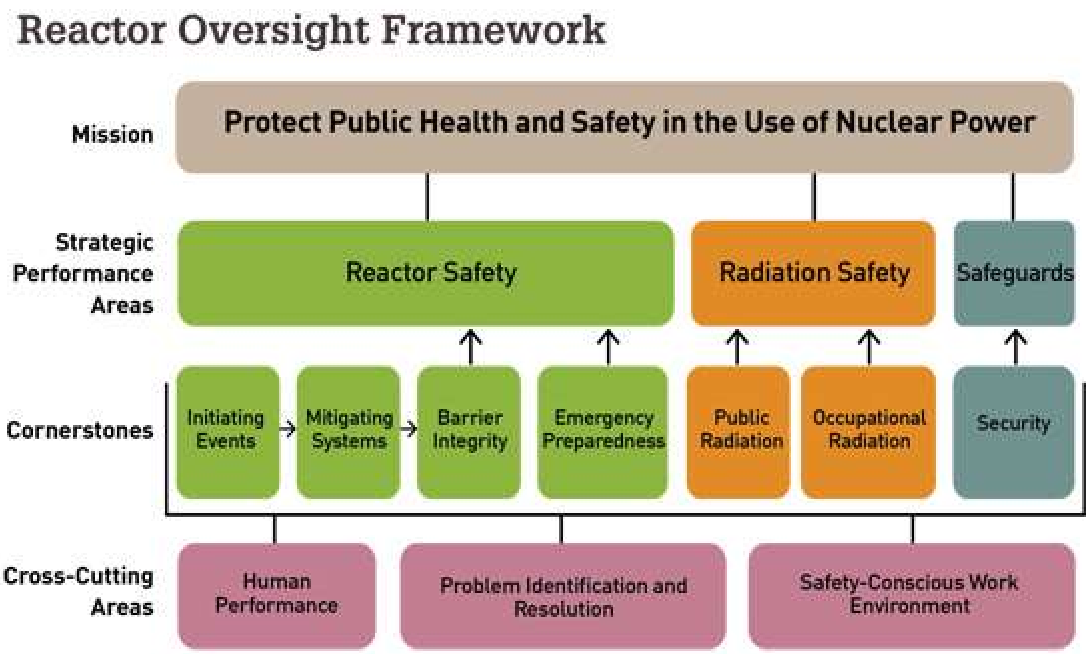


FIG. I-4. Reactor oversight framework of NRC.

Cornerstones of Safe Operation

The ROP is anchored in the NRC's mission to ensure public health and safety in the operation of commercial power plants.

The objective is to monitor performance in three strategic areas:

- Reactor safety (avoiding accidents and reducing the consequences of accidents if they occur);
- Radiation safety for both plant workers and the public during routine operations;
- Protection of the plant against sabotage or other security threats.

To measure plant performance, the oversight programme focuses on seven specific "cornerstones", which support the safety of plant operations in the three strategic areas.

In addition to the cornerstones, the ROP features three so-called "cross-cutting" elements, which affect, and are therefore part of, each of the cornerstones:

Human Performance:

This element monitors the licensee's decision-making process, availability and adequacy of resources to ensure nuclear safety, coordination of work activities, and personnel work practices.

Problem Identification and Resolution:

This element monitors the licensee's corrective action and operating experience programmes, and the licensee's self-assessments and independent assessments.

Safety-Conscious Work Environment:

This element monitors an environment in which workers feel free to raise nuclear safety concerns without fear of harassment, intimidation, retaliation, or discrimination.

Overall Description

Figure I-5 provides an overview of the ROP. For each cornerstone, the NRC develops findings from inspections, and licensees collect performance indicator data. The NRC evaluates inspection findings for safety significance using a significance determination process and compares performance indicators against prescribed risk informed thresholds. The Commission then assesses the resulting information and determines an appropriate response using the guidelines in an action matrix. Response can include supplemental inspections for selected issues or enforcement actions on significant inspection findings. The NRC communicates the results of its performance assessment and its inspection plans and other planned actions in publicly available correspondence, on the NRC web page, and through public meetings with each licensee.

