SMR Regulators' Forum

Pilot Project Report

Report from Working Group on Graded Approach

January 2018

APPENDIX II - REPORT FROM WORKING GROUP ON GRADED APPROACH

SMR REGULATORS FORUM

GRADED APPROACH WORKING GROUP (GA-WG) REPORT

Executive Summary

The concept of Graded Approach[1] is widely discussed in the IAEA safety framework including in documents applicable to nuclear power plants. The national regulatory frameworks for all SMR Regulators' Forum Member States were reviewed and in all cases, evidence of the use of a Graded Approach exists in one form or another. Essentially, the Graded Approach means that the level of analysis, verification, documentation, regulation, activities and procedures used to comply with a safety requirement should be commensurate with the potential hazard associated with the facility without adversely affecting safety. In some cases, analyses may result in the need for less protective measures, but the opposite is also true. Supporting information influences how the Graded Approach is applied in specific cases. In fact, a Graded Approach can also provide insights that lead to the need for more protective measures.

Use of the Graded Approach can enhance regulatory efficiency without compromising overall safety by focusing on specific issues that are important to safety.

Applying a Graded Approach in reviewing an application for a license[2] to perform a set of activities requires the regulatory staff to have a global understanding of a project, risks presented by activities and approaches to prevent and mitigate events following a defence in depth approach The use of grading by both an applicant for a license and the regulator is heavily influenced by the information supporting the safety proposal. So-called 'proven' approaches and concepts are generally well supported and lend themselves to a more straightforward safety case assessment. In those cases, a regulator's technical assessment can then be focused on more innovative part of the facility where uncertainties are higher and additional margins or even safety and control measures may be needed. Generally, the more proven the approaches and concepts are in a new reactor design, the more straightforward and efficient the regulatory review will be. This presents a significant conundrum for developers of new technologies such as Small Modular Reactors that utilize more advanced technologies with a goal to enhance both safety provisions and economic performance. In this case, the design may be composed of fewer systems, but these systems will seek to employ passive and inherent behaviours. The argument made by proponents is that this should lend itself to greater use of grading; however, in practice, these approaches are still developing the necessary evidence to demonstrate 'proven-ness'. Until the proven-ness has been established, it is difficult to claim credits for those features in a safety proposal because uncertainties need to be addressed and factored into the safety demonstration. In addition, regulatory attention in a technical assessment must factor in uncertainties from these proposals into licensing decisions. This is of particular importance for new SMR technologies, and particularly for demonstration projects and first-of-a-kind designs where uncertainties are greater. For example, a demonstration project generally integrates a number of novel features such a new fuels, passive and inherent features and compact arrangements of Structures, Systems and Components (SSCs). The intent is to demonstrate integrated performance and gather operating experience (OPEX) to further support safety claims and effectiveness of plant features. Lack of OPEX per novel feature increases uncertainties which are then individually reflected in safety analyses and affect the overall outcomes. The regulatory process would seek to understand how uncertainties are being addressed in the design and in operation until the OPEX has been generated and reviewed. In past practice, this has resulted in the need for supplemental measures in the demonstration plant such as greater safety margins, additional SSCs, restrictions on the operating envelope.

From a safety perspective, member regulators in the SMR Regulators Forum agree that SMRs should be treated as Nuclear Power Plants (NPPs) and that the starting point in use of the Graded Approach is the requirements established for NPPs. In general, IAEA and national regulations requirements and guidance can be applied to activities referencing SMRs. Nevertheless, there may be a need for regulators to define specific

[1] Alternate terminologies such as "proportionality" are used in some Member States but the intent of the term is essentially the same.
[2] Some Member States may refer to these as authorizations, or permissions.

requirements in special cases such as marine based facilities where different requirements are justified. Then, the way the applicant demonstrates that their requirements are met may be graded.

This report articulates common views and recommendations from the IAEA Member State regulatory bodies regarding the meaning of Graded Approach, how it is being used, common conditions and considerations concerning its use for application of technology neutral requirements to new technologies.

One of the key findings of this Working Group is that although grading has been used since the beginning of the nuclear power industry, questions remain within the regulated community about appropriate ways to perform grading in design and safety analysis work. There are numerous tools that one can use to implement the Graded Approach and document decision making around how to meet regulatory requirements; however, there is no consensus on appropriate application in specific cases. At the centre of this discussion remains the scope and depth of technical information needed to support a safety proposal: That is, the industry is asking 'what is necessary to demonstrate proven-ness'? Conversely, SMR proponents are looking for more objective-based regulatory approaches with less prescriptive requirements that also recognize new safety approaches. This has resulted in a dilemma for regulators who are seeking to develop a balanced regulatory framework adaptable for a wide range of technologies.

Member State regulatory bodies have the responsibility (e.g. per the IAEA Safety Fundamentals) to ensure that the national regulatory framework for safety is established and implemented to regulate the use of nuclear power. The regulatory framework in each country is developed using the national legal framework and considers both the IAEA safety framework and inputs from stakeholders such as industry, scientific bodies, government and the public. As a result, differences between national frameworks can and likely will always exist. However, regulators also have a history of collaborating in the development of requirements and guidance and are continuing to develop common approaches even if they are not identical. In many cases, similar requirements and guidance exist. The question is raised on the possibility to go further, by sharing views on a given concept, taking into account vendor's constraints in terms of design, manufacturing and operation to develop economically viable concepts, e.g., deploying an identical design in several countries.

One key conclusion of this report is that significant benefit could be gained if the IAEA were to lead the development of a technical document that further explains what the Graded Approach is, how it is used to ensure safety for Nuclear Power Plants and how existing tools are used to develop high quality information to inform a decision making process. As a result, the SMR Regulators' Forum should promote and participate in the development of this document. This document should also speak to specific case studies that explore the implications of measures such as passive safety, inherent safety and use of conservatism in addressing regulatory requirements taking into account the use of tools such as:

- Results from R&D activities;
- Safety analysis tools (e.g. hazard analysis, deterministic safety assessment, probabilistic safety assessment); and
- Quality-assured use of Professional Judgement (management system considerations).

The aim of this document is to inform both embarking countries and experienced countries exploring new technologies how regulatory frameworks can articulate the use of the Graded Approach in regulatory requirements and guidance.

1. Background

Regulators are either engaging or are preparing to engage with proponents who are preparing safety cases that will involve the use of SMR[3] technologies. These proposals are being anticipated to contain safety claims using novel approaches and technologies that will be based on present or alternate interpretations of existing regulatory requirements or present new safety approaches where regulatory requirements may not exist. This will require both the regulators and the regulated to assess the use of a Graded Approach[4] to confirm novel approaches or technologies being proposed will result in a level of safety commensurate with the risks presented by the proposed activities. The SMR Regulators' Forum agreed that there is a need to clarify the regulatory view of grading and what this means in the context of addressing novel approaches being proposed for SMRs.

The GA-WG was established to:

- Develop an understanding of each Working Group Member State's policies and application of the Graded Approach, with a focus on how it might be applied, by the regulator and the regulated, to address novel approaches and technologies being proposed for SMRs.
- Seek out and document existing sources of information on the possible use of the Graded Approach within the IAEA framework of documents with consideration of additional information that may be available from the OECD/NEA.
- To further elaborate (e.g. for industry and public understanding), what application of the Graded Approach means in the context of regulated activities that involve the use of SMRs.
- To identify common practices/positions to facilitate improved discussions between Member States.

The GA-WG established a two year project to explore and document:

- How the Graded Approach is considered and used by regulators, the regulated and the decision-making process (e.g. Commission Board). In this regard, this report elaborates on how this is done within existing frameworks for new build reactor facilities and discusses this topic in the larger context of how regulators are preparing to engage with proponents and stakeholders. For example, SMR specificities such as use of inherent safety principles, transport of factory fuelled and sealed reactor modules (particularly with irradiated fuel), multiple module facilities and/or multiple facility sites, and site acceptance of factory manufactured modules).
- The impacts of uncertainties on application of the Graded Approach. (using experience from existing facilities and new build projects) For example, the approach to grading would be different for activities involving a first-of-a-kind design versus an "nth"-of-a-kind.
- Tools used by regulators, their Technical Support Organisations and licensees to prepare and assess proposals that involve grading with a focus on SMR features, particularly when multiple features are used. For example, expectations regarding level of supporting information (evidence) from the proponent and levels of scientific information the regulator needs to conduct a suitable level of technical assessment.

This issue specific working group is composed of volunteer representatives from the following IAEA Member States who are also members of the SMR Regulators' Forum:

- Canada - CNSC
- France – IRSN
- Russian Federation – Rostechnadzor
- United States – U.S. NRC

The group is composed of subject matter experts from the regulatory bodies and/or their TSOs with skills/experience in the following areas:

[3] Refer to the Terms of Reference for the SMR Regulators' Forum for a definition of SMR.
[4] The starting point for WG discussions will be the IAEA definition of the term; however the survey will attempt to draw out differences from Member States.

- Broad knowledge of risk-insights (including safety analysis) in the regulatory agency and how they are addressed in management system processes and procedure for technical assessment and compliance.
- Experience in developing licensing bases (particularly in addressing novel features for nuclear power facilities and/or research reactors).
- Experience in defining and applying regulatory requirements under different risk scenarios.

2. Structure of Report

Section 3 of this report discusses the following topics based on the results of a Member State survey performed by the GA-WG. The survey questions are listed in Appendix V.

- Interpretations of the Graded Approach by Member States and how it is articulated in their regulatory frameworks, including how it is interpreted and articulated in the IAEA framework of Safety Standards and Guides.
- Commonalities and differences regarding the Graded Approach that exist among Member States and the reasons why they exist.
- Experience with the Graded Approach in Member States, including, applications, practices and key insights.
- Use of the Graded Approach in developing a safety proposal.
- Considerations in regulatory assessment of complex safety proposals using a Graded Approach.
- Considerations on Using the Graded Approach in the Licensing Process for Activities involving SMRs.

Section 4 then summarizes the conclusions of the GA-WG, makes recommendations for consideration by the IAEA and the participating Member States in their own regulatory framework development plans and includes possible common positions for inclusion in the overall SMR Regulators' Forum Report.

Appendix A provides a summary of the review of IAEA safety standards and guides performed by the GA-WG.

3. Discussion

3.1. INTERPRETATIONS OF DEFINITION OF GRADED APPROACH

3.1.1. Introduction

Society generally recognizes that although risks can and should be significantly reduced to the extent practicable, most risks cannot be completely eliminated for practical reasons. This recognition is normally articulated in government policy documents as well legislation designed to regulate industries where hazards exist but benefits to society can be realized if those hazards are controlled by appropriate means.

Specific to the nuclear energy sector, a fundamental safety principle in IAEA Member States is that it is the responsibility of the licensee of an activity to ensure that their facilities and activities do not pose an unreasonable risk5 to persons and that a focus is always maintained on safe conduct of activities. The processes of licensing, compliance and enforcement used by a regulatory body are designed to provide independent assurances that this is the case at all times.

Much of the conversation between stakeholders (e.g. regulator, proponent and the public) generally focuses on what level of risk is acceptable given the understanding of the factors that impact risk. By reducing the radionuclide inventory and therefore potential of energetic phenomenon that may occur, SMRs may offer the possibility of a significant reduction in consequences6, and therefore risk. However, safety and control measures will still be necessary to ensure safety and methods must exist to confirm they will be adequate, that is they will meet requirements established to ensure safety.

