APPLICATION OF GRADED APPROACH IN REGULATING NUCLEAR POWER PLANTS, RESEARCH REACTORS AND FUEL CYCLE FACILITIES

SUMMARY REPORT

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APPLICATION OF GRADED APPROACH IN REGULATING NUCLEAR POWER PLANTS, RESEARCH REACTORS AND FUEL CYCLE FACILITIES

- Summary Report of the Draft TECDOC -

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1. INTRODUCTION

This is a Summary Report of the IAEA draft TECDOC on the application of graded approach in regulating nuclear power plants, research reactors and fuel cycle facilities, prepared to support participants of the February 2021 Technical Meeting on the application of graded approach (GA) to the regulation of Nuclear Facilities.

For the purpose of this document, ***nuclear facilities*** or ***facilities*** are limited to nuclear power plants, research reactors and nuclear fuel cycle facilities.

1.1. BACKGROUND

Lessons learnt from IAEA Integrated Regulatory Review Service (IRRS) missions highlighted that the understanding and application of graded approach process differs across Member States and resulted in recommendations or suggestions to the regulatory bodies in most peer reviews. Additionally, many regulatory bodies in Member States highlighted that they are still experiencing difficulties in applying graded approach in a systematic and documented way, into their regulatory programmes. Further, during technical meetings and workshops, Member States indicated that there is a need for guidance on the application of graded approach to support regulatory functions for nuclear facilities.

The TECDOC will propose a generic methodology and document Member States practical examples on the application of the graded approach for all the regulatory functions articulated in IAEA Safety Standard GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [1]. The draft TECDOC featured thirty-one (31) practical examples on the use of graded approach which could be considered by regulatory bodies in Member States as a starting point or insights to develop their own approach. The methodology proposed, in general follows the high level principles described in INSAG-25, "A Framework for an Integrated Risk Informed Decision Making Process" [2], applied to the regulatory decision making.

It is recognized that in many specific technical areas the application of graded approach to focus regulatory attention to areas of greater safety significance is thorough and has been widely used historically. An example is the implicit use of graded approach when considering external events in siting and design of nuclear installations. This can be clearly seen in IAEA Safety Standards SSR-1 [3], SSR-3 [4], NS-G-1.5 [5], NS-G-2.13 [6] and in Safety Reports [7] related to this topic. In the cases such as these examples, not always the method used is described explicitly as graded approach, but it is clearly oriented to assign more attention to areas of more safety significance, which is the essence of the use of graded approach. In addition, an example on the explicit use of graded approach in the application of safety requirements for research reactors is seen in SSG-22 [8].

The practical examples in the Annexes of the draft TECDOC were required to meet a set of criteria to ensure that they will be meaningful to other Member States to use as the starting point to develop their customized approach. These criteria are described in Section 4 of this document.

A Technical Meeting is being organized to discuss the application of GA in the regulation of NIs among a wider audience and to seek more practical examples from other member states through contributions of papers to a Technical Meeting being organized to that effect.

1.2. OBJECTIVE OF THE SUMMARY REPORT

The primary objectives of this report are:

a) Summarize the methodology described in the TECDOC;
b) Show a subset of practical examples which comply with the criteria shown herewith;
c) Guide contributors of papers to the Technical Meeting.

2. BASIC PRINCIPLES OF THE GRADED APPROACH

2.1. GENERAL CONSIDERATIONS REGARDING GRADED APPROACH

The IAEA Safety Glossary [9] defines the 'graded approach' as follows:

1. 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 method in which:

   a) The significance and complexity of a product or service are determined;
   b) 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;
   c) 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 *facility*, and the stage in the *lifetime* of a *facility*.

2. An application of safety requirements that is commensurate with the characteristics of the practice or source and with the magnitude and likelihood of the exposures.

   Graded approach applies to the regulatory functions described in IAEA Safety Standard GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [1]. A graded approach should be utilized when:

   - establishing regulatory requirements and guidance;
   - establishing the level of authorization for regulated facilities;
   - planning and conducting reviews and assessments
   - planning and conducting inspections;
   - taking regulatory enforcement actions;
   - communicating with stakeholders.

2.2. GENERAL METHODOLOGY

This Section summarizes the proposed overarching methodology for graded approach. Specific applications of this methodology for all core regulatory functions are presented in Section 3.

The general methodology for graded approach presented in the TECDOC applies to the six regulatory functions and is divided into three main steps:

Step 1. Identifying the decision associated with the regulatory function;
Step 2. Identifying and ranking the applicable factors;
Step 3. Integrating the applicable factors into regulatory decision-making.