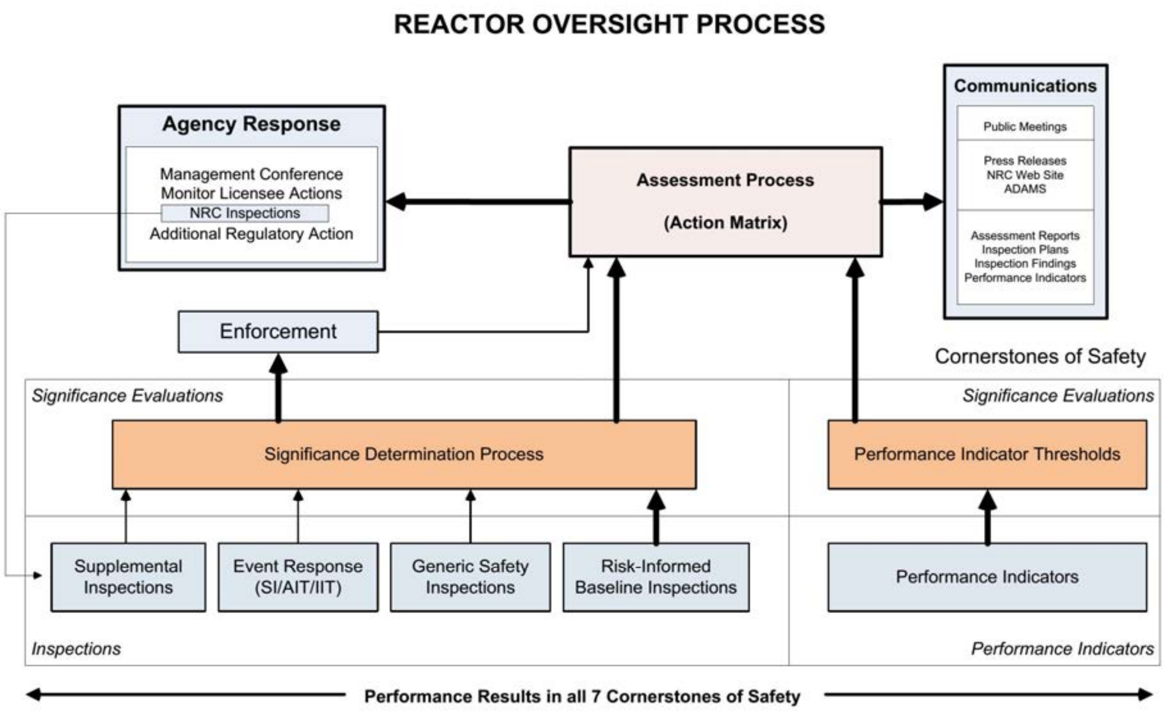


FIG. I-5. Reactor oversight process of NRC.

Measuring and Inspecting Nuclear Plant Performance

The NRC measures nuclear plant performance by monitoring objective performance indicators and by conducting the NRC inspection programme. Monitoring and inspection closely focus on those plant activities having the greatest impact on safety and overall risk. In addition, the NRC conducts both periodic and annual reviews of the effectiveness of each utility's programmes to identify and correct problems.

Performance indicators use objective data to monitor performance within each of the "cornerstone" areas as shown in Table I-4. The utilities generate the data that make up the performance indicators and submit these data to the NRC quarterly. Each performance indicator is measured against established thresholds which are related to their effect on safety.

While performance indicators can provide insights into plant performance in selected areas, the NRC's inspection programme provides a greater depth and breadth of information for monitoring and assessing plant performance. The inspection programme is designed to verify the accuracy of performance indicator information and to assess performance that is not directly measured by the performance indicator data.

The NRC staff evaluates and integrates the performance indicator data with findings of the NRC inspection programme to provide a broad assessment of the plant's safety performance.

The staff uses the significance determination process to determine the safety or security significance of inspection findings. This process provides an initial screening to identify those inspection findings that do not result in a significant increase in plant risk (a "green" finding).

Green indicates a finding of very low safety or security significance.

White indicates a finding of low to moderate safety or security significance.

Yellow indicates a finding of substantial safety or security significance.

Red indicates a finding of high safety or security significance.