[5] Regulatory mandates and regulatory terminologies vary from country to country but in addition to radiation safety may include other key areas such as environmental protection, security and safeguards

[6] For example, many small units instead of a single unit

To inform a stakeholder conversation about ‘reasonable risk’ in a specific technology application, one must compare a safety case proposal against requirements (i.e. rules society has agreed are necessary to be addressed to ensure risk remains low). The proponent makes a case that proposed safety and control measures have addressed those requirements and it is the regulator’s role to determine whether the proponent’s case is credible and should be permitted to perform the proposed activities.

3.1.2. What is the Graded Approach?

Based on discussions within the GA-WG informed by insights from the GA-WG survey, there was general agreement within the group that the concept of Graded Approach can be best described to be a set of processes, methodologies and procedures used by an organization as part of their management system to:

- evaluate risks,
- evaluate information on generally acceptable ways to address risks based on proven past practices,
- judge that safety and control measures will meet requirements necessary to ensure safety, and
- confirm that that safety and control measures are, in fact, performing their functions as designed

Use of a Graded Approach means that the level of analysis, verification, documentation, regulation, activities and procedures used to comply with a safety requirement needs to be commensurate with the potential hazards associated with the facility without adversely affecting safety. In some cases, analyses may result in the need for less protective measures, but the opposite is also true. In fact, a Graded Approach can also provide insights that lead to the need for more protective measures.

The output of the use of a Graded Approach is a quality-assured documented trail of how appropriate decisions (i.e. using judgement) have been made concerning issues important to safety. The credibility of judgement is directly impacted by the credibility (e.g. rationale and quality) of the processes, methodologies and procedures used.

Note on the term “Safety and Control Measures”

When used in this report, the term ‘safety and control measures’ is used to describe the complete set of human performance processes (e.g. under the licensee’s management system) acting in concert with design provisions for the technologies used by the licensee to perform licensed activities. These measures are used to demonstrate that the activities represent no unreasonable risk to persons as judged in the licensing process and confirmed through regulatory compliance activities. The use of safety and control measures is an integral part of a Defence-in-Depth strategy.

The proponent/licensee and the regulator use the Graded Approach in different ways:

Proponent/licensee

- The applicant for a license provides, in their application, sufficient evidence that their activities will be conducted safely and that they meet requirements. The amount of information expected to be submitted to support the safety claim is informed by the uncertainties presented by the approach or terminology.
- using a Graded Approach ensures that their resources are focused on implementation and management of appropriate safety and control measures.

Regulator

- The regulator uses a Graded Approach to:
    - decide how to review the application (using risk insights) and conduct the review
    - decide whether the application adequately demonstrates activities will be conducted safely and that they meet requirements
    - plan and perform compliance activities (e.g. inspections, programmatic reviews) against the licensing basis.
- Use of the Graded Approach enhances regulatory efficiency and keeps the focus on the regulator's assessment of proponent activities that impact safety.

3.1.3. Implications of uncertainties on judgement

Use of the Graded Approach must also address uncertainties in the underlying science to ensure that the final safety and control measures are credible. Regulators expect proponents to address uncertainties in their proposals by providing evidence that they have an understanding of the uncertainties and have factored them into their safety approach. This is of particular importance for new SMR technologies, particularly demonstration projects and first-of-a-kind designs, where uncertainties are greater and therefore the Graded Approach would be applied differently. For example, lack of operating experience would mean that more attention would need to be paid to the quality and sufficiency of the data underpinning the safety claims.

3.1.4. The Graded Approach in the IAEA Safety Framework

The concept of Graded Approach is articulated throughout the IAEA safety framework such as:

- Fundamental safety principles SF-1, 2006: Principle 3

  "*Safety has to be assessed and periodically reassessed throughout the lifetime of facilities and activities, consistent with a Graded Approach*."
- Fundamental safety principles SF-1, 2006: Principle 5

  "*Resources devoted to safety by the licensee and the scope are to be commensurate with the magnitude of the potential radiation risks*."

At the same time, there are societal expectations of a regulatory body around processes to ensure stability and consistency of regulatory control. The reason for this is that society needs confidence that decisions are being made taking into account societal concerns that exist within the regulator's legal mandate.

For example: GSR-Part 1 revision 1, *Governmental, Legal and Regulatory Framework for Safety*

Requirement 22: *The regulatory body shall ensure that regulatory control is stable and consistent*

> Clause 4.26. The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by individual staff members of the regulatory body. The regulatory body shall be able to justify its decisions if they are challenged. In connection with its reviews and assessments and its inspections, the regulatory body shall inform applicants of the objectives, principles and associated criteria for safety on which its requirements, judgements and decisions are based.

Requirement 26: Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a Graded Approach.

> Clause 4.39A. The regulatory body shall ensure, adopting a Graded Approach, that authorized parties routinely evaluate operating experience and periodically perform comprehensive safety reviews of facilities, such as periodic safety reviews for nuclear power plants. These comprehensive safety reviews are submitted to the regulatory body for assessment or are made available to the regulatory body. The regulatory body shall ensure that any reasonably practicable safety improvements identified in the reviews are implemented in a timely manner.
>
> Clause 4.41. Technical and other documents submitted by the applicant shall be reviewed and assessed by the regulatory body to determine whether the facility or activity complies with the relevant objectives, principles and associated criteria for safety.
>
> Clause 4.45. In the process of its review and assessment of the facility or activity, the regulatory body shall take into account such considerations and factors as:
>
> a) The regulatory requirements;
>
> b) *The nature and categorization of the associated hazards*;
>
> *c) The site conditions and the operating environment;*
>
> d) The basic design of the facility or the conduct of the activity as relevant to safety;
>
> e) The records provided by the authorized party or its suppliers;
>
> f) Best practices;
>
> g) The applicable management system;
>
> h) The competence and skills necessary for operating the facility or conducting the activity;
>
> i) Arrangements for protection (of workers, the public, patients and the environment);
>
> j) Arrangements for preparedness for, and response to, emergencies;
>
> k) Arrangements for nuclear security;
>
> l) The system of accounting for, and control of, nuclear material;
>
> m) The relevance of applying the concept of defence in depth to take into account inherent uncertainties (e.g. in the long term for the disposal of radioactive waste);
>
> n) Arrangements for the management of radioactive sources, radioactive waste and spent fuel;
>
> o) *Relevant research and development plans or programmes relating to the demonstration of safety*;
>
> p) *Feedback of operating experience, nationally and internationally, and especially of relevant operating experience from similar facilities and activities*;
>
> q) Information compiled in regulatory inspections;
>
> r) *Information from research findings*;
>
> s) Arrangements for the termination of operations.

The above clauses speak to the need for a technical assessment to be informed by uncertainties contained within proposals. Information to support a proposal needs to address how safety and control measures are ‘reasonably practicable’. The italicized items listed above are particularly important in introducing new technologies such as SMRs into a license application.

The use of the Graded Approach in safety assessment activities is reinforced in GSR-Part 4, Safety *Assessment for Facilities and Activities* as follows:

> Clause 1.5. *Implementation of the comprehensive set of requirements established in this Safety Requirements publication will ensure that all the safety relevant issues are considered. However, a Graded Approach must be taken to the implementation of the requirements, to provide flexibility.*

Hence, although it is anticipated that all the safety requirements established here are to be complied with, it is recognized that the level of effort to be applied in carrying out the necessary safety assessment needs to be commensurate with the possible radiation risks and their uncertainties associated with the facility or activity.

This clause clearly recognizes that uncertainties associated with novel approaches and/or technologies play a significant role in the scope and depth of safety assessment. This is in keeping with the requirements discussed above for GSR Part 1.

For research reactors, IAEA published SSG-22, Use of a Graded Approach in the Application of the Safety Requirements for Research Reactors to provide additional guidance to proponents of research reactors and regulators in application of the IAEA's safety requirements and guidance specific to a reactor used for the purposes of research. It needs to be recognized that the concept of a research reactor can range from non-power concepts to large facilities capable of putting out a significant (i.e. many megawatts) thermal output. For the larger facilities, the risks may be very similar to those found in a Nuclear Power Plant.

No parallel version of SSG-22 exists for Nuclear Power Plants to address the use of the Graded Approach for smaller nuclear power plants (which SMRs will be); however, if one carefully reads requirements and guidance in standards and guides applicable to NPPs, many examples of the use of the risk informed methodologies (which inform the Graded Approach) can be found.

3.1.5. The Graded Approach in Member States

This section presents a summary of how some Member States applying a Graded Approach.

<u>The Canadian Regulatory Framework</u>

In the Canadian regulatory framework, a Graded Approach is understood to mean a method or process by which elements such as the level of analysis, the depth of documentation and the scope of actions necessary to comply with requirements are commensurate with:

- the relative risks to health, safety, security, the environment, and the implementation of international obligations to which Canada has agreed
- the particular characteristics of a facility or activity In other words, a Graded Approach refers to how a set of risk-informed decision-making processes and tools will be used to ensure/assess that an approach addresses requirements.

The use of a Graded Approach is not a relaxation of requirements. This interpretation is in line with the IAEA definition and approach however CNSC's mandate extends into conventional hazards in addition to radiological hazards.

The application of a Graded Approach to both regulated activities (those of the licensee) and regulatory activities (those of the regulator) is long established in Canada and this practice is consistent with International Atomic Energy Agency (IAEA) requirements such as those described in GSR Part 1, Governmental, Legal and Regulatory Framework for Safety.

The Nuclear Safety and Control Act (NSCA) provides the Commission of the CNSC with the mandate to regulate the development, production and use of nuclear energy and the production, possession and use of nuclear substances, prescribed equipment and prescribed information. Use of risk informed approaches is articulated in the NSCA in clauses such as the following:

Section 3(a) Purpose (of the Act):

The purpose of this Acts is to provide for… … the limitation, to a reasonable level and in a manner that is consistent with Canada's international obligations, of the risks to national security, the health and safety of persons and the environment that are associated with the development, production and use of nuclear energy and the production, possession and use of nuclear substances, prescribed equipment and prescribed information;

Section 9 Objects (of the Commission):

The objects of the Commission are (a) to regulate the development, production and use of nuclear energy and the production, possession and use of nuclear substances, prescribed equipment and prescribed information in order to (i) prevent unreasonable risk, to the environment and to the health and safety of persons, associated with that development, production, possession or use, (ii) prevent unreasonable risk to national security associated with that development, production, possession or use,

Section 24 Licenses: 4)

No license shall be issued, renewed, amended or replaced — and no authorization to transfer one given — unless, in the opinion of the Commission, the applicant or, in the case of an application for an authorization to transfer the license, the transferee (a) is qualified to carry on the activity that the license will authorize the licensee to carry on; and (b) will, in carrying on that activity, make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed.

In 2005, the Commission published regulatory policy document P-299 Regulatory Fundamentals which directed the use of the Graded Approach in its regulatory activities.

Section 4.2 Basing Regulatory Action on Levels of Risk stated:

The CNSC:

1. *Regulates persons, organizations, and activities that are subject to the act and regulations in a manner that is consistent with the risk posed by the regulated activity*
2. *Recognizes that risk must be considered in the context of the CNSC's mandate under the act*
3. *Makes regulatory decisions and allocates resources in a risk informed manner*

P-299 represented an official documentation of this direction which continues to be used to this day.

The CNSC management system framework integrates this direction into all staff activities as well as requirements and guidance in the regulatory framework. Through the above, the regulated sector is also enabled to employ the Graded Approach (i.e. risk informing tools) when proposing appropriate safety and control measures that will meet requirements. This is further supported in the General Nuclear Safety and Control Regulations which articulate the obligations of licensees in Section 12.