In the context of the methodology described in this document, ***factors*** are the characteristics of facilities or other elements that could affect the safety of a facility 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 facility.

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

As mentioned in Section 2.1, graded approach may apply to all regulatory functions in a number of ways. The initial question would therefore be where to apply graded approach to the regulatory functions. That's to say, how a regulatory body would apply the three-step approach to grade the requirements and/or allocate the regulatory resources commensurate with the radiation risks of the facilities to be regulated.

2.2.1 Step 1 - Identifying the decision associated with the regulatory function

Initially, the methodology presented in this document requires identifying the regulatory decisions to be made and consider how the decision will impact the regulatory programme as a whole. This generic step is differently addressed 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 graded approach.

Table 1 – Key questions when applying Graded Approach to core regulatory functions

Regulatory Function	Key Questions when Applying Graded Approach
Regulations and Guides	• Are regulations and guidance adequate to control the risk associated with the facility?
Authorization	• Is the level of authorization (approval, consent) commensurate with the risk of the regulated facility? • Is the licence/conditions established for a facility set to control the risk of the regulated facility?
Review and Assessment	• Is regulatory effort allocated for the review/assessment commensurate with the risk (potential safety significance) of the item being assessed? • Is there a systematic way of determining safety significance of review issues from a review and assessment?

Regulatory Function	Key Questions when Applying Graded Approach
Inspection	• Is regulatory effort allocated for the inspection programme commensurate with the risk of 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	• Are resources allocated for communication activities commensurate with the safety significance and level of stakeholder interest?

2.2.2 Step 2 - Identifying and ranking 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 should then be ranked in accordance with their order of risk significance (**Step 2B**).
This subsection describes the proposed methodology to perform Step 2.

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; and
- **specific factors**, which depend upon the regulatory function considered.

Generic Factors

Characteristics of the facility are the most prominent ***generic factors*** when considering graded approach.

The facility is characterized in accordance with its level of radiological hazard. On this topic, the approach considers initially using a qualitative categorization of the facility, similar to the one presented in IAEA SSG-22 [8]. A first consideration is whether the facility 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 facility 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 reactor (experimental devices, tests, radioisotope production, reactor physics experiments, open access to core, fuel and experiment manipulation);
j. 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;
k. Proximity to population groups and the feasibility of implementing emergency plans;
l. Chemical hazards which potentially may trigger radiological hazards;
m. Complexity of the nuclear installation.

The factors suggested before for the individual characteristics of the facilities are also consistent with those considered in IAEA SSG-22 [8].

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 3 that analyses the application of the proposed methodology for each of the core regulatory functions.

Step2B - 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 safety significance for the facilities and affects the regulatory decision-making process.

The ranking process should be clearly defined as it will impact the final regulatory decision. Therefore, a generic method for ranking factors should consider analyzing 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 nuclear safety of a facility, the higher its significance.

The criteria for ranking the factors in respect of their safety significance must be objective and should 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 rank of the factors and insights on:

- the *risk* associated with the factor; and
- 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 an increased safety significance of the factor when the respective items important to safety and control measures are not adequate.

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

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

2.2.3 Step 3 - Integrating the ranked 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 analyzed 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 discussed in Table 1 above, a number of regulatory decisions could be made while applying graded approach. Nevertheless, they can be grouped into two generic types of regulatory decisions:

a. ***Allocation of resources and effort to regulating the facility***

   The first group, *allocation of resources and effort*, is related to focusing on regulatory activities and assigning available resources in accordance with the ranking results. The aim is at balancing the resource allocation and maximizing regulatory impact on higher priority areas. This would help keeping the regulatory oversight effective on the most safety significant areas.

   This group of decisions deals with defining the appropriate resources to be allocated by the regulator to perform a regulatory function or implement a regulatory decision. In general, these decisions must be done holistically, considering the resources available to the regulators and considering the whole spectrum of facilities to be regulated. The government must support the regulator 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, *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 should be made to confirm that the safety significance and the impacts on the decision are appropriately assessed.

Specific considerations should 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 should be commensurate with the risk associated with the facility
- **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.
- **Monitoring and feedback programmes** should be created to assess the effectiveness of the decision. For changes to regulations, the performance of the regulatory body and the plant operators in implementing the new regulations needs to be monitored. For changes to the design or operation of a nuclear facility, a monitoring process would usually be agreed with the facility operators and this would be included in inspection activities by the regulatory body. 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 should be implemented in the process to ensure achieving the expected results. In addition, the entire process might be revised and adjusted.

