IAEA-TECDOC-1980

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IAEA-TECDOC-1980

Application of a Graded Approach in Regulating Nuclear Installations

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APPLICATION OF A GRADED APPROACH IN REGULATING NUCLEAR INSTALLATIONS

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INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2021

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Printed by the IAEA in Austria
November 2021

IAEA Library Cataloguing in Publication Data

Names: International Atomic Energy Agency.
Title: Application of a graded approach in regulating nuclear installations / International Atomic Energy Agency.
Description: Vienna : International Atomic Energy Agency, 2021. | Series: IAEA TECDOC series, ISSN 1011–4289 ; no. 1980 | Includes bibliographical references.
Identifiers: IAEAL 21-01447 | ISBN 978-92-0-132021-6 (paperback : alk. paper) | ISBN 978-92-0-131921-0 (pdf)
Subjects: LCSH: Nuclear facilities — Regulation. | Nuclear facilities — Management. | Nuclear facilities — Safety measures.

FOREWORD

The application of a graded approach is essential to enabling regulatory bodies to use their generally limited resources to ensure the safety and security of nuclear installations, its employees, the general public and the wider environment. A systematic application of a graded approach to core regulatory functions is documented in the management system of the regulatory body and provides the tools for resource optimization so regulatory bodies can address issues accordingly. The graded approach is also a means for consistent regulatory decision making commensurate with the risk posed by an installation.

The application of a graded approach in regulatory functions is required in IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety. Some IAEA Safety Standards, safety reports and technical documents provide information on the application of a graded approach for specific applications, but they do not cover all regulatory functions and types of nuclear installation. Other IAEA Safety Standards provide high level recommendations for different areas regarding the application of a graded approach, but do not provide methodologies on its implementation. As a result, the documentation and guidance on applying a graded approach is not available in a coherent framework.

This publication addresses the basics of the application of a graded approach in the regulatory oversight of nuclear installations. It describes the current approaches of several regulatory bodies around the world and, on the basis of these examples, proposes a generic methodology for applying a graded approach in the regulation of nuclear installations. This publication also provides practical examples and information on developing and implementing strategies and processes for regulatory bodies in applying a graded approach. It is based on a compilation of state of the art international and national efforts and therefore supports the information available on the application of a graded approach to regulatory functions in regulating nuclear installations.

The IAEA wishes to thank all participants for their contributions to this publication. The IAEA officers responsible for this publication were M. Santini and S. Miranda of the Division of Nuclear Installation Safety.

CONTENTS

1. INTRODUCTION

1.1. BACKGROUND

IAEA Safety Standards Series No. GSR Part 1 (Rev. 1) [1] clearly states that all regulatory functions and safety requirements are required to be applied using a graded approach, i.e. the measures are required to be commensurate with the radiation risks associated with the facility or activity. Further, GSR Part 1 (Rev. 1) [1] also states in Requirement 16, para. 4.5, that "the regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach".

However, lessons learned from IAEA Integrated Regulatory Review Service (IRRS) missions have highlighted that the understanding and application of a graded approach process differs across Member States and most such peer reviews have resulted in recommendations or suggestions relating to application of a graded approach. Additionally, Member States have indicated that they are still experiencing difficulties in applying a graded approach in a systematic and documented way within their organizations. Further, during technical meetings/workshops, Member States have indicated that there is a need for guidance on the application of a graded approach to support regulatory functions for nuclear installations.

It is recognized that in many specific technical areas the application of a graded approach to focus regulatory attention on areas of greater safety significance is thorough and has been widely used historically. An example is the implicit use of a graded approach when considering external events in siting and design of nuclear installations. This can be clearly seen in IAEA Safety Standards Series No. SSR-1, Site Evaluation for Nuclear Installations [2], IAEA Safety Standards Series No. SSR-3, Safety of Research Reactors [3], IAEA Safety Standards Series No. SSG-68, Design of Nuclear Installations against External Events Excluding Earthquakes [4], IAEA Safety Standards Series No. NS-G-2.13, Evaluation of Seismic Safety for Existing Nuclear Installations [5] and in a Safety Report [6] related to this topic. In these examples, the method used is not always described explicitly as a graded approach, but it is clearly oriented to assign more attention to areas of greater safety significance, which is the essence of the use of a graded approach. In addition, examples on the explicit use of a graded approach in the application of safety requirements for research reactors and for management system are seen in IAEA Safety Standards Series No. SSG-22, Use of a Graded Approach in the Application of the Safety Requirements for Research Reactors [7] and IAEA-TECDOC-1740, Use of a Graded Approach in the Application of the Management System Requirements for Facilities and Activities [8].

1.2. OBJECTIVE

The primary objective of this TECDOC is to propose a generic methodology and document Member States' practices on the application of a graded approach for all the regulatory functions articulated in IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [1] and as applied to regulation of nuclear installations. Those practical examples on the use of a graded approach could be considered by regulatory bodies as a starting point to develop their own approach. In addition, the application of a graded approach to develop an integrated regulatory programme is also addressed.

1.3. SCOPE

The IAEA Safety Glossary [9] defines a nuclear installation as “Any nuclear facility subject to authorization that is part of the nuclear fuel cycle, except facilities for the mining or processing of uranium ores or thorium ores and disposal facilities for radioactive waste”. However, for the purposes of this publication, ‘nuclear installations’’ are limited to:

- Nuclear power plants;
- Research reactors (including subcritical and critical assemblies) and any adjoining radioisotope production facilities;
- Storage facilities for spent fuel;
- Facilities for the enrichment of uranium;
- Nuclear fuel fabrication facilities;
- Conversion facilities;
- Facilities for the reprocessing of spent fuel.

That is, dedicated facilities for the predisposal management of radioactive waste arising from nuclear fuel cycle facilities and nuclear fuel cycle related research and development facilities are not included in the scope of this publication. However, when the publication refers to nuclear installations, all activities conducted within that installation are also considered.

The TECDOC covers the application of a graded approach for nuclear installations and for all regulatory functions articulated in GSR Part 1 (Rev. 1) [1] and further described in IAEA Safety Standards Series No. GSG-13, Functions and Processes of the Regulatory Body for Safety [10]:

- Development of regulations and guides;
- Authorization;
- Review and assessment;
- Inspection;
- Enforcement;
- Communication and consultation with interested parties.

Although GSG-13 [10] describes emergency preparedness and response as a core regulatory function, emergency preparedness and response is excluded from the scope of this publication. The application of a graded approach to emergency preparedness and response is addressed in specific publications on this topic.

The methodology proposed, in general follows the high level concepts described in INSAG 25, A Framework for an Integrated Risk Informed Decision Making Process [11], applied to regulatory decision making.

1.4. STRUCTURE

Section 2 of this publication addresses the six core regulatory functions and other supporting regulatory activities and functions that may be applied with a graded approach. Section 3 describes a generic three-step methodology that can be used to apply a graded approach to the all regulatory functions in regulating nuclear installations. Generic and specific factors to be considered when using the methodology for applying a graded approach are also presented and analysed. Finally, Section 4 explains the use of the three-step methodology for the core regulatory functions and for an integrated regulatory programme. Specific factors applicable to each of the regulatory functions are introduced and discussed.

The Appendices provide additional information to support the use of a graded approach for the regulatory functions, including aspects to be analysed when identifying generic factors, methods for determining the relative importance of the applicable factors and considerations on the use of a graded approach for each of the core regulatory functions.

The Annexes provide practical examples of use of the proposed methodology for applying a graded approach in different Member States. The examples are grouped in accordance with the respective core regulatory function.

2. REGULATORY BODY FUNCTIONS

This section describes the functions of the regulatory body as defined in GSR Part 1 (Rev. 1) [1] and in GSG-13 [10], for which the application of a graded approach is advisable. Most of these functions are represented in processes of the regulatory body's integrated management system.

The main interfaces amongst core regulatory functions are presented in Fig. 1, as stated in para. 1.6 of GSG-13 [10][1].

2.1. CORE REGULATORY FUNCTIONS

(a) Regulations and guides

Requirement 32 of GSR Part 1 (Rev. 1) [1] states that:

> "The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based."

(b) Notification and authorization

Requirement 23 of GSR Part 1 (Rev. 1) [1] states that:

> "Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process."

(c) Review and assessment of facilities and activities

Requirement 25 of GSR Part 1 (Rev. 1) [1] states that:

> "The regulatory body shall review and assess relevant information — whether submitted by the authorized party or the vendor, compiled by the regulatory body, or obtained from elsewhere — to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization. This review and assessment of information shall be performed prior to authorization and

[1] Paragraph 1.6 of GSG-13 [10] also lists emergency preparedness and response among the core regulatory functions, but as indicated in Section 1.3 of this TECDOC, this is outside the scope of this TECDOC.

again over the lifetime of the facility or the duration of the activity, as specified in regulations promulgated by the regulatory body or in the authorization."

(d) Inspection of facilities and activities

Requirement 27 of GSR Part 1 (Rev. 1) [1] states that:

> "The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization."

(e) Enforcement

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

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

(f) Communication and consultation with interested parties

Requirement 36 of GSR Part 1 (Rev. 1) [1] states that:

> "The regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body."

2.2. OTHER REGULATORY ACTIVITIES AND FUNCTIONS

The following are important regulatory activities and functions that require the application of a graded approach by the regulatory bodies, as described in GSG-13 [10].

(a) Supporting functions

There are two categories of supporting functions that enable the regulatory body to implement its core functions effectively:

- 'Administrative functions' supporting the routine operations of the regulatory body (e.g. finance, management of documents and records, purchasing and control of equipment);
- 'Technical functions' directly relating to the effective implementation and fulfilment of the core regulatory functions (e.g. legal support, research and development, the functions of advisory committees, external expert support, liaison with other governmental organizations, international cooperation and assistance).

For example, independent regulatory research and development provides supporting information on the safety of the design and operation of nuclear installations. A graded approach could be used in determining the research efforts to be pursued, the priority of the research efforts, and the resources dedicated to those research efforts.

A graded approach may also be used for the development of annual budgets and periodically reallocating financial resources to address emerging safety significant issues or events.

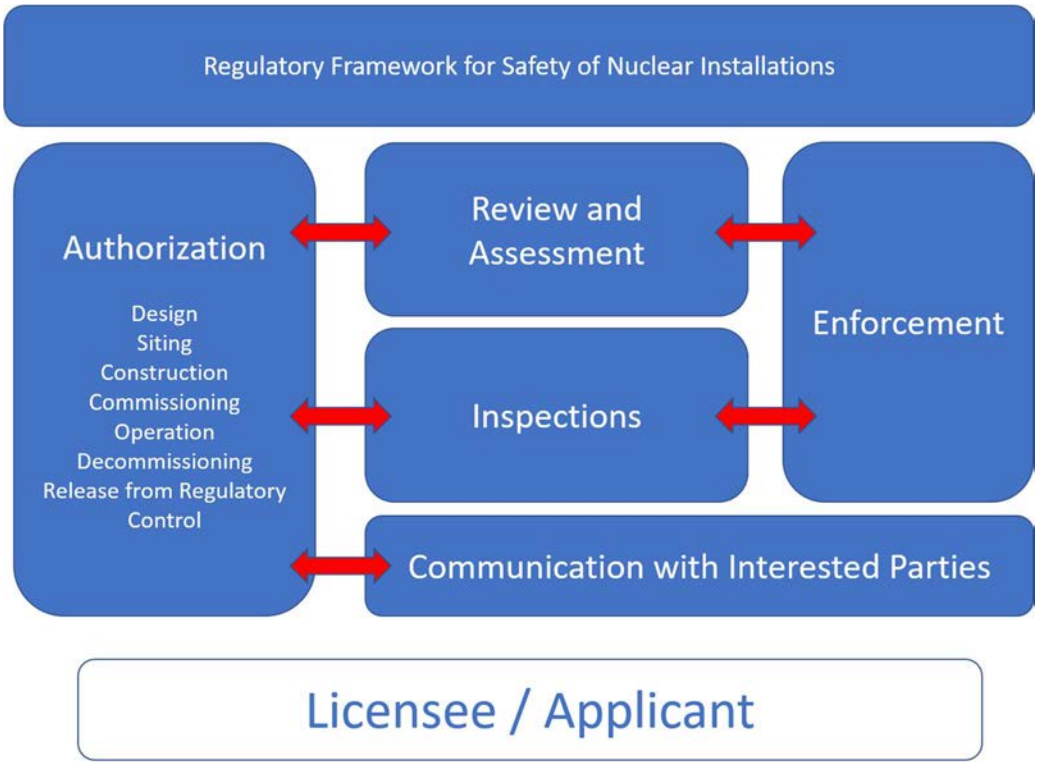

FIG. 1. Main interfaces amongst core regulatory functions

3. OVERARCHING METHODOLOGY FOR APPLICATION OF A GRADED APPROACH

3.1. GENERAL CONSIDERATIONS REGARDING A GRADED APPROACH

The IAEA Safety Glossary [9] defines ‘graded approach’ as follows:

> “For a system of control, such as a regulatory system or a safety system, a process or method in which the stringency of the control measures and conditions to be applied is commensurate, to the extent practicable, with the likelihood and possible consequences of, and the level of risk associated with, a loss of control.”

An example of a graded approach in general would be a structured method by means of which the stringency of application of requirements is varied in accordance with the circumstances, and the regulatory systems and the management systems used.

For example, a graded approach is a method in which:

(1) The significance and complexity of a product or service are determined;

(2) The potential impacts of the product or service on health, safety, security, the environment, and the achieving of quality and the organization’s objectives are determined;

(3) The consequences if a product fails or if a service is carried out incorrectly are taken into account.

The use of a graded approach is intended to ensure that the necessary levels of analysis, documentation and actions are commensurate with, for example, the magnitudes of any radiological hazards and non-radiological hazards, the nature and the particular characteristics of a nuclear installation, and the stage in the lifetime of the nuclear installation.

3.2. GENERAL METHODOLOGY

This Section summarizes the proposed overarching methodology for a graded approach. Specific applications of this methodology for the core regulatory functions are presented in Section 4.

The general methodology for applying a graded approach presented in this publication applies to the six core regulatory functions and is divided into three main steps:

(1) *Identifying the decision associated with the regulatory function*: regulatory decisions related to the regulatory function and possible alternatives are identified.

(2) *Identifying and ranking the applicable factors*: this step gathers all necessary information to support the analysis of the safety significance of the generic and specific factors associated with the regulatory decision. Risks and impacts associated with the factors are assessed. At the end of Step 2, the applicable factors are analysed and ranked;

(3) *Integrating the applicable factors into regulatory decision-making, including resource allocation*: factors are integrated to support regulatory decision-making. Typically, this integration of factors is made by professional judgement in consultation with the appropriate set of experts. The results are presented to the decision maker. At this point, the decision maker of the regulatory body can decide based on the safety significance of the applicable factors.

In the context of the methodology described in this publication, factors are the characteristics of nuclear installation or other elements that could affect the safety of a nuclear installation or impact the need of additional regulatory attention and, therefore, have influence on the regulatory decision making. For this reason, each factor would be related to the radiation risks associated with the nuclear installation. Radiation risks are determined and assessed on a case-by-case basis.

The methodology and its respective steps need to be logical, comprehensive and transparent. It is essential that processes, procedures and assumptions are properly documented to make the process repeatable, auditable, and subject to continuous improvement.

Figure 2 illustrates the three-step approach developed for the general methodology for applying a graded approach when performing regulatory functions.

As mentioned in Section 3.1, a graded approach may be applied to all regulatory functions in a number of ways.

The initial decision would therefore be where to apply a graded approach to the regulatory functions. That is to say, how a regulatory body would apply the three-step approach to grade the application of the requirements and/or allocate the regulatory resources commensurate with the radiation risks of the nuclear installation to be regulated.

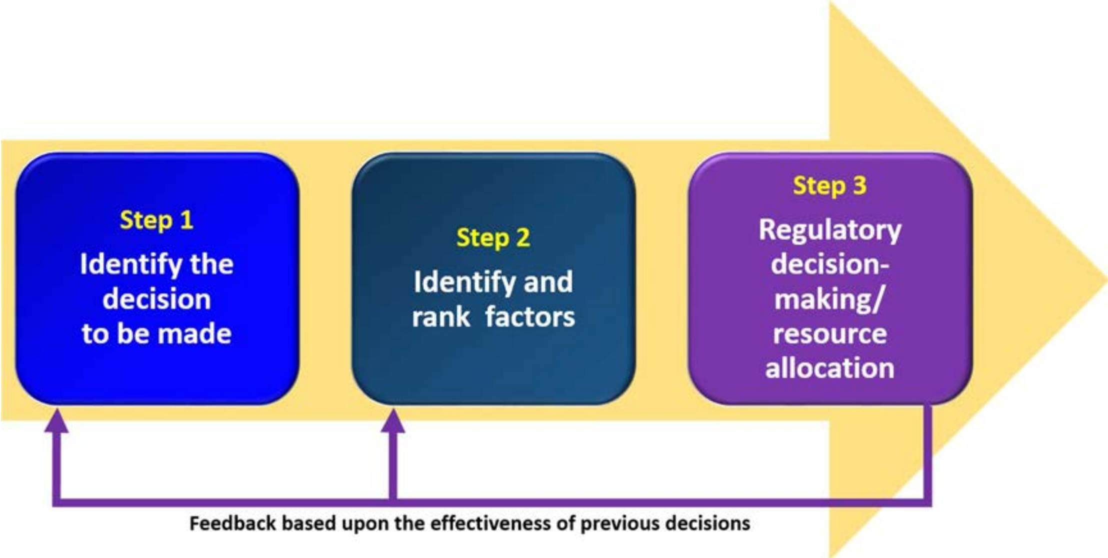

FIG. 2. Generic three-step methodology for applying graded approach to regulate nuclear installations

3.2.1. Step 1 - Identifying the decision associated with the regulatory function

Initially, the methodology presented in this publication involves identifying the regulatory decisions to be made and considering how the decision will impact the regulatory programme as a whole. This generic step is addressed differently depending upon the regulatory function.

Key questions are presented in Table 1 to support the identification of the decisions to be made by the regulatory body when applying a graded approach.

TABLE 1. KEY QUESTIONS WHEN APPLYING A GRADED APPROACH TO CORE REGULATORY FUNCTIONS

Regulatory Function	Key Questions when Applying a Graded Approach
Regulations and guides	• Are regulations and guidance adequate or commensurate with the risk associated with the nuclear installation?
Authorization	• Is the level of authorization (approval, consent) commensurate with the risk associated with the nuclear installation? • Is the licence/conditions established for an installation adequate to control the risk associated with the nuclear installation?
Review and assessment	• Is regulatory effort allocated for the review/assessment commensurate with the risk (potential safety significance) associated with the item being assessed? • Is there a systematic way of determining safety significance of review issues from a review and assessment?
Inspection	• Is regulatory effort allocated for the inspection programme commensurate with the risk associated with the item being assessed?
Enforcement	• Is there a systematic way of determining safety significance of findings resulting from an inspection? • Is the enforcement action commensurate with the safety significance of the non-compliance?
Communication and consultation with interested parties	• Are resources allocated for communication activities commensurate with the safety significance and level of stakeholder interest?

3.2.2. Step 2 - Identifying and prioritizing the applicable factors

After identifying the regulatory decision to be made, the next step is related to identifying, amongst the diverse factors that might be considered in the decision-making process, those that are applicable and might impact the final regulatory decision (Step 2A). The applicable factors are then ranked in accordance with their order of risk significance (Step 2B).

This subsection describes the proposed methodology to perform Step 2.

(a) Step 2A - Identifying the applicable factors

The first stage of Step 2 consists of the identification of the factors that are applicable to the regulatory decision under analysis. There are two types of factors to be considered at this stage:

— 'Generic factors', which are common to all regulatory functions;

— 'Specific factors', which depend upon the regulatory function considered.

(1) Generic factors

The characteristics of the nuclear installation are the most prominent 'generic factors' when considering a graded approach.

The nuclear installation is characterized in accordance with its level of radiological hazard. On this topic, the approach considers initially using a qualitative categorization of the nuclear installation, similar to the one presented in SSG-22 [7]. A first consideration is whether the nuclear installation is capable of generating a hazard within the building, on the site surrounding the building, or outside the site boundary.

The following list presents the factors to be considered, as applicable, in deriving the risks associated with a nuclear installation in accordance with its hazard:

(a) The reactor power (for pulsed reactors, energy deposition is typically used, while for accelerator driven subcritical systems, thermal power is typically used);
(b) The radiological source term;
(c) The amount and enrichment of fissile material and fissionable material;
(d) Spent fuel storage areas, high pressure systems, heating systems, which may affect the safety of the reactor;
(e) The type of fuel and its chemical composition;
(f) The type and mass of moderator, reflector and coolant;
(g) The amount of reactivity that can be introduced and its rate of introduction, reactivity control, and inherent and engineered safety features;
(h) The quality of the containment structure or other means of confinement;
(i) The utilization of the nuclear installation (experimental devices, tests, radioisotope production, reactor physics experiments, open access to core, fuel and experiment manipulation);
(j) The complexity of the nuclear installation;
(k) The presence of chemical hazards that potentially might trigger radiological hazards;
(l) The 'proven-ness' of the technology.

The factors suggested before for the individual characteristics of the nuclear installation are also consistent with those considered in SSG-22 [7].

In addition, other generic factors are related to the location of the nuclear installation.

(a) The location of the site, including the potential for external hazards (including those due to the proximity of other nuclear facilities) and the characteristics of airborne and liquid releases of radioactive material;
(b) Proximity to population groups;
(c) Feasibility of implementing emergency plans.

(2) Specific factors

Specific factors depend upon the regulatory function considered and the respective decision to be made. Because of this, they are discussed in Section 4 on the application of the proposed methodology for each of the core regulatory functions.

For example, when developing regulations and guides, using a graded approach to address a safety issue or emerging technology, the regulatory body considers the available regulatory instruments to analyse whether an existing regulation can be used or if a new one needs to be developed. This factor does not apply to other regulatory functions.

The number of nuclear installations to be regulated is a specific factor to be considered when applying a graded approach for authorization as large numbers of licensees may influence the necessity for delegation of authority on issuing licenses.

'Perceived' safety significance is an example of a specific factor associated with communication and consultation with interested parties. The level of public interest is directly proportional to the perceived safety significance of the issue or event being communicated. Communication tools are therefore selected to describe clearly and accurately the actual risk or safety significance to the public.

(b) Step 2B - Ranking the factors

The second stage of Step 2 is to rank the applicable factors identified earlier in the graded approach methodology.

It is important to note that this ranking process helps to differentiate those factors according to their safety significance for the installation and affects the regulatory decision-making process.

The ranking process needs to be clearly defined as it will impact the final regulatory decision. Therefore, a generic method for ranking factors considers analysing them in respect of their safety significance. In general, it is expected that the higher the risk and the impact of a factor on the safety of a nuclear installation, the higher its significance.

The criteria for ranking the factors in respect of their safety significance are expected to be objective; they also need to be defined and documented previously. This will allow for repeatability and improvement of the ranking process, as necessary.

The safety significance analysis would provide a ranking of the factors and insights on:

— The 'risk' associated with the factor. The risks are determined and assessed on a case-by-case basis;

— The 'impact of the factor', as a result of the adequacy of the existing items important to safety and/or control measures. This might lead to considering that the safety significance of a particular factor is increased if the respective items important to safety and control measures are not adequate.

This ranking process could be extended to a number of nuclear installations. It could be used to assess the safety significance of the factors in respect of a regulatory decision to be made when priorities are to be set for the regulatory activities. For example, when a graded approach is applied to inspections, this ranking of factors could be used to support the regulatory decision on how to allocate appropriate resources among inspection topics and installations given the order provided by this ranking process.

The way the applicable factors are ranked depends upon the practices in State. Therefore, it is not possible to provide a unique method for analysing and ranking the factors. The analysis of the practical examples on the use of a graded approach provided in the Annexes of this publication shows that there are different ways of assessing the factors.

In Appendix II, a generic method is proposed as an example to support States planning to develop new ways of ranking factors used for regulatory decisions or to compare it with their existing ones. Ranking of factors can also be achieved in a quantitative manner such as the numerical ranking exercise proposed in Appendix III.

3.2.3. Step 3 - Integrating the applicable factors into regulatory decision-making

The final step of the methodology is the integration of applicable factors and making the regulatory decision, considering how the decision will impact the regulatory programme as a whole.

At this stage, a regulatory decision and possible alternatives have already been identified, all necessary information to support the analysis of the safety significance of the generic and specific factors have been gathered, and risks and impacts have been assessed, including impacts to other aspects of the regulatory programme. Additionally, in Step 2 the applicable factors have been analysed and ranked.

Typically, this integration of factors is made by professional judgement in consultation with the appropriate set of experts. The results are presented to the decision maker. At this point, the decision maker of the regulatory body can make a risk-informed decision.

As set out in Table 1, a number of regulatory decisions could be made while applying a graded approach. Nevertheless, they can be grouped into two generic types of regulatory decisions:

(a) Allocation of resources and efforts to regulating the nuclear installation

The first group of regulatory decisions, ‘allocation of resources and effort’, is aligned with IAEA GSR Part 1 (Rev. 1) [1], Requirement 16, para. 4.5, on assigning available resources commensurate with the radiation risks. The aim is to balance resource allocation and maximize regulatory impact on higher priority areas.

This group of decisions deals with defining the appropriate resources to be allocated by the regulatory body to perform a regulatory function or implement a regulatory decision. In general, these decisions are made holistically, considering the resources available to the regulatory body and considering the whole spectrum of facilities to be regulated. The government is required to support the regulatory body to ensure that appropriate resources are always available, as defined in Requirement 3 of GSR Part 1 (Rev. 1) [1].

(b) Regulatory decision making

The second group of regulatory decisions, 'regulatory decision making', deals with selecting the decision to be made as a result of the analysis of safety significance of the factors. It is possible that alternative decisions are also available.

The integration of applicable factors may be an iterative process. For each factor under analysis, verifications are made to confirm that the safety significance and the impacts of the factor on the decision are appropriately assessed.

Specific considerations are expected to be made when integrating the applicable factors as proposed below:

- 'Flexibility' across each regulatory function to consider the wide variety of risk and hazard profiles. The decision in terms of development of regulations or use of regulatory actions is expected to be commensurate with the risk associated with the nuclear installation.

- 'Timeliness' of the implementation of the regulatory decisions or actions taking into account the safety significance of the factors considered in the decision.

- 'Consistency and transparency' are ensured by keeping records of the analyses performed, the basis for and the final decisions. Such records might be made publicly available.

- 'Differing opinions amongst the expert team or the regulatory staff' are likely to arise when a team of experts from different backgrounds is used for analysing and ranking the factors. Having an established and documented process that uses clear and objective criteria would support consensus and reduce subjectivity. However, in such situations, the final decision in the use of a graded approach will always rely on expert judgement based on the available information.

- 'Monitoring and feedback programmes' are created to assess the effectiveness of the decision. For changes to regulations, the performance of the regulatory body and the licensee implementing the new regulations needs to be monitored. For changes to the design or operation of a nuclear installation, a monitoring process would usually be agreed with the licensee and this would be included in inspection activities by the regulatory body. Additional information of performance monitoring can be found in IAEA-TECDOC-1909, Considerations on Performing Integrated Risk Informed Decision Making [12]. The monitoring programme needs to be consistent with the safety significance of the affected systems, structures and components. When the results from the decision-making process are not satisfactory, corrective actions might be implemented in the process to ensure achieving the expected results. In addition, the entire process might be revised and adjusted.

4. APPLICATION OF A GRADED APPROACH METHODOLOGY TO REGULATORY FUNCTIONS

This section describes the application of the graded approach methodology presented in Section 3.2 to each of the core regulatory functions. The typical analyses to be made in the three steps are discussed as well as the applicable factors that are specific to each of the regulatory functions, although the list of factors might not be exhaustive. When lower tier documents are analysed, additional specific factors may be identified.

In the Annexes of the TECDOC, many practical examples on the use of this methodology are presented to support States planning to implement a graded approach in their regulatory activities.

4.1. REGULATIONS AND GUIDES

"The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety", as stated in para. 2.5 of GSR Part 1 (Rev. 1) [1].

With regard to the contents of regulations and guides, GSR Part 1 (Rev. 1) [1] states that:

> "The regulations and guides shall provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization. They shall also establish the criteria to be used for assessing compliance. The regulations and guides shall be kept consistent and comprehensive and shall provide adequate coverage commensurate with the radiation risks associated with the facilities and activities, in accordance with a graded approach".

The government shall also "establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals", as stated in Requirement 1 of GSR Part 1 (Rev. 1) [1].

The implementation of the national policy and strategy for safety shall be done "in accordance with a graded approach, depending on national circumstances, to ensure that the radiation risks associated with facilities and activities, including activities involving the use of radiation sources, receive appropriate attention by the government or by the regulatory body", as defined in para. 2.4 of GSR Part 1 (Rev. 1) [1].

The need for applying a graded approach when developing regulations and guides is presented in para. 3.9 of GSG-13 [10]:

> "The regulatory body should establish a system to ensure that the development and implementation of regulations and guides is based on a graded approach, such that the application of regulatory requirements is commensurate with the radiation risks associated with the type of facility or activity".

The philosophy adopted by the regulatory body in establishing a regulatory framework will influence the need for a graded approach. Typically, regulatory bodies apply a combination of prescriptive and performance-based regulatory approaches depending on the nuclear installation and other factors described above. Appendix IV describes the principles of these two approaches.

If a prescriptive setting is taken, more emphasis needs to be applied in the application of a graded approach when developing the regulatory framework. The use of a graded approach is less of a factor when establishing a performance-based regulatory framework.

4.1.1. Proposed Methodology – Regulations and Guides

This subsection describes a proposed methodology in applying a graded approach to developing and revising regulations and guides.

— **Step 1:** Identify the decision that is associated with the development or revision of regulations and guides.

For Step 1 in identifying the decision, the following questions may be considered:

(a) Is a new regulatory framework being considered? Has the regulatory body reviewed the IAEA safety standards? Has the regulatory body reviewed the regulatory framework from other Member States for applicability?

(b) Is there a need for a new regulation, a revision of an existing regulation, or can the issue be addressed in lower level guidance documents? If the issue is specific to a small number of installations, can it be addressed through conditions in the authorization(s)?

(c) Is there a single topic being addressed, or several related topics? For example, do regulatory requirements exist for new technology reviews, e.g. spent fuel reprocessing? A regulatory body may need to develop a completely new set of regulations for a new technology.

— **Step 2:** Determine which factors are applicable to the decision and rank them.

For Step 2, in deciding which factors are applicable, the regulatory body needs to consider both the generic and specific factors.

In addition to the generic factors described in Section 2, the following specific factors for developing regulations and guides may be considered in the application of a graded approach:

(a) 'Operating experience feedback based on significant events' – Significant events may drive the need for additional regulations and guides.

(b) 'Statutory requirements' – Requirements established by legal framework of a State may override other factors.

(c) 'Urgency with respect to issue being addressed' – The choice of regulatory instrument may depend on the urgency in which the regulatory requirements or changes in the regulatory framework are needed. Since the development of regulations can take years in some States, to address safety significant issues, guidance or orders may be necessary prior to codifying those requirements. This factor might not apply to all States that have a framework that allows an amendment to an existing regulation in a short time based on exigent circumstances.

(d) 'Regulatory instruments available' – Based upon the safety significance of the issue, consideration is given to whether an existing regulation can be used or if a new one needs to be developed.

(e) 'Level of stakeholder involvement' – Increased stakeholder interest may need to be addressed. Those who would be affected by an accident have the right to know what the regulatory body is doing to prevent an accident. This includes the obligation to explain how safety standards are complied with. The regulatory body might also consider changes in the regulatory system when specific issues need to be addressed or the existing system is performing below expectations.

— **Step 3:** Integrate the applicable factors into the decision-making process.

For Step 3, in integrating the factors into the decision-making, the regulatory body needs to establish a formal documented process for objectively assessing the necessity for new regulations or revising existing ones as part of the regulatory body's management system. The formal process ought to include a regulatory impact analysis and may include an optimization analysis. Additionally, a graded approach ought to be considered when developing the content of the regulations.

For example, specific factors to consider in the development of criteria for elements of the safety analysis report are included in Annex I. Annex I also presents practical examples on the use of a graded approach for the development of regulations and guides.

4.2. AUTHORIZATION

IAEA Safety Standards Series No. SSG-12 [13] states in para. 2.5 that licenses and authorizations:

> "should be granted or denied in accordance with the national legal and governmental framework and need to cover all stages of the lifetime of the nuclear installation, namely, site evaluation, design, construction, commissioning, operation, decommissioning and subsequent release of the site from regulatory control".

GSR Part 1 (Rev.1) defines in para. 4.5 the responsibility of the regulatory body related to the structure of its organization and the management of resources [1]:

> "The regulatory body has the responsibility for structuring its organization and managing its available resources to fulfil its statutory obligations effectively. The regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach. Thus, for the lowest associated radiation risks, it may be appropriate for the regulatory body to exempt a particular activity from some or all aspects of regulatory control; for the highest associated radiation risks, it may be appropriate for the regulatory body to carry out a detailed scrutiny in relation to any proposed facility or activity before it is authorized, and also subsequent to its authorization".

GSG-13 [10] presents the objective of granting authorizations in para. 3.92:

> "The objective of granting authorizations is for the regulatory body to establish effective regulatory control for safety throughout the lifetime of a facility or activity. The authorization process should require assurance by the applicant that it can comply with all safety requirements".

GSG-13 [10] also recommends that authorizations cover all stages of the lifetime of a facility or activity, and who is responsible for issuing the authorizations:

"3.86. Authorizations should be granted or denied in accordance with the governmental, legal and regulatory framework and should cover all stages of the lifetime of a facility or activity. For a nuclear facility, for example, this encompasses site evaluation, design, manufacturing, construction, installation, commissioning, operation, decommissioning (or closure) and subsequent release of the site from regulatory control.

3.87. The legal framework of the State should set out the responsibilities for issuing an authorization and, in particular, should determine who is empowered to issue authorizations. Depending on the system used in the Member State, different authorizations may be issued by different authorities".

Among the principles for authorization, it is important to highlight that "the authorization of a facility or activity should be based on a predefined list of documents that are to be submitted to the regulatory body by the person or organization responsible for the facility or activity. These documents should be reviewed by the regulatory body", as indicated in para. 3.93(d) of GSG-13 [10]. In addition, "a clear and explicit set of requirements, criteria and standards forming the basis for authorization should be defined", as defined in para. 3.9(e) of GSG-13 [10].

For notification and authorization, para. 4.33 of GSR Part 1 (Rev. 1) [1] requires that:

"the extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach".

For standardization purposes, the contents of licences (or documents containing associated licence conditions) for each type of nuclear installation ought to be documented in the management system.

A graded approach for the licensing process needs to be considered in establishing the level of detail required in licensing documents and the level of authority of the person or body authorizing each stage of the licensing process. Authorization steps/stages could be predetermined in case of multistage licensing actions.

Types of authorizations include those specified within SSG-12 [13] and those described in Appendix V.

4.2.1. Proposed Methodology - Authorization

The following describes a proposed methodology in applying a graded approach to authorization of nuclear installations by determining the appropriate scope and depth of the documents to be submitted for each licensing stage and deciding on what level of the organization is the approval authority.

— **Step 1:** Identify the appropriate authorization.

In Step 1, in general, the regulatory body is given statutory authority to authorize nuclear installations, and it may delegate certain authorizations to staff at lower levels of the regulatory body's organization. Any delegations of authority ought to be documented in a formal guidance document within the management system. The development of the authorization process needs to consider the whole spectrum of nuclear installations regulated by the regulatory body.

— **Step 2:** Determine which factors are applicable to the decision, and how those factors are ranked.

For Step 2, in deciding which factors are applicable, the regulatory body needs to consider both generic and specific factors. The factors identified need to be analysed to establish their relative importance in making the final decision. Factors associated with statutory requirements would override others. In a graded approach, the ranking established in consideration of all factors ought to drive the delegation of authority on issuing the different types of authorization for the different stages in the lifetime of a nuclear installation.

In addition to the generic factors described in Section 2, the following specific factors may be considered in the application of a graded approach in authorization of nuclear installations:

(a) 'Statutory requirements' – Requirements established by the legal framework of the State would override other factors.

(b) 'Types of authorization' to be issued at various licensing stages (permits and licences).

(c) 'Level of stakeholder involvement' – Increased stakeholder interest ought to be addressed. Those who would be affected by an accident have a right to know what the regulatory body is doing to prevent an accident. This includes the obligation to explain how safety standards are complied with. It might entail changes in the regulatory system when specific issues need to be addressed or the existing system is performing below expectations.

(d) 'Number of nuclear installations to be regulated' – Large numbers of licensees might influence the necessity for delegation of authority on issuing licenses. The delegation of authority would support ensuring that adequate regulatory resources perform timely licensing actions while still applying due diligence.

— **Step 3:** Integrate the applicable factors into the decision-making process.

The regulatory body could determine the appropriate approval authority for licensing actions, as well as establishing the level of detail appropriate to the type of nuclear installation being licensed. Statutory authority to do this could be granted by government bodies.

For Step 3, in integrating the factors into the authorization process, the regulatory body ought to establish a formal documented process, which may include the delegation of authority based on the ranking established in Step 2, in consideration of the safety significance of the nuclear installation and volume of licensing actions before the regulatory body. The authorization process ought to be made part of the management system of the regulatory body's organization.

Additionally, for Step 3, the regulatory body may decide to issue standardized licences for all regulated nuclear installations. If the regulatory body decides that a graded approach is appropriate, then the contents of the licence need to be commensurate with the safety significance of the nuclear installation.

Practical examples on the use of a graded approach for authorization are presented in Annex II.

4.3. REVIEW AND ASSESSMENT OF FACILITIES

GSR Part 1 (Rev. 1) [1] includes Requirement 26, related to the use of a graded approach to review and assessment of a facility or an activity, which states:

> "Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."

IAEA Safety Standards GSR Part 4 (Rev. 1), Safety Assessment for Facilities and Activities [14], presents requirements for safety assessment, particularly focused on defence in depth and the application of a graded approach to assessments depending on their scope. Requirement 1 of GSR Part 4 (Rev. 1) [14] states when to use a graded approach to safety assessment:

> "A graded approach shall be used in determining the scope and level of detail of the safety assessment carried out at a particular stage for any particular facility or activity, consistent with the magnitude of the possible radiation risks arising from the facility or activity."

Furthermore, in para. 3.2 of GSR Part 4 (Rev. 1) [14], it is stated:

> "A graded approach shall be used in determining the scope and level of detail of the safety assessment carried out at a particular stage for any particular facility or activity, and the resources that need to be directed to it."

The application of a graded approach relieves the burden of generating a lot of detailed analyses and other documentation when they are not warranted based on risk and facilitates the regulatory review process by eliminating superfluous information. However, it is by no means a compromise in the requirements for defence in depth and high standards of safety. Similarly, a graded approach does not mean a compromise on the technical soundness of an analysis method chosen. Such a method has to be qualified in terms of its applicability and adequacy to the safety issue to be addressed.

GSG-13 [10] provides recommendations for regulatory bodies on performing regulatory processing with a graded approach, including reviews and assessments as stated in para. 3.93 (f):

> "A graded approach should be taken by the regulatory body when performing reviews, assessments or inspections throughout the authorization process."

SSG-12 [13] and GSG-13 [10] provide further recommendations in para. 2.19 (h) and para. 3.93 (f) respectively:

> "A graded approach should be taken by the regulatory body when performing reviews, assessments or inspections throughout the authorization or licensing process. Such an approach should be reflected in regulations and guides, and the extent of reviews, assessments or inspections should be appropriate to the magnitude and the nature of the hazard and the risk posed by the nuclear installation."

Paragraph 3.2 of GSR Part 4 (Rev. 1) [14] states:

> "The main factor to be taken into consideration in the application of a graded approach is that the safety assessment shall be consistent with the magnitude of the possible radiation risks arising from the facility or activity. The approach also takes into account any releases of radioactive material in normal operation, the potential consequences of anticipated operational occurrences and possible accident conditions, and the possibility of the occurrence of very low probability events with potentially high consequences."

In general practice, regulatory bodies develop a well-defined process for review and assessment that ought to be integrated into the management system.

Possible uses of a graded approach in different areas of review and assessment of nuclear installations are discussed in Appendix VI. Practical examples on the use of a graded approach to this core regulatory function are presented in Annex III.

4.3.1. Proposed Methodology - Review and Assessment

The following describes a proposed methodology in applying a graded approach to the review and assessment regulatory function for nuclear installations by determining the scope and depth of the review. In addition, a graded approach would be used in assessing the acceptability of proposed alternative methods, exemptions, exclusions, and novel approaches for meeting the intent of the requirements.

(a) Use of a graded approach for resource allocation

The following describes a proposed methodology to apply a graded approach for allocating adequate resources in a review and assessment process, aligned with GSR Part 1 (Rev. 1) [1], Requirement 16, para. 4.5.

— **Step 1:** Determine the scope and depth of the review based on applicable requirements.

Typically, a regulatory body will develop a review plan tailored to a specific nuclear installation.

— **Step 2:** Determine which factors are applicable to the decision, and how those factors are ranked.

In addition to the generic factors described in Section 2, the following specific factors may be considered in the application of a graded approach in the review and assessment process:

(a) 'Regulatory body resources' - Need for level of expertise for specific areas and consideration of competing resource needs. The "regulatory body should have sufficient full-time staff capable of either performing regulatory reviews and assessments, or evaluating assessments performed for it by consultants", as described in para. 3.155 of GSG-13 [10].

(b) 'Document submission requirements' – Such requirements may be defined for a specific requested review and assessment, e.g. design modifications or changes in approved documents. They may also be defined for each licensing/authorization stage in the lifetime of nuclear installations in the specific regulations. The amount of information to be reviewed by the regulatory body will influence the resource allocation.

(c) ‘Level of detail of information in the submissions’ - Level of detail of information in the submissions also plays an important role in deciding adequacy of resources for review and assessment of different nuclear installations, for example, more detail information may be required for high risk nuclear installations as compared to low risk nuclear installations.

(d) ‘Reviews and assessments performed by other regulatory bodies when applicable’ - This factor ought to take into account the differences in the legal and regulatory framework of the regulatory bodies concerned.

(e) ‘Experience and knowledge’ – The knowledge gained from operating experience in reviewing and assessing existing nuclear installations or utilizing the results from previous reviews.

(f) ‘Urgency for need of licensing action’ – Regulatory activities that are time sensitive may impact the resource effort associated with the review and assessment process.

(g) ‘Alternative approaches, different from those specified in requirements’ – Unique approaches taken by the applicant will involve greater effort to confirm that the intent of requirements is met.

(h) ‘Novel analysis methods, codes, and models are used’ – Methods, codes and models that have not been previously accepted or approved by the regulatory body will necessitate additional resource effort to determine acceptability.

(i) ‘Novel design features’ – New or unique design features will necessitate additional resource effort to determine acceptability.

(j) ‘Analysis shows low margins to safety limits’ – Increased scrutiny may need to be applied where there is reduced safety margin, or in determining whether or not compensatory measures are necessary.

— **Step 3:** Integrate the applicable factors into the decision-making process.

In integrating the factors into the review and assessment function, the regulatory body ought to establish a formal documented process for determining the appropriate resource effort for each review and make it part of the regulatory body’s management system.

The regulatory body ought to integrate the applicable factors into decision making on determining the appropriate resource effort that is commensurate with the scope and depth established for the review and assessment. When comparing appropriate resource needs with available resources, the organization will need to decide if there needs to be a re-prioritization of regulatory activities, or if additional resources need to be procured. When additional resources are needed, a regulatory body may request the government to provide them and may also resort to technical and scientific support organizations (TSOs) in support of its regulatory functions.

In some situations, based on the radiation risks posed by the nuclear installation, a revision of the scope and depth to ensure adequate review and assessment might also be implemented and support the allocation of appropriate resource effort. However, in some

States and due to the legal framework, the regulatory body might not be able to adjust the scope or depth of the review.

(b) Use of a graded approach in assessing deviations from requirements or in the review

A graded approach in the overall review of an application is used to determine the stringency of application of requirements, which varies based on the circumstances described in a submission. The acceptability of deviations from accepted practices or regulatory requirements ought to be commensurate with the hazard posed by the deviation. A determination of safety significance of the deviations ought to use a structured, documented method, preferably as part of the management system.

The following describes a proposed methodology to apply a graded approach for assessing acceptability of deviations being reviewed:

— **Step 1:** Identify deviations from requirements and assess the justifications provided for the deviation.

— **Step 2:** Determine which factors are applicable and rank them.

In addition to the applicable generic factors described in Section 2, the following specific factors may be considered in the application of a graded approach:

(a) ‘Document submission requirements’ – Such requirements may be defined for a specific requested review and assessment e.g. design modifications or changes in approved documents. They may also be defined for each licensing/authorization stage in the lifetime of nuclear installations in the specific regulations. The safety significance of information to be reviewed by the regulatory body in respect of the identified deviations will influence the regulatory decision-making.

(b) ‘Reviews and assessments performed by other regulatory bodies when applicable’ - This ought to take into account the differences in the legal and regulatory framework of the regulatory bodies concerned.

(c) ‘Experience and knowledge’ – The knowledge gained from operating experience in reviewing and assessing existing or similar facilities or utilizing the results from previous reviews.

(d) ‘Urgency for need of licensing action’ – Regulatory activities that are time sensitive may impact the decision associated with assessment of deviations from requirements or accepted practices.

(e) ‘Alternative approaches, different from those specified in requirements’ – Unique approaches described in applications will involve greater effort to confirm that the intent of requirements is met.

(f) ‘Novel analysis methods, codes, and models are used’ – Methods, codes and models that have not been previously approved by the regulatory body will necessitate additional resource effort to determine acceptability.

(g) ‘Novel design features’ – New or unique design features will necessitate additional resource effort to determine acceptability.

(h) ‘Analysis shows low margins to safety limits’ – Increased scrutiny may need to be applied where there is reduced safety margin, or in determining whether or not compensatory measures are necessary.

— **Step 3:** Integrate the applicable factors into the decision-making process.

In integrating the factors into the review and assessment function, the regulatory body ought to establish a formal documented decision-making process based on the safety significance of the applicable factors for assessing deviations from requirements or accepted practices in the review and make it part of the regulatory body’s management system [11].

In some jurisdictions, a documented integrated risk informed decision making (IRIDM) process is used. The integration of factors into making regulatory decision needs to take into account:

(a) Identification of the deviations in information and knowledge and assessment of the significance of the deviations;

(b) The need for adequate compensatory measures or additional controls to be identified to address the deviations.

As highlighted in IAEA-TECDOC 1909 [12] the quality of the information used in the IRIDM process “should be verified and validated to ensure that it appropriately represents the issue and options proposed based on the specified information requirements. This includes deterministic analysis and PSA and or other relevant probabilistic arguments.”

4.4. INSPECTION OF NUCLEAR FACILITIES

Paragraph 4.50 of GSR Part 1 (Rev. 1) [1] establishes requirements in respect of the use of a graded approach to inspection of facilities:

> “The regulatory body shall develop and implement a programme of inspection of facilities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach”.

The government is required to promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety including inspection of facilities, and for the enforcement of regulations, in accordance with a graded approach [1].

The manner, extent and frequency of inspections is required be in accordance with a graded approach, as stated in para. 4.52 of GSR Part 1 (Rev. 1) [1] and further recommendations are provided in para. 4.16 of IAEA Safety Standards Series No. GSG-12, Organization, Management and Staffing of the Regulatory Body for Safety [15]

Paragraph 2.5(d) of GSG-13 [10] states that:

> “Inspections of facilities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.”

Paragraph 3.244 of GSG-13 [10] also mentions that:

> "a pre-established graded approach to responding to special circumstances will assist in determining the appropriate level of resources for use in reactive inspections."

The use of detailed written guidelines to be used in inspections is presented in para. 3.26(c) of GSG-13 [10], which states that:

> "The regulatory body should provide its inspectors with written guidelines in sufficient detail to ensure that facilities are inspected to a common standard, based on a graded approach, and that there is a consistent level of safety".

An example of a licensing principle related to inspections is presented in para. 2.19(h) of SSG-12 [13]; it recommends that:

> "a graded approach should be taken by the regulatory body when performing inspections throughout the authorization process. Such an approach should be reflected in regulations and guides, and the extent of inspections should be appropriate to the magnitude and the nature of the hazard and the risk posed by the nuclear installation".

Inspection programmes generally are divided into one component that defines the minimum number and type of inspections to be carried out, plus additional inspections that are driven by the performance of the licensee (poor performance may trigger more inspections), events that have occurred at the installation or special circumstances that necessitate additional oversight, such as major temporary changes to the installation. The first set of inspections is called baseline, the additional inspections may be called reactive inspections[2].

A graded approach can be used to determine what to inspect, how often to inspect, and where to focus inspection resources. A graded approach could be applied to both the baseline inspection programme for all nuclear installations, and to reactive or supplemental inspections, depending on the severity of the performance deficiencies, the significance of the events or the magnitude of the temporary changes needing additional inspection oversight.

A graded approach can be developed for undertaking reactive inspections in response to significant events at the nuclear installation. The regulatory body ought to consider following up on events in three ways:

(1) Events of low safety significance receive minimal follow up, usually by a single inspector;
(2) Events of moderate safety significance receive more follow up, often by one or two inspectors;
(3) Events of greater safety significance are followed up by a team of inspectors.

Similar reasoning might also be made by considering the following additional aspects for conducting reactive inspections based on the safety significance of the event:

— The scope and depth of the documentation to be evaluated as part of the inspection;
— The seniority of staff involved in the inspection from both the regulatory body and the operating organization;

[2] In some States, some of the reactive inspections are called supplemental.

- The number of staff to be interviewed in the operating organization;
- The timing and urgency of follow up regulatory activities.

Additional guidance can be found in Appendix VII and practical examples on the use of a graded approach to this core regulatory function are presented in Annex IV.

4.4.1. Proposed Methodology – Inspection

The following describes a proposed methodology in applying a graded approach for determining the appropriate resource effort for inspection of nuclear installations. In addition, a graded approach would be used in developing baseline inspection programmes for different nuclear installations and adjusting the inspection programme in consideration of the generic and specific factors described below. The regulatory body ought to identify through written guidance what to focus attention on while conducting each specific inspection.

For the development of the inspection programme, the regulatory body needs to compare all nuclear installations holistically to focus more resources in accordance with the potential radiological hazard of the installations.

- **Step 1:** Identify structures, systems, and components (SSCs) that are important to safety.

  The regulatory body ought to have a documented methodology for identification of the safety significance of items. Deterministic and probabilistic safety analyses may be used to identify SSCs that are important to safety.

- **Step 2:** Determine which factors are applicable to the decision and rank them.

  States may want to consider performance indicators such as those described in IAEA-TECDOC-1141 [16].

  In addition to the generic factors described in Section 2, the following specific factors may be considered in the application of a graded approach in establishing a baseline inspection programme:

  (a) ‘Resources’ - Available regulatory resources, including the expertise of the inspectors, need to be considered in establishing oversight programmes across nuclear installations. Appropriate resource allocation and frequency of inspections are defined by considering the potential radiological hazard of the nuclear installations. More resources are often dedicated to the higher risk nuclear installations.

  (b) ‘Stage in the lifetime of the nuclear installation’ - Inspection of nuclear installations under construction follows an inspection programme to ensure the installation is constructed in accordance with the approved design. Inspection programmes for operating nuclear installations are also thorough to verify the licensee is conducting operations in a manner that protects public health and safety. Nuclear installations being decommissioned may have significantly lower risk to the public, in comparison with similar installations in operation and therefore need to have inspection programmes that are commensurate with the reduced risk. In all case, inspections are sample-based and graded in accordance to the radiological hazards and safety significance.

(c) 'Design of the installation' - The next generation of reactor designs rely more heavily on passive safety systems with fewer active components, and probabilistic safety analyses (PSAs) that are expected to be show core damage frequency (CDF) or large early release frequency (LERF) that are lower than the current generation of plants. The reduced numbers of components ought to translate into reduced sample requirements for the baseline inspection programme. Additionally, in general the reduced risk associated with the design may also translate into fewer samples needing to be inspected, or a reduction in the frequency of some inspections, in order to provide reasonable assurance that the installation is being operated safely and in accordance with its licence conditions. In addition, design modifications may necessitate adjustments to the baseline inspection programme.

The following factors may also impact changes to the inspection effort:

(a) 'Licensee performance' - Consideration needs to be given to enhancing or supplementing baseline inspections for licensees demonstrating declining performance. This can be accomplished by increasing sample sizes for inspections related to the declining performance, increasing the frequency of inspections, or scheduling additional inspections to ensure the licensee is addressing the declining performance. Likewise, reducing inspection sample sizes might be considered for licensees that have demonstrated sustained good performance.

(b) 'Operating and construction experience' - Operating and construction experience generally focuses on safety-significant issues. Regulatory bodies ought to determine whether specific operating experience applies to licensees they regulate, and ensure that those licensees enter that information into their corrective action programmes for disposition. These issues might be considered when selecting inspection samples. The licensee's consideration of domestic as well as international experience may influence development of the baseline inspection programme as well as changes to the reactive inspection programme.

(c) 'Regulatory body experience' - As experience is gained by the regulatory body in inspecting installations over time, there may be an opportunity to revise the inspection programme to ensure resources continue to be focused on areas of greatest safety significance. Regulatory body experience ought to also consider domestic as well as international experience when developing both baseline and reactive inspection programmes.

(d) 'Age of the installation' - As installations age and approach their design life, there ought to be an increased focus on equipment performance, particularly for items important to safety. For installations that are allowed to operate beyond their design life (life extension), licensees need to reinforce their ageing management programmes. These programmes may need to be monitored by the regulatory body, in addition to inspections that monitor equipment performance. Grading can be applied in determining the appropriate frequency of inspections, in selecting detection methods, as well as in establishing measures for prevention and mitigation of aging effects, which could be based on the estimated service lives of the SSCs, their complexity and their ease of replacement.

(e) 'Special and infrequently performed operational activities' - During the operating life of a nuclear installation, there may be times when the licensee is performing major rework during which the regulatory body needs to exercise some additional oversight. For nuclear power plants for instance, such activities include steam generator replacement, reactor vessel head replacement, refuelling activities and digital control modifications. Regulatory bodies need to plan to allocate additional inspection resources to ensure these infrequently performed activities are conducted safely.

(f) ‘Significant events’ - Regulating bodies need to consider additional inspection effort for any nuclear installation at which a significant event has occurred. That inspection effort ought to focus on understanding the event, causal factors, potential generic issues, equipment issues, and operator’s corrective actions and performance.

— **Step 3:** Integrate the applicable factors into the decision-making process.

In integrating the factors into the inspection function, the regulatory body ought to establish a formal documented process for determining the appropriate resource effort for each inspection and make it part of the management system.

The applicable factors and allocate resources for inspections are integrated by:

(a) Determining the appropriate resource effort needed to carry out the inspection programme, taking the applicable factors into account. In this step, the regulatory body determines the appropriate inspection sample size and frequency. Resources might also be allocated for contingency purposes, such as emergent safety significant issues or event response.

(b) Scheduling the inspections in accordance with the appropriate resource needs. When preparing the inspection programme, the organization will need to take into account the safety significance of the installation and the appropriate resource needs (including inspector expertise) to perform all required inspection activities. This provides assurance that the licensee is operating safely without imposing unnecessary regulatory burden. If multiple inspections need to be performed at the same time, the organization will need to decide if a revision of the scope and depth of the inspections is necessary, if there needs to be a re-prioritization of inspection activities, or if additional resources need to be procured.

Step 1 may be skipped if a regulatory body reviews or amends the inspection effort while maintaining the scope of the inspection programme. When new regulatory requirements necessitate updating the baseline inspection programme, the regulatory body will need to return to Step 1.

Non-compliances identified during inspections will be dispositioned using the enforcement process described in Section 4.5.

4.5. ENFORCEMENT

GSR Part 1 (Rev.1) [1] states in para. 4.54 that:

> “The response of the regulatory body to non-compliances with regulatory requirements or with any conditions specified in the authorization shall be commensurate with the significance for safety of the non-compliance, in accordance with a graded approach.”

Paragraph 2.5 of GSR Part 1 (Rev. 1) [1] requires that "laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety" are created by the government, including provision for the enforcement of regulations, in accordance with a graded approach.

GSG-13 [10] states in para. 3.299 that:

> "Regulatory enforcement activities should cover all areas of regulatory responsibility. Enforcement actions should be applied as necessary by the regulatory body using a graded approach appropriate to the legal system and the authorization practices of the State."

In establishing an enforcement policy for nuclear installations, enforcement actions also ought to apply a graded approach, since the severity and impact on safety of non-compliance with requirements may vary. Regulatory bodies ought to allocate resources and apply enforcement actions or methods in a manner commensurate with the safety or security significance of the non-compliance, increasing them as necessary to bring about compliance with requirements.

4.5.1. Proposed Methodology - Enforcement

The following describes a proposed methodology in applying a graded approach to enforcement for nuclear installation.

The regulatory body ought to develop a formal process for integrating the factors into the enforcement determination, and that process ought to be part of the management system. The formal process needs to include objectively determining the significance or severity of the non-compliance so that it is predictable and repeatable. The following describes a proposed methodology in applying a graded approach to determining an appropriate enforcement approach.

— **Step 1:** Identify the non-compliance and determine its safety significance or severity.

— **Step 2:** Identify the applicable factors to consider.

The factors ought to be ranked by importance depending on whether the factor mitigates or escalates the significance or severity of the non-compliance.

In addition to the generic factors described in Section 2, the following specific factors may be considered in the application of a graded approach for the enforcement process:

(a) 'Safety significance of the violation or non-compliance' - This will be one of the most important factors in determining the appropriate enforcement action. As the risk to workers or the public increases, the type of enforcement action ought to increase, commensurate with that risk.

(b) 'Identification credit' - The regulatory body might reduce the enforcement action if the licensee self-identified the issue. This policy will encourage licensees to find problems and correct them before the regulatory body identifies them by reducing the expected enforcement action.

(c) 'Timeliness of corrective actions' - This may be a factor that increases the severity of the enforcement action. For instance, if a violation or non-compliance is identified and not corrected within a reasonable period of time commensurate with the safety significance of the issue, then the regulatory body might consider a more stringent enforcement action.

(d) ‘Repetitiveness of a non-compliance’ - This factor increases the significance of the enforcement action.

(e) ‘Frequency of deficiencies or violations ought to be addressed’ - More frequent deficiencies might be indicative of a broader or systemic problem at the nuclear installation. The regulatory body might consider aggregating issues that are safety-significant over a relatively short period of time to identify possible adverse trends in licensee performance, and the subsequent response may be increased inspection or more significant enforcement actions.

(f) ‘Wilfulness’ - If a licensee wilfully violates a regulatory requirement, this escalates the seriousness of the violation, and the appropriate enforcement action ought to reflect that seriousness.

(g) ‘Comparison with enforcement actions previously used’ - Consistency ought to be ensured when selecting enforcement actions. In this regard, the regulatory body might also consider analysing non-compliances of similar safety significance and their respective enforcement actions.

— **Step 3:** Integrate the applicable factors into the decision-making process.

In integrating the factors into the enforcement function, the regulatory body ought to establish a formal documented process for determining the appropriate enforcement action and make it part of the regulatory body’s management system.

The regulatory body will integrate the applicable factors into the decision-making process to determine the appropriate enforcement action.

After the safety significance of the violation has been determined, the regulatory body dispositions it, and a graded approach can be used in determining the appropriate regulatory action based on the significance. The regulatory body needs to establish several options for disposition with defined criteria. Enforcement actions by the regulatory body may include, from para. 4.55 of GSR Part 1 (Rev.1) [1]:

— Recorded verbal notification;
— Written notification;
— Imposition of additional regulatory requirements and conditions;
— Written warnings;
— Penalties;
— Revocation of the authorization.

Additional enforcement actions may include:

— Orders;
— Decertification of an individual;
— Prosecution in a court of law.

Generic examples of the use of a graded approach for enforcement in different types of nuclear installations are discussed in Appendix VIII. Practical examples on the use of a graded approach in different States when defining enforcement actions are presented in Annex V.

4.6. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

Paragraph 4.69 of GSR Part 1 (Rev. 1) [1] states that "Public information activities shall reflect the radiation risks associated with facilities, in accordance with a graded approach", but also regulatory bodies might need to address the areas of significant public concerns or interest even if they radiation risk is not high.

IAEA Safety Standards Series No.GSG-6, Communication and Consultation with Interested Parties by the Regulatory Body [17] states in para. 2.15 that:

> "The regulatory body should adapt its methods for communication and consultation to the objectives and the expected interested parties, and in accordance with a graded approach."

To effectively regulate safety, the regulatory body is expected to have the public's trust and confidence. Being open and transparent with regulatory information gives the public better understanding of what the regulatory body does and contributes to more effective public participation in the regulatory process. Public input helps improve the decision-making process by ensuring the regulatory body considers all potential consequences of a decision. Communication with stakeholders ensures openness and transparency in regulatory decision-making and is vital to ensuring public trust in the regulatory body.

In the context of this TECDOC, a stakeholder is any party who has an interest in the regulatory oversight of nuclear installations. Stakeholders include:

- The general public;
- National government;
- State, provincial or regional government;
- Local government;
- Licensees;
- The nuclear industry;
- Regulatory bodies in other States;
- International organizations;
- The media;
- Radiation workers;
- Activist groups;
- Civic groups.

There are many communication tools available, and the regulatory body needs to consider a graded approach when determining the appropriate set of tools for communicating issues to stakeholders. The set of communication tools might include:

- Press releases;
- Social media;
- News media (newspapers, television, radio);
- Internet;
- Public meetings;
- Inspection reports;
- Documents for public comment;
- Community outreach;
- Information seminars or conferences;

— Regulatory body generic communications (information summaries, notices, letters, bulletins);
— Annual reports.

Social media and blogs have the potential to reach the greatest number of people in the shortest period of time. Information transmitted ought to be accurate and focused on the facts. A key message needs to be the actual safety significance of an action or incident to the public.

4.6.1. Proposed Methodology - Communication and Consultation

The following describes a proposed methodology in applying a graded approach to communication and consultation in respect of nuclear installations.

— **Step 1:** Identify the level of stakeholder involvement or the communication needed.

For Step 1, what needs to be communicated, and to whom? What installation or issue is being addressed that necessitates stakeholder involvement?

— **Step 2:** Determine which factors apply to the decision, and how those factors are ranked.

For Step 2, in deciding which factors apply, the regulatory body needs to consider both generic and specific factors. Identified factors are ranked to establish their relative importance in making a final decision. Statutory requirements would override other factors.

In addition to the generic factors described in Section 2, the following specific factors may be considered in the application of a graded approach for communication and consultation with interested parties:

(a) 'Public interest' – This is the most important factor for determining an appropriate level of communication with stakeholders. There are varying levels of public interest, depending on the situation. Issues impacting only the local community will likely garner only local or regional public interest. Issues impacting a large segment of the population may be of interest to the national public, or even the international community. For example, an accident at an operating nuclear power plant can lead to a public perception of great safety risk, making the event newsworthy to the international community. The level of public interest is directly proportional to the perceived safety significance of the issue or event being communicated. Similar reasoning applies to other interested stakeholders.

(b) 'Perceived safety significance' - It is acknowledged that nuclear power and radiation instil fear in some of the population, so the perception of safety significance is generally greater than the actual safety significance. Communication tools ought to be used to describe clearly and accurately the actual risk or safety significance to the public.

(c) 'Timely communication' – This factor is important to establish public trust that the regulatory body is taking appropriate action, and to ensure key messages are delivered promptly. Reactive communication generates distrust and the perception that the issues were hidden to the public.

(d) 'Types of activities' – In general, a communication plan needs to include:

— Significant events;

— Licensee performance;
— Development of the regulatory framework;
— Licensing activities;
— Public meetings.

(e) 'Statutory requirements' - Requirements established by legal framework of the States would override other factors. They may be related to provision of information such as emergency preparedness and response.

— **Step 3:** Integrate the applicable factors into the decision-making process.

For Step 3, the decision-making process involves determining appropriate communication tools, as well as which regulatory activities ought to be communicated to interested parties. The appropriate communication tools will depend in large part on the urgency of communicating to stakeholders and the public; consideration ought to be given to using social media tools initially to reach the greatest population in the shortest time. The perceived safety significance will also have a large impact on the appropriate communication tools.

One method to use in determining appropriate communication tools and key messages is to develop a prescribed communication plan for every nuclear installation and regulatory activity that may be of public interest. The communication plan ought to address different communication protocols based on the significance of an event at a nuclear installation. For example, a general emergency at an operating nuclear power plant will necessitate a very detailed communication plan using all tools available, while a less significant event may involve fewer tools, if any.

For Step 3 with respect to consultation with interested parties, the regulatory activities (e.g. siting, licensing amendments, and proposals for development of regulations) involving consultation are generally prescribed, and not amenable to using a graded approach. A graded approach for consulting with interested parties might be used with the amount of effort in reaching out to stakeholders. Typically, public interest will be the predominant factor in determining how much outreach is appropriate.

Considerations on public risks and the use of a graded approach for communication and consultation with interested parties are made in Appendix IX. Practical examples on the use of a graded approach for this regulatory function in different States are presented in Annex VI.

4.7. APPLICATION OF A GRADED APPROACH TO AN INTEGRATED REGULATORY PROGRAMME

The application of a graded approach to the integrated regulatory programme is paramount to ensure a balanced use of resources focusing on safety significant issues.

Typically, under the regulatory programme for a nuclear installation, regulatory bodies need to integrate the efforts of a group of combined functions needed for the regulatory oversight. For instance, for a nuclear installation in the operational stage of its life, the regulatory body may need to apply a graded approach for authorization, review and assessment, inspection, enforcement and communication and consultation with interested parties at the same time. The use of a holistic approach for applying simultaneously several of the regulatory functions ensures focusing resources in the areas of more significant safety impact, as required in GSR Part 1 (Rev. 1) [1].

In addition, regulatory programmes may comprise the oversight of a suite of different types of nuclear installation. The regulatory effort will necessarily be split among all those nuclear installations and consider all the regulatory functions.

The combination of nuclear installations and regulatory functions within the regulatory programme makes the allocation of resources a complex multi-dimensional problem if the focus is to be put on the most safety significant issues.

A graded approach could be used to support the regulatory body on making decisions by answering questions, such as:

- When a number of nuclear installations are considered, which installation ought to be prioritized with regard to the different regulatory functions to be performed? How can resources be allocated to ensure regulatory effectiveness and optimize the regulatory oversight?
- Within a nuclear installation, where ought regulatory attention to be focussed in terms of regulatory functions and activities to ensure and enhance regulatory effectiveness?
- If different regulatory functions compete for the same regulatory resources. which function ought to be prioritized?
- If the same regulatory function competes or overlaps for a number of nuclear installations, which installation ought to be prioritized?

4.7.1. Proposed Methodology

The following steps describe a proposed, high-level methodology in applying a graded approach to the combination of regulatory functions for a suite of nuclear installations.

— **Step 1:** Identify the combination of functions and or the suite of installations that need to be simultaneously addressed under the regulatory programme.

In general, the regulatory body identifies the regulatory functions that most impact the regulatory programme for a given installation or group of installations. The purpose is to consider the functions holistically to optimize the usage of regulatory resources focusing them on the most significant ones from the safety perspective.

— **Step 2:** Determine which factors are applicable to the decision, and how those factors are ranked.

In deciding which factors are applicable, the regulatory body considers both generic and specific factors. The factors identified need to be analysed to establish their relative importance in making the final decision.

In addition to the generic factors described in Section 2, for the application of a graded approach in this context of multiple regulatory functions, all specific factors of the functions are to be considered. In a graded approach, the ranking established in consideration of all factors drives the regulatory attention and allocation of the effort.

Some of the specific factors associated with the functions ought to be especially considered:

(a) ‘Statutory requirements’ – Requirements established by the legal framework of the State will override other factors.

(b) ‘Risk associated with operation of the installation’ – The installations with higher risk may be prioritized over those having lower risks. The regulatory functions for high risk facilities and activities involve more stringent safety verifications. The risk associated with the operation of the installation will depend, among other things, of their design complexity, radioactive inventory and the stage in their lifetime.

(c) ‘Regulatory body resources’ – In considering various functions and installations simultaneously under a regulatory programme, the same set of experts may be involved in completing various concurrent activities. For instance, experts needed for the review and assessment of a licensing submission, may also be needed, as technical experts, for conducting an inspection or being involved in an enforcement action. Similarly, efforts may be needed for the same topic for different installations simultaneously. If the regulatory body lacks the flexibility to obtain additional or external technical service to fill the resource gaps, the competing priorities might have to be resolved using a graded approach.

(d) ‘Urgency for need of a licensing action’ – Regulatory activities that are time sensitive may impact the resource effort associated with the regulatory programme, impacting the availability of resources for one or more functions, or for other facilities.

(e) ‘Licensee performance’ – The performance of the licensee may impact the urgency to increase or decrease regulatory attention in some areas or functions, allowing the shifting of the resources to functions or installations that necessitate more attention. For instance, if there is an urgent need due to statutory obligations, the number of inspections or the depth of the inspections may be reduced if the licensee’s performance is otherwise satisfactory. Similarly, if the performance of the licensee is poor, the regulatory body may need to augment the regulatory oversight through additional licence conditions or increase number of inspections and enforcement actions.

(f) ‘Perceived safety significance’ - It is acknowledged that nuclear power and radiation instil fear in some of the population, so the perception of safety significance is generally greater than the actual safety significance. Communication tools ought to be used to describe clearly and accurately the actual risk or safety significance to the public.

(g) ‘Regulatory body experience’ – As experience is gained by the regulatory body in oversight of installations over time, there may be an opportunity to regularly revise the regulatory programme activities to ensure resources continue to be focused on areas of greatest safety significance. Regulatory body experience needs to also consider domestic as well as international experience.

— **Step 3:** Integrate the applicable factors into the decision-making process.

The regulatory body could determine an appropriate and balanced allocation of resources by considering all the generic and specific factors holistically and performing a global impact assessment to ensure that the usage of resources is optimized.

In implementing the factors into the planning cycle of the regulatory programme, the regulatory body needs to establish a formal documented process.

An effective monitoring process also needs to be established to feed the information back into Step 2 and revise the allocation of resources, as necessary.

APPENDIX I.

COMPLEXITY OF THE NUCLEAR INSTALLATION: APPLICABLE GENERIC FACTORS

IAEA-TECDOC-1740 [8] presents in its Section 3.2 factors that might be considered when determining the complexity of a nuclear installation:

— Design complexity
— Procurement complexity
— Manufacturing and construction complexity
— Operation complexity
— Management complexity

In accordance with the methodology developed in this TECDOC [7], the generic factors are as follows:

> “(1) Design complexity
>
> The classification of the complexity of design is based on the difficulties likely to be encountered in the effective implementation of the design process. This classification reflects the complexity of the design process and not the complexity of the item or its function. It takes into account, for example, cases where a supplier carries out reviews of designs by other organizations prior to production. Other factors, such as safety, seismic and stress analyses, material selection and environmental impact analysis are essential in the evaluation of the complexity of design.
>
> (2) Procurement complexity
>
> The complexity of the procurement activities relates to the number and complexity of the organizations involved and the complexity of the item or service to be procured.
>
> (3) Manufacturing and construction complexity
>
> The complexity of manufacturing and construction activities is based on the processes involved and the degree of difficulty associated with each process in the achievement and verification of quality characteristics. Other aspects such as the number of close tolerances and the number of moving parts is also important in this case.
>
> (4) Operation complexity
>
> The complexity of operation is based on the number and the interrelations of the controls needed for the operational activities, the extent to which radioactive materials are handled, the reliability of the systems and components and their accessibility for maintenance, inspection, test and repair.

(5) Management complexity

The complexity of management can be determined by factors such as the size of the organization, the number of functions involved and the multiplicity of organizational interfaces.”.

APPENDIX II.

GENERIC METHOD FOR DETERMINING RELATIVE IMPORTANCE OF THE FACTORS

One possible way of performing the ranking of the applicable factors would be using a table where relevant safety aspects could be listed, and the applicable factors evaluated with regard to their influence in terms of risk and safety impact on each of the aspects. The following safety aspects, among others, could be considered in this method:

- Safety analysis (both deterministic and probabilistic);
- Regulatory requirements;
- Organizational safety culture, management, practices, human performance;
- Operating experience;
- Preliminary safety review.

Depending on the regulatory function, additional safety aspects may be considered to enhance the ranking criteria.

The quality, completeness, limitations and uncertainties of the safety analysis ought to be considered to ensure that the analysis appropriately represents the issues associated to the factors under consideration.

For the analysis of the factors, it is important to consider involving a multidisciplinary team of experts on nuclear safety from different areas, or a single senior manager/expert, depending on the staff available in the regulatory body. Each member of the team responsible for analysing and ranking the factors would be expected to have a high level of expertise in at least one of the areas to provide a significant input into the ranking process and to be able to deal with the diverse inputs with different measures. The team needs to cover all the disciplines involved in the regulatory decision being addressed and needs to be familiar with the nuclear installation (including its design and operation, and relevant operating experience). INSAG-25 [11] provides more details on integrated decision making.

The use of experts is important as they need to define and assess the objective criteria established to rank the factors. These experts will consider not only the requirements that are applicable to the nuclear installation and their own experience. but also lessons learned at nuclear installations in other States.

Regulatory bodies could also use numerical methods or algorithms to perform the analysis and ranking of factors. In this case, the applicable expert knowledge would be embedded in the algorithm and the input parameters used to run it. However, such methods are not easily available to regulatory bodies and might not be flexible enough to deal with all possible situations. In addition, even when numerical methods are available and valid for the ranking into being considered, a regulatory body may also incorporate expert judgment to the process to get a more comprehensive analysis for the oversight function.

After having established the criteria, ranks could be then attributed to each of the factors, based on the risks and impacts such factors would pose to the safety significance.

A possible approach for this process is giving marks to each of the factors. Both generic and specific factors need to be analysed and ranked. Such an approach might be straightforward when used for simple nuclear installations; however, it might be challenging when applied in situations where regulatory decisions involve complex installations such as nuclear power plants.

Once the factors are ranked in order of safety significance, this information could be used to support the regulatory decision-making processes.

There might be additional aspects that may also need to be taken into account when ranking the factors, such as:

- Statutory requirements – They are established by the legal framework of a State and might overrule the ranking process.
- Time constraints – Some regulatory decisions might take time to be implemented. This is clear in the development of new regulations. However, when an important safety issue emerges (due to an accident, for example), the initial decision might consider using alternative regulatory tools to allow the regulatory body to effectively and timely perform its functions until the new regulations are developed and approved.
- Consultation with stakeholders – Some issues might raise concerns on the stakeholders leading to an increased safety significance of a factor related to the oversight function.

APPENDIX III.

QUANTITATIVE METHOD FOR RANKING SAFETY FACTORS

III.1. RATIONALE SUPPORTING THE RISK RANKINGS OF SAFETY AREAS FOR NUCLEAR POWER PLANTS

This appendix presents an example of a quantitative method for ranking factors that might be used by regulatory bodies when allocating resources for regulatory activities.

To inform the development of the regulatory compliance programme for nuclear power plants, weighting factors are required. The weighting factors provided are one of several considerations used to allocate review and assessment and inspection effort amongst the selected safety areas in the example.

This appendix also provides information on the criteria and methodology used for weighting the safety areas.

Table 2 shows weighting factors assigned to safety areas that might be used by regulatory bodies. The table was developed using the considerations across several risk areas in the 'risk considerations' summarized in Section III.3 of this appendix. The weighting factors were based on a reactor facility, with well-established and well-performing programmes. As such, it does not account for licensee performance which needs to be considered on a facility-by-facility basis.

The rationale for the weighting factors is presented in Section III.2 of this appendix.

TABLE 2. WEIGHTING FACTORS FOR SAFETY AREAS

Safety Areas	Weighting (Percentage)
Management System	10.0
Human Performance Management	10.0
Operating Performance	12.5
Safety Analysis	7.5
Physical Design	10.0
Fitness for Service	7.5
Radiation Protection	10.0
Conventional Health and Safety	2.5
Environmental Protection	5.0
Emergency Management and Fire Protection	7.5
Waste Management	2.5
Security	7.5
Safeguard and Non-Proliferation	5.0
Packaging and Transport	2.5

III.2. RISK RANKING METHODOLOGY

Weighting factors are determined from the risk significance levels assigned for the safety areas. The methodology for arriving at the risk significance levels (RSL) for the safety areas is as follows:

III.2.1. Define the risk significance level criteria.

The risk significance levels for the safety areas for each risk consideration are populated on the following premise:

If the risk considerations are not addressed, will the safety and control measures for a particular safety area be adequate?

- A low RSL is assigned to that safety area under the particular risk area in cases where the safety and control measures will still be adequate even if the risk considerations are not addressed.
- A high RSL is assigned to that safety area under the particular risk area in cases where the safety and control measures will not be adequate if the risk considerations are not addressed.

Based on this rationale, the RSLs are defined in Table 3.

TABLE 3. RISK SIGNIFICANCE LEVEL

Risk Significance Level (RSL)	Impact on Adequacy/Effectiveness of Safety and Control Measures
RSL 0	There is no relation between the risk considerations and the particular safety area.
RSL 1	Not addressing the risk considerations has a negligible impact on the adequacy and/or effectiveness of safety and control measures for the particular safety area.
RSL 2	Not addressing the risk considerations has a moderate impact on the adequacy and/or effectiveness of safety and control measures for the particular safety area.
RSL 3	Not addressing the risk considerations has a medium impact on the adequacy and/or effectiveness of safety and control measures for the particular safety area.
RSL 4	Not addressing the risk considerations has a major/significant impact on the adequacy and/or effectiveness of safety and control measures for the particular safety area.

III.2.2. Determine the Risk Significance Level for each Safety Area

For each RSL assignment, a regulatory body might consider:

- How the safety areas take the risk considerations into account.
- How the risk considerations are implemented/put into place through implementation of the safety and control measures for the safety areas.

Potential results are presented in Table 4 and are used in the weighting factors for the safety areas in Table 2.

The left-hand column of Table 4 lists the safety areas. The top row in Table 4 represents the areas that are considered in this assessment.