Regulatory documents and industry standards articulate safety objectives to be met to achieve this. In some cases, where deemed necessary, requirements may be articulated in more precise manner to provide clear direction. An example of this can be found in specific technical quality assurance standards such as those used for welding and joining of materials.

When an individual or organization proposes to conduct, and later conducts activities that present risks, CNSC utilizes a number of risk-informed-decision making processes and tools to analyze and confirm that those activities will be/are being conducted safely. Regulatory tools include:

- analytical tools:
  - expert judgement
  - computer simulations
  - engineering and scientific calculations
  - CNSC laboratories
  - third party laboratories
- CNSC's risk informed decision making process (RIDM) - a formal method for analyzing complex risk scenarios. Key elements of the RIDM process are:
  - issue definition

    - risk estimate and evaluation → risk significance level
    - risk control measures (RCM)
    - monitoring of RCM implementation
- information tools:
    - regulatory research activities
    - information from other regulators (bilateral or organisations such as Multinational Design Evaluation Program -MDEP)
    - information from stakeholder participation
    - information from knowledge-management agencies such as the International Atomic Energy, Nuclear Energy Agency
- management system tools:
    - CNSC cost-benefit analyses applied to the regulatory framework activities
    - internal work processes and instructions to guide assessments and inspections
    - internal expert groups or committees to analyze and recommend paths forward for complex issues
    - The use of decision matrices that define processes to be followed based on risk considerations
- global processes of the CNSC:
    - participant funding program (allows for the conduct of independent research by interested members of the public)
    - licensing processes
    - Commission meetings and hearings

To address differing levels of risk for various activities, regulations under the NSCA are structured to reflect different risk groups. Common cross-cutting regulations that impact all facilities and activities are articulated as separate regulations.

Regulatory documents that apply to each activity type as well as pertinent Canadian Standards Association (CSA) standards are listed here: http://nuclearsafety.gc.ca/eng/acts-and-regulations/regulatory-documents/index.cfm and are aligned with the regulations for each activity/facility type. Where regulatory requirements and guidance in a regulatory document is intended to be applied to a range of facilities of differing risk, requirements and guidance are worded and structured, where applicable, to be interpreted and applied in a risk informed manner.

In addition, many standards of the Canadian Standards Association such as CSA N-286-12, *Management System Requirements for Nuclear Facilities* either permit the use of the Graded Approach or are structured into specific categories of risk to facilitate risk informed decision-making.

3.1.6. The Graded Approach in the Chinese Regulatory Framework

Insufficient opportunity existed to engage with China for the GA-WG survey. The working group recommends that China be engaged in future interactions given their substantive involvement in new SMR work in addition to a large new build NPP deployment plan.

3.1.7. The Graded Approach in the Finnish Regulatory Framework

The principle of Graded Approach was added into the Finnish Nuclear Energy Act in the year 2013 (499/2013).

Section 7a of the Act states now that “Safety requirements and measures to ensure the safety shall be sized and allocated proportionate to the use of nuclear energy risks.”

Regulatory Guide YVL A.3, “Management system for a nuclear facility” requires that:

"The impact of products and activities on nuclear and radiation safety shall be identified and taken into account in defining the requirements set to them. The requirements shall be defined according to the safety significance of the products and functions so that the products and activities most important to nuclear and radiation safety are subject to the strictest quality requirements and quality assurance requirements and the most extensive measures for ensuring compliance with the requirements. The definition of the requirements shall also utilise the Probabilistic Risk Assessment (PRA) in accordance with Guide YVL A.7. The management system shall describe the application of the PRA and the principles of risk-informed decision-making.

Regulatory Guide YVL A.5, "Construction and commissioning of a nuclear facility" requires that:

"The quality management and quality assurance requirements set for products and functions by the [licensee's or vendor's] management system shall be graded and instructed in accordance with Guide YVL A.3."

"In order to assure an adequate level of quality, grading shall take into account in the following: safety significance of the product or function, technical exactingness and complexity of the product or function, uniqueness of the product or function and the resulting lack of experience and the product or function is new or first-of-a-kind."

The Government Decree on Safety of Nuclear Power Plants 717/2013 requires that

"High quality proven technology that has been thoroughly researched and tested is to be used for the different levels of the defence-in-depth."

All new approaches require demonstration of safety. For example:

> It would be a task for the applicant and the fuel vendor to show that the fuel can be safely operated in all operational states and accident conditions. Regulatory Guide YVL B.1, Safety Design of a Nuclear Power Plant requires that:
>
> "*If shared structures, systems and components important to safety are designed for nuclear power plant units located at the same plant site, it shall be demonstrated by reliability assessments that this does not impair the capability of these structures, systems and components to carry out their safety functions. If cross-connections are designed between systems of different nuclear power plant units performing the same safety function, it shall be demonstrated that these make the safety functions more reliable than they would be without the connections*."
>
> The size of the emergency planning zone is in Finland site specific
>
> Based on the licensee's justification, STUK can review how the licensee has evaluated the matter, what are the major safety requirements licensee have identified for application and how the safety requirements are fulfilled. This provides the basis for STUK's review work and gives opportunity to use Graded Approach in STUK's own actions.

New Regulatory Guides are written for new NPPs. STUK makes separate implementation decisions of the new requirements for operating NPPs, reactors under construction and research reactors. Basis for the consideration is licensee's assessment how the facility and organization fulfill requirements and what are licensee's possible development actions to reach the new safety level. The licensee has a right to propose an alternative procedure or solution to reach the safety goals. STUK's final opinion is given in the implementation decision. When deciding possible additional requirements for improvements a Graded Approach principle is considered especially when looking at the overall safety of the plants. There must be good justifications for the improvements and limited resources must be focused on the topics that have the most beneficial influence on safety. STUK can also approve exceptions from certain requirements if improvement actions needed are not reasonably practicable.

The Guide YVL A.7 "Probabilistic risk assessment and risk management of a nuclear power plant" requires use of the Probabilistic Risk Assessment (PRA) as a tool in every lifecycle phase of nuclear power plant. Use of risk based applications supports the Graded Approach principle by giving importance and priorities for the matters as well as making related risks visible.

3.1.8. The Graded Approach in the French Regulatory Framework

Although the term "Graded Approach" is not currently used in France, regulations setting the general rules applicable to the design, construction and operation for nuclear installations state that:

> *"Their application is based on an approach that is proportional to the extent of the risks or drawbacks inherent to the installation"* (order of February 7, 2012 http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000025338573&dateTexte=20150918).

As a result, the concept of Graded Approach is already addressed by the French regulation.

Practically, the level of safety requirements to be met by the licensee depends on many factors and is appreciated on the basis of a case-by-case approach, by engineering judgment. The safety demonstration is primarily based on a deterministic approach; probabilistic safety assessments are used for appreciating the efficiency of the design and operating provisions implemented. Safety requirements to be met are defined according to the general safety goals which have been previously fixed by the safety authority for the installation. The licensee may argue its position using risk-informed arguments. At the end, the regulator will take position on the acceptability of design and organizational provisions set up by the licensee.

A "Graded Approach" would be mainly supported by credible technical evidence such as design and operating experience feedback, ongoing R&D works. Code validation is requested for all applications. Safety margins should be well supported and the risk of cliff-edge effects should be, as far as possible, ruled out.

Technical assessment supporting the regulator decision-making process is safety-focused. A preliminary and overall assessment of the application is first made to identify the main safety issues to be dealt with. Then strategies for technical assessment may be defined, especially when the review is limited in time. TSO should be able to justify that this safety-focused review give a sufficient confidence in the capability of the licensee to operate safety its installation.

Particular attention is paid to innovative features and topics raised by OPEX. For already proven technology and provisions, evidence is required to demonstrate "transferability" (conditions and modes of operations, qualification results for transposability).

Analytical tools used in France to support decision-making process are the following:

- Expert judgment (including expert panels)
- Computer simulations
- Independent engineering and scientific calculations (PRA, studies)
- R&D technical assessment support activities
- Operating feedback analysis

3.1.9. The Graded Approach in the Regulatory Approach of the Republic of Korea

Insufficient opportunity existed to engage with Korea for the GA-WG survey. The working group recommends that Korea be engaged in future interactions given their substantive involvement in new SMR work in addition to new build NPP deployment domestically and overseas.

3.1.10. The Graded Approach in the Regulatory Framework of the Russian Federation

In pursuance of the Article 24 of the Federal Law "On the Use of Atomic Energy" (No. 170-FZ dated of November 21, 1995): "The measures undertaken by the state safety regulatory authorities to exercise their responsibilities shall be commensurate with the potential hazard of the nuclear facilities and activities in the field of atomic energy use".

There is no direct definition of Graded Approach available.

Article 24 of the Federal Law "On the Use of Atomic Energy" (No. 170-FZ dated of November 21, 1995) states: "The measures undertaken by the state safety regulatory authorities to exercise their responsibilities shall be commensurate with the potential hazard of the nuclear facilities and activities in the field of atomic energy use".

This Article legally empowers the regulatory authority to apply the Graded Approach in its activity.

In pursuance of the Decree of the Government of the Russian Federation No. 373 dated of April 23, 2012 the permanent state supervision regime is to be introduced at high-hazard facilities, which envisages all-time attendance of high-hazard facilities by the authorized representatives of the regulatory authority and taking actions by them on supervision over safety. Thus, the permanent state supervision shall be established depending on the potential hazard of a facility.

Licensing of an activity related to operation of nuclear facilities shall be carried out in line with the "Administrative Regulations for the Federal Environmental, Industrial and Nuclear Supervision Service on Execution its State Function for Licensing the Activities in the Field of Atomic Energy Use" (approved by Rostechnadzor Order No. 453 dated of October 8, 2014) (hereinafter to be referred to as the Regulations for Licensing). The Regulations for Licensing envisage conduct of the safety case review, herewith the item 70 states that development and approval of the task order for conduct of a safety case review shall be carried out by the designated subdivision of Rostechnadzor, and in addition the amount of certain topical issues included into the task order can vary depending on the type of activity and potential hazard of a nuclear facility. Deadlines for conduct of the review shall also be established depending on the scope of documents submitted to obtain a license and on the assumption of potential nuclear and radiation hazard of the facility, where the declared type of activity is to be performed (item 71).

Categorization of nuclear installations (as well as of all nuclear facilities) considering the potential radiation hazard shall be performed based on the "Basic Sanitary Rules for Radiation Safety" (OSPORB-99/2010) approved by the Chief State Medical Officer of the Russian Federation.

In accordance with the OSPORB-99/2010, nuclear facilities are subdivided into four categories of potential radiation hazard.

- Category I comprises radiation facilities, where an accident can cause radiological impact on population, and population protection measures may be required.
- Category II embraces radiation facilities, where accident radiological impact is restricted by the sanitary protected zone.
- Category III embodies radiation facilities, where accident radiological impact is restricted by the object boundaries.
- Category IV implies radiation facilities, where accident radiological impact is restricted by the premises, where the works with the radiation sources are carried out.

Assignment of categories to a radiation facility is based on evaluation of accident consequences, the occurrence of which has no relation to transportation of radiation sources beyond the facility site boundaries and to hypothetic external impact (explosions resulted from missiles, aircraft crash or terrorist act).

Depending on the category of a nuclear facility the requirements to siting and operation, as well as to the size of the sanitary protected zone, are established.

In compliance with the General Safety Provisions for all nuclear facilities the systems and elements are classified depending on their impact on safety. The requirements depend on the safety class: the equipment of the higher safety class can be distinguished by more strict reliability and quality requirements.