3. APPLICATION OF A GRADED APPROACH METHODOLOGY TO REGULATORY FUNCTIONS

This Section describes the application of the graded approach methodology presented in Section 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 may not be exhaustive.

In the Annexes of the TECDOC, many practical examples on the use of this methodology are presented to support Member States willing to implement graded approach in their regulatory activities. This summary only features three examples of the TECDOC for illustration.

3.1. REGULATIONS AND GUIDES

This section describes a proposed methodology in applying the graded approach to developing and revising Regulations and Guides applied to Nuclear Facilities.

- **Step 1:** Identify the required 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:

  - 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?
  - Is there a need for a new regulation, a revision of an existing regulation, or can the issue be addressed in guidance documents? May the issue be addressed through conditions in the Authorization?
  - 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 regulator may need to develop a completely new set of regulations for the 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 regulator should 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 the graded approach:

  - **Type of regulated facilities** – The radiological hazards and complexity of the design of the facility will influence the extent of the regulations necessary to ensure the adequate application of safety requirements throughout the different stages in the lifetime of the facility.
  - **Operating Experience Feedback (OEF) based on significant events** – Significant events may drive the need for additional regulations and guides.

- **Mode of operation and utilization of the facility** – Regulatory framework should address expected modes of operation for a facility, and to account for the overall purpose of the facility.
- **Statutory requirements** – Requirements established by legal framework of a member state would override other factors.
- **Urgency with respect to issue being addressed** – The choice of regulatory instrument may depend on the urgency in which the regulatory requirements are needed. Since the development of regulations can take years in some jurisdictions, to address safety significant issues, guidance or orders may be necessary prior to codifying those requirements. This factor may not apply to all countries that have a framework that allows an amendment to an existing regulation in a short time based on exigent circumstances.
- **Regulatory instruments available** – Appropriate regulatory instrument may be determined by the safety significance of the issue.
- **Level of stakeholder involvement** – Increased stakeholder interest should be addressed.

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

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

3.2. AUTHORIZATION

This section describes a proposed methodology in applying the graded approach the authorization regulatory function for nuclear facilities 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 required authorization.

  In Step 1, in general, the regulatory body is given statutory authority, and it may delegate certain authorizations to lower levels of the organization. Any delegations of authority should be documented in a formal guidance document within the management system. The development of the Authorization process should consider the whole spectrum of nuclear facilities 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 regulator should consider both generic and specific factors. The factors identified should be analyzed 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 should drive the delegation of authority on issuing the different types of authorization for the different stages in the lifetime of a facility.

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

- **Type of regulated facilities** – 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 facility throughout its lifetime.
- **Mode of operation and utilization of the facility** – Authorization should address expected modes of operation for a facility and account for the overall purpose of the facility.
- **Statutory requirements** – Requirements established by legal framework of member states would override other factors.
- **Types of authorization to be issued at various licensing stages** (permits and licenses).
- **Level of stakeholder involvement** – Increased stakeholder interest should be addressed.
- **The number of nuclear facilities to be regulated** – Large numbers of licensees may 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 applying due diligence.

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

  For Step 3, the regulator must 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 must be granted by government bodies. The regulatory body may delegate authorities based on the ranking established in Step 2, in consideration of the risk significance of the facility and volume of licensing actions before the regulatory body.

  Additionally for Step 3, the regulatory body may decide to issue standardized licenses for all regulated facilities. If the regulatory body decides the graded approach is more appropriate, then the contents of the license should be commensurate with the safety significance of the facility.

3.3. REVIEW AND ASSESSMENT OF FACILITIES

The following section describes a proposed methodology in applying the graded approach to the review and assessment regulatory function for nuclear facilities by determining the scope and depth of the review. In addition, the 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.

Use of Graded Approach for Resource Allocation

The following describes a proposed methodology to apply the graded approach for allocating adequate resources for resource allocation in a review and assessment process.