Using Performance Indicators

Evaluation of Performance Indicator Data

Each plant operator reports performance indicators to the NRC quarterly. Following compilation and review by NRC staff, the NRC posts performance indicators on the NRC web page. NRC staff evaluates performance indicator data and integrates the data with inspection findings to develop an assessment of licensee performance. Each performance indicator is measured against the criteria using a colour coded system for safety performance:

Green indicates performance within an expected performance level where the associated cornerstone objectives are met.

White represents performance outside an expected range of nominal utility performance, but related cornerstone objectives are still being met.

Yellow indicates related cornerstone objectives are being met, but with a minimal reduction in the safety margin.

Red signals a significant reduction in safety margin in the area measured by the performance indicator.

Inspection Programmes

The revised oversight programme continues to use a variety of NRC inspectors who monitor plant activities. The programme includes baseline inspections common to all nuclear plants. The baseline inspection programme, based on the cornerstone areas, focuses on activities and systems that are "risk significant" (in other words, those activities and systems that have a potential to trigger an accident, can mitigate the effects of an accident, or can increase the consequences of a possible accident). The inspection programme will also review the cross-cutting issues of human performance, the safety-conscious work environment, and how the licensees find and fix problems. The NRC will perform inspections beyond the baseline at plants with performance below established thresholds, as assessed through information gained from performance indicators and NRC inspections. The NRC may also perform additional inspections in response to a specific event or problem that may arise at a plant.

NRC resident inspectors stationed at each nuclear power plant and inspectors based in one of the four NRC regional offices or in NRC headquarters will perform the inspections.

TABLE I-4. PERFORMANCE INDICATORS BY SAFETY CORNERSTONE

Performance indicators are reported quarterly by operators of nuclear power plants, reviewed by the NRC staff, and posted on the NRC's web page.	
Safety Cornerstone	**Performance Indicator**
Initiating Events	Unplanned Scrams (Automatic and Manual Reactor Shutdowns) per 7000 Critical Hours (IE01)
	Unplanned Power Changes per 7000 Critical Hours (IE03)
	Unplanned Scrams with Complications (IE04)
Mitigating Systems	Safety System Functional Failures (MS05)
	Emergency AC Power Systems (MS06)
	High Pressure Injection Systems (MS07)
	Heat Removal Systems (MS08)
	Residual Heat Removal Systems (MS09)
	Cooling Water Systems (MS10)
Barrier Integrity	Reactor Coolant System Specific Activity (BI01)
	Reactor Cooling System Leakage (BI02)
Emergency Preparedness	Drill/Exercise Performance (EP01)
	Emergency Response Organization Drill Participation (EP02)
	Alert and Notification System Reliability (EP03)
Public Radiation Safety	RETS/OCDM Radiological Effluent Occurrence (PR01)
Occupational Radiation Safety	Occupational Exposure Control Effectiveness (OR01)
Security	Not Publicly Available*

* Specific information related to findings and performance indicators associated with the security cornerstone will not be publicly available to ensure that security related information is not provided to a possible adversary.

For the inspection programme, the NRC used a risk informed approach to select areas to inspect within each cornerstone. The Commission chose the inspection areas based on their importance from the point of view of potential risk, past operational experience, and regulatory requirements.

The baseline inspection programme has three parts:

- Inspections of areas not covered by performance indicators or where a performance indicator does not fully cover the inspection area;
- Inspections to verify the accuracy of a licensee's reports on performance indicators;
- Thorough reviews of the utility's effectiveness in independently finding and resolving problems.

The NRC issues inspection reports for all inspections. The Commission makes these reports available to the public on the NRC web page and in the public document room at NRC headquarters.

Assessing Plant Performance

The inspection staff has developed a procedure called the "significance determination process" to help inspectors determine the safety significance of inspection findings. The staff will use the process for an initial screening review to identify those inspection findings that would not significantly increase risk and thus need not be analyzed further (i.e. a "green finding"). Remaining inspection findings, which may affect plant risk, will then be subject to a more thorough risk assessment, using the next phase of the significance determination process. This more detailed assessment may involve NRC risk experts from the appropriate regional office and further review by the licensee's plant staff. To determine appropriate further action, the NRC will use the final outcome of the review, evaluating whether the finding is green, white, yellow, or red.

