SMR Regulators' Forum

Pilot Project Report:

Considering the Application of a Graded Approach, Defence-in-Depth and Emergency Planning Zone Size for Small Modular Reactors

January 2018

FOREWORD

There is a sustained global interest in small modular reactors (SMRs), which have the potential to play an important role in globally sustainable energy development as part of an optimal energy mix. Such reactors have the potential to enhance energy availability and security of supply in both countries expanding their nuclear energy programmes and those embarking on a nuclear energy programme for the first time.

The International Atomic Energy Agency (IAEA) has several dedicated projects and activities concerning SMRs intended to support future Member States needs regarding SMR development and deployment. Over the years, the IAEA has produced a number of major publications and has convened a series of international forums addressing a variety of SMR issues.

This report presents the findings and recommendations of the SMR Regulators' Forum Pilot Project that met regularly between March 2015 and May 2017. The purpose of the pilot project was to identify, understand and address key regulatory challenges that may emerge in future SMR regulatory discussions thanks to the work performed within three working groups (WG). This report contains valuable information for the development of future international guidance in the field.

The Steering committee of the Forum was chaired by D. Jackson of the United States of America and K. Herviou of France served as vice-chair. The IAEA is the Scientific Secretariat and the technical officer responsible for this report was S. Magruder of the Department of Nuclear Safety and Security.

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EXECUTIVE SUMMARY

The SMR Regulators' Forum was formed in 2015 as a two-year pilot project to understand each member's regulatory views on common issues to capture good practices and understand key challenges that are emerging in SMR regulatory discussions. The project would enable regulators to inform changes, if necessary, to their requirements and regulatory practices. The following countries are members: Canada, China, Finland, France, Korea, Russia, United Kingdom and United States.

In 2014, the IAEA facilitated consultancy meetings resulting in an agreement to organize a SMR Forum. Issues for the Forum were identified, security and safeguards issues were excluded taking note that security may need to be included in the future due to claims that SMRs may result in reduced security requirements compared to large NPPs. Within the two-year pilot project, the Forum addressed the following three issues for both light-water and non-light-water reactor designs:

- Graded approach: Regulators are being approached with SMR safety case proposals that are seeking to relax regulatory requirements for design and safety analysis. Therefore, there is a need to clarify the regulatory view of grading and what this means. One key conclusion of this report is that significant benefit could be gained if the IAEA was to lead activities to further clarify the concept of Graded Approach is, how it is used to ensure safety for Nuclear Power Plant (NPP) and how existing tools are used to develop high quality information to inform a decision making process.
- Defence-in-depth: A number of SMR designers are proposing alternate ways to address DiD in their designs. The Forum looked at these approaches and attempted to develop common positions around certain regulatory practices to ensure that the fundamental principles of DiD are maintained.
- Emergency Planning Zones (EPZs): On the basis of the alleged characteristics of SMRs, smaller EPZs are being proposed by some SMR vendors. The Forum examined existing practices and strategies for understanding how flexible (i.e., risk informed) EPZs are established in order to have a common position on this issue.

The Forum distinguishes itself from existing fora/organizations such as the Nuclear Energy Agency fora (e.g. Multinational Design Evaluation Programme - MDEP, Generation IV International Forum - GIF, Group on the Safety of Advanced Reactors - GSAR, Committee on Nuclear Regulatory Activities - CNRA) and World Nuclear Association, Coordination in Reactor Design Evaluation and Licensing working group (CODEL), whose focus lies more on specific technical issues or particular designs. The IAEA publications on SMR designs served as references for the discussions during the project. The Forum adopted the following SMR definition for consistency in discussions. Small Modular Reactors typically have several of these features:

- Nuclear reactors typically <300 MWe or <1000 MWt per reactor;
- Designed for commercial use, i.e., electricity, production, desalination, process heat (as opposed to research and test reactors);
- Designed to allow addition of multiple reactors in close proximity to the same infrastructure (modular reactors);
- May be light or non-light water cooled; and
- Use novel designs that have not been widely analysed or licensed by regulators;

The main limitation encountered by the Forum is the fact that development and deployment of SMRs around the world is at a very early stage in terms of maturity of technologies and varying degrees of activity occurring in Forum member countries. Another constraint was the lack of sufficient information from SMR design vendors on the implications of such things as new novel design principles and features (e.g., passive systems) and whether these challenged or complemented DiD principles.