The risk consideration criteria are:

- Deterministic consideration criteria
  (a) Impact on Defence-in-depth

(b) Impact on safety margins
(c) Impact on safe operating envelope
(d) Impact on safety system mitigation and levels of impairment

— Probabilistic consideration criteria
  (a) Likelihood of initiating events
  (b) Availability and reliability of mitigating systems
  (c) Core Damage Frequency or Large Release Frequency

— Regulatory requirements criteria
  (a) Prescribed in laws and regulations
  (b) Condition of a licence
  (c) Compliance verification criteria of the licence

— Organizational consideration criteria
  (a) Impact of management programmatic failures
  (b) Impact of management of processes
  (c) Prioritizing safety and safety culture
  (d) Maintenance of human resources

— Other considerations
  (a) Operating experience based on examination of unplanned events
  (b) Periodic safety review

As an example, referring to the probabilistic risk considerations, it is considered that excluding information from the probabilistic safety analysis as input to the area of 'Fitness for service' has a risk significance level of 2 (RSL 2). Fitness for service elements might not be appropriately designed if they do not take insights from probabilistic considerations into account as there might not be an appropriate focus on safety-significant structures, systems and components.

Further information on these risk considerations is provided in Section III.3 of this appendix.

TABLE 4. RATIONALE FOR RISK SIGNIFICANCE LEVELS FOR SAFETY AREAS

Safety Area	Risk Area					Total	Rounded Weighting (%)
	Deterministic	**Probabilistic**	**Regulatory**	**Organizational**	**Other**		
Management system	**2**	**2**	**2**	**3**	**1**	**10**	**10.0**
	Deterministic considerations (including defence–in-depth and deterministic safety requirements, the conduct of design and deterministic safety analysis) are implemented through management system processes and procedures. Deterministic considerations are taken into account in the execution of management system elements and operational decision making. Management system elements might not be appropriately designed if they do not take defence–in-depth and deterministic considerations into account.	Probabilistic considerations (such as the conduct of probabilistic safety analysis) are implemented through management system processes and procedures. Probabilistic considerations are taken into account in the execution of management system elements and operational decision making. Management system elements might not be appropriately designed if they do not take insights from probabilistic considerations into account.	Regulatory requirements are implemented through management system processes and procedures. The requirements are not prescriptive, however. Management system elements might not be acceptable if they do not take regulatory requirements into account.	Organizational considerations (such as knowledge and competence) are essential for the safe conduct of the licensed activity and implemented through management system processes and procedures. Management system elements will likely not be acceptably designed if they do not take organizational considerations into account.	Operational experience and PSR should be taken into account in the continuous improvement of the management system. Note that continuous improvement is built into the management system.		

TABLE 4. RATIONALE FOR RISK SIGNIFICANCE LEVELS FOR SAFETY AREAS (cont.)

Safety Area	Risk Area					Total	Rounded Weighting (%)
	Deterministic	**Probabilistic**	**Regulatory**	**Organizational**	**Other**		
Human performance management	**2** Deterministic considerations (including defence–in-depth and deterministic safety requirements, the conduct of design and deterministic safety analysis) are implemented through elements of human performance, in particular training, personnel certification and staffing levels. Deterministic considerations are taken into account in the design of human performance elements. Human performance elements, such as training, personnel certification and staffing levels might not be appropriately designed if they do not take defence–in-depth and deterministic considerations into account.	**2** Probabilistic considerations (such as the conduct of probabilistic safety analysis) are implemented through elements of human performance, in particular training. Probabilistic considerations are taken into account in the design of human performance elements, specifically training and staffing levels. Human performance elements might not be appropriately designed if they do not take insights from probabilistic considerations into account.	**2** Regulatory requirements are implemented through elements of human performance. The requirements are not prescriptive, however. Human performance elements might not be acceptable if they do not take regulatory requirements into account.	**3** Organizational considerations (such as knowledge and competence) are essential for the safe conduct of the licensed activity and implemented through the human performance elements. Human performance elements will likely not be acceptably designed if they do not take organizational considerations into account.	**1** Operational experience and PSR should be taken into account in the continuous improvement of human performance elements such as training.	**10**	**10.0**

TABLE 4. RATIONALE FOR RISK SIGNIFICANCE LEVELS FOR SAFETY AREAS (cont.)

Safety Area	Risk Area					Total	Rounded Weighting (%)
	Deterministic	**Probabilistic**	**Regulatory**	**Organizational**	**Other**		
Operating performance	**2** Deterministic considerations (including defence–in-depth and deterministic safety requirements, the conduct of design and deterministic safety analysis) are implemented through operating performance elements. Deterministic considerations (including defence–in-depth and deterministic safety requirements) are taken into account in operating performance elements. Operating performance elements, such as procedures, safe operating envelope, outage management, accident management and severe accident management might not be appropriately designed if they do not take defence–in-depth and deterministic considerations into account.	**3** Probabilistic considerations (such as the conduct of probabilistic safety analysis) are implemented through elements of operating performance, in particular procedures, safe operating envelope, outage management, accident management and severe accident management Probabilistic considerations are taken into account in the design of operating performance elements. Operating performance elements will likely not be appropriately designed if they do not take insights from probabilistic considerations into account.	**3** Regulatory requirements are implemented through elements of operating performance. The requirements are not prescriptive, however. Operating performance elements will likely not be acceptable if they do not take regulatory requirements into account.	**3** Organizational considerations (such as knowledge and competence) are essential for the safe conduct of the licensed activity and implemented through the operating performance elements. Operating performance elements will likely not be adequately designed if they do not take organizational considerations into account.	**3** Operational experience and PSR should be is an important aspect of continuous improvement of all operating performance elements.	**14**	**12.5**

TABLE 4. RATIONALE FOR RISK SIGNIFICANCE LEVELS FOR SAFETY AREAS (cont.)

Safety Area	Risk Area					Total	Rounded Weighting (%)
	Deterministic	Probabilistic	Regulatory	Organizational	Other		
Safety analysis	**3**	**2**	**2**	**1**	**1**	**9**	**7.5**
	Deterministic considerations (including defence–in-depth and deterministic safety requirements, the conduct of design and deterministic safety analysis) are implemented through safety analysis elements. Deterministic considerations (including defence–in-depth and deterministic safety requirements) are taken into account in safety analysis elements. Safety analysis will likely not be acceptable if it does not take defence–in-depth and deterministic considerations into account.	Probabilistic considerations (such as the conduct of probabilistic safety analysis) are implemented through safety analysis elements. Probabilistic considerations are taken into account in the design of safety analysis elements. Safety analysis elements might not be appropriately designed if they do not take insights from probabilistic considerations into account.	Regulatory requirements are implemented through elements of safety analysis. The requirements are not prescriptive, however. Safety analysis elements might not be acceptable if they do not take regulatory requirements into account.	Organizational considerations (such as knowledge and competence) are important for the appropriate conduct of safety analysis.	Operational experience and PSR should be taken into account in the continuous improvement and updating of safety analysis.		

TABLE 4. RATIONALE FOR RISK SIGNIFICANCE LEVELS FOR SAFETY AREAS (cont.)

Safety Area	Risk Area					Total	Rounded Weighting (%)
	Deterministic	Probabilistic	Regulatory	Organizational	Other		
Physical design	**3**	**3**	**2**	**2**	**2**	**12**	**10.0**
	Deterministic considerations (including defence–in-depth and deterministic safety requirements, the conduct of design and deterministic safety analysis) are implemented through the physical design. Deterministic considerations (including defence–in-depth and deterministic safety requirements) are taken into account in the physical design. Physical design will likely not be acceptable if it does not take defence–in-depth and deterministic considerations into account.	Probabilistic considerations (such as the conduct of probabilistic safety analysis) are implemented through the physical design. Probabilistic considerations are taken into account in the physical design The physical design will likely not be appropriately designed if they do not take insights from probabilistic considerations into account as vulnerabilities in the plant design might not be identified, and reliability targets for plants components might not be set appropriately.	Regulatory requirements are implemented in the physical design. The requirements are not prescriptive, however. The physical design might not be acceptable if they do not take regulatory requirements into account.	Organizational considerations (such as knowledge and competence) are essential for the appropriate conduct of design activities. The physical design might not be acceptable if they do not take organizational considerations such as having adequate knowledge and competence into account.	Operational experience and PSR needs to be taken into account in the updating of the plant design.		

TABLE 4. RATIONALE FOR RISK SIGNIFICANCE LEVELS FOR SAFETY AREAS (cont.)

Safety Area	Risk Area					Total	Rounded Weighting (%)
	Deterministic	**Probabilistic**	**Regulatory**	**Organizational**	**Other**		
Fitness for service	**2** Deterministic considerations (including defence–in-depth and deterministic safety requirements, the conduct of design and deterministic safety analysis) are maintained through fitness for service elements. Fitness-for-service might not be acceptable if it does not take defence–in-depth and deterministic considerations into account, as there might not the appropriate focus on safety-significant structures, systems and components.	**2** Probabilistic considerations (such as the conduct of probabilistic safety analysis) are implemented through fitness-for-service. Fitness-for-service elements might not be appropriately designed if they do not take insights from probabilistic considerations into account as there might not be an appropriate focus on safety-significant structures, systems and components.	**2** Regulatory requirements are implemented in fitness-for-service. The requirements are not prescriptive, however. Fitness-for-service elements might not be acceptable if they do not take regulatory requirements into account.	**2** Organizational considerations (such as knowledge and competence) are essential for the appropriate conduct of fitness-for-service activities. Fitness-for-service elements might not be acceptable if they do not take organizational considerations such as having adequate knowledge and competence into account.	**1** Operational experience and PSR should be taken into account in the updating of the fitness-for-service elements.	**9**	**7.5**

TABLE 4. RATIONALE FOR RISK SIGNIFICANCE LEVELS FOR SAFETY AREAS (cont.)

Safety Area	Risk Area					Total	Rounded Weighting (%)
	Deterministic	Probabilistic	Regulatory	Organizational	Other		
Radiation protection	**2** Deterministic considerations (including defence–in-depth and deterministic safety requirements such as dose to workers and the public) are taken into account in the elements of the radiation protection programme. Radiation protection might not be acceptable if it does not take defence–in-depth and deterministic considerations into account, as there might not the appropriate focus on meeting ALARA for worker dose.	**1** Probabilistic considerations are taken into account in radiation protection, specifically with regards to estimate dose to the public. Radiation protection elements might not be met if they do not take insights from probabilistic considerations into account as there might not be an appropriate focus on meeting safety goals. However, this aspect is primarily addressed through physical design and safety analysis.	**3** Regulatory requirements are implemented through radiation protection elements. The requirements are prescriptive, however. Radiation protection elements will likely not be acceptable if they do not take regulatory requirements into account.	**2** Organizational considerations (such as knowledge and competence) are important for radiation protection. Radiation protection elements might not be acceptable if they do not take organizational considerations such as having adequate knowledge and competence into account.	**3** Operational experience and PSR is essential as worker dose is one of the key indicators for the effectiveness of the radiation protection elements. It also is an important aspect of continuous improvement of radiation protection elements, in particular addressing ALARA.	**11**	**10.0**

TABLE 4. RATIONALE FOR RISK SIGNIFICANCE LEVELS FOR SAFETY AREAS (cont.)

Safety Area	Risk Area					Total	Rounded Weighting (%)
	Deterministic	**Probabilistic**	**Regulatory**	**Organizational**	**Other**		
Conventional health and safety	**0** There is no relation between deterministic considerations and conventional health and safety.	**0** There is no relation between probabilistic considerations and conventional health and safety.	**1** Regulatory requirements are implemented through conventional health and safety elements. The regulations are both at the federal and provincial levels (the regulatory body has a secondary role with regards to conventional health and safety). Conventional health and safety regulations are prescriptive. Conventional health and safety elements will likely not be acceptable if they do not take regulatory requirements into account.	**2** Organizational considerations (such as knowledge and competence) are important for conventional health and safety. Conventional health and safety elements might not be acceptable if they do not take organizational considerations such as having adequate knowledge and competence into account.	**1** Operational experience and PSR should be taken into account in the continuous improvement of conventional health and safety elements.	**4**	**2.5**

TABLE 4. RATIONALE FOR RISK SIGNIFICANCE LEVELS FOR SAFETY AREAS (cont.)

Safety Area	Risk Area					Total	Rounded Weighting (%)
	Deterministic	**Probabilistic**	**Regulatory**	**Organizational**	**Other**		
Environmental protection	**1** Deterministic considerations (including defence–in-depth and deterministic safety requirements) are taken into account in the elements of the environmental protection programme. The facility should be designed and operated so that releases to the environment are minimized. Environmental protection might not be acceptable if it does not take defence–in-depth and deterministic considerations into account, as there might not the appropriate focus on minimizing releases to the environment.	**0** This aspect is primarily addressed through physical design and safety analysis.	**2** Regulatory requirements are implemented through environmental protection elements. The regulations are both at the federal and provincial levels. There is a mixture of non-prescriptive and prescriptive regulations. Environmental protection elements will likely not be acceptable if they do not take regulatory requirements into account.	**1** Organizational considerations (such as knowledge and competence) are important for environmental protection. Environmental protection elements might not be acceptable if they do not take organizational considerations such as having adequate knowledge and competence into account.	**3** Operational experience and PSR is essential as environmental releases are key indicators for the effectiveness of the radiation protection elements It also is an important aspect of continuous improvement of environmental protection elements, in particular minimizing releases to the environment.	**7**	**5.0**

TABLE 4. RATIONALE FOR RISK SIGNIFICANCE LEVELS FOR SAFETY AREAS (cont.)

Safety Area	Risk Area					Total	Rounded Weighting (%)
	Deterministic	**Probabilistic**	**Regulatory**	**Organizational**	**Other**		
Emergency management and fire protection	**1** Deterministic considerations (including defence–in-depth and deterministic safety requirements) are taken into account in the elements of the emergency management and fire protection programme. Emergency management is a key element of defence-in-depth. Emergency management and fire protection might not be acceptable if it does not take defence–in-depth and deterministic considerations into account.	**2** Probabilistic considerations are taken into account in emergency management and fire protection, specifically with regards to informing emergency management. Emergency management and fire protection elements might not be met if they do not take insights from probabilistic considerations into account.	**2** Regulatory requirements are implemented through emergency management and fire protection elements. The regulations are both at the federal and provincial levels. There is a mixture of non-prescriptive and prescriptive regulations. Emergency management and fire protection elements might not be acceptable if they do not take regulatory requirements into account.	**2** Organizational considerations (such as knowledge and competence) are important for emergency management and fire protection elements. Emergency management and fire protection elements might not be acceptable if they do not take organizational considerations such as having adequate knowledge and competence into account.	**2** Operational experience and PSR should be taken into account in the continuous improvement of emergency management and fire protection elements.	**9**	**7.5**

TABLE 4. RATIONALE FOR RISK SIGNIFICANCE LEVELS FOR SAFETY AREAS (cont.)

Safety Area	Risk Area					Total	Rounded Weighting (%)
	Deterministic	**Probabilistic**	**Regulatory**	**Organizational**	**Other**		
Waste management	**1** Deterministic considerations, in particular, defence–in-depth, is taken into account in the elements of the waste management programme. Waste management might not be acceptable if it does not take considerations such as having multiple barriers in place into account.	**0** There is no relation between probabilistic considerations and waste management.	**1** Regulatory requirements are implemented in waste management. The requirements are not prescriptive, however. Waste management elements might not be acceptable if they do not take regulatory requirements into account.	**1** Organizational considerations (such as knowledge and competence) are important for waste management. Waste management elements might not be acceptable if they do not take organizational considerations such as having adequate knowledge and competence into account.	**1** Operational experience and PSR should be taken into account in the continuous improvement of waste management practices.	**4**	**2.5**

TABLE 4. RATIONALE FOR RISK SIGNIFICANCE LEVELS FOR SAFETY AREAS (cont.)

Safety Area	Risk Area					Total	Rounded Weighting (%)
	Deterministic	**Probabilistic**	**Regulatory**	**Organizational**	**Other**		
Security	**1**	**0**	**3**	**2**	**2**	**8**	**7.5**
	Deterministic considerations, in particular, defence–in-depth, is taken into account in the elements of the security programme. Security might not be acceptable if it does not take considerations such as having multiple barriers in place into account.	There is no relation between probabilistic considerations and security.	Regulatory requirements are implemented through security elements. The requirements are prescriptive, however. Security elements will very likely not be acceptable if they do not take regulatory requirements into account.	Organizational considerations (such as knowledge and competence) are important for security elements. Security elements might not be acceptable if they do not take organizational considerations such as having adequate knowledge and competence into account.	Operational experience and PSR should be taken into account in the continuous improvement of security practices.		

TABLE 4. RATIONALE FOR RISK SIGNIFICANCE LEVELS FOR SAFETY AREAS (cont.)

Safety Area	Risk Area					Total	Rounded Weighting (%)
	Deterministic	**Probabilistic**	**Regulatory**	**Organizational**	**Other**		
Safeguards and non-proliferation	**0** There is no relation between deterministic considerations and safeguards and non-proliferation.	**0** There is no relation between probabilistic considerations and safeguards and non-proliferation.	**1** Regulatory requirements are implemented through safeguards and non-proliferation elements. The requirements are prescriptive, however. Safeguards and non-proliferation elements will likely not be acceptable if they do not take regulatory requirements into account.	**0** There is no relation between organizational considerations and safeguards and non-proliferation.	**3** National and international operational experience is very important in the continuous improvement of safeguards practices.	**4**	**5.0**

TABLE 4. RATIONALE FOR RISK SIGNIFICANCE LEVELS FOR SAFETY AREAS (cont.)

Safety Area	Risk Area					Total	Rounded Weighting (%)
	Deterministic	**Probabilistic**	**Regulatory**	**Organizational**	**Other**		
Packaging and transport	**0** There is no relation between deterministic considerations and packaging and transport.	**0** There is no relation between probabilistic considerations and packaging and transport.	**1** Regulatory requirements are implemented through packaging and transport elements. The requirements are prescriptive, however. Packaging and transport elements will likely not be acceptable if they do not take regulatory requirements into account.	**1** Organizational considerations (such as knowledge and competence) are important for packaging and transport elements. Packaging and transport elements might not be acceptable if they do not take organizational considerations such as having adequate knowledge and competence into account.	**1** Operational experience is important in the continuous improvement of packaging and transport practices.	**3**	**2.5**
Total	**20**	**17**	**27**	**25**	**25**	**114**	**100**

III.3. RISK CONSIDERATIONS USED IN THE DEVELOPMENT OF WEIGHTING FACTORS FOR THE SAFETY AREAS

III.3.1 Regulatory Requirements

A baseline compliance plan and reactive compliance plan focus on collecting the right data by verifying appropriate compliance verification areas using the most relevant, effective and efficient compliance verification activity.

Using regulatory requirements in a risk-informed approach allows a regulatory body to analyse, identify, prioritize and select compliance verification areas and the appropriate compliance verification activities by applying the following key elements:

- Compliance verification activities are appropriate to the regulatory programme and technically valid. This means they are tied to regulatory requirements, the regulations, operating licenses, licence condition compliance criteria and the licensing basis.
- A high-level assessment of licensee programmes is conducted during the licensing process. The purpose is to verify that the basis of the programme is well understood by the licensee and that the programme is based on appropriate standards. In addition to this high-level assessment, an in-depth compliance verification of licensee programmes may be conducted during the licensing period.
- Not all regulatory requirements are weighted equally. Non-compliances to certain regulatory requirements may be of negligible risk whereas non-compliances to other regulatory requirements may be of higher risk.
- When it is possible to pre-determine the risk of non-compliances in accordance with the definitions in the rating methodology, priority should be given to verify the most risk significant areas.
- Regulatory requirements are verified through the conduct of compliance verification activities. The most relevant, effective and efficient compliance verification activity should be selected based on the data to be collected. The benefits may justify the cost through focusing human and financial resources where they can add more value and by demonstrating tangible results, as well as minimizing administrative burden on licensees.

III.3.2 Deterministic Considerations

Nuclear power plant design information and the supporting safety analysis can be used to identify the more safety significant structures, systems and components and associated parameters, initiating events or important operational activities and administrative controls. This information can then be used to risk inform the baseline compliance plan and reactive compliance plan by focusing regulatory attention on the more safety significant design or performance expectations.

(a) Defence-in-depth

Defence-in-depth consists in a hierarchical deployment of different levels of equipment and procedures in order to maintain the effectiveness of physical barriers placed between radioactive materials and workers, the public or the environment, in normal operation, anticipated operational occurrences and, for some barriers, in accidents at the nuclear power plant.

It is applied to all organizational, behavioural and design-related safety and security activities to ensure that they are subject to layers of overlapping provisions, so that if a failure should occur, it would be compensated for or corrected without causing harm to workers, the public or the environment. This concept is applied throughout the design and operation of a reactor facility to provide a series of levels of defence aimed at preventing accidents and to ensure appropriate protection in the event that prevention fails.

(b) Deterministic Safety Analysis

The deterministic safety analysis confirms that the design is capable of meeting safety requirements, that it reflects effective defence-in-depth, and that the plant design and operation are acceptably robust. Deterministic safety analysis methods can be applied to a wide range of plant operating modes and events, including normal operation and abnormal operation resulting from equipment failures, operator errors and challenges arising from initiating events. The results can be used to better understand which initiating events are of more concern, the resulting plant behaviour and challenges to the plant's physical barriers and plant system performance. This information can then be used to focus compliance verification activities.

Using deterministic considerations in a risk-informed approach allows the regulatory body to analyse, identify, prioritize and select compliance verification activities by considering the following key areas:

— The use of an engineered physical barriers versus administrative barriers (e.g. programme, process, procedure) to protect against hazards.
— The engineered barrier is more robust and therefore may require less regulatory attention. An engineered physical barrier is preferable to an administrative barrier.
— Safety margins available to prevent risks to safe operation.
— Level of independence among the safety provisions for the various defence-in- depth levels.
— Potential for common cause and common mode failures.
— The need for greater attention to ensure reinforcement of prevention provisions.
— The importance of assessments on the impact of human and organizational factors on defence-in-depth.
— Provisions (emergency arrangements) for long-term and multi-unit nuclear accidents.
— Safety limits for reactor protection and control.
— Safety limits for engineered safety systems.
— Operational limits and reference settings for the control systems.
— Procedural constraints for operational control of processes.
— Identification of the allowable operating configurations.
— Physical security.

III.3.3 Probabilistic Considerations

Probabilistic Safety Assessment (PSA) is a widely accepted method for the estimation of nuclear reactor risk by using best estimated values/parameters to determine what can go wrong, how likely is it, and what are its consequences, and is intended to complement deterministic considerations by providing the likelihood and consequences of undesired outcomes/results (risk).

PSA provides insights into the strengths and weaknesses of the design and operation of a nuclear power plant. The results of plant specific PSA are used to support the licensees' decision-making process including licensing, operation and plant modifications.

Using probabilistic considerations in the risk-informed approach allows the regulatory body to analyse, identify, prioritize and select compliance verification activities by considering the following key areas:

— Dominant initiating events: internal hazards, and external hazards (both natural and man-made hazards).
— Structures, systems, components, programmes, and human actions whose failure have the greatest probability of leading to an event or accident.
— Structures, systems, components, programmes, and human actions whose failure have the greatest increase on reactor core damage frequency (level 1 PSA).
— Structures, systems, components, programmes, and human actions whose failure have the greatest probability of radioactive releases to the environment (level 2 PSA).

III.3.4 Organizational Considerations

Safety culture is the assembly of characteristics and attitudes in organizations and individuals which establishes, as an overriding priority, nuclear power plant safety issues receive the attention warranted by their significance. It is therefore essential that all duties important to safety be carried out correctly, with alertness, due thought and full knowledge, sound judgement and proper sense of accountability. Such aspects are generally intangible but nevertheless produce tangible results.

Organizational considerations include areas such as management and leadership, organization, human factors, human performance, and processes and practices.

Using organizational considerations in a risk-informed approach allows the regulatory body to analyse, identify, prioritize and select compliance verification areas and the appropriate compliance verification activities by applying the following key elements:

— Programmes, processes and procedures whose failure may cause unreasonable risk to the health and safety of persons and the environment;
— Individual awareness;
— Knowledge and competence;
— Commitment;
— Motivation;
— Supervision;
— Responsibilities.

III.3.5 Licensee Performance History

The conduct of both baseline and reactive compliance verification activities results in the collection of data such as observations, facts, findings and safety performance indicators. The data is integrated and analysed, and if the results indicate a decrease in licensee performance, increased regulatory scrutiny may be required.

Using licensee performance history in a risk informed approach allows the regulatory body to analyse, identify, prioritize and select compliance verification areas and the appropriate compliance verification activities by considering the following key elements:

— What is the safety significance of the data collected?
— What is the risk associated with not meeting the regulatory requirement(s)?
— What is the licensee’s overall performance in the area?

- What is the operational experience and lessons learned from similar issues at other nuclear power plants?
- What is the licensee's response to discovery issues?
- Is the licensee delivering on its commitments?

III.3.6 Other Risk Considerations

III.3.6.1 Operating Experience

A baseline compliance plan and reactive compliance plan include the examination of unplanned events and the conduct of event related compliance verification activities.

Using operating experience in a risk-informed approach allows the regulatory body to analyse, identify, prioritize and select compliance verification areas and the appropriate compliance verification activities by considering the following key elements:

All unplanned event reports received by the regulatory body are analysed. The results of event examinations are considered in order to determine and prioritize any follow-up compliance verification activities and compliance verification areas. These may occur at the nuclear power plant where the event occurred or at other nuclear power plants.

International emergent situations that may impact nuclear power plants are considered in order to determine and prioritize compliance verification areas. Examples include a Fukushima type event, and counterfeit, fraudulent and suspect items.

III.3.6.2 Periodic Safety Review

A Periodic Safety Review (PSR) is a systematic safety reassessment that assesses the cumulative effects of nuclear power plant ageing and modifications, operating experience, technical developments and siting aspects. It includes an assessment of plant design and operation against applicable current safety standards and operating practices, and has the objective of ensuring a high level of safety for operating nuclear power plants.

Using PSR in a risk-informed approach allows the regulatory body to analyse, identify, prioritize and select compliance verification activities by considering the following key areas:

- The inputs to and outputs of safety factors;
- Structures, systems and components that are in place to assure safety until the next PSR or end of planned operation;
- Extent to which the nuclear power plant conforms to codes, standards and operating practices;
- Extent to which the nuclear power plant conforms to the licensing basis;
- Lifetime limiting features;
- Implementation of identified reasonable and practicable safety improvements.

III.3.6.3 Engineering/Technical Judgement

Engineering/technical judgement is the making of independent, objective and informed decisions, especially in areas where there is a lack of standards. Engineering/technical judgement complements a risk-informed approach in determining both the baseline compliance plan and the reactive compliance plan and is defined as the application of mathematics and scientific, economic, social, and practical knowledge in order to regulate.

APPENDIX IV.

REGULATORY APPROACHES: PRESCRIPTIVE AND PERFORMANCE BASED

A combination of prescriptive and performance-based regulatory approaches can be used to regulate depending on the types of regulatory activities. The type of regulatory approach chosen by the regulatory body has a significant impact on how a graded approach is applied to the regulatory functions.

The principles of these two approaches are explained below:

IV.1. PRESCRIPTIVE APPROACHES TO REGULATION

Prescriptive approaches define how activities are to be undertaken (e.g. techniques or materials to use, what qualifications are to be held, where the function may be performed). This approach clearly emphasizes a known degree of risk mitigation over innovation or cost management.

This type of approach is typically chosen to ensure a measure of regulatory certainty or when there is consensus that a specific mitigation measure is the appropriate way to address a risk. Prescriptive tools are better suited where there is a large number of applicants and licensees, where the regulated activity is less complex, or both. From a graded approach perspective, the regulatory body may choose to provide more detailed requirements (in regulations and codes and standards), or where applicants and licensees simply need to know which rules to meet. The advantages and disadvantages of a prescriptive approach are listed in Table 5.

Prescriptive approaches are also used in areas such as, for example, technical codes and standards where research and development has shown that a specific method meeting specific quality standards is necessary to ensure safety. An example of this is a welding standard that defines the weld-filler material to be used, the number of weld passes required per thickness of metal to be joined and the acceptance criteria for post-weld quality checks.

TABLE 5. ADVANTAGES AND DISADVANTAGES OF PRESCRIPTIVE APPROACHES

Advantages	Disadvantages
• Minimal interpretation of the requirement is needed • Certainty: relatively straightforward to meet and results in predictable and consistent outcomes • Once the rule is specified by the regulatory body, quality assurance is used by the licensee to confirm the requirements are met. • Interactions with the regulatory body are minimal – limited to addressing variances and explaining non-compliances • Compliance activities by the regulatory body are straightforward to plan and execute.	• Reduction in ability to innovate. Only accepted methods are allowed. • Prescriptive rules are difficult to change (e.g. regulations might need to be amended) • Variations from the prescriptive rule typically require regulatory approval and evidence to support the variation is safe under the specific conditions. • Rule cannot be applied in a graded approach way. Assumes the worst risk case.

Applying a graded approach in a prescriptive regulatory framework is less flexible. For that reason, consideration to risk and safety significance need to be taken at the time of the development of the framework.

IV.2. PERFORMANCE-BASED APPROACHES TO REGULATION

Performance-based regulation puts more emphasis on specifying a performance standard for the desired outcome and does not deliberately constrain how compliance is to be achieved.

This type of approach is typically chosen to permit a measure of flexibility as long as the ultimate outcome is addressed. In performance-based approaches, safety principles are embedded in higher level requirements. The advantages and disadvantages of a performance-based approach are listed in Table 6.

An illustration of performance-based requirement might be: 'The design shall minimize the spread of contamination from areas of high contamination to areas of low contamination'.

This hypothetical performance-based requirement, as written, would be intentionally worded to underscore more specific requirements such as the need to maintain areas of higher contamination at the plant at a negative pressure differential (partial vacuum) with respect to areas of lower contamination and other accessible areas.

Another example of a performance-based requirement is an environmental release limit that is not to be exceeded in order to ensure no adverse environmental or health effects.

TABLE 6. ADVANTAGES AND DISADVANTAGES OF PERFORMANCE-BASED APPROACHES

Advantages	Disadvantages
• There are many ways to address the requirement (flexible to the user's needs). • Because they are more principle-based, they resist the test of time and might not require change as technologies and methodologies evolve. • Performance-based goals are straightforward to understand. • Can be interpreted in a risk-informed manner.	• The proponent needs to have the skills to interpret the requirement for their specific case. • May involve discussions with the regulatory body in advance to confirm an understanding of the requirement and to develop suitable compliance criteria. • Determining compliance with the requirement might not be simple, particularly if a performance-based requirement is a regulatory limit (licensees are expected to remain well below the limit in practice). • The proponent needs to provide suitable scientific and technical information to support their approach to compliance (may involve significant R&D).

In a performance-based regulatory framework, the regulatory body staff have flexibility to apply a graded approach to most regulatory functions. This ought to be done, however, using a very well documented process, developed on knowledgeable and experienced expert judgement.

IV.3. COMBINING PRESCRIPTIVE AND PERFORMANCE BASED APPROACHES: ACHIEVING A PRACTICAL BALANCE

In most cases, a mix of the two can be selected to balance between flexibility and regulatory certainty. Achieving a practical balance of approaches is a complex undertaking and this balance can change with time depending on factors such as:

— Changes to legislation;

- Maturity and composition of the industrial sector (e.g. new entrants generally need more guidance than highly mature companies);
- Compliance history of licensees;
- Domestic and foreign operating experience from good practices or challenging events;
- Inputs from scientific and engineering research;
- How much technological change occurs in that industrial sector to warrant the need for flexibility in regulation.

APPENDIX V.

GENERIC CASES OF APPLICATION OF A GRADED APPROACH TO THE AUTHORIZATION FUNCTION

The following subsections describe possible applications of a graded approach that may be considered in different areas of authorization of nuclear installations. Practical examples on the use of a graded approach to authorization are presented in Annex II.

V.I. AUTHORIZATION PROCESS APPLIED TO THE LIFETIME OF A NUCLEAR INSTALLATION

The licensing process need to cover all stages of the lifetime of a nuclear installation. Depending on national legislation, a typical authorization/licensing process will codify the following stages described in SSG-12 [13], as also shown in Fig. 3:

(a) Siting and site evaluation;
(b) Design;
(c) Construction;
(d) Commissioning;
(e) Operation;
(f) Decommissioning;
(g) Release from regulatory control.

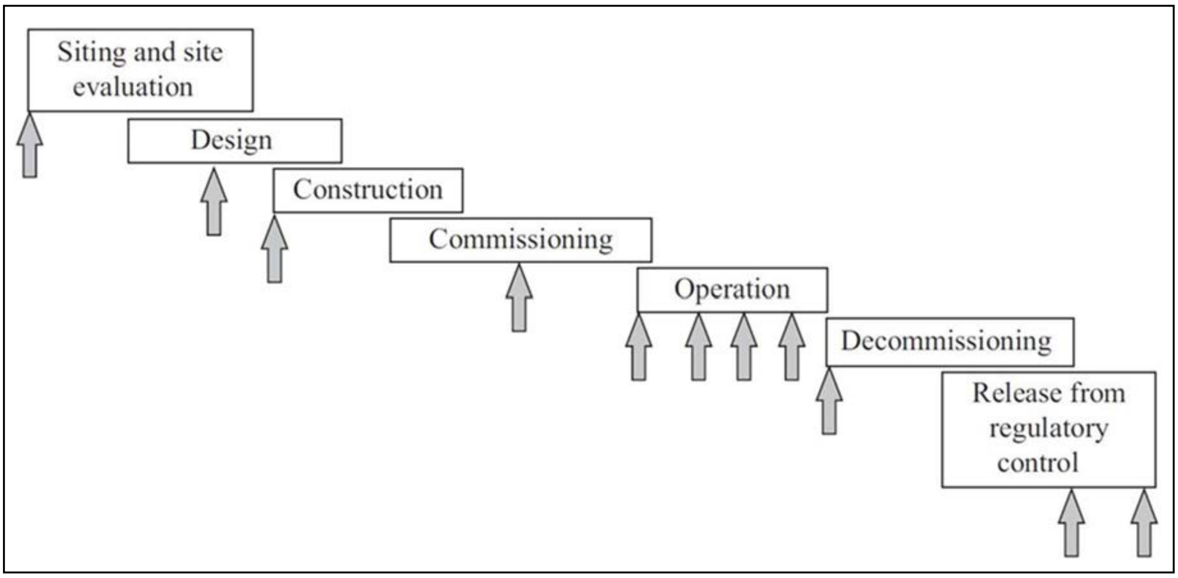

FIG. 3. Stages in the lifetime of a nuclear installation; the arrows indicate where hold points may be imposed (from IAEA SSG-12 [13]*)*

The authorization/licensing process during lifetime stages of a nuclear installation may vary depending upon the associated risk of the installation during each stage. For example, some licensing stages may be combined, or some stages may be skipped or may be optional.

V.2 LEVEL OF APPROVAL OF AUTHORIZATIONS

The level of approval of authorizations within the regulatory body at each stage or combination of stages ought to be clearly defined to avoid any ambiguity; this level of approval may depend upon the levels of risk or the nature of the facility or activity.

The factors to be considered for a graded approach in the level of approval may depend upon number of licenses to be issued or renewed. In some States, the same level for authorization is utilized as for the initial licences. However, in other States, a graded approach is applied for renewal, revalidation of licenses and extension in beyond design if no significant changes in the licensing basis are observed. For example, in case of significant changes, approval may be exercised by the initial approval level, while in case of low significant changes, approval may be delegated to lower management levels of the organization.

(a) Approval of design modifications

Sometimes licensees need to make changes in the design of the structures, systems and components (SSCs) of nuclear installations during manufacturing, construction, commissioning after issuance of the construction licence. In addition, during operation of the installation, licensees may need to make changes in the design of plant systems depending upon the new developments in design requirements, research and development, experience feedback from the reference facilities, changes in the design basis documents. These design modifications may be categorized as safety related or non-safety related. In applying a graded approach, the higher safety significance of the change the higher level of management would be involved in the approval process. Reciprocally, the approval of lower safety relevance changes may be delegated to lower management levels of the organization. In some cases of low level of safety significance or non-safety related design modifications the regulatory body may waive the need for regulatory authorization.

(b) Amendments

In some States the level of approval of licence amendments is delegated to lower management levels of the organization while in some other States, the same level as for initial licence is utilized.

(c) Authorization for re-start following outages

In some States, the authorization to re-start a nuclear power plant is required after plant shutdown for routine refuelling outage or some abnormal shutdown. In those cases, the upper management of the regulatory body grants the authorization in case of routine refuelling outage while, in case of abnormal outage, the level of authority may depend upon the circumstances.

(d) Authorization of operating personnel

Typically, authorizations of the operating personnel of nuclear installations are issued after qualification tests to ensure safe operation. These licenses are normally renewed on a periodic basis after re-qualification. Depending upon the number of licenses to be issued initially and subsequent periodic renewals, a graded approach can also be applied in the level of approval required within the regulatory body. For instance, the initial licence may be awarded by higher levels of management in the organization, while the periodic renewals may be delegated to lower management levels of the organization.

(e) Approval of documentation requirements for authorizations (licensing basis)

At the time of the initial licence, licensees are required to submit different documents such as the Site Evaluation Report (SER), Preliminary Safety Analysis Report (PSAR), Final Safety Analysis Report (FSAR), Emergency Preparedness Plan (EPP), Quality Assurance Programme (QAP), Management System Manual (MSM), Radiation Protection Programme (RPP), Radioactive Waste Management Programme (RWMP). These documents constitute the licensing basis.

A graded approach may be used for the level of authority for approval of the licensing basis documents. For instance, approval of the PSAR/FSAR may be done by the highest level of management of the organization, while approval of other documents such as the EPP, QAP, RPP, RWMP may be delegated to lower management levels of the organization.

(f) Authorization for changes in the licensing basis

At the time of issuance of initial licence the regulatory body will have approved the licensing basis, but during lifetime of the installation, licensees may need to make certain changes to these documents due to experience feedback, changes in the regulatory requirements or in the reference applicable standards and design modifications. Therefore, authorization of these changes is necessary before implementation as per regulatory requirements. Approvals by the regulatory body for changes in these approved documents may depend upon the safety significance of the changes to be made. However, the level of approval may remain the same as for initial approval of these documents.

Licensees may also be required to submit the relevant pages of FSAR revised due to design modifications in safety as well non-safety related SSCs for approval and incorporation in FSAR.

(g) Authorization of activities outside of the licence

These activities may be categorized as of high safety significance, low safety significance or non-safety related. To apply a graded approach in approval of these activities, the activities of high safety significance may be approved by highest level of management in the regulatory organization. Activities of low safety significance may be delegated to lower management levels of the organization.

(h) Authorization for waiver/extension of licence conditions or technical specification requirements or regulatory requirements

During the lifetime of a nuclear installation, the licensee may need to obtain waiver to regulatory requirements (regulations), licence conditions or other applicable requirements such technical specifications depending upon the situations. Normally different levels of approvals are utilized to complete such processes.

For example, when applying a graded approach, the waiver in regulations could be approved by top management; a waiver or extension in licence conditions could be approved by top management, while a waiver in technical specifications could be granted by senior management.

APPENDIX VI.

GENERIC CASES OF APPLICATION OF A GRADED APPROACH TO THE REVIEW AND ASSESSMENT FUNCTION

This appendix describes generic cases of a graded approach that may be considered in different areas of review and assessment of nuclear installations. Further information on the application of a graded approach for review and assessment, including topics to be considered, can be found in GSR Part 4 (Rev.1) [14]. Practical examples on the use of a graded approach to this core regulatory function are presented in Annex III.

(a) Level of detail of information in the licensing applications

In developing regulations and guides, the regulatory body ought to apply a graded approach to determine the adequacy of scope, level of detail of information and safety assessments to be included in the application for different types of installations. These ought to depend on the risks associated to the nuclear installation as well as its complexity. The level of detail and complexity of the required information will necessarily have an impact on the review and assessment function.

For instance, information typically required for applications for nuclear power plants, such as steam and power conversion system, human factor engineering, severe accident analysis and PSA reports, might not be required to be included in the application for research reactors and nuclear fuel cycle facilities. Conversely, the information on reactor utilization and research experiments required for research reactors is not needed for nuclear power plants.

A graded approach may also be applied in the scope and detail of information within the same type of installation, such as research reactors, depending upon their size, power and complexity. The regulatory body ought to provide guidance on the level of detail of the information submitted in support of the submission by the licensees, which ought to be commensurate with the level of risk of the activity that needs to be authorized.

To complete the review and assessment process effectively before the issuance of the authorization, a well-defined review plan needs to be developed as a first step.

(b) Review plan

The review plan may consider review schedule, resources estimates for each review, review of responses to additional information requests, review meetings for decisions on unresolved issues, steps for approval of documents. These factors of the review plan may vary from nuclear installation to nuclear installation depending upon their associated risks. The review plan ought to consider factors such as maturity of the design, type of nuclear installation and the complexity of the design.

The time to be allotted in the review plan of licensee submissions will consequently depend upon the type as well as radiation risk associated with the nuclear installation, and the scope and information detail of the submissions. In some States' legal frameworks, the allowed time for the regulatory body to make a decision is prescribed, which imposes a constraint on the review plan.

In estimating the review plan timeline, use of experts, and overall effort, a graded approach may also be applied by giving credit to mature designs, proven technology with operating experience, operational performance, or to the review of the same design done previously by the regulatory body from a different country.

(c) Considerations for expertise resource needs

(1) Number of experts and level of expertise of the reviewers

The level of complexity of the installation is an important contributor to the number of specific experts needed, and their level of experience, for an effective review and assessment for a given nuclear installation.

(2) Size of the review team

The size of review team also depends upon the scope, detail of information and safety assessments included in the safety case of the nuclear installation. For example, in general more personnel are involved in the review of nuclear power plants as compared to research reactors due to the larger magnitude of the scope, detail of information and safety assessments included in the SAR of these two types of nuclear installation. Furthermore, number of experts for review of regulatory submissions also varies with the size and power within the same types of nuclear installation, such as research reactors.

(d) Review of submission of design modifications

Design modifications are divided into two categories such as safety related and non-safety related. A graded approach is applied in such a way that the safety related design modifications are reviewed by the regulatory body before implementation while the non-safety design modifications might not be required to be submitted to the regulatory body, when implemented prior to operation of the installation.[3]

Credit in review of design modifications is also given to the already approved cases for the same installation or the reference facility. In some States, a graded approach is applied in such a way that design modifications are not submitted for approval, but the licensee carries out these modifications and the regulatory body verifies their implementation.

(e) Renewal or extension of the operating licence (OL) beyond design life

In many States with nuclear power programmes, periodic safety review (PSR), as described in SSG-25 [18], forms part of the regulatory system. However, some characteristics may vary depending on the national regulations. These include the scope and content of the PSR, the manner of its implementation and the regulatory activities.

PSR is therefore used for regulating the safety of plant operation in the long term and for dealing with requests for authorization to continue plant operation beyond an established licensed term or for a further period established in the original design. “A recent PSR can provide reassurance that there continues to be a valid licensing basis taking account of, for example, plant ageing and current safety standards and operating practices”, as described in para. 2.3 of SSG-25 [18].

[3] In some States, any modification after operation may be subject to a safety review, if there is more than a minimal increase in the frequency of occurrence of an accident previously evaluated, more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety, more than a minimal increase in the consequences of an accident previously evaluated, This might create a possibility for an accident of a different type than any previously evaluated , then a license amendment might be required, which requires regulatory approval.

The length of the review process will depend on the availability and retrievability of relevant information and the organizational structure of the operating organization. To provide a timely input, the PSR ought to be completed within three years, and normally less for subsequent PSRs, as described in para. 2.7 of SSG-25 [18].

A graded approach may be applied in selection of the PSR safety factors for different nuclear installations such as for research reactors some factors might not be considered as compared to nuclear power plants.

A practical example is provided in Annex III on the use of a graded approach for PSR of different types of nuclear installation.

APPENDIX VII.

CONSIDERATIONS OF A GRADED APPROACH APPLIED ON INSPECTION PROGRAMME

In developing an inspection programme for nuclear installations, the regulatory body ought to determine what to inspect, how to inspect, how often to inspect, and how much effort is appropriate to provide reasonable assurance that the installation is being operated safely.

The baseline inspection programme for any nuclear installation is defined to be the minimum inspection effort necessary to ensure the installation is being operated safely in a manner that protects the public health and safety. Using a graded approach, inspectors need to focus inspection efforts on structures, systems, and components (SSCs) that have the greatest safety significance, or more specifically, those that are classified as safety-related for nuclear power plants, or items relied on for safety for fuel cycle facilities. In addition, inspections need to focus on organizational factors which may be considered precursors of declining safety culture.

Because inspection resources may be limited, it is usually impossible to inspect everything that is safety significant. Therefore, the inspection programme ought to be a sampling programme, where sufficient samples are selected within each inspectable area to provide assurance that licensee performance in that area is adequate to ensure protection of the public health and safety. The inspection focus will vary based on the stage of the lifetime of the plant.

This appendix describes generic cases of application of a graded approach that may be considered in the development of the inspection programmes of nuclear installations. In order to describe the application of a graded approach for regulatory inspections in a clear and logical way, this appendix will focus on nuclear power plants. Analogous considerations may be applicable to research reactors and nuclear fuel cycle facilities.

Practical examples on the use of a graded approach to this core regulatory function are presented in Annex IV.

VII.1 BASELINE INSPECTIONS

— **Step 1:** Identifying the decision associated with the inspection programme

(a) Identifying activities, structures, systems, and components (SSCs) that are important to safety.

Safety-related SSCs perform functions involved in attaining and maintaining safe shutdown conditions during normal or accident conditions, mitigating the consequences of an accident, or preventing the occurrence of an accident. Those SSCs ought to be described in the licence application and the Safety Analysis Report (SAR). Most nuclear power plants have probabilistic safety assessments (PSAs) that provide information for determining the risk importance for each activity and SSC that might impact core damage frequency (CDF) and large release frequency (LRF). Risk depends on three things: what can go wrong, how likely is it, and what are the consequences? The greater the contribution to risk (i.e. the largest contribution to CDF or LRF), the greater the need to ensure that SSC can perform its design safety function under all conditions. The various importance measures resulting from the PSA provide a perspective on which SSCs contribute most to the current estimate of risk (Fussell-Vesseley importance, risk reduction worth) and which contribute most to maintaining the level of safety (risk achievement worth) [19].

(b) Determining what to focus attention on while conducting each specific inspection

(1) Construction stage

Inspectors ought to ensure that the safety related SSCs are procured, constructed, installed, and tested under a rigid quality assurance programme to ensure they are capable of meeting their design safety functions. Licensees implement the operational programmes (e.g. fire protection, security, radiation protection, emergency preparedness, in-service testing, environmental qualification) necessary to support each milestone of plant preparation for operation before the programme is required by regulations. The regulatory body needs to inspect the development of those operational programmes to ensure adequacy. Because of the importance of the Quality Assurance (QA) programme in the overall design, construction, and operation of the plant, this programme needs to be inspected for adequacy.

During construction of a reactor plant, the level of risk is significantly lower than for an operating plant until fuel is loaded into the reactor vessel. Figure 4 is an example of suggested inspection focus areas during the construction stage.

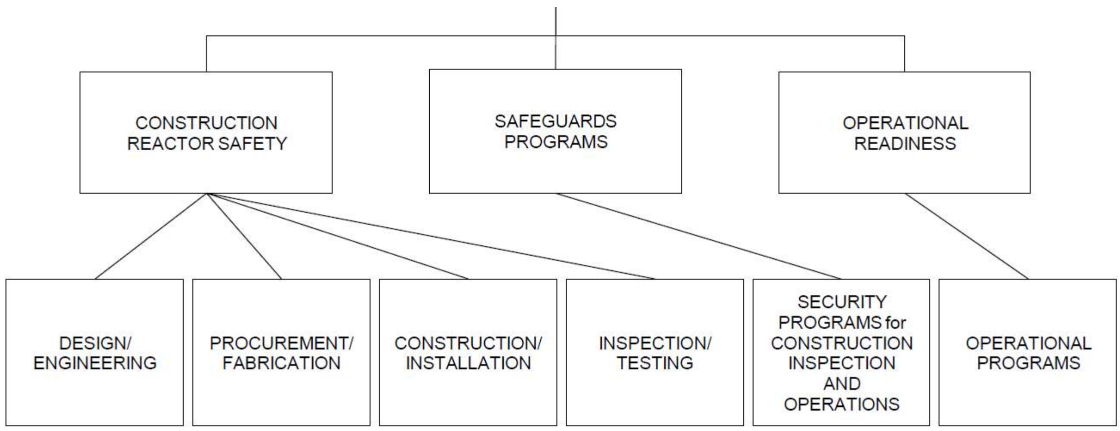

FIG. 4. Suggested inspection focus areas during the construction stage

The objectives of the construction inspection programme are to:

— Determine whether or not appropriate quality controls are implemented in the development of applications that will be or have been submitted to the regulatory body;
— Provide reasonable assurance that the plant has been constructed and will operate in conformity with the licence, rules, and regulations.

The construction inspection programme is conducted to support construction activities and the preparations for operation. Construction programme inspections confirm that an adequate level of quality in construction products is provided. Inspectors verify that operational programmes are consistent with their description in the FSAR, and ensure that the approved scope and content of the operational programmes are contained in the licensee's operational programme documents and procedures.

Prior to and during plant construction, inspections ought to be conducted to verify that the licensee has adequate oversight of the vendor activities, which could be reinforced by verifying the vendor activities as necessary.

(2) Operations stage

Once the reactor plant transitions to power operation, the inspection areas need to shift to focus on operations. Figure 5 is an example of potential inspection focus areas during power operations.

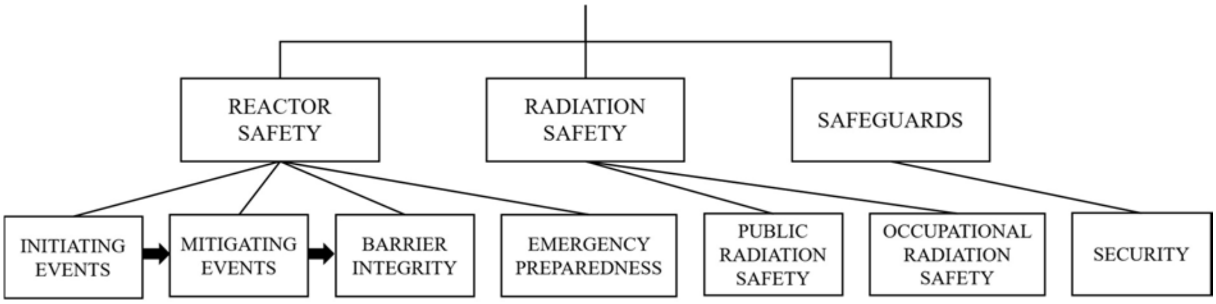

FIG. 5. Potential inspection focus areas during power operations

Safety-significant inspection needs to focus on activities and/or SSCs that:

- Might increase the frequency of events that upset plant stability and challenge critical safety functions;
- Ensure the availability, reliability, and capability of systems that mitigate the effects of initiating events to prevent core damage or releases;
- Provide reasonable assurance that the physical design barriers protect the public from radionuclide releases caused by accidents (i.e. fuel cladding, reactor coolant pressure boundary, containment);
- Ensure that licensees are capable of implementing adequate measures to protect public health and safety during a radiological emergency;
- Ensure adequate protection of workers and the public from exposure to radioactive material released into the public domain as a result of routine reactor operations;
- Provide assurance that the licensees' security system and material control and accounting programmes use a defence-in-depth approach and can protect against (1) the design basis threat of radiological sabotage from external and internal threats, and (2) the loss of radiological materials.

In order to identify the inspectable areas, there are certain attributes associated with the focus areas that need to be considered. These attributes include:

- Design;
- Configuration control;
- Equipment performance;
- Human performance;
- Procedure quality;
- Protection against external factors;
- Barrier performance;
- Emergency response organization readiness and performance;
- Radiation safety equipment and instrumentation;
- Physical protection;
- Access authorization;
- Access control;
- Security response to events.

Examples on the use of a graded approach for determining inspectable areas and other aspects related to regulatory inspections are provided in Annex IV.

Specific inspectable areas are then identified to ensure those attributes are addressed. Examples include:

- Surveillance testing;
- Equipment alignment;
- Online maintenance that increases the risk of the plant;
- Maintenance effectiveness;
- Post-maintenance testing;
- Operability evaluations;
- Plant modifications;
- Refuelling and outage activities;
- Alert and notification system testing;
- Emergency exercise evaluation;
- Identification and resolution of problem;
- Radiation monitoring instrumentation;
- Radiation worker performance;
- Radioactive material processing and transportation;
- Security (e.g. access control, physical protection).

Because external events are a significant contributor to overall plant risk, inspectors ought to also focus efforts on:

- Flood protection measures;
- Implementation of the fire protection plan;
- Licensee preparations for adverse weather.

Because of resource limitations, the inspection programme needs to be a sampling programme. A range of sample sizes, number of hours, and inspection frequency for each inspectable area ought to be established based on expert judgement, operating experience, and relevant risk information on how much inspection will be sufficient to ensure verification that the licensee is operating their plant in a manner that protects the public health and safety.

In a graded approach, the greatest inspection effort needs to be directed towards SSCs important to safety.

(3) Decommissioning stage

Reactor plants undergoing decommissioning present a significantly lower risk to the public, but potential risks to workers, and involve a significant change of the focus areas. Inspection emphasis ought to be placed on spent fuel cooling and storage, and radiological protection for the workers. The inspection programme ought to be implemented on or shortly after the date the licensee certifies permanent fuel removal from the reactor vessel.

The inspection programme for decommissioning reactor plants ought to focus on ensuring that:

- ‘Plant status’ - Licensee documents, programmes, and procedures are adequately implemented and maintained, and reflect the status of decommissioning at the plant.
- ‘Modifications, maintenance, and surveillance’ - Licensee activities, organizational structure, and programmatic controls provide reasonable assurance that

decommissioning and spent fuel storage can be conducted safely and in accordance with the regulatory requirements.
- 'Problem identification and resolution' - Licensee staff readily identify emergent problems, evaluate them, and correct issues of concern in accordance with the approved corrective action programme and other quality assurance requirements.
- 'Radiation protection' – The licensee adequately protects workers, the public, and the environment from hazards associated with ionizing radiation.

Inspectable areas might include:

- Safety reviews, design changes, and modifications;
- Self-assessment, auditing, and corrective action;
- Spent fuel pool safety;
- Maintenance, surveillance, and fire protection;
- Implementation of radiological controls and radiation protection programmes;
- Inspection of remedial and final surveys;
- Radioactive waste treatment, and effluent and environmental monitoring;
- Solid radioactive waste management and transportation of radioactive materials;
- Adverse weather preparations;
- Security.

Because of resource limitations, the inspection programme can only cover a sampling of licensee activities in any particular area, with an emphasis on those activities with relatively high radiation risk. The frequency of inspections ought to reflect the reduced risk associated with permanently shut down plants. Some inspections may need to be conducted annually, while others may need to be conducted based on the plant's decommissioning plan.

- **Step 2:** Determine which factors are applicable to the decision, and rank them

(a) Determining the initial baseline inspection programme

The initial baseline inspection programme for each installation type depends on several factors:

(1) Resources – Resource limitations will impact the upper limit of inspection samples to be monitored, or the frequency at which certain inspections are conducted.

(2) Type of installation – Limited inspection resources need to be apportioned according to the risk-significance of the installation, with more resources dedicated to the higher risk installations.

(3) Stage in the lifetime of the installation – As described above, operating installations represent a greater hazard to the public than installations under construction or in a decommissioning status, and therefore warrant a greater degree of oversight.

(4) Operating experience – Regulatory bodies ought to consider operating experience associated with SSCs to determine if there are SSCs that need greater oversight due to higher failure probabilities, which might impact the frequency at which these SSCs are inspected.

(5) Regulatory experience - New techniques, technologies, and methodologies need a greater degree of oversight than those for which the regulatory body has previous experience.

(6) Design of the installation – The baseline inspection programme ought to be evaluated for new reactor designs. Next generation reactors that rely more on passive safety systems will have lower baseline risk and are likely to have fewer components from which to sample. These factors may result in a reduction in overall inspection effort, with reduced sample sizes and corresponding reduced resource estimates to complete inspections.

(7) Licensee's past performance - Consideration ought to be given to enhance or supplement baseline inspections for licensees demonstrating declining performance. This can be accomplished by increasing sample sizes for inspections related to the declining performance, increasing the frequency of inspections, or scheduling additional inspections to ensure the licensee is addressing the declining performance. Likewise, reducing inspection sample sizes might be considered for licensees that have demonstrated sustained good performance.

(8) Licensee's planned schedule of activities – The timing and frequency of the inspections might be adapted to the planned schedule of activities to ensure relevant activities are conducted in compliance with the requirements and associated licence.

(9) Potential for the decommissioning activities to affect the health and safety of workers and the public - Exposure to these radioactive materials during decommissioning may have consequences for workers. Members of the public may also potentially be exposed to radioactive materials that are released to the environment during the decommissioning process. All decommissioning activities are assessed to determine their potential for radiation exposures that may result in health effects to workers and the public.

(10) Level of public interest - Fuel cycle facilities generally pose a lower radiation risk to the public. However, there is a greater risk of industrial hazards (e.g. chemical hazards) which have the potential for offsite release affecting the public.

(b) Adjusting the baseline inspection programme

After establishing a nominal sample size, resource estimate, and appropriate frequency for each inspectable area, there are a number of factors that will influence the decision to increase or decrease inspection effort.

(1) Operating performance - Given a range of inspection samples, the regulatory body may inspect the minimum number of samples for good performers, or increase the number of samples in inspectable areas in which the licensee is assessed to be deficient. For licensees exhibiting declining performance, consideration ought to be given to performing additional inspection, or supplemental inspections, described below. Depending on the risk significance and breadth of the identified performance issues, the supplemental inspections provide a range of activities including: oversight of the licensee's root cause evaluation of the issues and corrective actions; a focused team inspection (as necessary to evaluate extent of condition) for a moderate degradation in safety performance; or a broad scope multi-disciplined team inspection which would include inspection of multiple areas if it is determined that there has been a significant degradation in safety performance.

(2) Operating experience – Operating experience, either domestic or international, ought to be evaluated for applicability to the operating unit. Operating experience ought to inform sample selection, or to conduct additional one-time inspections to verify that the licensee is either not susceptible to the condition described or is capable of mitigating the consequences of the condition.

(3) Installation age – Installation age is normally not a factor until the installation starts nearing its design life. While inspectors need to verify that safety related SSCs are maintained or replaced based on vendor recommendations, equipment reliability will become a greater issue as the installation ages. The regulatory body may increase inspection samples or frequency if it determines equipment reliability is being challenged. Licensees may be expected to develop aging management programmes as the installation ages, and the regulatory body may want to verify that the necessary safety related SSCs are scoped into those programmes.

    In most research reactors, it is feasible to inspect most SSCs periodically and to replace components if necessary. Particularly important material aging concerns are corrosion in reactor tanks and vessels, where leak detection can be difficult, and repair or replacement might not be practicable. Similarly, the management of corrosion of inaccessible primary coolant piping and associated components is of key importance for reactor longevity.

(4) Significant events – Significant events need to be evaluated for risk significance, and appropriate inspection resources ought to be planned to react to those events. Further discussion is provided in the section on reactive inspections below. regulatory bodies ought to have a pre-planned graded approach to responding to a significant event at a nuclear installation. Deterministic criteria and/or risk information might be used in determining the appropriate response, similar to that for operating nuclear power plants. Regulatory response is discussed below in Section VII.3.

(5) Design – Design modifications (e.g. converting systems from analogue to digital) may need more or less inspection effort, depending on the regulatory body's and licensee's experience with the new technology.

— **Step 3:** Integrate the applicable factors into determining the optimal resource effort

Risk needs to be factored into the baseline inspection programme in the following ways:

(a) Inspectable areas are based on their risk importance in the areas of safety;
(b) The inspection frequency, how many activities to inspect, and how much time to spend inspecting activities in each inspectable area are based on risk information;
(c) The selection of activities to inspect in each inspectable area is based on plant-specific risk information.

The quality, completeness, limitations and uncertainties of the analysis used to support the evaluation of the risk needs to be considered to ensure that the analysis appropriately represent the issue under consideration.

After determining the inspectable areas, which includes the SSCs identified as safety-related or important to safety, the regulatory body needs to develop inspection procedures to guide inspectors. Each inspection procedure ought to establish a minimum sample size to give the regulatory body confidence that the licensee is operating the installation safely, and expected resource effort necessary to complete the applicable inspection. Available budgeted resources need to be apportioned to provide adequate oversight for each nuclear installation. The regulatory body may have to rely on expert judgment or benchmarking other oversight programmes to determine an appropriate frequency for each inspection type, i.e. quarterly, semi-annually, annually, biennially, or triennially.

The regulatory body ought to consider all of the factors described above in determining appropriate sample sizes and frequencies of inspections.

Once a baseline inspection programme has been established, the regulatory body ought to regularly assess the programme and make adjustments to optimize resource expenditures to ensure inspectors focus efforts on issues of greatest safety significance. The factors described above ought to be considered when making adjustments to the baseline inspection programme. The following describes a graded approach for how a regulatory body might consider adjusting inspection activities based on licensee operating performance.

VII.2 SUPPLEMENTAL INSPECTIONS

While the baseline inspection programme is expected to provide sufficient information to allow the regulatory body to meet the goal of ensuring licensees are maintaining safety at installations with an absence of risk-significant performance issues, supplemental inspections may be necessary to provide enhanced information regarding safety at installations where risk-significant performance issues have been identified, e.g. safety-significant inspection findings. When the regulatory body concludes that licensee performance is declining, the following (as shown in Fig. 6) is an example of a graded approach to conducting additional inspection:

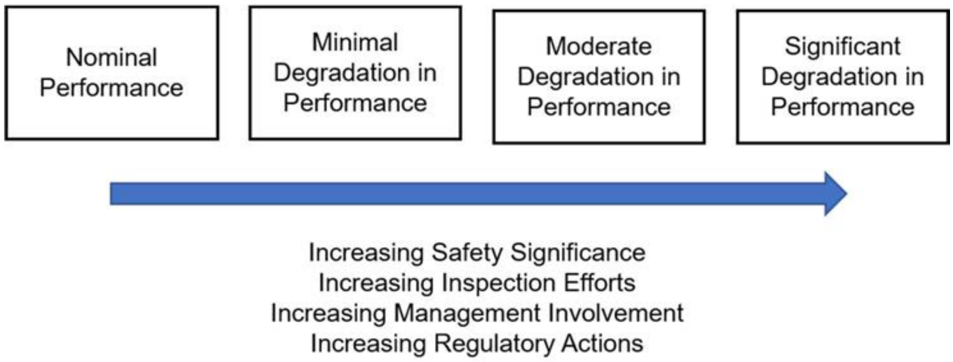

FIG. 6. Supplemental inspections due to degradation in licensee performance

The regulatory body ought to establish objective, measurable thresholds for each level of degraded performance. The breadth and depth of the supplemental inspections increase in proportion to the relative risk significance of the identified performance issues. At the lowest level, inspectors might review the licensee's evaluation of root and contributing causes, extent of condition and extent of cause, and corrective actions, and ought to be limited to specific issue(s) or the performance area of concern.

If licensee performance declines further, or more significant safety issues are identified, inspectors may review licensee's evaluation of root and contributing causes, extent of condition and cause, and corrective actions both for individual and collective issues. The inspection ought to determine if safety culture components caused or significantly contributed to risk significant performance issues and independently assesses the licensee's extent of condition. This type of response will need a greater inspection resource effort.

For licensees exhibiting a significant degradation in safety performance or long-standing performance issues, the regulatory body may consider a more comprehensive, diagnostic inspection of the licensee's programmes and operations. Inspectors may evaluate the key attributes of affected performance areas to determine if continued operation of the installation is acceptable and whether additional regulatory actions are necessary. The inspection independently assesses the extent of risk significant issues, the adequacy of the programmes and processes used to identify, evaluate, and correct performance issues, and evaluates the adequacy of programmes and processes in the affected performance areas. The inspection ought to develop insights into the overall root and contributing causes of identified performance deficiencies and evaluate the licensee's safety culture. This effort will be the most-resource intensive and may potentially span many months or even years before concluding that licensee oversight may return to baseline inspections alone.

The following describes a graded approach for how a regulatory body might consider assigning inspection resources in response to a significant operational event at a nuclear installation.

VII.3 REACTIVE INSPECTIONS

A significant event is any radiological, security, or other event at a licensed installation that poses an actual or potential hazard to public health and safety, security, property, or the environment.

A graded approach can be developed for responding to significant events at nuclear facilities. The regulatory body needs to consider following up on plant events in three ways: (1) events of low safety significance receive minimal follow up, usually by a single inspector, (2) events of moderate safety significance receive more follow up, often by one or two inspectors, and (3) events of greater safety significance are followed up by a team of inspectors.

The decision regarding a response for a significant event may be determined by its risk significance, complexity, and generic safety or security implications. Significant events at nuclear power plants may be evaluated on the basis of both deterministic criteria and risk significance (e.g. conditional core damage probability - CCDP) in order to define the appropriate level of response.

The following deterministic criteria ought to be considered when determining an appropriate response to an event at a nuclear power plant:

- Operation that exceeded, or was not included in, the design bases of the plant;
- Major deficiency in design, construction, or operation having a potential generic safety implication;
- Significant loss of integrity of the fuel, the primary coolant pressure boundary, or the primary containment boundary;
- Loss of a safety function or multiple failures in systems used to mitigate an actual event;
- Possible adverse generic implication;
- Significant unexpected system interaction;
- Repetitive failures or events involving safety-related equipment or deficiencies in operations;
- Question or concern pertaining to licensee performance; or
- Circumstance sufficiently complex, unique, or not well enough understood, or involving characteristics the investigation of which would best serve the needs and interests of the regulatory body.

If using deterministic criteria alone, the graded response could be based on actual safety consequences versus potential safety consequences. A larger inspection team and more detailed response ought to be considered for an event with actual safety consequences. A significant event at a nuclear power plant meeting any of the above deterministic criteria needs to be evaluated for risk. One method of evaluating the risk is to determine the CCDP based on the actual plant configuration, including equipment unavailable because of maintenance and testing.

The regulatory body ought to establish risk thresholds that, in concert with the deterministic criteria, could inform a regulatory response. Refer to the example in Table 7.

TABLE 7. TYPICAL REGULATORY RESPONSE BASED ON RISK THRESHOLDS

CCDP	Regulatory Response
CCDP < minimum threshold	no reactive inspection
Min threshold < CCDP < interim threshold	minimum reactive inspection team
Interim threshold < CCDP < higher threshold	larger reactive inspection team
CCDP > higher threshold	large incident investigation team

If it is determined that no reactive inspection is required, inspectors ought to still follow-up on the event to verify that the licensee conducted an adequate root cause evaluation and developed appropriate corrective actions.

If the regulatory body determines that the appropriate response is to implement a minimum reactive inspection, the inspection team may focus on the following:

- Identify potential generic safety concerns in a timely manner so the regulatory body may initiate follow-up actions.
- Emphasize fact-finding, i.e. fully understanding the circumstances surrounding an event and probable cause(s), including conditions preceding the event, chronology, systems response, equipment performance, precursors, human factors considerations, quality assurance considerations, radiological considerations, safeguards considerations, and safety culture component considerations.
- Base the fact-finding effort on the most timely, reliable evidential material, including interviews and other documented material related to the event previously obtained by internal audit or investigative groups. Inspectors ought to consider visiting vendors' or contractors' facilities, if necessary, to gather additional insights and/or to verify licensee conclusions that are dependent on vendor/contractor supplied information.

For significant events where it is determined that a greater response is necessary, the regulatory body ought to consider an augmented team inspection consisting of several inspectors with diverse experience. The objectives of the inspection would be similar to that for a minimum reactive inspection. The augmented team ought to assess the safety significance of the event and communicate to management the facts and safety or security concerns related to the event so that appropriate follow-up actions can be taken. The inspection ought to be sufficiently broad and detailed to ensure that the event and related issues are well defined, the relevant facts and circumstances are identified and collected, and the findings and conclusions are identified and substantiated by the information and evidence associated with the event. The inspection needs to also consider the adequacy of the licensee's actions during the event.

For events determined to be of high safety significance, the regulatory body ought to consider conducting an incident investigation. The incident investigation needs to emphasize fact-finding and determination of probable cause for a significant event. The scope of the investigation ought to be sufficient to ensure that the event is clearly understood, the relevant facts and circumstances are identified and collected, and the probable cause(s) and contributing cause(s) are identified and substantiated by the evidence associated with the event. The investigation ought to consider whether licensee and regulatory body activities preceding and during the event were timely and adequate. This type of event follow-up will be the most resource intensive.

Because research reactors generally do not have PSAs, the regulatory body will have to rely on deterministic criteria when determining an appropriate response to an event. The deterministic criteria are similar to that for an operating power reactor. In addition, an augmented inspection effort might be appropriate if the following additional deterministic criteria are met:

- The event led to a release of byproduct, source, or nuclear material to unrestricted areas that resulted in occupational exposure or exposure of a member of the public in excess of the applicable regulatory limit.
- The event involved the deliberate misuse of byproduct, source, or nuclear material from its intended or authorized use and had the potential to cause an exposure that exceeds regulatory limits.
- The event involved a significant infraction or repeated instances of nuclear security infractions that demonstrate the ineffectiveness of installation's security provisions.
- The event involved repeated instances of inadequate nuclear material control and accounting provisions to protect against theft or diversions of nuclear material.

The regulatory body may consider launching an 'incident investigation', which is often the highest level of reactive inspection, if any of the following types of deterministic criteria are met:

- Led to a significant radiological release (levels of radiation or concentrations of radioactive material in significantly exceeds regulatory limits of byproduct, source, or nuclear material to unrestricted areas;
- Led to a significant occupational exposure or significant exposure of a member of the public.
- Led to a site area emergency;
- Exceeded the licensee's safety limits and conditions;
- Involved the medical use of byproduct, source, or nuclear material and may have resulted in deterministic effects to a significant number of patients or individuals over a long period (months or years);
- Involved the medical, academic, or commercial use of byproduct, source, or nuclear material and resulted in the potential exposure of a significant number of individuals above occupational or public dose limits;
- Involved the deliberate misuse of byproduct, source, or nuclear material from its intended or authorized use, which resulted in the exposure of a significant number of individuals;
- Involved byproduct, source, or nuclear material, which may have resulted in a fatality;
- Involved circumstances sufficiently complex, unique, or not well enough understood, or involved nuclear security concerns.

Events at nuclear fuel cycle facilities meeting one or more of the deterministic criteria described below associated with the safety operations performance area are further evaluated based on additional risk insights, as applicable. The decision ought to consider risk insights associated with the event based on the best available information (e.g. the facility safety case, realistic assumptions regarding SSCs, other safety controls, operator actions)

The following suggested event characteristics might result in the lowest level of response by the regulatory body (e.g. one or two inspectors for several days):

— Involved safety function(s) that have been lost or significantly degraded.
— Involved repetitive failures or events involving SSCs or deficiencies in operations.
— Involved a high consequence event that was unlikely or a substantial increase in its likelihood.
— Involved an intermediate consequence event that was not unlikely or a significant increase in its likelihood.
— Led to a radiological release of source or nuclear material or a chemical release that had a reasonable potential in exceeding an occupational or public radiation regulatory limit.
— Led to an activation of the facility emergency plan.
— Involved a significant instance of inadequate nuclear material control and accounting provisions to protect against theft or diversion of nuclear material.
— Involved a nuclear security infraction that significantly weakened the effectiveness of the facility security provisions.
— Involved a major deficiency in design, construction, or operation having potential generic safety or nuclear security implications.
— Involved an un-analysed condition or unexpected system interactions that could reasonably lead to a significant safety or nuclear security concern.
— Involved a significant failure to obtain approval to implement a facility change or change process.

The following suggested event characteristics are more safety-significant, and therefore might result in a larger level of response (e.g. a team of inspectors for a week or longer):

— Led to a radiological release of source or nuclear material to unrestricted areas that resulted in occupational exposure or exposure to a member of the public in excess of the applicable regulatory limit.
— Led to an intermediate consequence event.
— Involved a high consequence event that was not unlikely or a very substantial increase in its likelihood.
— Involved a fire or explosion involving licensed material or hazardous chemicals produced from licensed materials.
— Involved the deliberate misuse of source or nuclear material from its intended or authorized use and had the potential to cause an exposure that exceeds regulatory limits.
— Involved a significant infraction or repeated instances of nuclear security infractions that demonstrate the ineffectiveness of facility security provisions.
— Involved repeated instances of inadequate nuclear material control and accounting provisions to protect against theft or diversions of nuclear material.
— Involved the failure of radioactive material packaging that resulted in external radiation levels or contamination of the packaging significantly exceeding regulatory limits.
— Involved a loss of classified or nuclear security information with potential disclosure to unauthorized individuals affecting national security or security of the facility.
— Involved a failure to control unauthorized disclosure of other classified information or nuclear security information that results in the removal of material from a controlled area and disclosure to an unauthorized individual.

The following suggested event characteristics are the most safety-significant, and would suggest that the regulatory body conduct a comprehensive investigation into the event to ensure the causal factors are understood, the licensee appropriately responded to the event, and to determine if there are any generic implications:

- Led to a significant radiological release (levels of radiation or concentrations of radioactive material that significantly exceeds regulatory limits).
- Involved an inadvertent criticality.
- Led to a high consequence event.
- Led to a significant occupational exposure or significant exposure to a member of the public. In both cases, 'significant' is defined as five times the applicable regulatory limit.
- Led to a site area emergency.
- Involved the commercial use of source or nuclear material and resulted in the potential exposure of a significant number of individuals above occupational or public dose limits.
- Involved the deliberate misuse of source or nuclear material from its intended or authorized use, which resulted in the exposure of a significant number of individuals.
- Involved source or nuclear material, which may have resulted in a fatality.
- Involved circumstances sufficiently complex, unique, or not well enough understood, or involved nuclear security concerns.
- Actual intrusion into the protected area or controlled access area or the established first-line physical barrier for controlling personnel access to the facility.

In the deterministic criteria described above, the thresholds for a high consequence event and intermediate consequence event ought to be established by the regulatory body based on risk insights.

APPENDIX VIII.

GENERIC EXAMPLES OF A GRADED APPROACH APPLIED TO THE ENFORCEMENT FUNCTION

Enforcement processes have the following basic steps:

(a) Identify the non-compliance and determine the safety significance.
(b) Identify the applicable factors to consider.
(c) Integrate the factors into the decision-making process to determine appropriate enforcement action.

— **Step 1:** Identify the non-compliance and determine safety significance

The enforcement process begins with the identification of violations and non-compliances, either through inspections or investigations, a licensee report, or substantiation of an allegation. Each case being considered for enforcement action ought to be reviewed on its own merits to ensure that the severity of the non-compliance is characterized at the level appropriate to the safety or security significance.

After a non-compliance is identified, the regulatory body assesses its severity or significance (both actual and potential) using a risk-informed evaluation process, whenever possible, and assign severity levels. A higher severity level may be warranted for non-compliances that have greater risk, safety, or security significance, while a lower severity level may be appropriate for issues that have lower risk, safety, or security significance.

There are several ways to determine safety significance for operating nuclear power plants. One method for nuclear power plants would be to use the plant's probabilistic safety assessment (PSA) to determine if the issue would have resulted in a significant change to the baseline core damage frequency (CDF) or large early release frequency (LERF). When using PSA as a basis, there ought to be pre-determined significance thresholds established to classify an issue as either high safety significance, moderate safety significance, low safety significance, very low safety significance, or minor. The greater the safety significance, the greater the expected regulatory action. In addition, when a PSA is used to evaluate a non-compliance, ensure that the conclusions of the analysis of the non-compliance are not impacted by PSA limitations or uncertainties.

PSA cannot be used for all performance deficiencies identified at a nuclear power plant. Because a PSA will likely not address the safety significance of non-compliances in security, radiation protection, or emergency preparedness areas, the safety significance needs to be determined using a different methodology, more likely deterministic instead of risk-based. The method ought to be risk-informed to the extent possible. One method would be to develop flow charts that lead to varying degrees of significance in each area developed by an expert panel. An example of criteria to consider when establishing the significance or severity levels is described below.

A graded approach to characterization of the safety significance of violations and non-compliances entails establishment of severity or significance levels with pre-defined thresholds. An example of severity level designations and descriptions is provided below:

(a) 'Severity Level I violations' are those that resulted in or could have resulted in serious safety or security consequences (e.g. violations that created the substantial potential for serious safety or security consequences or violations that involved systems failing when actually called on to prevent or mitigate a serious safety or security event).

(b) ‘Severity Level II violations’ are those that resulted in or could have resulted in significant safety or security consequences (e.g. violations that created the potential for substantial safety or security consequences or violations that involved systems not being capable, for an extended period, of preventing or mitigating a serious safety or security event).

(c) ‘Severity Level III violations’ are those that resulted in or could have resulted in moderate safety or security consequences (e.g. violations that created a potential for moderate safety or security consequences or violations that involved systems not being capable, for a relatively short period, of preventing or mitigating a serious safety or security event).

(d) ‘Severity Level IV violations’ are those that are less serious, but are of more than minor concern, that resulted in no or relatively inappreciable potential safety or security consequences (e.g. violations that created the potential of more than minor safety or security consequences).

(e) ‘Minor Violations’ are those that are less significant than a Severity Level IV violation. Minor violations do not generally warrant enforcement action and are not normally documented in inspection reports. However, minor violations need to be corrected by the licensee.

— **Step 2:** Identify the applicable factors to consider

After the safety significance of the violation or non-compliance has been established, the next step in a graded approach is to determine if there are any factors to be considered that might mitigate or escalate the significance of the issue.

For instance, the organization that identifies the violation is one such factor. The option to reduce the enforcement action for issues identified by licensees could be used to encourage licensees to self-identify problems.