- Federal requirements for Format and Content of a Safety Analysis Report establish what is expected by the regulator in safety submissions for a license application (light water reactors, fast reactors, research reactors, marine reactors) and administrative rules prescribe the set of specific documents that shall be submitted to the regulator. Separate technical requirements exist for power plants versus research reactors and marine reactors. Within these categories however, the requirements are size independent, but may identify different requirements for different technologies as necessary.
    a) In pursuance of the Federal Law "On the Use of Atomic Energy" (No. 170-FZ dated of November 21, 1995) in the part of nuclear facilities, the following types of activities in the field of atomic energy use are to be subject to licensing: siting, construction, operation and decommissioning of nuclear facilities, design and engineering of nuclear facilities, engineering and manufacturing of equipment for nuclear facilities, conduct of safety review (safety case review) for nuclear facilities and (or) activities in the field of atomic energy use. As it was previously mentioned, the Regulations for Licensing envisage the conduct of safety case review, herewith the item 70 states, that development and approval of the task order for conduct of a safety case review shall be carried out by the designated subdivision of Rostechnadzor, and in addition the amount of certain topical issues included into the task order can vary depending on the type of activity and potential hazard of a nuclear facility. Deadlines for conduct of the review shall also be established depending on the scope of documents submitted to obtain a license, and on the assumption of potential nuclear and radiation hazard of the facility, where the declared type of activity is to be performed (item 71).
    b) There are available special-purpose regulatory documents (federal regulations and rules, safety guidelines) for the following nuclear facilities: nuclear power plants, nuclear research installations, shipboard nuclear installations and maintenance vessels, nuclear fuel cycle facilities, radiation sources, storage facilities. The analysis of the operating experience is implemented in the form of analysis of malfunctions in operation of nuclear facilities and in the form of annual assessment of the nuclear or radiation safety state. NPP safety shall be justified with the use of validated software only; safety of research reactors is allowed to be justified with the use of both validated and verified software. The correctness of cliff-edge effects is assessed in the course of safety assessment review.
    c) In order to justify a Graded Approach probabilistic analysis is not applicable. Probabilistic Safety Analysis is required to substantiate the safety of the nuclear power plants. For other types of nuclear facilities probabilistic analysis can be used by the licensee in its sole discretion.

3.1.11. The Graded Approach in the Regulatory Framework of the USA

There is no specific definition for "Graded Approach" in the United States, but the concept of focusing on safety significance, especially using risk insights, is referenced throughout various policy and regulatory documents. The Probabilistic Risk Assessment (PRA) Policy Statement, "The use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities," (60 FR 42622, August 16, 1995) formalized the Commission's commitment to risk-informed regulation through the expanded use of PRA. The PRA Policy Statement states, in part, "The use of PRA technology should be increased in all regulatory matters to the extent supported by the state of the art in PRA methods and data, and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defence-in-depth philosophy." The Commission further articulated the concept of a Graded Approach in SRM-SECY-98-144, dated March 1999, "White Paper on Risk-Informed and Performance-Based Regulation," by noting that "A risk-informed approach to regulatory decision-making represents a philosophy whereby risk insights are considered together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to public health and safety." It is recognized that this approach could either eliminate unnecessary conservatism or support additional regulatory requirements.

Regulations highlighting a Graded Approach concept specifically applicable to SMR design certification applicants include categorization of structures, systems, and components (SSCs) for nuclear power plants (i.e., Title 10 of the Code of Federal Regulations (10 CFR) 50.69) and requirements to provide descriptions and results of design certification and combined license PRAs for 10 CFR 52 applicants (i.e., 10 CFR

52.47(a)(27) and 10 CFR 52.79(a)(46)). Since 10 CFR 50.69 is a voluntary regulation, a combined license applicant that would like to use risk-informed treatment of SSCs in accordance with 10 CFR 50.69 would additionally provide required information per 10 CFR 52.79(a)(18).

To implement these regulations, regulatory guidance is provided for applicants. Applicants may use RG 1.206 (provides guidance related to the standard form and content for a 10 CFR 52 application) and RG 1.200 (provides guidance related to the adequacy of the PRA used as the basis for risk information) to prepare their applications. RG 1.174 discusses a risk-informed, integrated decision-making process using risk information, defence-in-depth, and safety margins. If an applicant chooses to categorize the design SSCs in accordance with 10 CFR 50.69, RG 1.201 provides implementation guidance. Specific references are identified below:

- RG 1.174, Revision 2, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," May 2011
- RG 1.200, Revision 2, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," March 2009
- RG 1.201, Revision 1, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance," May 2006
- RG 1.206, Revision 0, "Combined License Applications for Nuclear Power Plants (LWR Edition)," June 2007

Acceptance criteria for the application review are provided in guidance for use by the regulatory staff. A Graded Approach for SMR reviews is defined in NUREG-0800, Introduction –Part 2. This section implements the Commission direction to more fully integrate the use of risk insights into pre-application activities and the review of applications, consistent with regulatory requirements and Commission policy statements. The objective is to align the review focus and resources to risk-significant SSCs and other aspects of the design that contribute most to safety in order to enhance the effectiveness and efficiency of the review process. The staff has (or will) develop a design-specific, risk-informed review plan for each SMR to address pre-application and application review activities. This design-specific review standard should provide acceptance criteria for the staff review that addresses any technology differences from the current staff review guidance and use risk insights, if available, to streamline the 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 current review guidance), and a progressively less-detailed review to other SSCs as the assigned safety/risk significance declines. That is, the regulatory staff may rely on the applicant's submittal identifying selected requirements (e.g., testing requirements, technical specifications, quality assurance, maintenance, etc.) consistent with the safety/risk categorization of the SSC to demonstrate satisfaction of performance-based acceptance criteria in lieu of detailed independent analyses. Review acceptance criteria for the SMR design-specific PRA used to develop the risk-significance information are provided in NUREG-0800, Section 19.0, including criteria for the evaluation of risk associated with a plant containing multiple modules. Specific references are identified below:

NUREG-0800, Introduction-Part 2, Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: Light-Water Small Modular Reactor Edition, Revision 0, January 2014

NUREG-0800, Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: Light-Water Small Modular Reactor Edition, Section 19.0, Probabilistic Risk Assessment and Severe Accident Evaluation for New Reactors, Revision 3, December 2015.

3.2. COMMONALITIES AND DIFFERENCES BETWEEN THE PARTICIPATING MEMBER STATES

What common elements exist between regulatory bodies?

All of the regulators that responded to the survey recognized the need for flexibility in approaches for safety and control measures without compromising safety. In many cases, they already have the tools and past experience to address SMRs related proposals. In others, specific new safety and control measure proposals may require the regulator to apply greater use of professional judgement until operating experience has been demonstrated. This will need stronger supporting information from the proponent when engaging with regulators to address the greater uncertainties presented by a lack of operating experience.

From a safety perspective, all regulators who responded to the survey agree that SMRs should be treated as Nuclear Power Plants (NPPs) and that the starting point in use of the Graded Approach is the requirements established for NPPs. The reason for this is:

- There is clear recognition that although SMR are smaller in size than NPP, the hazards from the inventory and energy contained in an SMR core are significant enough to require a disciplined application of a set of safety and control measures to ensure the risk from activities involving these reactors remains acceptably low.
- NPP requirements encompass all of the safety and control measures pertinent to activities that will be conducted using SMRs including generation of electricity and secondary uses of the reactor heat.
- There is a need to send a clear message to the greater public that all power reactor technologies are regulated within one set of safety requirements. At the same time, there is a need to recognize and encourage new technologies to offer significant improvements in performance such as lower potential consequences to persons during all operational states. For example, it is realistic to expect new technologies to be able to offer solutions that reduce off-site radiological consequences from accidents.

With this in mind, regulators may define specific requirements in special cases such as marine based facilities where different requirements are justified.

The IAEA Safety Fundamentals articulate that licensing, and the assessment that supports it, is a national responsibility. Cases involving use of the Graded Approach accepted in one country need to be compatible with the reviewing country's regulatory framework before accepting that approach.

All regulators use a combination of some of the following tools and approaches as part of their regulatory activities to both gather knowledge useful for regulation and to perform regulatory activities using a Graded Approach:

- technical analytical tools:
  - expert judgement (e.g. independent use of judgement or a more formal Expert Panel)
  - computer simulations
  - engineering and scientific calculations
  - laboratories, research support institutes (for independent testing or analysis)
- Decision-making processes for addressing complex safety issues.
- Information tools:
  - regulatory research activities
  - information from other regulators (bilateral or organizations such as Multinational Design Evaluation Program -MDEP)
  - information from stakeholders
  - information from knowledge-management agencies such as the International Atomic Energy, Nuclear Energy Agency
- Management system tools :
  - cost-benefit analyses applied to the regulatory framework activities
  - internal work processes and instructions to guide assessments and inspections
  - internal expert groups or committees to analyze and recommend paths forward for complex issues
  - The use of decision matrices that define processes to be followed based on risk considerations
- Decision making processes:
  - Licensing

    - Certification
    - Compliance (e.g. inspections, table top reviews)
    - Enforcement

Why do differences exist between regulatory bodies?

Although regulatory bodies may have different terminologies for the Graded Approach and application of risk informing tools, all regulatory bodies implement the basic principles of the Graded Approach. The way they do this (i.e. the ways various tools are used under different circumstances), can vary from country to country based on:

- The country's laws and legal framework
- Level of public involvement in the development of the regulatory framework and the decision making process
- Regulatory management system processes for analysis, technical assessment and approvals
- Maturity and types of technologies
- Historic experience by both the regulator and industry (including approach to safety culture)

Quality of operating experience and state of research and development

Questions have been posed in public forums such as SMR conferences on whether convergence or harmonization of methodologies used by regulators to implement the Graded Approach might be achievable. Many of the above listed factors would make such a goal a significant challenge to achieve in the long term. However, for new technologies such as SMRs, regulators are increasingly communicating with one another seeking to understand the different acceptable approaches being used for assessment of these technologies. The existence of this regulators' Forum is one example of this form of collaboration. These types of learning environments facilitate the ability of regulators to expand their experience and add to their already existing Graded Approach toolsets and permit the sharing of experiences to further improve the efficiency of technology reviews as well as licensing and compliance. This in itself facilitates efficiencies in reviewing both technologies and license applications and also permits extensive sharing of experiences.

3.3. EXPERIENCE WITH THE GRADED APPROACH IN MEMBER STATES, INCLUDING, APPLICATIONS, PRACTICES AND KEY INSIGHTS.

3.3.1 Areas where challenges exist

- Extent of the use of the Graded Approach used in various countries – Depending on the regulatory approach
    - Not all countries have technology neutral regulatory frameworks. Therefore applying it to other design concepts can involve significant analysis of requirements. For example codes and standard may be restrictive, however, in the majority of cases, the underpinning fundamental safety principles do exist and can be leveraged to make adaptations needed to use the existing frameworks for new technologies.
    - Different regulatory views of how the Graded Approach is to be applied. For example: applying guidance (how much is mandatory rather than suggested?) Licensees and regulators are both affected.
- Approach to addressing multiple unit/module site safety cases vary significantly from country to country. This impacts safety important areas such as:
    - Facility minimum complement (plant staffing)
    - Extent of emergency planning measures (and zones)
    - Environmental impact studies
- Vendors, utilities and other proponents have requested more clarity on specific applications of the Graded Approach for specific designs in order to understand licensing implications (cost and

timelines). However, in most cases, the amount, level and credibility of technical information is not available yet due to incomplete R&D or OPEX that is insufficient or not sufficiently relevant.