- **Step 1:** Determine the scope and depth of the review based on applicable requirements typically a regulator will develop a review plan tailored to a specific facility**.**

- **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 the graded approach in the review and assessment process:

  - **Type of regulated facilities** - The radiological hazards and complexity of the design of the facility will influence the resources and decision-making in the review and assessment process.
  - **Regulator resources** - Need for level of expertise for specific areas and consideration of competing resource requirements. 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].
  - **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 facilities in the specific regulations. The amount of information to be reviewed by the regulator will influence the resource allocation.
  - **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 facilities, for example, more detail information may be required for high risk facilities as compared to low risk facilities.
  - **Reviews and assessments performed by other regulatory bodies when applicable** - This factor should take into account the differences in the legal and regulatory framework of the regulatory bodies concerned.
  - **Experience and knowledge** – Another important factor is the knowledge gained from operating experience in reviewing and assessing existing facilities or utilizing the results from previous reviews.
  - **Urgency for need of licensing action** – Regulatory activities that are time sensitive may impact the resource effort associated with the review and assessment process.
  - **Alternative approaches, different from those specified in requirements** – Unique approaches described in applications will require greater effort to confirm that the intent of requirements is met.
  - **Novel analysis methods, codes, and models are used** – Methods, codes and models that have not been previously accepted or approved by the regulator will require additional resource effort to determine acceptability.
  - **Novel design features** – New or unique design features will require additional resource effort to determine acceptability.
  - **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 determining the appropriate resource effort required that is commensurate with the scope and depth established for the review and assessment. When comparing appropriate resource requirements 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 Support Organizations (TSO) in support of its regulatory functions.

In some situations, based on the radiation risks posed by the facilities, 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 jurisdictions, the regulatory body may not adjust the scope or depth of the review.

Use of Graded Approach in Assessing Deviations from Requirements or Accepted Practices in the Review

The 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 should be commensurate with the hazard posed by the deviation. A determination of safety significance of the deviations should use a structured, documented method, preferably as part of the management system.

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

- **Step 1:** Identify deviations from accepted practices where the applicant has provided insufficient justification for the deviation – could be discovered during the acceptance review or during the detailed review.

- **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 the graded approach in the review and assessment process:

  - **Type of regulated facilities** - The radiological hazards and complexity of the design of the facility will influence the resources and decision-making in the review and assessment process.
  - **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 facilities in the specific regulations. The safety significance of information to be reviewed by the regulator in respect of the identified deviations will influence the regulatory decision-making.
  - **Reviews and assessments performed by other regulatory bodies when applicable** - This should take into account the differences in the legal and regulatory framework of the regulatory bodies concerned.
  - **Experience and knowledge** – Another important factor is the knowledge gained from operating experience in reviewing and assessing existing or similar facilities or utilizing the results from previous reviews.

- **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.
- **Alternative approaches, different from those specified in requirements** – Unique approaches described in applications will require greater effort to confirm that the intent of requirements is met.
- **Novel analysis methods, codes, and models are used** – Methods, codes and models that have not been previously approved by the regulator will require additional resource effort to determine acceptability.
- **Novel design features** – New or unique design features will require additional resource effort to determine acceptability.
- **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 making regulatory decision taking into account:

  - Identification of the deviations in information and knowledge and assessing the significance of the deviations.
  - The need for adequate compensatory measures or additional controls to be identified to address the deviations.

3.4. INSPECTION OF NUCLEAR FACILITIES

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

- **Step 1:** Identify structures, systems, and components (SSCs) that are important to safety. The regulator should 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. For the development of the inspection programme, the regulator should compare all nuclear facilities holistically to focus more resources in accordance to the potential radiological hazard of the facilities

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

  Member States may want to consider performance indicators such as those described in IAEA-TECDOC-1141 (*Operational safety performance indicators for nuclear power plants*).

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

  - **Resources** - Available regulatory resources, including the expertise of the inspectors, need to be considered in establishing oversight programmes across

nuclear facilities. Appropriate resource allocation and frequency of inspections are defined by considering the potential radiological hazard of the regulated facilities. More resources are often dedicated to the higher risk facilities.

- **Type of regulated facilities** - Facilities that pose a greater risk to the public should be expected to have a greater inspection effort than facilities that pose less risk to the public. For instance, in general, operating power reactors pose a greater risk to the public than low power research and test reactors, and therefore would be expected to have a more comprehensive inspection programme.
- **Stage in the lifetime of the facilities** - Inspection of facilities under construction must have a inspection programme to ensure the facility is constructed in accordance with the approved design. Inspection programmes for operating facilities are also thorough to verify the licensee is conducting operations in a manner that protects the public health and safety. Facilities being decommissioned may have significantly lower risk to the public, in comparison with similar facilities in operation and therefore should 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.
- **Facility design** - The next generation of reactor plant 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 should 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 necessary to inspect, or a reduction in the frequency of some inspections, in order to provide reasonable assurance that the facility is being operated safely and in accordance with its license conditions. In addition, design modifications may require adjustments to the baseline inspection programme.