Another factor is the timeliness of corrective actions to restore compliance. If a licensee does not take timely corrective actions commensurate with the safety significance of the issue, then the regulatory body may consider increasing the regulatory response or escalating the enforcement action to encourage more timely compliance. However, the regulatory body needs to consider the complexity of the required corrective action when making this determination. If a plant shutdown is needed in order to implement the corrective action and technical specifications do not require a shutdown, then it would be prudent to allow the licensee to wait for the next planned shutdown in order to implement corrective actions.

If the violation is repetitive, that would be indicative of untimely or inadequate corrective action and ought to be a factor in determining the appropriate enforcement action.

— **Step 3:** Integrate the factors into the decision-making process to determine appropriate enforcement action

The regulatory body ought to have a pre-established process with enforcement options and objective criteria. There are several enforcement options mentioned in section 4.5 for the regulatory body to consider. The regulatory body ought to establish criteria for determining which option is the most appropriate so that the process is predictable and reliable.

(a) Nuclear power plants

Since operating nuclear power plants represent the greatest risk to the public, operators would be subject to the widest range of enforcement options. Nuclear power plant licensees are somewhat unique in that they normally have a formal corrective action programme in which they are expected to identify problems within their plants, enter them into their corrective action programmes, rank them based on the safety significance of the issue, and then implement corrective actions.

It is vital that all issues that may impact nuclear safety be identified and corrected. Because there are many more licensee staff around an operating reactor plant than inspectors on a daily basis, the licensee is more likely to identify problems. The licensee ought to be encouraged to identify and report problems by offering to give them credit through possibly reduced enforcement actions or penalties, or by enforcement discretion. Enforcement discretion allows the regulatory body to either escalate or reduce enforcement sanctions or otherwise refrain from taking enforcement action based on the unique circumstances of the violation or non-compliance.

(b) Research and test reactors

The enforcement process for research reactors may be identical to that for operating nuclear power plants. Violations and non-compliances are identified, the significance is determined, and then the appropriate enforcement action is assigned.

There are a few differences to be highlighted. First, research reactors represent a lower risk to the public than operating nuclear power plants, and thus the significance of violations is expected to be correspondingly lower, resulting in reduced severity of enforcement actions. In addition, typically the research reactors operators have far fewer staff, so while still desirable, self-identification of violations and non-compliances will be less likely, and research reactors will likely not have a PSA to use to evaluate the significance of violations and non-compliances.

The same factors that determine appropriate enforcement actions for operating nuclear power plants also apply to research reactors. For instance, credit ought to be considered for a research reactor licensee that identifies and corrects violations and non-compliances before the regulatory body does. If the violation is neither repetitive nor wilful, the regulatory body may consider reducing the severity of the enforcement action.

In determining the significance of violations at research reactors, the regulatory body ought to consider the factors described in section 4.5.

The regulatory body ought to also evaluate problems to determine if follow-up inspections are necessary to diagnose whether a safety concern represents an isolated case or may signify a broader, more serious problem. Licensee management controls (e.g. review, audit and safety committees, management reviews) may need to be examined to determine if weaknesses in these controls contributed to identified safety concerns.

(c) Nuclear fuel Cycle Facilities

Fuel cycle facilities also represent less risk to the public than operating nuclear power plants. Again, the enforcement process ought to be the same.

Once a violation or non-compliance at a fuel cycle facility has been identified, the next step is to characterize the safety significance. Fuel cycle facilities do not, in general, have PSAs, but they may have an approved integrated safety analysis (ISA). Risk assessment need to be based on controls, which might or might not include items relied on for safety (IROFS), credited before occurrence of the potential non-compliance. A control is a structure, system, component, or operator action, relied on to prevent or mitigate an accident of concern. The term 'control' implies that the engineered features or administrative actions are formally recognized, documented, implemented, and maintained as such by the licensee prior to occurrence of the potential non-compliance, and includes IROFS, other safety controls (e.g. double contingency controls), systems of controls working together to perform a single safety function, and formal licensee programmes (e.g. fire protection programme, chemical safety programme, material control and accounting programme).

The process for assessing the risk consists of (1) identifying the accident sequences or contingencies affected by the potential non-compliance, (2) determining the controls and other considerations applicable to those accident sequences or contingencies, including degraded or failed controls and those remaining available and reliable, (3) assessing the consequence of the sequences or contingencies based on the previous determination, and (4) assessing the likelihood of the consequence to determine the risk following the potential non-compliance. The consideration of likelihood may be done quantitatively, qualitatively, or deterministically.

In assessing the consequences, the regulatory body needs to assess the consequence associated with the accident sequence (e.g. high, intermediate, or low) as identified in the licensee safety basis documentation. For criticality events, the consequence will normally be presumed to be high, unless it occurs in a shielded facility where the shielding is credited as a mitigative IROFS. For radiological, chemical, and fire events, the consequence will be determined in accordance with the licensee's ISA methodology, with appropriate consideration given to any mitigative IROFS present. If the potential non-compliance involved the failure or degradation of a mitigative IROFS, the consequence may be increased as a result.

If more than one accident sequence or contingency is impacted, the regulatory body evaluates each of them in assessing overall safety-significance.

Table 8 is an example for characterizing the consequences of the violation or non-compliance at fuel cycle facilities.

TABLE 8. CONSEQUENCES OF VIOLATIONS OR NON-COMPLIANCES

High	Intermediate	Low
• Accidental criticality. • An acute radiological dose of 1 Sv or greater, or a chemical exposure that could endanger the life of a worker. • An acute radiological dose of 250 mSv or greater, or a chemical exposure that could lead to irreversible or other serious long-lasting health effects to a person outside the controlled area (public). • An intake of 30 mg or greater of uranium in soluble form by any individual located outside the controlled area. • An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material.	• An acute radiological dose of 250 mSv or greater, or a chemical exposure that could lead to irreversible or other serious long-lasting health effects to a worker. • An acute radiological dose of 50 mSv or greater, or a chemical exposure that could lead to mild or transient health effects to a member of the public. • A 24-hour averaged release of radioactive material outside the restricted area in concentrations exceeding regulatory limits. • An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material.	• A chronic radiological or chemical exposure due to licensed material or an acute exposure less than intermediate.

APPENDIX IX.

CONSIDERATIONS OF A GRADED APPROACH APPLIED ON COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES – PUBLIC ENGAGEMENT RISKS

This appendix presents considerations on aspects of public engagement risks related to the use of a graded approach on communication and consultation with interested parties. Practical examples on the use of a graded approach to this core regulatory function are presented in Annex VI.

IX.1. PUBLIC ENGAGEMENT RISKS

Public engagement risks may result from the deficiencies of the communication and consultation with interested parties. There are several compelling reasons for identifying and dealing with these risks:

(a) Public concerns, typically based on insufficient or incorrect information, may put pressure on and force regulatory bodies to spend time and effort on relatively minor risks, diverting resources from higher risk areas, contrary to the principle of a graded approach.

(b) The level of interest of the public may delay the implementation of safety improvements to the installations.

(c) Mistrust on the part of public stakeholders induces intense scrutiny on the part of the media and special interest groups that focuses on finding fault rather than on finding appropriate safety solutions. This fault finding leads to further losses of credibility for government decision-makers causing more concerns to the public.

(d) Regulatory credibility improves if the issues of concern to the public are identified promptly and dealt with proactively and in a timely manner.

(e) If technical information is passed to the public in a form that can be better understood, fewer misperceptions about risk will arise.

Objectives related to managing public engagement risks include:

(a) Improve visibility of the regulatory body to provide public and industry stakeholders with a better understanding of the processes a regulatory body uses to make decisions.

(b) Demonstrate openness, transparency, and impartiality in decision-making and operations.

(c) Improve communications with public stakeholders by making technical information more understandable for laypersons.

(d) Explain the role of the regulatory body to public stakeholders.

(e) Avoid the 'Decide/Announce/Defend' pattern for decision-making by involving stakeholders at the start of the decision process and throughout.

(f) Improve safety through improved two-way communications with public stakeholders.

(g) Improve the credibility of the regulatory body and public acceptance of its regulatory decisions.

(h) Improve trust with public.

(i) Correct misperceptions.

(j) Attain a better understanding of the concerns of the public.

Aspects also to be considered when managing public engagement risk:

(a) Avoid telling public stakeholders what they already know.

(b) Ensure that communications are backed up by action (walk the talk).

IX.1. RANKING PUBLIC ENGAGEMENT RISKS

The following factors may be used for ranking public risks:

(a) Proximity of the installation to large populated areas.

(b) 'Visibility' of the installation – reflecting media coverage.

(c) The quality and effectiveness of the outreach programme:

    (1) Regulatory outreach programme.
    (2) Licensee's outreach programme.

(d) Proximity to valued land/ecosystem;

(e) Size and nature of operation/installation:

    (1) Larger installations are perceived as generating greater risks.
    (2) The risks associated with installations used for medical purposes are perceived as more acceptable than those associated with installations used for commercial purposes.
    (3) The risks associated with nuclear power plants are considered less acceptable than those associated with research reactors.

(f) Actual/potential/perceived impacts of the installation on local population/environment.

(g) Results from stakeholder analysis.

(h) Familiar technologies vs. new technology (risks associated with familiar technologies perceived as more acceptable).

(i) Installations where the consequence of an event is perceived as high (nuclear power plants).

(j) Terminology associated with some installations; e.g. 'waste', 'nuclear'.

IX.2. PERFORMANCE INDICATORS TO EVALUATE PUBLIC ENGAGEMENT RISKS

The following performance indicators can be used in the ranking of public risk:

(a) Actual level of risk to the public from the facility or activity.

(b) Performance of licensee's communication / engagement programme.

(c) Results of safety reports:

   (1) From inspections;
   (2) From incident reporting;
   (3) From other sources (special interest groups, other government agencies).

(d) History of public concern:

   (1) Repeat concerns (this could mean that concerns remain to be addressed and this could affect credibility of the regulatory body);
   (2) Volume of complaints may be significant.

(e) Image of the licensee to the public:

   (1) As a result of media coverage;
   (2) As a result of local concerns.

(f) Level of public trust in the licensee.

(g) Recent media coverage (on installation operations or incidents):

   (1) Negative vs. positive coverage;
   (2) Duration of media coverage.

(h) Type of public response to issues arising with the installation

   (1) Large number of individual letters (more significant than a multitude of form letters).
   (2) Form letters vs. individual letters (a large number of form letters might not necessarily reflect broad public concern but would reflect an organized effort, which would have a higher risk associated with it).
   (3) Source/credibility/constituency of written response:

      i) All the letters repeat the same thing, or are issues diverse?
      ii) Is source a local citizen vs. a political or civic leader?

(i) Trends in reporting on particular facilities.

(j) Lack of engagement/silence in face of an arising issue.

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ANNEX I.

PRACTICAL EXAMPLES OF MEMBER STATES ON THE USE OF A GRADED APPROACH IN CORE REGULATORY FUNCTIONS: DEVELOPMENT OF RULES AND REGULATIONS

This annex collects practical examples from Member States of the use of a graded approach in different aspects of the development of rules and regulations. These contributions were developed by the contributing Member States based upon their own experience and describe how the general three-step methodology described in Sections 3.2 and 4.1 can be used.

This annex provides examples covering a wide range of possible applications of a graded approach. However, it is not comprehensive and additional applications, not covered herein, could also be envisaged by Member States.

I-1. GRADED APPROACH IN THE DEVELOPMENT OF REGULATIONS AND GUIDES – SELECTION OF REGULATORY INSTRUMENTS IN CANADA

This example illustrates the application of a graded approach to the process for selection of regulatory instruments in Canada.

— **Step 1: 'Identify the need for development or revision of regulations and/or regulatory documents'**

Through cyclical reviews, the CNSC ensures that the requirements, and guidance in its regulatory instruments are clear and comprehensive for all licensees, applicants and stakeholders. This is where regulatory policy analysis becomes an important and proactive process. It helps us to find whole of CNSC solutions to regulatory projects or issues while ensuring alignment with the CNSC's mandate and the wider Government of Canada priorities.

Analysis is the means through which we determine areas of content that will be covered in a regulatory instrument, requirements and guidance that have to be included and the type of instrument(s) to be used. It also allows us to obtain internal CNSC alignment on the content, through early and thorough consultation and collaboration.

The 'Conduct Regulatory Policy Analysis' process includes the regulatory policy analysis activities that occur before any regulatory method or instrument is formally considered or approved. It includes the activities for:

- analysing new regulatory issues or existing regulatory instruments
- proposing areas of content (requirements and guidance)
- assessing risks and impacts
- consulting stakeholders
- selecting and recommending regulatory instruments

This process is applicable to any CNSC regulatory document project, including the development of:

- Regulations
- REGDOCs
- Discussion Papers

— Standards developed by external organizations such as the CSA Group
— Other

— **Step 2: Determine which factors are applicable to the decision on regulatory instrument to be developed**

The potential impacts of the CNSC's proposed regulatory project on industry, the CNSC and other stakeholders are thoroughly considered. The CNSC addresses the principles in the Cabinet Directive on Regulation (CDR) such as Gender-Based Analysis Plus (GBA+) analysis [I-1].

The type of regulatory instrument that could best address the issue at hand while ensuring that consideration is given to international lessons learned and standards in the development of regulations and regulatory documents is assessed. Table I-1 presents factors to consider in the selection of the appropriate regulatory instrument.

CNSC staff also assess the importance and urgency in assessing the implications of not proceeding with regulatory instrument development

(a) Importance

— To what extent would the proposed initiative reduce regulatory uncertainty for licensees?
— To what extent would the proposed initiative align with CNSC or government priorities?
— To what extent would the proposed initiative promote consistent understanding of and compliance with regulatory expectations?

(b) Urgency

— When is the proposed initiative needed?
— How significant is the issue addressed by this initiative?
— To what extent does the current regulatory framework address this issue?

The characteristics below are not meant to be exhaustive. They are intended to provide some context around the choice of a possible regulatory instrument.

Note that, in some cases, it is possible to recommend two instruments and some tools for the same regulatory project – for instance, the development of a standard, as well as a REGDOC – within which the standard would be referenced – along with several communications products.

TABLE I-1. CHOICE OF REGULATORY INSTRUMENT

The CNSC may choose to develop the following Regulatory Instrument…	…if the characteristics below are present when analysing a project	Other considerations
Regulations Statutory instrument, the contravention of which may be subject to prosecution	– To assure that a compliance breech may be subject to prosecution under the NSCA – To ensure that a requirement is legally binding on licensees – To include legally binding requirements for all members of the public – To provide regulatory certainty and clarity to the regulated community on the CNSC's legal expectations.	– Approximately 18 months (when government or corporate priority) to four years for publication and enactment. – Requires Government of Canada's (GoC) approval to enact – Subject to the process for regulation making, including GoC consultation process. – Any future amendments also subject to the and GoC consultation and approval process
REGDOCs An articulation of the Commission's expectations as to how licensees will address the requirements found in regulations	– To clarify the intent of requirements found in regulations – To provide requirements and guidance to licensees on how to comply with requirements found in regulations – To document organizational guiding principles for conducting regulatory work – To provide proponents with information on completing their licence applications – To provide proponents with the Commission's expectations as to the programmes that should be submitted in support of a licence application.	– Approximately 18 months to three years to publish – CNSC public consultation process – Approved by CNSC Commission – Legally binding only if directly referenced in a licence
Codes or Standards – CSA Group – IAEA – ASME	– To enhance the level of technical detail in existing regulatory requirements and guidance – To promote consistent approaches for all similar facilities or licensees in Canada – To leverage technical or specialized expertise in a specific field through an external organization – To add a high-level of prescriptiveness to a specific regulated area	– Approximately two to three years to publication – Buy-in from industry required (potential significant cost implications and expression of voluntary adherence) – RFSC may formally request the development of a standard to the CSA Group or Standards Council of Canada. – As they are consensus based, there is no guarantee that the CNSC will find them fit-for-purpose

TABLE I-1. CHOICE OF REGULATORY INSTRUMENT (cont.)

The CNSC may choose to develop the following Regulatory Instrument…	…if the characteristics below are present when analysing a project	Other considerations
Licences and Certificates	– To ensure that licensee conducts all authorized activities in accordance with the licensing basis. – To ensure that applicants fully meet the requirements of the NSCA and associated regulations before they are permitted to engage in any nuclear-related activity. – Only issued once the CNSC is certain that licensees are prepared to meet all regulatory and safety requirements.	– Approved and issued by the Commission or by Designated Officers
Licence Condition	– Imposed by the Commission, a licence condition places legally enforceable restrictions or conditions on a specific licensee. – May point to a regulatory instrument, CNSC document or outside standard.	– May be amended by Commission or DO or at the request of a licensee
Licence Condition Handbook	– Specific guidance for licensees, aligned with their licence and licence conditions. – Content used to assess compliance with licence conditions.	– Non-binding as it is the licence condition that binds the licensee
Amend the NSCA CNSC keeps an evergreen list of potential amendments to the NSCA in order to quickly and efficiently leverage future opportunities to execute changes.	– Amending the NSCA may be necessary to obtain legislative power to regulate in a certain area in light of new developments or new programmes (in the past, for example, the Participant Funding Program, Monetary Penalties, etc.) – Consequential amendments to other Acts may be needed as a result of new CNSC developments.	

— Step 3: Integrate the applicable factors into the decision-making process

Three examples of use of the Importance and Urgency tool are provided below:

- development of information on application of a graded approach in REGDOC-3.5.3, Regulatory Fundamentals [I-2];
- development of requirements and guidance for fire protection; and
- development of requirements and guidance for chemistry control.

The analysis indicated that development of material on a graded approach had the highest importance and urgency (See Table I-2). The results are then used by decision makers in the prioritization for the development of regulatory instruments. Overall, the CNSC starts with considering the simplest and most specific option to address a gap or regulatory concern. If this option is not sufficient to address the gap or concern, more complex options, such as making a regulation, may be selected.

TABLE I-2. IMPORTANCE AND URGENCY FOR: PROPOSED REGULATORY DOCUMENTS ON GRADED APPROACH, FIRE PROTECTION PROGRAMMES AND CHEMISTRY CONTROL

Importance (answer the three questions below by entering, as appropriate a 9 (High), 5 (Medium) or 1(Low))				
1	**To what extent would the proposed initiative reduce regulatory uncertainty for licensees?**	**Graded Approach**	**Fire Protection**	**Chemistry Control**
	High (9) - High potential for reducing regulatory uncertainty and regulatory burden regarding Licensing and Compliance	9	5	9
	Medium (5) - Moderate potential for reducing regulatory uncertainty and regulatory burden regarding Licensing and Compliance			
	Low (1) - Minimal potential for reducing regulatory uncertainty and regulatory burden regarding Licensing and Compliance			
2	**To what extent would the proposed initiative align with CNSC or government priorities?**	**Graded Approach**	**Fire Protection**	**Chemistry Control**
	High (9) - Explicitly stated as a priority for the CNSC or the government	5	9	5
	Medium (5) - May be implied as a priority for the CNSC or the government			
	Low (1) - No relation to the stated priorities of either			
3	**To what extent would the proposed initiative promote consistent understanding of and compliance with regulatory expectations?**	**Graded Approach**	**Fire Protection**	**Chemistry Control**
	High (9) - Will significantly promote the consistent compliance with regulatory requirements	9	5	9
	Medium (5) - Will moderately promote the consistent compliance with regulatory requirements			
	Low (1) - Will not have an appreciable impact on the consistent compliance with regulatory requirements			
RESULT - (Number to be entered in the Regulatory Framework Proposal for Importance)		**7.67**	**7.67**	**7.67**

TABLE I-2. IMPORTANCE AND URGENCY FOR: PROPOSED REGULATORY DOCUMENTS ON GRADED APPROACH, FIRE PROTECTION PROGRAMMES AND CHEMISTRY CONTROL (cont.)

Urgency (answer the three questions below by entering, as appropriate a 9 (High), 5 (Medium) or 1(Low))				
1	**When is the proposed initiative needed?**	**Graded Approach**	**Fire Protection**	**Chemistry Control**
	High (9) - Required with the next two years, if not immediately	9	9	5
	Medium (5) - Required in the next two to four years			
	Low (1) - No urgency foreseen in the next four years			
2	**How significant is the issue addressed by this initiative?**	**Graded Approach**	**Fire Protection**	**Chemistry Control**
	High (9) - Significant risk to health and safety, the environment or our international obligations	5	1	5
	Medium (5) - Moderate risk to health and safety, the environment or our international obligations			
	Low (1) - Little or no risk to health and safety, the environment or our international obligations			
3	**To what extent does the current regulatory framework address this issue?**	**Graded Approach**	**Fire Protection**	**Chemistry Control**
	High (9) - Very little documentation and not fit for purpose	9	9	5
	Medium (5) - Documentation in place but it is not entirely fit for purpose			
	Low (1) - Documentation in place sufficient for purpose			
RESULT- (Number to be entered in the Regulatory Framework Proposal for Urgency)		**7.67**	**6.33**	**5.00**

I-2. OVERVIEW OF A GRADED APPROACH USED FOR REGULATORY FRAMEWORK IN PAKISTAN

In Pakistan, a comprehensive legal and regulatory framework is required to discharge the regulatory obligations. PNRA ordinance III of 2001 [I-3] empowers PNRA to devise, adopt, make and enforce rules, regulations, orders or codes of practice, policies and programs to achieve the protection of life health and property against the risk of ionizing radiation.

The legal and regulatory framework of PNRA comprises three tiers depicting the hierarchy of regulatory documents. The first tier comprises the PNRA Ordinance, followed by PNRA regulations (second tier) and regulatory guides issued there-under (third tier). The highest-level document, the PNRA Ordinance, describes the mandate, powers, functions and responsibilities of PNRA assigned by the Government of Pakistan. The regulations set the mandatory requirements for licensees/applicants. The regulations are developed and revised taking into account the obligations of PNRA Ordinance and international conventions, experience feedback and international practices. The regulatory guides are non-mandatory in nature and provide acceptable methods to meet the regulatory requirements of PNRA regulations and ensure their effective implementation.

PNRA follows a comprehensive process for the development of its regulations including rigorous internal reviews at various levels within PNRA which is followed by inviting comments from all the stakeholders such as the licensees, the Government, and the general public. The entire process of developing a new set of regulations or revising existing regulations takes approximately three years. The final draft is also reviewed by the Authority Members before issuance/gazette notification of the regulations.

I-2.1 Graded Approach application to the development of the Regulatory Framework

The principle of a graded approach (GA) is applied in all regulatory processes. This graded approach is based on the safety significance and importance of the process/activity related to safety, health, environment, security and quality; complexity of the process/activity; and the possible consequences if the activity is carried out incorrectly.

For the application of a graded approach to the development of the regulatory framework, the following salient features are applied:

- Regulatory requirements for high risk facilities are stringent as well as multi-layered as compared to those for low risk facilities;
- Detailed regulations have been established for nuclear power plants (NPPs) as compared to research reactors (RRs) or other nuclear facilities.

(a) GA in documentation requirements for licensing of nuclear facilities

This example describes the application of a graded approach to the documentation requirement in the application for a nuclear facility authorization.

(1) Considerations of GA

Licensing submissions/documents for different nuclear facilities depend upon the following factors:

- Type of nuclear installation;
- Potential radiological hazards, i.e. on-site and off-site radiological hazards potential;

- The location of the site, including the potential for external hazards (including those due to the proximity of other nuclear facilities) and the characteristics of airborne and liquid releases of radioactive material;
- Design complexity, etc.

(2) Rationale for GA

After taking the above factors into account, the rationale for application of GA in submission of licensing documents is described below.

(3) PSA level 1

Required for NPPs but not required for RRs due to less complexity in design and associated radiological risk.

(4) Emergency Preparedness Plans

According to potential radiological hazards, the nuclear facilities are categorized, in accordance with PAK/914 [I-4], as:

- 'HC-1 Facilities': nuclear facilities for which on-site events could give rise to severe deterministic health effects off the site (in case of NPPs);
- 'HC-II Facilities': nuclear facilities for which on-site events could give rise to doses to people off the site that warrant urgent protective actions (in case of high power RRs);
- 'HC-III Facilities': nuclear facilities for which on-site events that warrants urgent protective actions on the site only (low power RRs and other nuclear facilities).

(5) Pre-Service Inspection/In-Service Inspection Programme

- Required for NPPs and RRs;
- Not required for other nuclear facilities.

With consideration of the above, the document submission requirements at different licensing stages in the lifetime of nuclear facilities are defined and included in PAK/909 [I-5].

Practical examples are mentioned in Table I-3.

TABLE I-3. DOCUMENTS REQUIRED FROM THE LICENSEE/APPLICANT AT DIFFERENT LICENSING STAGES OF NUCLEAR FACILITIES

Licensing Stage	Submission of Different Documents	NPPs	RRs	NFCFs
1. Site Registration	Site Evaluation Report	Yes	Yes	Yes
	No Objection Certificates (NOCs) from relevant departments of federal, provincial and/or local governments	Yes	Yes	Yes
	Quality Assurance Programme applied during site evaluation for reference and record	Yes	Yes	Yes

TABLE I-3. DOCUMENTS REQUIRED FROM THE LICENSEE/APPLICANT AT DIFFERENT LICENSING STAGES OF NUCLEAR FACILITIES (cont.)

Licensing Stage	Submission of Different Documents	NPPs	RRs	NFCFs
2. Construction Licence	Preliminary Safety Analysis Report (PSAR)	Yes	Yes	Yes
	Design Probabilistic Safety Assessment (PSA) of full power internal initiating events (for NPPs only)	Yes	No	No
	Quality Assurance Programme for design and construction phases (for reference and record)	Yes	Yes	Yes
3. Permission for Commissioning	Commissioning programme	Yes	Yes	Yes
	Quality Assurance Programme for the commissioning stage	Yes	Yes	Yes
4. Permission to Introduce Nuclear Material in the Installation	Final Safety Analysis Report (FSAR)	Yes	Yes	Yes
	Probabilistic Safety Analysis (PSA) Level-I (for NPPs only)	Yes	No	No
	Physical Protection Programme	Yes	Yes	Yes
	Emergency Preparedness Plans	Yes	Yes	Yes
	Radiation Protection Programme	Yes	Yes	Yes
	Radioactive Waste Management Programme	Yes	Yes	Yes
	Environmental Monitoring Programme	Yes	Yes	Yes
	Initial Decommissioning/Closure plan	Yes	Yes	Yes
	Quality Assurance Programme for Operation	Yes	Yes	Yes
	Pre-Service Inspection/ In-Service Inspection Programme	Yes	Yes	No
	Fire Protection Programme for reference and record	Yes	Yes	Yes
	Programs for maintenance, testing, surveillance and inspection of structures, systems and components for reference and record	Yes	Yes	Yes
	Commissioning reports up to introduction of nuclear material for information, reference and record	Yes	Yes	Yes
5. Operating Licence	Results of first start up, criticality, low power tests, power ascension tests and full power tests	Yes	Yes	No
	Updates of all documents mentioned in item 4 of this table.	Yes	Yes	Yes
6. Revalidation of Operating Licence	Latest Periodic Safety Review (PSR)	Yes (all safety factors as per SSG-25 [I-6])	Yes (but with selected safety factors)	Yes (but with selected safety factors)
7. Licensing beyond design life (where applicable in case of NFCF)	Latest report of Periodic Safety Review (PSR).	Yes (all safety factors as per SSG-25 [I-6])	Yes (but with selected safety factors)	Yes (but with selected safety factors)

TABLE I-3. DOCUMENTS REQUIRED FROM THE LICENSEE/APPLICANT AT DIFFERENT LICENSING STAGES OF NUCLEAR FACILITIES (cont.)

Licensing Stage	Submission of Different Documents	NPPs	RRs	NFCFs
	Updates of all documents mentioned in item 4 of this table.	Yes	Yes (excluding PSA reports)	Yes (excluding PSA reports)
8. Licence for decommissioning (where applicable in case of NFCF)	Final Decommissioning plan	Yes	Yes	Yes
	Technical Specifications during decommissioning	Yes	Yes	Yes
	Quality Assurance Programme for decommissioning	Yes	Yes	Yes
	Emergency Preparedness Plan	Yes	Yes	Yes
	Physical Protection Programme	Yes	Yes	Yes
	Radiation Protection Programme	Yes	Yes	Yes
	Environmental Monitoring Programme	Yes	Yes	Yes
	Radioactive Waste Management Programme	Yes	Yes	Yes
9. Authorization for Closure (where applicable in case of NFCF)	Final Closure plan	Yes	Yes	Yes
	Post Closure plan	Yes	Yes	Yes

I-3. GRADED APPROACH FOR REGULATORY CONTROL OF MANAGEMENT SYSTEMS OF SUPPLIERS TO NUCLEAR INSTALLATIONS IN ROMANIA

In Romania, all suppliers of goods and services for nuclear installations have to obtain a licence from the regulatory body (CNCAN). This practical example describes how the Quality Management System is linked to the Safety Management System and risk evaluation to determine the graded level of regulatory oversight of suppliers of products and services to nuclear installations.

The implementation of a graded approach starts with the development of the Quality Management System by the responsible organizations involved in the activities (goods and services necessary for nuclear installations). The suppliers need to ensure that functional requirements, and specifications for the Structures, Systems, Equipment and Components or Services supplied to the nuclear installations are fulfilled.

— **Step 1: Determining the level of regulatory oversight to the suppliers of goods and services to nuclear installations**

The graded implementation of the Quality Management System needs to be reflected in:

(a) the level of management which grant approvals;
(b) extension of management review;
(c) level of detail and review of documentation;
(d) extension and type of verification;
(e) frequency and thoroughness of audits;
(f) extension of surveillance;
(g) extension of corrective actions needed;
(h) extension of record keeping;

(i) type and content of required training / qualifications of staff;
(j) extension of requirements for traceability of materials;
(k) establishing which records need to be kept and maintained during the lifetime of the nuclear installation;
(l) level of performing independent verifications;
(m) the level of detail of the identification, disposal and solving of nonconformities;
(n) extension and thoroughness of regulatory control performed by the regulatory body.

According to national regulation (Norms on the General Requirements for the Quality Management Systems Applied in the Build, Operation, and Decommissioning of Nuclear Installations, 2004 [I-7]), the owner of a nuclear installation has to issue the list of structures, systems, equipment and components important for the nuclear safety of the nuclear installation, (the 'Q List'), and classify those items in a scale from 1 to 4 according to its importance to nuclear safety and radiological risk caused by their failure. The 'Q List' is submitted to regulatory approval and it is distributed to the 'nuclear project participants' or suppliers to the nuclear installations.

The participants (including contractors) need to issue their own specific procedures for graded implementation of the requirements of the Quality Management System, according to the safety class. Such procedures have to be accepted by the owner, and also approved by the National Regulatory Body of Romania, CNCAN. The procedures to be issued by participants and contractors need to consider the methodology described in the regulation mentioned above [I-7].

The requirements for a Quality Management System for Nuclear Installations and Suppliers of Activities and Items for those are set in Romania in the national regulation issued 'Norms on the General Requirements for the Quality Management Systems Applied in the Build, Operation, and Decommissioning of Nuclear Installations', revised [I-7], and, the specific regulations for each activity, such as the design regulation 'Nuclear Safety Norms for the Design and Build of Nuclear Power Plants (NSN-02)', 2010, [I-8], or the operation regulation 'Nuclear Safety Norms for the surveillance, maintenance, testing and inspection in operation of nuclear installations (NSN – 16)', 2020 [I-9].

The criteria set in [I-7] describe, in general terms, the main elements or the parts of a Quality Management System, such as organization, design control, inspection and test control, and records management. These criteria are supplemented, as needed, with requirements from the regulations applicable to those specific activities in order to fulfil the specific requirements of the corresponding project.

For instance, the requirements of a Level I Quality Management System, implemented for a safety-related component, need to also satisfy the requirements specific to the design regulations. These safety-related items / components have to fulfil the highest Quality Management Class (Class I if the Quality Management System) and are also listed on the 'Q List'. The requirements of the specific Class indicate the Quality Management System for those items and activities important for the nuclear safety and waste confinement, in order to ensure that their characterization, design, construction and operations comply with all requirements.

— **Step 2: Determining and ranking applicable factors**

In Step 2 of the application of a graded approach to determine the level of regulatory oversight to the Quality Management of the Licensed Organizations, the following types of risks posed by the operation of the nuclear facility were identified:

— Risk on the Environment and Public Health and Safety;
— Risk Related to Project Maturity;
— Risk Due to the Complexity of the Activity;
— Risk Due to the Importance of the Data.

For each of these types of risks, Tables I-4 to I-7 indicate how a specific rank or a numerical value (from 1 to 5) is assigned, according to the severity of the risk.

According to the Quality Management System Regulation 'Norms for Establishing Graded Implementation of the requirements for Quality Management Systems in Item Fabrication and Services for Nuclear Installations (NMC-13)', 2004, [I-10], first the design authority of the nuclear installation has to establish the safety classes of all the SSCs of the installation, and after the category for the graded implementation of the QMS for the developing of these SSCs. Then, each supplier of services and items for these structures, systems and components, parts, or subcomponents need to use this category of QMS in the realization of the product.

(a) The Risk on the Environment and Public Health and Safety

The performance of an activity or an item has the potential for contaminating the environment, affecting the health of the staff and general public, and causing threats to the safety of the employees / staff and public. Table I-4 can be used to determine the level of the risk posed by the activity or item to the environment, health and safety.

TABLE I-4. RISK ON THE ENVIRONMENT, PUBLIC HEALTH AND SAFETY

Risk Level (Marks Assigned)	Description
1	No Risk for the Health and Safety and / or negligible inconveniences related to economic Costs
2	Limited Risk for Health and Safety
3	Moderate Risk for Health and Safety
4	Significant Risk for Health and Safety of the Staff of the Facility or Contractor or, Limited risk to the Public
5	Significant Risk for the Health and Safety of the Staff of the Facility or Contractor as well as to Public Health and Safety

The risk varies with the probability of an undesirable event multiplied with its consequences. In the early phases of the performance of the activity or the production of the item, the probabilities of undesirable events may be unknown. However, a qualitative level of the risk can be obtained by analysing the hazards which can lead to undesirable events. Complex activities require more detailed assessments.

(b) The Risk Related to Project Phase of Development

An error in the early phase of the life of the item has a strong probability to negatively influence to a lesser expanse than an error in a later stage of work.

This happens because each phase has its own self – assessment processes, corrective actions procedures, peer review, etc., which would fix the flaws and the faulty procedures, and that would ensure that the necessary actions were taken to prevent recurrence.

Table I-5 shows the levels of risks associated with each phase of the activity or production of the item.

TABLE I-5. RISK DUE TO THE PHASE OF DEVELOPMENT / IMPLEMENTATION OF THE PROJECT

Risk Level Assigned	Phase	Description
1	Applied Research	Fundamental systematic studies for the complete scientific knowledge or understanding of the matter
2	Technology Development	Systematic application of knowledge derived from research for direct use for the purpose of complying with specific requirements
3	Advanced Development	Effort which leads to a certain application or product. Advanced development can employ several scientific disciplines and explore innovation in a certain area of one or more technologies
4	Engineering Development	Systematic use of knowledge and understanding obtained through research and development, for obtaining detail design, construction and performance tests, production capacities, power systems prototype reliability, pilot plants, research facilities
5	Production / Operation	Production – Making of the item, in required amount, as raw material or with other parameters fulfilling the existing specifications or requirements Operation – Bringing the system or Project from Prototype or Testing Plan Stage or Operational Pilot to an operational Status at normal scale to fulfil specified objectives.

(c) Risk Due to the Complexity of the Activity

The risk associated with an error during the work to complete an activity or an item will be proportionate to the complexity of the activity. Table I-6 emphasizes the level of risk according to the complexity of the activity / item.

TABLE I-6. RISK DUE TO COMPLEXITY OF THE DESIGN /ACTIVITY

Risk Level Assigned	Description
1	Effort is minimal and simple
2	The efforts are significant but simple
3	The effort exhibits a certain complexity. It may include minor experiments related to the design and, the construction of experiments and / or testing equipment.
4	The effort is extended and complex. It may include major design and construction of experimental equipment and testing devices
5	The effort is extended and complex. It may include design and construction at large scale of experimental equipment and testing devices

(d) Risk Due to the Importance of the Data

The risk associated with major flaws, during the design, or with the failure to comply to the Regulatory and the Client's Quality Assurance expectations, during the works of execution of items / performing activities, frequently can be reflected in the importance of data.

Incorrect or erroneous (corrupt) information can terminate an item or an activity, which could perform acceptably in a different situation. Different activities or sources can also offer data generated by other activities, which frequently have no connection to that specific work.

Table I-7 presents the level of risk in accordance with the importance of the data generated for a certain project.

TABLE I-7. DATA IMPORTANCE

Risk Level Assigned	Description
1	Process / data are of information category
2	Data / processes will be used only in conceptual designs and will be verified before start of the activity
3	Erroneous data / processes will not have serious impact on Environment, Public Health and Safety and, costs and planning of the Project
4	Erroneous data / processes will have serious impact on costs and / or planning of the activity, but impact on the Environment, Public Health and Safety will be reduced
5	Erroneous data / processes will have serious impact on costs and / or the Environment, Public Health and Safety

— **Step 3: The Aggregate Risk**

In accordance with the graded approach methodology, Step 3 deals with integrating the applicable factors that have just been assessed and ranked to support decision making. In Romania, this is done by aggregating the risks (applicable factors) mentioned before. The approach for aggregating the risk is described below. The process is described in a regulation used by both the regulatory body and the licensed organizations, 'Norms for Establishing Graded Implementation of the requirements for Quality Management Systems in Item Fabrication and Services for Nuclear Installations (NMC-13)' [I-10].

The Aggregate Risk can be assessed by summing the levels caused by the risks on the environment, Health and Safety, the risk associated to the phase (stage) of maturity of the activity, the risk associated to complexity, and to the importance of data. This level of aggregate risk can be used with a table similar to Table I-8 to select the adequate quality standards as references for the Quality Management System.

Table I-8 is an example for a grading Scheme. Note that this Scheme may be not adequate for all organizations. The organizations which perform activities or services for the nuclear installations establish the Category for the graded implementation of QMS, using the methodology provided by the regulation NMC–13 [I-10], based on their own experience and specific activity (construction, procurement, maintenance and repairs services etc.). The organizations which manufacture SSCs, or parts of those, have to build these items, according to the QMS category already established by the design authority in the design phase.

TABLE I-8. ASSIGNMENT OF THE QUALITY MANAGEMENT CATEGORY

Aggregate Risk Level	Graded Implementation Category	Standards / Regulations
>14	I	The Quality Management System must address all the elements from the Romanian Regulation CNCAN nr. 66/30.05.2003: Norms on the General Requirements for the Quality Management Systems Applied in the Build, Operation, and Decommissioning of Nuclear Installations [I-7] and also, the specific regulations for the activities performed [I-8, I-9].

TABLE I-8. ASSIGNMENT OF THE QUALITY MANAGEMENT CATEGORY (cont.)

Aggregate Risk Level	Graded Implementation Category	Standards / Regulations
9 to 14	II	The Quality Management System must address all the elements from the Romanian Regulation CNCAN nr. 66/30.05.2003: Norms on the General Requirements for the Quality Management Systems Applied in the Build, Operation, and Decommissioning of Nuclear Installations, 2004 [I-7].
4 to 8	III	The Quality Management System must address all the elements of the adequate standards.
Less than 4	IV	The Quality Management System must be documented.

The regulatory body carries out its own assessment. As every part of the assessment made by experts is prone to subjective bias, the regulatory body minimizes the bias by using an interdisciplinary team of experts. Regulatory body staff, using expertise on plant design, safety analysis and other technical disciplines, assesses the correctness of the classification provided by the licensees. For safety significant activities, regulatory body staff also performs independent verifications. Additional information on this approach is provided later in this example.

The assignment of Graded Implementation Category (I through IV) is made in accordance to the Aggregate Risk Level as per Table I-8.

(a) Team Approach Within the Regulatory Body

The level / category of risk described is defined by a multidisciplinary team. This approach minimizes the subjective biases which might exist in the process. It also creates a forum of the working groups from different sections of the regulatory body, management and licensee, in a such way that the risks, costs and planning of an activity or manufacture of a product, can be understood by all parties involved. The approach is developed and documented by the licensees and it is independently verified by the regulatory body.

The level of risk can be established for the site of a nuclear facility, parts of such a site, or items and activities within this site. The categories assigned for each nuclear facility can be put in a manner similar to that shown in Table I-9.

TABLE I-9. EXAMPLE OF CLASSIFICATION FOR DIFFERENT NUCLEAR INSTALLATIONS IN ROMANIA

Activity / Type of Installation	Environment, Personnel Health and Safety	Phase	Complexity	Data Importance	Total	Graded Implementation Category
Nuclear Power Plant (NPP) Cernavoda	5	5	4	4	18	I
Project A (Tritium Removal Facility)	4	4	3	4	15	I
Project B (Reactor Liquid Metal Coolant ‘ALFRED’)	4	3	4	2	13	II
Project C (Research Reactor ‘TRIGA’)	3	5	3	2	13	II

TABLE I-9. EXAMPLE OF CLASSIFICATION FOR DIFFERENT NUCLEAR INSTALLATIONS IN ROMANIA (cont.)

Activity / Type of Installation	Environment, Personnel Health and Safety	Phase	Complexity	Data Importance	Total	Graded Implementation Category
Project D (Spent Fuel Interim Storage Facility - DICA)	4	5	3	4	16	I

The Category for the Graded Implementation obtained from Table I-9 should be a fair estimate of what is required for the item or activity under study.

However, it ought to be verified by the regulatory body if this category covers adequately the system functions or processes requiring control to enable prevention or correction of the possible nonconformances. For the same type of nuclear facility, in different phases of its life, the number of nonconformances may increase. That is why, the same function of the system can obtain different categories in different phases of the facility lifecycle.

Differences may appear from a facility to another in the same category due to the level of maturity of the management system and the specific activity (operation, construction etc.). The management system has to also encompass all functions specified in [I-7]. If doubt remains, or in contentious cases, examination should be made of the detailed requirements of this regulation, in the light of the characteristics of the item or the activity, before making the final choice. The example from the Project A from Table I-9 is presented below.

Project A was assessed with the Category I for the Quality Management System. However, the regulatory body decided that the same level of rigor specified in [I-7] is not mandatory for all 10 criteria – elements of the Quality Management System (see Table I-10).

For Project A, as shown in Table I-10, each function of the Quality Management System described in [I-7] was individually evaluated using the method of assigning the Values (Levels) of Risk from Tables I-4 to I-7. The category assigned to a particular function of the QMS may differ from the category of the overall management system. For some functions, the requirements can be relaxed from Category I to Category II (like in Functions 1, 2, 4, 7, 9, 10). This grading will allow the management a risk informed allocation of resources. Before finalizing the selection of category for each function of the Quality Management System, it needs to be verified that those categories meet all applicable jurisdictional requirements (Boiler and Pressure Vessels Authority, Health and Safety, Fire Protection, etc.).

TABLE I-10. EXAMPLE APPLICABLE TO PROJECT A - FROM TABLE I-9

Function of Quality Management System	Environment, Personnel Health and Safety	Phase	Complexity	Data Importance	Total	Graded Implementation Category
1. Definition of the Quality Management System	1	4	3	3	11	II
2. Training and Qualification of Personnel	2	4	3	3	12	II

TABLE I-10. EXAMPLE APPLICABLE TO PROJECT A - FROM TABLE I-9 (cont.)

Function of Quality Management System	Environment, Personnel Health and Safety	Phase	Complexity	Data Importance	Total	Graded Implementation Category
3. Quality Improvement, use of obtained experience	3	4	5	4	16	I
4. Documents and Records	1	4	4	4	13	II
5. Products, Processes and Practices Control	3	4	5	4	16	I
6. Design	3	4	5	4	16	I
7. Procurement	1	4	4	4	13	II
8. Verification. Inspection and Tests	3	4	5	4	16	I
9. Self-Assessment	1	4	4	4	13	II
10. Independent Assessment. Audit	1	4	4	4	13	II

This grading is in line with the following principles stated in the regulations:

— The design is of a chief importance for the quality assurance of the safety items. Experience has shown that 50% of causes that induced loss of quality of products is due to design flaws or mistakes. That is why design review is considered of the most importance and, the Graded Implementation category given for design and, use of experience is I.

— In the case of safety related components manufactured in small numbers, the integral control needs to be applied. The modern approach for Quality Verification is the Total Control, including verification starting from the research and development phase, design phase, and all manufacturing stages. The Graded Implementation category for Products, Processes and Practices Control, Verification. Inspection and Tests, has to be I.

— For those functions related to the Quality Assurance Program, such as the Manual and Procedures of the QMS (1), Training and Qualifications of Personnel (2), Documents and Records (4), Self-Assessment and Audit (9, 10), the experience has shown that specifying too comprehensive a quality program will not ascertain a higher degree of assurance. Selection of the correct category (II) for the quality program was made considering that the installation in Project A does not contain nuclear fuel, but still contain a smaller source term of radioactive hazard and, also poses an explosion hazard.

Table I-11 provides an overview of the content of the Quality Management System and of the regulatory control functions. Variations from one category of QMS to another are by no means uniform. Table I-11 also specifies the regulatory functions (processes and sub- processes) which are planned to implement the control for each element of the Quality Management System. The documents required for submittal to regulatory body are required by the specific regulation, Requirements for Licensing of Management systems used for the Build, Operation, and Decommissioning of Nuclear Installations [I-11]. This regulation provides licensees with guidance in the process of licensing and regulatory oversight.

The Category I to Category II, reflected in the documents to be submitted to the regulatory body, can be observed in Table I-12. The variations between Category I and II are due to the fact that a less comprehensive quality management system supplemented by design assurance or other control measures might be applied when manufacturing or constructing an item or performing an activity are less safety significant. If Category II is allocated to a Quality Assurance Program Function in the execution of a product important for safety, the Program is completed with a Design Review process, which analyse if the design of that product fulfils the client′s requirements, applicable standards and regulations. Upon successful completion of the Design review and confirmation that all requirements are met, the product can be executed by the supplier. Through the authorization process (licensing of the suppliers), the regulatory body verifies that the licensee has the best methods to satisfy the requirements, and with specified costs. The authorization and regulatory control processes ensure that:

- Design companies have adequate methods and procedures
- There is a control of sub-designers in place
- There is interchangeability in detail design
- Health and safety regulations are observed
- Past experience is used
- Modern techniques are used, such as: Fault Tree Analysis, (FTA), Management Oversight and Risk Tree (MORT), Failure Mode and Effect Analysis (FMEA), Technique for Human Error Rate Prediction (THERP), etc.

TABLE I-11. GRADED APPLICATION OF REGULATORY PROCESSES AND SUB – PROCESSES AND ACTIVITIES RELATED TO THE SUPPLIERS OF NUCLEAR INSTALLATION - PROJECT A - FROM TABLE I-9

Criterion / Element of Quality Management System	**Graded Implementation Category**	**Regulatory Requirements Applicable**	**Regulatory Process Applicable**		**Documents submitted to Regulatory Body**
1. Definition of the Quality Management System	II	Authorization of Quality Management System of Organizations performing nuclear activities (siting, design, research and development, manufacturing, software development, procurement, construction, commissioning, operation, decommissioning, main suppliers of products and services)	Authorization. Review and assessment	Audits. Evaluation of MS Documents. Reporting Requirements	- Application, Management decision, CV, Job Descriptions. - Quality manual and system procedures. - Procedure for classifying the SSCs. - Procedure for establishing the Quality Plan. - Annual internal and external audits plan. - List of QMS Responsible Personnel licensed by CNCAN. - Copy of the decision of setting up the company

TABLE I-11. GRADED APPLICATION OF REGULATORY PROCESSES AND SUB – PROCESSES AND ACTIVITIES RELATED TO THE SUPPLIERS OF NUCLEAR INSTALLATION - PROJECT A - FROM TABLE I-9 (cont.)

Criterion / Element of Quality Management System	**Graded Implementation Category**	**Regulatory Requirements Applicable**	**Regulatory Process Applicable**		**Documents submitted to Regulatory Body**
2. Training and Qualification of Personnel	II	Authorization of Quality Management System of Organizations	Authorization. Review and assessment	Certification/ authorization is required for MS responsible personnel	Training programs. Training materials (if required)
3. Quality Improvement, use of obtained experience	I	Authorization of Quality Management System of Organizations.	Authorization. Review and assessment.	Audits. Evaluation of MS Documents.	Management Quality Assurance Review Report
4. Documents and Records	II	Authorization of Quality Management System of Organizations.	Authorization. Review and assessment	Audits. Evaluation of MS Documents.	- Quality manual and procedures. - Procedure for establishing the quality plan. - Annual internal and external audits plan.
5. Products, Processes and Practices Control	I	Authorization of Quality Management System of Organizations. Authorization of activities and Practices	Authorization. Review and assessment. Inspection	Evaluation of MS Documents. Reporting Requirements. Audits. Regulatory Body surveillance through HP/WP.	Quality Plans accepted by the Utility (licensee) is required to be submitted to Reg. Body in advance of the activity to be performed by contractors. Quality Plan requirement (similar Inspection and Testing Plan required by ASME); Reg. Body establishes HP/WP (In – House Inspection Hold Points / Witness Points) Reg. Body Surveillance of Maintenance Activity during HP/WP.
6. Design Assurance	I	Authorization of Quality Management System of Organizations.	Authorization. Review and assessment.	Evaluation of MS Documents. Audits.	Design specifications, manual, as required
7. Purchasing	II	Authorization of Quality Management System of Organizations.	Authorization. Review and assessment.	Evaluation of MS Documents. Audits.	Procurement Specifications, as required

TABLE I-11. GRADED APPLICATION OF REGULATORY PROCESSES AND SUB – PROCESSES AND ACTIVITIES RELATED TO THE SUPPLIERS OF NUCLEAR INSTALLATION - PROJECT A - FROM TABLE I-9 (cont.)

Criterion / Element of Quality Management System	**Graded Implementation Category**	**Regulatory Requirements Applicable**	**Regulatory Process Applicable**		**Documents submitted to Regulatory Body**
8. Verification. Inspection and Tests	I	Authorization of Quality Management System of Organizations. Authorization of activities and Practices		Evaluation of MS Documents. Reporting Requirements Regulatory Body surveillance through HP/WP.	Quality Plans, Material specifications
9. Self-Assessment	II	Authorization of Quality Management System of Organizations.	Authorization. Review and assessment.	Evaluation of MS Documents. Audits.	Management Reports
10. Independent Assessment. Audit	II	Authorization of Quality Management System of Organizations.	Authorization. Review and assessment.	Evaluation of MS Documents. Audits.	Audit Reports.

TABLE I-12. MATRIX COMPARISON OF QUALITY MANAGEMENT SYSTEM CATEGORIES

Requirement	**Category I**	**Category II**	**Category III**	**Category IV**
QUALITY MANAGEMENT SYSTEM				
Licensing	X	X	X	X
Organization (Capability & experience in nuclear field)	X	X	X	-
Quality Audits (Internal)	X	X	X	-
QUALITY MANAGEMENT SYSTEM DOCUMENTS				
Manual	X	X	X	X
Inspection and Test / Plan / Checklist	X	X	X	X
Procedures / descriptions	X	X	X	-
RECORDS				
Inspection and Test	X	X	X	-
Disposition of Nonconforming Items	X	X	X	X
Feedback or Corrective Action	X	X	-	-
Qualification of special processes, personnel, etc.	X	X	X	-
Records of Acceptable Contractors	X	X	-	-
Audit and Analysis of Audit data	X	X	X	-
SYSTEM FUNCTIONS				
Design Assurance	X	X	-	-
Document Control	X	X	X	

TABLE I-12. MATRIX COMPARISON OF QUALITY MANAGEMENT SYSTEM CATEGORIES (cont.)

Requirement	Category I	Category II	Category III	Category IV
Measuring and Test Equipment	X	X	X	X
In Process Inspection	X	X	X	X
Identification and Traceability of Items	X	X	X	-
Manufacturing and Construction	X	X	X	X
Special Processes	X	X	X	
Quality Records	X	X	X	X
Purchasing	X	X	-	-

I-4. USE OF A GRADED APPROACH DURING DEVELOPMENT OF RULES AND REGULATIONS FOR RESEARCH INSTALLATIONS IN THE RUSSIAN FEDERATION

In the Russian Federation the prescriptive regulatory approach is used for regulating nuclear facilities on the use of nuclear energy. As described in Appendix IV, the use of prescriptive tools and requirements raise additional challenges to the nuclear regulator if a graded approach is to be applied to the regulatory functions. In this case, some aspects should be considered in the rules and regulations to allow grading the applicable requirements in a manner commensurate with the magnitude of the radiation risks of the activities.

This section provides a practical example on how to apply the three-step methodology in Section 3.2 for a graded approach in the development of rules and regulations for research installations (i.e. research reactors, critical and subcritical assembles and accelerator driven systems) in the Russian Federation.

One of the results of this process is the development of a number of regulations that set different safety requirements in accordance with specific types of nuclear facilities. For example, Table I-13 presents the Russian Federal Rules and Regulations applicable to research installations. This regulatory framework is the basis for the practical example discussed here.

Changes on the existing nuclear rules and regulations and the development of new regulatory tools are part of the role of Rostechnadzor as a nuclear regulator.

TABLE I-13. LIST OF RUSSIAN FEDERAL RULES AND REGULATIONS APPLICABLE TO RESEARCH INSTALLATIONS

Number	Title
NP-033-11	General Safety Provisions of Research Installations [I-12]
NP-008-16	Nuclear Safety Rules for Critical Assemblies [I-13]
NP-009-17	Nuclear Safety Rules for Research Reactors [I-14]
NP-048-03	Nuclear Safety Rules for Pulsed Research Reactors [I-15]
NP-059-05	Nuclear Safety Rules for Subcritical Assemblies [I-16]
NP-075-19	Requirements for Contents of the Action Plans for Protection of Personnel in the Event of an Accident at Research Installations [I-17]
NP-028-16	Safety Rules for Research Installations Decommissioning [I-18]
NP-092-14	Periodical Safety Analysis of Research Installations [I-19]

TABLE I-13. LIST OF RUSSIAN FEDERAL RULES AND REGULATIONS APPLICABLE TO RESEARCH INSTALLATIONS (cont.)

Number	Title
NP-049-17	Requirements for the Format and Content of a Safety Analysis Report of Research Installations [I-20]
NP-027-10	Provision on the Procedure of Investigation and Accounting of Operational Occurrences at Research Installations [I-21]
NP-106-19	Provision on the Procedure for Declaring an Emergency and Prompt Transfer of Information in Cases of Radiation-Hazardous Situations at Research Installations [I-22].

— Step 1: Identify the decision associated with the development or revision of regulations and/or guidance that is required

This Step 1 deals with assessing the existing Russian rules and regulations for nuclear research installations in order to identify whether revisions are needed. The purpose is to make them suitable for new technologies, existing conditions or lessons learned from incidents that need to be considered in the regulatory framework.

The results of these assessments fall into one of three categories:

(a) New regulations or a thorough review of the existing regulations are required;

(b) The existing regulations are applicable but additional regulatory guidance needs to be issued;

(c) The existing regulations are fully applicable to the new technology and, therefore, no revisions are needed.

The rules and regulations for the research installations (see Table I-13) are the starting point for the assessment of regulatory documents efficiency and a necessity of their revision or new documents development.

— Step 2: Determine which factors are applicable to the decision

In this example, the specific applicable factors used are type of nuclear research installation, stage of life cycle, systems and components, category of potential radiation risk and existing regulatory regulations.

Different types of facilities were considered in this example, such as research reactors, pulsed research reactors, critical and subcritical assemblies and accelerator-driven facilities. The safety requirements, including information to be provided in the safety analysis reports, may be different amongst these installations and commensurate with the respective radiation risk.

The stage of the lifetime of the installation is also a factor to be considered. For example, the radiation risks associated with a facility under decommissioning are different from those for a new research reactor or a facility that need to have its operating licence extended.

Structures, systems and components are considered taking into account their safety significance and the associated safety functions. The analysis might also include aspects associated with failure rate, design technology and maintenance, ageing management, periodical inspections and repair.

The categories of potential radiation risks are important to define requirements applicable to the operating lifecycle and to define emergency action plans.

— **Step 3: Integrate the applicable factors into the decision-making process.**

Considering the specific factors identified for the nuclear research installations, the existing Russian regulatory framework was reviewed by Rostechnadzor.

The analyses of the factors were based upon expert judgement and operating experience on the different types of facilities. A team of nuclear experts on research installations was used to weight the factors and decide which actions should be taken to revise the regulatory framework.

Table I-14 summarizes the main findings of the analyses made for the rules and regulations applicable to research installations, which are discussed below:

- It is possible to state that requirement grading has already been considered in the rules and regulations for factors like lifetime stage and safety significance of systems and components (see the cells with 'SG'). In such cases, the safety requirements were considered adequate and consistent with a graded approach. Therefore, revision is not required for these topics.
- In some cases, revision of the requirements is not even possible as there might be impacts on the nuclear safety of the installations in normal or abnormal situations. Table I-14 identifies such situations as 'SG'.
- It is also important to show that the category of the potential radiation risk has been implemented as an area to be revised and improved in the regulations considered in this example. Therefore, work on grading the requirements is currently in progress. Such situations are identified as 'GP' in Table I-14.
- The analysis also identified that the current safety requirements stated in NP-092-14 (Periodical Safety Analysis of Research Installations) [I-19] should be revised with regard to the factors identified as 'GP'. This work is currently in progress.

TABLE I-14. AREAS TO BE REVISED WITHIN THE DIFFERENT RULES AND REGULATIONS APPLICABLE TO RESEARCH FACILITIES

FRR	Differentiation trends			
	Type of nuclear research installation	Stage of the lifetime	Systems and components	Category of potential radiation risk
NP-033-11 [I-12]	SG	SG	SG	GP
NP-008-16 [I-13]	NA	SG	SG	GP
NP-009-17 [I-14]	NA	SG	SG	GP
NP-048-03 [I-15]	NA	SG	SG	GP
NP-059-05 [I-16]	NA	SG	SG	GP
NP-075-19 [I-17]	NA	NA	NA	SG
NP-028-16 [I-18]	SG	NA	SG	SG
NP-092-14 [I-19]	GP	NA	GP	GP
NP-049-17 [I-20]	SG	SG	SG	GP
NP-027-10 [I-21]	NA	NA	SG	GP
NP-106-19 [I-22]	NA	NA	NA	SG

Legend:: –

NA	–	Provision for requirement grading is 'not applicable'.
GP	–	Provision for requirement grading is 'in progress'.
SG	–	Safety requirement is 'sufficiently graded'.

The sections below provide detailed information on the rationale applied by Rostechnadzor and the results of the use of the methodology for the use of a graded approach with regard to the analysis of the specific factors identified in Step 2.

(a) Grading based on a type of research installation

Federal rules and regulations NP-008-16 [I-13], NP-009-17 [I-14], NP-048-03 [I-15] and NP-059-05 [I-16] contain nuclear safety requirements specifically for research reactors, critical and subcritical assemblies and accelerator-driven systems, so these documents are already graded based on a type of research installation and further grading on this factor is not applicable. Currently, the requirements of NP-092-14 [I-19] are definitely not graded, however, the grading process has already started. Provisions of NP-033-11 [I-12], NP-028-16 [I-18] and NP-049-17 [I-20] contain several requirements which regulate research installations of specific type. For example, the requirement of p. 3.3.2.9 NP-033-11 [I-12] relates only to research reactors and states that specific measures shall be provided to avoid criticality during initiation of emergency cooling system.

Also, the requirements of p. 3.3.2.5 NP-033-11 [I-12] relate only to subcritical assembly and allow it to operate without emergency shutdown system if criticality is not possible in any state of subcritical assembly. In accordance with requirements of p. 27 NP-028-16 [I-18] critical and subcritical assemblies may not dispose a decommissioning project if special safety measures for decommissioning are implemented and decommissioning programme is developed. According to requirements of p. 10.1 NP-049-17 [I-20] safety analysis report (SAR) of research installation shall contain information on nuclear safety provisions which depends on a type of installation. SAR of research reactor shall mandatorily contain description of reactivity effects, effects of xenon poisoning after power change and etc. SAR of pulsed research reactors shall provide parameters on neutron pulse, SAR of critical assembly shall contain maximum possible reactivity value, SAR of subcritical assembly or accelerator driven system shall include maximum value of effective multiplication factor.

(b) Grading based on a life cycle stage

NP-028-16 provides requirements for safety during decommissioning of research installations, thus this document is graded based on a life cycle stage. Scope of NP-092-14 [I-19] includes only research installations which have a licence for utilization, which is issued for more than 10 years, therefore these requirements are also graded on a life cycle stage. On the contrary, requirements of NP-027-10 [I-21], NP-106-19 [I-22] and NP-075-19 [I-17] are independent from a period of a life cycle stage so that they cannot be graded on this basis. Documents NP-033-11 [I-12], NP-008-16 [I-13], NP-009-17 [I-14], NP-048-03 [I-15], NP-059-05 [I-16] and NP-049-17 [I-20] are graded based on a life cycle and contain special requirements for safety on stages of construction, utilization and decommissioning of research installation. For example, chapters III, IV, V, VI and VII of NP-033-11 [I-12] have general requirements for a project, construction, commissioning, utilization, radiation protection measures in emergency and requirements for decommissioning of research installation. Chapters IV and V of НП-009-17, chapters 2 and 3 of NP-048-03 [I-15], chapters IV and V of NP-008-16 [I-13] and chapters 2 and 3 of NP-059-05 [I-16] contain requirements for nuclear safety in commissioning and utilization of research reactors, pulsed research reactors, critical and subcritical assemblies. These chapters provide requirements for commissioning works, power operation as well as temporary and permanent shutdown of installation. Besides, the provisions of p. 10 – 12 of NP-049-17 [I-20] state that different information shall be presented in SAR of research installation depending on a life cycle stage.

(c) Grading based on systems and components

NP-075-19 [I-17] provides requirements for the action plans for protection of personnel in the event of an accident so the grading based on systems and components factor is not applicable for this document. Similarly, NP-106-19 [I-22] contains the criteria and procedure for declaring emergency, procedure for prompt transfer of information and requirements to measures taken by the operating organization to ensure emergency response and depend only on the maximum possible impact of an accident at the facility on the health of the population and personnel. The requirements of NP-092-14 [I-19] are not graded on this parameter, however the grading and subsequent change of a document is in process. Requirements of NP-033-11 [I-12], NP-009-17 [I-14], NP-008-16 [I-13], NP-048-03 [I-15], NP-059-05 [I-16], NP-028-16 [I-18], NP-049-17 [I-20] and NP-027-10 [I-21] are already graded on the basis of systems and components and contain different requirements for different systems of research installations. For instance, chapter II of NP-033-11 [I-12] has general requirements for classification of research installation systems and components. Paras 13 – 45 of NP-009-17 [I-14]and chapter 2 of NP-048-03 [I-15] contain requirements for nuclear safety of a reactor core and other systems that are important for safety. Analogical requirements for critical and subcritical assemblies are provided in chapter III of NP-008-16 [I-13] and chapter 2 of NP-059-05 [I-16]. In accordance with requirements of annex 4 of NP-049-17 [I-20] and chapter II of annex of NP-028-16 [I-18] description of systems that are important for safety shall be provided in the SAR of the research installation. Also, in accordance with p. 32 NP-028-16 [I-18] during decommissioning the operator needs to establish regular maintenance procedures for systems that are important for safety, such as ageing management, periodical inspections and repair. Failure of any system or component in case of normal operation violation influences on categorization of violation in accordance with INES. The requirements for categorization are provided in annex 2 of NP-027-10 [I-21].

(d) Grading based on potential hazard

Potential hazard categories for nuclear facilities are established in accordance with the requirements of OSPORB-99/2009 ‘Main sanitary radiation safety rules’. Currently the requirements of NP-033-11 [I-12], NP-008-16 [I-13], NP-009-17 [I-14], NP-048-03 [I-15], NP-059-05 [I-16], NP-092-14 [I-19], NP-049-17 [I-20] and NP-027-10 [I-21] are not graded on this basis, however the grading is planned to be implemented in future. It should be mentioned that NP-075-19 [I-17], NP-106-19 [I-22] and NP-028-16 [I-18] are already graded on this basis. For instance, in accordance with p. 29 of NP-075-19 [I-17] actions of officials, including the personnel, participating in the elimination of the consequences of the accident should be developed taking into account potential hazard category of research installation and type of accident (local, regional or national). In addition, annexes 2 – 4 of NP-075-19 [I-17] contain the list of main actions of officials depending on potential hazard category. NP-106-19 [I-22] contains additional requirements for research installations with high potential hazard category, for example, the requirement for the creation and operation of an emergency center (separate from main and emergency control room). Also, the content of the research installation decommissioning database has to take into account potential hazard category (annex 2 of NP-028-16 [I-18]).

I-5. GRADED APPROACH FOR GENERIC DESIGN ASSESSMENT (GDA) PROCESS FOR REQUESTING PARTIES IN THE UNITED KINGDOM

In October 2019, the Office for Nuclear Regulation (ONR) published new ‘Generic Design Assessment (GDA) Guidance for Requesting Parties (RP)’ [I-23]. The guidance will be used for all future GDA work. A number of updates have been made to further enhance the effectiveness, efficiency and flexibility of the GDA process, whilst maintaining the high standards of safety, security, environmental protection and waste management it requires. It also maintains robustness and independence in regulatory decision-making.

The objective for GDA is to provide confidence that the proposed design is capable of being constructed, operated and decommissioned in accordance with the standards of safety, security and environmental protection required in Great Britain. For the RP, this offers a reduction in uncertainty and project risk regarding the design, safety, security and environmental protection cases so as to be an enabler to future licensing, permitting, construction and regulatory activities.

The following characteristics contribute to the objective of GDA by:

(a) enabling the regulators to interact with designers at an early stage, where they can have maximum beneficial influence. Any design changes required to address regulatory expectations are more easily implemented while the plant is still at the proposals stage rather than when construction has begun, or expensive plant items have been manufactured;
(b) employing a stepwise process, with the assessment becoming increasingly detailed at each Step. This allows the regulators to identify key design issues early in the process, thereby reducing the financial and regulatory risks for developers intending to construct a power station based on the design;
(c) being open and transparent regarding both the RP’s design and submissions, and the regulators assessments. Both the RP and the regulators will publish detailed information and the RP will promote a public comments process;
(d) distinguishing between generic and site-specific matters. This is particularly beneficial where a generic design is intended for construction on a number of different sites or where such detailed information is not yet available to the RP.

— Step 1: Identify the decision associated with the development or revision of regulations and/or guidance required.

The GDA process has been adopted since 2007 to assess GW-scale designs such as EDF Energy and AREVA UK EPR™ and the Westinghouse AP1000® designs, which completed GDA in 2012 and 2017 respectively. In 2013, the Hitachi-GE UK Advanced Boiling Water Reactor (ABWR) entered the GDA process and this was completed in 2017.

ONR’s new guidance reflects the changes seen in the nuclear industry in the decade since GDA was introduced, in particular the potential for Small Modular Reactor (SMR) designs (and other Advanced Nuclear Technologies) to enter GDA in the future.

In this example, ONR had to decide how to adapt the GDA guidance to accommodate design assessments for future SMR and more advanced technological design not yet deployed at the international level.

— **Step 2: Determine which factors are applicable to the decision, and how those factors are weighed.**

In this example, ONR had to consider a range of specific factors in order to reshape the GDA process:

(a) Different levels of technology maturity - GDA needed to offer more flexibility to better accommodate different levels of maturity of Advanced Nuclear Technologies (ANTs). For example, vendors may apply for regulatory assessments of concept designs and preliminary safety and security cases. On completion, ONR will issue a Step 2 Statement of assessment rather than a Design Acceptance Confirmation (DAC). This enhanced flexibility in the assessment activities will come accompanied by robust internal governance to agree scope of assessment that warrants deployment of regulatory resource and can therefore be accepted).

(b) Efficiency – The modernized GDA process needed to bring enhanced efficiencies to the process without changing its inherent objectives and advantages and without undermining the value of previous GDAs.

(c) Effective GDA entry process - There is a need for the GDA Entry Process to be sufficiently effective that it deters SMR designs with very low degrees of maturity to start the process. The new process needs to make provision for ONR to judge that proceeding with assessment of such designs would bring unnecessary high regulatory risks and thus would not warrant deployment of regulatory resources.

(d) Early engagement – The modernized GDA places needs to place greater emphasis on earlier engagement and agreement of scope and submissions. This will improve efficiency without sacrificing depth and extent of assessment. Earlier steps will need to have a much more extensive and deep technical content

— **Step 3: Integrate the applicable factors into the decision-making process.**

The modernized GDA now has 3 Steps which represents the most efficient way for ONR to conduct the assessment.

(a) GDA Step 1 is the initiation Step where matters such as the scope and timescales are agreed, and ONR's knowledge of the design and the RP's safety and security cases increases. Importantly, this Step includes the RP identifying any immediate gaps in meeting regulatory expectations and proposing how these will be subsequently resolved;

(b) GDA Step 2 is the fundamental assessment of the generic safety and security cases, to identify any potential 'showstoppers' that may preclude deployment of the design; and

(c) GDA Step 3 is the detailed assessment of the generic safety and security cases on a sampling basis.

At the end of each Step, ONR will provide an output which summarizes its regulatory position at that point in time, in addition to supporting assessment information. The outputs are:

— GDA Statement
— interim Design Acceptance Confirmation (iDAC)

— Design Acceptance Confirmation (DAC)

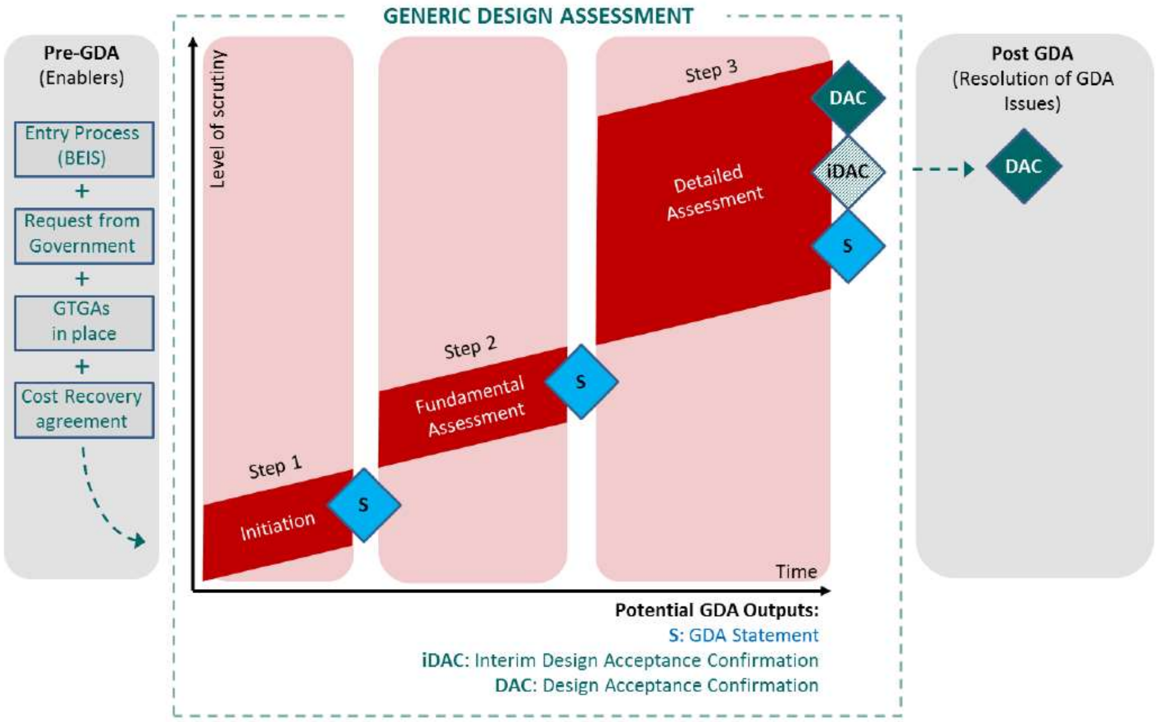

FIG. I-1. Generic Design Assessment

It is expected that most RPs would undertake a GDA with the objective of achieving a DAC, as for all previous GDAs completed to date. This provides the RP with the opportunity to address the most significant safety and security aspects. This offers the largest reduction in the uncertainty and project risks associated with the regulatory process for the proposed design, providing greater certainty for the intended operators and potential investors.

This approach might not be followed by all RPs as some of them may not wish or may not be able to target achieving a DAC at the commencement of a GDA. While this would not lead to the same level of reduction in uncertainty and project risk associated with the regulatory process as achieving a DAC, it may be better aligned with their overall project requirements. The decision to accept the scope, or otherwise, will be based on consideration of whether the assessment can be considered ‘meaningful including whether the deployment of regulatory resource is warranted.

(a) A graded approach to GDA:

TABLE I-15. EXAMPLES OF GRADED APPROACH TO GENERIC DESIGN ASSESSMENT – FULL PLANT DESIGN

Example	Description	Technical Assessment Topics	Steps	Output
Full plant design	This would be comparable to what has been completed for UK EPR^{TM}, AP1000^{R} and UK ABWR (for example a comprehensive review of reactor, nuclear steam supply system, fuel route, balance of plant and major essential support systems on a generic NPP site).	All	1,2 and 3	DAC, iDAC or no DAC

TABLE I-15. EXAMPLES OF GRADED APPROACH TO GENERIC DESIGN ASSESSMENT – FULL PLANT DESIGN

Example	Description	Technical Assessment Topics	Steps	Output
Major portions of a well-developed plant design (for example; one complete reactor module of a multi-module design where the interactions between modules are potentially safety significant but are declared out of scope by the RP)	A RP may wish to gain regularly confidence on the acceptability of one reactor module, but does not consider interactions between modules to be within scope. While ONR may consider it meaningful to assess the full safety and security justifications for one module in isolation, consideration of the interactions between modules would be needed to obtain a DAC from GDA. For those major portions that form part of the assessment the full breadth and depth of evidence expected by ONR would need to be available.	All	1, 2 and 3	GDA Statement
Major portions of the plant design (of limited design maturity)	A RP may wish to gain confidence that major portions of the plant design, that are integral to the design, are not "showstoppers". While all of the safety and security justifications for the full design would not be expected, significant supporting safety analysis and design justifications would still be required in order to understand the nuclear safety implications and interfaces of the systems, structures and components, to ensure that the assessment is meaningful.	Most	1 and 2	GDA Statement

TABLE I-16. EXAMPLES OF GRADED APPROACH TO GENERIC DESIGN ASSESSMENT – CONCEPTUAL FULL PLANT DESIGN

Example	Description	Technical Assessment Topics	Steps	Output
Conceptual full plant design	The RP may wish to gain regulatory confidence on the acceptability of a full plant design, but where the design and substantiation are not yet mature enough to complete a detailed assessment, then it would be possible to identify if there are any potential "showstoppers". This would need to include all significant aspects of safety and security in order for it to be considered meaningful.	Most	1 and 2	GDA Statement
Partial plant design (for example, a design where the deployment model relies on out of scope supporting systems, structures and components)	A RP may wish to gain regulatory confidence in some aspects of a plant design. The proposed scope does not include design features and safety significant systems, structures and components that ONR considers it necessary to assess in order to come to a reasoned regulatory judgement. It would therefore not be considered meaningful to assess this proposal, in the context of the objective for GDA (para. 8), and deployment of regulatory resource is not warranted.	Assessment not considered meaningful – no GDA undertaken.		

TABLE I-16. EXAMPLES OF GRADED APPROACH TO GENERIC DESIGN ASSESSMENT – CONCEPTUAL FULL PLANT DESIGN (cont.)

Example	Description	Technical Assessment Topics	Steps	Output
Distinguishing safety system (for example, the control and instrumentation technology and architecture)	A RP may wish to gain regulatory confidence on a different approach to an important safety system that is inherent to the design concept. The proposed scope does not include sufficient analysis and context to enable ONR to undertake a full and balanced assessment of the design. ONR in not in the position to qualify specific systems, structures or components which may be used in a range of applications. It would therefore not be considered meaningful to assess this proposal, in the context of the objective for GDA (para. 8), and deployment of regulatory resource is not warranted.	Assessment not considered meaningful – no GDA undertaken.		

I-6. GRADED APPROACH IN RULEMAKING IN U.S.

In response to the significant reactor accident at the Fukushima Dai-ichi facility in 2011, the U.S. NRC developed a 'lessons learned report' [I-24] to determine if any regulatory action was necessary for the U.S. operating nuclear reactors to enhance safety. The report resulted in several recommendations for Commission consideration, including requiring reliable hardened vent designs in BWR facilities with Mark I and Mark II containments, and enhancing spent fuel pool makeup capability and instrumentation for the spent fuel pool.

— **Step 1: Identify the decision associated with the development or revision of regulations and/or guidance required.**

In this case, the decision was whether to accept the recommendations in the Japan lessons learned report, and if accepting the recommendations, what were the appropriate regulatory tools to implement the recommendations.

— **Step 2: Determine which factors are applicable to the decision, and how those factors are weighed.**

In this example, the specific factors that were applicable were the type of facility, the industry experience based on significant events, the urgency with respect to the issue being addressed, and the regulatory tools available.

The regulatory tools available included issuance of a bulletin, issuance of an order, and development of a regulation. Regulations are generally time consuming, taking as long as two years to develop a final rule. Bulletins (1) request licensee actions and/or information to address significant issues regarding matters of safety, security, safeguards, or environmental significance that have great urgency, and (2) require a written response. An Order is a written NRC directive to modify, suspend, or revoke a licence; to cease and desist from a given practice or activity; or to take such other action as may be proper. Orders may be made immediately effective, without prior opportunity for a hearing, whenever the NRC determines that the public health, safety, interest, or common defense and security so requires. In such cases, the Order may provide, for stated reasons, that the proposed action be immediately effective pending further action.

The type of facility considered was the same design as the Fukushima plants, BWR with Mark I or II containments.

The significant event was the catastrophic flooding caused by the tsunami that struck the facility, resulting in a loss of all power and cooling flow to the reactors. This was a beyond-design-basis event for which the facility was unprepared.

Due to the nature of the event and widespread impact to the public with respect to radiation releases and evacuations, there was a great sense of urgency to ensure a similar event did not occur in the U.S.