Each calendar quarter (every 3 months), the resident inspectors and the inspection staff in the regional office will review the performance of all nuclear power plants in that region as measured by the performance indicators and by inspection findings. Every 6 months, the NRC staff will expand the review to include planning of inspections for the following 12-month period.

Each year, the final quarterly review will involve a more detailed assessment of plant performance (including discussion of cross-cutting areas) over the previous 12 months and preparation of a performance report, as well as the inspection plan for the following two years. This review is led by senior regional managers and includes NRC headquarters staff members, the regional staff, and the resident inspectors.

The NRC will make these annual performance reports available to the public on the NRC web page. The NRC staff will also hold public meetings at each plant to discuss the performance of the plant in the previous year.

In addition, NRC senior management will review the adequacy of actions of the Commission for plants with significant performance problems. The managers will also take a wider view of both the overall industry performance and the performance of NRC's regulatory programmes. The performance of plants requiring heightened agency scrutiny will then be discussed during a public meeting with the NRC Commissioners at NRC's headquarters.

NRC Response to Plant Performance

The NRC's quarterly reviews of plant performance (see Figure I-6) consider both performance indicators and inspection findings, will determine what additional actions, if any, the NRC will take if there are signs of declining performance. Under the ROP, the NRC's quarterly review more strongly links regulatory actions to performance criteria. The Commission believes this creates a more predictable approach to enforcement. The process uses five levels of regulatory response with NRC regulatory review increasing as plant performance declines. The appropriate regional office manages the first three levels of regulatory review. The last two levels call for an response by the Commission, involving senior management attention from both headquarters and regional offices.

The oversight programme uses tools that the NRC has traditionally used when dealing with declining plant performance and violations. However, the ROP uses these tools in a more predictable manner that is commensurate with the decreased safety performance. The ROP uses a system of specified NRC actions if performance declines. The NRC generally reserves fines for violations such as discriminating against workers raising safety concerns or for willfully misreporting required information.

The NRC's actions for performance less than the "green" level may include meetings with the utility, additional inspections, and required reviews and response by the utility. Further declines in performance would warrant stronger action by the NRC, up to a civil order or the suspension of the operating license.

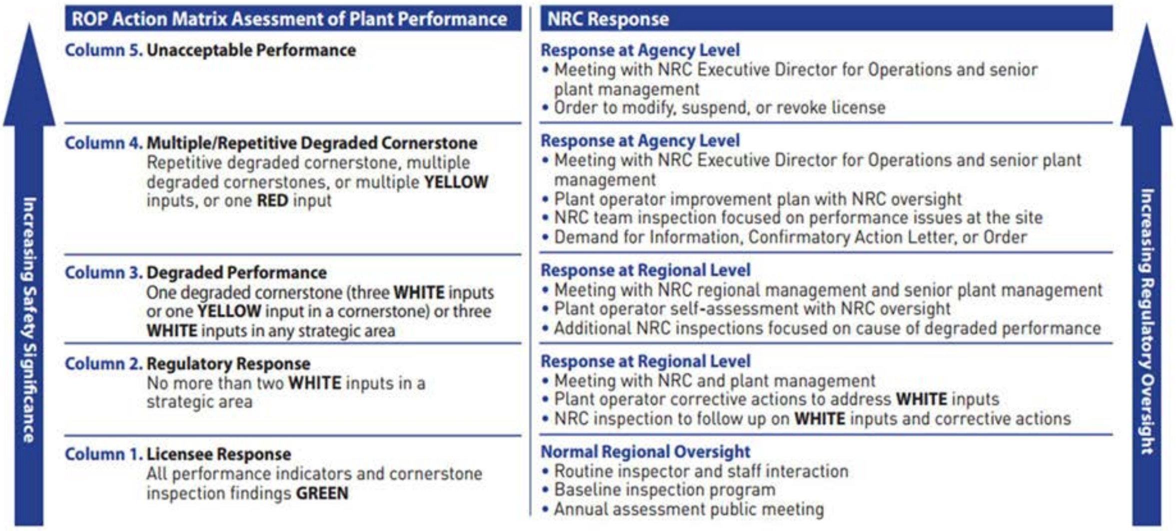


FIG. I-6. NRC response plan to ROP assessment of plant performance.