In addition to the reports from the working groups on the issues noted above, the report provides recommendations for additional areas of interest for future work of the Forum. These include exploring where efficiencies can be gained by sharing of information and closer cooperation between regulators.

1 INTRODUCTION

In the last decade, there has been a significant, increasing interest in small modular reactors (SMR) from its Member States. Due to their smaller size, SMRs offer a viable alternative to larger reactors because they appear to require lower investments in both reactor and associated nuclear infrastructure due to their inherent safety characteristics and in terms of needed political and financial commitments. SMRs can be built in larger numbers, more quickly and in remote locations throughout the world. For these reasons, SMRs might represent a more attractive option to both embarking countries and countries expanding their existing nuclear power programmes. Forum's Regulators recognize that some SMR designs may offer a significant safety enhancement over existing nuclear power plants.

Forum Members States may struggle with the licensing of SMRs due to uncertainties regarding applicable safety requirements, which at present focus mainly on the reactor designs commercially deployed. National safety requirements need to take into account the specific features of SMRs, not only in terms of applying a Graded Approach to existing safety requirements (due to their smaller size and lower risk impact), but also in updating them when new features may represent a risk to safety (e.g. siting requirements for underground or underwater reactors).

1.1. BACKGROUND

The idea of establishing an international forum for regulators to discuss issues associated with licensing SMRs was first raised in mid-2012 after bilateral discussions between the U.S. and Canada. Initial considerations were that the Forum could be associated with NEA/MDEP. Four factors contributed to the decision to ask the IAEA to function as the Scientific Secretariat, (1) the MDEP Technical Steering Committee decided not to expand the scope of MDEP to include SMR issues, (2) the U.S. and Canadian regulators noted that IAEA/INPRO had sponsored several well-attended meetings on SMRs, (3) senior managers at the IAEA were supportive of the idea of an SMR Regulators' Forum, and (4) the membership of the IAEA is much larger than MDEP and would allow for discussions with a much more diverse group of countries.

At the INPRO Dialogue Forum on Licensing and Safety Issues for Small and Medium-sized Reactors, held in Vienna in July/August 2013, there was explicit interest expressed by a number of IAEA Member States to evaluate and discuss the benefits of forming a Regulators' Forum which would specifically address regulatory issues in safety and licensing of SMRs.

As a result, consultancy meetings, facilitated by the IAEA, were held in Vienna 18-20 February 2014, and 22-24 July 2014. The outcome of these consultancy meetings was an agreement to organize a Small Modular Reactor Regulators' Forum on a 2 year pilot basis. A draft Terms of Reference (ToR) and draft Pilot Project Plan were also produced.

1.2. OBJECTIVES OF THE TWO-YEAR PILOT PROJECT

The pilot project was established to obtain an understanding of each member's regulatory views on common issues identified in the scope (Section 1.4) below to capture good practices and methods, enabling regulators to inform changes, if necessary, to their requirements and regulatory practices.

The objectives of the two-year pilot project were:

A. Share regulatory experience amongst Forum Members and strive to reach common understanding on discussed issues;

B. Document and disseminate the results of the discussions; and

C. Interact with key stakeholders, where possible, to effectively inform Forum activities.

1.3. STRUCTURE OF THE FORUM

The Forum structure defined for the two-year pilot project is provided in Figure 1 below. The structure includes a Chairperson, Vice-chairperson, Steering Committee and Issue specific Working Groups.