- The concept of "proven" approaches and technologies can differ between regulatory regimes.
    - Regulators do not define what "proven" means but may provide objectives to demonstrate "proven-ness". Each regulator may ask for different supporting information depending on national practice, codes and standards. The nature of "proven-ness" of approaches or specific technologies remains subject to professional judgement (reasonable assurance) including:
        - Credibility of supporting information
        - State of validation/verification
        - Applicability of the approaches or specific technologies to the specific nuclear application
        - Transferability of information from one regulatory jurisdiction to another or even one operator to another
        - Qualifications and characteristics of the license applicant (regardless of the qualifications of the vendor)
- Public process and levels of public acceptance of nuclear power can vary significantly from country to country, site to site. This can influence the amount of supporting information needed to substantiate use of a Graded Approach.

3.3.2 Existing Practices that can be employed for SMRs:

Level of detail required in the Preliminary Safety Analysis Report (PSAR)

- Russian Federation - The level of design detail required during the construction approval process is at the Preliminary Safety Analysis Report (PSAR) level. The design should be complete down to the component procurement specifications. Although this requires a significant amount of effort at the onset for both the licensee and their vendors, this improves certainty for the later operating licenses.
- France – the PSAR to be provided by an applicant in the frame of the construction license should fully demonstrate the safety of the installation, as envisaged. The SAR will then demonstrate the safety of the installation, as-built.
- The Decree 2007-1557 of 2 November 2007 concerning basic nuclear installations and the supervision of the transport of radioactive materials with respect to nuclear safety stipulates that "The preliminary safety case […] takes the place of the hazard assessment required in […] the Environmental Code until commissioning of the installation. It comprises an inventory of the risks of whatever origin arising from the planned installation, as well as an analysis of the steps taken to prevent these risks and the description of the measures designed to minimise the probability of accidents and their effects. Its content must be commensurate with the scale of the hazards from the installation and, in the event of an incident, their foreseeable effects […]. It in particular presents the possible hazards from the installation in the event of an accident, whether or not radiological. It thus describes:

    1. *The accidents that could occur, whether the cause is on-site or off-site, including a malicious act;*
    2. *The nature and scope of the potential effects of a possible accident;*
    3. *The steps envisaged to prevent these accidents or minimise the probability or effects thereof.*

    With regard to accidents of off-site origin, the operator takes account of the impact of installations which, whether or not under its responsibility and owing to their proximity to the planned installation, are liable to aggravate the risk and effects of any accident. The preliminary safety case confirms that in view of the current state of knowledge, current practices and the vulnerability of the installation environment, the project is able to achieve a risk level that is as low as possible in economically acceptable conditions."

- Practices for ensuring that the information generated by computer codes for use in safety demonstrations are of sufficient quality (All Forum Member States):
    - Canada: The applicant for a license is required to demonstrate that information obtained from software is quality assured. CSA N286.7, Quality assurance of analytical, scientific, and design computer programs describes criteria by which the demonstration will be assessed by the Canadian Nuclear Safety Commission during the licensing process. The pre-licensing vendor design review process provides an opportunity for the vendor to demonstrate that they are addressing the expectations in this standard in their technology development program. This would provide early feedback to the vendor that can be used for discussions with potential utilities investigating that reactor design.
    - Russian Federation: Rostechnadzor requires that all computer codes either be certified (mandatory for NPPs) or in certain cases validated (research reactors). Rostechnadzor has published a document that recommends the approach for preparing validation reports and certification is performed by the Expert Council on Certification of Computer Codes facilitated by Rostechnadzor and composed of representatives from the TSO and key industry players.
    - USA: According to the regulation 10 CFR 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Processing Facilities," "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. This includes computer code verification associated with safety-related analyses
    - France: the applicant should provide evidence on the validation of the tools used to support the safety demonstration. For codes used for accidental safety studies demonstrating the integrity of the first barrier of nuclear reactors, IRSN has developed a set of requirements to be fulfilled but the applicant. It states that the validation procedure must be progressive in order to minimize compensations for error. The validation process must include several stages (verification, validation of separate effects, overall validation) followed by a transposition indissociable from this validation. The uncertainties must be quantified for each stage. The consistency of the modelling choices must be ensured for each stage of validation, between stages, and between the stages and the cases of use. A validation file comprising all of these elements must be drawn up. This validation file is assessed by IRSN during the review of the safety case.
    - Beyond these aspects, there is a very strong link - and hence a need for consistency - between the validation of the scientific calculation tools, the study methods and the application studies based on these tools. In particular, the modelling choices made during the application studies must be consistent with those made for validation. Furthermore, the uncertainties determined during validation are exploited using the study methods in the application studies
- Licensing approach for multiple unit facilities. (Canada)

  Current practice for the existing fleet of multiple unit nuclear power facilities in Canada has shown that a single license enveloping all activities for the facilities on the site can be done efficiently and in consideration of:

    - technical / configuration differences between units
    - units of different vintage (age differences)
    - units in a station that are in various lifecycle stages, for example, units operating, units in refurbishment and units in safe storage state awaiting decommissioning.

  The Canadian licensing process (see REGDOC 3.5.1, *Licensing Process for Class I Nuclear Facilities and Uranium Mines and Mills*) under the *Nuclear Safety and Control Act* addresses the activities proposed to be conducted by an applicant.

The number and nature of licenses is proposed by the applicant and ultimately decided on by the Commission during the licensing process.

Operating experience with single licenses for multiple-unit facilities has shown that licensees needs to consider how they will manage the differences between units as described above, in all of their programs for operating and maintaining the facility as a whole. This would include, for example, an aging management program for "common services" features that are shared between modules – including civil structures, common electrical systems and compressed air systems. This will be particularly important for cases such as:

- multiple-module SMRs where a utility proposes to put only a few modules into service at the onset, with an option to install and operate more units in the future
- spent modules that may be removed and replaced with newer modules, which could differ technically from the original unit

For a proposal for a multiple- module license to construct or operate a facility, it important for the applicant to consider the facility's ultimate total capacity over its life and the timelines for deploying the modules. This will play a role in, for example the environmental assessment (study of potential adverse impacts to the environment) as well as the safety analyses that will support the facility's safety case. In the license application, the CNSC expects the applicant's programs and processes to describe how multiple-unit activities will be managed under all safety and control areas. For example:

- configuration management – addressing differences between units
- human performance – personnel training and preventing errors such as performing maintenance on the wrong unit

If an applicant proposes to construct and operate a facility, all of the activities associated with the proposal will be considered in the license application, including construction and operation of multiple modules (or units) on a single site. The NSCA permits the Commission the flexibility to encompass all activities either under one single license, or multiple licenses depending on the nature and timelines of the proposed activities. This requires the applicant to demonstrate they meet the requirements applicable to the activities proposed to be licensed. The CNSC already has a number of licensees with multiple reactors operating under a single license.

License Application Guides (LAG) such as RD/GD 369: *License Application Guide, License to Construct a Nuclear Power Plant* and regulatory requirements articulated in REDOCs such as REGDOC 2.5.2, *Design of Reactor Facilities – Nuclear Power Plants* and RD-367, *Design of Small Reactors* expect the safety case to address multiple unit accident and set requirements at the facility level.

The CNSC is aware that a small number of reactor developers are developing reactors with replaceable reactor core modules. Beyond CANDU refurbishment activities (which replaces a limited number of reactor components), there is no regulatory precedent in Canada for the complete replacement of reactor vessels in a facility.

- Use of a Graded Approach during licensing and construction/plant operation of an SMR (USA):
    - Risk-Informed Applications: An SMR applicant can voluntarily implement a regulation related to risk-informed categorization and treatment of structure, systems, and components (i.e., 10 CFR 50.69 and the accompanying Regulatory Guide 1.201). Regulatory guidance is also available for additional risk-informed applications (e.g., in-service inspection of piping, in-service testing, and technical specifications).
    - Standardization: Licensing per 10 CFR 52 requires more detailed design and operational information for a design certification application than for a 10 CFR 50 construction permit. "Incorporating by reference" a certified design into their application, combined license applicants need only address departures from the certified design and site-specific

features/information, streamlining their licensing process. Additional efficiencies are gained by subsequent combined license applicants who follow the same approach as the previous applicants using the same certified design.

- Licensing Process: The use of risk insights may be used to enhance the effectiveness and efficiency of the review process. Using a Graded Approach, regulatory staff could apply the most rigorous review techniques to SSCs with the highest safety and risk significance (analogous to the typical review process using the current review guidance), and a progressively less-detailed review to other SSCs as the assigned safety/risk significance declines. That is, the regulatory staff may consider alternative ways to meet review acceptance criteria. If the applicant's submittal identifies selected requirements (e.g., testing requirements, technical specifications, quality assurance, maintenance, etc.) consistent with the safety/risk categorization of the SSC, the staff may rely on that requirement to demonstrate satisfaction of performance-based acceptance criteria in lieu of detailed independent analyses.
- Inspections: During construction/plant operation inspections, risk insights may be used to prioritize areas of focus for the inspectors.

- Experience in licensing using a standardized fleet of reactors (France)

  1. Overall approach

  In France, the choice to build and operate standardized fleets of reactors was made in the beginning of the 1970's. Despite the fact that France does not have a process for a design certification, the applicant has followed a trend of developing 'standard safety analysis reports'. The nuclear island (primary system, safety system architecture, supporting system partially) is designed by considering site envelope characteristics. Technical assessment of the first-of-a-kind reactor is very detailed but then, the assessment of the following is mainly focused on site-related aspects and possible design evolutions. This is a form of Graded Approach as applied to licensing activities.

  2. Commissioning of reactors

  Different types of commissioning tests are distinguished; some of those are only performed on the first-of-a-kind reactor:

  - First-plant-only tests aim to check a new concept, the principle of a non-experiment solution or to get standard functional data for different operating configuration.
  - So-called normal and systematic commissioning tests are done accordingly with a standard program aiming to check the good operation of the different parts of the installation and performances. These tests are performed on each plant.
  - Long program and short program may be apply during some commissioning phases, particularly during power increase phase. The « long program » is realized for the first reactor of the series to be commissioned in order to check the validity of some hypotheses considered in accident studies and the design of the protection system. A « short program » is then performed for any reactor belonging to the same series.
  - Operating procedures validation tests: validation of some emergency operating procedures is performed during the commissioning (total loss of external supply for instance). This validation is performed only one time on the first reactor (first-plant-only test).

- Grading in safety assessment

  (France) When an application is submitted, a preliminary and overall assessment of the application is made to identify the main safety issues to be dealt with. As a priority, evolutions regarding existing reactors are examined as well as topics raised by operating feedback. Then strategies for technical assessment may be defined, for each thematic, especially when time for the review is limited. It is formalized by the TSO and discussed with the safety authority. TSO should be able to justify that this safety-focused review give a sufficient confidence in the capability of the licensee to operate safety its installation. For instance, for accident studies, priority is given for studies performed with new methodologies, studies with a limited margin to the acceptance criteria…

(Canada) The license application structure for Nuclear Power Plants (regardless of size) is outlined in CNSC License Application Guides. The safety and control areas to be addressed by an applicant are the same regardless of size and function, but the measures proposed by the applicant are permitted to be commensurate with risk. Regulatory Documents and industry codes and standards, containing requirements and guidance that can be interpreted in a risk informed manner form the basis for the safety and control measures proposed by the applicant. CNSC utilizes a Conduct of Technical Assessment (CTA) process within a project management framework to establish scope and depth of review on a case by case basis for applications. CNSC uses internal processes for each Safety and Control Area to guide technical reviewers in their specific reviews and assist in the use of professional judgement. In certain cases, use of specific assessment tools such as Risk Informed Decision Making (RIDM) or specific technical teams may be suggested to support conclusions. The CTA process provides checks and balances such as peer and management level reviews to ensure that use of judgement (e.g. in acceptance or use of grading) is appropriate in specific instances. Decision making is documented as part of the assessment process. The applicant is also expected to show that such quality assurance measure have been applied in their decision-making.