— **Step 3: Integrate the applicable factors into the decision-making process**

Shortly after the Fukushima event, the NRC issued a bulletin [I-25] with the following objectives:

(a) To require that addressees provide a comprehensive verification of their compliance with the regulatory requirements of Title 10 of the Code of Federal Regulations (10 CFR) Section 50.54(hh)(2) [I-26];
(b) To notify addressees about the NRC staff's need for information associated with licensee mitigating strategies under 10 CFR 50.54(hh)(2) [I-26] in light of the events at Japan's Fukushima Daiichi facility in order to determine if 1) additional assessment of programme implementation is needed, 2) the current inspection programme should be enhanced, or further regulatory action is warranted;
(c) To require that addressees provide a written response to the NRC in accordance with10 CFR 50.54(f) [I-26].

10 CFR 50.54.hh (2) [I-26] requires that each licensee develop and implement guidance and strategies intended to maintain or restore core cooling, containment, and spent fuel cooling capabilities under the circumstances associated with loss of large areas of the plant due to explosions or fire.

In response to the recommendations from the lessons learned report, the NRC subsequently issued NRC Order on Mitigation Strategies (EA-12-049) on March 12, 2012 [I-27]. The Order required provisions for mitigation strategies for beyond-design-basis external events. An Order was issued because of the urgency associated with the event, and widespread stakeholder concerns. The NRC concluded that a sequence of events such as the Fukushima Dai-ichi accident was unlikely to occur in the U.S because of existing regulatory requirements and existing plant capabilities, and continued operation and continued licensing activities did not pose an imminent threat to public health and safety. However, the NRC concluded that additional requirements have to be imposed on licensees to increase the capability of nuclear power plants to mitigate beyond-design-basis external events. These additional requirements were needed to provide adequate protection to public health and safety. This Order required a three-phase approach for mitigating beyond-design-basis external events. The initial phase requires the use of installed equipment and resources to maintain or restore core cooling, containment, and SFP cooling. The transition phase requires providing sufficient, portable, onsite equipment and consumables to maintain or restore these functions until they can be accomplished with resources brought from off site. The final phase requires obtaining sufficient offsite resources to sustain those functions indefinitely.

The events at Fukushima demonstrated that reliable hardened vents at boiling-water reactor facilities with Mark I and Mark II containment designs are important to maintain core and containment cooling. The operators were unable to successfully operate the containment venting system early in the event. The inability to reduce containment pressure inhibited efforts to cool the reactor core. If additional backup or alternate sources of power had been available to operate the containment venting system remotely, or if certain valves had been more accessible for manual operation, the operators at Fukushima may have been able to depressurize the containment earlier. The NRC issued a second order, 'Issuance of Order to Modify Licenses with Regard to Reliable Hardened Containment Vents (EA-12-050)', on March 12, 2012, to address this concern [I-28].

Additionally, the NRC issued a third order on March 12, 2012, NRC Order on Spent Fuel Pool Instrumentation (EA-12-051) [I-29], requiring all licensees have a reliable means of remotely monitoring wide-range spent fuel pool levels. The lack of information on the condition of the spent fuel pools at Fukushima contributed to a poor understanding of possible radiation releases and adversely impacted effective prioritization of emergency response actions by decision makers. Reliable and available indication is essential to ensure plant personnel can effectively prioritize emergency actions.

The Commission determined that the spent fuel pool instrumentation required by this Order represented a significant enhancement to the protection of public health and safety and was an appropriate response to the insights from the Fukushima Dai-ichi accident.

On June 6, 2013, the NRC issued another order modifying the requirements of Order EA-12-050 [I-28]. This order, 'Issuance of Order to Modify Licenses with Regard to Reliable Hardened Containment Vents Capable of Operation Under Severe Accident Conditions (EA-13-109)', requiring licensees with Mark I and Mark II containments to "upgrade or replace the reliable hardened vents required by Order EA-12-050 with a containment venting system designed and installed to remain functional during severe accident conditions" [I-30].

The next step was to codify the requirements set forth in the Orders that were issued in response to the Fukushima event. The U.S. NRC rulemaking process is described in Management Directive 6.3, 'Rulemaking Process' [I-31]. A rulemaking plan is required for all rulemakings, except those that the Commission has explicitly delegated to NRC staff as a staff-delegated rulemaking. Commission approval of the rulemaking plan is required before the staff may initiate rulemaking activities.

The staff have to submit to the Commission a rulemaking plan for a proposed or direct final rulemaking action for Commission review and consideration. The rulemaking plan provides a preliminary outline of the scope and impact of the contemplated action sufficient for the Commission to determine whether the contemplated rule is needed. Commission approval of the rulemaking plan is required before the agency expends significant resources on the contemplated action.

The following rulemakings are exempt from the rulemaking plan requirement because the Commission has delegated them to the staff as staff-delegated rulemakings:

(a) The annual Revision of Fee Schedules rulemaking is delegated to the Chief Financial Officer (CFO).

(b) Certificates of compliance for spent fuel storage casks rulemakings are delegated to the Executive Director for Operations (EDO).

(c) Recurring rulemakings for incorporation by reference of American Society of Mechanical Engineers standards and related documents into Title 10 of the Code of Federal Regulations (10 CFR), Section 50.55a, 'Codes and Standards' [I-32], are delegated to the Director of the Office of Nuclear Reactor Regulation (NRR) as defined in Section III.B.8 of this directive.

(d) Administrative rulemakings (for administrative changes, such as updating addresses and phone numbers and correcting typographical errors) are delegated to the EDO and redelegated to the Director of the Office of Nuclear Material Safety and Safeguards (NMSS).

(e) Rulemaking plans do not need to be prepared for rulemakings that are mandated by statute or implement U.S. Government policy on export licensing controls, and involve no discretion as to the content of the rule. The Commission has not approved delegating to the staff the authority to initiate rulemaking for matters that require a limited exercise of discretion. To proceed with a rulemaking on these matters involving the exercise of minor levels of discretion, the staff have to request Commission approval to proceed with rulemaking.

(f) Periodic updates of the civil penalty amount.

The technical lead office is responsible for developing the regulatory basis, in coordination with the rulemaking project manager (PM). The regulatory basis often includes detailed information about the following:

(a) Why a current regulation or policy needs to be changed;

(b) Why alternatives to rulemaking are not the recommended options;

(c) Different approaches to resolve the issue;

(d) Supporting scientific, policy, legal, economic, or technical information;

(e) Stakeholder interactions in developing the technical portion of the regulatory basis and stakeholder views;

(f) Preliminary cost/benefit considerations;

(g) Any backfitting or issue finality considerations, as appropriate; and

(h) Any limitations on the scope and quality of the regulatory basis.

The staff will engage internal and external stakeholders during the development of the regulatory basis.

The staff will inform the Commission offices of significant stakeholder interactions through a Commissioner Assistant's Note or other appropriate communication.

The regulatory analysis process, an integral part of NRC decision-making, systematically provides complete disclosure of relevant economic information supporting a regulatory decision. The conclusions and recommendations included in a regulatory analysis are neither final nor binding but are intended to enhance the soundness of decision-making by NRC managers and the Commission. The NRC conducts rulemaking regulatory analyses using cost-estimating best practices that include methods for the treatment of uncertainty and assessing factors that are difficult to quantify.

A regulatory analysis helps ensure that:

(a) The NRC's regulatory decisions made in support of its statutory responsibilities are based on adequate information concerning the need for and consequences of proposed actions.

(b) Appropriate alternative approaches to regulatory objectives are identified and analysed.

(c) No clear, preferable alternative is available to the proposed action.

The NRC's regulations governing nuclear power reactors and certain nuclear materials licenses contain provisions that restrict the NRC's capability to impose new requirements on licensees or, in certain applications related to power reactors, to take a different position from a previous NRC position. These are denoted as backfitting and issue finality restrictions (issue finality is the terminology in 10 CFR Part 52, 'Licenses, Certifications, and Approvals for Nuclear Power Plants' [I-33]).

The Commission has recognized, in exceptional circumstances, that some proposed rules may not meet the requirements specified in the Backfit Rule but nevertheless should be adopted by the NRC. Hence, the Commission advised the NRC staff that it would consider, on a case-by-case basis, whether a proposed regulatory action should be adopted as an 'exception' to the Backfit Rule. The Commission decided to administratively exempt the Fukushima Orders from the Backfit Rule and the issue finality requirements in 10 CFR 52.63 [I-34] and 10 CFR Part 52 [I-33], Appendix D, paragraph VIII because of the unprecedented event, extensive stakeholder engagement, and broad endorsement for timely action.

With regard to a proposed rulemaking, the Commission may take one of the following actions:

(a) Approve the rulemaking action as submitted,

(b) Approve the rulemaking action subject to specified changes,

(c) Disapprove the rulemaking action entirely, or

(d) Direct that the rulemaking action be revised and issued or revised and resubmitted to the Commission for reconsideration.

In August 2019, the NRC issued a final rule, 10 CFR 50.155 [I-35], 'Mitigation of beyond design basis events', making NRC Order EA-12-049 [I-27], 'Order Modifying Licenses With Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis Events' (Mitigation Strategies Order), and Order EA-12-051 [I-29], 'Order Modifying Licenses With Regard to Reliable Spent Fuel Pool Instrumentation' (Spent Fuel Pool Instrumentation Order), generically applicable. The final rule was published in the Federal Register on August 9, 2019 (84 FR 39684 [I-36]) with an effective date of September 9, 2019.

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ANNEX II.

PRACTICAL EXAMPLES OF MEMBER STATES ON THE USE OF A GRADED APPROACH IN CORE REGULATORY FUNCTIONS: AUTHORIZATION

This annex collects practical examples from Member States of the use of a graded approach in different aspects of authorization. These contributions were developed by the contributing Member States based upon their own experience and describe how the general three-step methodology described in Sections 3.2 and 4.2 can be used.

This annex provides examples covering a wide range of possible applications of a graded approach. However, it is not comprehensive and additional applications, not covered herein, could also be envisaged by Member States.

II-1. GRADED APPROACH IN AUTHORIZATIONS OF NUCLEAR INSTALLATIONS IN CANADA

This example illustrates the application of a graded approach to authorization in Canada.

The CNSC's Commission tribunal is an independent, quasi-judicial tribunal and a court of record, with the powers, rights, and privileges necessary to carry out its duties and enforce its orders. It has a central role in CNSC operations and operates at arm's length from the government with no ties to the nuclear industry. The Commission may issue, renew, suspend in whole or in part, amend, revoke or replace a licence, or authorize its transfer for the following activities:

(a) possess, transfer, import, export, use or abandon a nuclear substance, prescribed equipment or prescribed information;
(b) mine, produce, refine, convert, enrich, process, reprocess, package, transport, manage, store or dispose of a nuclear substance;
(c) produce or service prescribed equipment;
(d) operate a dosimetry service for the purposes of this Act;
(e) prepare a site for, construct, operate, modify, decommission or abandon a nuclear facility; or
(f) construct, operate, decommission or abandon a nuclear-powered vehicle or bring a nuclear-powered vehicle into Canada.

— **Step 1: What authorizations are designated and delegated in Canada, and to whom?**

In general, the regulatory body is given statutory authority, and it may delegate certain authorizations to lower levels of the organization.

— **Step 2: Factors applicable to the decision**

In addition to the applicable general factors described in Section 3, the following specific factors are considered in the application of a graded approach in authorization of nuclear facilities:

(a) Type of regulated facility – the radiological hazards and complexity of the design of the facility will influence the level of authorization necessary to ensure safe conduct of the licensed activity.

(b) Mode of operation and utilization of the facility – authorization should address expected modes of operation for a facility, and to account for the overall purpose of the facility.

(c) Statutory requirements – requirements established by legal framework of the State.

(d) Types of authorization to be issued at various stages - permits and licenses, and the safety significance of changes requiring authorization.

(e) Level of stakeholder involvement – increased stakeholder interest will sometimes drive the perceived significance of an issue higher, resulting in increased authorization levels.

(f) The number of nuclear facilities to be regulated – large numbers of applicants and licensees may influence the necessity for delegation of authority.

— **Step 3: Integrate the applicable factors into the decision-making process.**

In view of the factors above, it has been established through the 'Nuclear Safety and Control Act' [II-1], and by the CNSC Commission tribunal, that the following authorizations may be carried out by CNSC staff:

- Authorizations maybe granted by the Commission or a person designated by the commission. Persons designated by the Commission are referred to as 'Designated Officers'.
- Delegation of the administration of licence conditions.

Large volumes of authorizations for certain regulated activities, and a large number of decisions pertaining to administration of licence conditions was a major factor in setting these lower-level authorizations. Further information regarding Designated Officers and delegated persons are provided below.

(a) Designated Officers

Under subsection 37(1) Nuclear Safety and Control Act (NSCA) [II-1], the Commission may designate a person as a Designated Officer (DO). Further, under subsection 37(2) and paragraph 65.01(b) of the NSCA, the Commission may authorize a DO to have specific statutory powers and to carry out authorities under the NSCA. Because of the statutory powers held by DOs, a decision of a DO is as effective as a decision of the Commission.

A DO may carry out authorizations and make regulatory decisions for lower-risk activities. The risk is based on complexity and the hazard, relative to other regulated activities. CNSC staff and managers in specific positions are designated as DOs and include:

- Senior staff
- Regulatory Programme Directors;
- Director Generals
- Vice-President, Technical Support Branch

— Executive Vice-president and Chief Regulatory Operations Officer, Regulatory Operations Branch

A DO may:

— certify and decertify prescribed equipment for the purposes of the NSCA [II-1];
— certify and decertify persons as qualified to carry out their duties under this Act or the duties of their employment, as the case may be. These persons include nuclear energy workers and other persons employed in a nuclear facility or other place where a nuclear substance or prescribed equipment is produced, used, possessed, packaged, transported, stored or disposed of.
— issue, renew, suspend in whole or in part, amend, revoke or replace, or authorize the transfer of the following licences:

  (a) Nuclear Substances, Prescribed Equipment and Prescribed Information
  (b) Dosimetry Services
  (c) Particle Accelerators, Irradiators, Teletherapy Machines, Brachytherapy Machines

— confirm, amend, revoke or replace any order made by an inspector; or
— authorize the return to work of persons whose dose of radiation has or may have exceeded the prescribed radiation dose limits.

(b) Delegated Persons

Delegation of the administration of licence conditions that may include a limit, requirement or hold point, which requires a licensee to meet certain criteria. Delegations are documented in the record of decision pertaining to the licence application and in the facility-specific licence and its accompanying licence condition handbook.

Delegations to CNSC staff include verification that specific criteria are met regarding:

— fitness-for-service of the facility to return to operation following a serious process failure;
— removal of hold points following major maintenance outages such as refurbishments, or implementation of improvements identified in periodic safety reviews; and
— changes to documents or operations proposed by licensees.

Information on these aspects is provided below.

(1) Authorization for consent to restart a reactor after a serious process failure

The following CNSC staff has the authority for consent to restart a reactor after a serious process failure:

— Director, Regulatory Programme Division
— Director General, Directorate of Power Reactor Regulation
— Executive Vice-president and Chief Regulatory Operations Officer, Regulatory Operations Branch

The written request for restart of the reactor is to include the following information:

— a description of the event;

- the causes of the event;
- the consequences and safety significance of the event;
- a recovery plan including corrective actions, and fitness for service assessment on the systems/components impacted from the failure if applicable. This needs to be completed prior to reactor restart;
- a statement regarding plant readiness to resume safe operation. This has to include any conditions that the licensee proposes to impose upon reactor restart and/or subsequent reactor operation to ensure safe operation of the nuclear facilities; and
- an extent of completion of the conditions mentioned in the statement regarding plant readiness to resume safe operation.
- the documentation and communication to licensee staff (including additional training, if necessary); and
- applicable historical operating experience (OPEX) review for comparable events.

(2) Regulatory Hold Points

In support of major maintenance outages, the Commission has delegated the authority for the removal of regulatory hold points for the return to service of each unit undergoing a major outage to the Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch.

For each of the regulatory hold points, the licensee has to submit Completion Assurance Documents (CADs). In addition to these CADs, the licensee needs to submit CADs following sustained operation at 100% full rated power that will specify activities that were completed between 35% and 100% full rated power. Each CAD has to present evidence that all pre-established conditions for removal have been met. Details on the pre-established conditions are documented in facility-specific licence condition handbooks.

(3) Authorization of changes to documents or operations proposed by licensees

Licensees have to conduct the activities described in their licence in accordance with the licensing basis, defined as:

- the regulatory requirements set out in the applicable laws and regulations;
- the conditions and safety control measures described in the facilities' licence and the documents directly referenced in that licence;
- the safety and control measures described in the licence applications and the documents needed to support those licence applications;

unless otherwise approved in writing by the Commission.

CNSC licences are not intended to unduly inhibit the ongoing management and operation of the facility or the licensee's ability to adapt to changing circumstances and continuously improve, in accordance with its management system. Where the licensing basis refers to specific configurations, methods, solutions, designs, etc., the licensee is free to propose alternate approaches as long as they remain, overall, in accordance with the licensing basis and have a neutral or positive impact on health, safety, the environment, security, and safeguards.

Licensee assess changes to confirm that operations remain in accordance with the licensing basis and provide written notification of changes to the facilities or their operation, including deviation from design, operating conditions, policies, programs and methods referred to in the licensing basis. In turn, CNSC staff verify that changes to licensee documents or the design of the installation to verify that the changes are in the safe direction and within the licensing basis. This consent is communicated to licensees by the Regulatory Programme Director.

If the proposed change is not in the safe direction, the licensee will have to obtain approval from the Commission Tribunal.

Not in the safe direction means:

- a reduction in safety margins,
- a breakdown of barrier,
- an increase (in certain parameters) above accepted limits,
- an increase in risk,
- impairment(s) of special safety systems,
- an increase in the risk of radioactive releases or spills of hazardous substances,
- injuries to workers or members of the public,
- introduction of a new hazard,
- a reduction of the defense-in-depth provisions,
- reducing the capability to control, cool and contain the reactor while retaining the adequacy thereof,
- causing hazards or risks different in nature or greater in probability or magnitude than those stated in the safety analysis of the nuclear facility.

II-2. OVERVIEW OF A GRADED APPROACH USED FOR AUTHORIZATION IN PAKISTAN

PNRA regulates all types of civilian nuclear facilities and radiation facilities. PNRA Ordinance III of 2001 [II-2] empowers the Authority for granting licenses/authorizations. Accordingly, all nuclear facilities in the country are licensed/authorized by PNRA. This licensing process encompasses all stages of the lifetime of nuclear facilities and includes various licenses and authorizations e.g. site registration, construction licence, fuel load permit, operating licence, revalidation of operating licence, licensing beyond design life, licence for decommissioning of a nuclear facility or closure and removal from regulatory control. As per regulatory framework, these authorizations and licenses are issued based on thorough review and assessment of licensing submissions to ensure safe operation. The licenses and authorizations normally impose certain generic and specific conditions according to the outcome of regulatory processes.

PNRA also performs licensing of main control room (MCR) operating personnel for nuclear facilities in order to ensure that qualified and trained personnel operate these installations according to national regulations and applicable codes & standards.

In applying a graded approach, responsibilities and powers for approval/issuance of authorizations/licenses has been delegated to different levels of management in the organization for different types of facilities.

II.2.1 Types of Authorizations

The different authorizations of nuclear facilities are divided in to three categories for effective regulatory control such as:

(a) Authorization/licensing stages of nuclear facilities

Depending on regulatory requirements, different authorization/licensing stages are defined in the regulations on licensing of nuclear facilities (PAK/909) [II-3]. A well-defined licensing process is followed for effective control during all stages of the lifetime of the nuclear facilities. Furthermore, the application of GA is important for some additional authorizations such as amendment of existing authorization/licenses.

(b) Authorization for specific activities

During the lifetime of the nuclear facilities, some specific activities also need authorization/approval from PNRA. These include but not limited to:

(1) Authorization for initial criticality of reactors;
(2) Authorization for restart up of nuclear facilities after routine and accidental/abnormal outages;
(3) Authorization for approval of safety related design modifications before implementation;
(4) Authorization for changes to the licensing basis documentation (Final Safety Analysis Report (FSAR), Technical Specifications (TS), Quality Assurance Programme (QAP)/Management System Manual (MSM), Emergency Preparedness Plans (EPP), Radiation Protection Programme (RPP), Radioactive Waste Management Programme (RWMP), Environmental Monitoring Programme (EMP), Physical Protection Programme (PPP), etc.).

(c) Licensing of Operating Personnel.

To ensure safe operation of nuclear facilities, licensing of NPPs and Research Reactors (RRs) operating personnel is also mandatory as per clause 11 of PNRA regulations on the safety of nuclear power plants operation (PAK/913) [II-4] and clause 11.2 of regulations on the safety of Nuclear Research Reactor(s) Operation (PAK/923) [II-5], respectively.

II-2.2 Application of GA for approval of Authorization/licensing of different stages of nuclear facilities

Facilities are categorized on the basis of radiological risk such as high-risk facilities (Nuclear Facilities) and low risk facilities (radiation facilities). The use of a graded approach for authorization is considered on the basis of these categorizations.

Based on the above categorization, the licensing/authorization authority is delegated to top management in the organization for all stages in case of nuclear facilities. Details are given in Table II-1.

TABLE II-1. LICENSING/AUTHORIZATIONS STAGES OF NUCLEAR FACILITIES AS PER PAK/909 [II-3]

No.	Authorization at Different Stages/Steps
1	Site Registration
2	Construction Licence
3	Permission for Commissioning
4	Permission to Introduce Nuclear Material into the Installation

TABLE II-1. LICENSING/AUTHORIZATIONS STAGES OF NUCLEAR FACILITIES AS PER PAK/909 [II-3] (cont.)

No.	Authorization at Different Stages/Steps
5	Operating Licence
6	Revalidation of Operating Licence
7	Licensing Beyond Design Life
8	Licence for Decommissioning of a Nuclear Facility
9	Removal from Regulatory Control

A Member (Executive) is authorized for approval of Authorization/Licenses for all the above mentioned stages/steps, amendment and extension in operating licence.

II-2.3 Application of GA for approval of Authorization of Specific Activities

The authority for approval of specific activities during licensing process is delegated to various management levels. Practical examples are given in Tables II-2 and II-3.

TABLE II-2. APPROVAL OF LICENSING DOCUMENTS, DESIGN MODIFICATIONS AND CHANGES IN OTHER REGULATORY APPROVED DOCUMENTS

No.	List of Documents	Approving Authority
1	SER/PSAR/FSAR	DG (T)*
2	Documents required under PNRA Licensing Regulations (EPP, RPP, PPP, QAP etc.)	DG (T)
3	Design Modifications	DG (T)
4	Change in already approved documents	DG (T)

* DG (T): Director-General (Technical)

TABLE II-3. PERMISSION TO CRITICALITY

No.	Activity	Approving Authority
1	Initial criticality of the plant	Member Executive - M (E)
2	Permission for criticality after refuelling outage/long shutdown	Director-General (Technical) - DG (T)
3	Permission for criticality after abnormal shutdown	Depends upon the safety significance of the event and dealt on case to case basis

II-2.4 Application of GA for approval of Licensing of Operating Personnel

The authority for approval, issuance and renewal of licenses to main control room (MCR) operating personnel of nuclear facilities is delegated to various management levels. Detail is given in Table II-4.

TABLE II-4. AUTHORIZATION OF LICENSED OPERATORS

No.	Licence	Approving Authority
1	Approval of MCR operator’s licenses	Director-General (Inspection and Enforcement) DG (I & E)
2	Annual renewal of MCR operators’ licenses	Regional Directors

II-2.5 Summary of a Graded Approach in Licensing/Authorization

GA is being applied with consideration of radiological risks associated with different facilities as licence approval authority is delegated to top management in case of nuclear facilities (higher risk facilities) while licence approval and issuance authority is delegated to line management (regional directors) in case of radiation facilities (lower risk facilities).

In case of licensing and authorization of nuclear facilities, GA is applied as follows:

- Licensing/authorization is approved by top management (Member executive)
- Authority for authorization of specific activities is delegated to top management (Member executive) and senior management (DG (T))
- Authority for approval of licenses to MCR operating personnel is delegated to senior management (DG (I & E))
- Authority for renewal of licenses to MCR operating personnel is delegated to line management (regional directors).

II-3. USE OF GRADED APPROACH IN LICENSING OF NUCLEAR FACILITIES IN THE RUSSIAN FEDERATION

In the Russian Federation a prescriptive regulatory approach is used for regulating nuclear facilities on the use of nuclear energy. As described in Appendix IV, the use of prescriptive tools and requirements raise additional challenges to the nuclear regulator if a graded approach is to be applied to the regulatory functions. In this case, some aspects should be considered in the order of inspections to allow grading the licensing process in a manner commensurate with the magnitude of the radiation risks of the activities.

This appendix provides a step 3 'Integrate the applicable factors into the decision-making process' of three-step methodology developed in this TECDOC for a graded approach in the licensing of nuclear facilities in the Russian Federation.

An order of licensing in the Russian Federation is established in accordance with chapter 5 of Federal Law No 170-FZ on 21.11.1995 'On the Use of Atomic Energy' [II-6], para. 5.3.2 of Russian Government decree No 401 on 30.07.2004 'On Federal Ecological, Technical and Nuclear Supervision Service' [II-7] and Russian Government decree No 280 on 29.03.2013 'On Licensing of Activities in Nuclear Energy Use' [II-8]. Special requirements for research installations licensing are provided in Administrative Regulation of Rostechnadzor No 453 on 08.10.2014 'Administrative regulations for providing of State Service on Licensing of Activities in Nuclear Energy Use by Federal Ecological, Technical and Nuclear Supervision Service' [II-9].

Licensing of facilities (including issue (reissue) of licenses and amendments, as well as revocation and resumption of licenses) is implemented by central office (CO) of Rostechnadzor and its territorial offices (TO). Authorities of Rostechnadzor central and territorial offices in licensing in nuclear energy depend on an applicant (Operator or Service Organizations - goods and services suppliers of the operator), stage in the life cycle and type of facility. Applicants list includes operators and service organizations, that apply to Rostechnadzor for a licence.

Licensing activities include (depending on an object) project activities, siting, construction, operation and decommissioning of the nuclear facilities.

Licensing of nuclear facilities (such as NPPs) is implemented by central office of Rostechnadzor (in case applicant is an operator) and by territorial offices (in case applicant is a service organization). However, licensing of subcritical assemblies' operators is implemented only by territorial offices and licensing of research installations is implemented only by central office of Rostechnadzor. Distribution of authorities between central and territorial offices of Rostechnadzor during licensing is shown in Table II-5.

TABLE II-5. DISTRIBUTION OF AUTHORITIES BETWEEN CENTRAL AND TERRITORIAL OFFICES OF ROSTEHNADZOR DURING LICENSING

Life Stage of the Nuclear Facility	**Type of Facility**	**Licensee**	
		Operator	**Service organizations**
		Who Authorizes in Rostechnadzor	
	Nuclear power plants		
	ENI	Central Office (CO)	Territorial Offices (TO)
Siting	Research reactors and critical assemblies		
	Subcritical assemblies	TO	TO
	NFCF	CO	TO
	Nuclear power plants		
	ENI	CO	TO
Construction	Research reactors and critical assemblies		
	Subcritical assemblies	TO	TO
	NFCF	CO	TO
	Nuclear vessels	CO	CO
	Nuclear power plants		
	ENI	CO	TO
Operation	Research reactors and critical assemblies		
	Subcritical assemblies	TO	TO
	NFCF	CO	TO
	Nuclear vessels	CO	TO
	Nuclear power plants		
	ENI	CO	TO
Decommissioning	Research reactors and critical assemblies		
	Subcritical assemblies	TO	TO
	NFCF	CO	TO
	Nuclear vessels	CO	TO
Closing	RWDS	CO	CO

Abbreviations for Table II-5:

ENI	experimental nuclear installations including prototypes of nuclear reactors;
NFCF	Comprises NF NFC: nuclear facilities of nuclear fuel cycle (enrichment facilities, reprocessing facilities etc.);
NM NFC	facilities for production, reprocessing and usage of nuclear fuel; and
RWDS	radioactive waste disposal site.

II-4. GRADED APPROACH APPLIED TO REGULATORY CONTROL FOR PERMISSIONING DECISIONS IN THE UK

ONR's permissioning process [II-10] enables it to "control the activities of duty holders and to respond to duty holders who require permission to start, continue or cease specified activities under relevant legislation. By this means, ONR exercises suitable, proportionate, targeted, regulatory oversight on such activities".

— **Step 1: Identify the proportionate level of regulatory control**

ONR needs to decide upon the level of regulatory control to exert for any authorization (permissioning decision), informed by a range of factors (described in Step 2). ONR has powers to:

(a) grant a licence to an applicant;
(b) attach conditions to the licence, and to vary or revoke those conditions;
(c) vary a licence, to reduce the area of the licensed site;
(d) consent to particular actions, usually to the commencement of a given activity;
(e) approve particular arrangements or documents, generally to 'freeze' them so they cannot be changed without ONR agreement;
(f) notify the licensee that it requires certain information to be submitted, for example a safety case;
(g) issue specifications to require the submission of particular documents for examination, or specify that something needs to be done in a particular way, for example the form in which radioactive waste is stored;
(h) issue agreements to proceed with an agreed course of action;
(i) direct the licensee to shut down particular operations;
(j) revoke a nuclear site licence.

— **Step 2: Determine which factors are applicable to the Authorization (permissioning) decision, and how those factors are weighed.**

In this example, ONR's scheme of delegation allows for a graded approach to seniority of regulatory staff and rigour of permission, depending upon the type of authorization.

The rigour and seniority with which ONR uses its formal powers, derived powers or flexible hold point control depends upon a range of factors:

(a) Risk and hazard potential;
(b) Complexity;
(c) Novelty;
(d) Margins of safety;
(e) Capability of the equipment;
(f) Effect on any principal/significant systems, structures or components;
(g) Previous regulatory history.

Although construction and inactive commissioning may not pose an immediate nuclear safety hazard, ONR may choose to permission these phases of a facility's lifetime using primary powers to get regulatory control in the development of plant operations (e.g. to prevent the foreclosure of options) to ensure the licensee has reduced risks so far as is reasonably practicable at the point the hazard could be realized.

ONR has found over the years that it is not always appropriate to use primary powers to put into effect regulatory control of an operation. Nevertheless, it remains desirable in the interests of nuclear safety for ONR to control and have oversight of some of the licensee's arrangements and operations or proposed operations. In these cases, regulatory control and oversight may be achieved through the use of 'secondary power' Licence Instruments.

The licensee is required to make and implement arrangements under many Licence Conditions (LCs). Through some of these LC arrangements, the licensee can choose to provide powers to ONR through which ONR derives power to permission selected activities on the licensed site. Such powers provided by the licensee for ONR are termed 'derived powers'.

The main advantages of ONR using secondary powers are that the licensee arrangements provide ONR with the flexibility to exercise proportionate regulatory control and to discharge this control in an efficient and effective manner. In addition, it allows the licensee (following consultation with ONR) the flexibility of updating the powers as circumstances change.

(a) Use of flexible 'hold point release' mechanisms

The permissioning of activities on a licensed site using derived powers is predominantly done by ONR issuing primary or derived power Licence Instruments (LIs), by persons with commensurate delegated authority. The activities most likely to require permissioning by exercise of primary or derived power LIs are those of greater safety significance and/or stakeholder interest.

In addition to LIs, the permissioning of activities on a licensed site can also be achieved by 'hold point control'. This occurs when a derived (or primary) power LI is not deemed proportionate to control lower safety significant proposals. Hold point control may be used to permission and/or ensure that the implementation of the proposal complies with their extant arrangements.

The mechanism for doing this is by defining regulatory hold points. How these hold points are established and released should be identified within the licensee's arrangements and considered fit for purpose by ONR.

— **Step 3: Integrate the applicable factors into the decision-making process:**

Exercising a flexible approach to permit activities is with the agreement of the licensee and at the discretion of ONR. Both ONR and the licensee need to be content with the powers derived in the licensee's LC compliance arrangements, and the arrangements made by the licensee to manage and respond to interventions made by ONR as part of the accepted process.

The licensee's arrangements for the provision of flexible permissioning should be clearly described in documents, which are acceptable to ONR for the purpose of facilitating regulatory control using these powers. This should include the use of LIs and may allow for ONR to exercise flexible hold point control. ONR inspectors engaged in permissioning should ensure they are familiar with the licensee's arrangements.

Delegation of authority to issue different levels of permission are set out below:

- the Chief Nuclear Inspector is the only person in practice who will carry out the functions of granting or withdrawing a Nuclear Site Licence under the Nuclear Installations Act 1965. The Chief Nuclear Inspector may decide, on a case by case

basis, that these functions may be carried out by a Deputy Chief Nuclear Inspector. Any such arrangements are made in writing.
- The CNI has delegated to divisional directors the power to: Amend licences; Grant consents and approvals and give directions; Vary or withdraw consents, approvals and directions.
- Authority to Issue specifications, agreements and notifications and Directions of consent during a nuclear emergency is delegated to a Superintending Inspector.
- Principal Inspectors are able to release hold points under flexible hold point control arrangements.

III-4.1. Example – Sellafield flexible hold point control

Sellafield hazard and risk reduction programmes are managed in a graded according to a 'Stream Activity Plan'. This plan is developed and agreed with the regulators to provide an overview of the safety significant stages within a given portfolio of work and identification of the Hold Points at which the ONR intends examination and hence require formal 'Agreement' to proceed, or indeed via less formal release mechanisms.

- 'Periodic review' is a key element of preparing a 'Stream Activity Plan', and agreed in a quarterly Licensee – Regulator meeting

- 'Each Stream Activity Plan' identifies the activity stages, decisions and Hold Points between activities, logic links within the streams. The 'Stream Activity Plan' allows agreement with the regulators on what depth of regulatory focus is required for the activities of the facility.

- 'Hold points for more formal Licence Instruments' such as key commissioning activities associated with hazard and risk reduction, particularly those involving higher risk activity associated with intentional break of containment

- 'Engagement Windows' are used as an alternative to a formal Hold Point for progression between stages of (typically) lower hazard activities. Progression of projects through Engagement Windows does not rely on request and receipt of regulator acknowledgement as for a Licence Instrument. Instead, documentation for agreed activities is submitted for information and the Engagement Window is then a 'window of opportunity' for the regulator to gain confidence in the specified activities.

II-5. GRADED APPROACH IN AUTHORIZATIONS OF NUCLEAR INSTALLATIONS IN THE US

II-5.1. Rulemaking Example

- **Step 1: Identify the required authorization**

Rulemaking authority for the NRC is vested in the Commission by the Atomic Energy Act of 1954, as amended (42 U.S.C. 2201) [II-11]. The Commission establishes rules and regulations to govern the civilian uses of nuclear materials and facilities in order to protect public health and safety, promote the common defense and security, and protect the environment.

The Commission has delegated the authority to develop, revise, and/or issue certain types of rulemakings to the NRC staff.

— **Step 2: Determine which factors are applicable to the decision, and how those factors are weighted**

The specific factors applicable to determine appropriate authorization for rulemaking activities include the type of rulemaking, statutory requirements, the level of stakeholder involvement, and the resource impact on licensees.

Statutory requirements carry the greatest weight. The Energy Reorganization Act of 1974 [II-12] allows the Commission to delegate certain regulatory functions to the NRC staff. For example, the Act states that the Director of Nuclear Reactor Regulation shall perform such functions as the Commission shall delegate, including principal licensing and regulation involving all facilities and materials licensed under the Atomic Energy Act of 1954, as amended, and associated with the construction and operation of nuclear reactors licensed under the Atomic Energy Act of 1954 [II-11], as amended. In addition, the Act states the Director of Nuclear Material Safety and Safeguards shall perform such functions as the Commission shall delegate, including principal licensing and regulation involving all facilities and materials, licensed under the Atomic Energy Act of 1954 [II-11], as amended, associated with the processing, transport, and handling of nuclear materials, including the provision and maintenance of safeguards against threats, thefts, and sabotage of such licensed facilities, and materials.

The type of rulemaking is another factor considered when determining appropriate authorizations. For instance, there are certain rules that require routine revision because of updating of codes and standards, or establishing annual fees for licensees. These types of rulemakings are repetitive in nature and generally do not require changes in policy; therefore, the Commission may delegate these types of rulemakings to the NRC staff.

Some types of rulemakings may elicit strong stakeholder interest that may result in the Commission retaining rulemaking authority instead of delegating to staff. The Commission may retain authority for rulemakings that may have a significant impact on resource requirements for licensees.

— **Step 3: Integrate the applicable factors into the decision-making process**

The Commission is responsible for the following:

- Directing the initiation and prioritization of rulemaking activities, including through the review, approval, and denial of rulemaking plans;
- Approving, modifying, or denying each advance notice of proposed rulemaking, proposed rule (including supplemental proposed rules), final rule (including direct final rules and interim final rules), and action on a petition for rulemaking.

The Commission has exclusive authority to issue rules concerning the following:

- A significant question of policy;
- Title 10 of the Code of Federal Regulations (10 CFR) Part 7, ‘Advisory Committees’ [II-13], and 10 CFR Part 9, Subpart C, ‘Government in the Sunshine Act Regulations’ [II-14], concerning matters of policy; and
- Issuance and revision of policy statements.

A rule involving a significant question of policy and has to be submitted to the Commission for approval and issuance if it (a) represents a major change in existing Commission policy; (b) addresses a major new issue; or (c) would result in a major commitment of resources by a class of licensee.

In determining whether a rule involves a significant question of policy, the technical lead office for the rulemaking action needs to consider the following:

- The impact of the action on licensees and the public;
- The degree of controversy that could be associated with the action;
- The existence of significant public health, safety, environmental, common defense and security, or safeguards issues;
- The applicability of existing precedent; and
- Resources that will be required for implementation.

(a) Delegations of Authority to the Executive Director for Operations (EDO)

The Commission has delegated some rulemaking authority to the EDO with the expectation that this delegation should improve the efficiency and effectiveness of the NRC's rulemaking process. In addition to assuring that all rulemaking is conducted in accordance with the Commission's general policy guidance and that all rules involving significant questions of policy are considered by the Commission itself, the Commission expects this delegation of rulemaking authority to strengthen the systematic development and timely completion of NRC rulemaking initiatives and to expedite the NRC rulemaking process by providing a mechanism for the prompt resolution of differing staff views.

The Commission has delegated the following rulemaking authority to the EDO:

- the authority to initiate and issue rules explicitly delegated to the staff. The Commission specifically delegated to the staff the incorporation by reference of American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code (BPV Code) [II-15] and Operation and Maintenance of Nuclear Power Plants (OM Code) in 10 CFR 50.55a, 'Codes and standards' [II-16], revisions to certificate-of-compliance rules; and rules that make corrections or administrative changes.
- the authority to initiate and issue certain rulemaking actions that do not raise a significant policy issue or are corrective in nature or result in a rule of a minor, corrective, or nonpolicy nature that does not substantially modify existing precedent (i.e. the incorporation of ASME Code cases, certificates of compliance, and statutorily mandated rules where there is no discretion).
- the authority to initiate and issue administrative rulemakings (such as updating addresses and phone numbers and correcting typographical errors).

The EDO has the following authority:

(1) The Commission has delegated to the EDO the authority to initiate and issue certain rulemakings. The Commission's delegation to the EDO includes the authority to issue preliminary proposed, draft proposed, and final versions of these rulemaking actions.

(2) After the Commission approves the rulemaking plan, the EDO may release preliminary proposed rule language and preliminary regulatory basis documents for

public review or comment. The staff have to notify the Commission before publicly releasing preliminary proposed rule language for a proposed rule that has not been submitted to the Commission.

i. The EDO may redelegate this authority, as appropriate, and has redelegated it to:
   — The Director of the Office of Nuclear Material Safety and Safeguards (NMSS),
   — The Director of the Office of Nuclear Reactor Regulation (NRR).

ii. The Directors of NMSS, and NRR may redelegate this authority to the appropriate staff level.

(3) The EDO delegates to the Director of NRR the authority to approve the following:

All rulemaking packages and associated Commission memoranda containing amendments to 10 CFR 50.55a, 'Codes and Standards' [II-16], pertaining to the incorporation by reference of the ASME BPV and OM Codes. This delegation of authority only applies to recurring 10 CFR 50.55a [II-16] rulemakings pertaining to Section III and Section XI of the ASME BPV Code [II-15], the ASME OM Code, and the related regulatory guides that approve or disapprove ASME Code cases.

The delegation of authority applies only to rulemakings that represent the updating of basic codes and standards previously approved by the Commission for incorporation by reference. In exercising this rulemaking authority, the Director of NRR shall seek the concurrences or the determination of no legal objection of all applicable NRC offices. This authority was delegated due to the routine nature of revising the current regulation, and they do not constitute changes in policy.

The Director of NRR may not redelegate this authority.

(4) The EDO has also designated design certification and other rulemaking activities related to new and advanced reactors to the Office Director level.

(5) The EDO redelegates to the Director of NMSS the authority to issue administrative rulemakings (for administrative changes, such as updating addresses and phone numbers and correcting typographical errors).

(b) Delegations of Authority to the Chief Financial Officer (CFO)

The Commission has delegated certain rulemaking authority to the CFO, specifically:

— the authority to initiate and issue a rule that revises the annual fee regulations in— (i) 10 CFR Part 170, 'Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, As Amended' [II-17], and

— 10 CFR Part 171, 'Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Material Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Programme Approvals and Government Agencies Licensed by the NRC' [II-18].

— the authority to develop and promulgate rules needed to carry out the CFO's responsibilities. The CFO's rulemaking authority does not extend to the promulgation of a proposed or final rule that involves a significant question of policy. Policy matters associated with the fee rules are resolved through separate Commission direction before they are included in rulemaking.

Again, these rulemakings are routine and do not constitute changes in policy.

II-5.2. Licensing Example

— Step 1: Identify the required authorization

The NRC uses a graded approach when determining appropriate authorities for licensing activities. Licensing activities include initial construction and operating licenses for nuclear facilities, renewed operating licenses, and licence amendments.

— Step 2: Determine which factors are applicable to the decision, and how those factors are weighted

The NRC considers the following factors in determining the appropriate authorizations: statutory authority, type of facility, number of nuclear facilities to be regulated, and stage of life cycle.

Statutory requirements are most heavily weighted when determining authorities. The type of facility is not a factor for authorizing the initial construction and operation of the facility; the Commission retains authority for issuing initial operating licenses. However, it is a factor for authorizing renewed licenses and licence amendments. Fuel cycle facilities pose a lower risk to the public, and therefore authorizations are delegated down.

The number of nuclear facilities is a factor in that the more facilities being regulated, the more licence amendments that will need to be processed. The NRC processes hundreds of licence amendment requests at any given time. In order to ensure licensing actions are authorized as efficiently as possible, this function is delegated to staff, as the Commission would be overwhelmed with the volume of licence amendments.

The stage in the life cycle of the facility is another factor considered under authorization. Authorization for initial construction and operating licenses may remain at the highest level of the regulatory body, where licence extensions which may be of a lesser scope, may be delegated to a lower level.

— Step 3: Integrate the applicable factors into the decision-making process

The statutory authority for licensing nuclear facilities in the U.S. originates in the Atomic Energy Act of 1954 (as amended) [II-11]. The Atomic Energy Act of 1954 (as amended) authorizes the NRC to issue 40-year initial licenses for commercial power reactors. Title 10 of the Code of Federal Regulations (10 CFR) Part 52, ‘Licenses, Certifications, and Approval for Nuclear Power Plants’ [II-19] states that the authority for issuing early site permits, design certifications, combined construction and operating licenses for operating nuclear power plants rests with the Commission.

10 CFR Part 54, ‘Requirements for Renewal of Operating Licenses for Nuclear Power Plants’ [II-20], describes the requirements for nuclear power plants to apply for licence renewals for a period of 20 years. The licence renewal review process provides continued assurance that the current licensing basis will maintain an acceptable level of safety for the period of extended operation. Since there is no change in the mode of operation, and the licence renewal process

is narrowly focused on ensuring licensees have aging management plans for passive, long-lived SSCs, the Commission has delegated the authority to issue renewed operating licenses for nuclear power plants to the Director of the Office of Nuclear Reactor Regulation (NRR).

The authority to extend operating licenses for non-power reactors (research and test reactors) is at the Branch Chief level because they represent an even lower risk to the public than operating nuclear power plants.

Authority for lower level licensing actions for operating nuclear power plants is delegated to lower level supervisors. Because of the large volume of licence amendment requests, Branch Chiefs are authorized to issue typical licence amendments with some exceptions. The Director of NRR maintains the authority to issue extended power uprates (seven percent or greater). For stretch power uprates (less than seven percent), that decision is delegated to a Division Director because these uprates generally require fewer plant modifications and a reduced review effort. Extended power uprates typically involve plant modifications, resulting in a more complex licensing review.

For fuel cycle facilities, authority to issue, renew, amend and terminate by-product, source and special nuclear material licenses resides at the Division Director level. This level is appropriate based on the reduced risk to the public posed by these facilities.

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[II-16] U.S. NUCLEAR REGULATORY COMMISSION, Codes and Standards, 10 CFR 50.55a, US NRC, Washington, DC (2019).

[II-17] U.S. NUCLEAR REGULATORY COMMISSION, Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, As Amended, 10 CFR 170, US NRC, Washington, DC (2015).

[II-18] U.S. NUCLEAR REGULATORY COMMISSION, Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Material Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Programme Approvals and Government Agencies Licensed by the NRC, 10 CFR 171, US NRC, Washington, DC (2015).

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[II-20] U.S. NUCLEAR REGULATORY COMMISSION, Requirements for Renewal of Operating Licenses for Nuclear Power Plants, 10 CFR 54, Washington, DC (2015).

ANNEX III.

PRACTICAL EXAMPLES OF MEMBER STATES ON THE USE OF A GRADED APPROACH IN CORE REGULATORY FUNCTIONS: REVIEW AND ASSESSMENT

This annex collects practical examples from Member States of the use of a graded approach in different aspects of the review and assessment function. These contributions were developed by the contributing Member States based upon their own experience and describe how the general three-step methodology described in Sections 3.2 and 4.3 can be used.

This annex provides examples covering a wide range of possible applications of a graded approach. However, it is not comprehensive and additional applications, not covered herein, could also be envisaged by Member States.

III-1. GRADED APPROACH FOR REVIEW AND ASSESSMENT OF MODIFICATIONS WITHIN BEL V (BELGIUM)

Bel V, Technical and Scientific Support Organization (TSO) and part of the Belgian Regulatory Body (RB), uses a graded approach for review and assessment of modifications submitted by the licensees of the nuclear facilities. The graded approach, integrated in Bel V’s internal management system, depends on the importance for safety and on the complexity of modification.

— **Step 1: Determine the scope and depth of the review based on applicable requirements.**

Mainly for historical reasons, the Belgian RB is composed of 2 parts: Federal Agency for Nuclear Control (FANC) and Bel V, organized as the TSO of the FANC. Bel V is in charge of most of the regulatory inspections and performs review and assessment.

In the Belgian regulatory framework, the licensees have to inform the RB about all intended modifications to their nuclear facilities. A first step of graded approach – both for the licensees and for the RB – is already embedded in the regulatory framework:

- ‘Important Modifications’ are those that require a revised Authorization Licence. A specific procedure is applicable. Example of such Important Modification is the replacement of steam generators.

- ‘Non-Important Modifications’ (NIM) are those that do not need a revised Authorization Licence but are safety related. They have to be assessed and formally approved by Bel V. It is required that the safety level has to be increased or proved as unchanged with the proposed modification.

- ‘Minor modifications’, having no safety impact. For them, no systematic regulatory review is required. Example of such Minor Modification is the replacement of a valve on a system that is non-safety related and for which corrosion, leak, fall and other adverse conditions cannot have any impact on safety-related SSC.

The Integrated Regulatory Review Service (IRRS) mission performed in 2013 gave a recommendation on the development of a graded approach for the modifications (NIM) that are to be assessed and approved by Bel V.

As the assessment and approval of NIM involves plant inspectors as well as safety analysts[4], representatives of both of them took part in the development of a tool with well-defined criteria to come to a graded approach.

The approach was developed in several steps:

- Defining and working out of the basic approach;
- Benchmarking on 10 NIM (taken from the past as being illustrative for different types of NIM), leading to some adaptations of the approach;
- the scoring tool was also modified: new or revised criteria and adapted weights so that the final scoring could match the engineering judgment (of the above mentioned working group) on the category to be selected for the NIM considered in this benchmark; this resulted in criteria and weights that are found adequate in the Belgian context (but maybe not applicable as such for other countries);
- Integration of the approach in the Bel V Management system (via the Processes on Inspections and on Safety assessment);
- 6 months test period;
- Evaluation of feedback;
- Fine-tuning of the approach and its application;
- Re-integration in the Bel V Management System.

The tool was first developed for nuclear power plants (NPPs). It was then adapted to the other nuclear facilities. This tool is an Excel sheet that has to be filled in when receiving a NIM within Bel V.

— **Step 2: Determine which factors are applicable to the decision, and how those factors are ranked.**

Basically, two factors are considered in the decision to be made regarding the graded approach to be applied for the assessment and the approval of the NIM:

- ‘Risk based’ part, for evaluation of the importance for safety of the NIM;
- ‘Performance based’ part, aiming at an evaluation of the complexity of the NIM.

This evaluation is performed by the inspector (see hereunder the ‘how in practice’).

(a) Ranking the Importance for safety of the NIM

Fourteen (14) questions are raised in the Excel sheet. For each of them, a yes / no answer is expected. If the answer is no, the score is 0. If the answer is yes, a score between 2 and 8 is given, depending on the importance of the item.

- For the NPP, the first three (3) questions are related to the classification of the SSC to be modified. If the SSC has a safety function (according to the Safety Analysis Report) and is directly connected to the primary circuit, or assessed as of top level of

[4] RB experts or specialists in dedicated safety related domains such as fire protection, mechanical structural integrity, neutronics, I&C.

safety significance according to PSA, the score is 8. If the SSC has a safety function (according to the Safety Analysis Report) and is not directly connected to the primary circuit, or assessed as of medium level of safety significance according to PSA, the score is 5. For other safety related SSC, the score is 2.

- The next question is whether the modification is on the licensee's organization or processes.
- Two (2) questions are related with the potential of common mode failure increase or decrease.
- Three (3) questions aim at identifying if the modification has a potential on the 3 main safety functions (control of reactivity, removal of decay heat, confinement of radioactive material). If a yes is answered, the score for this question is 6.
- If the modification can have an impact on more than one safety function, the score is 8.
- Three (3) questions are raised to score the impact on radiation protection and on releases.
- The last question is about the impact of the modification on the safe management of radioactive waste.

The highest score is kept, and a normalization formula is applied so to have a figure between 1 and 2 for the final scoring of the importance.

For other nuclear facilities, the questions are almost the same, with adapted wording (criticality instead of reactivity, no mention of PSA as they don't exist for non NPP) and adapted criteria (more emphasize on radiation protection and less on safety function 'removal of decay heat').

(b) Ranking the Complexity of the NIM

Seven (7) questions are raised in the Excel sheet. For each of them, a yes / no answer is expected. If the answer is no, the score is 0. If the answer is yes, a score between 1 and 6 is given, depending on the evaluated complexity. The same questions and the same scores apply for NPP and other nuclear facilities.

- The first three (3) questions score the involvement of only one, 2 or 3 or more than 3 expertise areas (for instance fire protection, electricity, mechanicals, radiation protection etc.) identifying the level of multi-disciplinarity of the NIM.
- A question is on the amount of licensee's documentation (safety analysis report, operating procedures etc.) that need to be adapted.
- A question is on whether the modification implies new, non-proven or complicated design.
- A question is on whether the modification is a precedent for future cases.
- The highest score is kept. It may be reduced by a factor 2 if similar modifications have been satisfactorily implemented in the past in same or equivalent installations.

As for the scoring of the importance, a normalization formula is applied so to have a figure between 1 and 2 for the final scoring of the complexity.

- **Step 3: Integrate the applicable factors into determining the optimal resource effort required that is commensurate with the scope and depth established for the review and assessment.**

The final scoring (R) is given by the multiplication of the scores related with the importance and the complexity. R is thus a figure between 1 and 4.

Three (3) categories are then defined:

- Category 1 ($R \geq 2.5$): Modification will be submitted to a detailed analysis;
- Category 2 ($1.5 \leq R < 2.5$): Modification for which only specific aspects will be analysed;
- Category 3 ($R < 1.5$): Modifications for which no technical analysis will be performed.

It has to be noted that room for final judgement is kept, with a justification to be documented in the Excel sheet. This final judgement is performed by the inspector and can be challenged by the safety analysts (see hereunder).

(a) How in practice?

When the inspector receives a modification file for a NIM, he has to perform a first screening in order to be able to apply the scoring sheet. This leads to the above-mentioned categorization. He may than create a work request to the safety analysts for Cat. 1 and 2 for the review and assessment, with reference to the scoring sheet.

(1) If the NIM has to be considered as a category 1, the work request will clearly indicate the expectations concerning the technical analysis, stressing that an in-depth analysis of the modification is requested. Different expectations (or scope of analysis) might be formulated for the different safety analysts involved. In particular, in case of a multi-disciplinary analysis, a leading expert is designated in charge of the consolidation of the analysis results. The deadline for execution and the estimated hourly budget for performing the work will also be indicated.

(2) If it's a category 2, the work request will clearly indicate the expectations concerning the technical analysis, indicating in particular the issues that should be examined. In particular, the inspector is often the best placed to indicate important focus points based on the context of the modification or past experience (for instance, similar modifications that were already treated and/or badly designed in the past, …). The work request needs to also indicate, if useful, those issues that do not need a technical analysis. The deadline for execution and the estimated hourly budget for performing the work will be indicated.

(3) If the NIM has to be considered as a category 3, the safety analysts are simply informed that a modification file has been introduced by the licensee.

The safety analysts have 1 week to agree on the proposed categorization or to propose another category if deemed necessary.

The analysis is then performed according to the agreed graded approach.

At the end of the review and assessment, the conclusions (approval, comments, questions, request for clarification…) for the categories 1 or 2 NIM are transmitted to the inspector for final check and transmission of the outcome to the licensee. For the category 3 NIM, the inspector may approve the modification without further technical analysis. Inspections are nevertheless performed to verify that even for low category modifications, the licensee comply with the regulations and correctly implement its modifications (check of the internal modification process implemented by the licensee). In that context, it has to be noted that the above mentioned categories are not communicated to the licensee.

This process and the associated tool were presented in 2017 during the IRSS follow-up mission. The recommendation was closed and a 'good practice' was furthermore identified.

(b) Practical examples

To give a better understanding of the method, three (3) real examples of NIM are given.

(1) Category 1 NIM (detailed analysis)

- Following the identification that some temperature transmitters on the containment spray system were not qualified, a NIM was created for their replacement by qualified ones.
- Rating the importance: the maximum weight (8) was selected on the question about the SSC, because the containment spray system has a safety function (according to the Safety Analysis Report) and is directly connected to the primary circuit, or assessed as of top level of safety significance according to PSA. Other possible criteria was on the main safety function 'confinement of radioactive material' but this give a weight of 6.
- After the normalization formula, the score for the importance is 2 (highest possible value).
- Rating the complexity: 2 expertise areas were identified as potentially involved in the further examination of the NIM, namely the Bel V experts involved in I&C and those in charge of the qualification of equipment. This lead to a complexity scoring of 3 (1,5 after use of the normalization formula).
- The multiplication of 2 and 1,5 gives a R value of 3, meaning that the NIM had to be analysed as a category 1.

(2) Category 2 NIM (only specific aspects will be analysed)

- Following the identification that some pressure and temperature transmitters on ventilation systems were not qualified, a NIM was created for their replacement by qualified ones.
- Rating the importance: the SSC have a safety function (according to the Safety Analysis Report) and are not directly connected to the primary circuit, or assessed as of medium level of safety significance according to PSA, so that the value is 5.
- After the normalization formula, the score for the importance is 1,625.
- Rating the complexity: 2 expertise areas were identified as potentially involved in the further examination of the NIM, namely the Bel V experts involved in I&C and those in charge of the qualification of equipment. This leads to a value of 3.
- As similar modification had been satisfactorily examined and implemented in the past in same or equivalent installations, this value was divided by a factor 2 (so to have 1,5 for scoring the complexity).
- The multiplication of 1,625 and 1,5 giving a R value of 2,4375, the NIM had to be analysed as a category 2.

(3) Category 3 NIM (no technical analysis performed)

- In the framework of a Fire Hazard Analysis, the licensee identified the need to better physically separate electrical cabinets related to the cooling of the spent fuel pool.
- Rating the importance: the SSC have a safety function (according to the Safety Analysis Report) and are not directly connected to the primary circuit, or assessed

as of medium level of safety significance according to PSA, so that the value is 5. The SSC is also important for the safety function ‘removal of the decay heat’ (weighted as 6). The maximum value to take into account for the two applicable criteria is 6.
- After the normalization formula, the score for the importance is 1,75.
- Rating the complexity: only 1 expertise area was identified as potentially involved in the further examination of the NIM, namely the Bel V experts involved in fire protection. This leads to a value of 1. The complexity scoring was thus of 1,2 after use of the normalization formula.
- The multiplication of 1,75 and 1,2 giving a R value of 2,1, so the NIM had normally to be analysed as a category 2. An engineering judgement was applied, considering the fact that the modification to be performed was in fact very simple (the electrical cabinets were unchanged, only the electrical cables were to be shortened or replaced by longer ones (identical model) so that increased physical separation could be gained).

This NIM was therefore classified in category 3. The involved safety analysts were informed and approved the above mentioned rationale.

III-2. GRADED APPROACH FOR REVIEW AND ASSESSMENT (ENVIRONMENTAL ASSESSMENTS, SITE EVALUATION AND SITE PREPARATION) FOR A RANGE OF NUCLEAR INSTALLATIONS IN CANADA

This annex provides examples of the regulatory focus and effort for the review and assessment of a site preparation licence application for a range of reactor technologies.

— **Step 1: Determine the regulatory focus and effort for the review and assessment of a site preparation licence application for a range of reactor technologies.**

The following information is provided:

- High-level descriptions of the reactor facilities (power level, complexity and novelty);
- Scope and criteria for the ERA;
- Description of site preparation activities, and applicable criteria; and
- Factors to consider in determining the extent of the review and assessment of the ERA and licence to prepare site submissions.

The technologies considered are:

- Nuclear Battery: ~ 600 kW in size
- High Temperature Gas Reactor: ~10 MW in size
- Traditional NPP: ~600-1000 MW in size

(a) Background on Site Evaluation, Site Preparation and Environmental Risk Assessment

Site evaluation is a process that continues throughout the lifetime of the proposed facility, to ensure that the facility’s design basis and safety case remains current with changing environmental conditions or modifications to the facility itself. Site evaluation is based on, in a large part, an environmental risk assessment (ERA).

An ERA is a systematic process that identifies, quantifies and characterizes the risk posed by contaminants (nuclear or hazardous substances) and physical stressors in the environment. It is a practice or methodology that provides science-based information to support decision-making and to prioritize the implementation of mitigation measures.

ERA topics include:

- Atmospheric environment
- Surface water environment
- Aquatic environment
- Geological and hydrogeological environment
- Terrestrial environment
- Ambient radioactivity
- Human health and non-human biota

Under site evaluation, this information is used to assess whether a site is suitable for the construction and operation of the nuclear reactor facility (or nuclear installation).

Site preparation activities include, but are limited to:

(a) construction of site access control measures;
(b) clearing and grubbing of vegetation;
(c) excavation and grading of the site to a finished elevation;
(d) installation of services and utilities (domestic water, fire water, sewage, electrical, communications, natural gas) to service the future nuclear facility;
(e) construction of administrative and support buildings inside the future protected area;
(f) construction of environmental monitoring and mitigation systems; and
(g) construction of flood protection and erosion control measures.

In addition, site preparation activities may involve construction of facility structures, systems and components (SSCs), including:

(a) facility foundation structures (including support pilings)
(b) facility intake and outlet channels and structures (including cooling ponds, cooling towers and related connections to the ultimate heat sink)
(c) non-nuclear facility SSCs, such as a plant water treatment plant, if it can be shown that the design of these systems will be independent of the reactor technology(ies) being considered and will be sufficient for any reactor technology proposed for the site

ERA requirements and guidance for reactor technologies are found in REGDOC-2.9.1, Environmental Protection: Environmental Principles, Assessments and Protection Measures, version 1.1 [III-1] and CSA standard N288.6, Environmental risk assessment at class I nuclear facilities and uranium mines and mills [III-2].

Site Preparation requirements and guidance for reactor technologies are found in REGDOC-1.1.1, Site Evaluation and Site Preparation for New Reactor Facilities [III-3].

(b) Technologies considered

(1) Nuclear Battery (~ 600 kW)

— ~600 KW electrical
— Solid State, Passively cooled
— Heat Pipe Primary Heat Transport
— No moving mechanical parts
— LEU TRISO fuel (3x108 particles)
— Graphite Moderator
— 15 Year life span
— Core Dimensions – 2.5 metre diameter, 2 metre height
— Core buried in ground
— Passive safety which can't be overridden
— No need for immediate human action
— 600°C Operating Fuel Temperature (700°C with control rods withdrawn)

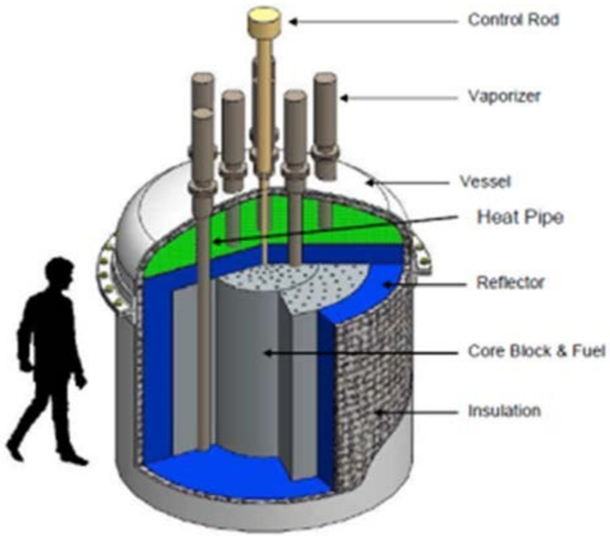

FIG. III-1. Nuclear Battery

(2) High-temperature Gas Reactor

— 5 MW electrical
— Helium Heat Transport System
— Graphite block moderator
— Up to 20-year life span
— Core Dimensions (RPV ~10 m high, 3 m diameter)
— Facility is 20 m tall (partially subterranean)
— Graphite block moderator
— Passive air residual heat removal system
— Passive shut down via negative reactivity coefficient with increased temperature
— Also has rod-based shutdown system and active residual heat removal

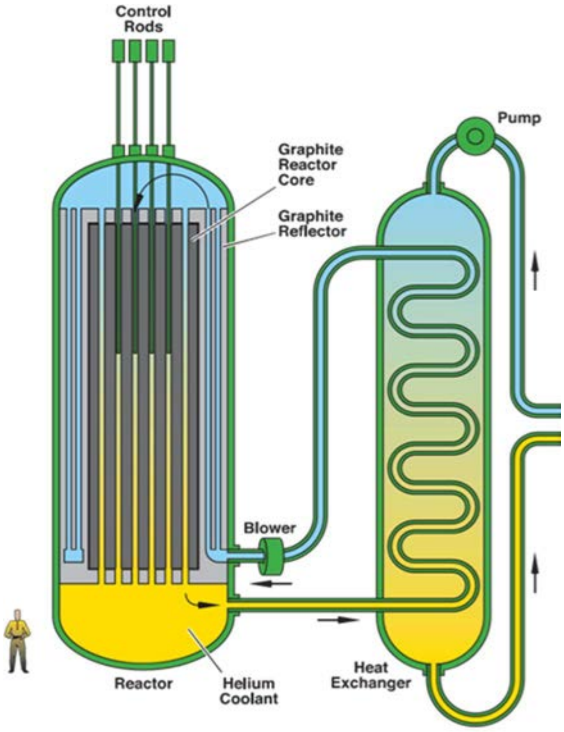

FIG. III-2. High-Temperature Gas Reactor (adapted from [III-4])

(3) Traditional NPP

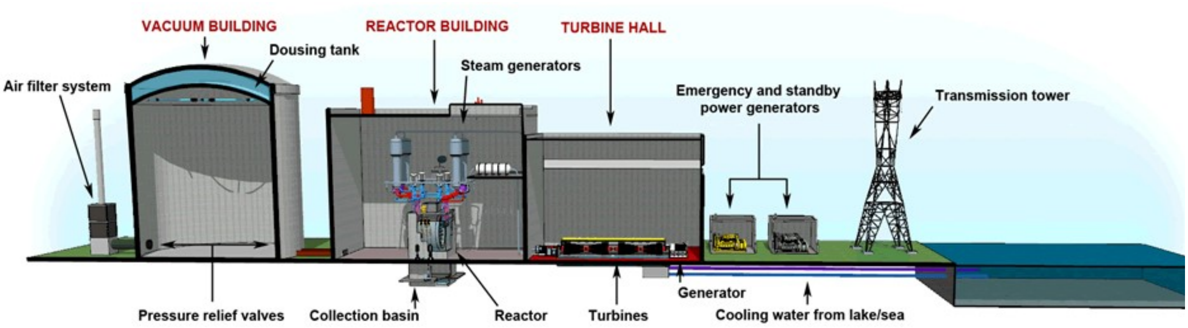

FIG. III-3. Traditional NPP

- ~750 MW electrical
- Heavy Water Moderator and Heat Transport
- Online Fuelling
- On site fuel storage
- 2 active redundant shut down systems
- Active cooling, with passive backup in the event of power loss
- Many backup emergency systems to mitigate accident consequences
- Operators, maintenance and security on site 24/7
- Relatively large plant and complex systems when compared with previous 2 SMRs

Information on the factors used in the assessment (Step 2) and on the integrated assessment (Step 3) is provided below.

(c) Determining the size of the Study Areas

Key considerations include:

- Proposed footprint and layout of structures
- Excavation depth
- projected release to the environment under postulated accident conditions

FIG. III-4. Footprint of a study area

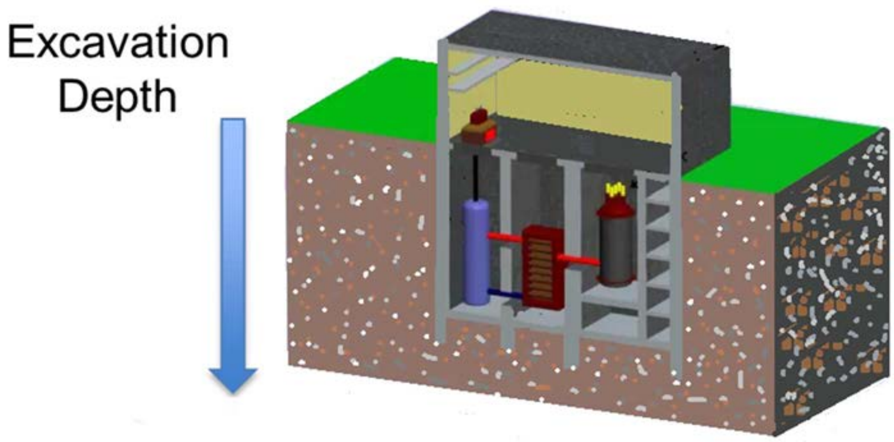

FIG. III-5. Excavation depth

(1) Study Areas

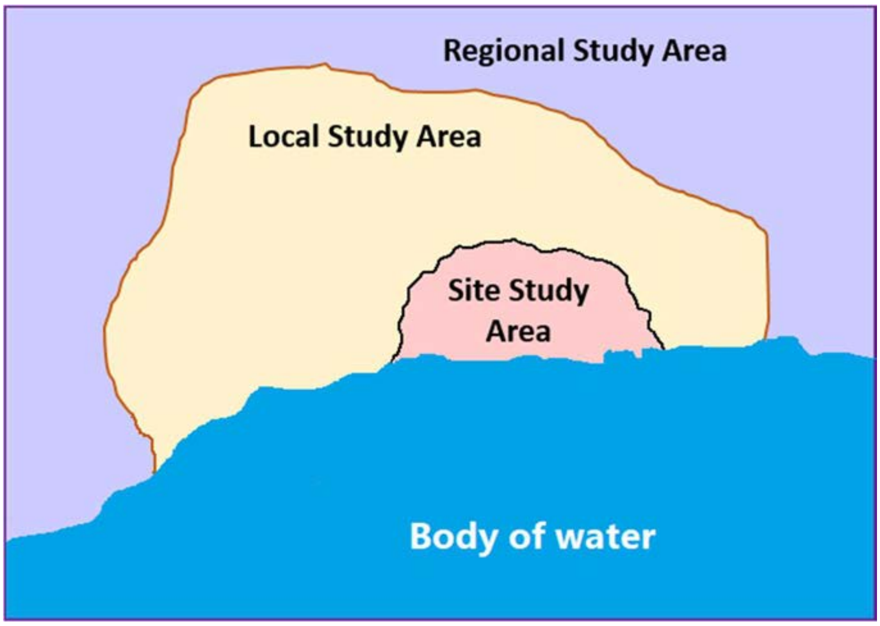

FIG. III-6. Types of study areas

(2) Study Area Sizes: Nuclear Battery

Considerations

- Expected to have very small footprint
- Near surface location
- Projected negligible or very small release to the environment under accident conditions

Conclusions

- Small Study Area
- A limited amount of data to support site characterization would be needed
- Accident and malfunction analysis is straightforward due to simple design

(3) Study Area Sizes: HTGR

Considerations

- Small HTGR is expected to have a moderate size footprint
- May be located deep in the ground to address security issues by design
- Projected small release to the environment under accident conditions

Conclusions

- Expectation of a small Study Area
- A limited amount of data to support site characterization would be needed
- Accident and malfunction analysis is moderate due to a design that is of moderate complexity and has few systems

(4) Study Area Sizes: NPP

Considerations

— NPP will have a large footprint
— Deep excavation
— Projected larger releases to the environment under accident conditions

Conclusions

— Large Study Area
— Amount of data to support site characterization is extensive
— Accident and malfunction analysis is extensive due to a complex design with several systems

(d) Considerations for the study areas and resulting focus and effort for the review and assessment for the three technologies are presented below.

(1) Size of Study Areas for Reactor Technologies: Informing Environmental Risk Assessments (ERA) and Site Evaluation

TABLE III-1. CONSIDERATIONS ON SIZE OF STUDY AREAS FOR REACTOR TECHNOLOGIES

Factors	Nuclear Battery (~ 2 MWth)	High-temperature Gas Reactor (~ 10 MWth)	Large Water-cooled NPP (> 1000 MWth)
• Proposed footprint: layout of structures in the final layout state • Excavation depth • Proposed exclusion zone (including size and boundary) and proposed emergency planning zones	• Nuclear battery is expected to have a very small footprint • Near-surface location • Negligible release during accidents • Study areas are small • Limited amount of data to support site characterization would be needed • Accident and malfunction analysis is straightforward due to simple design	• Small HTGR is expected to have a moderate size footprint • May be located deep to address security issues by design • Small release during accidents • Study areas are relatively small • Limited amount of data to support site characterization would be needed • Accident and malfunction analysis is moderate due to a design that is of moderate complexity, and has a few process and safety system	• NPP will have a large footprint • Deep excavation • Larger release during accidents • Study areas are large • Amount of data to support site characterization is extensive • Accident and malfunction analysis is extensive due to a complex design, and has several process and safety systems

The regulatory focus and effort across most topics in Site Evaluation and ERA are proportional to the size of the study area (data collected). The study area is based on:

— footprint;
— excavation depth;
— area impacted by normal operation, and accidents and malfunctions.

(2) Licence to Prepare Site: Consideration of topics in the Safety Case

The topics of physical design, safety analysis and operating performance are technology-dependent:

— the plant footprint and depth of excavation is size dependent
— the selected cooling technology will impact the extent of excavation / earthworks
— the presence and size of the exclusion zone and emergency planning zones and associated land use implications is dependent on the limiting credible accident(s)
— a preliminary, system-level, safety analysis is needed to support the design. The extent of safety analysis is proportional to complexity, novelty, potential harm and uncertainty in the design

All other topics in a safety case are generally technology-neutral

(e) Considerations for the regulatory focus and effort for reviews in the areas of physical design, safety analysis and operating performance are provided in the following tables.

(1) Physical Design

TABLE III-2. CONSIDERATIONS ON PHYSICAL DESIGN

Factors	**Nuclear Battery (~ 2 MWth)**	**High-temperature Gas Reactor (~ 10 MWth)**	**Large Water-cooled NPP (> 1000 MWth)**
• Design of any permanent feature that may support facility safety • As pertaining to site preparation: information on the design measures such as flood protection and erosion control.	• Nuclear battery is expected to have a very small footprint. • Review of design is simple due to very few, if any permanent features	• Small HTGR is expected to have a moderate size footprint, but may be located deep to address security issues by design • Exclusion zone and emergency planning zones are likely to be relatively small • Cooling needs are to be determined, but it is likely air-cooled • Some earthworks may be necessary	• NPP will have a large footprint, with deep excavation. • Exclusion zone and emergency planning zones are likely to be relatively large (similar to that for the Darlington New Nuclear Project) • Likely that access to two ultimate heat sinks is needed (a Fukushima-related requirement). • Earthworks will be extensive

(2) Safety Analysis

TABLE III-3. CONSIDERATIONS ON SAFETY ANALYSIS

Factors	Nuclear Battery (~ 2 MWth)	High-temperature Gas Reactor (~ 10 MWth)	Large Water-cooled NPP (> 1000 MWth)
• Hazard Analysis, • Supports establishment of emergency planning zones & bounding envelope parameters	• Small number of Postulated Initiated Events • Deterministic safety analysis dominated by external events • Probabilistic safety analysis complexity likely low but influenced by passive and inherent behaviours and simple design • Severe accident analysis simpler • Consequences very limited in area	• Small number of Postulated Initiated Events • Deterministic safety analysis dominated by external events • Probabilistic safety analysis complexity likely low but influenced by passive and inherent behaviours as well as design complexity • Severe accident analysis simpler • Consequences very limited in area	• Significant complexity of Postulated Initiated Events due to complex design • Deterministic safety analysis needs to consider both external events and complex internal events • Severe accident analysis is complex • Consequences could be more wide ranging in area.

(3) Operating Performance

TABLE III-4. CONSIDERATIONS ON OPERATING PERFORMANCE

Factors	Nuclear Battery (~ 2 MWth)	High-temperature Gas Reactor (~ 10 MWth)	Large Water-cooled NPP (> 1000 MWth)
• Operating performance includes an overall review of the conduct of the licensed activities and the activities that enable effective performance. • The area that site preparation activities are conducted on, and extent of excavation are technology-specific • Site preparation activities involve developing the foundation for the facility – it needs to be done right.	• Nuclear battery has a small footprint, so the cleared area is small and the excavation is not deep • Site preparation activities are minimal and likely deferred to construction	• HTGR has a medium-sized footprint, so the cleared area is not extensive, but excavation may be deep (to address security-by-design) • Site preparation activities are moderate – mainly due to excavation	• NPP has a large footprint, so the cleared area is large. Excavation is deep due to the size of the facility • Site preparation activities are moderate

To summarize, the extent of safety and control measures governing the licensed activity is informed by:

- Novelty of activities (uncertainties);
- Complexity of activities; and
- Analysis of potential for harm.

III-3. GRADED APPROACH FOR REVIEW AND ASSESSMENT OF AN APPLICATION FOR AN AUTHORIZATION TO CONSTRUCT A REACTOR FACILITY IN CANADA

This example provides an approach for establishing the regulatory effort for the review and assessment of a construction licence application in Canada.

— **Step 1: Determine regulatory effort for the review and assessment of the application**

The scope of the assessment is primarily established by the topic and objectives. The depth of the assessment is primarily established by the topic, objectives, review criteria and review procedures.

— **Step 2: Factors to consider in establishing the effort for review and assessment of a construction licence application**

Factors to consider in developing the scope and depth of reviews are presented below.

(a) Establishing the Scope of the Review

The specific area of technical review, as defined in the applicable Chapter, Section or sub-Section of REGDOC-1.1.2, Licence Application Guide: Licence to Construct a Nuclear Power Plant [III-5], along with objectives should be considered in establishing the scope of the review. This regulatory document is based on the IAEA's GS-G-4.1, 'Format and Content of the Safety Analysis Report for Nuclear Power Plants' [III-6].

(b) Establishing the Depth of the Review

The review of the construction licence application is comprised of the review of a large number of 'topics' that correspond to the chapters, sections and sub-sections of REGDOC-1.1.2 [III-5]. Topics being considered in the construction licence application pertain to the licensed activity (construction and fuel-out commissioning of the facility), and to the design and safety analysis of the facility.

The topics may be broadly separated into 2 groups, for the purposes of establishing the depth of the review:

(1) Group 1 topics are of greater importance, and may include:

- Programmes, processes and procedures for the safe conduct of construction and fuel-out commissioning activities;
- Safety analysis methodologies to demonstrate that the design of the installation meets regulatory requirements; programs, processes and information that pertain to many aspects of design;

— Design of SSCs important to safety (per section 7.1 of REGDOC-2.5.2, Design of Reactor Facilities: Nuclear Power Plants) [III-7];
— SSCs whose design and operational characteristics need to be taken into account in the design of safety systems (e.g. reactor core behaviour under normal and accident conditions[5]).

Figure III.7 depicts Group 1 topics pertaining to reactor design, and their inter-relations.