Violations of NRC Requirements

For each violation of regulations found during NRC inspections, the staff will evaluate the violation to determine its effect on plant safety and risk. If the violation is of very low safety significance, the staff will discuss the violation in an inspection report and take no formal enforcement action. In such cases, the NRC expects the utility to resolve the violation through its corrective action programme and taking steps to prevent a recurrence. The staff may also review the issue during future NRC inspections.

If the NRC risk evaluation finds that the violation has higher safety significance, the NRC will issue a notice of violation. The Commission may also issue a notice of violation if the licensee fails to correct a violation of low safety significance in a reasonable period of time or if the Commission finds the violation to be willful.

The notice of violation requires the licensee to respond formally to the NRC with planned actions to correct the violation and steps for preventing the violation from occurring again. The Commission will then review the licensee's actions in a later inspection.

Normally, these violations will not be subject to a fine. However, some violations may warrant a fine because of their unusual significance. Possible examples include exceeding a safety limit specified in a reactor license or the inadvertent startup of a reactor.

In addition, some violations will call for the traditional enforcement approach, including the possible issuance of fines. Examples of such violations include the following:

- Discrimination against workers for raising safety issues or other willful violations;
- Actions that may adversely affect the NRC's ability to monitor utility activities, including failure to report required information, failure to obtain NRC approval for plant changes, failure to maintain accurate records, or failure to provide the NRC with complete and accurate information;
- Incidents with actual safety consequences, including radiation exposures above NRC limits, releases of radioactive material above NRC limits, or failure to notify government agencies when emergency response is required.

ANNEX II. EXAMPLE OF SAFETY AND CONTROL FACTORS AND THEIR PERFORMANCE OBJECTIVES IN CANADA

II-1. DEFINITIONS OF SAFETY AND CONTROL AREAS

1. Management system

The management system safety and control area (SCA) covers the framework that establishes the processes and programmes required to ensure an organization achieves its safety objectives, continuously monitors its performance against these objectives, and fosters a healthy safety culture.

Performance objectives

There is an effective management system that integrates provisions to address all regulatory and other requirements to enable the licensee to achieve its safety objectives, continuously monitor its performance against those objectives, and maintain a healthy safety culture.

2. Human performance management

The human performance management SCA covers activities that enable effective human performance through the development and implementation of processes that ensure that licensees have sufficient staff in all relevant job areas (i.e. people with the necessary knowledge, skills, procedures and tools in place to safely perform their duties).

Performance objectives

Workers are sufficient in number, and human performance is managed so that all workers are capable, competent, qualified and supported to perform their work tasks safely.

3. Operating performance

The operating performance SCA includes an overall review of the conduct of the licensed activities and the activities that enable effective performance.

Performance objectives

Plant operation is safe and secure, with adequate regard for health, safety, security, radiation and environmental protection, and international obligations.

4. Safety analysis

The safety analysis SCA involves maintaining the safety analyses that support the overall safety case for the facility. Safety analysis is a systematic evaluation of the potential hazards associated with the conduct of a proposed activity or facility. It considers the effectiveness of preventive measures and strategies in reducing the effects of such hazards. For nuclear power plants, safety analysis is primarily deterministic in demonstrating the effectiveness of implementing the fundamental safety functions of “control, cool and contain” through a defence in depth strategy. To identify challenges to physical barriers, risk contributors are considered using probabilistic safety analysis. However, appropriate safety margins need to be applied to address the uncertainties and limitations of probabilistic safety analysis.

Performance objectives

Updates to safety analysis effectively incorporate feedback from various sources to continually demonstrate the ability to adequately control power, cool the fuel and contain or limit any releases from the plant.

5. Physical design

The physical design SCA relates to activities affecting the ability of structures, systems and components (SSCs) to meet and maintain their design basis, taking into account new information as it arises, as well as changes in the external environment.

Performance objectives

SSCs that are important to nuclear safety and security continue to meet their design basis.

6. Fitness for service

The fitness for service SCA covers activities that affect the physical condition of SSCs over time, including programmes that ensure all equipment is available to perform its intended design function.