3.4. CONSIDERATIONS IN USE OF THE GRADED APPROACH IN DEVELOPING A SAFETY PROPOSAL

3.4.1. Introduction

A credible safety proposal plays a key role in coming to a decision about whether proposed activities present no unreasonable risk to the workers, the public and the environment7. To be credible, claims in the safety proposal must be defensible by the proponent who will be undertaking the activities that involve risks. The justification of the use of a Graded Approach is highly dependent on the credibility of the supporting information and an understanding of the uncertainties that influence a safety case.

Proponents of SMR concepts, like any developer of a new technological concept in any industry, face the challenge of assembling the necessary credible supporting information to show that safety and control measures to be used by a licensee will be appropriate for the risks presented by the activities.

A well-structured safety proposal, which normally includes use of a Graded Approach, should:

- Demonstrate that safety as a whole will not be compromised.
- Be based on regulatory requirements in consideration of available guidance.
- Be considered in an overall defence-in-depth context.
- Use supporting information that has been demonstrated to be credible, relevant to the specific application, appropriately quality-assured.
- Show how the licensee’s approved management system processes and procedures were used to evaluate the proposal in a credible manner. For example, the balance of various safety analyses performed and the use of professional judgment and the roles of each.
- demonstrate that the overall intent of the requirement(s) has been met and,
  - Provide a high level answer to “how were alternatives to the proposal considered?”
  - Be supported by documented and traceable evidence including quality assured:
    - research and development activities (e.g. experiments, peer-reviewed papers)
    - calculations and analyses
    - results from validated models
  - Identify any applicable codes and standards and limitations imposed by them.

[7] The types of risks, the scope being considered (i.e. worker health, public health, environmental protection) and the definition of what is ‘(un)reasonable’ is established by the individual regulatory mandates and frameworks in each Member State.

The analysis of a proposal should be conducted for a representative8 facility (whether single or multiple units) and consider aspects such as:

- significance and complexity of each activity;
- possible consequences in case of failure;
- inventories of radiological and hazardous substances and what they are used for
- radiological source terms
- characteristics of airborne and liquid releases of radioactive or hazardous materials
- presence of high energy systems (or systems with high potential energy) that could result in high energy events (e.g. explosions, leaks, fires)
- location of the facility or activities including proximity to the public
- potential for external hazards
- maturity level of the technology and operating experience associated with the activities;
- Lifecycle stage of the facility.

Complexity, maturity (e.g. proven technologies/methodologies) of preventive and mitigation measures should be considered, including but not limited to:

- operational experience
- human factors considerations including potential for human error
- overall reliability, effects of maintenance and aging of equipment

3.4.2 Use of Operating Experience

Operating experience (OPEX) used to support technical information in a proposal needs to demonstrate:

- lifecycle approach that considers operation and maintenance over the life of the facility. Also consider areas such as
    - Lessons learned from plant / multiple plant behaviours at a macro level (traditional OPEX focuses on specific incidents/phenomena/systems/components)
    - Human performance
    - waste management, decommissioning
- relevancy: how much the OPEX is applicable to this specific proposal, for example:
    - neutronic similarity, differences in environmental conditions
    - where do gaps in understanding exist that need to be addressed in R&D moving forward
- how is OPEX being used to drive improvements in safety and control measures for future concepts such as human performance, design features, enhanced or more efficient analysis methodologies
- Sufficiency: The quality and quantity of information should be sufficient to form an understanding of reasonable risk in consideration of uncertainties. This means judgement of sufficiency should take into account:
    - The nature of the activities being proposed. It is possible to make regulatory decisions with insufficient data or even no OPEX. However, the activities that would be permitted would be restricted to account for the increased level of uncertainties. For example, the purpose of a demonstration reactor is to generate additional OPEX data to address gaps. Therefore expected information to support initial operation of that reactor would be less than for a

[8] A representative facility should be a facility layout for the number of units (i.e. reactor/turbine pairs) that would be typically deployed. For example, if a particular design is expected to be deployed as a four module (i.e. unit) facility, the four unit facility would be the representative facility.

commercial scale power plant and additional safety and control measures may be warranted (e.g. use of licensing hold points or additional inspections/commissioning tests)

  - OPEX was collected over a long enough period of time (e.g. it is difficult to show that a few months of data from a research reactor can support safe long term operation for a power reactor. This means that a proposal would need to show how the gaps in data would be addressed through, for example, R&D activities or use of prototypes/demonstration facilities).

- Quality: Modern processes (e.g. rigour, peer reviews, documentation) for ensuring quality OPEX data collections have advanced significantly from those used in the past. This means that data sets collected many decades ago may be useful but may not meet the quality requirements set in QA standards for data collection. Although older data remains useful, it would likely need to be supported with modern quality assured data such as from supplementary experiments/calculations.

3.4.3 R&D program (scope and depth)

The R&D program works with the OPEX program to provide the necessary information to support both safety claims and that construction and operation of the facility will not pose an unreasonable risk. SMR designs considering the use of multiple overlapping innovative features need to demonstrate how past and future R&D supports use of a Graded Approach. To ensure predictable licensing timelines, the R&D program needs to be connected to the timelines for the safety case development such that major issues/uncertainties are resolved prior to licensing. The objectives of the R&D program should also consider the nature of the activities being planned. For example, a demonstration reactor can be used as part of the R&D program to complete work; however, a minimum set of completed R&D is still required to proceed with construction and operation of the demonstration facility. Similar to OPEX, gaps in the R&D may warrant the use of additional safety and control measures to address uncertainties.

3.4.4 Quality of Computer Codes

For a new technology there are two general approaches being used by designers:

- Attempt to use existing computer codes but apply/adapt them for different circumstances– (e.g. fluid dynamics between water cooled versus molten salt)

- Develop new computer codes

In both cases, there is the need to demonstrate and document applicability of the codes and an understanding of the code's limitations. This overall understanding typically influences which additional experiments are needed to either validate & verify codes or address areas the codes to not cover.

Quality assurance for codes is needed to demonstrate that data is:

Credible

The user of the codes must demonstrate that the codes meet quality assurance requirements and are generating information that is of sufficient quality to support the safety claim.

Supporting passive and inherent features in a safety proposal may represent a significant challenge to the V&V of computer codes. Codes need to model a wide but realistic range of postulated operating conditions and the physics that exist under those conditions. This may not be possible due to limitations of the software or the complexity of modelling.

A decision whether/how to apply a Graded Approach must be informed by the limitations of the modelling outputs.

3.4.5 Equipment qualification (testing, QA)

An Equipment Qualification Program is a program under a licensee's management system. It is used to demonstrate, for equipment important to safety that the safety performance requirements are met during both normal operation and accident conditions (in consideration of aging effects) and that performance requirements can be reasonably met for Design Extension Conditions. The definition of "reasonably" can vary from one Member State to the next and may or may not extend the design basis for that equipment.

There are two typical kinds of qualification:

1. Verification using experiments under realistic conditions
2. Qualification by analysis – where previously qualified equipment either in a different nuclear application or from other industrial applications

Some of the challenges for SMRs in this area include:

- Working with minimal to no OPEX for an equipment type.
- Qualification of equipment housed in integrated vessels. (effects of components due to exposure to neutron field)
- Defining all of the possible environmental conditions under which the equipment will be required to be operable. (a particular challenge for passive equipment)
- OPEX from larger NPP designs may require additional information to demonstrate scalability for SMRs.

3.4.6 Safety Analysis

Safety analysis is a complementary tool that can be used to combine all of the results of the other tools and to understand and address uncertainties. Safety analysis further supports an understanding of the effects from phenomena while considering equipment and system performance against acceptance criteria.

Safety analysis involving passive features is highly complex because the range of operating conditions can be quite large. This means that large uncertainties can emerge in safety analysis results. The use of multiple levels of passive features in a safety proposal can multiply these uncertainties. As a result, the qualification process for passive features and results from experiments play a greater role in reduce uncertainties by produce data of higher confidence.

Inherent safety features by definition avoid hazards instead of controlling them and do not require any intervention by systems or human action. A demonstration of inherent safety is generally supported with information derived from experiments and an understanding of the physics involved in the inherent response. Such information can also be supported by computational analyses.

More traditional safety approaches (e.g. active systems/components), would rely on traditional safety analysis methodologies that use a combination of information from experiments and equipment qualification.

3.5. CONSIDERATIONS IN REGULATORY ASSESSMENT OF COMPLEX SAFETY PROPOSALS USING A GRADED APPROACH.

Section 3.1.1 provided a high level overview of the IAEA’s interpretation of the use of the Graded Approach in Member State regulatory frameworks. One of the key lessons drawn from the IAEA safety framework is that the Graded Approach needs to be applied cautiously taking into account an understanding of the hazards in a specific case, confidence in the performance of measures for prevention and mitigation of accidents and control measures as part of an integrated safety approach and impacts of all uncertainties. For new technologies such as SMRs, uncertainties can and will be significant until operating experience has been gained. Any proposal seeking to employ such technologies needs to characterize these uncertainties and explain how they ultimately impact the safety case. This analysis work is necessary for a regulator to determine whether confidence exists that requirements are being sufficiently met. In some cases, where sufficient information is not available, the regulator may need to impose additional safety and control measures until sufficient operating experience has been accumulated.

3.5.1 Conduct of technical assessment for complex safety proposals

For complex cases, a Graded Approach is applied by the regulator in their conduct of technical assessment to ensure the review focuses on areas important to safety and that the review conclusions reflect a holistic view of safety that is informed by specialist contributions. The use of multiple levels of novel approaches and innovative features (which SMR developers are introducing) makes this assessment more complex. This requires a project management approach.

To do this, a multi-phased approach may be used as follows:

- An individual or team with a high level of experience but with a generalist background should examine the proposal to determine what the main challenges in technical assessment are (e.g. novel approaches, innovative features). The team should be formed of both Project Management and Technical Facilitator roles and both work together and decide to what extent different specialist resources should be applied to review the adequacy of the proposal. The strategy is articulated in an assessment plan.
- Specialists need to conduct their individual reviews according to the overall assessment plan and use generic guidance documents and Technical Facilitator to guide the review scope and depth. The assessment plan and Technical Facilitator should ensure cross functional communication to share information, findings and information and also provide for problem escalation mechanisms.

3.5.2 Application of the Graded Approach to Regulator's Compliance Verification Activities

Compliance verification of a licensee's activities normally follows a risk-informed methodology directly informed by the licensing process and by the experience and compliance history of the licensee. This approach is part of a regulator's management system for compliance and enforcement and is therefore expected to be documented following a quality assured process. The use and validation of professional judgement is part of this process.

Generally, regulators establish baseline compliance programs that would be applicable to any licensee. This program would be based on a common set of risk factors. However, novel approaches may justify additional activities until compliance history has been established.

For activities involving SMR technologies, quality and nature of information supporting the proposed safety and control measures will play a role in the scope, depth and types of compliance verification activities performed by the regulator.

The licensing basis for a facility establishes the necessary compliance criteria for activities on a case-by-case basis. Technical assessment of an applicant's proposed safety and control measures looks for:

- where risks warrant regulatory attention in compliance verification;
- adequacy of the proposed measures;
- where uncertainties exist;
- areas where the applicant has committed to performing additional work to address uncertainties but an activity should proceed with additional protective measures in place.