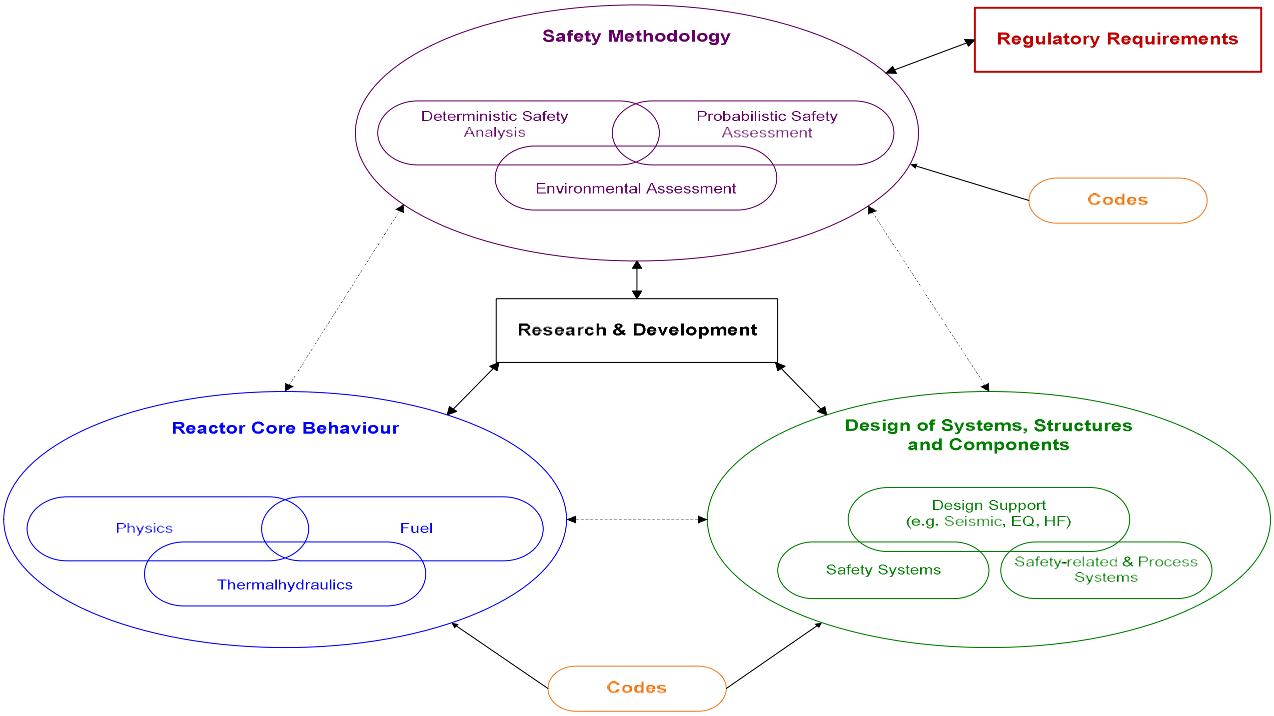

FIG. III-7. Reactor design topics and their inter-relations

(2) Group 2 topics may include:

— procedures for the safe conduct of construction and fuel-out commissioning activities;
— design of SSCs important to safety, that are not Group 1 SSCs;
— programs and procedures not directly related to the licensed activities of construction and fuel-out commissioning, but are required by the NSCA and its regulations to be submitted in a construction licence application.

Within a topic, a tiered approach can be taken when establishing the depth of the review:

— Tier 1: High Priority Items that will be reviewed using the detailed review criteria and procedure that is documented in the applicable WI (typically, the review would be carried out to the individual clause level of a Code or Standard).

[5] Reactor core behaviour is separated out due to its impact on safety analyses and on design requirements for reactor control and shutdown systems. The reactor core behaviour also has an impact on design requirements for systems, structures and components important to safety.

— Tier 2: Medium priority topics that are reviewed by confirming appropriate criteria, codes or standard were used as the basis of the design. Detailed clause by clause review is not performed.

Factors that need to be taken into account in establishing the depth of the review include:

- the significance of the topic in view of supporting safe conduct of the licensed activity. Appendix 1 to this Annex, organized by safety and control areas (SCAs), provides information on factors to consider for specific topics addressed in the construction licence application;
- for systems, structures and components (SSCs), their safety classification[6.] Table III-5 illustrates a proposed approach for identifying the safety significance of SSCs;
- operational experience;
- engineering experience;
- information from deterministic safety analyses; and
- information from probabilistic safety assessments (PSAs).

A more in-depth review should be done in cases where:

- Alternative approaches, different from those specified in the regulatory framework are employed;
- Novel analysis methods, codes and models are used;
- There are novel design features;
- Analyses show low margins to safety limits;
- There are areas lacking adequate support R&D or where R&D is not yet performed or is work in progress;
- The Environmental Assessment (EA) process has identified the need for additional specific mitigation measures;
- Omissions and exclusions are identified.

In addition, the number of disciplines involved in assessing a topic should be taken into account in establishing the effort for the review and assessment.

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[6]The classification of SSCs can also provide insights in establishing the depth of the review (from REGDOC-2.5.2, Design of Reactor Facilities: Nuclear Power Plants [III-7]). All SSCs are identified as either important or not important to safety. The criteria for determining safety importance are based on:

1. Safety function(s) to be performed; Consequence of failure;
2. Probability that the SSC will be called upon to perform the safety function; and
3. The time following a PIE at which the SSC will be called upon to operate, and the expected duration of that operation.

SSCs important to safety include:

1. Safety systems;
2. Complementary design features;
3. Safety support systems; and
4. Other SSCs whose failure may lead to safety concerns (e.g., process and control systems).

Safety group: Assembly of structures, systems and components designated to perform all actions required for a particular postulated initiating event to ensure that the specified limits for AOOs and DBAs are not exceeded. It may include certain safety and safety support systems, and any interacting process system.

Safety support system: A system designed to support the operation of one or more safety systems.

Safety system: A system provided to ensure the safe shutdown of the reactor or the residual heat removal from the core, or to limit the consequences of anticipated operational occurrences and design basis accidents.

TABLE III-5. SAFETY SIGNIFICANCE OF TOPICS

<table>
<tr><th rowspan="3">Topic</th><th rowspan="3">Type of Topic*</th><th colspan="3">for SSCs: Safety Classification</th><th rowspan="3">Importance</th></tr>
<tr><th rowspan="2">System Classification – Deterministic Approach</th><th colspan="2">Importance – Probabilistic Safety Analysis Approach</th></tr>
<tr><th>Risk Reduction (> 0.05 important)</th><th>Risk Increase (> 2 important)</th></tr>
<tr><td>-</td><td>-</td><td>-</td><td>-</td><td>-</td><td>Typically, the higher (greater) of rankings from the deterministic and probabilistic approaches</td></tr>
</table>

* The ‘Type of Topic’ includes the topics listed for Groups 1 and 2, above.

— **Step 3: Regulatory effort for review and assessment of construction licence applications for a large light-water cooled NPP and a small high-temperature gas reactor.**

A hypothetical illustration of the approach is provided in Table III-6. The commentary on the estimated review effort for the topic in the review of a large water-cooled NPP and for a simple high-temperature gas reactor is provided below.

An expert judgment approach was taken in this example. Overall, the regulatory effort depends on the complexity and novelty of the topic, and the number of specialist groups needed to carry out the review.

TABLE III-6. RATIONALE FOR THE RESOURCE ESTIMATES FOR THE REVIEW OF LICENCE APPLICATIONS FOR CONSTRUCTION OF A GENERIC LARGE NPP AND SMALL HIGH TEMPERATURE GAS REACTOR

Safety and Control Area	Topic	Rationale for the Review of a Generic 1000+ MWe NPP (#s in brackets are the specific criteria listed for Tier 1 items) *'normalized' effort for the review of the material submitted to address the topic (relative to the review with the most effort)	Rationale for the Review of a Generic 10 MWth HTGR) * estimated person-days effort for the review of the material submitted to address the topic
Management System	Management Systems	Group 1 (1, 3), Tier 1 need to understand programs, processes, procedures for governance of design, operation and maintenance of the facility few specialist groups involved 0.4*	lower Perhaps a simpler management system since the technology is simpler, resulting in less regulatory effort needed 0.3*
	Control of Modifications	Group 1 (1, 3), Tier 1 relatively straightforward review – but important to look at the details of how modifications will be conducted multiple specialist groups involved 0.2	same Programmatic, not technology-specific 0.2

TABLE III-6. RATIONALE FOR THE RESOURCE ESTIMATES FOR THE REVIEW OF LICENCE APPLICATIONS FOR CONSTRUCTION OF A GENERIC LARGE NPP AND SMALL HIGH TEMPERATURE GAS REACTOR (cont.)

Safety and Control Area	**Topic**	**Rationale for the Review of a Generic 1000+ MWe NPP (#s in brackets are the specific criteria listed for Tier 1 items)** ***'normalized' effort for the review of the material submitted to address the topic (relative to the review with the most effort)**	**Rationale for the Review of a Generic 10 MWth HTGR)** *** estimated person-days effort for the review of the material submitted to address the topic**
Human Performance	Qualification and Training of Personnel	Group 1 (1, 3), Tier 1 a comprehensive review is needed for all safety-related positions multiple specialist groups involved 0.68	lower There might be some reduction in scope since there may be less personnel, and less positions to review training for. 0.55
	Certification of Personnel	Group 1, Tier 1 a comprehensive review is needed to verify certification program is high quality few specialist groups involved 0.6	lower There might be some reduction in scope since there may be less personnel, and less positions to review training for 0.4
Operating Performance	Operating Procedures	Group 1 (1), Tier 1 a comprehensive review is needed to verify operating procedures are adequate. Will need to focus on procedures to support fuel out commissioning multiple specialist groups involved 0.3	lower There may be fewer and simpler operating procedures since the technology is simpler, resulting in less regulatory effort needed. However, there may be novel operating aspects 0.2

TABLE III-6. RATIONALE FOR THE RESOURCE ESTIMATES FOR THE REVIEW OF LICENCE APPLICATIONS FOR CONSTRUCTION OF A GENERIC LARGE NPP AND SMALL HIGH TEMPERATURE GAS REACTOR (cont.)

Safety and Control Area	Topic	Rationale for the Review of a Generic 1000+ MWe NPP (#s in brackets are the specific criteria listed for Tier 1 items) *'normalized' effort for the review of the material submitted to address the topic (relative to the review with the most effort)	Rationale for the Review of a Generic 10 MWth HTGR) * estimated person-days effort for the review of the material submitted to address the topic
Operating Performance	Construction and Commissioning Program	Group 1 (1), Tier 1 a comprehensive review is needed to assess and understand details of the construction program, effort spread out over several divisions multiple specialist groups involved 0.8	lower Construction program should have less detail owing to simpler reactor design, resulting in less regulatory effort needed 0.4
	Accident Management including Severe Accident Management	Group 1 (1, 2), Tier 1 a comprehensive review is needed to verify SAM procedures are adequate. multiple specialist groups involved 0.6	lower Effort may be reduced if the technology is simpler, and there are not so many pathways to a severe accident 0.4
Safety Analysis	Identification, Scope and Classification of Postulated Initiating Events	Group 1 (2, 3), Tier 1 a comprehensive review is needed to verify all relevant IEs identified multiple specialist groups involved 0.28	lower Extent of review may not be as great due to simpler design and plant models 0.2

TABLE III-6. RATIONALE FOR THE RESOURCE ESTIMATES FOR THE REVIEW OF LICENCE APPLICATIONS FOR CONSTRUCTION OF A GENERIC LARGE NPP AND SMALL HIGH TEMPERATURE GAS REACTOR (cont.)

Safety and Control Area	**Topic**	**Rationale for the Review of a Generic 1000+ MWe NPP (#s in brackets are the specific criteria listed for Tier 1 items)** ***'normalized' effort for the review of the material submitted to address the topic (relative to the review with the most effort)**	**Rationale for the Review of a Generic 10 MWth HTGR)** *** estimated person-days effort for the review of the material submitted to address the topic**
Safety Analysis	Deterministic Safety Analysis	Group 1 (2, 3), Tier 1 a comprehensive review is needed to verify DSA adequate. Many scenarios/events to assess multiple specialist groups involved 1	lower Deterministic safety analysis is less complex owing to simpler reactor design, resulting in less regulatory effort needed 0.7
	Probabilistic Analysis	Group 1 (2, 3), Tier 1 a comprehensive review is needed to verify PSA adequate. Many scenarios/events to assess multiple specialist groups involved 0.68	lower Probabilistic safety analysis is less complex owing to simpler reactor design, resulting in less regulatory effort needed 0.5
	Severe Accidents	Group 1 (2, 3), Tier 1 a comprehensive review is needed to verify severe accident analysis is adequate. Many scenarios/events to assess multiple specialist groups involved 0.72	lower Severe accident analysis maybe less complex owing to simpler reactor design, resulting in less regulatory effort needed. Need to take into account novel features and operational aspects 0.4

TABLE III-6. RATIONALE FOR THE RESOURCE ESTIMATES FOR THE REVIEW OF LICENCE APPLICATIONS FOR CONSTRUCTION OF A GENERIC LARGE NPP AND SMALL HIGH TEMPERATURE GAS REACTOR (cont.)

Safety and Control Area	**Topic**	**Rationale for the Review of a Generic 1000+ MWe NPP (#s in brackets are the specific criteria listed for Tier 1 items)** ***'normalized' effort for the review of the material submitted to address the topic (relative to the review with the most effort)**	**Rationale for the Review of a Generic 10 MWth HTGR)** *** estimated person-days effort for the review of the material submitted to address the topic**
Physical Design	Evaluation of Site Specific Hazards	Group 1 (3), Tier 1 a comprehensive review is needed to verify and external hazards identified and assessed. multiple specialist groups involved 0.34	lower Facility built on a brownfield site. Effort less as there is existing data, 0.2
	Safety Objectives and Goals	Group 1 (3), Tier 1 a comprehensive review is needed to verify the adequacy of the info submitted to address the many topics addressed in this section multiple specialist groups involved 0.4	same No change 0.4
	Classification of Structures, Systems and Components	Group 1, (3, 4), Tier 1 a comprehensive review is needed to verify SSCs appropriately classified. This topic is essential to the safety case, and in setting design and quality requirements for SSCs multiple specialist groups involved 0.24	lower Simpler design results in less information to review under this topic. However novel aspects of the design and operation may need additional effort 0.18

TABLE III-6. RATIONALE FOR THE RESOURCE ESTIMATES FOR THE REVIEW OF LICENCE APPLICATIONS FOR CONSTRUCTION OF A GENERIC LARGE NPP AND SMALL HIGH TEMPERATURE GAS REACTOR (cont.)

Safety and Control Area	**Topic**	**Rationale for the Review of a Generic 1000+ MWe NPP (#s in brackets are the specific criteria listed for Tier 1 items)** ***'normalized' effort for the review of the material submitted to address the topic (relative to the review with the most effort)**	**Rationale for the Review of a Generic 10 MWth HTGR)** *** estimated person-days effort for the review of the material submitted to address the topic**
Physical Design	Human Factors Engineering	Group 1 (3), Tier 1 a comprehensive review is needed to verify HF addressed in design of SSCs. few specialist groups involved 0.2	same Simpler design results in less information to review under this topic. However novel aspects of the design and operation may need additional effort 0.2
	In-service Monitoring, Inspection, Testing and Repairs	Group 1 (3), Tier 1 a comprehensive review is needed to verify monitoring, inspection, testing addressed in design of SSCs. multiple specialist groups involved 0.3	lower Simpler design results in less information to review under this topic. Novel materials may warrant additional effort 0.2
	Civil Engineering Works and Structures	Group 1 (3), Tier 1 a comprehensive review is needed to verify addressed in design of structures. few specialist groups involved 0.25	same Simpler design results in less information to review under this topic, but novel design features may warrant additional effort 0.25
	Pressure Boundary Design	Group 1 (3), Tier 1 a comprehensive review is needed to verify pressure boundary design. few specialist groups involved 0.6	Lower Simpler design results in less information to review under this topic. There may be novel materials that warrant additional effort 0.5

TABLE III-6. RATIONALE FOR THE RESOURCE ESTIMATES FOR THE REVIEW OF LICENCE APPLICATIONS FOR CONSTRUCTION OF A GENERIC LARGE NPP AND SMALL HIGH TEMPERATURE GAS REACTOR (cont.)

Safety and Control Area	Topic	Rationale for the Review of a Generic 1000+ MWe NPP (#s in brackets are the specific criteria listed for Tier 1 items) *'normalized' effort for the review of the material submitted to address the topic (relative to the review with the most effort)	Rationale for the Review of a Generic 10 MWth HTGR) * estimated person-days effort for the review of the material submitted to address the topic
Physical Design	Environmental Qualification	Group 1 (3), Tier 1 a comprehensive review is needed to verify environmental qualification of SSCs. multiple specialist groups involved 0.2	same Simpler design results in less information to review under this topic. There may be novel materials that warrant additional effort 0.2
	Seismic Qualification	Group 1 (3), Tier 1 a comprehensive review is needed to verify seismic design of SSCs. multiple specialist groups involved 0.3	lower Simpler design could result in less information to review under this topic. 0.2
	Design of the Fuel System	Group 1 (3, 4, 5), Tier 1 a comprehensive review is needed to verify adequacy of fuel system design. multiple specialist groups involved 0.29	lower Simpler design could result in less information to review under this topic. 0.2
	Nuclear Design and Core Nuclear Performance	Group 1 (4, 5), Tier 1 a comprehensive review is needed to verify adequacy of core nuclear performance. multiple specialist groups involved 0.48	same Although design could be simpler, this is one of the most important topics 0.48

TABLE III-6. RATIONALE FOR THE RESOURCE ESTIMATES FOR THE REVIEW OF LICENCE APPLICATIONS FOR CONSTRUCTION OF A GENERIC LARGE NPP AND SMALL HIGH TEMPERATURE GAS REACTOR (cont.)

Safety and Control Area	**Topic**	**Rationale for the Review of a Generic 1000+ MWe NPP (#s in brackets are the specific criteria listed for Tier 1 items)** ***'normalized' effort for the review of the material submitted to address the topic (relative to the review with the most effort)**	**Rationale for the Review of a Generic 10 MWth HTGR)** *** estimated person-days effort for the review of the material submitted to address the topic**
Physical Design	Design of the Reactor Coolant System and Reactor Auxiliary Systems	Group 1 (4), Tier 1 a comprehensive review is needed to verify adequacy of RCS and auxiliary systems. multiple specialist groups involved 0.25	same Although design could be simpler, there may be novel aspects with regards to novel reactor materials 0.25
	Safety Systems	Group 1 (4), Tier 1 a comprehensive review is needed to verify adequacy of safety systems. multiple specialist groups involved 0.95	Lower Simpler design results in less information to review under this topic 0.7
	Instrumentation and Control	Group 1 (4, 5), Tier 1 a comprehensive review is needed to verify adequacy of I & C systems. multiple specialist groups involved 0.58	lower Simpler design results in less information to review under this topic. However, there may be novel features that will need more attention 0.4
	Control Room Facilities	Group 1 (4), Tier 1 a comprehensive review is needed to verify adequacy of control room design. multiple specialist groups involved 0.16	lower Simpler design results in less information to review under this topic. However, there may be novel features that will need more attention 0.12

TABLE III-6. RATIONALE FOR THE RESOURCE ESTIMATES FOR THE REVIEW OF LICENCE APPLICATIONS FOR CONSTRUCTION OF A GENERIC LARGE NPP AND SMALL HIGH TEMPERATURE GAS REACTOR (cont.)

Safety and Control Area	**Topic**	**Rationale for the Review of a Generic 1000+ MWe NPP (#s in brackets are the specific criteria listed for Tier 1 items)** ***'normalized' effort for the review of the material submitted to address the topic (relative to the review with the most effort)**	**Rationale for the Review of a Generic 10 MWth HTGR)** *** estimated person-days effort for the review of the material submitted to address the topic**
Fitness-for-Service	Maintenance, Surveillance, Inspections and Testing	Group 1 (1, 3), Tier 2 an overview is needed at construction licence review stage 0.3	lower Simpler design results in less information to review under this topic 0.12
Radiation Protection	-	Group 1 (3), Tier 1 a comprehensive review is needed to verify adequacy of radiation protection aspects of the design. few specialist groups involved 0.4	lower Simpler design results in less information to review under this topic 0.2
Environmental Protection	-	Group 1 (1), Tier 1 only need to focus on provisions to support fuel out commissioning multiple specialist groups involved 0.2	same Programmatic 0.2
Emergency Preparedness and Fire Protection	-	Group 1 (1), Tier 1 Comprehensive review of fire protection is needed. Emergency preparedness is more complex if building on a brownfield site, next to an operating NPP. multiple specialist groups involved 0.2	same Programmatic 0.2

TABLE III-6. RATIONALE FOR THE RESOURCE ESTIMATES FOR THE REVIEW OF LICENCE APPLICATIONS FOR CONSTRUCTION OF A GENERIC LARGE NPP AND SMALL HIGH TEMPERATURE GAS REACTOR (cont.)

Safety and Control Area	**Topic**	**Rationale for the Review of a Generic 1000+ MWe NPP (#s in brackets are the specific criteria listed for Tier 1 items)** ***'normalized' effort for the review of the material submitted to address the topic (relative to the review with the most effort)**	**Rationale for the Review of a Generic 10 MWth HTGR)** *** estimated person-days effort for the review of the material submitted to address the topic**
Security	-	Group 1 (1), Tier 1 a comprehensive review is needed to verify adequacy site security/site access. few specialist groups involved 0.2	same There may be similar effort for simpler technology, depending if novel security approach proposed 0.2

III.3.1 Tools to inform regulatory focus and effort during Review and Assessment

The CNSC has developed a process and criteria for the evaluation of an applicant's (or proponents) proposal for the siting, construction or operation of a wide range of nuclear facilities and activities [III-8]. It is particularly well-suited to addressing innovative activities or facilities within the nuclear industry that are new to Canada. It is used during pre-licensing provide early feedback to proponents. It incorporates both operational and deployment considerations across the lifetime of the activity/facility.

Process outcomes provide information on applicability of an environmental assessment, public and Aboriginal consultation, nuclear liability, security/safeguards considerations, potential timelines, areas of potential delay, useful REGDOCs and standards, and key points that, if changed, may invalidate the strategy. The result provides supplementary guidance to a proponent on the use of the regulatory framework for their proposal.

The proponent:

- gains a better understanding of the regulatory process;
- understands which aspects of their proposal may trigger additional regulatory scrutiny and can consider whether scaling their proposal is desirable; and
- understands what would need to be provided as part of a licence submission.

The CNSC:

- is made aware of the potential project for planning purposes;
- comes to agreement as to how the potential project would be handled internally; and
- is made aware of potential problem areas and identifies resolution paths.

In addition, it highlights areas that may need more (or less) regulatory attention, and as such, informs resource allocation for application reviews.

Criteria in the process document [III-8] also has been incorporated in REGDOC-1.1.5, Supplemental Information for Small Modular Reactor Proponents [III-9], to provide guidance to applicants when developing licence applications for site preparation, construction, operation of small modular reactors.

(a) Criteria used in the Licensing Strategies for Novel Nuclear Technologies Process and in REGDOC-1.1.5, Supplemental Information for Small Modular Reactor Proponents [III-9]

Criteria are organized according to the CNSC's safety and control areas (SCAs). SCAs are the technical topics that CNSC staff use across all regulated facilities and activities to assess, evaluate, review, verify and report on regulatory requirements and performance. The sections below provide SCA-specific information that a proponent need to consider when determining the extent of the emphasis to give each SCA in a licence application for the siting, construction or operation of a nuclear installation.

(1) Management system

The management system SCA covers the framework that establishes the processes and programs required to ensure that an organization achieves its safety objectives, continuously monitors its performance against those objectives, and fosters a healthy safety culture.

This SCA covers the following specific areas:

- Management system.
- Organization.
- Performance assessment, improvement and management review.
- Operating experience.
- Change management.
- Safety culture.
- Configuration management.
- Records management.
- Management of contractors.
- Business continuity.

Nuclear installations may be complex, with many managed processes, procedures and work instructions are needed to control potential hazards, and poor safety culture can jeopardize safety and the protection of the environment.

Inadequate licensee performance in Management System will manifest itself in terms of poor structure of managed processes, poor implementation of managed processes, unclear procedures, poor job conditions, inadequate corrective actions, and lack of awareness of operating experience from within the plant and within the nuclear industry. These deficiencies may, in turn, result in an increase in active errors, and in the number of latent conditions in the plant (where persons and/or equipment may not perform their intended function when required to do so under abnormal situations, or where the inappropriate response may exacerbate the situation).

Factors to consider when developing management system information are listed in section 2.1.1 of REGDOC-1.1.5 [III-9].

(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 a sufficient number of licensee personnel are in all relevant job areas and have the necessary knowledge, skills, procedures and tools in place to safely carry out their duties.

This SCA covers the following specific areas:

- Human performance program
- Personnel training
- Personnel certification
- Initial certification examinations and requalification tests
- Work organization and job design
- Fitness for duty

Nuclear installations require a high level of training is required for plant activities, and the need for human factors considerations is extensive.

Inadequate licensee performance in Human Performance Management will manifest itself in terms of poor job conditions, inadequate understanding of tasks and other activities that can be influenced by the assigned task (awareness of task dependencies), increased probability of inappropriate human response during abnormal situations and normal work, inadequate corrective actions, and lack of awareness of operating experience from within the plant and within the nuclear industry. These deficiencies may, in turn, result in an increase in active errors, and in the number of latent conditions in the plant (where persons and/or equipment may not perform their intended function when required to do so under abnormal situations, or where the inappropriate response may exacerbate the situation).

Factors to consider when developing human performance management information are listed in section 2.1.2 of REGDOC-1.1.5 [III-9].

(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.

This SCA covers the following specific areas:

— conduct of licensed activity
— procedures
— reporting and trending
— outage management performance
— safe operating envelope
— severe accident management and recovery
— accident management and recovery

Nuclear installations may be complex, many managed processes are needed to control identified hazards, the procedures need to be clear to keep the facility within its safe operating envelope and for people and the facility respond appropriately during events.

Inadequate licensee performance in Operating Performance will manifest itself in terms of lack of adherence to procedures, unclear procedures, readiness of staff to respond to situations, communications issues, poor control of outage activities and a decline in the control of management over plant operations. These deficiencies may, in turn, result in an increase in active errors, and in the number of latent conditions in the plant (where persons and/or equipment may not perform their intended function when required to do so under abnormal situations, or where the inappropriate response may exacerbate the situation).

Factors to consider when developing operating performance information are listed in section 2.1.3 of REGDOC-1.1.5 [III-9].

(4) Safety analysis

The safety analysis SCA covers the safety analysis that supports 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 and considers the effectiveness of preventive measures and strategies in reducing the effects of such hazards.

This SCA covers the following specific areas:

— deterministic safety analysis
— hazard analysis
— probabilistic safety analysis
— criticality safety

- severe accident analysis
- management of safety issues (including R & D programs)

Safety Analysis is key in providing assurance that the design and accompanying process, procedures for facility operation will meet regulatory requirements, and that the safe operating envelope and design basis remain valid.

Inadequate performance in the licensee's Safety Analysis program may result in an inability to detect and address safety issues in a timely manner. This, in turn, may result in plant operation outside of the licensing basis (e.g. safety margins not appropriate, operation outside the safe operating envelope).

Factors to consider when developing safety analysis information are listed in section 2.1.4 of REGDOC-1.1.5 [III-9].

(5) Physical design

The physical design SCA relates to activities that affect the ability of structures, systems and components to meet and maintain their design basis, given new information arising over time and taking changes in the external environment into account.

This SCA covers the following specific areas:

- Design governance
- Site characterization
- Design of the installation
- Structure design
- System design
- Component design

Nuclear installations have extensive defence-in-depth provisions, are dependent on administrative controls and human performance for operation of the facility within the safe operating envelope and design basis.

The design of the installation is dependent on Fitness for Service activities in order to maintain the design basis and operate within the safe operating envelope. Periodic inspection and maintenance of systems, structures and components is needed to limit the risk associated with plant operation.

The design of the installation is also dependent on Safety Analysis activities as this programme serves to confirm that the installation is operating within its safe operating envelope, and adequate safety margins are maintained.

Inadequate performance in Physical Design may result in an increase in active errors, and in the number of latent conditions in the plant (where equipment may not perform its intended function when required to do so under abnormal situations). Without a systematic review of the external environment, the facility may not be able to withstand challenging external events.

Factors to consider when developing physical design information are listed in section 2.1.5 of REGDOC-1.1.5 [III-9].

(6) Fitness for service

The fitness for service SCA covers activities that impact the physical condition of structures, systems and components to ensure that they remain effective over time. This area includes programs that ensure all equipment is available to perform its intended design function when called upon to do so.

This SCA covers the following specific areas:

- Equipment fitness for service / equipment performance
- Maintenance
- Structural integrity
- Aging management
- Chemistry control
- Periodic inspection and testing

Fitness for Service activities are carried out to maintain the design basis and operate within the safe operating envelope. Periodic inspection and maintenance of systems, structures and components is needed to limit the risk associated with plant operation.

Inadequate performance in maintenance, structural integrity, aging management, chemistry control, and periodic inspection and testing programs may result in an increase in unanticipated SSC failures, facility operation outside the safe operating envelope, and in the number of latent conditions in the plant (where equipment may not perform its intended function when required to do so under abnormal situations).

Factors to consider when developing fitness-for-service information are listed in section 2.1.6 of REGDOC-1.1.5 [III-9].

(7) Radiation protection

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

This SCA covers the following specific areas:

- Application of ALARA
- Worker dose control
- Radiation protection program performance
- Radiological hazard control
- Estimated dose to public

The potential for exposure is high and the number of persons that could be exposed is large given the large number of tasks that are undertaken on a daily basis in the plant. A number of administrative controls are needed to limit personnel exposures. In addition, nuclear power plants have a number of administrative provisions and engineered systems and components to:

- Control the exposure of workers to radiation
- To protect the public and environment from radioactive materials

Adverse trends are likely due to declining of equipment performance, personnel not following procedures, or the use of inadequate procedures.

Inadequate performance with regards to Radiation Protection may result in increased radiation exposure to workers, increased contamination levels in the plant, and both can adversely impact on the ability of licensee staff to carry out activities (such as inspections, testing, maintenance work).

Factors to consider when developing radiation protection information are listed in section 2.1.7 of REGDOC-1.1.5 [III-9].

(8) Conventional health and safety

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

This SCA covers the following specific areas:

- Performance
- Practices
- Awareness

In terms of Conventional Health and Safety, inadequate performance may result in plant personnel being subject to undesirable working conditions, which, in turn, will likely compromise their ability to undertake their work (e.g. inspections, testing, maintenance work). Depending on the situation, there may be increases in the exposure of plant personnel to hazardous substances.

Factors to consider when developing conventional health and safety information are listed in section 2.1.8 of REGDOC-1.1.5 [III-9].

(9) Environmental protection

The environmental protection SCA covers programs 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.

This SCA covers the following specific areas:

- Effluent and emissions control (releases)
- Environmental management system
- Assessment and monitoring
- Protection of the public
- Environmental risk assessment

Nuclear installations have a number of administrative provisions and engineered systems and components to:

- Control the exposure of workers to hazardous substances
- To protect the public and environment from radioactive and hazardous substances

Adverse trends are likely due to declining of equipment performance, personnel not following procedures, or the use of inadequate procedures.

Inadequate performance with regards to Environmental Performance may result in increases in the releases of nuclear and hazardous substances to the environment. This in turn, may result in increased risk to the public and the environment.

There is a shared obligation on the CNSC and other regulatory bodies to ensure that licensees do meet all provincial and federal regulatory requirements related to the environment.

Factors to consider when developing environmental protection information are listed in section 2.1.9 of REGDOC-1.1.5 [III-9].

(10) Emergency management and fire protection

The emergency management and fire protection SCA covers emergency plans and emergency preparedness programs that exist for emergencies and for non-routine conditions. This area also includes any results of participation in exercises.

Note: The emergency management SCA includes conventional emergency and fire response. Operations, design and analysis in the context of fire protection for a nuclear facility are discussed in the appropriate SCAs of operating performance, safety analysis and physical design.

This SCA covers the following specific areas:

- Conventional emergency preparedness and response
- Nuclear emergency preparedness and response
- Fire emergency preparedness and response

The likelihood of potential off-site release is low; however, the consequences are potentially high as a large number of persons could experience health effects in the worst-case event. The on-site consequences for a major event are also significant as a large number of workers are likely to experience health effects. Emergency responses, for all but minor situations are complex. An off-site response is likely to be required (e.g. local fire brigades), and communication to persons surroundings is complex (in some cases, the plant location is more remote, so communication with residents spread out over a larger area is time consuming; in other cases, a large number of persons will have to be contacted communication to all is time consuming, and evacuation of a large number of persons presents significant logistical problems.

Inadequate performance with regards to emergency preparedness and fire protection may result in an inadequate response to emergencies by station personnel and off-site responders. Depending on the nature of the emergency, the inadequate response could have significant impacts on workers, the public and the environment.

Factors to consider when developing emergency management and fire protection information are listed in section 2.1.10 of REGDOC-1.1.5 [III-9].

(11) Waste management

The ‘waste management’ SCA covers internal waste-related programs that form part of the facility’s operations up to the point where the waste is removed from the facility to a separate waste management facility. This area also covers planning for decommissioning.

The waste management SCA covers the following specific areas:

- Waste characterization
- Waste minimization
- Waste management practices
- Decommissioning plans

It is important to minimize waste volumes, and to adequately characterize low, intermediate and high-level waste for management and disposal of waste in the future. In addition, it is important to store low, intermediate and high-level waste inside the facility and on the site in appropriately designed and operated facilities.

Inadequate performance, regarding Waste Management may result in unanticipated releases of nuclear and hazardous substances to the environment.

Factors to consider when developing waste management information are listed in section 2.1.11 of REGDOC-1.1.5 [III-9].

(12) Security

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

The security SCA covers the following specific areas:

- Facilities and equipment
- Response arrangements
- Security practices
- Drills and exercises
- Cyber security

Inadequate licensee performance with respect to Security may result in intrusions onto the licensed site, theft of proprietary information, prescribed information and prescribed equipment, increased possibility of sabotage, etc.

Factors to consider when developing security information are listed in section 2.1.12 of REGDOC-1.1.5 [III-9].

(13) Safeguards and non-proliferation

The safeguards and non-proliferation SCA covers the programs and activities required for the successful implementation of the safeguards agreement between Canada and the International Atomic Energy Agency (IAEA), as well as all other measures arising from the Treaty on the Non Proliferation of Nuclear Weapons.

The safeguards and non-proliferation SCA covers the following specific areas:

- Nuclear material accountancy and control
- Access and assistance to the IAEA
- Operational and design information
- Safeguards equipment, containment and surveillance
- Import and export

In Safeguards, there is a need to control and account for prescribed materials and information. Inadequate performance in Safeguards may result in loss of control of prescribed materials and information and non-conformance with measures of control and international obligations to which Canada has agreed.

Factors to consider when developing safeguards information are listed in section 2.1.13 of REGDOC-1.1.5 [III-9].

(14) Packaging and transport

The packaging and transport SCA covers programs that cover the safe packaging and transport of nuclear substances to and from the licensed facility.

The packaging and transport SCA is not included in an application for a licence to prepare site. This SCA is only included in an application for a licence to construct, and an application for a licence to operate.

The packaging and transport SCA covers the following specific areas:

- Package design and maintenance
- Packaging and transport
- Registration for use

Inadequate performance in Packaging and Transport may result in releases of nuclear and hazardous substances to the environment in the event of a transportation incident.

Factors to consider when developing packaging and transport information are listed in section 2.1.14 of REGDOC-1.1.5 [III-9].

III-4. GRADED APPROACH FOR REVIEW AND ASSESSMENT - ASSESSMENT OF SAFETY ISSUES USING A RISK-INFORMED DECISION-MAKING METHODOLOGY IN CANADA

The CNSC’s risk-informed decision-making process has been applied to develop the path forward for resolution of safety issues. In this example, we:

(a) describe the safety issue,
(b) provide information on the risk assessment for the issue, including reference to criteria used to determine the risk significance, and
(c) describe the risk control measures that were implemented.

A similar approach for risk-informed decision making is also presented in [III-10].

III-4.1 Issue Description

Containment is equipped with sumps to collect the water lost from the primary circuit after a LOCA in order to recirculate the water in the ECC recovery phase of the accident. The sumps are covered with a screen which is intended to prevent debris penetration to the suction of the ECCS pumps.

The thermal insulation used inside the containment and the total area of the screen above the sump together with dust and debris that occur in containments form a combination that raises safety concerns regarding the possibility of maintaining ECCS circulation after a medium or large LOCA. Operational experience based on events in Sweden and in the USA has demonstrated that even a relatively small amount of similar fibres can effectively block a large portion of the screen area. Sump screens need to be designed and installed to ensure that the screening function is maintained.

Break-up of thermal insulation around equipment and pipes inside the containment can, under LOCA conditions, lead to an impairment of ECC recirculation by clogging the sump screens and/or the ECCS heat exchangers. The ECCS function can also be affected by inadequately screened debris.

A postulated Loss of Coolant Accident (LOCA) would dislodge significant quantities of insulation material, both fibrous and particulate. Much of this debris is expected to be transported to the reactor building sump with the coolant lost from the reactor through the break. ECC recirculation recovers water from the sump, cools it and returns it to the reactor to cool the core. The ECC strainers are located in the sump and protect the ECC recirculation flow path by preventing the debris from entering the ECC system. As a result, a layer builds up over the strainer surface. The strainers should be designed with sufficient surface area that the debris bed does not impede flow.

In addition, preliminary research findings of the Integrated Chemical Effects Test (ICET) programme in the United States have raised concerns about the formation of deposits on Emergency Core Cooling (ECC) system strainers. The ICET programme assessed the impact of reactor building sump chemistry following a LOCA and possible implications for ECC strainers during recirculation following a LOCA. In some of the ICET tests a gelatinous deposit was discovered on the fibre samples in the tank. There is a concern that such chemical deposits could lead to a partial blockage of the strainer thereby impairing the ECC recirculation.

— **Step 1: Assess the adequacy of Emergency Core Coolant System sump screens in Canadian CANDU reactors**

— **Step 2: Identify the factors used in the assessment**

Table III-9 through Table III-15 provide criteria for the factors used in the assessment:

- Impact on plant safety
- Radiological risk to the public
- Severe accident risk

The specific likelihood and consequence criteria are used to determine the risk significance level for the scenarios in the respective risk areas.

— **Step 3: Perform the integrated assessment**

The assessment was performed according to the factors, as described below.

(a) Risk Assessment Summary

The risk assessment for this safety issues is provided in Tables III-7 and III-8.

In carrying out the assessment scenarios depicting the safety issues are developed, then the likelihood and consequences criteria applicable to the scenario are selected. Using Tables III-11, III-14 and III-15, the risk significance levels for the respective risk areas are determined.

This safety issue has the potential to severely impair a special safety system (ECC recirculation) when the system is needed (LOCA). While the frequency of LOCA will not be changed, the off-site doses to the public can be significantly higher than those estimated in the Safety Report. Licensees have demonstrated that serious chemical effects that have been identified for other reactor designs do not occur with CANDU reactors. However, at this time, the possibility of other chemical effects specific to CANDU has not been eliminated; therefore, there is uncertainty in assessing the likelihood of this impairment. To address this risk, we recommend that licensees complete the current R&D programme. When this R&D programme is completed, we expect to have sufficient information to estimate the risks to the public with a higher confidence and recommend design changes, if needed.

On this basis, the overall Risk Significance Level was judged to be a '3', although it could be 2 for plants with large area strainers.

(b) Risk Control Measures

Recommended risk control measures are as follows:

(1) Operating Reactors: Address closure criteria for GAI 06G01, which include performing the planned chemical effects tests to improve knowledge understanding of the potential chemical effects.

(2) Life Extension: Address closure criteria for GAI 06G01, which includes performing the planned chemical effects tests to improve knowledge understanding of the potential chemical effects. Consider implementing practicable design changes.

(3) New Build: It is expected that the issue will be addressed via improved design.

The results of the experimental programme have indicated that the chemical effects observed in PWRs are not occurring under CANDU-specific conditions.

TABLE III-7. RISK ASSESSMENT FOR ECC STRAINER EFFECTIVENESS

RISK AREA	SCENARIO	LIKELIHOOD		CONSEQUENCES		RISK SIGNIFICANCE LEVEL
		Category	Comments	Category	Comments	Category
Risk of Negative Impact on Safety (refer to Tables III-9 through III-11 for risk-ranking criteria)	Strainer partially blocked due to fouling/chemical effects and subsequent pump cavitation results in recirculation pumps not being able to inject water into core to cool the fuel	L2	There are still uncertainties with regards to the effect of chemical effects on strainer fouling and subsequent blockage. Based on current knowledge of chemical effects, the likelihood for impairment due to chemical effects is estimated to be 25 to 50% (the range in strainer area is quite large amongst the Canadian plants). The results of testing may reduce uncertainties in estimating the likelihood of strainer blockage.	C2	Defence in depth is degraded and the safety function of cooling is impaired	3
Increased Doses to Public (refer to Tables III-12 through III-14 for risk-ranking criteria)	LOCA + consequential loss of recirculation	L2	Frequency of LOCA (10^{-2} (small LOCA) to 10^{-4} (Large LOCA)) as a DBA is not significantly changed by a ~ 25% to 50% likelihood of ECC impairment with loss of long-term recirculation	C2	Consequential loss of ECC recirculation will lead to additional fuel failures For Darlington, public doses for this scenario is less than dose limits for LOCA (LOCA dose is well below the C6R0 (0.3% of the Class 3 (LLOCA)) dose limit), but with loss of ECC recirculation, the dose is ~11mSv (~40% of the Class 3 dose limit of 30).	2

TABLE III-7. RISK ASSESSMENT FOR ECC STRAINER EFFECTIVENESS (CONT.)

RISK AREA	SCENARIO	LIKELIHOOD		CONSEQUENCES		RISK SIGNIFICANCE LEVEL
		Category	Comments	Category	Comments	Category
	LOCA + Consequential Loss of recirculation + Failure of containment	L2	Frequency of LOCA + Loss of Containment as a DBA is not changed significantly if there is strainer blockage	C3	For Darlington, the LOCA with consequential loss of recirculation and with containment failure could be as much as 12 times the Class 5 C6R0 dose limit. However, this estimate is based on early impairment of ECC. If the impairment is later, the consequences will be less. The severity depends on the degree of strainer fouling and the time at which ECC begins to be impaired.	3

TABLE III-8. RISK ASSESSMENT FOR ECC STRAINER EFFECTIVENESS – SEVERE ACCIDENTS RISKS

RISK AREA	SCENARIO	RISK SIGNIFICANCE LEVEL	COMMENTS
Severe Accidents Risks (refer to Table III-15 for risk-ranking criteria)	Strainer blockage leads to increased probability of failure of ECC recirculation in comparison with that determined in the PSA. Therefore, we expect that CDF and other Safety Goals will be greater than previously determined in the PSA.	3, but could be 2	The ranking will depend on the risk significance of ECC recirculation for specific plants

TABLE III-9. QUALITATIVE CRITERIA FOR CONSEQUENCE CATEGORIES FOR RISK OF NEGATIVE IMPACT ON SAFETY

CONSEQUENCE CATEGORY	CRITERIA
C3	▪ Defence in depth is insufficient or unacceptable (one or more levels of protection are lost, the safety function is disabled) ▪ Impossibility (i.e. lack of knowledge, data, tools) to assess conditions relevant for safety when compliance verification is impossible ▪ Continuous deterioration of plant safety ▪ Excessive increase of the time at risk of plant operation
C2	▪ Defence in depth is degraded (one or more levels of protection are affected, the safety function is impaired) ▪ Difficulty (i.e. insufficient information, data, tools) to assess conditions relevant for safety when compliance verification is impossible ▪ Incomplete restoration of safety ▪ Significant increase of the time at risk of plant operation
C1	▪ Levels of protection / safety functions are affected but not significantly ▪ Inadequate confidence in accuracy of data, models and code predictions ▪ Non-sustainable long term safe operation ▪ Increase of the time at risk of plant operation

TABLE III-10. CRITERIA FOR LIKELIHOOD CATEGORIES FOR RISK OF NEGATIVE IMPACT ON SAFETY

LIKELIHOOD CATEGORY	CRITERIA
L3	▪ The consequences will very likely occur (> 75% chance)
L2	▪ The consequences will likely occur (25% - 75% chance)
L1	▪ The occurrence of consequences is unlikely (< 25% chance)
L0	▪ The occurrence of consequences is highly unlikely (< 5% chance)

TABLE III-11. RISK MATRIX FOR RISK OF NEGATIVE IMPACT ON SAFETY

CONSEQUENCES				
C3	2	3	4	4
C2	1	2	3	3
C1	1	1	2	3
	L0	L1	L2	L3

LIKELIHOOD

TABLE III-12. CRITERIA FOR CONSEQUENCE CATEGORIES FOR RADIOLOGICAL RISK TO PUBLIC AT DBA

CONSEQUENCE CATEGORY	CRITERIA
C1	▪ No significant additional radioactive releases would occur, such that the public doses calculated in the existing Safety Report are expected to be bounding.
C2	▪ The radioactive releases would lead to public doses greater than those determined in the Safety Report, but still less the limits for the applicable class of the accident.
C3	▪ The radioactive releases would lead to public doses may exceed the limits for the applicable class of the accident. The releases would not trigger off-site protection measures.
C4	▪ The radioactive releases would require initiation of off-site protection measures.

TABLE III-13. CRITERIA FOR LIKELIHOOD CATEGORIES FOR RADIOLOGICAL RISK TO PUBLIC AT DBA

LIKELIHOOD CATEGORY	CRITERIA
L1	▪ Frequency of accident scenario is greater than 10^{-7} /year but less than the DBA frequency limit; the accident is beyond design basis.
L2	▪ Frequency is not significantly different from, or is the same as that, originally assigned in the Safety Report; re-classification of the event is not necessary.
L3	▪ Frequency of the accident scenario is significantly greater than that considered in the Safety Report; the accident sequence may have to be re-classified into a higher frequency category.

TABLE III-14. RISK MATRIX FOR RADIOLOGICAL RISK TO PUBLIC AT DBA

CONSEQUENCES				
	C4	3	4	4
	C3	1	3	4
	C2	1	2	3
	C1	1	1	2
		L1	L2	L3

LIKELIHOOD

TABLE III-15. RISK MATRIX FOR SEVERE ACCIDENTS RISKS

RISK LEVEL	CRITERIA
1	▪ The increase of the Safety Goals[7] is negligible. ▪ The Safety Goals remain below the accepted targets.
2	▪ All or some Safety Goals increase, but remain less than the accepted limits.
3	▪ All or some Safety Goals may exceed the accepted limits.
4	▪ All or some Safety Goals significantly exceed accepted limits

III-5. OVERVIEW OF GRADED APPROACH APPLIED TO REVIEW AND ASSESSMENT (R&A) IN PAKISTAN

PNRA uses a graded approach to review and assess licensing submissions for all licensing stages of nuclear facilities. Different factors considered for application of a graded approach (GA) are described below:

- Scope and detail of information in the licensing submissions
- Allocation of resources (human resources and duration) for review and assessment of different types of nuclear facilities
- Allocation of resources (human resources and duration) for review and assessment of similar types of nuclear facilities with difference in design or power level
- Selection of safety factors during periodic safety review (PSR) of different types of nuclear facilities

[7] For the purpose of this table, the Safety Goals are quantitative risk indicators specific to severe accident conditions, calculated in PSA. The quantitative Safety Goals defined in CNSC REGDOC-2.5.2 [III-7] are Core Damage Frequency, Large Release Frequency and Small Release Frequency.

III-5.1. Application of GA in the Scope and Detail of Information in Licensing Submissions

Scope and detail of information in licensing submissions varies for different types of nuclear facilities.

(a) Factors for application of GA

The major considerations for application of GA in the scope and detail of information in the licensing submissions of different types of nuclear facilities are given below:

(1) Type of facility
(2) Complexity of design
(3) Categorization of nuclear facilities based on potential radiological hazards [III-11], such as:
    — 'HC-1 Facilities': nuclear facilities for which on-site events could give rise to severe deterministic health effects off site (NPPs).
    — 'HC-II Facilities': nuclear facilities for which on-site events could give rise to doses to people off the site that warrant urgent protective actions (high power RRs).
    — 'HC-III Facilities': nuclear facilities for which events warrant urgent protective actions on site only (low power RRs and other nuclear facilities).

(b) Rationale for GA

In view of above mentioned factors, the scope and detail of information in licensing submissions varies. Reference documents for scope and detail of information in safety Analyses Report (SAR) for different type of nuclear facilities are given in Table III-16.

TABLE III-16. REFERENCE DOCUMENTS FOR APPLICATION OF GA IN SCOPE AND DETAIL OF INFORMATION IN SAR

Type of Nuclear Facilities	Reference Document for SAR
NPPs	NUREG-0800 [III-12], RG 1.70 [III-13], RG 1.206 [III-14], and IAEA safety standards
RRs	NUREG-1537 [III-15], SSG-20 [III-16] and IAEA safety standards
NFCF	NUREG-1520 [III-17] and NUREG-1567 [III-18]

Table III-17 compares the scope and detail of information in the SARs to be submitted for NPPs versus NFCFs and RRs when GA is applied.

TABLE III-17. COMPARISON OF SAR OF NPPS AND RRS/NFCFS

Chapter No.	Titles	Remarks
1	Introduction and General Description of the Plant	-
2	Site Characteristics	-
3	Design of Structures, Components, Equipment and Systems	-
4	Reactor	-
5	Reactor Coolant System and Connected Systems	-
6	Engineered Safety Features	-

TABLE III-17. COMPARISON OF SAR OF NPPS AND RRs/NFCFs (cont.)

Chapter No.	Titles	Remarks
7	Instrumentation and Controls	-
8	Electric Power	-
9	Auxiliary Systems	-
10	Steam and Power Conversion System	This chapter is not required for RRs and NFCF
11	Radioactive Waste Management	-
12	Radiation Protection	-
13	Conduct of Operations (Training, EPP, Plant Procedures and Physical Protection are also covered in this chapter)	Offsite EPP is not required for RRs (low power) and NFCF
14	Initial Test Programme	-
15	Accident Analysis	-
16	Technical Specifications	-
17	Quality Assurance Programme	-
18	Human Factors Engineering	This chapter is not required for RRs and NFCF
19	Probabilistic Safety Assessment and Severe Accident Analysis	This chapter is not required for RRs and NFCF

In addition to the above, SARs for RRs include specific chapters as provided in Table III-18.

TABLE III-18. SPECIFIC CHAPTERS OF SARs OF RRs

Sr. No.	Title of Chapters
1.	Safety objectives and engineering design requirements
2.	Reactor utilization
3.	Decommissioning

III-5.2. The application of a graded approach in allocation of resources (human resources and duration) for review and assessment of different types of nuclear facilities

(a) Factors for application of a GA

- GA factors in allocation of resources for R&A are based on facility characterization, associated radiological hazards, document submission requirements and scope & detail of information in licensing submissions.
- Experience from previous reviews and availability of expertise in specific areas.

(b) Rationale in the application of a GA for resource allocation

More resources are required for review and assessment of documents of a facility with:

- Off-site hazard potential as compared to facility with on-site hazards potential only
- More complex design, as in case of complex design/systems, more safety assessments and analyses are required from the licensee/applicant,
- More detailed licensing submission requirements.

Availability of relevant expertise in specific areas can reduce the allocation of resources for review and assessment activities.

Practical examples regarding resource allocations for review of SARs and PSRs of different type of nuclear facilities are given in Tables III-19 and III-20.

TABLE III-19. USE OF A GA IN ALLOCATION OF RESOURCES FOR REVIEW AND ASSESSMENT OF DIFFERENT TYPE OF NUCLEAR FACILITIES

Activities	Facility	Number of Experts	Duration in Months	Man-Months
Review of Revised FSAR	K-1 (scope of the revision was to include PSR-2 commitments and design modifications made)	31	6.25	193
	PARR-I (scope of the revision was to modify the FSAR according to format of SSG-20 [III-16])	17	6.5	110

TABLE III-20. EXAMPLE OF THE USE OF A GA IN HUMAN RESOURCE REQUIREMENTS FOR PSR OF DIFFERENT NUCLEAR FACILITIES

S.No.	Nuclear Facility	Number of Experts	Duration in Months	Man-Months
1	PSR-1 (C-1)	36	15	540
2	PSR-2 (K-1)	42	18	756
3	PSR-1 (PARR-1)	23	15	345
4	PSR-1 (PARR-2)	22	08	176

III-5.3. Application of a graded approach in allocation of resources (human resources and duration) for review and assessment of similar types of nuclear facilities with difference in design or power level

Although the submission requirements are almost the same, however, in case of similar type of nuclear facilities (such as NPPs), the resource allocation for review and assessment of these submissions also varies.

(a) Factors for application of a GA

- Complexity of design
- Relevant expertise and their availability, experience of previous reviews of existing facilities
- New or already approved design, novel design and analysis methods and
- Same or new site

(b) Rationale for a GA in resource allocation

- Less resources are required, if review of the submissions of reference facility is once conducted by regulatory body, then focus is made to the design changes or additional systems incorporated in the design as a result of emerging technologies and advancement
- Based on past experience of similar type of review and assessment of specific type of facility, less resources are required as the regulatory review will concentrate on the problematic/weak areas based on outcome of previous experience

— The resources for the review and assessment is further reduced, if operating experience of the similar plant is available
— Availability of previous review experts can also reduce the allocation of resources for R&A.

Practical examples of GA in resource allocation for review and assessment of similar type of nuclear facilities are given in Table III-21.

TABLE III-21. GA IN RESOURCE ALLOCATION FOR REVIEW AND ASSESSMENT OF SIMILAR TYPE OF NUCLEAR FACILITIES

Activities	Facility	Number of Experts	Duration in Months	Man-Months
Site Evaluation Report	C-3 (Already reviewed site)	08	03	24
	K-2 (New site)	10	6.25	62
Review of PSAR	C-3/4 PSAR (Proven technology and already reviewed plant)	59	06	354
	K-2 PSAR (New design)	68	16	1088
Review of FSAR	C-2	64	12	768
	C-3 (Proven technology and already reviewed plant)	62	10	620

III-5.4. Application of a GA in selection of safety factors during periodic safety review (PSR) of nuclear facilities

Review and assessment of PSR reports is performed for revalidation of operating licenses after ten (10) years or licence beyond design life as per regulatory requirements of PNRA regulations. SSG-25 is utilized for selection of safety factors. Selection of safety factors is mutually agreed between PNRA and licensee.

(a) Considerations for application of a GA in selection of safety factors during PSR

Selection of safety factors for PSR depends upon type of nuclear facilities such as NPPs, RRs etc.

(b) Rationale for GA in selection of safety factors

If any assessment, analysis or safety factor was not required at the time of initial licensing stage, then the same may not be considered/included in the PSR unless specifically required by PNRA.

Detail of selection of PSR factors for different nuclear facilities is given in Table III-22.

Furthermore, selection of some factors of PSRs within the similar type of nuclear facilities at the same site also depends upon the organization setup. For example, in case of RRs in Pakistan, due to same site and same management, two safety factors (organization and emergency planning) were not considered in PSR of PARR-2 as these were already covered in PSR of PARR-1. Practical examples for selection of safety factors of PSRs within the similar type of nuclear facilities at the same site are provided in Table III-23.

TABLE III-22. GA IN SELECTION OF SAFETY FACTORS DURING PSR OF DIFFERENT NUCLEAR FACILITIES

General Factors	Specific Factors	NPPs	RRs
Safety factors relating to the plant	Plant design	Yes	Yes
	Actual condition of structures, systems and components (SSCs) important to safety	Yes	Yes
	Equipment qualification	Yes	Yes
	Ageing	Yes	Yes
Safety factors relating to safety analysis	Deterministic safety analysis	Yes	Yes
	Probabilistic safety assessment	Yes	Not required
	Hazard analysis	Yes	Yes
Safety factors relating to performance and feedback of experience	Safety performance	Yes	Yes
	Use of experience from other plants and research findings	Yes	Yes
Safety factors relating to management	Organization, the management system and safety culture	Yes	Yes
	Procedures	Yes	Yes
	Human factors	Yes	Not required
	Emergency planning	Yes	Yes
Safety factors relating to the environment	Radiological impact on the environment	Yes	Yes

TABLE III-23. THE USE OF A GRADED APPROACH IN SELECTION OF DIFFERENT FACTORS WITHIN THE SAME TYPE OF NUCLEAR FACILITIES DUE TO CONSIDERATION OF SAME ORGANIZATION, SITE AND PREVIOUS PSRs

Specific Factors/Facility	PARR-1	PARR-2
Plant design	Yes	Yes
Actual condition of structures, systems and components (SSCs) important to safety	Yes	Yes
Equipment qualification	Yes	Yes
Ageing	Yes	Yes
Deterministic safety analysis	Yes	Yes
Probabilistic safety assessment	Not required	Not required
Hazard analysis	Yes	Yes
Safety performance	Yes	Yes
Use of experience from other plants and research findings	Yes	Yes
Organization, the management system and safety culture	Yes	Not included in PARR-2 PSR as this factor was already covered in PARR-1 PSR (same organization).
Procedures	Yes	Yes
Human factors	Not required	Not required
Emergency planning	Yes	Not included in PARR-2 PSR as this factor was already covered in PARR-1 PSR (same site).
Radiological impact on the environment	Yes	Yes

III-6. USE OF A GRADED APPROACH DURING REVIEW AND ASSESSMENT OF APPLICATIONS RELATED TO NUCLEAR FACILITIES IN THE RUSSIAN FEDERATION

In the Russian Federation a prescriptive regulatory approach is used for regulating nuclear facilities and activities on the use of nuclear energy. As described in Appendix IV of this TECDOC, the use of prescriptive tools and requirements raise additional challenges to the nuclear regulator if a graded approach is to be applied to the regulatory functions. In this case, some aspects need to be considered in the order of inspections to allow grading the licensing process in a manner commensurate with the magnitude of the radiation risks of the activities.

This annex provides a step 3 ‘Integrate the applicable factors into the decision-making process’ of three-step methodology developed in this TECDOC for a graded approach in the review and assessment of applications for nuclear facilities in the Russian Federation.

An order of licensing in the Russian Federation is established in accordance with chapter 5 of Federal Law No 170-FZ on 21.11.1995 ‘On the Use of Atomic Energy’ [III-19], para. 5.3.2 of Russian Government decree No 401 on 30.07.2004 ‘On Federal Ecological, Technical and Nuclear Supervision Service’ [III-20] and Russian Government decree No 280 on 29.03.2013 ‘On Licensing of Activities in Nuclear Energy Use’ [III-21]. Special requirements for research installations licensing are provided in Administrative Regulation of Rostechnadzor No 453 on 08.10.2014 ‘Administrative regulations for providing of State Service on Licensing of Activities in Nuclear Energy Use by Federal Ecological, Technical and Nuclear Supervision Service’ [III-22].

In order to issue a licence Rostechnadzor organizes the safety review of nuclear installation, considering the radiological risk associated to the facility and activity, which determines the level of detail of the information required. The number of documents to be provided depends on a type of facility and activity.

Table III-24 contains an approximate list of documents to be provided for a safety review depending on a licensed activity and facility.

TABLE III-24. LIST OF DOCUMENTS TO BE PROVIDED FOR A SAFETY REVIEW DEPENDING ON A LICENSED ACTIVITY AND FACILITY

	Nuclear Power Plants			**Research Installations**			**Nuclear Fuel Cycle Facilities**		
	Documents required for R= required; RS = required for some types of installation; −=not required								
	Construction	Operation	Decommissioning	Construction	Operation	Decommissioning	Construction	Operation	Decommissioning
Safety Analysis Report	R	R	R	R	R	R	R	R	R
Quality Assurance Programme	R	R	R	RS	R	R	R	R	R
Emergency Instruction for Design Basis Accidents	-	R	R	-	R	RS	-	R	R
Emergency Instructions for Protection of Personnel	-	R	R	-	R	R	-	R	R
Emergency Instructions for Beyond Design Basis Accidents	-	R	R	-	R	R	-	R	R
Nuclear Safety Instruction[8]	-	R	-	-	-	-	-	R	-
Technological Instruction[9]	-	R	-	-	R	-	-	R	-
Probabilistic Safety Analysis	R	R	-	-	-	-	-	-	-
Ageing Management Programme	-	R	R	-	R	R	-	R	R
Decommissioning Programme	-	-	R	-	-	R	-	-	R
Complex survey report[10]	-	RS	R	-	RS	R	-	RS	R

[8] In the Russian Federation, this is a document that contains main technical means and procedures for ensuring safety of handling with fissile materials and nuclear fuel. The document is prepared for NPPs and Nuclear fuel cycle facilities.

[9] This is the main operational document in any facility in the Russian Federation. It contains operational limits and conditions for all systems. It also contains main instructions for personnel. This document is a basis for all documentation of a facility.

[10] This is a report that contains results of a survey that is implemented during the preparation for a long-term operation of a facility. It contains results of a survey of all systems and describes their current status and ageing. This report is required when the facility is going to operate more than it was originally planned.

III-7. GRADED APPROACH TO CONDUCTING REVIEW AND ASSESSMENT IN THE UK

— **Step 1: Determine the regulatory focus and effort for the review and assessment of licensee safety case submission**

Assessment of licensee submissions is a fundamental and major component of ONR's work. In preparation for any assessment exercise, it is necessary to be mindful of the need to (See [III-23]):

- ensure assessment work is appropriately comprehensive and proportionate;
- maximize the effectiveness of available effort;
- promote consistency in the standard of assessment;
- identify potential pitfalls and provide advice on ways to avoid them, and
- ensure appropriate recommendations/conclusions are reached.

— **Step 2: Determine which factors influence extent and rigour of a licensee safety case submission**

(a) Adequacy of Information Supplied by the licensee

The inspector carrying out the assessment [III-23] needs to consider the presentation of this information and the quality of the submission prior to commencing assessment. Factors to consider include:

- Is it comprehensive, coherent, accurate and consistent?
- If not, is the missing information or assumed prior knowledge already to hand?
- Is it adequately structured?
- If a staged submission, does the information supplied match the scope of the staged submission?
- Is the level of detail sufficient?

It is the licensee's responsibility to demonstrate the safety of the plant, the delivery of the appropriate security outcomes, or compliance with relevant legislation, and a poorly presented or structured submission prevents that responsibility being fulfilled. The licensee should have reached a properly objective and valid conclusion and this position needs to be demonstrable via the documentary evidence.

Submissions ought to consist of three elements: claims, argument and evidence. The claims represent the licensee's perception of the objectives to be met, and may be explicitly stated or implicit, in which case they should be self-evident. The evidence is the raw information or data that underpins the ability to show that the requirements are met. The evidence should either be stated in the submission itself or referenced from it. The arguments are what link the evidence to the claims, they do the 'showing' that the claims are met - they 'tell the story'. Caution should be applied when documentation consists either of vast amounts of evidence with very little in the way of argument, or very extensive arguments with little evidence.

(b) Sampling

It is seldom possible or necessary to assess a submission in its entirety. Sampling is used to limit the areas scrutinized, to limit the total effort to be applied, and to improve the overall efficiency of the assessment process. In general, the inspector needs to undertake a broad review of the highest level claims and arguments and then undertake the majority of sampling in areas of high significance, areas of novelty or high uncertainty since weaknesses in these areas is potentially serious. If sampling is done carefully it can be expected to test for weaknesses in the submission as a whole. A powerful technique to apply is 'deep thin slice' sampling, where deliberate scrutiny of a number of detailed matters across a narrow field is applied. In spite of the narrow view taken this technique is very good at revealing generic weaknesses.

Judgement is necessary both in deciding whether to assess a particular submission at all - significance is the usual criterion here though there can be others - and in the time and hence degree of sampling that should be allocated if it is assessed. Example factors that ought to be considered are set out below:

- The fault tolerance of a system being considered or modification requested by the licensee;
- The contribution of a system or fault to core damage frequency in the case of NPP considerations;
- The age of facilities or NPP under review; older facilities designed to earlier standards may warrant increased assessment focus.

However, whatever submissions and samples are assessed, it is important always to apply sufficient rigour to arrive at defensible judgements, since they may well be challenged either at the time or at any time later. Shortage of time may restrict the range of cases or the areas that are sampled, but should not restrict the depth and rigour of assessment. As the assessment progresses inspectors need to be alert to avoid unnecessary mission creep but equally they should be prepared to change their sample as further information becomes available.

(c) Judging adequacy

It is the responsibility of the inspector carrying out the assessment to judge when and if a submission is adequate. Although it can be assumed that the licensee believes a submission to be adequate, the inspector must have in mind a clear and independent image of what adequacy means, and must be able to recognize when it has been achieved.

Judging adequacy is normally straightforward against prescriptive duties, but is more challenging against non-prescriptive requirements (e.g. against the duty to reduce risk ALARP or against other goal-setting standards in legislation or licence conditions). Within ONR we are usually able to make judgments by comparing the licensee's submission against RGP. RGP refers to those good practices that have been previously assessed and judged to meet the requirement in question (whether that be reducing risks ALARP or another goal-setting outcome). There are a number of sources of RGP against which ONR inspectors form their judgements comprising:

- Safety Assessment Principles [III-24];
- Technical Inspection and Assessment Guides (See http://www.onr.org.uk/operational/index.htm); and
- Wider national or international engineering Codes and Standards (e.g. ASME for PWR NPP).

For nuclear safety, the key written sources are ONR's Safety Assessment Principles (SAPs), Technical Assessment Guides (TAGs).It should be noted that RGP is not mandatory and is only a starting point for situations that do not fall within the scope of the circumstances under which the RGP has been derived. ONR inspectors must be mindful that a licensee is always free to take an alternative approach providing it can still demonstrate the required safety or security goal. More information on the definition of ALARP and the use of RGP in judging compliance with ALARP and other goal-setting requirements can be found in the ALARP TAG [III-25]. Within ONR, consistency and rigour of application of RGP is assured through systematic peer review and acceptance processes, embedded into the integrated management system (and described in step 3).

— **Step 3: Integrate the applicable factors into the review and assessment**

(a) Undertaking the Assessment

Prior to commencing any assessment the assessor needs to:

- understand the reason for their assessment;
- understand the scope of their assessment (e.g. interfaces with other specialisms or the scope of assessment if there are a series of staged submissions); and
- consider if they are a suitably qualified and experienced person (SQEP) to undertake the agreed scope or if other advice is required.

(b) Assessment rating

Inspectors should apply an assessment rating to formal permissioning assessments to inform the level of response that needs to be sought against any identified shortfalls, using the guidance on the next page. The assessment rating should be given against the licensee's formal submission. This means that the rating should not take account of regulatory interventions undertaken by ONR inspectors following the formal submission to improve the quality of the submission and/or safety standards. Responses to queries or points of clarification should not be considered improvements to the case and therefore should not form part of the rating process.

Significant shortfalls need to only be recorded if permissioning was not granted or significant modification was sought to the case during the assessment process. If significant modification was required to the submission during the assessment process to enable permissioning, regulatory follow up should be targeted at the failing in licensee's due process. Conversely, assessment ratings should not be applied to licensee's draft submissions provided for information or early engagement. These documents would likely be incomplete and require improvements as part of the licensee's processes and therefore it is not appropriate to rate these submissions in a draft state. In such cases the rating should again be applied to the submission formally supplied to ONR once it has completed the licensee's due process.

(c) Systematic peer review

Peer Reviewers need to consider the following points:

(1) The outcome of the assessment should be clear to potential readers with the conclusions fully supported by the text in the report.

(2) If the report appears incomplete with elements missing or if the judgements are considered inaccurate, the reasons for this view should be clearly stated in the Peer Report feedback. In extreme cases, it may be necessary to resubmit the report for Peer Review.

(3) Avoid returning minor comments if these do not contribute to the quality or the value of the report. The comments should not express the preferences of the Peer Reviewer. Do not burden the Author and delay the production of the report by generating a high number of minor comments. If this is symptomatic of a larger issue, then only that larger issue should be raised. However, consider that the report may be published.

(4) The experience and track record of the Author.

(5) The degree of sampling the Author has undertaken of the duty-holder's submission to ensure that the sample is appropriate to the assessment objectives. See below for more details.

(6) For safety cases and security plans, the significance of the case assessed, with a focus on critical aspects.

(7) For security plans, the significance of the plan is assessed.

(8) Accepted relevant good practice, and where relevant, past precedents.

(9) Novelty and complexity related to the risks under consideration.

(10) The quality of underpinning research and consultation (if applicable).

(11) The perceived quality of any output from assessment carried out by the duty holder's own internal regulator.

(12) Potentially contentious matters, particularly if they are likely to set a precedent.

(13) Avoid bringing unconscious bias into their review, for example by having preconceptions over the acceptability of technologies, techniques, use of particular styles or a notion of quality.

The Peer Reviewer needs to also consider the following questions and note any shortfalls in the Peer Review feedback:

(1) Is the purpose of the report understood and is it sufficiently developed to allow a meaningful Peer Review to take place?

(2) Does the report comply with the Enforcement Policy Statement?

(3) Is the scope adequate for the declared subject or purpose, is it clear and consistent with the aims of the assessment?

(4) Are any exclusions from the scope clearly identified and valid?

(5) Does the output or decision meet the intent of the assessment and is it clearly linked to the assessment process?

(6) Does the report clearly lay out the basis of the duty-holder safety case or security plan and demonstrate a clear understanding of it?

(7) Has the Author considered whether the assumptions and inputs in the duty-holder's safety or security plan case reasonable and justifiable?

(8) Is the technical/legal content of the report soundly based and is there adequate explanation of any uncertainties? Are such uncertainties acceptable in the light of the output/outcome and have steps been taken to reduce or mitigate any uncertainty?

(9) Was the stated sampling strategy followed, was the sampling undertaken during the assessment reasonable and does it cover the critical aspects?

(10) Is the Peer Reviewer satisfied that the report Author has considered the duty-holder's ALARP arguments and has he/she recorded them within his/her report the reasons why he/she is satisfied that the duty-holder has adequately considered a range of measures to make potential safety or security improvements and has reduced the risks ALARP?

(11) Is it clear the Author has understood the technical basis of the duty-holder safety case or security plan along with the attendant ONR expectations.

(12) Is relevant good practice identified and any divergence from it discussed and justified?

(13) Is there a resolution route for unresolved Regulatory Issues: are these likely to compromise the output / outcome and thereby the Regulatory decision?

(14) Are the recommendations SMART and are there any 'loose ends' remaining in the report?

(15) If novel techniques are presented in the duty-holder's safety case or security plan, is it the Author's opinion that they are acceptable, valid and justified (further specialist advice and support may have to be sought in some cases)?

(16) Have appropriate underpinning references supporting the duty-holders submission been proportionately assessed by the Author and do they consider them to be consistent with relevant good practice?

(17) Are the conclusions of the Author's report consistent with previous practice or if not has any significant deviation been justified?

(18) Is it clear that where a Technical Support Contractor has been used to support the assessment that the legal and technical decisions were made by ONR?

(19) Is the language used in the report suitable for publication outside of ONR?

(20) Only a limited examination of the duty-holder's safety case or security plan is expected during the Peer Review as this should be summarized and explained in the Assessment Report.

TABLE III-25. ESTIMATED RESOURCES FOR REVIEW ACTIVITIES

Indicative Assessment Findings	Rating	ONR Response
• Relevant good practice generally met, or minor shortfalls identified, when compared with appropriate benchmarks. • There may be some opportunities for improvement to reduce risks to ALARP or enhance security measures. • There may be some examples of standards being used as a reference at national/international level. • Relatively minor, if any, deficiencies in the technical quality of the safety case or security plan when judged in terms of being intelligible, complete, valid, evidential, robust, integrated, balanced, and forward looking. • No regulatory intervention and guidance needed with relatively minor, if any, issues being raised for clarification. • Relatively minor, if any, deficiencies in safety case compliance arrangements or their implementation under LC13, LC14, LC15 and LC23. • Relatively minor, if any deficiencies in security plan compliance arrangements under NISR 2003 [III-26]. • Safety case, periodic review or security plan submitted on time or slightly late. • There may be some examples of best practice which have been observed and recorded.	**Green**	**No Formal Action** • Provide feedback on the rating and key points to be recorded in the Assessment Report. • If appropriate, provide regulatory advice on how to address any identified areas for improvement. • Expect the licensee/duty holder to address any identified improvements and manage resolution via their internal management controls. • If safety case or periodic safety review supports a permissioning decision recommend issuing consent/approval/agreement. • If security plan supports a permissioning decision recommend issuing approval. • Make a Level 4 Regulatory Issues Database entry, if necessary, to monitor licensee/duty holder progress. • Record any examples of best practice in the Assessment Report and acknowledge these to the licensee/duty holder. • Record advice given regarding continuous improvement and best practice.

TABLE III-25. ESTIMATED RESOURCES FOR REVIEW ACTIVITIES (cont.)

Indicative Assessment Findings	Rating	ONR Response
• Significant shortfall against relevant good practice or established standards when compared with appropriate benchmarks. • Significant or systematic failure in the technical quality of the safety case or security plan when judged in terms of being intelligible, complete, valid, evidential, robust, integrated, balanced, and forward looking. • Significant regulatory intervention and guidance needed with many technical issues being raised requiring regulatory follow-up. • Significant or systematic failure in safety case compliance arrangements or their implementation under LC13, LC14, LC15 and LC23. • Significant gaps in dutyholder ability to demonstrate achievement of security outcomes. • Significant or systematic failure in security plan compliance arrangements or their implementation under NISR 2003 [III-26]. • • Safety case, periodic review or security plan improvements submitted well past agreed time.	**Amber**	**Seek Improvement** • Provide feedback on the rating and key points from the assessment to be recorded in the AR. • Identify and discuss any significant shortfalls with the licensee/duty holder, at an appropriate level. • Review the shortfall(s) against the ONR Enforcement Management Model, ONR-ENF-GD-006 [III-27]. • If the safety case supports a permissioning decision consider withholding consent/approval/agreement. • If the security plan supports a permissioning decision consider withholding approval. • Make a Regulatory Issues Database entry at Level 3 or above to log any enforcement communication and to track progress. • Follow-up and close out the Regulatory Issue when complete.

TABLE III-25. ESTIMATED RESOURCES FOR REVIEW ACTIVITIES (cont.)

Indicative Assessment Findings	Rating	ONR Response
• Major non-compliance with defined or established standards necessary to ensure nuclear safety or security. • Major inadequacies in the safety case or security plan which require prompt regulatory intervention. • Persistent need for regulatory intervention and guidance with multiple issues requiring frequent regulatory contact. • Major shortfall in safety or security requirements revealed as a result of a periodic review of the safety case or security plan, an incident on the site, or any examination, inspection, maintenance or test of any part of a plant indicating that the safe operation or safe condition of the plant may be affected so giving rise to a significant and discernible risk gap to members of the public or workers under the EMM. • Submission of safety case, periodic review or security plan severely delayed, when the intent of the submission is to justifying continued operation when a major shortfall in safety or security requirements has been revealed. • Failure to deliver safety case or security improvements and commitments previously identified in ONR enforcement communications.	**Red**	**Demand Improvement** • Provide feedback on the rating and key points from the assessment to be recorded in the AR. • Raise the identified shortfall(s) with the relevant licensee/duty holder leadership and note the potential for enforcement action. • Draw the matter to the attention of the relevant Programme Delivery Lead. • Review the shortfall(s) against the ONR Enforcement Management Model, ONR-ENF-GD-006 [III-27]. • If safety case or periodic safety review supports a permissioning decision withhold consent/approval/agreement. • If security submission supports a permissioning decision withhold approval. • If safety case or periodic safety review is intended to support continued operation issue a direction under LC31 to shutdown plant, operation or process. • Make a Regulatory Issues Database entry at Level 1 or 2 to log the enforcement communication and to track progress. • Consider if a holding to account, or similar meeting, with the licensee/duty holder is appropriate. Follow-up and close out the Regulatory Issue when complete.

III-8. GRADED APPROACH FOR REVIEW AND ASSESSMENT IN THE US

The U.S. NRC uses a graded approach for reviewing applications to construct and operate nuclear facilities. A graded approach depends on the risk to the public and the complexity of the design of the installations.

— **Step 1: Determine the scope and depth of the review based on applicable requirements, as well as the time available to conduct the review and assessment.**

The NRC has established Standard Review Plans (SRPs) for communicating the applicable requirements to be addressed in nuclear facility construction and operating licence applications. The scope and depth of the review depends primarily on the type of regulated facility. The NRC will revise SRPs to account for unique installation designs.

NUREG-0800 [III-12] is the standard review plan (SRP) for the review of the safety analysis report (SAR) for nuclear power plants. The SRP is intended to be a comprehensive and integrated document that provides the reviewer with guidance that describes methods or approaches that the staff has found acceptable for meeting NRC requirements. While 10 CFR Part 52 [III-28] describes the general requirements for a licence application for a design certification, or a combined construction and operating licence, the SRP provides the detail the NRC staff requires to determine the adequacy of the application. It includes requirements to describe accident analyses for postulated accident scenarios for the reactor design, how the design will mitigate the effects of the accident, and it specifies the acceptance criteria being used to ensure the design is able to meet the regulations. NUREG-0800 [III-12] also contains the review requirements for the proposed technical specifications for the operating nuclear power plant.

Because NUREG-0800 [III-12] was intended for reviewing the SAR for nuclear power plants, applicants and the NRC staff found it very cumbersome to use for reviewing the SAR for non-power reactors because of the significant differences in complexity and hazards. NUREG-1537 [III-15] was developed as the standard review plan for the review of the SAR for non-power reactors, or research and test reactors (RRs). Potential accident scenarios for RRs are significantly different from power reactors, so there is likely to be less analyses to review. Likewise, the technical specifications for operating RRs are significantly less complicated to review.

NUREG-1520, 'Standard Review Plan (SRP) for Fuel Cycle Facilities Licence Applications' [III-17], provides NRC guidance for reviewing and evaluating the health, safety, and environmental protection aspects of applications for licenses to possess and use special nuclear material (SNM) to produce nuclear reactor fuel. This guidance is specific to fuel cycle facilities regulated under Title 10 of the Code of Federal Regulations (10 CFR) Part 70, 'Domestic Licensing of Special Nuclear Material' [III-29] that is, facilities that are authorized for or are seeking a licence to possess and use more than a critical mass of SNM. 10 CFR Part 70 [III-29] identifies risk-informed performance requirements and requires applicants and existing licensees to conduct an integrated safety analysis (ISA) and submit an ISA Summary, as well as other information. In order to provide reasonable assurance that the facility will be operated in a manner that will protect the public health and safety, the staff focuses on the descriptive commitments of the safety programme in the licence application and the description of processes, hazards, controls, and management measures in its ISA Summary and onsite ISA documentation. The staff evaluates the information that the applicant provides and, through independent assessments, determines whether the applicant has proposed an adequate safety programme that is compliant with regulatory requirements. The licensing decision is ultimately based on information with a sufficient level of detail that permits reviewers to understand process system functions and, functionally, how items relied on for safety (IROFS) can perform as intended and be reliable.