Performance objectives

SSCs – the performance of which might affect safety and/or security – remain available, reliable and effective and consistent with design, analysis, and quality control measures.

7. Radiation protection

The radiation protection SCA covers the implementation of a radiation protection programme in accordance with the *Radiation Protection Regulations*. This programme has to ensure that contamination and radiation doses received by individuals are monitored, controlled and maintained as low as reasonably achievable (ALARA).

Performance objectives

The health and safety of persons are protected through the implementation of a radiation protection programme that ensures that radiation doses are kept below regulatory dose limits and are optimized and maintained as low as reasonably achievable (ALARA).

8. Conventional health and safety

The conventional health and safety SCA covers the implementation of a programme to manage workplace safety hazards and to protect personnel and equipment.

Performance objectives

Conventional health and safety work practices and conditions achieve a high degree of personnel safety.

9. Environmental protection

The environmental protection SCA covers programmes that identify, control and monitor all releases of radioactive and hazardous substances and effects on the environment from facilities or as the result of licensed activities.

Performance objectives

The licensee takes all reasonable precautions to protect the environment and the health and safety of persons. This includes identifying, controlling and monitoring the release of nuclear materials and hazardous materials to the environment.

10. Emergency management and fire protection

The emergency management and fire protection SCA covers emergency plans and preparedness programmes for emergencies and for non-routine conditions (including any results of participation in exercises).

Performance objectives

Emergency preparedness measures and fire protection fire protection capabilities are in place to prevent and mitigate effects of nuclear and hazardous substances releases, both on-site and off-site, and fire hazards, in order to protect workers, the public and the environment.

11. Waste management

The waste management SCA covers a facility's internal waste related programmes up to the point where the waste is removed and transferred to a separate waste management facility. This SCA also covers planning for decommissioning.

Performance objectives

A facility specific and waste stream specific waste management programme is fully developed, implemented and audited to control and minimize the volume of nuclear waste generated by the licensed activity. Waste management is included as a key component of the licensee's corporate and safety culture. A decommissioning plan is maintained.

12. Security

The security SCA covers the programmes required to implement and support the security requirements stipulated in the regulations, in the licence, in orders, or in expectations for their facility or activity.

Performance objectives

Loss, theft or sabotage of nuclear material or sabotage of the licensed facility are prevented.

13. Safeguards and non-proliferation

The safeguards and non-proliferation SCA covers the programmes and activities required of the licensee to successfully implement the obligations arising from the Canada/IAEA safeguards agreements and the *Treaty on the Non-Proliferation of Nuclear Weapons*.

Performance objectives

The licensee conforms with measures required to meet Canada's international safeguards obligations through:

(a) Timely provision of accurate reports and information;
(b) Provision of access and assistance to IAEA inspectors for verification activities;
(c) Submission of annual operational information and accurate design information on plant structures, processes and procedures;
(d) Development and satisfactory implementation of appropriate facility safeguards procedures;
(e) Demonstration of capability, as confirmed through CNSC onsite evaluations, to meet all requirements in support of physical inventory verifications of nuclear material by the IAEA.

14. Packaging and transport

The packaging and transport SCA covers the safe packaging and transport of nuclear materials to and from the licensed facility.

Performance objectives

Packaging and transport of nuclear substances are conducted in a safe manner.

II-2. PERFORMANCE RATING

Performance ratings used in this publication (see also Table I-2 in Annex I) are defined as follows:

Fully satisfactory (FS)

Safety and control measures implemented by the licensee are highly effective. In addition, compliance with regulatory requirements is fully satisfactory and compliance within the SCA or specific area exceeds requirements and CNSC expectations. Overall, compliance is stable or improving, and any problems or issues that arise are promptly addressed.

Satisfactory (SA)

Safety and control measures implemented by the licensee are sufficiently effective. In addition, compliance with regulatory requirements is satisfactory. Compliance within the area meets requirements and CNSC expectations. Any deviation is minor, and any issues are considered to pose a low risk to the achievement of regulatory objectives and CNSC expectations. Appropriate improvements are planned.