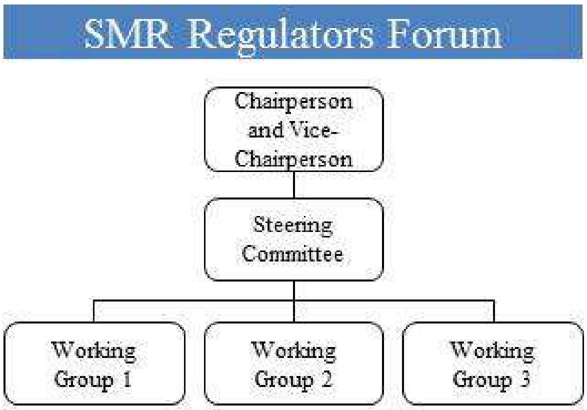

Figure 1. Forum Structure

Through Working Groups, the Forum addressed the following issues for both light-water and non-light-water reactor designs:

- Graded approach
- Defence-in-depth
- Emergency Planning Zone

For the pilot phase of this Forum, membership to the Forum is limited to the IAEA Member States who participated in the initial sessions of this Forum: Canada, China, Finland, France, Republic of Korea, Russian Federation and United States. The United Kingdom joined the Forum during the second year of the project.

At request of Forum members, the IAEA provided a Scientific Secretary made available through an extra budgetary contribution from Forum member(s) to facilitate and promote the Forum's activities. The IAEA provided general and professional support staff to facilitate the implementation of the Forum activities and develop and maintain a communication platform and provide advice on the IAEA Safety Standards.

1.4. SCOPE OF THE PROJECT

Within a two-year pilot project, the Forum addressed the following issues for both light-water and non-light-water reactor designs:

Graded Approach

Problem description: Regulators are being approached by SMR proponents who ask how to apply a Graded Approach for fulfilling regulatory requirements for design and safety analysis. Therefore, there is a need to clarify the regulatory view of grading and what this means.

The Forum members shared information about different methodologies used by regulators and licensees when addressing design and safety analysis requirements. They noted that there is a need to document the various regulatory approaches.

The below considerations stimulated discussions for the Graded Approach working group:

- Comparison between regulatory frameworks for research reactors and NPPs, how they are graded and what implications for SMRs might be;
- Understanding and documenting different methodologies;
- Grading, taking into account multi-module operation; and
- Informing emerging countries who are developing new regulatory frameworks.

Defence in Depth for SMRs

Problem description: A number of SMR designers are proposing alternate ways to address defence-in- depth (DiD) in their designs. The working group was tasked with looking at these approaches and attempting to develop common positions around certain regulatory practices to ensure that the fundamental principles of DiD are maintained.

The below considerations stimulated discussion for the DiD working group:

- Different regulatory approaches for DiD (WENRA);
- Structural and functional DiD (Safety injection accumulators, classification of passive systems);
    - Inherent core characteristics
    - Sole reliance on passive safety systems
- Flexibility in the implementation of DiD for SMRs;
- Shared control room for multi-module facilities (shared SSCs);
- Common cause failure considerations; and
- Different methods of applying single failure criteria.

<u>Emergency Planning Zones (EPZ)</u>

Problem description: Because of the characteristics of SMRs, smaller emergency planning zones (EPZs) are being proposed.

Referring to the following sub-topics, the group examined existing practices and strategies for understanding how flexible (i.e., risk informed) EPZs are established in Member States. The group also reviewed existing IAEA safety requirements and guidance to determine if any changes are needed.

The below considerations stimulated discussion for the working group:

- Siting;
- Source Term for water-cooled reactors (Sources Codes, Standards);
- Source Term for non-water-cooled reactors (Sources Codes, Standards); and
- Consequences from multiple module accidents.