NUREG-1567 [III-30] is the Standard Review Plan for Spent Fuel Dry Storage Facilities (FSRP), which provides guidance to the NRC staff for reviewing applications for licence approval or renewal for commercial independent spent fuel storage installations (ISFSIs). An ISFSI may be co-located with a reactor or may be away from a reactor site. These installations may be designed for the storage of irradiated nuclear fuel and associated radioactive materials. These installations are far less complex than other nuclear facilities. The review process of an ISFSI application involves six major phases: (1) site evaluation, (2) operations systems evaluation, (3) criteria and technical design evaluation, (4) evaluation of proposed programs that support protection of worker and public health and safety, (5) evaluation of accidents, and (6) evaluation of proposed technical specifications.

—Step 2: Determine which factors are applicable to the decision, and how those factors are weighted.

The specific factors considered when determining resource optimization include: type of regulated facility, experience and knowledge, urgency for need of licensing action, alternative approaches, and novel design features.

The type of facility generally dictates the depth of review and the resource requirements in order to review all requirements specified in the SRP as efficiently as possible.

The NRC is able to determine reasonable review schedules and resource requirements because of significant experience in reviewing licence applications for all types of facilities.

Additional resources need to be planned to review alternative approaches to approved methodologies described in the applicable SRP.

Novel design features, such as the reliance on passive safety systems for the next generation of nuclear reactors, require additional resources to review because of a lack of experience in assessing their ability to meet their design functions.

In some instances, there is an urgency associated with the review and assessment. These generally involve licensees who require an immediate change to their technical specifications to avoid unnecessarily shutting down the plant. In these cases, there is a need for immediate staff review before approval is granted.

—Step 3: Integrate the applicable factors into determining the optimal resource effort required that is commensurate with the scope and depth established for the review and assessment.

The review and assessment of nuclear power plants requires the greatest resource effort due to the regulatory requirements, the complexity of design, and the relative risk to the public.

The staff has revised NUREG-0800 [III-12] to account for differences in new reactor designs, such as small modular reactors (SMRs, electrical generation capacity of 300 MWe or less per module), and specifically the NuScale design. This includes a risk-informed and integrated review framework utilizing a graded approach for review and assessment. Four review levels (labeled as A1 (safety-related, risk-significant), A2 (safety-related, non-risk-significant), B1 (non-safety-related, risk-significant), and B2 (non-safety-related, non-risk-significant) correlate to the safety classification and risk significance of the SSC under review. Using a graded approach, the staff applies the most rigorous review techniques to SSCs with the highest safety and risk significance (analogous to the typical review process using the SRP), and a progressively less-detailed review to other SSCs as the assigned safety/risk significance declines.

In the SMR review framework, satisfaction of design-based acceptance criteria for categories A1 and B1 continues to be demonstrated using current methods, including independent analysis and evaluations, confirmatory calculations, computer modeling, and other similar techniques. Satisfaction of design-based acceptance criteria for categories A2 or B2 may also be demonstrated using these current methods, or by the use of selected requirements as discussed below. Satisfaction of performance-based acceptance criteria in the framework may be demonstrated by use of traditional methods as described above, through the use of test or performance data from selected requirements, or through a combination of these techniques. The blend of techniques selected by the DSRS technical writers and the reviewers are guided by the SSC safety/risk categorization determined by the applicant and verified by the staff. The NRC requirements that need to be met by an SSC do not change under the SMR framework. Under a graded approach, the NRC staff may rely on the applicant's submittal with selected requirements to demonstrate satisfaction of performance-based acceptance criteria in lieu of detailed independent analyses. They may also be used to demonstrate satisfaction of design-based acceptance criteria for category A2 and B2 SSCs. For example, satisfaction of acceptance criteria related to the capability, availability or reliability of an SSC may be addressed through the satisfaction of these selected requirements, to an extent consistent with the safety/risk categorization of the SSC. Review levels A1 through B2 reflect a graded approach to reviews in that performance-based activities within selected requirements are increasingly applied to satisfy design-specific review standard (DSRS) acceptance criteria in lieu of applying traditional analysis and evaluation techniques.

The verification of whether an SSC is safety-related (i.e. satisfies any of the criteria in 10 CFR 50.2 [III-31], risk-significant, or both is accomplished through current evaluation and decision processes. Risk significance is measured relative to the likelihood and consequences of severe accidents which involve core damage and can lead to containment failure with a large release of radioactivity.

The NRC staff determined whether to develop a new DSRS section after considering whether significant differences in the functions, characteristics, or attributes of the NuScale design required major revision of the related SRP section guidance, or whether structures, systems, and components identified in the NuScale design are unique and not addressed by the current SRP. The staff revisited these criteria after publishing the draft version of this DSRS section (issued in June 2015) and determined, based on the most recent NuScale design, that the related SRP section is appropriate to perform the NRC safety review. Therefore, this DSRS section will not be issued as final and the related SRP section will be used for this portion of the NuScale review. In deciding to use the related SRP section, the staff has not necessarily determined that the SRP section is wholly applicable without modification. For example, as the NRC staff gains greater understanding of the NuScale design or if the design changes during the review, the staff would assess whether different or supplemental review criteria are needed.

The Atomic Energy Act (AEA) of 1954 [III-32] was written to promote the development and use of atomic energy for peaceful purposes and to control and limit its radiological hazards to the public. The AEA states that utilization facilities for research and development should be regulated to the minimum extent consistent with protecting the health and safety of the public and promoting the common defence and security. The licensed thermal power levels of non-power reactors are several orders of magnitude lower than current power reactors. Therefore, the accumulated inventory of radioactive fission products in the fuel of non-power reactors is proportionally less than power reactors and requires less stringent and less prescriptive measures to give equivalent protection to the health and safety of the public. Thus, even though many of the regulations of Title 10 apply to both power and non-power reactors, the regulations may be implemented in a different way for each category of reactor and are intended to be consistent with protecting the health and safety of the public. Because the potential hazards may also vary widely among non-power reactors, regulations also may be implemented in a different way within the non-power reactor category.

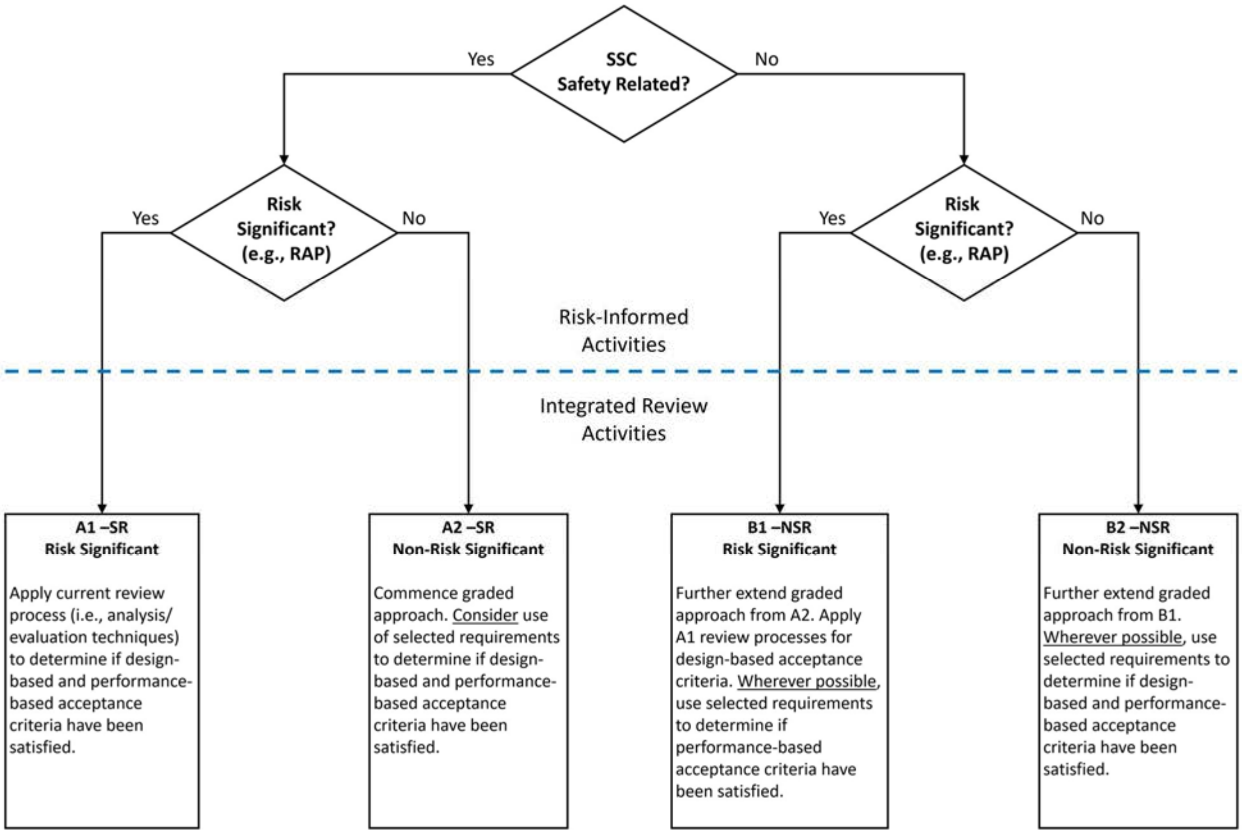

FIG. III-8. Determination of Review Levels (A1 through B2) for design-specific review standard (DSRS)

The NRC establishes goals for completion times for different types of licence applications. The goal for the length of time it should take to perform new design certification (DC) safety reviews for large light-water reactors (LWRs) under 10 CFR Part 52 [III-28] has been set at 42 months. For large LWR DC reviews, the following review timeliness goals are used:

- two months for completion of the acceptance review
- 42 months for completion of the safety review (factors such as the uniqueness of the design, the need for and extent of vendor testing required, and whether technical or policy matters are effectively addressed in pre-application reviews, will affect the ability of the staff to apply this goal in some cases)
- eight months after completion of Phase 4 of the safety review for completion of rulemaking (total rulemaking duration of 13 months).

For small modular reactors (SMRs), DC reviews, the goal of 39 months from acceptance of the application to completion of rulemaking is used.

There are many factors that support or inhibit review efficiency. Examples of internal factors include staff resource management, work prioritization, support for hearings, review phase discipline, critical skills availability, budgetary limitations, computational tool availability for unique reactor designs, the overall staff workload and capacity, and resolution of policy issues that may require rulemaking. Examples of external factors include application quality, applicant experience, the degree of design finality, whether or not the technology presented is familiar to the staff, and the availability of contracted subject matter expertise. Efficiencies may be realized as review staff gain experience with systems and technologies referenced in prior reviews.

The following table summarizes the estimated resource effort for certain DCs and reviews of combined operating licenses (COLs). An FTE is a full-time equivalent (FTE), which represents one staff member working full time on the project.

TABLE III-26. ESTIMATED RESOURCES FOR REVIEW ACTIVITIES

Review Activity	**Staff (FTE)**			**Contractor ($K)**
	Licensing	**Inspection**	**Research**	
Pre-Application Review for AP1000 (Phase 2)	2	0	0	$0
Early Site Permit Review (existing site)	16	4	0	$1700
Early Site Permit Review (new site)	20	4	0	$2100
Design Certification for AP1000	24	1	5	$1500
Combined Licence for Standard Certified Design	23	65	0	$1100

For applications to renew operating licenses, the goal to complete reviews is 22 months if there is no hearing, and 30 months if there is a hearing associated with the application. The reduced time is because the review is limited in scope to ensure operating nuclear plant licensees can manage aging for long-lived, passive safety related SSCs for an additional 20 years. Typical licence renewal reviews require approximately 20 FTE and $350,000 in contractor support.

The NRC generally manages resources based on licensee notification of pending licence applications. There is an expectation that licensing reviews are completed on schedule. Applicants have to plan budgets, order equipment, and develop contracts well in advance of issuance of the licence, so timeliness is very important. Limited regulatory resources are apportioned to ensure review schedules are maintained. Management establishes priorities when there are limited resources to complete the reviews.

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ANNEX IV.

PRACTICAL EXAMPLES OF MEMBER STATES ON THE USE OF GRADED APPROACH IN CORE REGULATORY FUNCTIONS: INSPECTION

This annex collects practical examples from Member States of the use of a graded approach in different aspects of inspection. These contributions were developed by the contributing Member States based upon their own experience and describe how the general three-step methodology described in Sections 3.2 and 4.4 can be used.

This annex provides examples covering a wide range of possible applications of a graded approach. However, it is not comprehensive and additional applications, not covered herein, could also be envisaged by Member States.

IV-1. GRADED APPROACH TO DETERMINE THE BASELINE NUMBER OF INSPECTIONS IN NUCLEAR FUEL CYCLE FACILITIES AND RESEARCH REACTORS IN CANADA

— **Step 1: Specify the decision to be made**

Determine the relative regulatory effort for the baseline compliance programs for fuel cycle facilities and research reactors based on risk ranking for the facility. This will support adequate compliance activities to ensure safety, based on the assessed potential nuclear safety risks associated with the facility or activities.

— **Step 2: Identify factors to be used**

A high level risk ranking of the facilities and activities that fall under the regulatory mandate of the Directorate of Nuclear Cycle Facilities Regulation (DNCFR) is conducted in view of the CNSC's strategic outcome 'Safe and secure nuclear facilities and processes used solely for peaceful purposes and an informed public on the effectiveness of Canada's nuclear regulatory regime' and mission as guiding principles. The licensed facilities and activities are then categorized as low, medium or high risk based on the criteria listed in Table IV-1.

TABLE IV-1. HIGH-LEVEL RISK RANKING CRITERIA USING 'SAFE OPERATIONS' CONSIDERATIONS

Consideration	Criteria
What types of hazards exist?	- amounts/types of hazardous substances (not radioactive) - nature of hazardous substances - complexity of process - extent of handling (human-machine interaction)
What are the consequences of failure? - On workers - On public - On the environment	- nuclear criticality safety - level of containment - dose to workers and the public - long term consequences - off-site consequences
How complex are the operations?	- breadth of operations - number of workers on site - project stage (level of physical activity/state of operations)

Then, using a risk matrix (Table IV-2) together with facility/activity-specific ratings, possible risk management actions are considered in order to place DNCFR facilities and activities into High, Medium and Low risk categories.

TABLE IV-2. RISK MATRIX

Impact Or Consequence	**Risk Management Actions/effort**		
High	**Considerable**	**Must Manage and Monitor**	**Extensive managing and monitoring**
Medium	**Accept but monitor**	**Worthwhile**	**Must Manage and Monitor**
Low	**Accept risk**	**Accept but Monitor**	**Manage and Monitor**
	Low	**Medium**	**High**
	Likelihood or Probability		

Table IV-3 provides some examples of guidance that may be used to support risk rankings for facilities.

TABLE IV-3. EXAMPLES OF RISK RANKINGS FOR FACILITIES AND ACTIVITIES

If the facility or activity has….	**Then…**
Large quantities of nuclear substances, more complex operations Several licensed facilities on the same site (nuclear research and test establishments)	Risk matrix => medium likelihood/high impact High Risk, Must Manage and Monitor
Complex operations, many workers on site (operating mines)	Risk matrix => Medium likelihood/high impact (environment – on and off-site impact, and workers) High Risk, Must Manage and Monitor
Active nuclear and uranium processing, or facility decommissioning (Class IB Facilities)	Risk matrix => low likelihood/medium impact Low Risk, Accept but Monitor
Small quantities of nuclear substances, limited handling activities, low complexity of operations The licences in this category authorize the possession of nuclear substances. These licences include waste storage and processing facilities	Risk matrix = Low likelihood/low impact Low Risk, Accept Risk

— **Step 3: Establish risk rankings for facilities, to support extent of the baseline compliance programme**

Table IV-4 is an illustrative example that provides a description of the facilities, their associated hazards and the risk ranking for the facility based on the factors listed in Table IV-1 and considerations outlined in Table IV-3.

TABLE IV-4. EXAMPLE: RISK RANKING OF NUCLEAR FUEL CYCLE FACILITIES AND RESEARCH REACTORS

Facility Description	Hazards	Consequences	Risk Ranking
Metal recycling and alloy production	Uranium, exposure to acid solutions, fire	Damage to the facility from fire. Limited to injuries to workers in the immediate area	Low – low nuclear substance inventory, hazardous substances used – on-site consequences moderate, off-site consequences low – complexity of operation is low
Reactor for research, activation analysis	Radiological	Some release to the environment from a fuel failure, although of small magnitude (small source term). In case of failure, the release from the core would be contained/ significantly delayed within the reactor vessel. Exposure to staff from neutron activation sources, failure of an encapsulated source.	Low – low nuclear substance inventory – on-site, off-site consequences negligible – complexity of operation is low
Reactor for research, isotope production, neutron radiography	I-125 release, uncontrolled criticality incident (very low likelihood)	Uncontrolled criticality leading to fuel failure (extremely unlikely). Consequences are doses to personnel I-125 exposure to workers because of human error in fuel handling. The consequence is some low-level exposure to workers.	Medium – moderate nuclear substance inventory – on-site consequences moderate, off-site consequences low – complexity of operation is moderate
Manufacturing UO2 pellets for CANDU fuel bundles	Liquid hydrogen is used in the furnaces that prepare the material to be formed into pellets. Fire initiated by the liquid hydrogen is a potential hazard.	Major damage to the facility with a resulting fire plume release. Limited to injuries to workers in the immediate area	Medium – moderate nuclear substance inventory, hazardous substances used – on-site & off-site consequences moderate – complexity of operation is moderate

TABLE IV-4. EXAMPLE: RISK RANKING OF NUCLEAR FUEL CYCLE FACILITIES AND RESEARCH REACTORS

Facility Description	Hazards	Consequences	Risk Ranking
Fabricating CANDU fuel bundles (starting from UO2 powder)	Transforms UO_2 to fuel pellets fabricating bundles for CANDU reactors. Liquid hydrogen used in the furnaces to prepare the pellets could initiate a fire.	Damage to the facility and release of plume to the environment. Possibility of injury to workers	Medium – moderate nuclear substance inventory, hazardous substances used – on-site consequences moderate, off-site consequences low – complexity of operation is moderate
Tritium Light Production Facility	A fire at the facility that results in the inventory of tritium released	Release of tritium to the environment. Potential for injuries work directly in the area where tritium is handled Plume generated by such a fire could drift over a populated area. (exposure would be in the 0.5 mSv range)	Medium – moderate nuclear substance inventory, – on-site & off-site consequences moderate – complexity of operation is moderate
Cobalt and medical isotopes- Multiple radioactive material shipping/ week	Cobalt pool is emptied- High local doses in the building. Large inventory of radioisotopes (including noble gases and iodine) could be released in case of serious fires. Most hazards are localized and to workers	Large fire in ventilation room affecting charcoal filters-> large release to surrounding community (low probability) Fire to most critical processes or in ventilation room: overexposure to workers, potentially higher exposure to public.	Medium – moderate nuclear substance inventory, – on-site & off-site consequences moderate – complexity of operation is moderate
Class II Irradiators and radiation devices manufacturing	Localized hazards (to workers only)	Potential overexposure to few workers.	Medium – moderate nuclear substance inventory, – on-site & off-site consequences moderate – complexity of operation is moderate

TABLE IV-4. EXAMPLE: RISK RANKING OF NUCLEAR FUEL CYCLE FACILITIES AND RESEARCH REACTORS

Facility Description	Hazards	Consequences	Risk Ranking
Purifying Uranium Ore Concentrate & converts it to Uranium Trioxide	- yellowcake held on site from various mining facilities around the world Fire scenario involving the kerosene which is used as part of the solvent extraction process that purifies the uranium to uranium trioxide.	A fire that would result in the facility being damaged to the point that a major interruption in UO_3 supply. - an event would/could lead to some injuries to workforce.	High – large nuclear substance inventory, hazardous substances used – on-site & off-site consequences moderate – complexity of operation is high
Converting UO3 to UO2 powder for fuel production & to UF6 for export to enrichment facilities	aqueous hydrogen fluoride release from a railcar or site storage inventory - cold trap failure in the building resulting in a UF_6 liquid release in the facility.	A major release of HF. A cold trap release could impact a small number of workers. The community could be impacted by the release of HF.	High – moderate nuclear substance inventory, hazardous substances used – on-site consequences high, off-site consequences moderate/high (if HF leak) – complexity of operation is high

(a) Development of the 10 Year Baseline Inspection Programme

The approach taken to develop the recommended Type II baseline inspections for all safety and control areas for low-, medium- and high-ranked facilities was to:

- identify the ranking factors for the safety and control area (SCA); and
- recommend the baseline inspections to be conducted over a 10-year period for the SCA.

Table IV-5 provides the ranking factors for the management system SCA (as example for one SCA). Table IV-6 provides the recommended management system inspections for low-, medium- and high-ranked facilities, as per classification presented in Table IV-4.

The recommended Type II baseline inspections for all safety and control areas for low-, medium- and high-ranked facilities (Table IV-7). (A Type II inspection is planned and documented activity to verify the results of licensee processes and not the processes themselves. Type II inspections are typically routine (item-by-item checklist) inspections and rounds of specified equipment and/or facility material systems, or of discrete records, products or outputs from licensee processes).

TABLE IV-5. MANAGEMENT SYSTEM RANKING FACTORS

Low	**Medium**	**High**
• Low level of safety significant and complex operations identified in the safety case • Operations are simple and require defence-in-depth (human, organizational and technological) aspects commensurate to prevent or reduce undesired effects to health and safety, environment, security and continuity of operations • Events have no foreseeable adverse effects to health and safety, environment, security and continuity of operations	• Medium level of safety significant and complex operations identified in the safety case • Operations are moderately complex and require defence-in-depth (human, organizational and technological) aspects commensurate to prevent or reduce undesired effects to health and safety, environment, security and continuity of operations • Events could result in a minor adverse effect to health and safety, environment, security and continuity of operations	• High level of safety significant and complex operations identified in the safety case • Operations are significantly complex and require defence-in-depth (human, organizational and technological) aspects commensurate to prevent or reduce undesired effects to health and safety, environment, security and continuity of operations • Events could result in a major adverse effect to health and safety, environment, security and continuity of operations

TABLE IV-6. RECOMMENDED INSPECTION APPROACH FOR THE MANAGEMENT SYSTEM FOR LOW-, MEDIUM- AND HIGH-RANKED FACILITIES

Low	Medium	High
• SME review of licensee submissions (e.g. annual or quarterly reports, event reports) • Standardized SME-endorsed management system checks incorporated into general Type II inspection matrices and inspection reports shared with SMEs for information	• SME review of licensee submissions (e.g. annual or quarterly reports, event reports) • Standardized SME-endorsed management system checks incorporated into general Type II inspection matrices and inspection reports shared with SMEs for information • Two Type II-focused (SCA/SpA specific) inspection per 10 year licence period	• SME review of licensee submissions (e.g. annual or quarterly reports, event reports) • Standardized SME-endorsed management system checks incorporated into general Type II inspection matrices and inspection reports shared with SMEs for information • Three Type II-focused (SCA/SpA specific) inspection per 10 year licence period

TABLE IV-7. RECOMMENDED TYPE II BASELINE INSPECTIONS FOR ALL SAFETY AND CONTROL AREAS FOR LOW, MEDIUM AND HIGH-RANKED FACILITIES

SCA	**Number of Type II Baseline Inspections Over a 10 Year Period**					
	High Risk ranked DNCFR Facility/Activity		**Medium Risk ranked DNCFR Facility/Activity**		**Low Risk ranked DNCFR Facility/Activity**	
	#	**Comment**	**#**	**Comment**	**#**	**Comment**
Management System	3		2			
Human Performance	2		1			
Operating Performance**	1	primarily assessed by reviews of licensee submissions		primarily assessed by reviews of licensee submissions		
Safety Analysis*	2	in relation to nuclear criticality	1	in relation to nuclear criticality		
Physical Design**		primarily assessed by reviews of licensee submissions		primarily assessed by reviews of licensee submissions		
Fitness for Service	2	inspections from PD moved to FFS as decided at management workshop Aug 15	1	inspections from PD moved to FFS		
Radiation Protection	2		1			
Conventional Health & Safety**						
Environmental Protection	2		1			
Emergency Management and Fire Protection	2		1			
Waste Management	2					

TABLE IV-7. RECOMMENDED TYPE II BASELINE INSPECTIONS FOR ALL SAFETY AND CONTROL AREAS FOR LOW, MEDIUM AND HIGH-RANKED FACILITIES (cont.)

SCA	Number of Type II Baseline Inspections Over a 10 Year Period					
	High Risk ranked DNCFR Facility/Activity		Medium Risk ranked DNCFR Facility/Activity		Low Risk ranked DNCFR Facility/Activity	
	#	Comment	#	Comment	#	Comment
Security*	2	for high security sites	1	for high security sites		
Safeguards*						
Packaging and Transport*	2		1			
General Type II Inspection***	10	* Covers multiple SCAs and includes SME endorsed checks	5	* Covers multiple SCAs and includes SME endorsed checks	3	* Covers multiple SCAs and includes SME endorsed checks
Total	**32**		**15**		**3**	

* if applicable this is the baseline (activity based, not facility based)
** criteria included as part of all General Type II inspections
*** covers multiple SCAs and includes SME endorsed checks

IV-2. OVERVIEW OF APPLICATION OF GA IN INSPECTIONS OF NUCLEAR FACILITIES AND INSPECTION AREAS DURING DIFFERENT LICENSING STAGES IN PAKISTAN

Regulatory Inspections are conducted in all phases of nuclear facility's lifetime. Regulatory inspections are conducted to achieve high level of assurance that all activities performed by the licensee during all phases of the nuclear installation are executed safely and are in accordance with the regulations, licence conditions and commitments of the licensee.

IV-2.1. Types of Inspection

According to its Inspection Programme, PNRA mainly conducts two types of inspections namely planned and reactive inspections. Either type of inspection may be announced or unannounced, however, announced inspections are more common.

— Planned Inspections: Planned inspections are conducted in accordance with a baseline inspection plans developed by the respective directorates of PNRA. They are scheduled in advance and are not initiated by unusual or unexpected circumstances.

— Reactive Inspections: Reactive inspections are conducted in response to an unexpected, unplanned or unusual situation or event, in order to assess its significance and implications and the adequacy of corrective actions. A reactive inspection may be occasioned by an isolated situation or a series of lesser events occurring at the particular facility under consideration or may be in response to a generic problem encountered at another plant, or identified during the review and assessment process.

IV-2.2. Applying a graded approach in Inspections

PNRA applies GA in regulatory inspections for optimization of regulatory resources such as human resources, time and economical resources during different licensing stages of the nuclear facilities for all types of nuclear facilities without compromising on safety.

(a) Factors for application of GA in inspections

For application of a graded approach in resources for inspections, there are certain factors which are taken into account. These are:

(1) Type of facility (i.e. risk to public and workers)
(2) Design of the installation (complexity)
(3) Availability of resources
(4) Stage in the lifetime of the installation
(5) Inspectors' experience
(6) Licensee performance

(b) Rationale for application of GA in Inspections

Rationales for application of GA in inspections of nuclear facilities are described below:

(1) More resources are required for facilities with off-site hazard potential as compared to on-site hazards potential;
(2) Radiological hazards and complexity of design of the facility influences the allocation of resources for inspections: complex design/systems more inspections with more resources are required;
(3) Stage of the lifetime of the installation. The resource allocation for inspections depends upon the licensing stage:
    — More inspections are performed during commissioning phase as compared to construction/manufacturing phase of the nuclear facility;

    — More inspections are performed during refuelling outages of NPPs as compared to routine operation.

(4) Availability of relevant experts in specific areas can also reduce the allocation of resources for inspections;
(5) Performance of the contractors during construction or performance of the plant during operation may also affect the resource allocation for inspections.

(c) Salient Features for Optimization of Resources

To optimize the resources with consideration of GA, some salient features which show the differences in the management of inspections at different Nis, are described below:

(1) More attention is given to safety significant areas;
(2) Resident inspectors are deployed at NPPs as compared to RRs or NFCFs;
(3) General surveillances are performed only at NPPs;
(4) Daily inspections of MCRs logbook are performed at NPPs during operation;
(5) Participation in morning meetings of NPPs to have first-hand information on important issues;
(6) Frequency of inspections is high at NPPs as compared to RRs or NFCFs;
(7) Number of inspectors involved is less at RRs as compared to NPPs.

(d) Considerations for determination of safety significant areas

The evaluation of SSCs is performed with consideration of the following;

(1) More attention is given to systems and components related to primary side than to secondary side.
(2) Safety classification
(3) Contribution towards CDF based on PSA modelling

Some other aspects considered for selection of inspection areas:

(1) Experience feedback (national and international)
(2) Design modifications
(3) Feedback from review and assessment
(4) Experience feedback from previous inspections

(e) Frequencies of inspections

(1) In some licensing stages (such as manufacturing, installations, commissioning and decommissioning) of the nuclear facilities, frequency for inspection is not defined as these activities are performed only one time in the life cycle of the plant.
(2) Frequency for periodic inspections during operation stage of the plant is defined as inspections are performed repeatedly to ensure compliance with regulatory requirements for safe operation of the plant. Some frequencies for periodic inspections in different areas for NPPs are given in Table IV-8.

TABLE IV-8. FREQUENCY OF INSPECTIONS IN DIFFERENT AREAS FOR NPPS

S. No.	Areas for Periodic Inspections	Frequency for Inspections
1.	Shift Change Over	Annual
2.	MCR and Local Area Operators Shift Compliment Verification	
3.	Radiation Protection Programme	3 years
4.	Radioactive Waste Management Programme	
5.	PSR Corrective Action and Implementation Status Verification	3 years (where applicable)
6.	Verification of FRAP Implementation	
7.	Quality Assurance Programme	5 years
8.	Plant modifications / call-up cards / OEF / LERs / Preventive Maintenance Programme / Data Management	
9.	EPP and EMP	
10.	Verification of Operator Training & Retraining Process	
11.	Physical Protection Programme	
12.	Fire Protection Programme	
13.	Safety Culture	
14.	Plant Chemistry	
15.	Procurement and Inventory Verification	
16.	Industrial Safety	
17.	In-service Inspection Programme and Aging Management	6 years
18.	Verification of Technical Specification Compliance	10 years
19.	General Surveillance of Plant Areas & Log Review	Daily
20.	Surveillance Tests	As per frequency defined in TS (Monthly, Quarterly, Annually etc.,)

TABLE IV-8. FREQUENCY OF INSPECTIONS IN DIFFERENT AREAS FOR NPPS (cont.)

S. No.	Areas for Periodic Inspections	Frequency for Inspections
21.	Tagging of Equipment	Post-RFO (Post-Refuelling Outage)
22.	Calibration of Measuring and Testing Equipment	Pre-RFO
23.	Training of Radiation workers/RFO-Contractors	Pre-RFO
24.	Personnel Qualification for execution of RFO Jobs	Pre-RFO
25.	FME Compliance Verification	During RFO

IV-3. USE OF A GRADED APPROACH DURING INSPECTIONS OF RESEARCH INSTALLATIONS IN THE RUSSIAN FEDERATION

In the Russian Federation a prescriptive regulatory approach is used for regulating nuclear facilities and activities on the use of nuclear energy. As described in Appendix IV of this TECDOC, the use of prescriptive tools and requirements raise additional challenges to the nuclear regulator if a graded approach is to be applied to the regulatory functions. In this case, some aspects ought to be considered in the order of inspections to allow grading the inspections in a manner commensurate with the magnitude of the radiation risks of the activities.

This appendix provides a practical example on how to apply the three-step methodology developed in this TECDOC for a graded approach in the inspections of research installations (i.e. research reactors, critical and subcritical assembles and accelerator driven systems) in the Russian Federation.

Inspections of research installations in the Russian Federation are implement during review of licence application and during operation of facilities. A general order of inspection activities is established in chapter 5 of Federal Law No 170-FZ on 21.11.1995 ‘On the Use of Atomic Energy’ [IV-1] and para. 5.3.8 of Russian Government decree No 401 on 30.07.2004 ‘On Federal Ecological, Technical and Nuclear Supervision Service’ [IV-2]. Exact requirements for inspection activity on research installations are stated in Administrative regulation of Rostechnadzor No 248 on 07.07.2013 ‘Administrative Regulation on State Function of Federal Ecological, Technological and Nuclear Supervision Service for Federal State Supervision on Nuclear Energy’ [IV-3] and in a guide document RD-04-24-2000 ‘Guidelines for Inspections of Research Installations’.

— **Step 1: Identify the decision associated with the order of inspection activities that is required**

This step 1 deals with assessing the decision whether the inspection of research installation is necessary to implement or not. The purpose is to examine the operating organization for the conditions and a justification for the implementation of the declared activities, the ability to provide operational safety of research installation and the adequacy of information provided in the safety review documents.

The results of these assessments may vary as follows:

(a) Non-compliance with safety requirements is not identified;

(b) Insignificant non-compliance with safety requirements is identified. The prescription to remove the safety deviation is issued to operator;

(c) Significant non-compliance with safety requirements is identified. The prescription to remove the identified non-compliance as well as administrative penalties in accordance with Russian legislation are issued to operator.

— **Step 2: Determine which factors are applicable to the decision, and how those factors are weighted**

In this example, the specific applicable factors used were purpose, form, type, order, type and power of research installation.

Other important factors to be considered are:

(a) The stage of the lifetime of the installation. Radiation risks associated with a facility under decommissioning are different from those for a new research reactor or a facility that need to have its operating licence extended.

(b) The safety significance and the associated safety functions of structures, systems and components.

(c) The analysis might also include aspects associated with failure rate, design technology and maintenance, like ageing management, periodical inspections and repair.

The categories of potential radiation risks are important to define requirements applicable to the operating lifetime and to define emergency action plans.

— **Step 3: Integrate the applicable factors into the decision-making process.**

During review of the operator's applications for a licence, Rostechnadzor implements inspections in order to confirm the level of competence of the research installation[11] operator to fulfil the safety objectives, to prove the information provided in the licence application documents and to assess the elements required to operate the research installation in compliance with the legislation. Inspections of operators during they licensed activities are implemented in order to confirm fulfilment of regulatory requirements for the research installations, including the Russian Federation legislation, federal rules and regulations, requirements of the project documentation as well as other suitable requirements. In addition, the inspections are aimed at verifying the Operator's corrective measures to address the research installation safety deficiency.

Depending on a research installation life cycle stage, during the review of the application inspections are also implemented to check construction activities and preparedness for commissioning or decommissioning, as well as current safety condition.

Inspections of operators during licensed activities may be planned and unplanned as well as may also differ by its scope (complex, target and operative). Planned inspections are implemented in accordance with Rostechnadzor and its territorial offices plans. Unplanned inspections can be implemented in case of violations. All inspections are based on a working programme, which defines aim, scope, operators' services, terms of the inspection and documents to be provided by the operator for the inspection.

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[11] In the Russian Federation, research installations include research reactors, critical and subcritical assemblies, and accelerator-driven systems.

Complex inspections[12] have to be implemented at least once every 5 years. Their duration most commonly does not exceed 20 days.

Depending on the power and type of a research installation, target inspections need to be implemented with varying frequency; for example, for research reactors with 1 MWt power or more, once a year; once every 2 years for pulsed reactors; reactors with power less than 1 MWt and critical assemblies; and one time every 3 years for subcritical assemblies as well as installations under construction or installations that are at a decommissioning stage. The duration of these inspections does not have to exceed 15 days.

Depending on the power and type of operating research installation, routine (not target) inspections need to be implemented at least once a quarter for research reactors with 1 MWt power or more, once every half a year for pulsed reactors and critical assemblies and once a year for subcritical assemblies as well as constructed installations and installations that are at a decommissioning stage. The duration of these inspections does not have to exceed 3 days.

IV-4. POSSIBLE DEVELOPMENT OF A GRADED APPROACH DURING INSPECTIONS OF NUCLEAR FACILITIES IN THE RUSSIAN FEDERATION

In the Russian Federation the prescriptive regulatory approach is used for regulating nuclear facilities and activities on the use of nuclear energy. As described in Appendix IVof this TECDOC, the use of prescriptive tools and requirements raise additional challenges to the nuclear regulator if a graded approach is to be applied to the regulatory functions. In this case, some aspects ought to be considered in the order of inspections to allow grading the inspections in a manner commensurate with the magnitude of the radiation risks of the activities.

This appendix provides a possible approaches for determining the frequency of planned inspections, depending on the established risk category as a part of step 2 ‘Determine which factors are applicable to the decision, and how those factors are weighted’ of the three-step methodology developed in this TECDOC for a graded approach in the inspections of nuclear facilities in the Russian Federation.

The basics of a risk-based approach to safety regulation were laid down in the Federal Law ‘On the Use of Atomic Energy’ [IV-1] six years ago (corresponding changes were made to Article 24 in 2011). According to this law, measures implemented by state safety regulatory authorities must be proportionate to the potential danger of nuclear facilities and activities in the field of atomic energy use. Nuclear facilities are complex technological objects, each of them is characterized by its own life cycle. And its potential hazard dynamically changes from insignificant (at the construction stage) to significant (during operation). In this regard, at various stages of the life cycle, regulation in general, and control (supervision) in particular should have their own characteristics. At the stage of siting, design and construction of the facility, the main task should be solved - the elimination of errors and design and construction defects that could affect the safety during its operation. The level of potential hazard of nuclear facilities at further stages of the life cycle depends on the appearance of radioactive substances and / or radioactive waste, and the beginning of the generation of ionizing radiation. At the operation stage, the hazard level can vary. It may be due to scheduled repairs, extension of the operating life, and events or accidents. However, until recently, the application of the principle

[12] Complex inspections include checks of the full scope of safety important features of a facility (including different systems and documentation). A large number of Rostechnadzor specialists from Central Office and Territorial Offices take part in such an inspection.

of proportionality contained in Federal Law No. 170 [IV-1] was limited. The provisions of the Federal Law 'On the Protection of the Rights of Legal Entities ...' No. 294 [IV-4] (as amended until 2015) established a uniform intensity of supervisory measures (inspections including) for all types of state supervision.

In accordance with Law No. 294 [IV-4], scheduled inspections could be carried out no more than once every 3 years. To date, Federal Law No. 294 [IV-4] has been supplemented by an article providing for the application of a risk-based approach in supervision activities. These changes also determine the general procedure for applying a risk-based approach. During determining the hazard class, the severity of the negative consequences of non-compliance with safety requirements is taken into account, and when determining the risk category, the probability of non-compliance with safety requirements is additionally taken into account.

According to Federal Law No. 294 [IV-4], the list of types of federal state control (supervision) for which a risk-based approach is applied, as well as the criteria and rules for classifying the activities of facilities as a specific risk category (hazard class) are determined by the Government of the Russian Federation. In support of this article, the Government of the Russian Federation adopted Decree No. 806 approving the Rules for classifying the activities of facilities as a specific risk category or a specific hazard class. Currently, the working group at Rostechnadzor, with the involvement of all stakeholders, is developing criteria for classifying research nuclear facilities as a specific risk category or a specific hazard class. The purpose of the work of this working group is to include state supervision of research nuclear facilities in the list of types of state control for which a risk-based approach is applied.

Depending on the criteria, three types of risk evaluation models might be applied – 'static', 'quasi-dynamic' and 'dynamic'. For example, 'the dynamic' model in risk evaluation could take into account violation of regulatory requirements that took place on a nuclear installation. On the contrary, the 'static' model does not take into account this criterion. The 'quasi-dynamic' model might be applied in order to consider constructive differences on nuclear facilities and differences in utilization if the 'static' model is already being widely used for assessment of nuclear facilities risk. In the 'quasi-dynamic' model nuclear facility risk category depends on some dynamic factor such as utilization regime. Other factors during evaluation will be static for example type of nuclear facility, potential radiation hazard category, power and etc. An example flow-chart of the 'static', 'quasi-dynamic' and 'dynamic' models is shown in the figure below.

At the first stage of implantation a risk-based approach, it is proposed to use a static risk assessment model, establishing four hazard classes. It is proposed to use the existing categorization of objects according to their potential radiation hazard in accordance with sanitary requirements as the main risk criterion used to classify an object into the corresponding hazard class. The category of potential radiation hazard is determined based on the radiation consequences for the population and personnel at the maximum radiation accident. In the accident at a Category I radiation facility, radiation exposure of the population is possible and measures to protect them may be required. Category IV includes objects whose radiation exposure during an accident is limited to rooms where work with radiation sources is carried out. It should be noted that the implantation of a static model of risk assessment will not require significant time and financial costs, because hazard class will directly depend on the already defined categories of potential radiation hazard. An example of establishment of inspections duration based on the 'static' model is shown in Table IV-9.

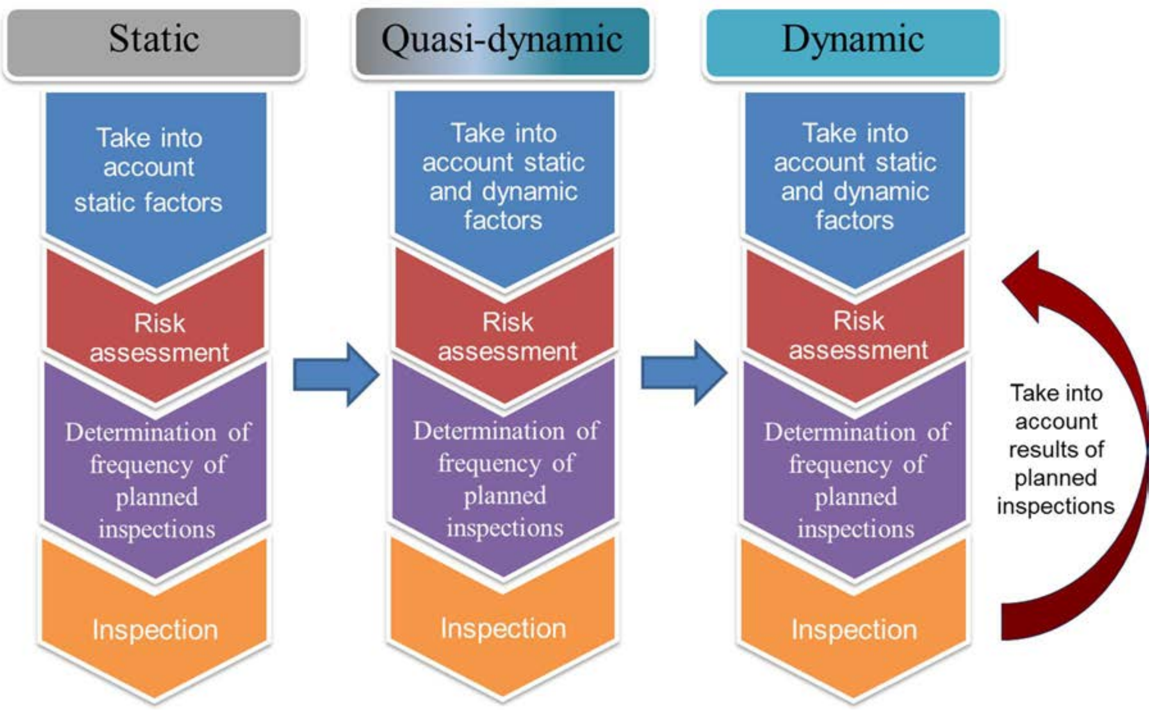

FIG. IV-1. Flow-chart of implantation a risk-based models

At the second stage, instead of hazard classes, it is proposed to use risk categories defined using a 'quasi-dynamic' risk assessment model. The advantage of this model is a higher level of flexibility (the ability to consider the current operating mode or the life cycle stage of research nuclear facilities, as well as taking into account their design features (type of research nuclear facility, thermal power, pulse generation method). Within the framework of the 'quasi-dynamic' model, two main groups of research nuclear facilities are distinguished: research reactors and research nuclear facilities, different from research reactors (critical assemblies, subcritical assemblies, subcritical electro-nuclear reactors). Separation of research reactors into a separate group is due to the fact that they have the most significant structural, technical and functional differences from the rest of the research nuclear facilities. At the same time, the diversity of research reactors, due to the difference in rated power (see Fig. IV-2), design of active zones, types of coolants, also does not allow combining them into one risk category.

TABLE IV-9. STATIC MODEL OF RISK ASSESSMENT

Hazard class	**Risk criteria**	**Frequency of planned inspections**
I	Category I facility potential radiological hazard	1 time per year
II	Category II facility potential radiological hazard	1 time in 2 years
III	Category III facility potential radiological hazard	1 time in 3 years
IV	Category IV facility potential radiological hazard	not more than 1 time in 4 years but not less than 1 time in 5 years

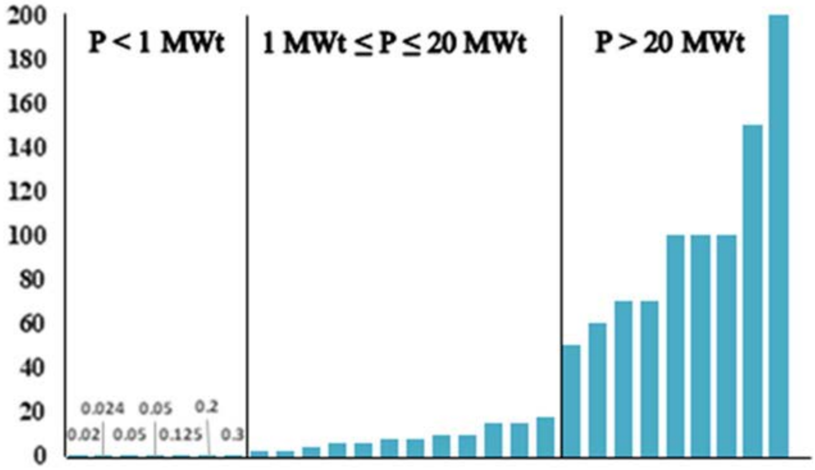

FIG. IV-2. Distribution of Russian research reactors (operating in stationary mode) by thermal power

For research reactors, within the framework of the ‘quasi-dynamic’ model, the risk category is established depending on the thermal power of the reactor core and the pulse generation method. The reactors of the first group (with a power less than 1 MW) are low-power reactors designed for demonstration and testing of reactor technologies, as well as for scientific research. These reactors characterized by such design features as: natural circulation of the primary coolant, free cooling, the absence of emergency cooling systems, and a small volume of nuclear materials in the core.

The second group of research nuclear facilities (with a power of 1 MW to 20 MW) includes medium-power reactors designed primarily for scientific research and the production of radiopharmaceuticals. These reactors are mainly water-cooled pool type reactors. These reactors differ from the first group of reactors in a more complex core cooling system (several cooling circuits, the presence of circulation pumps).

The third group of research reactors includes vessel type reactors with a thermal power of over 20 MW. In addition to thermal power, these reactors differ from other research reactors in many systems important to safety. In particular: experimental channels in the core, complex cooling systems and core cooling systems, special water purification and gas treatment systems, recombination systems, etc. In addition, to increase power in the active zones of such research reactors highly enriched nuclear fuel is used.

The proposed thermal power classification of research reactors is not applicable to pulsed research reactors, since the latter have a significant difference in the average value of the thermal power during operation in the pulsed mode. The maximum value of power in a single pulse can reach 2000 MW. For pulsed research reactors it is proposed to use differentiation according to the principle mode of the reactor operation (periodic and aperiodic pulsed reactors). The first type of reactor is potentially more dangerous, because there is a possibility of failure of moving parts that affect reactivity. Periodic pulsed reactor is reactor in which a power pulse is initiated and suppressed by reactivity members (for example, a movable reflector). Aperiodic pulsed reactor is reactor in which a power pulse after initiation is suppressed due to the negative reactivity effects.

Table IV-10 shows the proposed procedure for determining the risk category depending on the type of reactor, stage of its life cycle and operation mode. Typically, nuclear facilities are the most dangerous at the stages of their commissioning, transient conditions and during startup and run mode. At these stages, the scope of work associated with testing and experimental work is substantial. The list of limits and conditions for safe operation for the facilities operated at these stages is the most comprehensive. In this connection, the amount of control performed by the regulatory body ought to be maximal. Periodic pulsed research reactors are very similar in thermophysical and dynamic properties to reactors with a stationary neutron flux. By the number of requirements for the number and composition of systems important for the safety such reactors during risk assessment can be referred to the reactors with a thermal power of 1 to 20 MW. Aperiodic pulsed reactors are self-quenched reactors with natural core cooling. During risk assessment such reactors can be referred to the reactors with a thermal power of less than 1 MW. The proposed procedure for determining the risk category also takes into account the operation mode of the research nuclear facility (from the startup and run mode to the final shutdown mode).

Research nuclear facilities other than research reactors (subcritical electro-nuclear reactors, critical assembles, subcritical assembles) are not characterized by such a parameter as stationary thermal power. The configuration and scope of systems important to safety at such facilities is much simpler than at research reactors. The cooling system in such installations is completely absent. Critical assembles have external neutron sources to achieve criticality. Therefore, their operation is accompanied by a higher degree of risk (compared with subcritical assembles). As a result, this facilities during risk assessment are allocated to a separate group (see Table IV-11).

TABLE IV-10. DETERMINATION OF RESEARCH REACTOR RISK CATEGORY

Facility potential radiological hazard category	Research reactor risk category								
	Thermal power of core, P (MWt) / Type of pulse research reactor								
	P > 20 MWt			1 MWt ≤ P ≤ 20 MWt or Periodic pulsed reactor			P <1 MWt or Aperiodic pulsed reactor		
	Life-cycle stage/ Operational mode								
	A	B	C	A	B	C	A	B	C
I	I	I	II	I	I	II	I	I	II
II	I	I	II	II	II	III	II	III	III
III	II	II	III	III	III	IV	III	IV	IV
IV	III	III	IV	III	IV	IV	IV	IV	IV

Legend:
A – commissioning, operation in startup and run mode and in temporary shutdown mode
B – operation in long time shutdown mode and permanent shutdown mode
C – siting, construction and decommissioning

TABLE IV-11. DETERMINATION OF NUCLEAR RESEARCH FACILITY RISK CATEGORY

Facility potential radiological hazard category	Nuclear research facility risk category								
	Subcritical reactors			Critical assemblies			Subcritical assemblies		
	Life-cycle stage/ Operational mode								
	A	B	C	A	B	C	A	B	C
I	II	II	III	II	II	III	II	II	III
II	II	II	III	II	II	III	III	III	IV
III	III	III	III	III	III	IV	III	IV	IV
IV	IV	IV	V	IV	IV	V	IV	IV	V

Legend:
A – commissioning, operation in startup and run mode and in temporary shutdown mode
B – operation in long time shutdown mode and permanent shutdown mode
C – siting, construction and decommissioning

Table IV-12 shows the procedure for determining the frequency of planned inspections, depending on the established risk category, proposed to the ‘quasi-dynamic’ model. The ‘quasi-dynamic’ model assumes for the grouping of the research nuclear facilities into five risk categories, in contrast to the static model, which assumes the grouping of the research nuclear facilities into 4 groups according to the degree of potential radiation hazard. Such an approach characterizes the ‘quasi-dynamic’ model as more flexible. For the 5th risk category by the ‘quasi-dynamic’ model, the frequency of checks is less often set less often than for the 4th category according to the static model. Thus, the implementation of a quasi-dynamic risk assessment model will reduce regulatory burden on the both regulatory body and operators.

With all the advantages with respect to the static model, the ‘quasi-dynamic’ model does not fully consider the dynamics of the research nuclear facilities safety conditions. In particular, the ‘quasi-dynamic’ model does not take into account detected non-compliance with safety requirements during operations, as well as the degree of their potential negative consequences. In addition, the ‘quasi-dynamic’ model does not take into account the achieved level of safety culture at the research nuclear facility. At the third stage of implementation a risk-based approach within the framework of a dynamic model, when determining a risk category, it is proposed, in addition to ‘quasi-dynamic’ factors, to take into account such dynamic factors as: the presence or absence of non-compliance with safety requirements and events or accidents during operation. For risk assessment it is proposed to take into account the number and significance of non-compliance with safety requirements identified during a certain period of control and supervision activities. It is proposed to use a complex indicator, estimated using the formula given on this slide, for the aggregate accounting of such heterogeneous factors in one indicator.

TABLE IV-12. QUASI-DYNAMIC MODEL OF RISK ASSESSMENT

Risk category	Frequency of planned inspections
I	1 time per year
II	1 time in 2 years
III	1 time in 3 years
IV	not more than 1 time in 4 years but not less than 1 time in 5 years
V	not more than 1 time in 5 years but not less than 1 time in 6 years

The proposed procedure for assessing the risk category and, accordingly, the frequency of planned inspections for dynamic model depends both on the risk category defined on quasi-dynamic model and a complex indicator that takes into account the significance and number of non-compliance with safety requirements during control and supervision activities and events or accidents during research nuclear facility operation. The dynamic model allows a change of the frequency of planned inspections. The proposed model does not allow changing the risk category for objects for which risk category was assigned as I in the ‘quasi-dynamic’ model. At the same time, the proposed model allows the absence of inspections for research nuclear facilities for which the risk category was assigned as V in the ‘quasi-dynamic’ model, and the complex indicator does not exceed the established threshold value. The threshold values K1-K4 necessary for decision-making on changing the risk category can be determined taking into account the experience gained in the implementation of static and quasi-dynamic risk assessment models. The procedure for determining the frequency of planned inspections, depending on the established risk category, proposed by the 'dynamic' model is shown in the table below.

TABLE IV-13. QUASI-DYNAMIC MODEL OF RISK ASSESSMENT

Risk category	**Risk criteria**		**Frequency of planned inspections**
	Quasi-dynamic factors of risk assessment	**Comprehensive safety indicator**	
I	Risk category I by quasi-dynamic model	not applicable	1 time per year
II	Risk category II by quasi-dynamic model	S ≥ K1	1 time in 2 years
III	Risk category II by quasi-dynamic model	S < K1	1 time in 3 years
	Risk category III by quasi-dynamic model	S ≥ K2	
IV	Risk category III by quasi-dynamic model	S < K2	not more than 1 time in 4 years but not less than 1 time in 5 years
	Risk category IV by quasi-dynamic model	S ≥ K3	
V	Risk category IV by quasi-dynamic model	S < K3	not more than 1 time in 5 years but not less than 1 time in 6 years
	Risk category V by quasi-dynamic model	S ≥ K4	
VI	Risk category V by quasi-dynamic model	S < K4	no planned inspections

Summarizing all of the above, it can be said that the concept of introducing a risk-informed approach in the implementation of control and supervisory activities in the field of safety of research nuclear facilities consists in the consistent consideration of all factors affecting the safety of research nuclear facilities. The static model of risk assessment is based on the main static factor - the potential radiation hazard of the facility, which is initially determined in the facility project based on the radiation consequences for the population and personnel in the event of a maximum radiation accident. The quasi-dynamic model, in addition to the static factor, takes into account factors related to the design features of the facility, the stage of the life cycle and the operation modes. Finally, the dynamic model is based on the risk category defined in the 'quasi-dynamic' model and takes into account the significance and number of non-compliance with safety requirements and events or accidents during facility operation.

The above proposals for the stage-by-stage implementation of a risk-based approach have several advantages:

a) Minimization of time and financial costs at the initial stage of introducing a risk-based approach through the use of the existing facilities categorization on their potential radiation hazard according to sanitary rules.

b) The possibility of not revolutionary, but evolutionary development of the risk assessment system with a gradual increase in its flexibility by supplementing the used risk criteria with various dynamic factors;

The possibility of further development of the risk assessment system through the introduction of modern science-based approaches instead of subjective expert assessments.

IV-5. GRADED APPROACH TO PRIORITIZING SYSTEM BASED INSPECTION PROGRAMMES IN THE UK

System Based Inspections (SBIs) [IV-5] are an essential element of ONR's overall intervention on a nuclear site and consist of a series of inspections which are intended to establish that the basic elements of a site/facility safety case as implemented in Structures, Systems and Components (SSCs) are fit for purpose and that they will fulfil their safety functional requirements.

The overarching aim is to ensure that SSCs playing a key role in ensuring nuclear safety will be inspected twice during the nominal ten-year timescale associated with a Periodic Safety Review (i.e. every 5 years). Having identified the key systems/structures for the site or facility, the inspections should be transposed onto a 5-year plan in an appropriate sequence and aligning with, for example, plant outages as necessary.

— **Step 1: Identify and prioritize safety systems to inspect**

Whilst it is recognized that a SBI approach is appropriate for some nuclear licensed sites, the number and type of SSCs to be targeted will vary commensurate with the hazard and risks presented by the site. Additionally, the approach taken to identify the key Safety Systems and Structures associated with a SBI on a multi-facility site is different to that required for an 'island' reactor site. Whilst approximately 15 - 25 key Safety Systems and Structures may be identified for a higher hazard site; for a lower hazard facility (such as a radioactive waste store) 2 or 3 systems might be appropriate as determined or informed by the relevant Safety Case.

— **Step 2: Determine which factors are applicable to prioritization of SSCs and how those factors are weighed.**

Selection of SSCs to inspect is principally based on a prioritization informed by claims made in the deterministic safety case and the PSA (where a PSA exists for the facility) i.e:

For an advanced gas-cooled reactor, the systems in Table IV-14 are typically prioritized as follows:

TABLE IV-14. TYPICAL PRIORITIZATION OF SAFETY SYSTEMS

No	Safety System Grouping
1	Sea defences, flood protection, and drainage
2	Data Processing System / Distributed Control System
3	Boiler Feed

TABLE IV-14. TYPICAL PRIORITIZATION OF SAFETY SYSTEMS (cont.)

No	Safety System Grouping
4	Auxiliary Cooling (including Pressure Vessel Cooling System)
5	Seawater Systems
6	Electrical – No Break Supplies
7	Electrical – Emergency generation and short break supplies
8	Electrical – Transformers, Grid Systems and Main Electrical System
9	Emergency Equipment (AIC, ECC, etc.)
10	Fire Detection, Suppression, Barriers, Doors and Dampers
11	Fuelling Machine and Decay Store
12	Ponds and Flasks
13	Fuel Assemblies & plug unit maintenance facilities
14	Irradiated Fuel Dismantling Facilities & vaults
15	Gas Circulators
16	Turbine Protection Systems
17	H&V Systems
18	Liquid Radiological Waste
19	CO2 Storage and Distribution
20	CO2 Processing and Blowdown (including Bypass Gas Plant, Auxiliary Boilers and O2/COS Injection)
21	Reactor Post-trip Systems
22	Reactor Safety Systems (Trip Parameters)
23	Shutdown Systems
24	Buildings structures and infrastructure

— **Step 3: Integrate the applicable factors into assignment of Regulatory Attention Levels**

(a) Higher hazard facilities

Typically, for a SBI on an operational reactor or complex nuclear chemical plant it will need about two to three days site-time to carry out a meaningful inspection with an expectation that this will be undertaken by inspectors of appropriate disciplines. The site inspector will normally (but doesn’t have to be) part of the team. So, for example, for the gas circulator system on an Advanced Gas-Cooled Reactor (AGR) power station the team may be the site inspector, plus mechanical and electrical specialists. The specialist support may also come from a Technical Support Contractor (TSC).

SBI inspections should be coordinated, where possible, across several facilities within a Division to allow inter-facility comparisons to be made (if that would be beneficial) and in order to be as efficient and effective as possible. In addition, the site visits should be coordinated with other necessary planned visits to achieve maximum efficiency and deliver value for money.

(1) Conducting the Inspections

The inspections are designed to determine whether the SSC being inspected are able to fulfil their safety duties (safety functional requirements) adequately, in line with the safety case.

To carry out a SBI it is important to check the SSC inspectors evaluate compliance against six licence condition arrangements. It is important that this is not a review of the arrangements that the licensee has put in place for each of the licence conditions, rather the adequacy of their implementation in relation to a particular SSC. It is also important therefore that the inspection team has identified beforehand the relevant matters from the safety case that will allow them to determine whether the SSC will adequately meet its safety functional requirements. The inspectors are required to form an overall judgement as to whether the SSC adequately fulfils the requirements of the safety case.

(b) Lower hazard facilities

A modified approach to SBIs should be adopted for decommissioning sites. Once decommissioning has commenced, the facility is permanently shut down and the safety case is progressively modified as each successive decommissioning project is implemented to defuel, decommission and remove systems and equipment. The safety case is periodically re-baselined at key points in the process, for example, completion of the removal of the reactor fuel. This means that the safety case is in a constant state of change with a general trend of reducing risk; noting however that there may be finite periods of significant increases in risk during de-commissioning work where novel processes and techniques are deployed

In order for ONR to establish that implementation of the safety case is fit for purpose, it is necessary to align the SBI programme with the decommissioning activities on the site. For inspection planning purposes, the key site decommissioning projects and milestones should be obtained from the site's decommissioning programme and used to build a suitable 5-year plan.

IV-6. USE OF A GRADED APPROACH FOR THE INSPECTION PROGRAMME FOR NUCLEAR INSTALLATIONS IN THE US

IV-6.1. Baseline Inspection Programme

(a) Operating Nuclear Power Plants

The NRC regulatory framework for oversight of operating nuclear power plants consists of seven cornerstones of safety: initiating events, mitigating systems, barrier integrity, emergency preparedness, occupational radiation safety, public radiation safety, and security. The baseline inspection programme is the minimum inspection needed to provide assurance that licensee performance meets the cornerstone objectives and the plants are being operated safely.

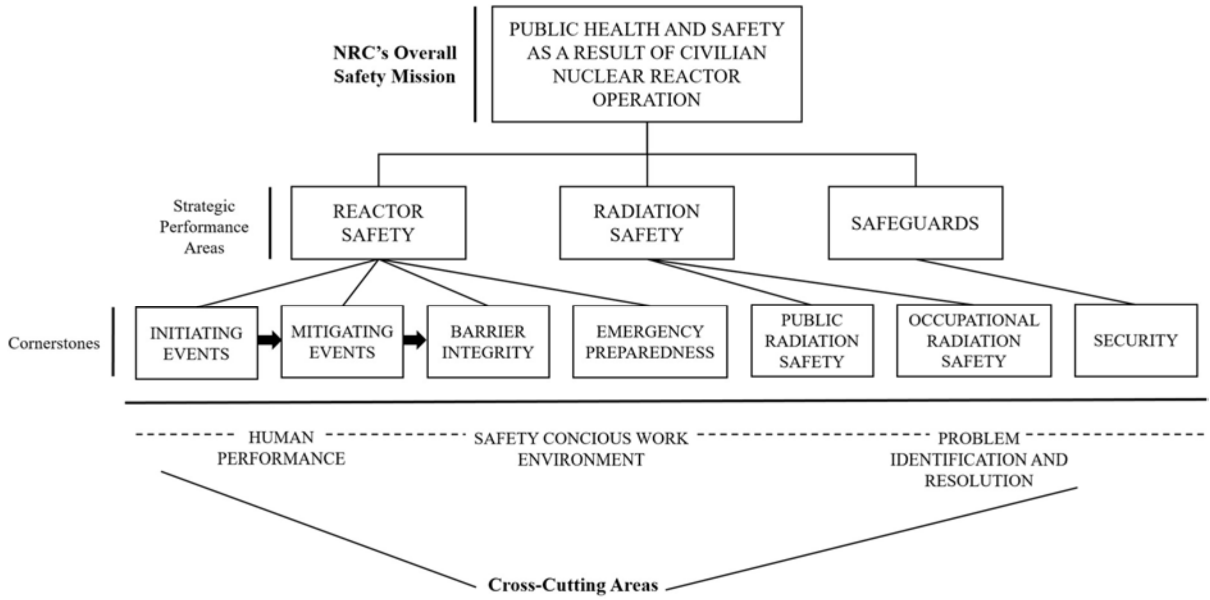

FIG. IV-3. U.S.NRC cornerstones of safety

Inspection Manual Chapter 0308, Attachment 2, 'Technical Basis for the Inspection Program' [IV-6] describes the scope of the inspectable areas and explains why each area is included in the baseline programme. Reasons may be that (1) the area is linked to the NRC's mission, (2) the inspectable area involves a key attribute of a cornerstone of safety, and (3) risk information justifies including the area in the baseline inspection programme.

— Step 1

The staff identified the activities, structures, systems, and components (SSCs) that are safety-related or important to safety using information in the licence application, the FSAR, PSA, inspection experience, and history of problems at plants for the cornerstones in the reactor safety strategic performance area.

— Step 2

In developing the baseline inspection programme, several factors were considered. The type of facility was a factor. Specifically, pressurized water reactors (PWRs) have different in-service inspection (ISI) requirements than boiling water reactors (BWRs). For instance, PWRs have steam generators with thousands of tubes that require periodic non-destructive evaluation (NDE) to ensure tube integrity. Inspectors need to review the NDE results, therefore, more hours should be planned for ISI inspections at PWRs.

Operating experience was used to focus inspections on areas where safety-significant SSCs have a higher failure probability, informing the sample size requirements for inspections of licensee surveillances. The frequency of some inspection activities was based on licensee operating cycles. Refuelling activities and ISI are planned based on licensee refuelling schedules.

Regulator experience was a significant input to development of the current baseline inspection programme. Decades of inspector experience helped inform the necessary sample sizes and inspection guidance throughout the programme. For most inspections, inspectors have annual minimum sample requirements, which may be spread out quarterly. Problem identification and resolution (PI&R) team inspections were originally conducted annually. Experience showed that licensee corrective action programme implementation did not change significantly from year to year, so that inspection frequency was changed to biennial.

Each safety cornerstone required some inspection effort to ensure the cornerstone objectives were being met.

— **Step 3**

The baseline inspection programme was developed by using a risk-informed approach to determine a comprehensive list of areas to inspect (inspectable areas) within each cornerstone of safety. Inspectable areas are also part of Step 1 in the process in that they describe on what to focus inspection activities. Each cornerstone has several attributes from which the inspectable areas are derived. These inspectable areas were selected based on their risk significance (i.e. they are needed to meet a cornerstone objective as derived from a combination of probabilistic risk analyses insights, operational experience, deterministic analyses insights, and requirements in regulations). The following two figures demonstrate the attributes and the derivation of the inspectable areas for the initiating events and mitigating systems cornerstones. All the cornerstones are described in SECY-99-007, 'Recommendations for Reactor Oversight Process Improvements,' dated January 8, 1999 [IV-7].

The first row consists of the attributes that are important to ensuring the cornerstone objective is met. The objective of the initiating events cornerstone is to limit the frequency of those events that upset plant stability and challenge critical safety functions, during shutdown as well as power operations. For the mitigating systems cornerstone, the objective is to monitor the availability, reliability, and capability of systems that mitigate the effects of initiating events to prevent core damage. Licensees reduce the likelihood of reactor accidents by maintaining the availability and reliability of mitigating systems. Mitigating systems include those systems associated with safety injection, decay heat removal, and their support systems, such as emergency alternating current (AC) power. Once the inspectable areas were identified, an expert panel determined the minimum inspection sample size necessary to provide assurance that the cornerstone objectives are met.

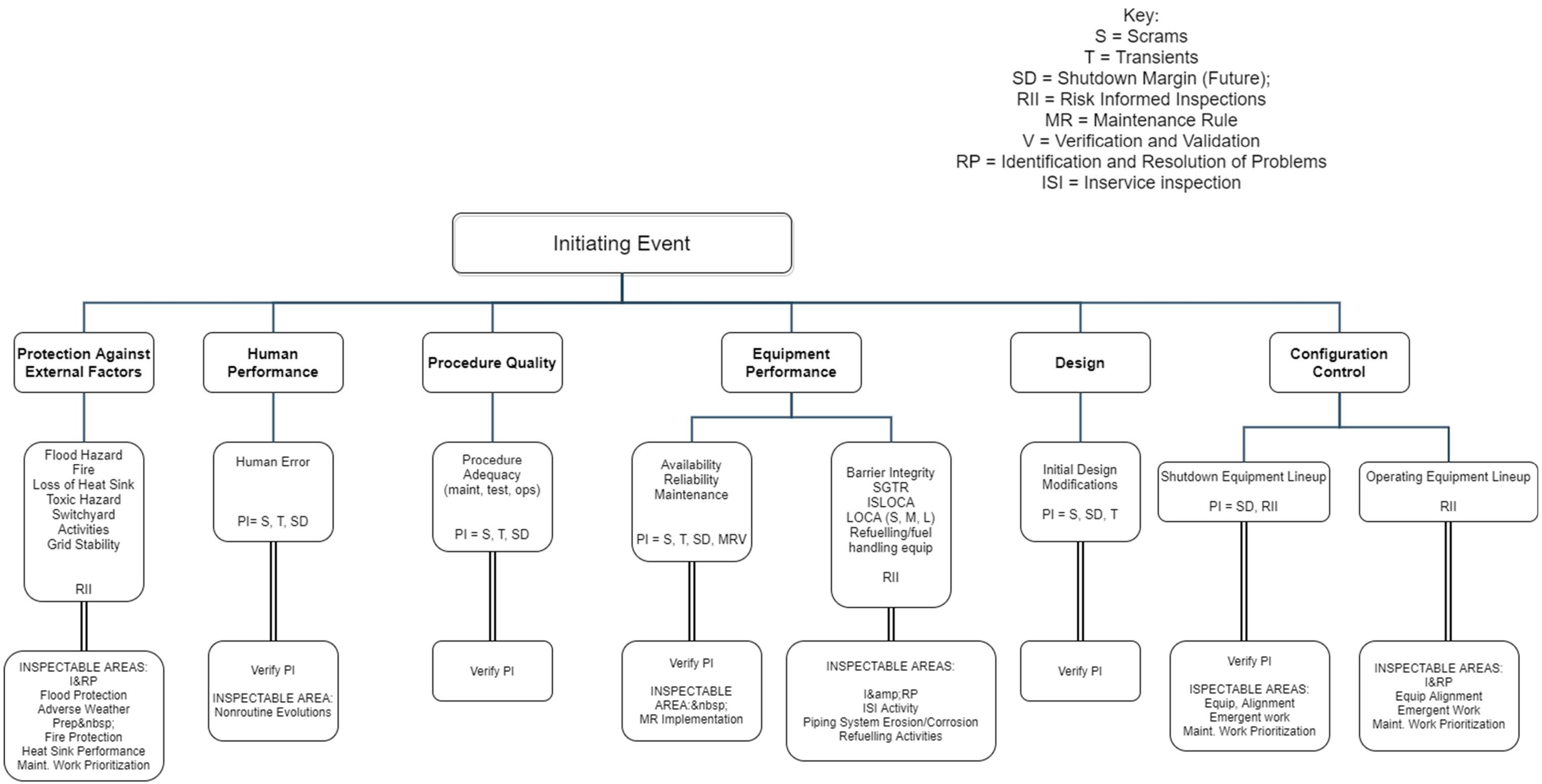

FIG. IV-4. Attributes and Inspectable Areas for the Initiating Events Cornerstone (from [IV-7])

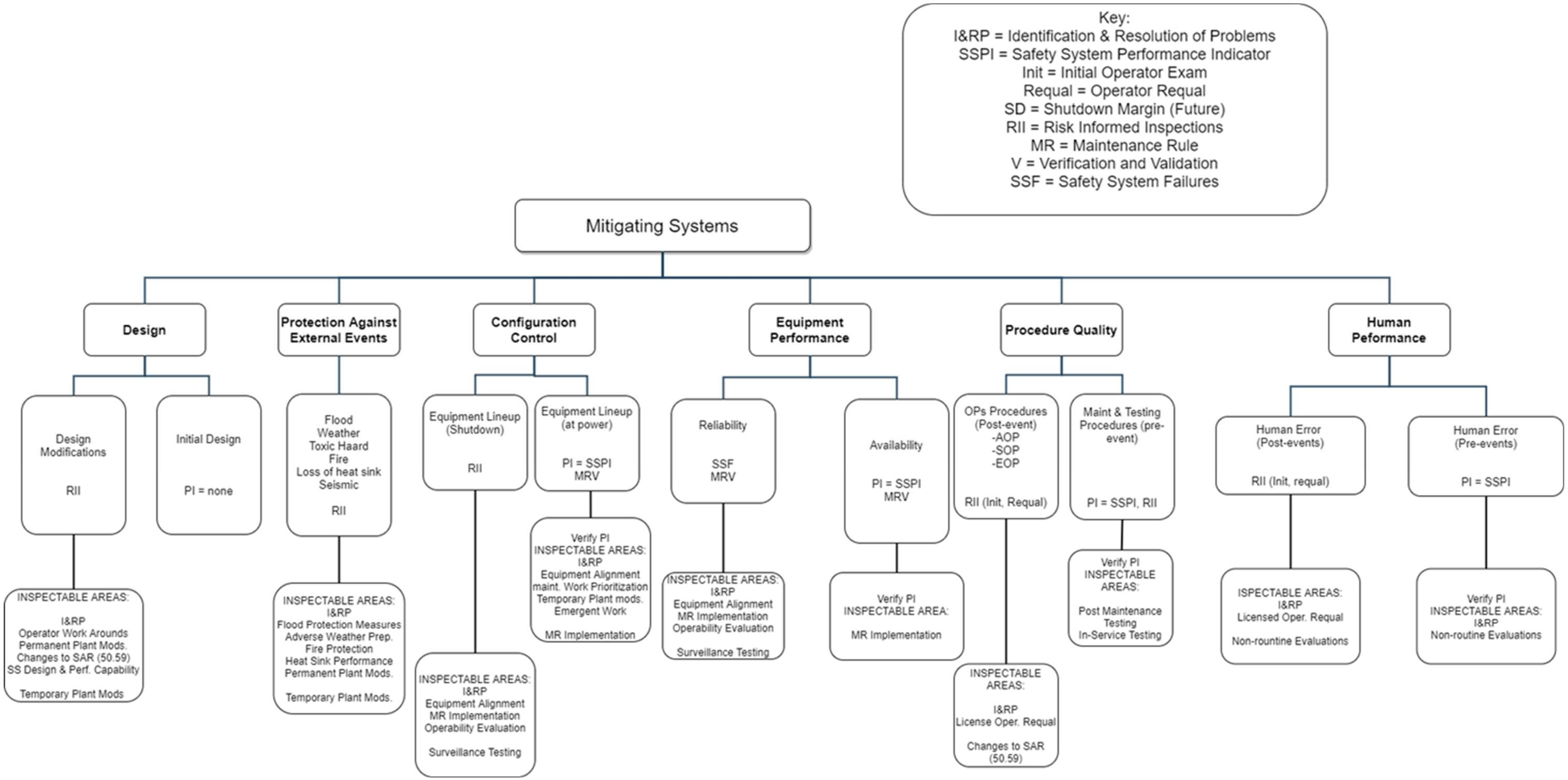

FIG. IV-5. Attributes and Inspectable Areas for the Mitigating Systems Cornerstone (from [IV-7])

The scope of inspection within each inspectable area was determined using the same risk-informed approach. The NRC staff developed Risk Information Matrices (RIMs) which are tools to be used in determining which activities, systems, or components are to be inspected in the baseline inspection programme. Details are described in SECY-99-007, 'Recommendations for Reactor Oversight Process Improvements', dated January 8, 1999 [IV-7]. The following is a sample from part of the RIM developed that includes the inspection frequency, the number of activities or components to inspect, and total hours expected in the baseline programme for each inspectable area. This RIM also describes the basis for these items. The data was derived from Individual Plant Examination (IPE) and Individual Plant Examination External Events (IPEEE) risk analyses, inspection experience, and history of problems at plants for the cornerstones in the reactor safety strategic performance area.

TABLE IV-15. RISK INFORMATION MATRIX (from [IV-7])

CORNERSTONE			INSPECTABLE AREA	PERFORMANCE INDICATOR	FREQUENCY	HOURS FOR 2-UNIT SITE PER YEAR	LEVEL OF EFFORT	BASES
I 20	M 80	B	Adverse Weather Preparations	None	As conditions require	12 to 18 hrs/year	Select 1 non-failure tolerant SSCs, supplemented by 1 site- specific high risk SSCs. The non-failure tolerant SSCs (i.e. highly reliable RWST), whose failures may contribute a small amount to the total CDF, but create a large CCDP, could result in failures of other SSCs due to instrument line freezing or other CCF failures. Use plant history, IPE, IPEEE to determine vulnerability and assign final hours. Baseline inspection to be performed prior to seasonal susceptibilities. Hours include 6 hrs for Identification and Resolution of Problems/Issues.	Conditions leading to Loss of Offsite Power, freezing temperatures, high winds, flooding dominate risk. Conditions can lead to common cause failure of mitigation equipment and to initiating events.
I	M 80	B 20	Changes to Licence Conditions and Safety Analysis Report	None	Annual	32 hr/yr	Review licensee evaluations made per 10CFR50.59 requirements. If the initial screening indicates that the issues potentially increase risk, select the issue for review. Select a minimum of 5 significant evaluations for indepth review. Includes 8 hrs of Identification and Resolution of Problems/Issues	Changes can be made without prior NRC approval only if they do not increase risk. Adequate licensee performance while evaluating impact of changes prevents changes that increase risk from being made. Success criteria for PRA could change if licence basis changes.

TABLE IV-15. RISK INFORMATION MATRIX (from [IV-7]) (cont.)

CORNERSTONE			INSPECTABLE AREA	PERFORMANCE INDICATOR	FREQUENCY	HOURS FOR 2-UNIT SITE PER YEAR	LEVEL OF EFFORT	BASES
I 40	M 60	B	Emergent Work	None	Bimonthly	60 hrs/yr	Selection of risk significant activities should be made using licensee's configuration specific risk assessment or from a ranking of system importance. RIM2 should be used if plant specific information has not yet been developed. Select 2 activities per month. Hours estimate assumes 3 hrs/month of observation and 2 hr/month of Identification and Resolution of Problems/Issues.	Troubleshooting while trying to determine cause of emergent equipment problems can lead to inadvertent risk significant initiating events. In addition, high risk configurations with multiple out-of-service SSCs may occur during rolling on-line maintenance due to emergent work.
I 30	M 60	B 10	Equipment Alignment	None	Semi-annual and as required by maintenance	76 hrs/yr	One system walkdown every 6 months. If available system success criteria from the site-specific risk study, and the system design basis should be reviewed to focus the inspection. RIM2 should be used for system selection if plant specific information has not yet been developed. In conjunction with maintenance on higher risk systems, validate critical features on line-up of the train or system providing the backup function. Hours based on 8 hrs semi-annually for a complete risk important system walkdown; 4 hrs/month in walkdowns to support verification of operable system train because other train is OOS, and 1 hr/month for Identification and Resolution of Problems/Issues.	High risk configurations may occur during normal operations and on- line maintenance activities due to multiple out-of-service SSCs, and such configurations can lead to high Core Damage Probability.