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

- **Licensee performance** - Consideration should 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.
- **Operating and construction experience** - Operating and construction experience generally focuses on safety-significant issues. Regulatory bodies should determine if specific operating experience applies to licensees they regulate, and ensure 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.
- **Regulator experience** - As experience is gained by the regulator in inspecting facilities 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.

Regulator experience should also consider domestic as well as international experience when developing both baseline and reactive inspection programmes.

- **Age of the facility** - As facilities age and approach their design life, there should be an increased focus on equipment performance, particularly for items important to safety. For facilities that are allowed to operate beyond their design life (life extension), licensees should reinforce their ageing management programmes. These programmes should 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.
- **Special and infrequently performed activities** - During the operating life of a nuclear installation, there may be times when the licensee is performing major rework during which the regulator should provide some additional oversight. For nuclear power plants for instance, such activities include steam generator replacement, reactor vessel head replacement, refuelling activities, digital control modifications, etc. Regulators should plan to provide additional inspection resources to ensure these infrequently performed activities are conducted safely.
- **Significant events** - Regulating bodies should consider additional inspection effort for any nuclear facility at which a significant event has occurred. That inspection effort should 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 making allocation of efforts by means of:

    - **Determining the appropriate resource effort** required to carry out the inspection programme, taking the applicable factors into account. In this step, the regulator determines the appropriate inspection sample size and frequency. Resources must also be allocated for contingency purposes, such as emergent safety significant issues or event response.
    - **Scheduling the inspections** in accordance with the appropriate resource requirements. When preparing the inspection programme, the organization will need to take into account the safety significance of the facilities and the appropriate resource requirements (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 activities, or if additional resources need to be procured.

Step 1 may be skipped should a regulatory body review or amend the inspection effort while maintaining the scope of the inspection programme. When new regulatory requirements necessitate updating the baseline inspection programme, the regulator should return to Step 1.

Non-compliances identified during inspections will be dispositioned using the enforcement process described in Section 3.5.

3.5. ENFORCEMENT

The following describes a proposed methodology in applying the graded approach to the enforcement regulatory function for nuclear facilities.

The regulator should develop a formal process for integrating the factors into the enforcement determination, and that process should be part of the management system. The formal process should 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 the 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 should be ranked by importance and determine if 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 the graded approach for the enforcement process:

  - **Safety significance of the violation or non-compliance** - This will be one of the greatest factors in determining the appropriate enforcement action. As the risk to workers or the public increases, the type of enforcement action should increase, commensurate with that risk. The other factors listed may either mitigate or escalate the type of the enforcement action.
  - **Identification credit** - The regulator might mitigate the enforcement action if the licensee self-identified the issue. This policy will encourage licensees to find problems and correct them before the regulator identifies them by reducing the expected enforcement action.
  - **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 regulator might consider a more stringent enforcement action.
  - **Repetitiveness of a non-compliance** - This factor increases the significance of the enforcement action.
  - **Frequency of deficiencies or violations should be addressed** - More frequent deficiencies might be indicative of a broader or systemic problem at the nuclear installation. The regulator 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 significant enforcement actions.
  - **Wilfulness** - If a licensee wilfully violates a regulatory requirement, this escalates the seriousness of the violation, and the appropriate enforcement action should reflect that seriousness.

- **Step 3:** 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 regulator must disposition it, and a graded approach can be used in determining the appropriate regulatory action based on the significance. The regulator should establish several options for disposition with defined criteria. Enforcement actions by the regulatory body may include, from paragraph 4.55 of GSR Part 1 (Rev.1):

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

Additional enforcement actions may include:

- Orders;
- Decertification of individual; and
- Prosecution in a court of law.

3.6. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

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

- **Step 1:** Identify the level of stakeholder involvement or the communication required.

  For Step 1, what needs to be communicated, and to whom? What facility or issue is being addressed that requires 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 regulator should consider both generic and specific factors. Identified factors should be 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 the graded approach for communication and consultation with interested parties:

  - **Public interest** – This is the single 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.

- **"Perceived" safety significance -** Oftentimes with the public, perception is reality. 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 should be used to describe clearly and accurately the actual risk or safety significance to the public.
- **Timely communication** – This factor is important to establish public trust that the regulator 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.
- **Types of activities** – In general, a communication plan should include:
  - Significant events;
  - Licensee performance;
  - Regulatory framework development;
  - Licensing activities; and
  - Public meetings.
- **Statutory requirements -** Requirements established by legal framework of member 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 should 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 should 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 facility and regulatory activity that may be of public interest. The communication plan should address different communication protocols based on the significance of events at nuclear facilities. For example, a general emergency at an operating nuclear power plant will require a very detailed communication plan using all tools available, while a lesser significant event may require fewer tools, if any.