1.5. SRUTCTURE OF THIS REPORT

This report presents the results of the Pilot Project of the SMR Regulators' Forum. It includes information on the background and structure of the Forum, as well as the objectives of the Pilot Project (Section 1.2), main findings of the Pilot Project (Section 2), conclusions, recommendations and common positions reached during the Pilot Project (Section 3) and recommendations for future work (Section 4)

The appendices to this report contain SMR project status and issues in Forum Member States (Appendix I), reports from each of the Forum working groups (Appendices II – IV), and the survey sent out by the Graded Approach and Defence-in-Depth working groups (Appendix V).

1.6. CONSTRAINTS AND LIMITATIONS

The working groups experienced a number of constraints and limitations. They established their scope of work accordingly and implemented other appropriate mitigation measures to address these constraints and limitations. The major constraints and limitations are discussed below.

Limited familiarity with SMR designs and availability of design information

The development and deployment of SMRs around the world is at a very early stage in terms of maturity of technologies and varying degrees of activity occurring in WG Member States. Many regulatory bodies of participating countries have exchanged limited information with SMR designers. Consequently, most WG members have limited personal knowledge and experience with SMR designs that could be brought to the Forum at the beginning of the project. Compounding this limitation is the fact that although IAEA has a number of initiatives to collect and disseminate information on SMR designs, most detailed design information is considered proprietary by SMR vendors and not available publicly. For example, limited design information was available on safety systems. Additionally, although one member had a significant amount of information on a design being developed in its country, it was unable to share such information.

To gain familiarity with many SMR designs, WG members identified a number of documents on SMR designs and safety issues. Members also researched their own files for publicly available information on SMR designs they had received from vendors. For studies like this in the future, it may be fruitful to pursue interactions with SMR designers and vendors to see if they would be willing to discuss design details with the Forum or through the IAEA.

Limited information about application of existing DiD requirements to SMRs

Another constraint was the lack of information from SMR design vendors on the implications of such things as new novel design principles and features (e.g., passive systems) and whether these challenged or complemented DiD principles. For example, to what extent does a multi-module facility design include coupling of modules and sharing of systems? Are designers concluding that provisions for DiD in levels 3 and 4 can be reduced in the presence of simple "inherently safe" design features normally associated with DiD level 1? The WGs could address this limitation only by drawing on information available to them from their limited interactions with designers and regulatory bodies.

Limited time available for the WGs to work together

The limitation of time available for face-to-face discussion is common among international working groups. This limitation was especially constraining for this Forum. Working group members were faced with competing priorities within their sponsoring organizations resulting in limited attendance at Forum meetings from some Member States. There was also limited availability for the WG chairs to meet to understand the relationship between the three. Achieving the group's main objective and reaching agreement on complex issues in SMR designs required significant discussion.

Limited interaction with other conferences, organizations, etc.

Members of the Forum had limited interaction with other organizations during the two-year pilot project. The limitation resulted in the working groups having minimal interaction into activities performed by other regulatory Forums (e.g. IAEA, OECD-NEA) to ensure work was not duplicated and regulatory messaging remains consistent.

1.7. SMR DEFINITION

The SMR Regulators' Forum used the following SMR Definition: Small Modular Reactors typically have several of these features:

- Nuclear reactors typically <300 MWe or <1000 MWt per reactor;
- Designed for commercial use, i.e., electricity, production, desalination, process heat (as opposed to research and test reactors);
- Designed to allow addition of multiple reactors in close proximity to the same infrastructure (modular reactors);
- May be light or non-light water cooled; and
- Use novel designs that have not been widely analysed or licensed by regulators

It should be noted that the IAEA publications on SMR designs served as references for the discussion.

1.8. SMR-SPECIFIC FEATURES

The SMR-specific features that were considered by the WGs have been grouped into four categories: facility size, use of novel technologies, modular design and deployment. These categories are not mutually exclusive. They simply provide a useful framework for identifying important SMR specific features. The key SMR specific features are listed below:

Facility size:

- smaller plant footprint (as compared to a conventional NPP);
- small power of the core:
  - reduced decay heat load;

  - increased core stability;
  - smaller inventory of radionuclides;
  - passive safety.