Below expectations (BE)

Safety and control measures implemented by the licensee are marginally ineffective. In addition, compliance with regulatory requirements falls below expectations. Compliance within the area deviates from requirements or CNSC expectations to the extent that there is a moderate risk of ultimate failure to comply. Improvements are required to address identified weaknesses. The licensee is taking appropriate corrective action.

Unacceptable (UA)

Safety and control measures implemented by the licensee are significantly ineffective. In addition, compliance with regulatory requirements is unacceptable and is seriously compromised. Compliance within the overall area is significantly below requirements or CNSC expectations, or there is evidence of overall non-compliance. Without corrective action, there is a high probability that the deficiencies will lead to an unreasonable risk. Issues are not being addressed effectively, no appropriate corrective measures have been taken, and no alternative plan of action has been provided. Immediate action is required.

The above definitions indicate that the licensee's degree of compliance with requirements is a key consideration for determining the rating category, although other aspects are also part of the determination of

(a) The effectiveness of the licensee's safety and control measures;
(b) The degree to which the licensee meets the CNSC's expectations; and
(c) The need for corrective action and the speed with which the licensee resolves issues.

II-3. RATING METHODOLOGY

The methodology for rating licensees relies on multiple sources of input and involves both the judgment of CNSC staff and a systematic computational roll-up of results. The methodology is based on ratings made at two distinct levels:

(a) Specific Areas;
(b) Safety and Control Areas (SCAs).

The rating methodology described in this section is used for Canadian nuclear power plant licensees and for Canadian waste management facility licensees. The ratings for these two types of licensee are reported in the Regulatory Oversight Report for Canadian Nuclear Power Generating Sites. The methodology is illustrated in Figure II-1. To simplify the illustration, only four specific areas and two SCAs are shown in Figure II-1.

Steps shown, from top to bottom, are as follows:

Step 1: Identifying the findings and additional information

Findings are identified for each specific area using information from a variety of sources, including CNSC staff compliance verification inspections and desktop reviews. Each finding is assigned to the most applicable specific area under an SCA.

CNSC staff also consider for specific areas any additional information, not captured in the database of findings, that could be used to:

(a) Adjust or inform the initial rating that was based strictly on the degree of compliance; or
(b) Form the basis for a rating in the absence of information or opinion on the degree of compliance.

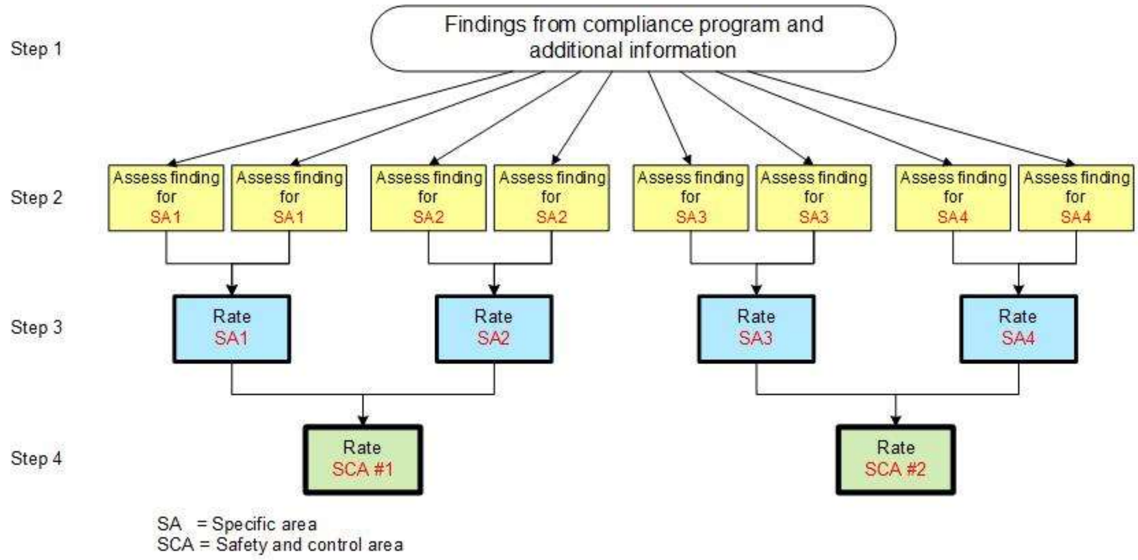


FIG. II-1. Methodology for determining performance ratings.