  For Step 3 with respect to consultation with interested parties, the activities (e.g., siting, licensing amendments, and proposals for development of regulations) requiring consultation are generally prescribed, and not amenable to using the graded approach. The 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.

4. CRITERIA USED FOR THE EXAMPLES IN THE TECDOC

The examples in the Annexes of the TECDOC were selected based on the following contents criteria:

1. Each Annex (example) should have a reference in the applicable section in the body of the report.
2. It should align with the 3-step methodology as much as possible. If not, it should explain the alternative method.
3. It may demonstrate only one step of the methodology.
4. Specific, easy to follow. If possible, it should contain reference to the RB publicly available document (regulation, guideline, procedure, policy, etc).
5. When available, it should show rank of factors, or relative ranking level (numbers do not need to be real numbers from the program, but they should show proportionality. Should avoid unsubstantiated numbers not to mislead other RB trying to use the method).

The criteria established for the acceptance of papers for the Technical Meeting are slightly different from these described in this Section. In the Technical Meeting, the criteria are more flexible to allow for considering different graded approach methodologies being used by Member States. However, the methodology to be presented must be comprehensively described and the proposed practical examples should follow a similar formatting than those used in the Appendixes of this Summary Report.

Refer to the acceptance criteria for submitting papers presented in the information sheet of the Technical Meeting.

APPENDIXES

As part of the Summary of the TECDOC, the Appendixes provide examples on the use of the graded approach methodology for a regulatory function in practical situations.

The draft TECDOC provides thirty-one (31) practical examples to all core regulatory functions to support regulatory bodies on grading requirements and resource allocation on their regulatory activities.

Appendix I. PRACTICAL EXAMPLE: GRADED APPROACH IN AUTHORIZATIONS OF NUCLEAR FACILITIES IN CANADA

This example illustrates the application of the 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?

The regulatory body's Commission 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 generic factors described in Section 2.2, the following specific factors are considered in the application of the graded approach in authorization of nuclear facilities:

- **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 facility.
- **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.

- **Statutory requirements** – requirements established by legal framework of member state.
- **Types of authorization to be issued at various stages** - permits and licenses, and the safety significance of changes requiring authorization.
- **Level of stakeholder involvement** – increased stakeholder interest will sometimes drive the perceived significance of an issue higher, resulting in increased authorization levels.
- **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*, 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.

Designated Officers:

Under subsection 37(1) Nuclear Safety and Control Act (NSCA) [11], 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 [11];
- 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:
  - Nuclear Substances, Prescribed Equipment and Prescribed Information
  - Dosimetry Services
  - 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.

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 provide below.

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 shall be completed prior to reactor restart;
- a statement regarding plant readiness to resume safe operation. This shall 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.

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 shall submit Completion Assurance Documents (CADs). In addition to these CADs, the licensee shall 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 shall 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.

Authorization of changes to documents or operations proposed by licensees

Licensees shall 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 facility design 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 items important to safety,
- 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, and
- causing hazards or risks different in nature or greater in probability or magnitude than those stated in the safety analysis of the nuclear facility.

Appendix II. PRACTICAL EXAMPLE: 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. The graded approach depends on the risk to the public and the complexity of the design of the facilities.

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 license 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 facility designs.

NUREG-0800 [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 describes the general requirements for a license application for a design certification, or a combined construction and operating license, 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 also contains the review requirements for the proposed technical specifications for the operating nuclear power plant.

Because NUREG-0800 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 [13] 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 License Applications [14]," 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;" that is, facilities that are authorized for or are seeking a license to possess and use more than a critical mass of SNM. 10 CFR Part 70 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 license 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 [15] is the Standard Review Plan for Spent Fuel Dry Storage Facilities (FSRP), which provides guidance to the NRC staff for reviewing applications for license 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 installations. 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 ranked.

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 license 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 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 modelling, 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 must be met by an SSC do not change under the SMR framework. Under the 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.