The regulator may choose to accept the applicant's proposed approach and measures but may also supplement these measures with regulatory tools to ensure risk remains acceptable such as:

- license conditions
- hold points in activities
- limits on activities until a performance objective has been achieved
- reporting

On a case-by-case basis a First of a Kind SMR project may see enhanced compliance verification activities in areas where, for example:

- a licensee process is demonstrating a new approach or technique (e.g. new procurement methodology, new installation process for civil structures);
- commissioning activities are being used to collect data to validate key design assumptions in the safety case.

3.6. CONSIDERATIONS IN THE USE OF GRADING AS APPLIED TO THE LICENSING PROCESS FOR PROJECTS INVOLVING SMRs

Regulators in the Forum have noted interest by proponents in ensuring that the licensing process in a Member State should be graded or somehow streamlined talking into account purported features being included in SMR technologies. It is important to recognize that licensing is a process of providing an authorization to a person or organizational entity to perform a proposed set of activities commensurate with the regulatory requirements of that Member State9. Thus, the licensing process is focused on the measures that will be in place to perform those activities safely. The technologies being proposed are an important part of these measures but technology is only one piece in the regulatory discussion which also must consider organizational measures.

Regulators represented in the Forum are investigating avenues to ensure the licensing process is efficient, effective and timely for SMRs without compromising the fundamental principles the licensing process must address such as:

- informed and transparent decision making – time to permit stakeholders to bring pertinent information into the licensing process and to show that the information has been respectfully considered
- ensuring the information required in an application to make a licensing decision is clear in developing a licensing basis
- Anticipating impacts on technical assessment – preparing in advance with capacity and capabilities to address submissions that will propose novelties, and determine adequacy of supporting information, in the assessment process.
- internal and external consultation/participation – generally remains the same but some internal management processes may be optimized.

In addition to the above, for a First-of-a Kind design being proposed to be built and operated in a Member State, the regulator needs to take into account:

- the applicant's experience
- the strength of the applicant's safety case for the specific project being proposed taking into account design and site uncertainties
- the availability and pertinence of supporting technical information, operating experience needed to support safety claims against the Member State's regulatory framework

Experience from use of similar or the same technologies from other parts of the world can be factored in by both the applicant and the regulator but in the end, the licensing process must remain focussed on the applicant's proposal to conduct activities safely.

For projects that are subsequent to the First-of-a-Kind, the same process is followed; however, the amount of operating experience generated will result in efficiencies in some part of the technical assessment and decision making. Differences between sites, applicant characteristics (if a new company applying for a license) and optimizations made to the design will need to be assessed and will influence timelines. This form of Graded Approach in licensing uses precedent to inform the process.

Design certification has been used by some regulators as a form of Graded Approach to licensing in an effort to establish a form of design acceptance of a non-site-specific reactor concept. The intent of this approach is to provide conditional approval of design approaches with the provision that the future licensees will construct and operate the concept as-designed and agree to meet certain regulatory acceptance criteria as a condition to being permitted to proceed to the operating phase. This approach is useful for Member States that are planning to construct and operate many 'copies' of the same design on multiple sites because it establishes a standard design envelope that can be reflected in each site specific safety case10. As stated above, however, licensing remains focused on how the applicant is addressing these commitments.

One of the limitations of a certification process is that future design optimization by the vendor (e.g. to reduce costs or improve efficiency) may require significant regulatory approvals and any issues that are found may result in follow-up by existing licensees. For countries planning to deploy only a small number of facilities on a limited number of sites, certification as a form of Graded Approach to licensing is likely less useful and efficient than one that uses a precedent-based approach.

[9] Member state requirements may draw from IAEA safety standards and guides but must also address the Member State's legal framework.

[10] It should be noted that site characteristics may result in design enhancements to take into account site specific effects such as external events.

3.6.1 IAEA Views on the Licensing Process

IAEA Specific Safety Guide SSG-12, *Licensing Process for Nuclear Installations*, (which includes NPPs, fuel cycle facilities and research reactors and is applicable to SMR facilities) establishes fundamental principles that need to be addressed in national licensing processes including:

1. Assessment of the license application against published regulatory requirements (including regulations) and guidance
2. Documenting the bases for licensing
3. Transparency of the decision making process including sufficient stakeholder involvement
4. Consistent and fair treatment of applicants for licenses

The licensing process generally involves the following key phases:

1. Submission of an application (including all information supporting safe conduct of the proposed activities)
2. A sufficiency review of the application and time for resolution of requests for additional information
3. Detailed technical assessment of the application which may include submission of additional supporting information as justified by the regulatory body
4. Licensing basis development and recommendations to the decision maker
5. Public hearings or other decision-making forums that include sufficient time for review of the application, interventions and recommendations
6. Development of the final decision including the rationale for the decision and any additional conditions the license should contain
7. Issuance of the license/authorization

Items 5 and 6 can form the largest part of the licensing timeline, and is generally independent of facility size and cannot be shortened without reducing the credibility of the licensing process.

Items 1 to 4 are highly dependent on the nature of the activities being proposed, and the completeness and quality of the application, which includes all of the supporting technical information. Although a SMR design can be purported to be ‘simpler and safer’ the nature of the supporting information determines the duration of Steps 1-4. It is not obvious that a smaller reactor design means a shorter duration for technical assessment. Where multiple levels of novel features are being proposed, the time to complete the review is influenced by the time needed to confirm the proposed safety and control measures meet regulatory requirements. In SSG-12, the use of the Graded Approach is discussed from Clause 2.46 to 2.50 and reinforces that technical assessment of a licensee’s safety case must be conducted under a continual awareness of changing risk based on the information provided. That is, an assessment should evolve based on what is reviewed allowing for changes in focus as needed to provide additional emphasis based on discovery. All Forum Member States use this approach.

4. Conclusions, Recommendations and Common Positions

Enhancement to the Current Definition of a Graded Approach

Rationale: Despite the existing IAEA definition of Graded Approach, there remain different interpretations as to what it means, who applies it and how it is applied. There is a need to enhance the overall understanding of this term by further describing how it is used for Nuclear Power Plants (including SMRs) and that it does not represent a reduction in overall safety. In fact a document that goes into more depth on the application of the Graded Approach (similar to that which already exists for research reactors) including sample case studies would be useful for all stakeholders. Section 3.1 presents additional information the GA-WG feels needs to be articulated in the IAEA safety framework for Nuclear Power Plants.

The GA-WG recommends that the IAEA champion such a document for Nuclear Power Plants that encompasses SMRs and that the GA-WG actively participate in the drafting of this document.

Addressing Operating License Jurisdictional Issues for Factory Fuelled Transportable Reactors

Factory fuelled and sealed transportable reactor modules represent a unique issue to regulation that will require further discussion about the role of the 'factory' licensee versus the site licensee during the manufacturing, testing, delivery/installation and commissioning phase. Some questions to be addressed include:

- When the module is being assembled (and possibly tested) at the factory, what is the role of the deployment site licensee?
- The factory requires an operating license to load fuel into each reactor module, perform any testing and store the module prior to deployment in a guaranteed shutdown state. The operating license for such activities would likely begin with the requirement applicable to NPP (and a safety case) but the Graded Approach will be applied commensurate with the scope of activities. When constructions of site structures are in progress under a construction license, it is for the purpose of future installation and operation of the reactor module. What is the role of the site licensee in the reactor factory's activities? Is any factory testing part of commissioning? How much commissioning can be credited given transport may introduce stresses to the reactor module?

4.1. POTENTIAL COMMON POSITIONS

Common Position on Treatment of SMRs when Applying Regulatory Requirements and Guidance

From a safety perspective, all regulators agree that SMRs should be treated as Nuclear Power Plants (NPPs) and that the starting point in use of the Graded Approach is the requirements established for NPPs. The reason for this is:

- There is clear recognition that although SMR are smaller in size than NPP, the hazards from the inventory and energy contained in an SMR core are significant enough to require a disciplined application of a set of safety and control measures to ensure the risk from activities involving these reactors remains acceptably low.
- NPP requirements encompass all of the safety and control measures pertinent to activities that will be conducted using SMRs including generation of electricity and secondary uses of the reactor heat.
- There is a need to send a clear message to the greater public that all power reactor technologies are regulated within one set of safety requirements. At the same time, there is a need to recognize and encourage new technologies to offer significant improvements in performance such as lower potential consequences to persons during all operational states. For example, it is realistic to expect new technologies to be able to offer solutions that significantly reduce off-site radiological consequences from accidents.

With this in mind, regulators may define specific requirements and/or guidance in special cases such as marine based facilities where justified.

The existing IAEA safety framework for Nuclear Power Plants, as currently articulated, can be applied to activities referencing the use of SMR facilities (either single plant or multiple unit/module facilities). Although many documents have expressed that they are applicable to water cooled reactor concepts, the SMR Regulators Forum agrees that the fundamental principles in the majority of the requirements and guidance can and should be addressed for SMRs including non-water cooled facilities taking into account the Graded Approach. In some cases, guidance does not yet exist or be applicable to certain SMR applications (e.g. Factory fuelled transportable reactors). The IAEA safety framework allows for the alternative proposals to be made. Any alternative approach is expected to demonstrate equivalence to the outcomes associated with the use of the requirements. Section 1.6 of SSR-2/1 (Rev. 1), Safety of Nuclear Power Plants: Design, supports this point.

Common Position on Global Harmonization of Regulatory Requirements

Member State regulatory bodies have the responsibility (per the IAEA Safety Fundamentals) to ensure that the national regulatory framework for safety is established and implemented to regulate the use of nuclear power. The regulatory framework in each country is developed using the national legal framework and considers both the IAEA safety framework and inputs from stakeholders such as industry, scientific bodies, government and the public. As a result, differences between national frameworks can and likely will always exist. For this reason, harmonization of most requirements and guidance globally will remain a significant long term and complex challenge that will require significant cooperative investments by Member State governments. The regulatory bodies play a partial, but important, role in this discussion. However, there are two points that can be made based on GA-WG lessons learned:

1. There are specific areas where a certain amount of harmonization/agreement can be achieved following approaches developed by the NEA MDEP Codes and Standards Working Group. For example:

    a) common regulatory acceptance criteria for fuel qualification programs

    b) agreement on factors used to establish emergency planning zones

    c) common regulatory acceptance criteria for human factors engineering programs

    The Graded Approach Working Group recommends that the next phase of work identify a list of such areas and prioritize them for discussion between regulators within the Forum.

2. Regulators have a history of collaborating in the development of requirements and guidance and are continuing to develop common approaches even if they are not identical. In many cases, similar requirements and guidance exist. Work in this area should continue

Common Position: Application of the Graded Approach to the Licensing Process for Activities Referencing SMRs

A number of proponents (such as industry or energy policy decision makers) of SMR technologies are requesting that licensing processes be modified/adapted or even simplified to address unique features presented by SMRs such as smaller size, difference in design and alternative approaches for construction (e.g. modularity).

Members of the SMRs' Regulators Forum agree that, in many cases, it is not necessary to develop new licensing processes for SMRs as the existing processes are sufficient but efficiencies can be gained in existing processes.

Certification of reactor or module designs is an acceptable approach to use in a licensing process; however, it is not necessary to have it in place to have an efficient licensing process. The decision to adopt a certification regime is a national decision.