TABLE IV-15. RISK INFORMATION MATRIX (from [IV-7]) (cont.)

CORNERSTONE			INSPECTABLE AREA	PERFORMANCE INDICATOR	FREQUENCY	HOURS FOR 2-UNIT SITE PER YEAR	LEVEL OF EFFORT	BASES
I 10	M 90	B	Fire Protection	None	Triennial	36 hours/3 yrs 12 hr/yr Residents	Selection of areas inspected should consider insights from the plant specific fire risk analysis. Regional SRA to provide input. Walkdown all accessible areas of high significance. Hours are based on a regional based Programme Implementation Review, and 4 hours of Identification and Resolution of Problems/Issues. Residents should perform a monthly walkdown of high fire risk areas (hours based on One hr/walkdown) to verify transient combustible loading and fire doors/barriers.	Estimated fire risk is comparable to many internal initiating events. If potential fire initiators, aids to propagation, or fire barrier breaches exist, safe shutdown of the plant may not be possible due to the failures of the inspectable features and areas.
I 40	M 60	B	Flood Protection Measures	None	Annual	20 hrs/yr	Internal and External flood protection barriers and actions review. Select from both the external and internal flooding scenarios, perform walkdown of areas, being sensitive to insights from the plant specific flood risk studies. Includes 4 hrs/yr of Identification and Resolution of Problems/ Issues.	IPE and IPEEE summaries indicate that CDF contributions by internal flooding is generally one order of magnitude higher than that by external flooding (less than 1.0E-5 CDF) for most BWR and PWR plants except BWR 1/2/3. At some sites flooding can be a significant contributor to risk.

REACTOR SAFETY CORNERSTONES (I=Initiating Events; M=Mitigating Systems; B=Barrier; X or a number indicates the Inspectable Area is mapped to that Cornerstone; When a number is present in a column, it represents the approximate percentage of the total hours of inspection to be performed for that Cornerstone)

The purpose for using a graded approach is to optimize inspection resources based on available resources. Like regulatory bodies from all States, the NRC has finite resources that are split between oversight of operating reactors, RRs, fuel cycle facilities, and materials users, such as industrial and medical isotope users. Because of the overall risk to the public posed by operating reactors, a significant number of resources are expended in their oversight. This includes placement of at least two resident inspectors at every operating reactor site to perform the core baseline inspections. They are supplemented by region-based inspectors. Because of the many safety systems dedicated to mitigating events and their importance, the majority of inspection hours are budgeted for that cornerstone. The overall resource effort planned to complete the baseline inspection programme for operating nuclear reactors as determined by an expert panel was based on risk insights and inspector experience.

These planned inspection hours are periodically realigned and adjusted based on new requirements and additional operating and inspector experience.

(b) Research Reactors

A graded approach for the baseline inspection program for research reactors depends primarily on reactor power. The planned resource estimate for baseline inspections for operations at Class I research reactors (greater than 2 MW power) is approximately 79 hours annually. Class II research reactors (less than 2 MW power) are inspected biennially. The types of inspections at research reactor facilities are similar to those for power reactors, such as operator licensing, operations and maintenance, radiation protection, emergency preparedness, surveillances, etc., although on a much smaller scale.

(c) Fuel Cycle Facilities

Because fuel cycle facilities are generally more complex than research reactors with additional hazards, the baseline inspection program is more comprehensive requiring a greater resource effort. However, because the risk to the public is generally lower than that posed by operating nuclear power plants, the inspection program for FCFs is less resource intensive. Because of the unique nature of FCFs, the inspection program needs to be tailored for each type of facility. The following table summarizes the resource effort for inspection of FCFs in the U.S.

FCF inspections, resource estimates, and frequency of inspections for the various types of fuel cycle facilities are listed in Inspection Manual Chapter (IMC) 2600, Appendix B, ‘NRC Core Inspection Requirements’ [IV-8]. The following table lists the inspection procedures applicable to FCF oversight.

TABLE IV-16. FUEL CYCLE FACILITY INSPECTION PROCEDURES (EXCERPT FROM [IV-8])

IP Number	Title
40100	Independent Safety Culture Assessment Follow-up
71152	Problem Identification and Resolution
71153	Follow-up of Events and Notices of Enforcement Discretion
84850	Radioactive Waste Management - Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61
88003	Reactive Inspection for Events at Fuel Cycle Facilities
88005	Management Organization and Controls

TABLE IV-16. FUEL CYCLE FACILITY INSPECTION PROCEDURES (EXCERPT FROM [IV-8]) (cont.)

IP Number	Title
88010	Training
88071	Configuration Management Programmatic Review
88075	Event Follow Up
88161	Corrective Action Programme (CAP) Implementation at Fuel Cycle Facilities
92701	Follow up
92702	Follow up on Corrective Actions for Violations and Deviations
92703	Follow up of Confirmatory Action Letters or Orders
92709	Contingency Plans for Licensee Strikes or Lockouts
92711	Implementation of Licensee Contingency Plans During a Strike/ Lockout
92712	Resumption of Normal Operations After a Strike
93001	OSHA Interface Activities
93800	Augmented Inspection Team
93812	Special Inspection
93100	Safety-Conscious Work Environment Issue of Concern Follow-up
95003.02	Guidance for Conducting an Independent NRC Safety Culture Assessment

IV.6.2. Adjusting the Inspection Programme

There are several factors to consider when determining if more or less inspection of operating reactor facilities is appropriate. The following two factors will be discussed in detail below: licensee performance, and significant events.

(a) Supplemental Inspection Programme

The US Nuclear Regulatory Commission (NRC) inspection programme incorporates additional inspection in response to declining licensee performance using a graded approach. Plants, whose performance is declining based on inspection results and performance indicators will receive additional plant specific inspection, referred to as supplemental inspections, as described by the Action Matrix (Table IV-17). Declining performance is demonstrated by a licensee moving to the right in the Action Matrix, necessitating additional inspection and oversight. The further to the right a licensee moves, the greater degree of oversight needed.

—Step 1: Identify what to inspect

Declining performance is demonstrated by the identification of safety-significant inspection findings or performance indicators. The performance deficiency associated with the inspection finding or the cause of declining performance demonstrated by the performance indicator crossing a significance threshold should be the focal point of the supplemental inspection. A licensee moving to Column 4 of the Action Matrix has demonstrated a significant performance decline, and oversight will include a comprehensive diagnostic inspection of all licensee programs and activities.

—Step 2: Identify factors

There are generally no additional factors to consider when determining appropriate supplemental inspection effort. The Action Matrix provides a predictable regulatory response based on objective performance inputs. The Action Matrix describes a graded approach for addressing performance issues and was developed with the philosophy that within a certain level of safety performance (e.g. the licensee response band), licensees would address their performance issues without additional NRC engagement beyond the baseline inspection programme. Performance is measured using inspection findings and performance indicators (PIs). NRC actions beyond the baseline inspection programme will normally occur only if assessment input thresholds are exceeded. There may be unique factors in the performance inputs that would suggest that the required regulatory action is not commensurate with the plant performance. In those cases, a deviation could be issued to modify the regulatory actions specified by the Action Matrix.

— **Step 3: Integrate factors**

A licensee moving to Column 2 of the Action Matrix would receive the baseline inspection programme, plus a supplemental inspection. The supplemental inspection, described in Inspection Procedure 95001, 'Supplemental Inspection Response to Action Matrix Column 2 Inputs' [IV-9], has an estimated resource effort of 40 - 120 hours to review the licensee's causal evaluation, extent of condition evaluation, and corrective actions to address the performance issue. The lower end of the range is to inspect simple performance deficiencies, while the upper end is to inspect more complicated issues, or when there are two safety-significant issues in the same cornerstone. A licensee moving to Column 3 would receive the baseline inspection, plus a supplemental inspection described in Inspection Procedure 95002, 'Supplemental Inspection for One Degraded Cornerstone or Any Three White Inputs in a Strategic Performance Area' [IV-10], with an estimated resource effort of 200 hours to review the licensee's causal evaluation, extent of condition, extent of cause, corrective actions, and inspectors will complete an independent extent of condition evaluation.

A licensee in Column 4 has demonstrated significant degradation in safety performance, and the supplemental inspection, Inspection Procedure 95003, 'Supplemental Inspection for Repetitive Degraded Cornerstones, Multiple Degraded Cornerstones, Multiple Yellow Inputs or One Red Input' [IV-11], is a 3000-hour diagnostic inspection of all licensee programs, reflective of the safety significance of the performance issues. This supplemental procedure is more diagnostic than indicative, and includes reviews of programs and processes not inspected as part of the baseline inspection programme, and may require several years for the licensee to prepare and for the regulator to inspect. While the procedure does allow for focus to be applied to areas where performance issues have been previously identified, the procedure requires that some sample reviews be performed for all key attributes of the effected strategic performance areas. The rationale behind this is that additional NRC assurance is required to ensure public health and safety, beyond that provided by the baseline inspection programme and the PIs at those facilities where significant performance issues have been identified.

This inspection is generally conducted over a period of one to three years, depending on the extent of the performance problems, so the resource burden is distributed across several years.

TABLE IV-17. REACTOR OVERSIGHT PROCESS ACTION MATRIX

		Licensee Response Column (Column 1)	Regulatory Response Column (Column 2)	Degraded Performance Column (Column 3)	Multiple/ Repetitive Degraded Cornerstone Column (Column 4)	Unacceptable Performance Column (Column 5)	IMC 0350 Process[1]
RESULTS		All assessment inputs (performance indicators and inspection findings) green; Cornerstone objectives fully met	One or Two white inputs in a strategic performance area; Cornerstone objectives met with minimal degradation in safety performance	One degraded cornerstone (3 or more white inputs or 1 yellow input), or 3 white inputs in any strategic performance area; Cornerstone objectives met with moderate degradation in safety performance	Repetitive degraded cornerstone, Multiple degraded cornerstones, Multiple yellow inputs, or One red input; Cornerstone objectives met with longstanding issues or significant degradation in safety performance	Overall unacceptable performance; Plants not permitted to operate within this band; Unacceptable margin to safety	Plants in a shutdown condition with performance problems are placed in the IMC 0350 process
RESPONSE	Regulatory Performance Meeting	None	Branch Chief or Division Director meets with licensee	Regional Administrator or designee meets with senior licensee management.	EDO/DEDO or designee meets with senior licensee management	EDO/DEDO or designee meets with senior licensee management	RA/EDO or designee meets with senior licensee management
	Licensee Action	Licensee corrective action	Licensee root cause evaluation and corrective action with NRC oversight	Licensee cumulative root cause evaluation with NRC oversight	Licensee performance improvement plan with NRC oversight	-	Licensee performance improvement & restart plan with NRC oversight
	NRC Inspection	Risk-informed baseline inspection programme	Baseline and supplemental inspection (IP 95001)	Baseline and supplemental inspection (IP 95002)	Baseline and supplemental inspection (IP 95003)	-	Baseline and supplemental as practicable; Special inspections per restart checklist.

TABLE IV-17. REACTOR OVERSIGHT PROCESS ACTION MATRIX (cont.)

		Licensee Response Column (Column 1)	**Regulatory Response Column (Column 2)**	**Degraded Performance Column (Column 3)**	**Multiple/ Repetitive Degraded Cornerstone Column (Column 4)**	**Unacceptable Performance Column (Column 5)**	**IMC 0350 Process[1]**
RESPONSE	Regulatory Actions[2]	None	Supplemental inspection only	Supplemental inspection only; Plant discussed at AARM if conditions met	10 CFR 2.204 DFI; 10 CFR 50.54(f) letter; CAL/Order; Plant Discussed at AARM	Order to modify, suspend, or revoke licence; Plant discussed at AARM	CAL/Order requiring NRC approval for restart; Plant discussed at AARM
COMMUNICATION	Assessment Letters	Branch Chief or Division Director reviews and signs assessment letter w/ inspection plan	Division Director reviews/signs assessment letter w/ inspection plan	Regional Administrator reviews/signs assessment letter w/ inspection plan	Regional Administrator reviews/signs assessment letter w/ inspection plan	-	N/A. RA or 0350 Panel Chairman review/ sign 0350-related correspondence
	Annual Involvement of Public Stakeholders	Various public stakeholder options involving the senior resident inspector or Branch Chief	Various public stakeholder options involving the BC or DD	Regional Administrator or designee discusses performance with senior licensee management	EDO/DEDO or designee discuss performance with senior licensee management	-	N/A. 0350 Panel Chairman conducts periodic public status meetings
	External Stakeholders[3]	None	State Governors	State Governors, DHS, Congress	State Governors, DHS, Congress	State Governors, DHS, Congress	
	Commission Involvement	None	None	Possible Commission meeting if licensee remains for 3 years	Commission meeting with senior licensee management within 6 months.[4]	Commission meeting with senior licensee management	Commission meetings as requested; Restart approval in some cases.
INCREASING SAFETY SIGNIFICANCE →							

(b) Reactive Inspection Programme

The NRC uses a graded approach to determine an appropriate response to significant events. The NRC responds to plant events in three ways: (1) events of low safety significance receive minimal follow up, usually by the resident inspectors, (2) events of moderate safety significance receive more follow up, often by one or two regional inspectors, and (3) events of greater safety significance are followed up by a special team. The follow-up of more extensive, non-routine events is outside of the scope of the baseline inspection programme and would be performed with reactive inspection resources. The graded response will consist of an Investigative Inspection Team (IIT), Augmented Inspection Team (AIT), or Special Inspection (SI) in order of decreasing level of response. The process is described in NRC Management Directive 8.3, 'Incident Investigation Program' [IV-12].

— Step 1: Identify what to inspect

The event itself will dictate the focus area of the reactive inspection. The inspection objective is to promptly disseminate the facts, conditions, circumstances, and causes of significant events and to identify appropriate follow-up actions. Inspectors also promptly identify and convey potential generic safety concerns for follow-up.

— Step 2: Identify factors

The following deterministic criteria should be considered when determining an appropriate response to an event at a nuclear power plant:

(a) Operation that exceeded, or was not included in, the design bases of the facility.
(b) Major deficiency in design, construction, or operation having a potential generic safety implication.
(c) Significant loss of integrity of the fuel, the primary coolant pressure boundary, or the primary containment boundary.
(d) Loss of a safety function or multiple failures in systems used to mitigate an actual event.
(e) Possible adverse generic implication.
(f) Significant unexpected system interaction.
(g) Repetitive failures or events involving safety-related equipment or deficiencies in operations.
(h) Question or concern pertaining to licensee performance.
(i) Circumstance sufficiently complex, unique, or not well enough understood, or involving characteristics the investigation of which would best serve the needs and interests of the Regulatory Body.
(j) Failure of licensee safety-related equipment or adverse impact on licensee operations as a result of a safeguards-initiated event (e.g. tampering).

For events at operating power reactors, the deterministic criteria described above is one factor. The change in risk to the facility resulting from the event is another factor to consider. The risk metric of conditional core damage probability (CCDP) is used to best reflect the full extent of any loss of defence-in-depth due to the event, regardless of whether the cause is due to licensee performance or otherwise. Numerical risk estimation by itself is not meaningful unless accompanied by an understanding of the most influential related assumptions and uncertainties.

— Step 3: Integrate factors

The following table lists appropriate power reactor event response options as a function of CCDP. The overlap of options relative to CCDP levels provides the opportunity to select different inspection or investigation options based on factors like uncertainty of the risk estimate coupled with the deterministic insights. Risk insights should also be used in considering the number of inspectors, their expertise, and the areas of focus. In addition to risk, the regulator should assess whether degraded conditions could increase the likelihood of a large early release resulting from containment failure.

TABLE IV-18. POWER REACTOR EVENT RESPONSE AS A FUNCTION OF CCDP

Estimated CCDP				
CCDP < 1E-6	**1E-6 –> 1E-5**	**1E-5 –> 1E-4**	**1E-4 –> 1E-3**	**CCDP > 1E-3**
No Additional Inspection				
	SI			
		AIT		
			IIT	

The resources required to complete this inspection are highly variable and dependent on the circumstances involved. Although infrequent, regulator response to significant events is planned and budgeted.

Events of low significance, such as uncomplicated reactor trips, may be followed up by inspectors on the next planned inspection to verify that the events are not complicated by loss of mitigation equipment or other factors. Inspectors should review facility events to determine whether the regulator should devote additional effort and resources to respond to the event. This should require only minimal resources.

More significant events requiring a team of inspectors will require a greater resource effort commensurate with the safety significance of the event.

REFERENCES TO ANNEX IV

[IV-1] RUSSIAN FEDERATION, On the Use of Atomic Energy, Federal Law No. 170-FZ, Russian Federation Government, Moscow (1995).

[IV-2] RUSSIAN FEDERATION, On Federal Ecological, Technical and Nuclear Supervision Service, Russian Government decree No 401, Russian Federation Government, Moscow (2004).

[IV-3] ROSTECHNADZOR, Administrative Regulation on State Function of Federal Ecological, Technological and Nuclear Supervision Service for Federal State Supervision on Nuclear Energy, Administrative Regulation of Rostechnadzor No 248, Rostechnadzor, Moscow (2013).

[IV-4] RUSSIAN FEDERATION, On Protecting the Rights of Juridical Bodies and Individual Entrepreneurs in the Context of State Control (Supervision) and Municipal Control, Federal Law No. 294-FZ, Russian Federation Government, Moscow (2008).

[IV-5] OFFICE FOR NUCLEAR REGULATION, Guidance for Intervention Planning and Reporting, ONR-INSP-GD-059 Revision 6, ONR, Bootle (2018).

[IV-6] U.S. NUCLEAR REGULATORY COMMISSION, Inspection Manual Chapter 0308, Attachment 2, Technical Basis for Inspection Program, US NRC, Washington, DC (2019).

[IV-7] U.S. NUCLEAR REGULATORY COMMISSION, Recommendations for Reactor Oversight Process Improvements, SECY-99-007, U.S. NRC, Washington, DC (1999).

[IV-8] U.S. NUCLEAR REGULATORY COMMISSION, NRC Core Inspection Requirements, Inspection Manual Chapter 2600 Appendix B, U.S. NRC, Washington, DC (2018).

[IV-9] U.S.NUCLEAR REGULATORY COMMISSION, Supplemental Inspection Response to Action Matrix Column 2 Inputs, Inspection Procedure 95001, US NRC, Washington, DC (2016).

[IV-10] U.S. NUCLEAR REGULATORY COMMISSION, Supplemental Inspection for One Degraded Cornerstone or Any Three White Inputs in a Strategic Performance Area, Inspection Procedure 95002, US NRC, Washington, DC (2011).

[IV-11] U.S. NUCLEAR REGULATORY COMMISSION, Supplemental Inspection for Repetitive Degraded Cornerstones, Multiple Degraded Cornerstones, Multiple Yellow Inputs or One Red Input, Inspection Procedure 95003, US NRC, Washington, DC (2015).

[IV-12] U.S. NUCLEAR REGULATORY COMMISSION, Incident Investigation Program, Management Directive 8.3, US NRC, Washington, DC (2014).

ANNEX V.

PRACTICAL EXAMPLES OF MEMBER STATES ON THE USE OF A GRADED APPROACH IN CORE REGULATORY FUNCTIONS: ENFORCEMENT

This annex collects practical examples from Member States of the use of a graded approach in different aspects of enforcement. These contributions were developed by the contributing Member States based upon their own experience and describe how the general three-step methodology described in Sections 3.2 and 4.5 can be used.

This annex provides examples covering a wide range of possible applications of a graded approach. However, it is not comprehensive and additional applications, not covered herein, could also be envisaged by Member States.

V-1. GRADED APPROACH TO COMPLIANCE VERIFICATION AND ENFORCEMENT IN CANADA

This example illustrates Canada's approach to enforcement.

V-1.1. The CNSC's approach to enforcement

Under the Nuclear Safety Control Act (NSCA) [V-1] and its associated regulations, various levels of regulatory action can be taken by the CNSC to correct non-compliance by a licensee and protect the health, safety and security of Canadians and the environment.

Assuring compliance with legislation, regulations and licensing requirements is one of the CNSC's core business processes and is carried out through compliance verification and enforcement.

Together, these activities enable the CNSC to provide assurances to Canadians of the continuing compliance and safety performance of licensees.

(a) Compliance verification

Regular inspections and evaluations verify that licensees are complying with laws and regulations, as well as the conditions of their licence. In this way, the CNSC can assure licensees are operating safely and adhering to their licence conditions.

The CNSC verifies compliance through site inspections and the review of operational activities and licensee documentation. We require licensees to report routine performance data and unusual occurrences. In addition, we conduct investigations of unplanned events or accidents involving nuclear materials or substances. We also collect samples and subsequently analyse them in our laboratory.

(b) Enforcement

The CNSC uses a graduated approach to enforcement to encourage and compel compliance and deter future non-compliances.

When a non-compliance (or a continued non-compliance) has been identified, CNSC staff assess the significance of the non-compliance, and determine the appropriate enforcement action, based on the CNSC's graduated approach to enforcement. Each enforcement action is a discrete and independent response to non-compliance.

V-1.2. Compliance and enforcement actions

Measures used to encourage and compel compliance and deter further non-compliances include:

- Informing licensee/discussion
- Written notices
- Requests under General Nuclear Safety Regulations Section 12(2) [V-2]
- Orders
- Increased regulatory scrutiny
- Licensing actions
- Administrative monetary penalties
- Decertification
- Prosecution

The CNSC's approach to compliance includes activities to encourage compliance, verification activities to assess the actual level of compliance and graduated enforcement actions in cases of non-compliance (up to and including licensing actions [including revocation of licences] and/or prosecution for an offence).

Enforcement actions can be applied independently or in combination with other actions. Regulatory judgment is applied, and multiple factors taken into account, to determine the most appropriate enforcement strategy for any given situation. If the initial enforcement action does not result in timely compliance, other actions will be used.

Enforcement actions are described below.

(a) Informing licensee/discussion

It is possible for certain types of non-compliances to be corrected or prevented by simply having a discussion with the person subject to enforcement action or by using letters or meetings to resolve the issue.

(b) Written notice

Written notices indicate to the person subject to enforcement action that a response is requested and indicate a timeframe for taking corrective actions depending on the risk associated with the non-compliance and the complexity of any corrective actions required.

Written notices will usually suffice to compel either a licensee or the person subject to enforcement action back into compliance.

(c) Request under General Nuclear Safety and Control Regulations 12 (2) [V-2]

A request under subsection 12(2) of the General Nuclear Safety and Control Regulations [V-2] consists of a letter issued by the Commission or a person authorized by the Commission requesting certain information or directing the person to take a specific action, with a response required within a specified time.

(d) Orders

An order is a powerful legal instrument used to compel someone to do something in the interest of health, safety, security, the environment or compliance with international obligations. Orders can only be issued when there is unreasonable risk to health and safety. Failure to comply with an order can lead to further regulatory measures, including prosecution or licensing actions. Read about orders in G273: Making, Reviewing and Receiving Orders under the Nuclear Safety and Control Act [V-3].

(e) Increased regulatory scrutiny

Increased regulatory scrutiny in the form of additional licensee reporting requirements or increased inspection frequency may be useful in ensuring compliance.

Increased regulatory scrutiny may include:

— increased reporting requirements
— increased inspection frequency
— increased frequency of meetings with the licensee
— increased scope of the inspection
— modified inspection technique/strategy

(f) Licensing actions

In accordance with section 25 of the NSCA [V-1], the Commission may, on its own motion, renew, suspend in whole or in part, amend, revoke or replace a licence.

(g) Administrative monetary penalties

An administrative monetary penalty (AMP) is a monetary penalty imposed by the regulator, without court involvement, for the violation of a regulatory requirement. It is administrative in nature; therefore, there is no criminal record associated with it and the burden of proof is less than that for criminal proceedings. Administrative monetary penalties can be imposed for violations of regulatory requirements. Individuals who are not compliant with the NSCA could incur fines of up to $25,000 and $100,000 for corporations.

(h) Decertification

Decertification – the removal of certification to operate or undertake a licenced activity – occurs when the Commission has reasonable grounds to believe that a person or company is no longer qualified or capable of operating a regulated facility or activity.

(i) Prosecution

Prosecution is the laying of charges against a person in accordance with federal or provincial legislation.

V-1.3. Graded approach to compliance verification and enforcement

— **Step 1: Identify the non-compliance and determine its safety-significance and severity level**

—Step 2: Factors to Consider in the selection and escalated use of enforcement tools

The following information provides guidance for selecting the appropriate compliance options. It is not meant to limit the options to those listed.

If the situation warrants it, any compliance action(s) can be taken at any point, resulting in a wide range of compliance strategies, all of which have the ultimate goal of achieving compliance in a timely manner.

Depending on the non-compliance, any compliance action can be used independently or in combination with other actions. Regulatory judgment is applied and multiple factors are taken into account to determine the most appropriate compliance strategy for a given situation.

The primary factors taken into account when choosing the appropriate compliance options include (without being limited to):

(1) The regulatory significance of the non-compliance,
(2) The level of associated risk*;
(3) The compliance history of the regulated individual or corporation,
(4) The urgency of required action,
(5) The deterrent effect of the regulatory action, and
(6) The service line-specific compliance and enforcement strategy.

This is meant to be guidance only and if the situation warrants it, any enforcement tool can be applied at any point in the enforcement process. Table V-1 is not meant to limit the options to those listed.

Note: Risk ranking is determined by considering the probability and consequence of non-compliance associated with the given facility and activity type(s). The methodology used to determine risk ranking is based on Canadian Standards Association guideline CAN/CSA-IEC/ISO 31010, Risk Management – Risk Assessment Techniques [V-4]. Refer to Table V-2 for general guidance for determining safety significance.

TABLE V-1. RATIONALE FOR SELECTION AND ESCALATION OF ENFORCEMENT TOOLS (from [V-4])

IF	**AND** the following tools have been ineffective, or are deemed inappropriate	**THEN** you may choose
The actual or potential consequences to the environment, health, safety, security or international obligations present a low risk	Regular Interaction (discussion, meeting or letter) Written notice	Increased regulatory scrutiny Administrative monetary penalty
There are multiple low risk non-compliances or if low risk non-compliances are repeated	Regular Interaction (discussion, meeting or letter) Written notice	Increased regulatory scrutiny Administrative monetary penalty Licensing action

TABLE V-1. RATIONALE FOR SELECTION AND ESCALATION OF ENFORCEMENT TOOLS (from [V-4]) (cont.)

IF	**AND** the following tools have been ineffective, or are deemed inappropriate	**THEN** you may choose
The actual or potential consequences to the environment, health, safety, security or international obligations present a medium risk	Regular Interaction (discussion, meeting or letter) Written notice	Increased regulatory scrutiny Administrative monetary penalty Licensing action Formal request under GN 12 (2)
There are multiple medium risk non-compliances or if medium risk non-compliances are repeated	Regular Interaction (discussion, meeting or letter) Written notice Formal request under GN 12 (2)	Increased regulatory scrutiny Issuing an order Administrative monetary penalty Licensing action
The consequences to the environment, health, safety, security or international obligations present a high risk	Regular Interaction (discussion, meeting or letter) Written notice Increased regulatory scrutiny	Issuing an order Administrative monetary penalty Licensing action Formal request under GN 12 (2) Decertification of persons Investigation and prosecution
High risk non-compliance is repeated	Regular Interaction (discussion, meeting or letter) Written notice Increased regulatory scrutiny Formal request under GN 12 (2)	Issuing an order Administrative monetary penalty
There are multiple high risk non-compliances		Immediate issuance of an order Administrative monetary penalty Licensing action Decertification of persons Investigation and prosecution
There is unreasonable risk to the environment, to the health and safety of persons, to national security or to international obligations,		Immediate issuance of an order Administrative monetary penalty Licensing action Decertification of persons Investigation and prosecution
Note: Remember, when choosing the appropriate enforcement action to use, additional consideration needs to be given to the following: • The wilfulness of the non-compliance; and • The Directive on the Health of Canadians, which requires that the CNSC shall take into account the health of Canadians who, for medical purposes, depend on nuclear substances produced by nuclear reactors.		

TABLE V-2. GENERAL GUIDANCE FOR DETERMINING SAFETY SIGNIFICANCE

Functional areas	**Management**	**Facility and equipment**	**Core control processes**				**Other**
SCA / safety significance		**Defence in depth (barriers)**	**Radiation protection**	**Environmental protection**	**Security**	**Conv. health and safety**	
High	Widespread systemic failure of management control over safety- significant work practices.	Compromise to barriers where defence in depth would be considered inadequate. Compromise to safety due to a situation that was not previously evaluated and believed to be probable.	Exposures to multiple workers in excess of regulatory limits. Widespread contamination to several persons or to a place.	Nuclear or hazardous substances being released to the environment exceeding regulatory limits (including public exposure) or that results in significant impact to the environment.	Delaying the implementation of an effective security plan that includes off-site response forces.	Fatality or serious injury.	See Directorate specific examples
Medium	Local failure or systematic failure of one or more elements in management control over safety- significant work practices.	Compromise to barriers where defence in depth would be considered reduced, however redundancy remains. Compromise to safety due to a situation that was not previously evaluated and believed to be probable.	Exposure to a worker in excess of regulatory limits. An incident that would result in a licensee exceeding action levels (section 6 of RPR). Limited contamination that could affect a few persons or limited area.	Nuclear or hazardous substances being released to the environment exceeding action levels (including public exposure) or that results in impact to the environment outside the licensing basis.	Delaying the implementation of an effective security plan. Situation where Category 1 or 2 sources are accessible by unauthorized persons.	Serious injury or lost-time accident.	See Directorate specific examples
Low	Partial failure of an element in the management control over a safety- significant work practice.	Reduced redundancy that is not likely to prevent a safety- related system from meeting its design intent.	Increased dose below reportable limits. Contamination that could affect a worker.	Release of hazardous or nuclear substances to the environment below regulatory limits.	Failed security barrier from not being corrected.	Minor injury.	See Directorate specific examples

With regards to AMPs, the amount of a penalty is determined by the Commission the regulatory significance of the non-compliance and the following set of factors:

(a) the compliance history of the person who committed the violation;
(b) the degree of intention or negligence on the part of the person;
(c) the harm that resulted or could have resulted from the violation;
(d) whether the person derived any competitive or economic benefit from the violation;
(e) whether the person made reasonable efforts to mitigate or reverse the violation's effects;
(f) whether the person provided all reasonable assistance to the Commission; and
(g) whether the person brought the violation to the attention of the Commission.

Regulatory requirements were categorized based on the potential regulatory significance of the non-compliance: Categories A, B and C with C being high significance. The 'Administrative Monetary Penalty Regulations' [V-5] stipulate the category for each applicable regulation. The matrix listed below was used in determining the regulatory significance of a non-compliance with the specific regulation. For each category under the Nuclear Safety and Control Act [V-1], the potential consequences arising from the non-compliance was determined. An expert elicitation process was used to perform this assessment.

TABLE V-3. MATRIX USED FOR DETERMINING SAFETY SIGNIFICANCE OF A NON-COMPLIANCE

Nuclear Safety and Control Act (NSCA) Category	Consequence	Imminent Threat	Possible Threat	Loss of Redundancy	Administrative Requirements
Protect Workers	☐	☐	☐	☐	☐
Protect Public	☐	☐	☐	☐	☐
Protect Environments	☐	☐	☐	☐	☐
National Security	☐	☐	☐	☐	☐
International Obligations	☐	☐	☐	☐	☐

— Step 3: Selecting the Appropriate Enforcement Action

A risk informed decision making process has to be used when determining the appropriateness of an enforcement action and when proceeding with enforcement escalation. If initial enforcement action does not result in timely compliance, escalated enforcement action should be utilized. Steps in selecting the appropriate enforcement tool are described below:

(a) Assess the significance of a non-compliance by considering the following criteria:

(1) the actual safety consequences
(2) the potential safety consequences
(3) the number or recurrence of non-compliances; and

(4) the willful aspects of the non-compliance situation.

Note: Judgment need to be exercised in the use of risk significance as a factor in decisions regarding the appropriateness of the enforcement action.

(b) Assess the level of enforcement activity that may be required. This will vary depending on:

(1) the severity of the non-compliance,
(2) the risk classification of the key risk areas or criteria; and
(3) the level of risk tolerance that the CNSC is willing to accept.

Note: Risk tolerance will vary depending on internal and external influences and environmental scanning. Depending on the current environment, attention to certain risk areas may increase or decrease as appropriate.

When choosing the appropriate enforcement tool to use, additional consideration needs to be given to the following:

(1) The wilfulness of the non-compliance
(2) The Directive on the Health of Canadians which requires the CNSC to take into account the health of Canadians who, for medical purposes, depend on nuclear substances produced by nuclear reactors.

(c) Choose an enforcement tool from the following list using Tables V-1 and V-2 as guidance:

(1) Discussion, meetings or letters
(2) Written Notices
(3) Formal Requests under General Nuclear Safety and Control Regulations 12 (2) [V-2]
(4) Orders
(5) Administrative Monetary Penalties (AMPs) (see further information on AMPs, above)
(6) Increased Regulatory Scrutiny
(7) Licensing Action
(8) Decertification of Persons
(9) Investigation and Prosecution

Note: Publicity, while not an enforcement action, may be used to inform stakeholders that a licensee or a person is, or has been, the subject of regulatory enforcement actions.

Note: Information in Step 2 provides general guidance and each situation should be examined individually. Inspectors and Designated Officers should use their experience and judgment when making a final enforcement decision. Divisional and Directorate policies need to also be considered when making a decision

V-2. GRADED APPROACH FOR THE DETERMINATION OF VALUES OF ADMINISTRATIVE MONETARY PENALTIES IN CANADA

This example describes the use of a graded approach to determine administrative monetary penalties in Canada using the approach to enforcement described in Section V-1 of Annex V.

V-2.1. Administrative Monetary Penalty for Violation of a Condition of a Licence

— Step 1: Identification of the regulatory decision to be made

Based on the notification made by Company A of a failure to comply with the requirements of a licence condition, and on the investigation of the incident that was made after the violation, CNSC decided to apply an administrative monetary penalty and its amount had to be determined.

(a) Violation

Failure to comply with a condition of a licence in violation of Paragraph 48(c) of the Nuclear Safety and Control Act [V-1].

— Step 2: Identification and prioritization of the applicable factors associated with the regulatory decision

For the determination of the amount of the monetary penalty, CNSC considers seven factors to be assessed as presented in [V-5]:

(1) the compliance history of the person who committed the violation;
(2) the degree of intention or negligence on the part of the person;
(3) the harm that resulted or could have resulted from the violation;
(4) whether the person derived any competitive or economic benefit from the violation;
(5) whether the person made reasonable efforts to mitigate or reverse the violation's effects;
(6) whether the person provided all reasonable assistance to the Commission; and
(7) whether the person brought the violation to the attention of the Commission.

(a) Relevant facts

The facts relevant to the violation and the penalty calculation are as follows:

(1) Company A holds a CNSC licence authorizing the use and possession of fixed nuclear gauges

(2) The licence includes licence condition titled 'Vessel or Hopper Entry', which requires that 'entry into the vessel or hopper is performed in accordance with written procedures acceptable to the Commission or a person authorized by the Commission'.

(3) Company A submitted a vessel entry procedure which was accepted by the CNSC and referenced in the licence.

(4) Subsequently Company A issued a 'Safe Work Permit' to enter the Blast Furnace Ore Hoppers. A Texas Nuclear 5010A fixed nuclear gauge containing a maximum of 37 GBq Am-241/Be is installed on each hopper. Later, two contractor workers entered one of the ore hoppers to construct scaffolding and allow access to the upper

portions of the hopper. The workers remained in the hopper for approximately 1.5 hours to carry out their work.

(5) After this, Company A staff identified that the fixed nuclear gauge affixed to the vessel had not been closed in accordance with the accepted vessel entry procedures. The CNSC was notified of the situation.

(6) Based on the information provided on Company A estimates a potential maximum radiation exposure to the contractors of 40.5µSv each. This dose estimate was confirmed by CNSC staff.

(7) Company A investigated the cause of the incident and determined that there were two factors:

- Incorrect work documents for the vessel entry were used; the documentation did not identify the presence of fixed nuclear gauges nor provide work instructions for locking out the fixed nuclear gauges.
- The radiation warning signage at the entry to the vessel was illegible.

(b) Assessment and prioritization of the applicable factors

In consideration of the seven factors in section 5 of the Administrative Monetary Penalties Regulations (Canadian Nuclear Safety Commission) [V-5], the amount of the penalty was determined based on the following relevant facts:

(1) Compliance history: Assessed score = 0

A Type II inspection carried out in October 2016 identified no items of non-compliance with respect to a previous vessel entry.

(2) Intention or negligence: Assessed score = +1

The licensee's use of an incorrect document package was the primary cause of the event and exposure to workers. This demonstrates a level of negligence on the part of the licensee. The licensee did not follow the approved procedure.

(3) Actual or potential harm: Assessed score = +1

Access to the vessels was not managed according to CNSC approved procedures and resulted in two contract workers being exposed to low doses of radiation. Although the doses received by the two contract workers were below the limit for members of the general public, the doses were not consistent with the ALARA principle. The doses could have been higher had the work been closer to the fixed nuclear gauge(s) or taken a longer period of time to complete the work.

(4) Competitive or economic benefit: Assessed score = 0

There is no identifiable competitive or economic benefit as a result of this non-compliance.

(5) Efforts to mitigate or reverse effects: Assessed score = 0

There were no substantive effects as a result of this violation that required mitigation.

(6) Assistance to Commission: Assessed score = -2

Once the licensee reported the non-compliance to the CNSC, the licensee provided a detailed event report, developed a corrective action plan and provided all information requested by the CNSC.

(7) Attention of Commission: Assessed score = +1

Licensee radiation safety staff were made aware of the non-compliance two days after the incident. The licensee did not notify the CNSC until three days after the incident, contrary to the regulatory requirement of reporting immediately.

— Step 3: Integrate the applicable factors into the decision-making process.

This step presents the calculation of the administrative monetary penalty by integrating the factors and respective weights/priorities in accordance with the procedure described in [V-5].

(a) Category of violation

Category A ☐ Category B ☐ Category C ☒

(b) Penalty range

Category	Minimum	Maximum	Maximum – minimum
A	$1,000	$12,000	$11,000
B	$1,000	$40,000	$39,000
C	**$1,000**	**$100,000**	**$99,000**

(c) Determining factors

Factors	Scale of regulatory significance	Assessed score
1. Compliance history	0 ☒ +1 ☐ +2 ☐ +3 ☐ +4 ☐ +5 ☐	0
2. Intention or negligence	0 ☐ +1 ☒ +2 ☐ +3 ☐ +4 ☐ +5 ☐	+1
3. Actual or potential harm	0 ☐ +1 ☒ +2 ☐ +3 ☐ +4 ☐ +5 ☐	+1
4. Competitive or economic benefit	0 ☒ +1 ☐ +2 ☐ +3 ☐ +4 ☐ +5 ☐	0
5. Efforts to mitigate or reverse effects	-2 ☐ -1 ☐ 0 ☒ +1 ☐ +2 ☐ +3 ☐	0
6. Assistance to Commission	-2 ☒ -1 ☐ 0 ☐ +1 ☐ +2 ☐ +3 ☐	-2
7. Attention of Commission	-2 ☐ -1 ☐ 0 ☐ +1 ☒ +2 ☐ +3 ☐	+1
	Total	**1**
	÷ **29** [(1)] [rounded to 2 decimal points]=	**0.03**
	x 99000 [total] =	**2,970**
	+ $ 1000 [minimum for the category] =	**$3,970**

(1) 29 being the maximum value of regulatory significance

Therefore, the administrative monetary penalty associated with failure to comply with a condition of a licence in violation of Paragraph 48(c) of the Nuclear Safety and Control Act [V-1], by applying a graded approach, was '$3,970.00'.

V-2.2. Administrative Monetary Penalty for Violation of a Condition of a Licence – different situation

— Step 1: Identification of the regulatory decision to be made

Based on the notification made by Company B of a failure to comply with the requirements of a licence condition, and on the investigation of the incident that was made after the violation, CNSC decided to apply an administrative monetary penalty and its amount had to be determined.

(a) Violation

Failure to comply with a condition of a licence, in accordance with paragraph 48(c) of the Nuclear Safety and Control Act [V-1]. Specifically: Company B failed to verify whether work is being performed correctly and according to approved procedures (as outlined in Company B's Licence Conditions Handbook section 2 – 'SCA - Management System – the licensee shall implement and maintain a management system').

— Step 2: Identification and prioritization of the applicable factors associated with the regulatory decision

Like the previous example, for the determination of the amount of the monetary penalty, CNSC considers seven factors to be assessed as presented in [V-5]:

(1) the compliance history of the person who committed the violation;
(2) the degree of intention or negligence on the part of the person;
(3) the harm that resulted or could have resulted from the violation;
(4) whether the person derived any competitive or economic benefit from the violation;
(5) whether the person made reasonable efforts to mitigate or reverse the violation's effects;
(6) whether the person provided all reasonable assistance to the Commission; and
(7) whether the person brought the violation to the attention of the Commission.

(a) Relevant facts

The facts relevant to the violation and the penalty calculation are as follows:

(1) Company B holds a CNSC operating licence authorizing the conversion of uranium oxide powder into uranium products, including the use of HF in the process. This licence requires 'the licensee shall implement and maintain a management system'

(2) A small release of hydrogen fluoride (HF) occurred within a UF6 plant. CNSC then conducted a reactive compliance inspection at the PHCF which focused on Company B's management system and maintenance programs.

(3) During the reactive inspection, CNSC staff found evidence that daily time cards were not completed properly in accordance with Company B's procedures.

(4) CNSC staff raised this observation during the reactive inspection with Company B's staff as this was a non-compliance with Company B's internal procedures. Internal procedures require that a qualified person or area operator have to issue a daily notification clearance to the worker before beginning the job.

(5) As a result of the reactive inspection, CNSC staff issued an enforcement action in an inspection report for Company B to take necessary actions to ensure that work is conducted in a defined and systematic manner according to approved work instructions and procedures.

(6) To address this enforcement action, Company B put in place an initiative to better define and communicate basic operating fundamentals. As part of this initiative, Company B's management team met with every employee on site to ensure that the expectations pertaining to responsibility, communication and verification, are clearly understood.

(7) Company B implemented a procedure improvement objective and monitored targets to ensure this initiative stays on track. Subsequently, CNSC staff reviewed and accepted the corrective actions to address the aforementioned enforcement action identified in the inspection report.

(8) In addition to the aforementioned enforcement action identified during the reactive inspection at the facility, CNSC staff identified other non-compliances related to procedural non-adherence in numerous inspection reports

(9) Approximately 2.5 years later Company B notified the CNSC Duty Officer to report that Company B's Emergency Response Team (ERT) was activated in response to a possible HF leak in the UF6 plant.

(10) Company B confirmed that an HF leak took place while a worker was in the process of calibrating a piece of equipment (gauge).

(11) The affected worker was directed to Company B's medical department where they received precautionary medical attention due to exposure to HF. The worker was not injured and there were no environmental impacts as a result of this event.

(12) Shortly thereafter, Company B began a preliminary investigation of the HF leak.

(13) CNSC staff conducted a reactive inspection at the PHCF in response to the reported HF leak and received the following preliminary investigation information from Company B:

— Company B staff did not comply with a section of Company B's. A qualified person or area operator did not issue a daily notification clearance to the worker before beginning the job as required by Company B's procedure.
— Company B staff did not comply with another section of Company B's procedure. A special safety clearance was not obtained before work was performed on equipment containing HF as required.
— Company B staff did not comply with the maintenance plan. Specifically, an HF notification and safety clearance from the Production Department was not obtained prior to conducting the work and the impulse line valve was not closed (tag off) and isolated as required by the maintenance plan.

(14) As a result of Company B's preliminary investigation, Company B issued a bulletin to their staff stating the following:

- Company B's investigation determined that "… it quickly became apparent that no safe work clearance had been performed prior to the start of the work. As a consequence of that, the line was not properly isolated and the employee was not wearing the appropriate PPE, which puts the employee, fellow employees on the ERT and the site at risk due to this lack of compliance."
- The bulletin continued on to state "… As a management team, we find this incident very disappointing. This behaviour has to stop immediately. There is ZERO tolerance for not completing the safe work clearance process when required. Completing a safe work clearance is a foundational aspect of working safely at our site, and to bypass this process puts our entire facility at risk. It is absolutely mandatory that safe work clearances are performed prior to the start of maintenance work at all hours of the day, in all areas of our facility …..."

(15) The above mentioned facts demonstrate that Company B's corrective actions since 2014 were not effective in ensuring that Company B staff are adhering to the requirements described in their procedure.

(b) Assessment and prioritization of the applicable factors

The administrative monetary penalty is based on the failure of Company B to verify whether work is being performed correctly and according to approved procedures and not due to the HF leak. In consideration of the seven factors in section 5 of the Administrative Monetary Penalties Regulations (Canadian Nuclear Safety Commission) [V-5], the amount of the penalty was determined based on the following relevant facts:

(1) Compliance history: Assessed score = 4

There is evidence that failure to verify that the procedure was adhered to has occurred frequently since 2014 despite the licensee's corrective actions.

Company B has acknowledged a lack of procedural adherence with Company B's procedure.

CNSC staff expect licensees to: 1) conduct regular verification to confirm procedural adherence and 2) to perform work systematically and in accordance with approved procedures.

(2) Intention or negligence: Assessed score = 2

Company B was negligent for not independently verifying that work was being carried out by staff according to corporate procedures. Certain procedures outline Company B's expectations for staff; requiring that a notification and safety clearance is needed before any maintenance work is performed in order for the protection of its workers and company property.

Licensees are responsible for conducting routine verifications of their management processes to ensure adherence to procedures. Licensees are expected to carry out work according to requirements that are specified in up-to-date approved procedures. Company B stated that they had not performed verifications related to their procedure.

CNSC staff expect that all licensees will ensure the safety of their staff and will take steps to verify that all procedures that impact worker safety are being adherence to.

(3) Actual or potential harm: Assessed score = 3

HF is extremely corrosive and toxic; exposure to HF can significantly harm persons and the environment. Adherence to approved procedures is critical to avoid exposure/release of HF.

Non-adherence to approved procedures while working with hazardous materials has the potential to cause injurious harm to workers and the environment.

(4) Competitive or economic benefit: Assessed score = 0

Company B did not appear to have derived any competitive or economic benefit as a result of the violation.

(5) Efforts to mitigate or reverse effects: Assessed score = 0

Since the initial situation, Company B has taken corrective actions to address CNSC staff concerns related to procedural non-adherence. However, the effectiveness of Company B's corrective actions did not prevent recurrences of the violation. While Company B has, since the small release of HF event earlier, taken corrective actions to better define and communicate the importance of adhering to procedures, they have not effectively mitigated the effects of procedural non-adherence of their workers.

(6) Assistance to Commission: Assessed score = -2

Company B was involved and cooperated in investigative measures. Company B provided all requested information to CNSC staff.

(7) Attention of Commission: Assessed score = -2

The subsequent HF leak was reported to the CNSC Duty Officer in accordance with regulatory requirements.

— **Step 3: Integrate the applicable factors into the decision-making process.**

This step presents the calculation of the administrative monetary penalty by integrating the factors and respective weights/priorities in accordance with the procedure described in [V-5].

(a) Category of violation

Category A ☐ Category B ☐ Category C ☒

(b) Penalty range

Category	Minimum	Maximum	Maximum – minimum
A	$1,000	$12,000	$11,000
B	$1,000	$40,000	$39,000
C	**$1,000**	**$100,000**	**$99,000**

(c) Determining factors

Factors	Scale of regulatory significance	Assessed score
1. Compliance history	0 ☐ +1 ☐ +2 ☐ +3 ☐ +4 ☒ +5 ☐	4
2. Intention or negligence	0 ☐ +1 ☐ +2 ☒ +3 ☐ +4 ☐ +5 ☐	2
3. Actual or potential harm	0 ☐ +1 ☐ +2 ☐ +3 ☒ +4 ☐ +5 ☐	3
4. Competitive or economic benefit	0 ☒ +1 ☐ +2 ☐ +3 ☐ +4 ☐ +5 ☐	0
5. Efforts to mitigate or reverse effects	-2 ☐ -1 ☐ 0 ☒ +1 ☐ +2 ☐ +3 ☐	0
6. Assistance to Commission	-2 ☒ -1 ☐ 0 ☐ +1 ☐ +2 ☐ +3 ☐	-2
7. Attention of Commission	-2 ☒ -1 ☐ 0 ☐ +1 ☐ +2 ☐ +3 ☐	-2
	Total	**5**
	÷ **29** [(1)] [rounded to 2 decimal points]=	**0.17**
	x 99000 [total] =	**16,830**
	+ $1,000 [minimum for the category] =	**17,830**

[(1)] 29 is the maximum value of regulatory significance

Therefore, the administrative monetary penalty associated with failure to comply with a condition of a licence in violation of Paragraph 48(c) of the Nuclear Safety and Control Act [V-1], by applying a graded approach, was '$17,830.00'.

V-3. GRADED APPROACH TO MAKING ENFORCEMENT DECISIONS IN THE UK

ONR's enforcement guidance [V-6] reflects how it regulates the nuclear industry and relevant areas of the non-nuclear industry and is applicable to all of ONR's purposes.

This enforcement guidance provides a framework for making consistent enforcement decisions, it is not a mechanistic decision-making tool. It guides inspectors in considering the key aspects of a dutyholder's shortfall in performance; to arrive at the most appropriate enforcement decision for the circumstances. Enforcement decisions are based on the level of risk, the authority of the relevant standard and the application of factors (dutyholder and strategic).

The ONR Enforcement Management Model (EMM) is intended to:

(a) ensure consistency in the enforcement decision making process;
(b) ensure proportionality and targeting by considering the risk based criteria against which decisions are made;
(c) provide a framework for making enforcement decisions transparent, and for ensuring that those who make decisions are accountable for them;
(d) help inspectors assess their decisions in complex cases, and allow peer review of enforcement action; and
(e) guide less experienced inspectors in making enforcement decisions

— Step 1: Identify the non-compliance

Following an identified health, safety or security risk, e.g. inspection and investigation, inspectors use the ONR EMM to consider the level of risk or compliance gap to identify proportionate enforcement actions to secure compliance.

ONR inspectors often operate in an environment where they are regularly in contact with dutyholders during the course of their work to carry out risk informed and targeted interventions. ONR inspectors usually have the opportunity to regularly monitor the response to identified shortfalls and where necessary escalate where dutyholders fail to respond appropriately.

— Step 2: Determine which factors are applicable to the enforcement decision

(a) Deriving a Baseline Enforcement Level (BEL)

The concept of risk level is used in the ONR EMM as an overall indicator of how far away from an adequate standard the particular circumstances encountered by the inspector actually are. The risk level takes account of the level of harm including potential harm (consequences) and the adequacy of the control measures in place to provide protection. The risk level is used for the purpose of selecting a baseline enforcement level (BEL). The ONR EMM is designed to specify a higher BEL where the gap to relevant good practice (benchmark standard) is greater; and in circumstances where the consequences are more severe. Four risk levels are used in the ONR EMM: extreme, substantial, moderate and nominal.

The risk level matrix uses two parameters; the consequence level is a relative measure of the actual or potential harm to workers or the public (including possible civil disruption). The control measures level is a relative measure of the extent to which relevant good practice set out in benchmark standards has been satisfied.

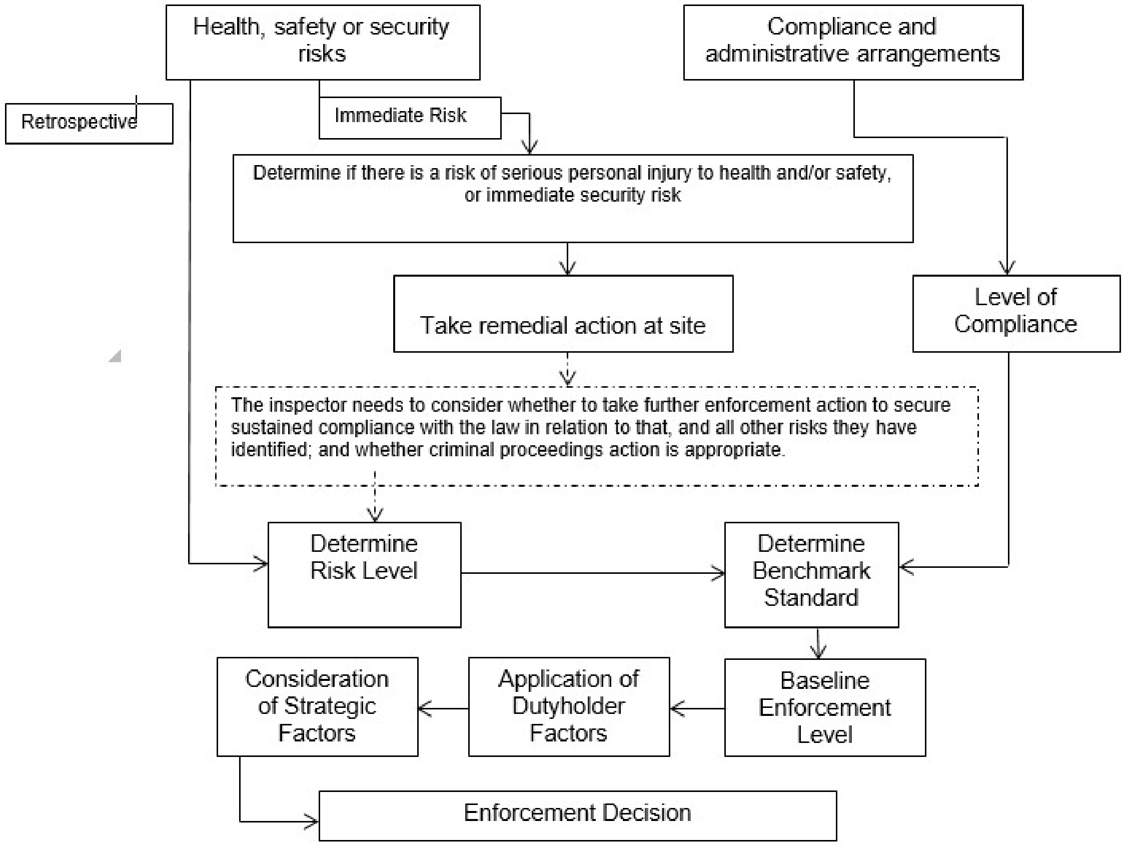

FIG. V-1. Enforcement Decision Making Flowchart

TABLE V-4. DERIVATION OF 'RISK LEVEL'

Consequence	Serious	Nominal	Substantial	Extreme
	Significant	Nominal	Moderate	Substantial
	Minor	Nominal	Nominal	Moderate
		Broadly satisfied	Weakened	Absent/ inadequate
		Control measures		

The authority of the relevant Benchmark that is being used to evaluate the circumstances requiring enforcement is the next factor to be considered. The ONR EMM is designed to specify a higher BEL in circumstances where the legal requirement is more explicitly defined. Benchmarks are derived from security and safety standards which come from various sources. These standards have differing 'authorities', e.g. They could be specified in law, or may be a reasoned description of what the law seeks to achieve set down in guidance. This influences the decision about the proportionate level of enforcement.

A higher level of enforcement is expected where a dutyholder has failed to meet well known and defined standards compared to situations where there is less information or guidance available. There may be a range of standards that are relevant to the matter(s) being considered; the standard used should be that which best describes the circumstances. Standards are divided into three categories to capture their broad range of authority; Defined, Established and Interpretative.

Table V-5 provides further guidance on standards, and their legal authority.

The next step in the ONR EMM process requires inspectors to determine the Baseline Enforcement Level (BEL). This is the baseline level of enforcement that is appropriate to deliver compliance; it reflects, and is proportionate to, the risk to health, safety or security or the seriousness of any breach of the law and is consistent with regulatory action taken across the UK. To determine the BEL the Risk Level and Benchmark Standard are compared in Table V-6.

TABLE V-5. DERIVATION OF BENCHMARK STANDARD

BENCHMARK STANDARDS	
WHAT IS THE AUTHORITY OF THE APPROPRIATE STANDARD?	
Descriptor	**Definition**
Defined Standard	Minimum standard specified by Acts, Regulations, Orders and ACoPs. For example, Regulatory Reform (Fire Safety) Order 2005, The Fire (Scotland) Act, Management of Health and Safety at Work Regulations 1999, Health and Safety at Work Act 1974, Nuclear Industries Security Regulations 2003, Control of Asbestos Regulations 2012, Working at Height Regulations 2005, Confined Spaces Regulations 1997 ACoP, Ionising Radiations Regulations, Carriage of Dangerous Goods and Use of Transportable Pressure Equipment 2009.
Established Standard	Codes of Practice and other standards linked to legislation, published or commonly known standards of performance interpreted by regulators or other specialists, industry or other organizations. For example, British Standards, Licence Conditions, Security and Safety Assessment Principles, Cabinet Office Security Policy Framework, TIGs, TAGs and IAEA Standards.
Interpretative Standard	Standards which are not published or available generally, but are examples of the performance needed to meet a general or qualified duty.

TABLE V-6. DERIVATION OF BASELINE ENFORCEMENT LEVEL

Risk Level	Benchmark Standard	Baseline Enforcement Level (to secure compliance with the law)	Consider Prosecution
Extreme	Defined	Notice / Direction / LC Powers	Yes
	Established	Notice / Direction / LC Powers	Yes
	Interpretative	Notice / Direction / LC Powers	-
Substantial	Defined	Notice / Direction / LC Powers	-
	Established	Enforcement Letter	-
	Interpretative	Enforcement Letter	-
Moderate	Defined	Enforcement Letter	-
	Established	Regulatory Advice	-
	Interpretative	Regulatory Advice	-
Nominal	Defined	Regulatory Advice	-
	Established	No Action	-
	Interpretative	No Action	-

(b) Modify BEL against dutyholder factors

Having identified the BEL relative to the circumstances; the inspector now needs to ensure relevant dutyholder factors are considered to arrive at the most appropriate enforcement action. The dutyholder factors have the potential to only escalate the enforcement action; the inspector will be best placed to consider these factors given their ongoing interactions with the dutyholder from carrying out our functions.

The list below presents a series of dutyholder factors which may escalate the enforcement decision, note that not all factors may apply. This is a further aid for inspectors in reaching an enforcement decision.

(1) Factors to consider
- What is the inspection history of the dutyholder?
- What is the level of confidence in the dutyholder?
- Does the dutyholder have a history of relevant, formal enforcement being taken or relevant advice being given?
- Is there a relevant incident history?
- Is the dutyholder deliberately seeking economic advantage?
- What is the standard of general compliance which is relative?

(c) Modify BEL against Strategic factors

There is a range of strategic factors which may impact on the enforcement decision. Inspectors have to ensure that public interest are considered. The outcomes when considering the strategic factors will be either the enforcement decision is unaffected or the enforcement decision should be subject to management review because it does not address all the strategic factors. There is no ranking of importance with the strategic factors. However, the final question the inspector and delivery lead is expected to ask is: ‘Does the proposed action meet the principles and expectations captured in the Enforcement Policy Statement (EPS)?’

(1) Factors to consider
- Does the action coincide with the Public Interest?
- Are vulnerable groups protected?
- What is the long-term impact of the action?
- What is the effect of action?
- What is the functional impact of the action?

— Step 3: Integrate the applicable factors into the enforcement decision

(a) Undertake relevant enforcement action

A range of enforcement tools are available as defined in the previous tables. ONR inspectors will execute in a graded manner the enforcement tool following derivation of the baseline enforcement level and application of relevant dutyholder and strategic factors which may or may not escalate the enforcement decision.

(b) Undertake Decision review

Decision review is undertaken to support enforcement decisions which have a higher profile. The process of decision review provides additional robustness to the EMM process and supports consistency and credibility of enforcement decisions in ONR. The decision review process requires the Delivery & Professional Lead to consider:

(1) that the application and evidence for dutyholder factors has been appropriately applied if the BEL has been escalated;
(2) that the application of strategic factors is addressed by the proposed enforcement action;
(3) whether the proposed enforcement action meets the EPS;
(4) For consideration of prosecution that the enforcement action meets the Code for Crown Prosecutors in England and Wales or the Prosecutors Code in Scotland.

If there is a difference of opinion in relation to the enforcement decision then this should be rectified by utilizing ONR guidance on Resolving Differences of Professional Opinion in ONR [V-7] specifically Dealing With Differences in Professional Opinion on Enforcement Action. Where the decision has been challenged, the decision should not be enacted, even if the Enforcement Decision Record (EDR) has been accepted by the delivery lead.

V-4. USE OF A GRADED APPROACH TO DETERMINE SAFETY SIGNIFICANCE OF INSPECTION FINDINGS AND ENFORCEMENT ACTIONS IN THE US

The following is a discussion of the NRC's process for determining safety-significance of inspection findings at operating nuclear power plants in order to determine the appropriate regulatory response and enforcement action for violations and non-compliances.

— **Step 1: Identify the non-compliance and determine safety significance or severity level**

Non-compliances and inspection findings may be identified by NRC inspectors, the licensee during routine monitoring of the plant, or may be self-revealed through failure of a system or component to accomplish its design function. An inspection finding is defined to be a

licensee's failure to meet a requirement or standard (a standard includes a self-imposed standard such as a voluntary initiative or a standard required by regulation) that was reasonably within the licensee's ability to foresee and correct and should have been prevented.

Once a non-compliance or finding is identified, it is screened for safety significance. The NRC uses a significance determination process (SDP), described in Inspection Manual Chapter 0609, 'Significance Determination Process' [V-8]. Inspection findings are assigned a colour representing the safety significance of the finding. The following definitions include the quantitative and qualitative descriptions for each colour. Quantitative definitions only apply for facilities that have a probabilistic safety assessment (PSA). The symbol 'Δ', for significance determinations that use core damage frequency (CDF) and large early release frequency (LERF) as metrics, refers to the difference between the CDF (or LERF) resulting from the degraded condition(s) caused by deficient licensee performance and the nominal CDF (or LERF) of the facility. In other words, the quantitative determination estimates the increase in risk resulting from a degraded condition(s) caused by deficient licensee performance above a baseline risk profile. A graphical representation of the quantitative significance of findings is displayed in the figure below.

(a) 'Red' (high safety or security significance) is quantitatively greater than $10^{-4}\Delta$CDF or $10^{-5}\Delta$LERF. Qualitatively, a Red significance indicates a decline in licensee performance that is associated with an unacceptable loss of safety margin. Sufficient safety margin still exists to prevent undue risk to public health and safety.

(b) 'Yellow' (moderate safety or security significance) is quantitatively greater than 10^{-5} and less than or equal to 10^{-4} ΔCDF or greater than 10^{-6} and less than or equal to 10^{-5} ΔLERF. Qualitatively, a Yellow significance indicates a decline in licensee performance that is still acceptable with cornerstone objectives met, but with significant reduction in safety margin.

(c) 'White' (low safety or security significance) is quantitatively greater than 10^{-6} and less than or equal to 10^{-5}ΔCDF or greater than 10^{-7} and less than or equal to 10^{-6} ΔLERF. Qualitatively, a White significance indicates an acceptable level of performance by the licensee, but outside the nominal risk range. Cornerstone objectives are met with minimal reduction in safety margin.

(d) 'Green' (very low safety or security significance) is quantitatively less than or equal to 10^{-6} ΔCDF or 10^{-7} ΔLERF. Qualitatively, a Green significance indicates that licensee performance is acceptable and cornerstone objectives are fully met with nominal risk and deviation.

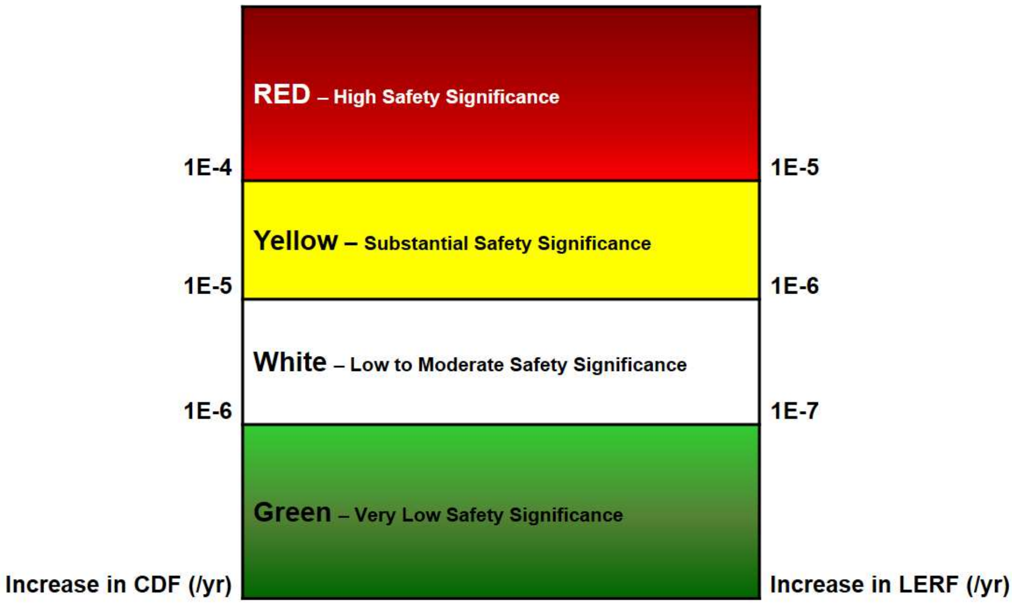

FIG. V-2. Safety Significance of Inspection Findings

—Step 2 – Identify applicable factors to consider

In determining the appropriate enforcement response to a violation, the US NRC considers the following factors:

(a) The safety significance or seriousness of the violation or non-compliance;
(b) Who identified and reported the non-compliance, i.e. whether the non-compliance was self-reported or identified during an independent inspection;
(c) Timeliness of corrective actions to restore compliance with the requirements;
(d) The frequency and number of deficiencies;
(e) Whether or not the identified deficiency is repetitive; and
(f) Wilfulness

In addition, the NRC considers other factors, discussed below.

(a) Whether the violation resulted in actual safety or security consequences. In evaluating actual consequences, the regulator is expected to consider issues such as whether the violation resulted in the onsite or offsite releases of radiation or radiation exposures exceeding regulatory limits, onsite or offsite chemical hazard exposures resulting from licensed or certified activities, accidental criticality, core damage, loss of significant safety barriers, loss of control of radioactive material or radiological emergencies, any violations during an actual General Emergency that prevents offsite response organizations from implementing protective actions (under their emergency plans) to protect public health and safety, or whether the security system did not function as required and, as a result of the failure, a significant event or an event that resulted in an act of radiological sabotage occurred.

(b) Whether the violation had potential safety or security consequences. In evaluating potential consequences, the regulator should consider whether the violation created a credible accident, security failure, or exposure scenario that could potentially have significant actual consequences. For facilities under construction, consider the actual or potential impact of the violation on the quality of construction and its resulting effect on the safety and security of the facility.

(c) Whether the violation impacted the ability of the regulator to perform its regulatory oversight function. Consider the safety and security implications of non-compliances that may affect the regulator's ability to carry out its statutory mission. These types of violations include failures to provide complete and accurate information; failures to receive prior approval for changes in licensed activities, when required; failures to notify the regulator of required changes in licensed activities, when required; and failures to comply with reporting requirements, etc.

(d) Whether the violation involved wilfulness. Wilful violations are of particular concern because the regulatory program is based on licensees and their contractors, employees, and agents acting with integrity and communicating with candour. The regulator should not tolerate wilful violations. Therefore, a violation may be considered more significant than the underlying non-compliance if it includes indications of wilfulness.

— **Step 3: Integrate factors into decision-making process to determine appropriate enforcement action**

The final safety significance of the inspection finding is determined by consensus of several staff members and managers under the Significance and Enforcement Review Panel (SERP) process. The appropriate enforcement tool is generally dictated by the safety significance of the finding. The factors described above will either result in mitigating or escalating the significance, resulting in a lesser or greater enforcement action.

The NRC Enforcement Manual [V-9] describes several enforcement options with defined criteria. The following are enforcement actions listed by increasing significance:

(a) 'Minor violations' – Violations of minor safety or security concern generally do not warrant enforcement action or documentation in inspection reports but need to still be corrected by the licensee. To determine if a violation or performance deficiency is minor or not, inspectors need to evaluate the following questions:
   — Could the performance deficiency reasonably be viewed as a precursor to a significant event?

- If left uncorrected, would the performance deficiency have the potential to lead to a more significant safety concern?
- Does the performance deficiency relate to a performance indicator that would have caused the performance indicator to exceed a threshold?
- Is the performance deficiency associated with one of the cornerstone attributes listed at the end of this attachment and did the performance deficiency adversely affect the associated cornerstone objective?

If the response to any of these questions is 'yes', that would indicate the violation is more than minor.

(b) 'Non-Cited Violations (NCV)' – An NCV would be the lowest level of formal notification of a violation but would not require a written response from a licensee. Rather, the expectation is that the licensee would put the issue into their corrective action programme, if they have one. An NCV might be considered when the issue is identified by the licensee instead of the regulator. This low level of enforcement action would encourage licensees to identify and correct their own deficiencies before the regulator finds them. Other factors in determining if an NCV is appropriate is whether or not the violation is repetitive, or if it was wilful.

(c) 'Notice of Violation (NOV)' – An NOV represents an escalation in the level of enforcement. An NOV is a formal notification of a violation that often will require a formal response from the licensee on how they plan to correct the violation. The same factors used in determining if an NCV is appropriate will impact the decision to issue an NOV. If the violation is identified by the regulator, if the licensee failed to correct a previously identified violation within a reasonable period of time, if it is a repetitive violation, or if it was committed wilfully would all be factors to consider when concluding that an NOV is the appropriate enforcement action.

(d) 'Civil penalty' – A civil penalty is a monetary penalty that the regulator may consider imposing for significant violations. The amount of the penalty takes into account the gravity of the violation as the primary consideration and the ability to pay as a secondary consideration. Thus, operations involving greater nuclear material inventories, significantly higher consequences resulting from a release or exposure to radioactive material and consequences to the public and workers receive higher civil penalties. In evaluating whether daily civil penalties are appropriate, the regulator should consider such factors as whether the violation resulted in actual consequences to public health and safety or to the common defence and security, the safety significance of the violation, whether the violation was repetitive because of inadequate corrective actions, the degree of management culpability in allowing the violation to continue or in not precluding it, the responsiveness of the licensee once the violation and its significance were identified and understood, whether the continuing violation was wilful, and the duration of the violation.

(e) 'Orders' – An Order is a written directive to modify, suspend, or revoke a licence; to cease and desist from a given practice or activity; or to take such other action as may be proper.

The following figure depicts the NRC process for determining whether or not to issue escalated enforcement for a very low safety significance violation or non-compliance (i.e. green, or severity level (SL) IV) at a nuclear facility that has an approved corrective action programme (CAP). This is generally applicable to operating nuclear power plants, since these are the only facilities required to have an approved CAP. A non-cited violation (NCV) is characterized as non-escalated enforcement. Factors that will impact the decision on whether or not to escalate the enforcement action are displayed in the figure. An NCV requires only that the licensee enter the issue into their CAP, and does not require a formal response from the licensee. A Notice of Violation is considered escalated enforcement, and normally requires a formal response from the licensee acknowledging the violation, and describing their plans for bringing the plant back into compliance. The 'D' represents enforcement discretion, which provides the regulator with the option to increase or reduce the expected enforcement action based on the merits of the issue.

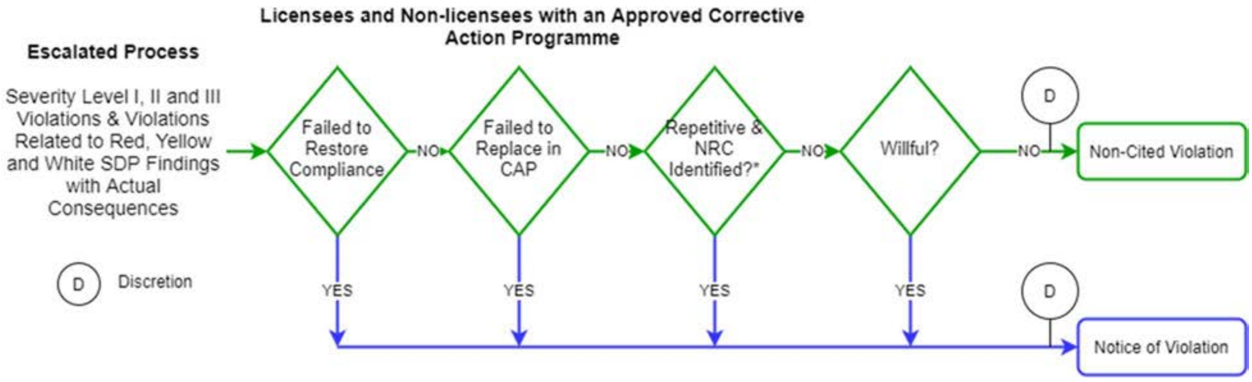

FIG.V-3. Enforcement Evaluation – Severity IV Violations and Violations Related to Green SDP Findings – Facilities With An Approved Corrective Action Programme (From [V-9])

The following figure describes the methodology for determining the appropriate enforcement action for very low safety-significant violations or non-compliances at facilities that do not have approved CAPs, i.e. research and test reactors, and fuel cycle facilities.

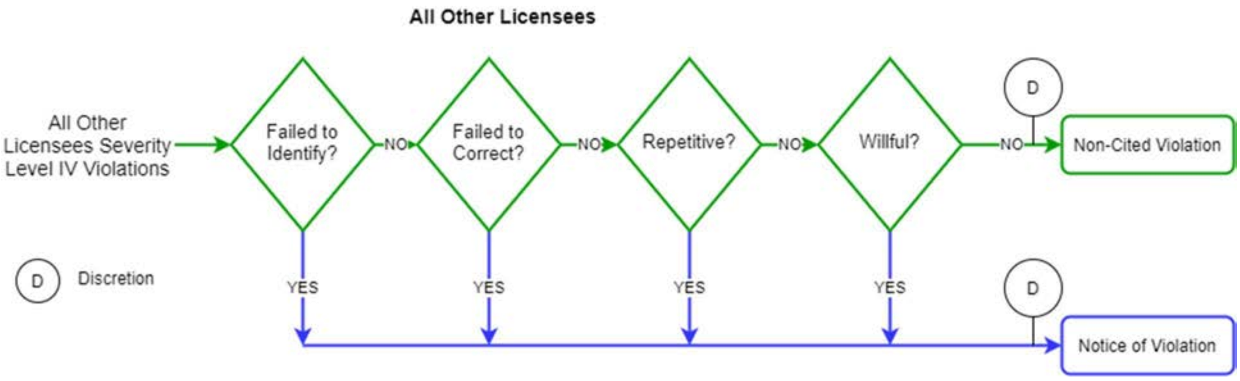

FIG. V-4. Enforcement Evaluation – All Other Licensees Severity Level IV Violations (from [V-9])

The following figure describes the NRC process for determining appropriate escalated enforcement actions for violations that are considered safety-significant (i.e. Red, Yellow, or White finding, or SL I, II, or III violations). The options involve issuing a Notice of Violation with or without a civil penalty, and if issuing a civil penalty, what the appropriate amount of the penalty ought to be.

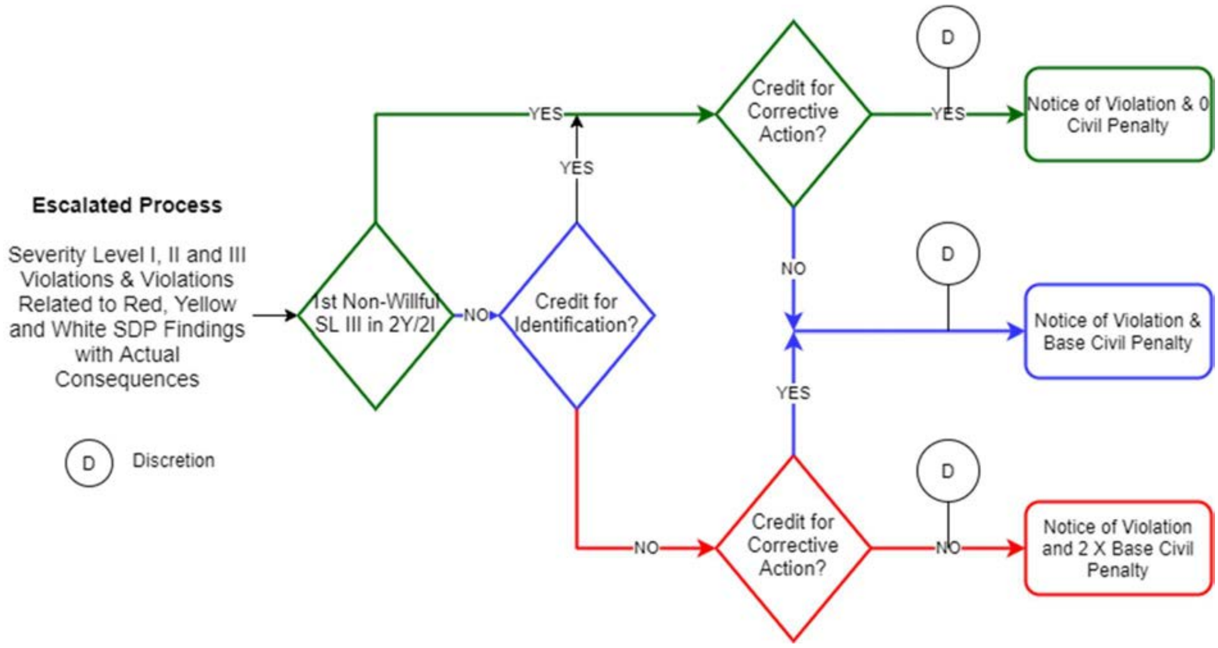

FIG.V-5. Escalated Progress – Violations considered Safety Significant (from [V-9])

The civil penalty assessment process considers four decision points. Although each of these decision points may have several associated considerations for any given case, the outcome of the assessment process for each violation or problem, absent the exercise of discretion, is limited to one of the following three results: no civil penalty, a base civil penalty, or a base civil penalty escalated by 100 percent. The four decision points are the following:

(a) Did the licensee have any previous escalated enforcement action (regardless of the activity area) within the past 2 years of the inspection at issue, or the period between the last two inspections, whichever is longer?