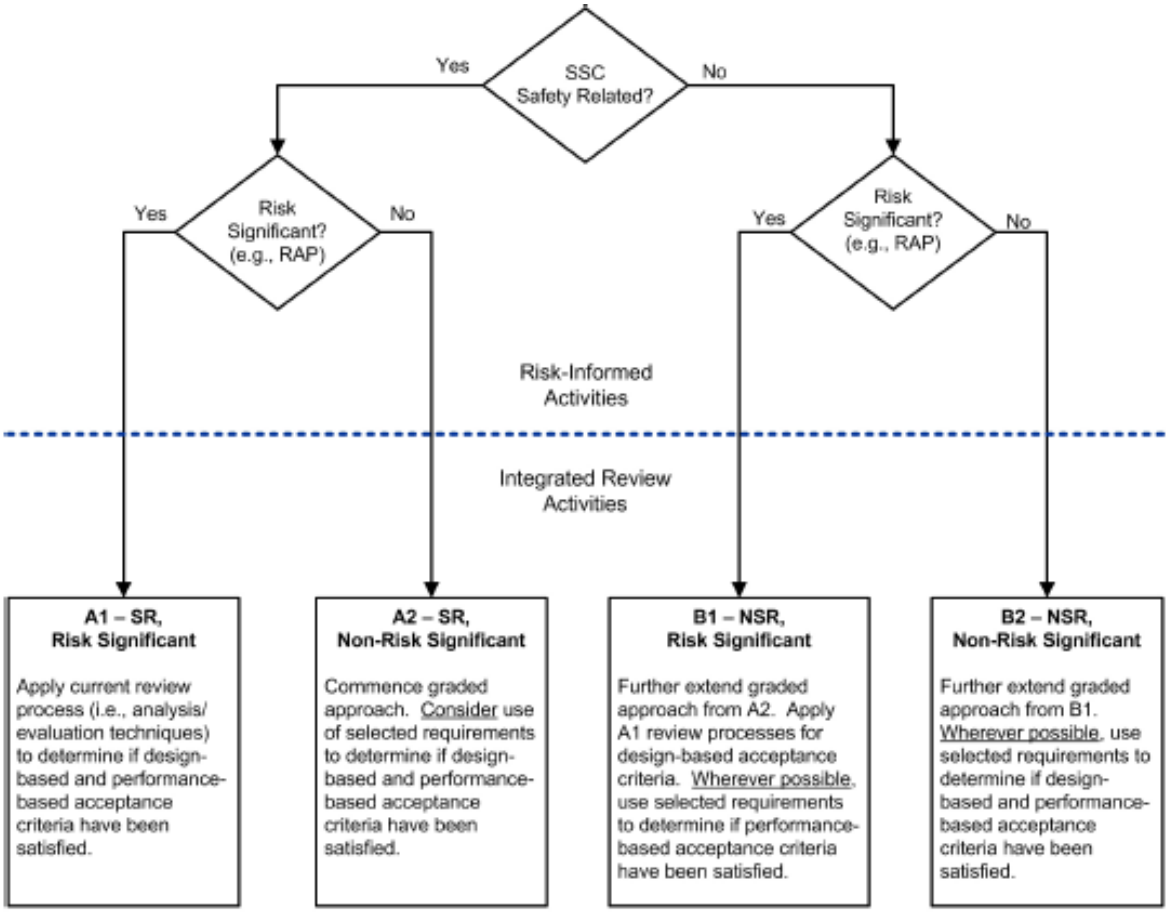

FIG. 1 - Determination *of Review Levels (A1 through B2) for design-specific review standard (DSRS)*

The verification of whether an SSC is safety-related (i.e., satisfies any of the criteria in 10 CFR 50.2), 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 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.

The NRC establishes goals for completion times for different types of license 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 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, which represents one staff member working full time on the project.

Table 2 – Estimated resources for review activities

	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 License 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 license renewal reviews require approximately 20 FTE and $350,000 in contractor support.

The NRC generally manages resources based on licensee notification of pending license applications. There is an expectation that licensing reviews are completed on schedule. Applicants must plan budgets, order equipment, and develop contracts well in advance of issuance of the license, 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.

Appendix III. PRACTICAL EXAMPLE: ENFORCEMENT - GRADED APPROACH TO MAKING ENFORCEMENT DECISIONS IN THE UK

ONR's enforcement guidance [16] 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:

- ensure consistency in the enforcement decision making process;
- ensure proportionality and targeting by considering the risk based criteria against which decisions are made;
- provide a framework for making enforcement decisions transparent, and for ensuring that those who make decisions are accountable for them;
- help inspectors assess their decisions in complex cases, and allow peer review of enforcement action; and
- 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.