IAEA Specific Safety Guide SSG-12, Licensing Process for Nuclear Installations, (which includes NPPs, fuel cycle facilities and research reactors and is applicable to SMR facilities) establishes the following fundamental principles that should be addressed in national licensing processes including: Assessment of the license application against published regulatory requirements (including regulations) and guidance

1. Documenting the bases for licensing

2. Transparency of the decision making process including sufficient stakeholder involvement

3. Consistent and fair treatment of applicants for licenses

The licensing process generally involves the following key phases:

1. Submission of an application (including all information supporting safe conduct of the proposed activities)

2. A sufficiency review of the application and time for resolution of requests for additional information

3. Detailed technical assessment of the application which may include submission of additional supporting information as justified by the regulatory body

4. Licensing basis development and recommendations to the decision maker

5. Public hearings or other decision-making forums that include sufficient time for review of the application, interventions and recommendations

6. Development of the final decision including the rationale for the decision and any additional conditions the license should contain
7. Issuance of the license/authorization

Items 5 and 6 can form the largest part of the licensing timeline, and is generally independent of facility size and cannot be shortened without reducing the credibility of the licensing process.

Items 1 to 4 are highly dependent on the nature of the activities being proposed, and the completeness and quality of the application, which includes all of the supporting technical information. Although a SMR design can be purported to be 'simpler and safer' the nature of the supporting information determines the duration of Steps 1-4. It is not obvious that a smaller reactor design means a shorter duration for technical assessment. Where multiple levels of novel features are being proposed, the time to complete the review is influenced by the time needed to confirm the proposed safety and control measures meet regulatory requirements. In the Safety Guide SSG-12, the use of the Graded Approach is discussed from Clause 2.46 to 2.50 and reinforces that technical assessment of a licensee's safety case must be conducted under a continual awareness of changing risk based on the information provided. That is, an assessment should evolve based on what is reviewed allowing for changes in focus as needed to provide additional emphasis based on discovery. All Forum Member States use this approach.

Common Position work requiring more development under the next programme of work:

Issue #1: Application of the Graded Approach to Demonstration Facilities, First of a Kind Plants and Nth of a Kind Plants

The levels of uncertainties as well as the level of completeness of technical information supporting safe conduct of activities strongly influences the time needed to conduct technical assessment for licensing or other assessment and compliance activities that occur as the licensee conducts their activities under their license. Examples would include:

1. Assess cases for exceptions to codes and standards
2. Regulatory concurrence for key as-built modifications
3. Construction inspections
4. Analysis of impacts from non-conformances (with working level codes or technical specifications)
5. Regulatory witnessing and technical assessment of commissioning activities

Demonstration facilities and First-of-a-Kind Plants may and often do present additional levels of uncertainties that may require additional regulatory effort to resolve. This impacts on all regulatory licensing and compliance activities and this means that timelines for placing a plant into service will be longer than for subsequent projects. This applies whether building discrete separate plants or adding modules to an existing facility.

However, once precedent has been set through deployment of the first facility, efficiencies are realized when a technical assessment can focus on:

1. Site characteristics
2. Potential design evolution
3. The applicant's qualifications and ability to conduct the licensed activities.
4. Experience gained by both the regulator and the licensee

4.2. CONCLUSIONS AND RECOMMENDED PATH FORWARD FOR FUTURE WORK

The concept of Graded Approach is widely discussed in the IAEA safety framework and is mentioned in documents applicable to nuclear power plants. Appendix A provides a high level sampling of some of the IAEA documents by the GA-WG. The review indicated that, as expected, the IAEA does not prescribe any specific methodologies, but does present enough guidance to allow Member States to develop appropriate acceptance criteria under their regulatory framework.

One of the key findings of this Working Group is that although grading has been used since the beginning of the nuclear power industry, questions remain within the regulated community about appropriate ways to perform grading in design and safety analysis work. In the past, when the technologies were still in the early stages of development, the decisions to implement certain safety approaches were based on a mix of engineering judgment and scientific investigation with minimal public engagement. In modern transparent regulatory frameworks the same approaches remain valid and are, in fact, well supported by operating experience gained over decades; however, the public is seeking more information showing the rationale behind conclusions made by regulators and proponents of projects. In other words, the proponents and the regulators are being asked to show how they have applied a Graded Approach in making risk-informed decisions.

In the past two years of work within the GA-WG, the national regulatory frameworks for all SMR Regulators' Forum Member States were reviewed and in all cases, evidence of the use of a Graded Approach exists in one form or another. However it is recognized that more could be done to document how the methodologies used to perform grading are appropriate in each case.

From a safety perspective, member regulators in the SMR Regulators Forum agree that SMRs should be treated as Nuclear Power Plants (NPPs) and that the starting point in use of the Graded Approach is the requirements established for NPPs. In general, IAEA and national regulations requirements and guidance can be applied to activities referencing SMRs. Nevertheless, there may be a need for regulators to define specific requirements in special cases such as marine based facilities where different requirements are justified. Then, the way the applicant demonstrates that their requirements are met may be graded.

One key conclusion of this report is that significant benefit could be gained if the IAEA were to lead the development of a technical document that further explains what the Graded Approach is, how it is used to ensure safety for Nuclear Power Plants and how existing tools are used to develop high quality information to inform a decision making process. As a result, the SMR Regulators' Forum should promote and participate in the development of this document. This document should also speak to specific case studies that explore the implications of measures such as passive safety, inherent safety and use of conservatism in addressing regulatory requirements taking into account the use of tools such as:

- Results from R&D activities,
- Safety analysis tools (e.g. hazard analysis, deterministic safety assessment, probabilistic safety assessment)
- Quality-assured use of Professional Judgement (management system considerations)

One of the main advantages of such an effort would be to establish common ground between regulators on which grading approaches might be acceptable from one Member State to the next under different circumstances. Even if requirements cannot be harmonized between Member States due to legal structure differences, acceptance of common methodologies can facilitate the use of one regulator's conclusions to inform another's technical assessment work. Such work would also inform both embarking countries who are developing their regulatory frameworks in light of new technologies.

Recommendations on Path Forward

In the next phase of work for the SMR Regulator's Forum, the GA-WG should complete a review of IAEA Safety Standards and Guides (see Appendix A) and present recommendations to the IAEA for future consideration.

In the next phase of work for the SMR Regulator's Forum, the GA-WG should collaborate with the other SMR Regulators' Forum working groups to provide greater clarity to the IAEA of the concept of "proven" when applied to technologies or methodologies. The rationale for this is that the level of proven-ness is directly tied back to the methods used to perform grading or to assess the adequacy of grading. For example, a low degree of proven-ness of a technology increases the uncertainties in prediction of safety performance in Probabilistic Safety Assessments. Therefore other methods of grading may be more appropriate. This is particularly important where SMR developers are planning FOAK/demonstration facilities to gather operational experience and information needed to support safety cases for a future fleet of reactor facilities referencing that design11. A few areas for SMRs that merit a discussion of the meaning of "proven" could be:

- The state of qualification of fuel and impacts on the safety case for a FOAK versus an nth of a kind. A TRISO HTGR would be a good example given that the DiD approach of a typical design relies heavily on fuel and physics performance.
- Identifying and demonstrating resilience to Design Extension Conditions with Passive and Inherent safety features.
- Single operator, multiple reactor interface architectures

[11] By their very nature, the lack of operating experience means that the safety case will have greater uncertainties that will need to be addressed by use of conservatism or additional safety and control measures.

Graded Approach Working Group Members

M. deVos	Canada
Y. Flauw	France
K. Herviou	France
L. Mrowca	United States
D. Polyakov	Russian Federation

Appendix A: GA-WG Review of IAEA Safety Standards and Guides

The following IAEA documents were sampled by the GA-WG to examine how use of the Graded Approach is articulated in requirements and guidance. Conclusions for each document are provided in the table below. A general conclusion is that the IAEA does not prescribe any specific methodologies, but does present enough guidance to allow Member States to develop appropriate acceptance criteria under their regulatory framework.

Specific Requirements			
NPP	**RR**	**Fuel Cycle Facilities**	**WG Comments on articulation of use of Graded Approach and applicability of document in face of specific SMR features and approaches**
Site Evaluation for Nuclear Installations Safety Requirements Series No. NS-R-3, *Development of successor document SSR1 is currently in progress*			This standard is technology neutral and by definition would include SMRs within the existing scope of requirements. The term Graded Approach is only explicitly mentioned in Section 6 Quality Assurance. However it is important to note that application of the Graded Approach is implied throughout the requirements through the articulation of the requirements using a performance based language and tone. The requirements are intended to be applied in conjunction with topic specific guidance contained in corresponding Specific Safety Guides. The requirements language in NS-R-3 do not prescribe how the Graded Approach is to be applied, thereby providing the flexibility for Member States to develop appropriately balanced approaches (that can adapt with OPEX) NS-R-3 does not explicitly address marine-based facilities but the principles and requirements can be applied to the site characterization for such a facility. One of the main issues to be addressed is the definition of a site in this instance particularly given that the facility can be relocated. The IAEA document development project to develop successor document SSR-1 Site Evaluation for Nuclear Installations is seeking to add clarifications on the use of the Graded Approach including in some cases clarifications of the rationales for specific requirement. The level of detail needed in an evaluation to meet the requirements established in SSR1 will vary according to the type of installation being sited. Nuclear

Specific Requirements			
NPP	**RR**	**Fuel Cycle Facilities**	**WG Comments on articulation of use of Graded Approach and applicability of document in face of specific SMR features and approaches**
			power plants will generally require the highest level of detail. Users will still be required to use the Specific Safety Guides for further elaboration on suitable methodologies and criteria to address the requirements.
Safety of Nuclear Power Plants: Design Specific Safety Requirements Series No. SSR-2/1	**Safety of Research Reactors Safety Requirements** Series No. NS-R-4	**Safety of Nuclear Fuel Cycle Facilities Safety Requirements** Series No. NS-R-5	SSR-2/1 (Rev. 1) Per clause 1.6: "…this standard is primarily written with land-based stationary nuclear power plants water cooled reactors designed for electricity generation or for other heat production applications… …may also be applied, with judgement, to other reactor types, to determine the requirements that have to be considered in developing the design" By default, this would include SMRs within the existing scope of requirements. The term Graded Approach is not explicitly expressed in this standard. However it is important to note that application of the Graded Approach is implied throughout the requirements through the articulation of the requirements using a performance based language and tone. The requirements are intended to be applied in conjunction with topic specific guidance contained in corresponding Specific Safety Guides. The safety principles articulated in requirements would be applicable to a marine facility however the supporting safety guides would require additional use of risk-informing tools to understand and address the characteristics of risks presented by a marine-based facility. Some gaps in guidance are likely and would need to be addressed. For example, guidance on the use of multiple unit control rooms and shared SSCs for multiple unit SMR facilities should be investigated. The requirements language in SSR-2/1 (Rev. 1) do not prescribe how the Graded Approach is to be applied, thereby providing the flexibility for Member States to develop appropriately balanced approaches (that can adapt with OPEX)

<table>
<tr><th colspan="4">Specific Requirements</th></tr>
<tr><th>NPP</th><th>RR</th><th>Fuel Cycle Facilities</th><th>WG Comments on articulation of use of Graded Approach and applicability of document in face of specific SMR features and approaches</th></tr>
<tr><td colspan="3">Safety of Nuclear Power Plants: Commissioning and Operation
Specific Safety Requirements
Series No. SSR-2/2</td><td>SSR-2/2 is sufficiently general and can be used for SMRs with two exceptions when addressing factory fueled (sealed) transportable reactors: a) Fuel handling, b) Emergency preparedness and response.

Additional requirements and guidance should be investigated to address the relationship of commissioning and potential operation of factory fueled and sealed modules at the factory of origin versus those activities at the deployment site. For example, clarity is needed on fitness for installation and service at the site.</td></tr>
<tr><td colspan="4"></td></tr>
</table>