Step 2: Assessing the findings and additional information

CNSC staff evaluate the safety significance of each finding and assign it to the appropriate category: high, medium, low, negligible or compliant. The significance depends on the degree to which a specific area's effectiveness is negatively affected and is determined in the context of the verification criteria for the inspection or desktop review that generated the finding. The five categories of safety significance are:

High: Licensee's measures are absent, completely inadequate or ineffective in meeting expectations or the intent of CNSC requirements and compliance expectations.

Medium: Performance significantly deviates from expectations or from the intent or objectives of CNSC requirements and compliance expectations.

Low: Performance deviates from expectations or from the intent or objectives of CNSC requirements and compliance expectations.

Negligible: Performance insignificantly deviates from expectations or objectives of CNSC requirements and compliance expectations.

Compliant: Performance meets applicable CNSC requirements and compliance expectations.

Step 3: Rating the specific area

CNSC staff consider the safety significance of all relevant findings and additional information (e.g. event reports, technical reviews of licensee reports, observations from surveillance and monitoring) and assess the overall effectiveness of the safety and control measures for the specific area. The assessment is in the context of the performance objective for the relevant SCA.

The determination of the degree of compliance of the findings and additional information is based upon the following guidelines:

Fully Satisfactory

These are strong indicators of compliance (e.g. compliant findings). The non-compliances are very few and very minor (e.g. very few or zero non-compliances of low significance, and have been addressed promptly). There may be evidence of exceeding minimum required as per applicable requirements. The list of example criteria for the rating 'Fully Satisfactory' at the beginning of the rating form may have some criteria that are relevant to specific requirements that could be exceeded.

Satisfactory

Some non-compliances of low significance are allowed, but with evidence of compliance and no non-compliances of medium significance.

Below Expectations

There is a finding of medium significance and/or a number of distinctly different findings of low significance.

Unacceptable

There is a finding of high significance or a combination of findings of medium and low significance.

The results of the degree of compliance assessment are converted to a numerical value using the following grid:

Fully Satisfactory	8.1 to 10.0
Satisfactory	6.1 to 8.0
Below Expectations	4.1 to 6.0
Unacceptable	0.0 to 4.0

Step 4: Rating the safety and control area

Individual specific area values are averaged to determine the overall SCA value, which is then converted into an SCA rating using the ranges shown above in the grid in Step 3.

Additional details on the safety and control areas (SCAs) and the applicable regulatory document(s) for each SCA are available on the CNSC web page

ABBREVIATIONS

BMUB	Federal Ministry for the Environment, Nature Conservation, and Nuclear Safety, Germany
CNSC	Canadian Nuclear Safety Commission
GIN	German Information Notice
INES	International Nuclear and Radiological Event Scale
INPO	Institute of Nuclear Power Operations
IRRS	Integrated Regulatory Review Service
IRS	IAEA, OECD/NEA International Reporting System for Operating Experience
ISA	Integrated Safety Assessment
KHNP	Korea Nuclear and Hydro Power
KINS	Korean Institute of Nuclear Safety, Republic of Korea
NPP	Nuclear Power Plant
NRC	Nuclear Regulatory Commission, United States of America
NSSC	Nuclear Safety and Security Commission, Republic of Korea
OEF	Operating Experience Feedback
ONR	Office for Nuclear Regulation, United Kingdom
OPIS	Operational Performance Information System for Nuclear Power Plants
PNRA	Pakistan Nuclear Regulatory Authority
PSR	Periodic Safety Review
R&D	Research and Development
RIPI	Risk Informed Periodic Inspection
ROP	Regulatory Oversight Process
RPV	Reactor Pressure Vessel
SARM	Site Annual Review Meeting
SCA	Safety and Control Area
SPI	Safety Performance Indicator

SSCs	Structures, Systems and Components
WANO	World Association of Nuclear Operators

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Consultancy Meetings

1st Consultancy Meeting: Vienna, Austria: 27 – 30 June 2017
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