(b) Should the licensee be given credit for actions related to identification of the violation? A regulator should encourage licensees to promptly identify violations of requirements. While the decision regarding credit for identification can become complicated, the overarching consideration is whether the regulator should give credit for a licensee's efforts to identify the violation.

(c) Were the licensee's corrective actions prompt and comprehensive? The purpose of the corrective action factor is to encourage licensees to (1) take the immediate actions necessary upon discovery of a violation that will restore safety, security, and compliance with the licence, regulation(s), or other requirement(s) and (2) develop and implement (in a timely manner) the lasting actions that will not only prevent recurrence of the violation at issue, but will be appropriately comprehensive, given the significance and complexity of the violation, to prevent occurrence of violations with similar root causes.

In view of the circumstances of the violation, should the regulator exercise enforcement discretion to either escalate or reduce the amount of the civil penalty? Enforcement Discretion may be exercised by either escalating or reducing the amount of the civil penalty determined after applying the civil penalty adjustment factors to ensure that the proposed civil penalty reflects all relevant circumstances of the particular case.

REFERENCES TO ANNEX V

[V-1] CANADA MINISTRY OF JUSTICE, Nuclear Safety and Control Act (S.C. 1997, c.9), Nuclear Safety and Control Act, Ministry of Justice, Ottawa (1997).

[V-2] CANADIAN NUCLEAR SAFETY COMMISSION, General Nuclear Safety and Control Regulations, SOR/2000-202, Ministry of Justice, Ottawa (2000).

[V-3] CANADIAN NUCLEAR SAFETY COMMISSION, Making, Reviewing and Receiving Orders under the Nuclear Safety and Control Act, G-273, CNSC, Ottawa (2003).

[V-4] CANADIAN STANDARDS ASSOCIATION, Risk management - Risk Assessment Techniques, CAN/CSA-IEC/ISO 31010-10, CSA, Toronto (2010).

[V-5] CANADIAN NUCLEAR SAFETY COMMISSION, Administrative Monetary Penalties Regulations, SOR/2013-139, CNSC, Ottawa (2013).

[V-6] OFFICE FOR NUCLEAR REGULATION, Enforcement, ONR-ENF-GD-006 Revision 2, ONR, Bootle (2019).

[V-7] OFFICE FOR NUCLEAR REGULATION, Resolving differences of professional opinion in ONR, NS-INSP-IN-002 (Rev 5), ONR, Bootle (2019).

[V-8] U.S. NUCLEAR REGULATORY COMMISSION, Significance Determination Process, Inspection Manual Chapter 0609, US NRC, Washington, DC (2018).

[V-9] U.S. NUCLEAR REGULATORY COMMISSION, Enforcement Manual, Revision 11, US NRC, Washington, DC (2019).

ANNEX VI.

PRACTICAL EXAMPLES OF MEMBER STATES ON THE USE OF A GRADED APPROACH IN CORE REGULATORY FUNCTIONS: COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

This annex collects practical examples from Member States of the use of a graded approach in different aspects of communication and consultation with interested parties. These contributions were developed by the contributing Member States based upon their own experience and describe how the general three-step methodology described in Sections 3.2 and 4.6 can be used.

This annex provides examples covering a wide range of possible applications of a graded approach. However, it is not comprehensive and additional applications, not covered herein, could also be envisaged by Member States.

VI-1. GRADED APPROACH FOR COMMUNICATION - INDIGENOUS CONSULTATION PROCESS IN CANADA

This example illustrates Canada's approach for Indigenous consultation.

— **Step 1: Determine the level of engagement with Indigenous peoples for projects involving nuclear facilities**

In Canada, the Crown's unique relationship with Indigenous peoples gives rise to the duty to consult, and where appropriate accommodate Indigenous peoples when the Crown contemplates conduct that might adversely impact potential or established Indigenous and/or treaty rights. As an agent of the Crown, the CNSC has responsibility for fulfilling its legal duty to consult, and where appropriate accommodate Indigenous peoples when its decisions may have an adverse impact on potential or established Indigenous and/or treaty rights.

The common law duty to consult, and where appropriate accommodate is raised when the following three factors are present:

- contemplated Crown conduct
- potential adverse impact caused by the Crown conduct (e.g. decision by the Commission)
- potential or established Indigenous and/or treaty rights

— **Step 2: Identify the factors used to determine the level of engagement**

The CNSC's Indigenous consultation process applies a graded approach to determine the appropriate level and scope of consultation activity (ies) for proposed licensed activities. Upon receipt of a licence application, an initial assessment is conducted to determine if the potential to trigger the legal duty to consult Indigenous peoples exists.

This initial assessment regarding the Duty to Consult is based on research, analysis and consideration of, including but not limited to, the following factors:

- historic or modern treaties in the region of the regulated facility
- potential impacts to the health and safety of the public, the environment and any potential or established Indigenous and/or treaty rights and related interests

- proximity of the regulated facility to Indigenous communities
- existing relationships between Indigenous groups and licensees or the CNSC
- traditional territories
- traditional and current use of lands
- settled or ongoing land claims
- settled or ongoing litigation related to a potentially impacted group
- membership in a broader Indigenous collective or tribal council or Indigenous umbrella group

The following questions can be used in determining if Indigenous consultation is appropriate and – if so – with whom and to what extent.

(a) Identifying potential adverse impacts

(1) Does the activity described in the licence application have likely or potential impacts on land, water and resources? Are these changes significant? What is the spatial extent of the potential impacts? Are there potential impacts beyond the immediate footprint of the regulated facility?
(2) Are there any Indigenous groups that claim traditional territory that encompasses the location of the regulated facility?
(3) Are there any First Nations reserve lands, treaty lands, or Indigenous communities located near the regulated facility?
(4) Does the activity described in the licence application involve lands or resources that are currently the subject of land claim negotiations or are part of existing comprehensive land claim agreements or self-government agreements?
(5) Have any environmental or other assessments of the regulated facility been carried out? Have any environmental or other assessments been undertaken for similar activities in the vicinity of the regulated facility? If so, what adverse impacts on rights and/or related interests are revealed, if any, by these assessments?

(b) Assessing the significance of potential adverse impacts

(1) Certainty of adverse impacts – what is the likelihood that the impact will occur?
(2) Magnitude of the adverse impacts – what is the nature and degree of the impact?
(3) Duration and frequency of the adverse impacts – are the potential adverse impacts that have been identified likely to be of a temporary or permanent nature? How often will the impact occur?
(4) Reversibility – is the adverse impact reversible?
(5) Spatial extent of the adverse impacts – will these be localized in nature or broader? How does the geographic extent of the adverse impact relate to the geographic extent of the right, as practiced?

(c) Additional considerations

(1) Are you aware of the nature and scope of any asserted rights and/or related interests in the area?
(2) Has the Indigenous group continually occupied the area near the regulated facility?
(3) Does the group still occupy the area? If the Indigenous group does not still occupy the area, at what period of time did they occupy it?
(4) Are there historical and/or current traditional Indigenous practices occurring in the area?
(5) What is the Indigenous perspective on the importance, uniqueness, or value of a particular use, area, activity or species?

(6) What is the Indigenous group's capacity to participate in consultation activities? (capacity can include time, financial resources, technical expertise, technology, etc.)
(7) Is the Indigenous group asserting that the claimed Indigenous rights were exercised prior to European contact (or for the Métis, prior to effective control)? Do they continue to exercise these rights today in a traditional or modernized form? What impacts to an Indigenous group's rights have occurred in the past?
(8) Are you aware of any communication from Indigenous groups who are raising concerns about the regulated facility, similar facilities, or similar adverse effects in the area?
(9) Are you aware of any past grievances or issues that an Indigenous group may have with industry or government? How were these grievances addressed?
(10) Have any Indigenous groups expressed concerns about the activity described in the licence application and suggested any remedial measures that may accommodate the adverse impacts on their rights and/or related interests?
(11) Could the status of land claims and self-government agreements have implications with respect to the activity described in the licence application? Does this Indigenous group have a sovereign government?
(12) Are there any cultural activities or events that may prevent many community members from participating in engagement activities?
(13) Does the Indigenous group have its own consultation protocol? Licensees and the CNSC may want to consider whether consultation agreements with Indigenous groups could support consultation activities. These arrangements can help to define roles and responsibilities, identify points of contact, determine timelines and steps to be followed, and sometimes address capacity needs.
(14) Has the Indigenous group been involved in recent litigation or have judgments been rendered that clarify rights of the Indigenous group?
(15) Is the Indigenous group involved in the negotiation for treaty land entitlements?
(16) Is the Indigenous group currently involved in any other consultations with industry or government?

The result of the initial assessment will determine whether formal consultation is required, and, if so, the appropriate level of consultation activity. The consultation matrix, Table VI-1 provides additional details on criteria used in the assessment.

— **Step 3: Perform the integrated assessment in view of the factors**

Table VI-2 provides information for four hypothetical indigenous communities and illustrates how the criteria above and the Consultation matrix are used to determine the level of engagement.

TABLE VI-1. CONSULTATION MATRIX*

Potential Impact of Decisions or Actions regarding a proposed project on potential or established Indigenous and Treaty Rights and Traditional Uses	Considerations regarding inclusion or exclusion	Level of Engagement	Notification and Follow-up
No impact on rights	• Administrative changes proposed to a licence • Minor operating procedure change which will not impact the environment and/or potential rights.	None	No notification is required beyond what is typically provided to the public or required by legislation.
Unlikely or unknown impacts - more information required (Based on information in application or project description, adverse impacts to rights unlikely but more information warranted or for other reasons, written notification warranted.)	• Potential or established rights exist in the vicinity of the projects • Project within vicinity of known traditional territory • Project distance to reserve or Indigenous community • Specific claims – ongoing or settled (e.g. rights, land) within project area • Litigation (ongoing or settled) – explain • Previous CNSC activities initiated with Indigenous groups • Previous provincial /territorial/municipal activities with Indigenous groups • Other – explain rationale	Good governance	Written notification of project and decision-making process is provided. Follow-up calls to ensure receipt of information. If interest shown, continue to share project information.
May cause minor impact on rights.	• Low potential to cause adverse impacts to potential or established Indigenous or treaty rights	Low	Written notification of project and decision-making process is provided. Follow-up calls to ensure receipt of information. If interest shown, continue to share project information.

TABLE VI-1. CONSULTATION MATRIX* (cont.)

Potential Impact of Decisions or Actions regarding a proposed project on potential or established Indigenous and Treaty Rights and Traditional Uses	Considerations regarding inclusion or exclusion	Level of Engagement	Notification and Follow-up
Short-term disturbance with potential to cause a significant impact on rights OR Long-term disturbance with potential to cause a minor impact on rights	• Potential to cause adverse affects to potential or established Indigenous or treaty rights • Likelihood of adverse impacts to the environment	Medium	Written notification of project and decision-making process is provided and seek input from identified Indigenous groups. Follow-up calls to ensure receipt of information. May propose meetings or meet with Indigenous group(s) upon request. Follow-up consultations may be required.
May cause a potentially significant impact on rights	• Likely adverse impacts to potential or established Indigenous or treaty rights • High likelihood of significant adverse impacts to the environment	High	Written notification of project and decision-making process is provided and seek input from identified Indigenous groups. Follow-up calls to ensure receipt of information. Offer to meet with Indigenous group(s) to discuss project and seek input. Follow-up consultations likely required.

*See CNSC REGDOC 3.2.2: Indigenous engagement [VI-1] for more information on the CNSC's approach to Indigenous consultation and expectations for CNSC proponents and licensee

TABLE VI-2. DETERMINATION OF LEVEL OF ENGAGEMENT WITH INDIGENOUS COMMUNITIES

Indigenous Groups	Preliminary Level of Consultation	Rationale
A This group consists of descendants of several historic communities that are in the vicinity of the project. There is an ongoing comprehensive land claim.	Medium	**Assessment of Potential Rights Impacts**: • Potential or established rights exist in the vicinity of the project. The project is located with the land claim boundary. • On-going Comprehensive Land Claim negotiations which once concluded will provide clarity around rights and interest in the area and will form a modern treaty • Title claim to territory • Project within vicinity of known traditional territory • Litigation (ongoing or settled) • There is a low likelihood of impacts on potential or established rights as the facility is located in a restricted fenced in site • Construction of the facility could potentially adversely impact the surrounding environment • The proposed facility is a long-term facility (over 50 years) located within the asserted traditional territory of a number of Indigenous groups **Consideration of Other Factors**: • Requests from Indigenous groups • Type of CNSC regulatory decision making process (public hearing)
B This group consists of several communities that are in the vicinity of the project. This group has submitted a statement regarding the assertion of their rights in their ancestral territory.	Medium	**Assessment of Potential Rights Impacts**: • Represents First Nations with potential or established rights exist in the vicinity of the project • Have asserted title to territory • On-going negotiations regarding land claim. Project is located within the claim area. • Project within vicinity of known traditional territory • There is a low likelihood of impacts on potential or established rights as the facility is located in a restricted fenced in site • Construction of the facility could potentially adversely impact the surrounding environment • The proposed facility is a long-term facility (over 50 years) located within the asserted traditional territory of a number of Indigenous groups **Consideration of Other Factors**: • Requests from Indigenous groups • Type of CNSC regulatory decision making process (public hearing)

TABLE VI-2. DETERMINATION OF LEVEL OF ENGAGEMENT WITH INDIGENOUS COMMUNITIES (cont.)

Indigenous Groups	Preliminary Level of Consultation	Rationale
C The group has an established treaty with the Crown. The proposed project is in the geographic area of the group. The project is located a far distance from the lands where group members live and typically exercise their rights.	Low	**Assessment of Potential Rights Impacts**: • Project within vicinity of known treaty and traditional territory • Reserve lands are located a far distance from project site • There is a low likelihood of impacts on potential or established rights as the facility is located in a restricted fenced in site • Construction of the facility could potentially adversely impact the surrounding environment • The proposed facility is a long-term facility (over 50 years) located within the asserted traditional territory of a number of Indigenous groups **Consideration of Other Factors:** • Requests from Indigenous groups • Type of CNSC regulatory decision making process (public hearing)
D This group is a political forum for collective decision-making, action, and advocacy for First nations and is not a rights bearing Indigenous community.	Good Governance	**Assessment of Potential Rights Impacts:** • Umbrella organization **Consideration of Other Factors:** • Requests from Indigenous groups • Type of CNSC regulatory decision making process (public hearing)

VI-2. GRADED APPROACH FOR COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES IN CANADA – DETERMINATION OF PUBLIC INVOLVEMENT FOR A LICENSING DECISION

This example illustrates Canada's approach for the determination of the type of Commission Hearing (which impact on public involvement) for a licensing decision by the Commission. In application of a graded approach to the core regulatory function of communication and consultation with interested parties (see Section 4.6), the Commission carries out licensing decisions for all higher-risk nuclear facilities [VI-2], specifically Class I nuclear facilities [VI-3] and uranium mines and mills [VI-4]. Lower-risk licensing decisions – such as nuclear substance, radiation device or import/export licensing – are carried out by CNSC Designated Officers.

— **Step 1: Determine the type of public hearing by which the licensing decision should be made.**

All licensing decisions by the Commission upon application by an applicant / licensee need to be carried out through a public hearing. Canada's Nuclear Safety and Control Act (NSCA) [VI-2] also allows for persons who have an interest in the matter being heard, expertise in the matter or information that may be useful to the Commission in coming to a decision to intervene in the hearing. At the same time that the hearing type is being determined, a graded approach is used to determine whether the Commission will accept interventions in its consideration of a matter and, if interventions are accepted, whether the Commission will allow written submissions only, or written submissions and an oral presentation [VI-5]. A graded approach is also used to determine whether the hearing will be held in the host community of the nuclear project or at CNSC Headquarters in Ottawa, Ontario.

The main consideration for this step is to determine how the Commission can best consider the matter before it as fairly, expeditiously and informally as possible.

The CNSC's public hearings can be divided into three main types of proceedings:

(a) 'Public hearing based on written submissions': During a public hearing based on written submissions, the Commission considers a written submission from the applicant, CNSC staff and, if permitted, written interventions.
(b) 'One-part public hearing': All of the evidence from the applicant, CNSC staff and intervenors (if applicable) is heard by the Commission in a single proceeding. The proceeding could take place on a single day or over several days. All interventions, written and oral (if permitted), are also considered by the Commission during this proceeding.
(c) 'Two-part public hearing': During Part 1 of a two-part public hearing, the Commission hears submissions from the applicant and then from CNSC staff. During Part 2, which is at least 60 days after Part 1, the applicant and CNSC give a brief overview of what was presented in Part 1, along with supplementary information, as required. The Commission then considers the written and oral (if permitted) interventions.

—Step 2: Identify the factors that may be used to determine the type of CNSC public hearing for the fair, informal and expeditious consideration of the matter before the Commission.

REGDOC-3.4.1, Guide for Applicants and Intervenors Writing CNSC Commission Member Documents [VI-6], provides factors that the Commission may use in determining the hearing type and also the location of the hearing. These same factors may also be used by the Commission to determine whether it will allow for interventions to be submitted and whether these will be permitted and whether these will be permitted only through written submissions, or by written submissions and/or oral presentations. The factors include:

(a) the level of public interest that may be generated by the application. This includes considerations such as

(1) whether the public is showing interest in or has previously shown an interest in the matter, or whether the matter presents the potential for controversy
(2) the level of controversy that may be generated by the matter (i.e. region, interested community, Indigenous rights issues)
(3) whether the hearing should be held in the community

(b) the nature of the application, i.e. licence issuance, amendment or renewal

(1) whether the application represents an administrative or a more substantive or technical request
(2) whether the licensing action authorizes any new or different licensed activities
(3) whether the application is proposing the use of new or unproven technology
(4) the effect that the matter may have on the function of safety-related systems

(c) whether the matter was previously examined in the context of other licensing proceedings and/or environmental assessments conducted by the Commission

(d) whether the matter requires an expeditious and efficient disposition of the matter

One-part hearings generally deal with less complex matters or those of a limited public interest, including lower-risk nuclear facilities including fuel fabrication and nuclear substance processing facilities.

Two-part public hearings are typically held for to consider complex, more significant licensing activities such as the licence issuance or renewal for major facilities, such as nuclear power plants or uranium mines and mills.

TABLE VI-3. HEARING TYPE DECISION-MAKING MATRIX

Potential Impact of Licensing Decision	Considerations Regarding Type of Hearing	Interventions to be Considered
Low interest, low impact	• Administrative changes proposed to a licence such as a change in corporate entity • Minor operating procedure change which will not have any adverse impacts the environment and/or the health, safety and security of persons • Change in licence condition that does not have an impact on operations • A matter that may need to be dealt with in an expeditious manner • Does not need to be held in the community that is home to the facility	None
Medium interest, low impact	• Minor change in operations • Project within vicinity of known Indigenous traditional territory, reserve or community • Change in technology that has low impact • The local community and/or other stakeholders have previously shown or are showing an interest in the matter • Does not need to be held in community • Low risk of adverse impact to the environment and/or the health, safety and security of persons • A matter that may need to be dealt with in an expeditious manner	Written interventions only
Low interest, medium impact	• Minor changes in operations • Project within vicinity of known Indigenous traditional territory, reserve or community • Change in technology that could have a low-to-medium impact • The local community and/or other stakeholders have previously shown or are showing an interest in the matter • Low level of controversy anticipated to be generated by the matter • Low risk of adverse impact to the environment and/or the health, safety and security of persons • Does not need to be held in community	Written and/or oral interventions
Medium interest, medium impact	• Change in operations, licence conditions, authorizations • Project in vicinity of or on known Indigenous traditional territory, reserve or community • The local community and/or other stakeholders have previously shown or are showing a moderate level of interest in the matter • May need to be held in the community, depending on interest • Medium level of controversy that may be generated by the matter • Change in technology or operations that could have a medium-level impact on safety-significant systems • Potential for impacts on the environment and persons	Written and/or oral interventions

TABLE VI-3. HEARING TYPE DECISION-MAKING MATRIX (cont.)

Potential Impact of Licensing Decision	Considerations Regarding Type of Hearing	Interventions to be Considered
Medium interest, high impact	• Project in vicinity of or in known Indigenous traditional territory, reserve or community • Potential for impacts on the environment and persons • The local community and/or other stakeholders have previously shown or are showing a moderate level of interest in the matter • May need to be held in the community, depending on interest • Medium level of controversy that may be generated by the matter • Major in technology or operations that could have a high-level impact on safety-significant systems	Written and/or oral interventions
High interest, medium impact	• Project in vicinity of or on known Indigenous traditional territory, reserve or community • High level of interest from local community and/or stakeholders • High level of controversy that may be generated by the matter • Should be held in the community • Potential for impact on environment and persons • Major licensing request (i.e. issuance or renewal) for medium-risk nuclear facility such as a nuclear fuel fabrication facility or nuclear substance processing facility • Application for new facility or novel / unproven technology	Written and/or oral interventions
High interest, high impact	• Project in vicinity of or on known Indigenous traditional territory, reserve or community • High level of interest from local community and/or stakeholders • Higher level of potential for impact on the environment and persons • Major licensing action for a nuclear power plant or uranium mine and mill • Should be held in the community • High level of controversy that may be generated by the matter • Application for new facility or novel / unproven technology	Written and/or oral interventions

— **Step 3: Perform the integrated assessment for the type of hearing to be carried out in view of the factors.**

The table below provides information for seven hypothetical licensing matters and illustrates how the criteria above and hearing type decision-making matrix are used to determine the type of CNSC public hearing for the fair, informal and expeditious consideration of the matter before the Commission.

TABLE VI-4. ASSESSMENT FOR HEARING TYPE USING DECISION-MAKING MATRIX

Licensing Matter	Type of Hearing and Interventions	Assessment of Considerations
Hearing A Low interest, low impact An administrative licence amendment involving a corporate name change and no change to operations.	Public hearing in writing, no interventions permitted	• Administrative changes proposed to a licence • No change to operations and no adverse impacts on the environment and/or the health, safety and security of persons • A matter that should be dealt with in an expeditious manner • No impacts on the public identified and matter was not likely to generate any controversy
Hearing B Medium interest, low impact A one-year licence renewal with no change in licensed activities/operations to allow the licensee additional time to put forth a completed application for a more comprehensive licence renewal	Public hearing in writing, written interventions permitted. Initially interventions were not permitted. However, the public submitted concerns and comments about the application and, as such, the Commission decided to permit written interventions, with four requests to intervene filed.	• No change in operations • Project on known Indigenous traditional territory, reserve or community • Though a licence renewal for a Class IB facility, no active operations on the facility and full hearing would be held after the one-year renewal • The local community and other stakeholders have previously shown and are showing an interest in the matter • No change to operations • No anticipated adverse impacts on the environment and/or the health, safety and security of persons • No controversy or low level of controversy expected
Hearing C Low interest, medium impact Licence renewal for a Class IB facility which processes and stores nuclear substances, and constructs and operates cyclotrons	One-part public hearing, carried out over one day, allowed written and oral interventions, in the community, no requests to intervene filed.	• Facility located in Ottawa • Project within vicinity of known Indigenous traditional territory, reserve or community • The local community and/or other stakeholders have previously shown low interest in the matter • Low level of controversy anticipated to be generated by the matter • Low risk of adverse impact to the environment and/or the health, safety and security of persons • Class IB facility near a residential area • Although oral and written interventions were permitted, no interventions received (default to allow written and oral interventions for Class I facilities and uranium mines and mills.
Hearing D Medium interest, medium impact Licence renewal for decommissioned uranium mine and mill in northern Saskatchewan	One-part public hearing, carried out over one day, allowed written and oral interventions, held in Ottawa even though the affected community is ~3,700 km away in northern Saskatchewan, 12 requests to intervene filed.	• Change in operations and authorizations that has an impact on licensed area • Licence renewal for uranium mine and mill • Project on known Indigenous traditional territory, reserve or community • The local community and/or other stakeholders have previously shown or are showing interest in the matter • Medium level of controversy that may be generated by the matter • Held in Ottawa; suggested by intervenors that, due to interest, should be held in community • Very little activity occurring at the site; active decommissioning had been completed

TABLE VI-4. ASSESSMENT FOR HEARING TYPE USING DECISION-MAKING MATRIX (cont.)

Licensing Matter	Type of Hearing and Interventions	Assessment of Considerations
Hearing E High interest, medium impact Licence renewal for a research and testing site including both Class I and Class II facilities, as well as waste management facilities.	One-part public hearing, written and oral interventions permitted, carried out over three days, held in the community, with 88 requests to intervene filed.	• Site includes nuclear waste management facility and research reactor Project in vicinity of or on known Indigenous traditional territory or community • High level of interest from local community and/or stakeholders • High level of controversy that may be generated by the matter; should be held in the community • Low potential for impact on environment and persons • Major licensing request (i.e. issuance or renewal) for medium-risk nuclear facility
Hearing F Medium interest, high impact Licence renewal for a nuclear waste management facility proposed to store all of the licensee's used fuel until a permanent storage location is determined.	One-part public hearing, written and oral interventions permitted, carried out over one day in Ottawa, with 12 requests to intervene filed.	• Class IB waste management site for used fuel waste, as well as intermediate-level waste. • The licensee proposed the construction of additional fuel processing and storage facilities at the site. • Medium level of interest from local community and/or stakeholders; medium level of controversy was expected • High potential for impact on the environment and persons • Project in vicinity of known Indigenous traditional territory, reserve or community
Hearing G High interest, high impact Licence renewal for eight-unit (six units operating, two units in safe storage) nuclear power plant near major city.	Two-part public hearing, written and/or oral interventions permitted, Part 1 held in Ottawa (one day), Part 2 held in the community (4 days), with 155 requests to intervene filed.	• Licence renewal for a nuclear power plant • High level of interest from local community and/or stakeholders; should be held in the community • High level of potential for impact on the environment and persons • High level of controversy that may be generated by the matter • Project in vicinity of known Indigenous traditional territory, reserve or community

VI-3. GRADED APPROACH FOR COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES IN THE UNITED KINGDOM – PRIORITIZING INTERNATIONAL ENGAGEMENT

In 2019, ONR published for the first time a Strategic Framework for International Engagement [VI-7]. This framework sets out the priority objectives and criteria for ONR's international engagement to 2025 to support our organizational strategy for 2020-2025. It defines the over-arching governance structure for agreed priority international engagements and criteria for considering requests to participate in international fora and events over and above those identified as priority engagement. The Framework is a living document that will be reviewed annually to reflect the evolving international and political context and ONR's changing priorities.

— **Step 1: Characterize international engagement activities**

The first exercise undertaken was to characterize the full extent of international activity undertaken by inspectors across the international arena, involving several hundred individual activities each year across a range of multilateral and bilateral fora. The principle areas of international engagement are set out in the diagram below:

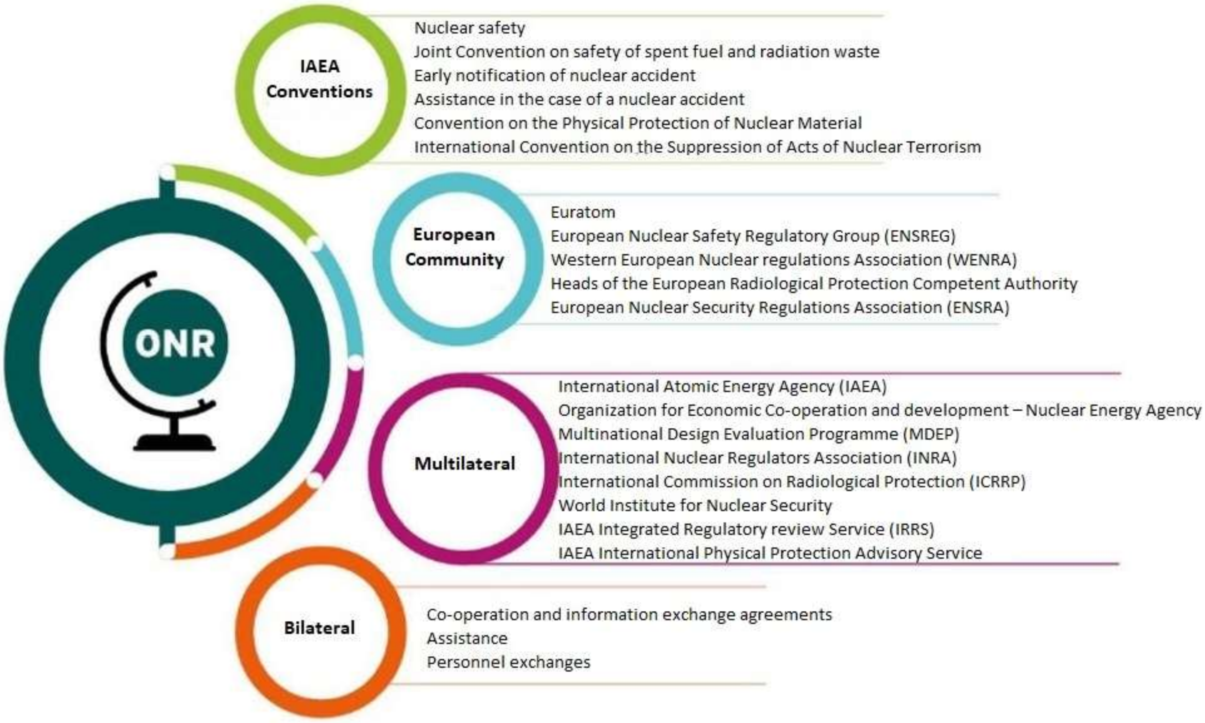

FIG. VI-1. ONR's international footprint

— **Step 2: Determine which factors are applicable in the prioritization activity**

In developing this strategy, ONR identified four strategic objectives and associated priorities against which international engagement would be prioritized:

(a) Objective 1 – To influence the development of international standards, guidance and relevant good practice to ensure they are fit of purpose to achieve UK regulatory objectives and support high levels of safety and security across the globe through our own learning and sharing our expertise.

(b) Objective 2 - To promote international openness and transparency in nuclear regulation by actively sharing UK regulatory knowledge and experience and engaging in peer review activities.

(c) Objective 3 - To promote continuous professional development and organizational learning in ONR and other sovereign regulators by sharing expertise in nuclear safety, security, safeguards and radioactive waste management regulation.

(d) Objective 4 - To draw from our reputation as a world class regulator by actively seeking opportunities to learn from other nations and so improve our own performance.

To introduce consistency and proportionality into business planning, all ONR's international engagements were prioritized against 'engagement categories:

(a) Category A – Agreed priority engagements that support and fulfil international treaty and convention obligations or directly influence development of international standards and guidance;

(b) Category B – Agreed priority engagements judged to demonstrably support and align to at least one of ONR's strategic themes;

(c) Category C – Agreed international engagements undertaken to maintain visibility, provide knowledge transfer, secure professional development or necessary to support routine regulatory business and specific to a Directorate.

—**Step 3: Integrate the applicable factors into the decision-making process.**

Once the international engagements are appropriately categorized, the level of business justification required for each category is graded accordingly. ONR's strategic framework constitutes a 'de-facto' business justification for Category A and B international activities. This streamlines the effort and governance required for international activity.

Category C activities are only undertaken if there is a compelling business need, and demand more explicit 'ad-hoc' business justification. This enables ONR to be more selective over which activities are supported at this level, which are predominantly elective in nature.

An internal International Steering Group (ISG) will provides corporate oversight of and governance for this strategic framework. The purpose of the ISG is to provide the appropriate mechanism for corporate oversight and governance of the framework to ensure alignment across our international activities. The key objectives of the ISG are to:

(a) ensure the totality of ONR's international engagement is well-planned, prioritized and aligned to this Framework; and use this information to monitor to what extent the strategy objectives are met/achieved and provide advice on where objectives may need to change;

(b) act in an advisory capacity on international business priorities informed by an analysis of ONR's international travel pattern.

VI-4. GRADED APPROACH FOR COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES IN THE US

The U.S. NRC uses a graded approach when communicating with stakeholders regarding licensee performance. The ROP Action Matrix (Table IV-17) discussed in Inspection Manual Chapter 0305, 'Operating Reactor Assessment Programme' [VI-8], describes the level of regulator management involvement for communication activities (public meetings, assessment letters) for varying levels of licensee operating performance. As licensee performance declines as evidenced by moving right in the Action Matrix, there is an increased level of NRC management involvement.

—**Step 1: Identify Stakeholder Involvement**

The NRC holds annual public meetings for all reactor licensees to discuss performance. The licensee will be invited, as will the general public. Oftentimes a local press release will announce the meeting specifics so interested members of the public can plan to attend. The

NRC uses this opportunity to engage interested stakeholders on the performance of the plant and the role of the NRC in ensuring safe plant operations.

The licensee management is always invited to the annual public meeting, since the meeting is being held to discuss their operating performance for the previous year. Where public interest is high, often the media will participate to monitor and report on the meeting.

— Step 2: Determine which factors are applicable

Stakeholder (public) interest is the primary factor used in determining the type of public meeting. Where public interest is high, there may be activist groups attending, and they will want to engage the NRC representatives directly.

Perceived safety significance is the other most important factor. The public may equate significant events, scrams, and inspection findings with declining safety performance of the licensee, and that will like result in increased public interest.

Timeliness is the other important factor when communicating with the public when there is a significant operational event at a nuclear power plant. The public will want timely reassurance that their health and safety has not been compromised by the event. It is also an important factor for licensees who have demonstrated declining performance during the previous year.

— Step 3: Integrate the applicable factors into the decision-making process.

(a) Licensee Performance Meetings

Licensee performance is another area for which there is often a high degree of local public interest, local government interest, and interest from activist groups. A graded approach to communicating with stakeholders regarding licensee performance could be implemented for regulator management engagement, as well as levels of external stakeholders to be notified. For instance, if the regulator holds an annual public meeting to discuss the licensee's performance, the regulator might send a lower level manager to participate in the meeting for a licensee that is assessed to be performing well. As licensee performance declines, more senior management participation would communicate the regulator's concern to the public, and to the licensee. In addition, if performance at an operating nuclear power plant declines, there may also be more interest from external stakeholders, with an expectation to notify local, regional, or national government entities, depending on the plant performance level.

There are many different types of public meetings to consider. Public stakeholder involvement can be a formal public meeting, an informal open house, poster sessions, or virtual meetings held over the internet, depending on the historic level of public interest and level of licensee performance.

The NRC conducts an annual public meeting to discuss licensee operating performance for all operating nuclear power plants. A graded approach is used to determine the timing, type of meeting, and the level of management involvement. The level of management involvement is determined by the licensee position in the ROP Action Matrix.

For plants with significant performance issues that have been in Column 3, 4, or 5 of the Action Matrix, there is often more public interest, and timeliness of communication is important. For these licensees, involvement of the public in a meeting or some other appropriate venue should be scheduled within 16 weeks of the end of the assessment period. Public involvement should include a formal public meeting with the licensee if one has not already been held to close out the performance issues.

For plants that have been in Column 1 or 2 of the Action Matrix during the entire assessment period, timeliness becomes less of a factor, and public interest is usually lower. Therefore, NRC identifies the best opportunity for this engagement. Public stakeholder involvement can be a meeting tailored to the public, an open house for the public, poster sessions, virtual meetings, or other similar activities that allow the NRC to effectively engage public stakeholders. Participating in an event sponsored by another organization can be considered if such an event would maximize public engagement.

The region may decide whether the outreach activity should be conducted onsite or in the vicinity of the site. The outreach effort needs to be scheduled to ensure that it is accessible to members of the public. NRC may also adapt the activity in accordance with its the audience and the stakeholders. For example, a public assessment meeting may be scheduled with the licensee and a public event may be planned to discuss topics of local interest. In determining what type of event or forum to conduct, the regions should consider, among other things, plant performance, public interest in plant performance, any discussion the regions need to have with the licensee, and any other areas of public interest.

For plants with heightened stakeholder interest, media inquiry, or contentious issues, regions should consider sending an appropriate level of management needed to respond to stakeholder interest and effectively conduct the meeting.

(b) Significant Events

As discussed above, an accident at an operating nuclear power plant will result in the greatest public interest extending to the international community. Radioactive releases have the potential to contaminate large sections of land and impact a large population. Regulators ought to have a communications plan for all types of significant events at nuclear power plants.

For significant operational events, the regulator should consider developing some kind of event response and assessment communications plan, which should be implemented following a significant operational event or discovery of a significant degraded plant condition.

The communication plan for event response and assessment need to consider:

- a communications team;
- central tracking of controlled correspondence;
- formalized questions and answers (Q&A) for common and expected significant events; for use by Public Affairs staff during initial event response;
- a dedicated Web page for each event; and
- coordination with other government response agencies.

The communication plan for significant events at a nuclear power plant should include use of press releases, social media, news media, and the internet to ensure timely and accurate communication and periodic status updates for the greatest number of people. Specific communication activity assignments are determined by the communications team. Communication activities should consider the degree of public interest, and the perceived significance of the event. Events which have the highest potential for offsite radioactive releases should utilize the full range of communications tools. For events of lesser significance; (e.g. an event that involves an actual or a potentially substantial degradation of the level of safety of the plant with no potential for offsite radioactive releases), it may not be necessary to activate a communications team. However, the public affairs staff should communicate the safety significance to the public in a timely manner.

Follow-up inspections for significant events at operating reactors may also have high public interest based on communication activities associated with the event itself. If there is high public interest, consideration should be given to making the inspection exit meeting a public meeting. This promotes confidence that the regulator is providing appropriate oversight of licensee activities.

(c) Research and Test Reactors

The relative safety risk to the public from research and test reactors (RRs) is lower than that posed by operating nuclear power plants; therefore, public interest is likely to be lower, as well. Because of their low profiles and low impact in the local communities, their existence may not be widely known by the general public. However, there is a potential for a significant event to occur at an RR for which the public would expect to be notified. The communication plan discussed for significant events at operating nuclear power plants should also have guidance for communicating significant events at RRs. Because the public risk is lower, the communication plan should reflect the lower risk and lower expected public interest.

(d) Fuel Cycle Facilities

While fuel cycle facilities generally pose a lower safety risk to the public, there is often a greater public interest because of the economic impact the facilities have on their local communities. Fuel cycle facilities are somewhat unique in that in addition to the potential radiation hazards associated with working with nuclear fuels, there is a greater risk of industrial hazards (e.g. chemical hazards) which have the potential for offsite release affecting the public. The communication plan described for significant events at operating nuclear power plants should also contain provisions to communicate with stakeholders for significant events at fuel cycle facilities. The focus of communication efforts should be towards the local community, since that is where public interest will be greatest. Again, the communication effort should be commensurate with the perceived significance of the event.

If the regulator holds annual performance assessment public meetings with the licensee to discuss their operating performance, the use of a graded approach would be similar to that for performance assessment meetings at operating nuclear power plants. Consideration needs to be given to have more senior regulator management participate as licensee performance declines. This provides assurance to the public that the regulator is showing the appropriate level of attention for licensees demonstrating declining performance.

REFERENCES TO ANNEX VI

[VI-1] CANADIAN NUCLEAR SAFETY COMMISSION, Indigenous Consultation, REGDOC 3.2.2, CNSC, Ottawa (2016).

[VI-2] CANADA MINISTRY OF JUSTICE, Nuclear Safety and Control Act (S.C. 1997, c.9), Nuclear Safety and Control Act, Ministry of Justice, Ottawa (1997).

[VI-3] CANADIAN NUCELAR SAFETY COMMISSION, Class I Nuclear Facilities Regulations, SOR/2000-204, CNSC, Ottawa (2000).

[VI-4] CANADIAN NUCLEAR SAFETY COMMISSION, Uranium Mines and Mills Regulations, SOR/2000-206, CNSC, Ottawa (2000).

[VI-5] CANADIAN NUCLEAR SAFETY COMMISSION, Canadian Nuclear Safety Commission Rules of Procedure, SOR/2000-211, CNSC, Ottawa (2000).

[VI-6] CANADIAN NUCLEAR SAFETY COMMISSION, Guide for Applicants and Intervenors Writing CNSC Commission Member Documents, REGDOC-3.4.1, CNSC, Ottawa (2017).

[VI-7] OFFICE FOR NUCLEAR REGULATION, ONR Strategic Framework for International Engagement to 2025, ONR, Bootle (2019).

[VI-8] U.S. NUCLEAR REGULATORY COMMISSION, Operating Reactor Assessment Program, Inspection Manual Chapter 0305, US NRC, Washington, DC (2019).

ANNEX VII.

PRACTICAL EXAMPLES OF MEMBER STATES ON THE USE OF A GRADED APPROACH TO AN INTEGRATED REGULATORY PROGRAMME

This annex collects practical examples from Member States of the use of a graded approach in an integrated regulatory programme. These contributions were developed by the contributing Member States based upon their own experience and describe how the general three-step methodology described in Sections 3.2 and 4.7 can be used.

This annex provides examples covering a wide range of possible applications of a graded approach. However, it is not comprehensive and additional applications, not covered herein, could also be envisaged by Member States.

VII-1. OVERVIEW FOR APPLICATION OF GRADED APPROACH IN PRIORITIZING MULTIPLE REGULATORY ACTIVITIES IN PAKISTAN

VII-1.1. Introduction

PNRA regulates all facilities and activities involving ionizing radiations in the country. Sometimes, the situation arises that multiple regulatory activities have to be performed at the same time or these activities overlap each other for the same facility or different nuclear facilities. In such situation, PNRA considers various factors for decision making to prioritize these activities for their timely completion and without compromising on effectiveness of regulatory oversight processes. Such factors are described below:

- Regulatory Requirements;
- Complexity;
- Risk Associated with the Facility or Activity;
- Regulatory body resources;
- Performance of Licensee and Experience of Regulatory Body;
- Licensing of New Design;
- Urgency for need of a licensing action.

VII-1.2. Rationale of the applicable factors

Following were different factors considered for decision making regarding licensing of NPPs and review and assessment of documents submitted in this regard;

(a) Regulatory Requirements

Regulatory requirements are developed with inherent feature of graded approach at different licensing stages of different nuclear facilities. For example, comprehensive assessments are carried out before permitting licensee to introduce nuclear material in the reactor core for the first time (Fuel Load Permit (FLP)) whereas, issuance of operating licence involves only update of the documents submitted at FLP stage by incorporating the outcome of FLP review and results of the tests performed during commissioning of the plant.

(b) Complexity

Licensing of complex facilities or activities involve more rigorous safety verification process in comparison with the licensing of less complex facilities or activities. Generation III NPPs are more complex due to combination of active and passive design features as well as use of digital I&C systems that was not the case in earlier generation II design NPPs. PNRA also prioritized its competence development for review of generation III NPPs in comparison to generation II NPPs.

(c) Risk Associated with the Facility or Activity

Regulatory processes are designed considering risk associated with the facility or activity. Regulatory functions for high risk facilities and activities involve more stringent safety verifications in comparison with the regulatory functions for facilities and activities involving low risk. Moreover, if facilities with different risk compete for regulatory attention then facility with high risk will be preferred by the regulatory body.

(d) Regulatory body resources

Experienced personnel are employed for regulatory functions i.e. licensing, review and assessment, etc. Distribution of human resources is graded based upon safety significance of these functions if carried out in parallel to each other.

(e) Performance of Licensee and Experience of Regulatory Body

Regulatory attention is graded based upon performance of licensee. More regulatory efforts are focused on licensee that has poor regulatory compliance in comparison to those having better regulatory compliance. Similarly, regulatory functions for the area in which regulatory body has rigorous experience and competence require less efforts and minimum effort result in effective outputs.

(f) Licensing of New Design

The safety assessment of NPP design that is being reviewed by regulatory body first time is more challenging in comparison with the review of safety assessment of NPP design that is already reviewed earlier by regulatory body. Review and assessment of new design NPP requires more regulatory attention, resources, etc.

(g) Urgency for need of a licensing action

Urgency of the project is also considered in prioritization of the activity based on the potential impact on safety, health, environment, quality etc. The activity is prioritized due to its nature posing a risk to safety of the public, worker and the environment.

VII-1.3. Practical Examples

Some practical examples are given below:

- Review of submissions for issuance of fuel load permit to K-2
- Review of PSR-2 for revalidation of C-1 operating licence
- Licensing of operating personnel of NPPs and RRs
- Licensing of design organization

(a) Prioritization of Regulatory Activities

Keeping in view the above rationale and expert judgement, application of graded approach was implemented in the following manner:

(1) Usually review and assessment of licensing submission is carried out by TSO, however, in case of two parallel licensing activities i.e. K-2 and C-1, an alternate arrangement was made for review of C-1 submissions. K-2 FLP application was reviewed by TSO considering complexity of new design whereas, C-1 OL revalidation application was reviewed by augmented team comprising of experts from PNRA keeping in view the operating performance history of the licensee.

(2) Application for licensing of operating personnel was received from research reactor (PARR-1) and from K-2 at the same time. The licensing of operating personnel for K-2 was prioritized in view of the urgency of a licensing action as availability of minimum shift complement was one of the pre-requisites for FLP, whereas, PARR-1 was already in operation having necessary shift crew.

(3) Application for licensing of design organization for safety related structures, systems, and components was received, however, regulations for licensing of design organization was not available at that time. A licensing process for licensing of these facilities was finalized and implemented accordingly considering the urgency of licensing action. Regulatory process of licensing was prioritized over development of regulatory framework which usually takes around three years for completion.

VII-2. PRACTICAL EXAMPLE: INTEGRATED REGULATORY PROGRAMME - GRADED APPROACH TO PRIORITIZING REGULATORY ATTENTION AND RESOURCES IN THE UK

— **Step 1: Identify level of regulatory attention and resources to assign to a licensee**

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 [VII-1]:

— Significantly Enhanced
— Enhanced
— Routine

Attention levels are assigned based on judgment, underpinned by qualitative and quantitative assessment 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 in Step 2.

The level of attention ONR assigns to each licensee will define:

[1] Excluding defence nuclear licensed sites

- How ONR's management prioritizes those sites, facilities and licensees that should warrant a higher degree of proactive regulatory oversight through inspection, assessment, permissions or indeed enforcement attention;
- Aspects of dutyholder performance that ONR should focus its specialist resources and attention in order to secure an improved aspect of safety and security performance;
- The relative importance to assign to inspection and assessment depending on the facility's lifecycle; e.g. an NPP approaching end of generating life may require that ONR shifts its focus towards evaluation of safety submissions underpinning near term defueling, and organizational capability of the licensee to transition from operator to site closure.

— **Step 2: Determine which factors influence Regulatory Attention Level**

(a) Safety Attributes

(1) 'Safety performance' as a product of dutyholder compliance recorded across the various safety purposes, incidents on the site and delivery against agreed or required safety enhancements.

(2) '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.

(3) 'Safety Leadership and Culture' relating to a framework [VII-2] adopted by ONR's Human & Organizational Capability specialism for assessing licensee performance against Leadership and Management for Safety (LMfS) themes.

(b) Security Attributes

(1) 'SyAPs Plan Development'. The industry is currently in the process of developing nuclear site security plans for ONR to assess against our Security Assessment Principles (SyAPs) [VII-3].

(2) 'Security Strategic Enablers'. This relates directly to SyAPs Fundamental Security Principles (FSyPs) 1-5 [VII-3], measured by how appropriate the arrangements are in meeting the associated outcomes.

(3) 'Security Operations'. This relates directly to FSyPs 6-10 [VII-3] in terms of how appropriate the dutyholders' security operations are in meeting the associated outcomes.

(4) '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 enhanced (or significantly) 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 resource allocated to a site to support an enhanced inspection programme or undertake additional 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 [VII-1].

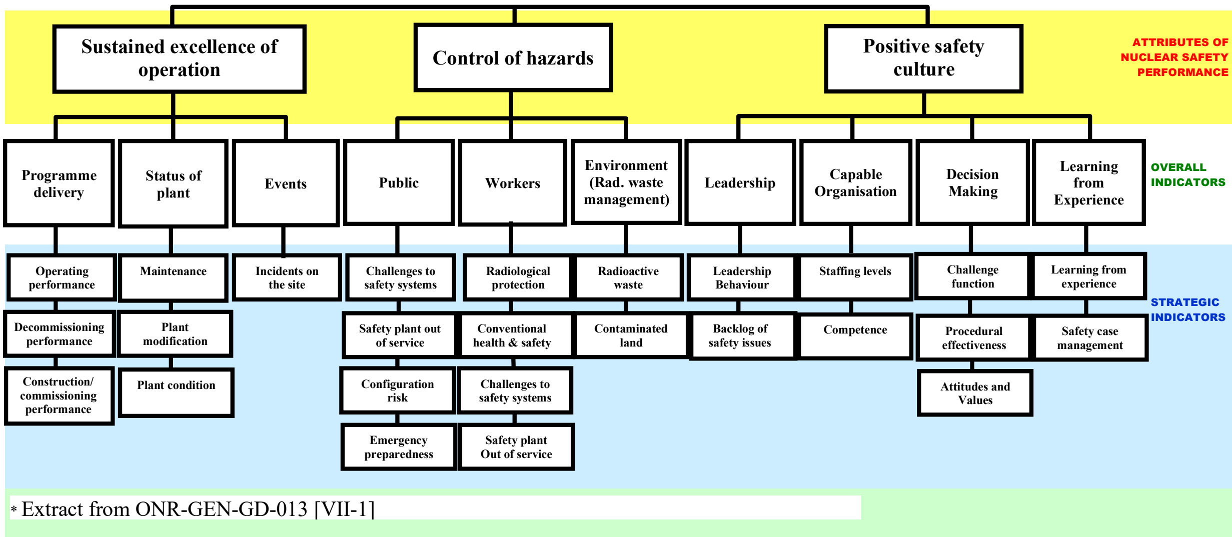

FIG. VII-1. Nuclear Safety Performance Indicator Framework (from [VII-1])

— **Step 3: Integrate the applicable factors into assignment of Regulatory Attention Levels**

For each licensed site, ONR inspectors complete the assessment template on the following page, assigning ratings to each individual indicator. An overall judgement is then made as to the overall level of attention to be assigned to a licensee. This is fundamentally judgement based and not intended to be algorithmic.

ONR's regulatory leadership team undertakes a moderation exercise to look for consistency of analysis and identify outliers and emerging cross-industry trends that warrant specific regulatory attention.

At the end of each year, for sites receiving enhanced attention, we undertake an assessment of their performance, and thence evaluate whether our regulatory strategy for securing a return to routine attention remains valid and appropriate.

The illustrative diagrams below show how ONR assimilates the overall performance of a licensee against a range of factors, for an ageing NPP installation and a UK defence installation in the UK. It shows the influencing factors that have resulted in an enhanced level of regulatory attention for two very different types of facilities:

(a) UK NPP – Advanced gas-cooled reactor

An 'overall integrated regulatory attention level' is assigned to each site for safety and security, informed by the constituent levels of attention for each indicator. This is not a forensic exercise but one based on overall judgement. The diagram illustrates those areas of the site that warrant increasing levels of specific attention. It will also inform where ONR's specialist resources are prioritized in order to influence improvements in safety and security to best effect.

FIG. VII-2. Assessing Overall Performance - UK NPP

(b) UK defence installation

The installation maintains and refits the UK's nuclear submarines, part of the UK nuclear deterrent. Security is not explicitly considered for this installation because ONR does not regulate security on defence sites in the UK. That matter is reserved for the Ministry of Defence.

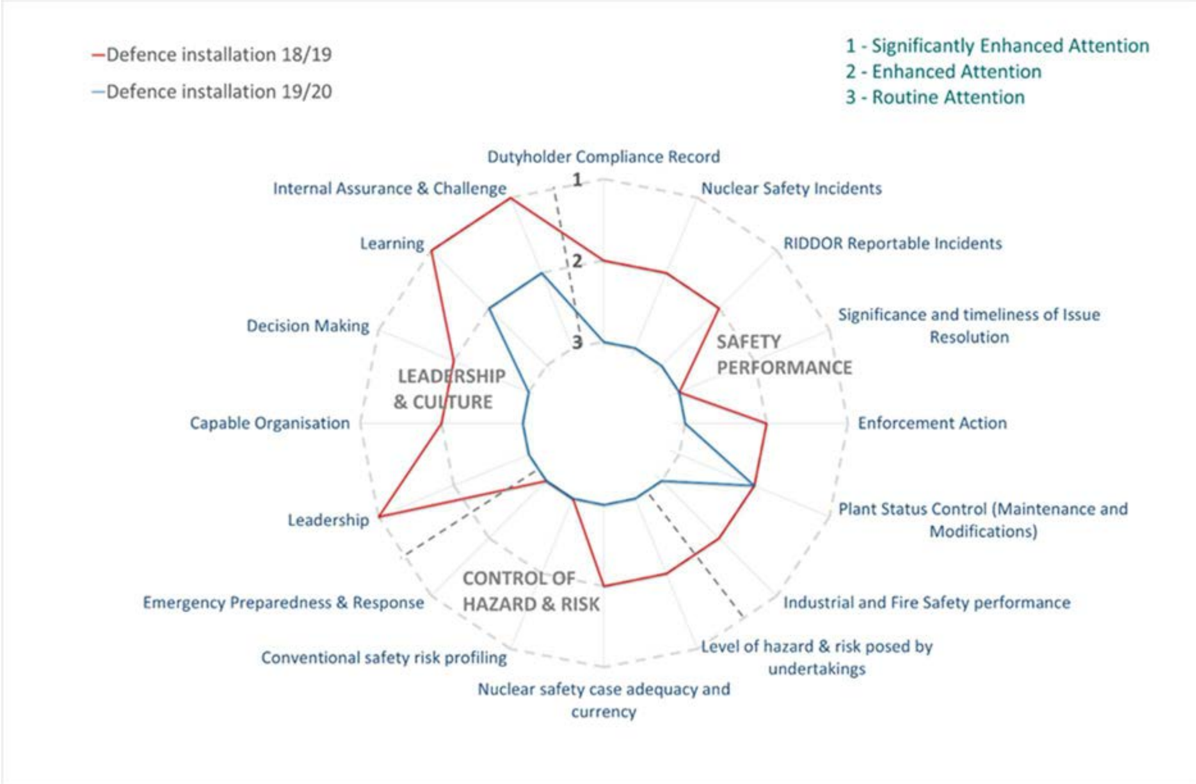

FIG. VII-3. Assessing Overall Performance - UK Defence Installation

(c) Nuclear Safety and Security attributes

TABLE VII-1. NUCLEAR SAFETY ATTRIBUTES - INTEGRATING FACTORS INTO ASSIGNING REGULATORY ATTENTION LEVEL

Name of Dutyholder and Licensed Site					
Safety Performance		**Control of Hazards and Risks**		**Safety Leadership and Culture**	
Dutyholder compliance record	*Provide sufficient (but succinct) narrative to justify enhanced or significantly enhanced Attention level assigned to each attribute, where relevant.* *Divisions may wish to record narrative to support Routine Attention at their discretion.*	Level of Hazard and Risk posed by the dutyholder's undertakings		Leadership	
Record Attention Level here (1, 2 or 3)					
Number and significance of Nuclear Safety incidents		Nuclear safety case adequacy and currency		Capable organization	
Number and significance of Industrial Safety incidents and RIDDOR reportable events		Transport Package Assessment		Decision Making	
Number and significance of regulatory issues and timeliness of resolution		Maturity of CHS risk prioritization and profiling		Learning	
Enforcement action taken and under consideration				Internal Assurance and Challenge	
Plant status (control of modifications and maintenance)		Emergency preparedness and response capability			
Delivery of Industrial and Fire Safety Improvements					
Overall Safety Attention Level			**Outline action plan by which ONR will secure (where practicable) a return to Routine attention**	*Completed for Enhanced and Significantly Enhanced Attention Levels only. This should be articulated even where it is unlikely that a dutyholder and/or site will achieve a return to Routine Attention in the short term due to (such as higher hazard facilities at Sellafield due to their intolerable risk).*	
Initial Attention Level (1, 2 or 3)			**Proposed or existing Level 1 or 2 Regulatory Issues for tracking dutyholder progress**	*Completed for Enhanced and Significantly Enhanced Attention Levels only*	
Divisional Moderation and supporting justification for any amendment to initial attention level					

TABLE VII-2. NUCLEAR SECURITY ATTRIBUTES - INTEGRATING FACTORS INTO ASSIGNING REGULATORY ATTENTION LEVEL

<table>
<tr><th colspan="8">Name of Civil Nuclear Security Dutyholder</th></tr>
<tr><th colspan="2" rowspan="2">Overall Security Attention Level</th><th>Initial</th><th>Final</th><th colspan="4">Justification for Attention Level Moderation (if applicable)</th></tr>
<tr><td>Record attention level here</td><td>Record attention level here</td><td colspan="4">Insert text here if applicable</td></tr>
<tr><td colspan="3">Evidence Underpinning Attention Level</td><td colspan="5">Insert text here, to include:
• Underpinning basis for level of ONR regulatory attention
• Dutyholders successes and improvements</td></tr>
<tr><td colspan="3">Action Plan (only required for attention levels 1 and 2)</td><td colspan="5">Insert text here, to include:
• Regulatory action taken to return dutyholder to Routine attention level
• Any current or new Regulatory issues to be recorded on the RIS</td></tr>
<tr><th colspan="2">SECURITY ASSESSMENT PRINCIPLES PLAN DEVELOPMENT</th><th colspan="2">SECURITY STRATEGIC ENABLERS</th><th colspan="2">SECURITY OPERATIONS</th><th colspan="2">SECURITY DELIVERY</th></tr>
<tr><td>Record attention level here</td><td>Insert justification here to include:
• Summary of dutyholder plan development/quality and ONR dutyholder assessment process as applicable.</td><td>Record attention level here</td><td>Insert text here, to include:
• Summary of key points against indicators
• Reporting by exception, only minimal detail required where level 3 is assigned
• Action plan where level 1 or 2 is consequence of poor performance</td><td>Record attention level here</td><td>Insert text here, to include:
• Summary of key points against indicators
• Reporting by exception, only minimal detail required where level 3 is assigned
• Action plan where level 1 or 2 is consequence of poor performance</td><td>Record attention level here</td><td>Insert text here, to include:
• Summary of key points against indicators
• Reporting by exception, only minimal detail required where level 3 is assigned
• Action plan where level 1 or 2 is consequence of poor performance</td></tr>
</table>

VII-3. USE OF A GRADED APPROACH TO AN INTEGRATED REGULATORY PROGRAMME IN THE U.S.

— **Step 1: Identify the combination of functions and or the suite of facilities that need to be simultaneously addressed under the regulatory programme.**

The U.S. Nuclear Regulatory Commission (NRC) employs over 2800 staff members. However, not all staff are available for direct oversight functions. Roughly 20 percent are dedicated to corporate support functions, which includes administrative services, financial management, information technology, human resources, training, and acquisitions. The organizational structure is such that all regulatory functions (i.e. development of regulations, authorizations, review and assessment, inspection, enforcement, and communication and consultation with interested parties) are conducted simultaneously for all types of nuclear installations and all types of nuclear materials users licensed to operate in the U.S. This includes power reactors (operating, under construction, and being decommissioned); research and test reactors; fuel cycle facilities, including uranium recovery, conversion, and enrichment activities; fuel fabrication and development; transportation of nuclear materials, including certification of transport containers, and reactor spent fuel storage; safe management and disposal of spent fuel and high-level radioactive waste; and the safe and secure use of radioactive materials in medical, industrial, and academic applications.

At this time, the NRC provides oversight for 94 operating nuclear power units with two additional units under construction, 31 operating research and test reactors, three uranium recovery facilities, one uranium conversion plant, a uranium enrichment facility, five fuel fabrication plants, 24 power plants in a decommissioning status, and many licensees authorized to possess radioactive isotopes for medical, industrial, and academic uses.

— **Step 2: Determine which factors are applicable to the decision, and how those factors are ranked.**

The following factors are applicable to determining the appropriate resources:

Statutory requirements – This factor is ranked first in importance because the NRC is legally bound to follow applicable laws. The NRC has been granted regulatory oversight authority under the Atomic Energy Act (AEA) of 1954 [VII-4], as amended, and the Energy Reorganization Act of 1974 [VII-5], which created the agency.

(a) Budgeted resources – This factor ranks equally high as the statutory requirements. Each year Congress appropriates an annual operating budget for the NRC to conduct its regulatory activities, equating to a number of staff available. The budget limits the oversight work that can be accomplished each year.

(b) Regulatory body experience – This factor plays a role in the budget requested by the agency when planning for expected or future licensing, review and assessment, and inspection activities. This is also an important factor in hiring practices to ensure appropriate subject matter experts are available, e.g. seismic experts.

(c) Number and type of licensees – Large numbers of licensees will impact the number of resources needed for review and assessment and inspection, in particular. In general, operating nuclear power plants will require more resources for oversight than research and test reactors, or materials users. Units in a decommissioning status require far less oversight. There are a very large number of materials users licensed in the U.S., including doctors, technicians, radiographers, and academicians. The large number of licensees could be a challenge to oversee with limited resources.

(d) Licensee performance – This factor is important as declining licensee performance, particularly for operating nuclear power plants, could potentially divert resources directed toward increased inspection and enforcement that may or may not be planned or budgeted.

(e) Emergency response – While the NRC has a robust emergency response organization, emergencies resulting in significant risk to the public require a response from the regulatory body commensurate with the significance of the event. During the Fukushima event, the NRC staffed its emergency organization for several weeks, as well as provided significant technical support, requiring a shifting of resources.

(f) Urgency for need of a licensing action – Occasionally urgent licensing actions require additional resources to address in a timely manner, e.g. emergency technical specification amendments.

(g) Emergent work – Unplanned activities requiring a regulatory response occur frequently. Significant safety issues at nuclear facilities, whether generic or plant-specific, generally need to be addressed quickly, often because of high stakeholder interest in addition to the safety significance of the issue. These issues will likely require a reprioritization of resources to deal with the emergent work.

As this is an integrated programme, all of the specific factors applicable to the individual regulatory functions also play a role.

— **Step 3: Integrate the applicable factors into the decision-making process.**

(a) Baseline Resource Requirements

The question of how to determine appropriate resource requirements to conduct all of the regulatory functions of the regulatory body is largely a budget question. How does the NRC develop and execute its budget?

Statutory requirements are factored into the organization of the NRC. The Energy Reorganization Act of 1974 established several offices with distinct functions. The law established the Office of Nuclear Reactor Regulation (NRR) whose functions include principal licensing and regulation involving all facilities, and materials licensed under the AEA, as amended, associated with the construction and operation of nuclear reactors, as well as the review the safety and safeguards of all such facilities, materials, and activities. It also established the Office of Nuclear Material Safety and Safeguards whose functions include principal licensing and regulation involving all facilities and materials, licensed under the AEA, as amended, associated with the processing, transport, and handling of nuclear materials, including the provision and maintenance of safeguards against threats, thefts, and sabotage of such licensed facilities, and materials, as well as reviewing safety and safeguards of all such facilities and materials licensed under the AEA, as amended. These two offices execute most regulatory functions for the majority of licensees overseen by the NRC.

After the terrorist attacks of 9/11, the NRC created a new Office of Nuclear Security and Incident Response (NSIR) to assume the role of maintenance of safeguards against threats, theft, and sabotage of licensed facilities. This necessitated a large shift in staffing. There is also an Office of Enforcement with specialists in executing the Commission's enforcement policy, and there is an Office of Public Affairs with the primary responsibility of communicating with the public. Each of these offices are able to conduct their regulatory functions using funds budgeted for those activities.

The AEA, as amended, directed the agency to impose the minimum amount of regulation for medical therapy, industrial and commercial applications, and research and development uses of nuclear materials consistent with its obligations under this Act to promote the common defense and security and to protect the health and safety of the public. Thus, oversight of these licensees requires far fewer resources than for more complex facilities, such as operating nuclear power plants.

Regulatory experience plays a key role in developing budget requests. The NRC has 46 years of experience licensing and inspecting nuclear facilities. Instead of developing a new budget from the ground up every year, the NRC employs baseline budgeting, which is a process by which a budget is prepared using the latest execution data and adjusts for programmatic and fact-of-life changes and projections for new or changing work. The number and type of licensees also play a key factor in the budget formulation. There are many licenses held by materials users; the NRC is assisted by the States in overseeing many of those licensees. The Agreement State program exists in which the NRC authorizes individual States to oversee and inspect materials users (i.e. users of medical isotopes, radiographers and industrial users, and academic users) within their States, as long as their program meets NRC guidelines. These Agreement States oversee approximately 88 percent of materials users licensed in the U.S., while the NRC provides oversight for the rest.

In a recent example, the NRC budget requested funding for 1755 staff dedicated to nuclear reactor safety, or 62.6 percent of the total staff. The budget requested funding for 462 staff dedicated to nuclear materials and waste safety, or 16.5 percent of the total staff. The remaining request was for corporate support staff. This reflects a graded approach to oversight, reflective of the greater degree of risk to the public associated with nuclear reactors.

Under the operating reactors business line, resources are used to conduct baseline inspections at all operating plants; to inspect research and test reactors; to review and approve licence amendments; to review licence renewal applications; and to review construction permit applications and operating licence applications for facilities such as manufacturing new medical radioisotopes. Resources are adjusted as operating reactor licensees notify the NRC of planned decommissioning.

The new reactors business line utilizes resources for new design certification reviews, early site permit application reviews, construction inspection for facilities under construction, and vendor inspections. Because there are relatively few new reactors under construction and only a few applications for design certifications and early site permits, the staffing level for the new reactors business line is substantially lower than for operating reactors. The budget request for new reactors includes 285 positions, or 16 percent of the staff budgeted for reactor safety. The agency has placed a high priority on inspection and oversight of the two new reactor units under construction because of their national importance in that they are the first reactors to be built in the U.S. in decades, and they are the first units that rely on passive safety systems. There are 17 inspectors dedicated to inspecting their construction to ensure the regulator is not responsible for delaying startup, and to ensure the units are constructed in accordance with their licensing and design bases.

Of the 1755 staff budgeted for nuclear reactor safety, 1470 are dedicated to operating reactors, nearly 84 percent. Operating reactor facilities have the greatest number of resources dedicated due to their complexity and safety significance. Budgeting for the inspection program for operating reactors is fairly straight-forward. There are at least two resident inspectors assigned full time to each operating nuclear power plant (three inspectors at three-unit sites). There are 56 sites staffed with resident inspectors. In addition to the resident inspectors, there are region-based inspectors who specialize in annual inspections for security, radiation protection, and emergency preparedness. Each of the four regions is staffed with enough specialized inspectors to support the baseline inspection program for all of the operating reactor plants within their regions. Each site receives over 2300 hours of direct inspection effort each year, not including time spent daily touring the plant, preparing for inspections, and administrative tasks. Additionally, headquarters staff support the oversight of operating power plants through development of inspection and assessment guidance, oversight of operator licensing, generic communications and operating experience programs, oversight of research and test reactors, and vendor inspections.

NRR consists of several divisions focusing on specific regulatory functions. There is a division of operating reactor licensing consisting of nearly 100 staff, processing hundreds of licence amendment applications each year. The optimal staffing of 100 ensures efficient processing of those applications based on the average number received. They are supported by three divisions of approximately 220 technical reviewers and risk analysts who review and assess the acceptability of those amendments for documentation in safety evaluation reports. There is a division of reactor oversight employing approximately 70 staff that develop inspection and performance assessment guidance, oversee operator licensing, develop generic communications and operating experience for distribution to licensees and inspectors, and provide oversight of vendors.

NRR also provides oversight of the 31 research and test reactors (RTRs). There are approximately 10 inspectors dedicated to inspecting those facilities. The number of inspectors is relatively low based on the low number of reactors, and the reduced risk to the public represented by those facilities. There are no resident inspectors for RTRs, and they are inspected annually or biennially. There are only 13 licensing staff dedicated to RTRs because there are relatively few facilities, and relatively few licence amendment requests and requests for construction and operating licenses.

The Office of Nuclear Material Safety and Safeguards provides the regulatory functions for spent fuel storage and transportation, nuclear materials users, decommissioning and low-level waste, and fuel facility business lines. Approximately one quarter of the staff compared to reactor safety perform the regulatory functions in these areas because they represent significantly less risk to the public. Again, while there are thousands of licensees authorized to use radioactive isotopes, the NRC provides oversight for only about 25 percent of them. The rest are overseen by their respective Agreement States. The budget request funds 201 staff for regulatory functions and oversight of materials users. There are 102 staff assigned to spent fuel storage and transportation, and 86 dedicated to decommissioning and low-level waste. There are 73 staff budgeted for fuel cycle facilities. The lower number of staff is primarily due to the relatively few fuel cycle facilities requiring oversight.

The regulatory function of developing regulations is also a function of NMSS. There is a dedicated rulemaking division responsible for developing new regulations for both reactors and materials programs. This division is responsible for the development, documentation, tracking, and reporting of rulemaking activities, as well as the regulatory analysis that supports agency decision-making for rulemaking. There are 40 staff dedicated to developing regulations for the NRC. The rulemaking process is complex and typically requires approximately two years to complete a final rulemaking. There can be as many as 20 different proposed rules being processed at any given time, as well as the processing of petitions for rulemaking received from stakeholders.

The following table summarizes the distribution of staff resources by business line. This represents a graded approach to an integrated regulatory programme that implements all regulatory functions simultaneously for all types of nuclear facilities and nuclear materials users. The primary factors are safety-significance of the facilities and the numbers of each type of facility or licensee.

TABLE VII-3. DISTRIBUTION OF STAFF RESOURCES BY BUSINESS LINE

Business Line	Staff Requested
Operating Reactors	1470
New Reactors	285
Spent Fuel Storage and Transportation	102
Nuclear Materials Users	201
Decommissioning and Low-Level Waste	86
Fuel Facilities	73

The Office of Enforcement provides enforcement support for both reactor and materials business lines. There are approximately nine enforcement specialists located in headquarters, and at least three enforcement specialists assigned in each region. The relatively low number of staff is reflective of the relatively few numbers of issues requiring escalated enforcement.

The regulatory function of communication and consultation with interested parties is a responsibility of all staff. The four staff assigned to the headquarters Office of Public Affairs generally handle public and media relations with regard to agency policy, programs, and generic issues, while public affairs officers in each NRC region handle public affairs activities involving mostly licensed nuclear facilities in their regions. All staff members are responsible for communicating with stakeholders when necessary based on their assignment.

The NRC is fortunate in that each office generally has enough staff such that it is not necessary for a person to have to perform simultaneous regulatory functions. Each person is typically dedicated to a specific function, such as inspecting, licensing, enforcement, etc. Occasionally a person has unique expertise in a subject where that person may be engaged in different functions, but that is rare.

(b) Adjusting Resources

Most NRC regulations and guidance were originally developed using a traditional deterministic approach, which served the NRC, industry, and the public well in ensuring the safety of commercial nuclear facilities. However, since the Three Mile Island accident, there has been a growing recognition that thinking about risks, implementation strategies, and traditional deterministic factors together provides a fuller, more complete, picture of safety. This holistic approach – often referred to as risk-informed decision-making (RIDM) – enables the staff and licensees to focus attention on the more risk-significant areas, and use resources more efficiently and effectively. Risk should be factored into decision-making processes when generic safety issues arise in order to minimize resources spent on issues that are very low safety significance. The goal to minimize resources on low risk issues not only applies to the regulator, but also the licensee. The licensee should also be focusing their resources on issues of greatest safety significance.

Each fiscal year Congress appropriates a certain amount of money for the NRC to perform its regulatory functions, which may be more or less than the amount requested. Upon receipt of the appropriation, the staff prepares budget execution plans for managing resources. Shortfalls and emergent needs occur for several reasons. For example, the Commission identifies new priority work, a need arises after the budget is submitted, there is an unanticipated increase in the workload, funds are diverted for an emergency, or a project is delayed to future years. Offices and regions identify to the Budget Director budget shortfalls and emergent needs. The items are classified as high, medium, or low priority. At an agency level, the Office of the Chief Financial Officer (OCFO) issues guidance on how to prioritize shortfalls and emergent needs for funding. OCFO coordinates the preparation of an agencywide funding priority list and maintains it throughout the year. The shortfalls and emergent needs are prioritized agencywide on a 'shortfall list' to be funded as funds become available during execution. The CFO and Executive Director for Operations recommend to the Commission an overall agency prioritization of the items on the shortfall list. The Commission makes the final decision on the prioritization.

What factors can impact how resources are utilized? When unplanned emergent work is identified that has a high priority, managers determine what other work to defer or shed in order to accomplish the new tasking. At an Office or Division level, priorities are generally set by due dates that need to be met. Emergent tasking resulting from Congressional or Commission direction typically has very high priority. Regulatory actions with flexible or no due dates may be deferred. In general, the NRC uses a Planning, Budgeting, and Performance Management (PBPM) process when executing the budget. The process is performance driven. Performance management provides the use of goals, indicators, targets, analysis, and data-driven reviews to improve the results of programs and the effectiveness and efficiency of agency operations. Each business line develops performance indicators to track performance towards established goals. These goals are tied to the NRC Strategic Plan. If emergent work is identified that could negatively impact a performance indicator, business line leads will generally place a higher priority on its accomplishment. Work that has a lesser impact on the indicators, or no impact, is subject to be shed or deferred.

As an example, typically a licence amendment request will involve publication of a Federal Register Notice soliciting stakeholder comments on the proposed request for 30 to 60 days, and to offer an opportunity to request a hearing on the issue. If a licensee requests an emergency licence amendment, the review will have a high priority. If a licensee believes that a proposed amendment is needed even sooner than can be issued under exigent circumstances, the licensee may apply for the amendment per the provisions of 10 CFR 50.91(a)(5) [VII-6]. This regulation states, in part, that:

> "Where the Commission finds that an emergency situation exists, in that failure to act in a timely way would result in derating or shutdown of a nuclear power plant, or in prevention of either resumption of operation or of increase in power output up to the plant's licensed power level, it may issue a license amendment involving no significant hazards consideration without prior notice and opportunity for a hearing or for public comment. In such a situation, the Commission will not publish a notice of proposed determination on no significant hazards consideration but will publish a notice of issuance under § 2.106 of this chapter, providing for opportunity for a hearing and for public comment after issuance."

If a licence amendment request meets the criteria for an emergency situation, the request may be granted with an expedited review. This will automatically have a high priority for the staff assigned to the review.

Licensee performance can have a significant impact on resources. For example, a reactor licensee whose performance degrades to Column 4 of the Reactor Oversight Process Action Matrix (See Table IV-17 in Annex IV-6) will be subject to a supplemental inspection with a resource estimate of approximately 3000 hours of additional inspection. These inspections are relatively rare and not normally planned in the budget; however, the inspections are usually spread out over a two- to three-year period using a large team of inspectors. The team is typically comprised of inspectors from all four regions, which may require reassignment of other inspectors to backfill for the supplemental inspection team.

Emergency response is another factor that can have a significant impact on resource utilization. As stated earlier, the terrorist attacks of 9/11 resulted in a reorganization within the NRC to create the new Office of NSIR. The inspection program was also adjusted after this incident. Additional security inspections were developed as part of the baseline inspection program due to the nature of the event and the national interest in ensuring the nuclear power plants were safe from terrorist attack. Resources spent on security inspections went from 98 hours annually to 278 hours annually. The NRC attempts to make changes to the baseline inspection program for operating reactor facilities resource neutral, so there was a reduction in reactor safety inspections to compensate for the increased focus on security. The staff evaluated each inspection procedure to determine where inspection samples could be reduced and still maintain assurance that nuclear facilities were being operated safely. Ultimately, the baseline inspection program resource requirements increased by about 100 hours annually. The NRC also dedicated staff to assessment of licensee security measures, and rulemaking to address required licensee onsite actions necessary to enhance the capability of the facility to mitigate the consequences of an aircraft impact.

During the accident at Fukushima, the NRC Emergency Operations Center was staffed around the clock to monitor the event, with additional staff sent to Japan to monitor and provide advice to the Japanese responders, and a team at headquarters dedicated to identifying lessons learned for the U.S. This event was a high priority for the NRC due to the impact to public health and safety in Japan, the potential impact in the U.S., and the extremely high interest from the U.S. Congress. There was a very high degree of stakeholder and public concern, as well, which contributed to the increased urgency to determine an appropriate response to the event for the U.S. operating reactor fleet. Resources had to be shuffled around to support the emergency and to continue day-to-day regulatory functions at the same time. Several Orders were issued on the basis of a substantial increase in the overall protection of the public health and safety. Eventually, a new organization was formed comprising a division of staff dedicated to implementing the recommendations from the lessons learned task force. This organization pulled staff members from other funded organizations performing regulatory functions for operating reactors. While there wasn't a significant impact on inspection resources, there was on licensing, project managers, and technical reviewers, which resulted in an increased backlog of licence amendment requests. Managers had to establish new priorities for licensing actions requiring regulatory approval to minimize delays and the impact to operating reactor licensees. A higher priority was established for licensees requiring amendments where plant modifications needed to be accomplished that could only be scheduled during an upcoming refuelling outage because the reactor needed to be shutdown. Licensing actions where plant modifications to improve plant safety or reduce risk requiring a long lead time to order expensive components were also prioritized high. The NRC makes every attempt to avoid delaying plant modifications that improve safety. Codifying the new requirements was also an agency priority, so resources were shifted to ensure the new regulations were issued as quickly as possible.

REFERENCES TO ANNEX VII

[VII-1] OFFICE FOR NUCLEAR REGULATION, Guidance on the Assignment of Dutyholder Attention Levels, ONR-GEN-GD-013 Revision 0, ONR, Bootle (2019).

[VII-2] OFFICE FOR NUCLEAR REGULATION, Guidance for undertaking Leadership and Management for Safety Reviews, NS-TAST-GD-093 Revision 2, ONR, Bootle (2019).

[VII-3] OFFICE FOR NUCLEAR REGULATION, Security Assessment Principles for the Civil Nuclear Industry, Version 0, ONR, Bootle (2017).

[VII-4] UNITED STATES, Atomic Energy Act of 1954, US Government Printing Office, Washington, DC (1954).

[VII-5] UNITED STATES, Energy Reorganization Act of 1974, US Government Printing Office, Washington, DC (1974).

[VII-6] U.S. NUCLEAR REGULATORY COMMISSION, Notice for public comment; State consultation, 10 CFR 50.91, Washington, DC (2007).

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Vienna, Austria: 24–28 September 2018, 1–5 April 2019, 2–6 December 2019

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