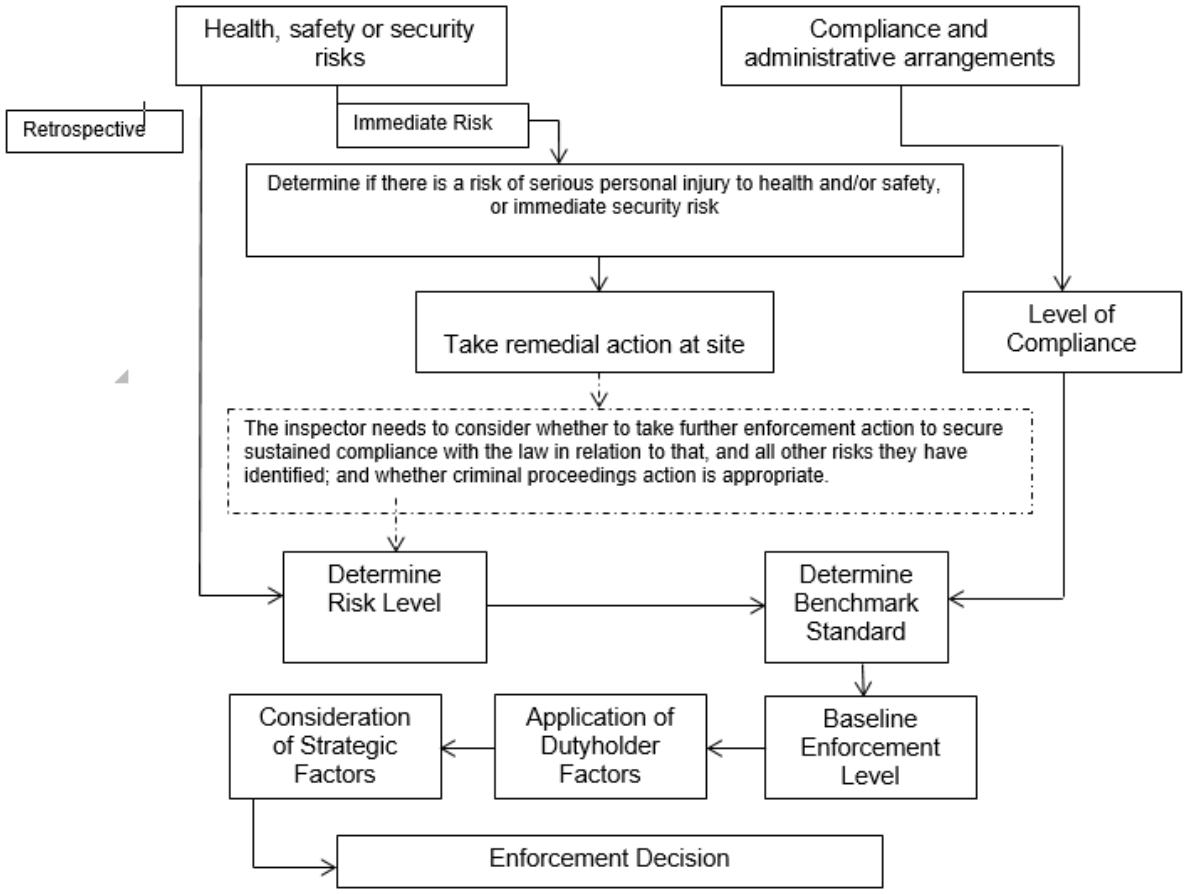

FIG. 2 - Enforcement decision making flowchart

Step 2 – Determine which factors are applicable to the enforcement decision and rank them.

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.

Table 3 - Derivation of 'Risk Level'

Consequence	Control measures: Broadly satisfied	Weakened	Absent/ inadequate
Serious	Nominal	Substantial	Extreme
Significant	Nominal	Moderate	Substantial
Minor	Nominal	Nominal	Moderate

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 4 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 5.

Table 4 - 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 organisations. 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 5 – Derivation of Baseline Enforcement Level

		Baseline Enforcement Level (to secure compliance with the law)	**Consider Prosecution**
Risk Level	**Benchmark Standard**		
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	

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 table below lists 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.

- **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?

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 must ask is: 'Does the proposed action meet the principles and expectations captured in the Enforcement Policy Statement (EPS)?'

- **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

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.

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:

- that the application and evidence for dutyholder factors has been appropriately applied if the BEL has been escalated.
- that the application of strategic factors is addressed by the proposed enforcement action.
- whether the proposed enforcement action meets the EPS,
- 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 utilising ONR guidance on Resolving Differences Of Professional Opinion In ONR (Ref. 10) 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.

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