Use of novel technologies:

- passive cooling mechanisms:
  - natural circulation;
  - gravity driven injection.
- integral design (incorporation of primary system components into single vessel);
- non-traditional or different number of barriers to fission product release;
- unique fuel designs (e.g., ceramic materials, molten salt fuel).

Modular design

- compact and simplified designs
  - practical elimination of some severe accidents
  - inherent safety features (e.g., longer grace periods)
  - fewer structures, systems and components (SSCs)
    - elimination of some traditional initiating events
  - introduction of new events
    - internal to single module
    - module to module interactions
    - new construction techniques
- production, assembly and testing in factory
- multi-module facilities
  - control room staffing
  - sharing of SSCs among modules
  - modules dependence/independence
  - multi-module failure in hazards conditions

Deployment (siting and transportation)

- siting:
  - on ground;
  - underground;
  - on sea;
  - under water;
  - movable;
  - in regions lacking in essential infrastructure (e.g., electrical grid, cooling water).
- module transportation:
  - during construction;
  - during the operation of other modules;
  - for refueling purposes in some designs.

As mentioned in Section 1.6, the WG members found it difficult to establish a definitive list of common SMR features due to the early stage of their development and limited publicly available detailed design information. Their judgment relies on a small set of available SMR documents, and is presented without feedback from SMR designers. For these reasons, the list of SMR features is non-exhaustive; their implications should be considered cautiously and will be considered for review in a latter phase of the Forum.

2. MAIN FINDINGS FROM THE PROJECT

2.1 USE OF A GRADED APPROACH FOR SMRs

The concept of Graded Approach1 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 licence2 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 licence 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 parts 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 (FOAK) 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 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.

This report articulates common views and recommendations from the following four Forum Members regulatory bodies about what "Graded Approach" means, how it is being used, common conditions and considerations concerning its use for application of technology neutral requirements to new technologies:

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[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 permission.

- Canada – CNSC;
- France – IRSN on behalf of ASN;
- Russian Federation – Rostechnadzor; and
- United States – U.S. NRC.

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.

Forum Members' 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 NPP 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 analysis, 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.

2.2 APPLICATION OF THE DEFENCE-IN-DEPTH CONCEPT

SMR designers purport to have enhanced safety performance through inherent, passive and novel safety design features. There are design options for remote regions with less developed infrastructures, factory-builds, multiple-modules, transportable floating and seabed-based units. Any of these SMR features could challenge traditional licensing processes including legal and regulatory frameworks. Some SMR specific features have raised questions about how the principles of DiD are being incorporated into SMR designs.

The SMR Regulators' Forum Defence-in-Depth Working Group was established to identify, understand and address key regulatory challenges with respect to DiD that may emerge in regulatory activities relating to small modular reactors (SMRs). This group's work will help enhance safety and efficiency in licensing, and enable regulators to inform changes to their requirements and regulatory practices. This report articulates common views and recommendations about Defence-in-Depth from the following Forum Members' regulatory bodies:

- Canada – CNSC;
- Finland – STUK;
- France – IRSN on behalf of ASN;
- Republic of Korea –Korea Institute of Nuclear Safety;
- Russian Federation – Rostechnadzor; and
- United States – U.S. NRC.

The DiD WG agreed that, as a fundamental principle for ensuring nuclear safety, the DiD concept is valid for SMRs and should be a fundamental basis of the design and safety demonstration of SMRs. However, since it is recognized that the DiD principles were developed for and applied mainly to large NPPs, the WG discussed their application to SMRs considering the SMR design specifics.

The working group members issued several findings that were divided into three groups: WG common positions, WG recommendations and WG observations. Opportunities to further develop safety guidance to help with the safety assessment of DiD as applied to SMRs were identified and include:

- Demonstration of reinforcement of DiD levels 1 and 2;
- Development of safety criteria and requirements for passive safety systems and inherent safety features;
- Application of failure criteria for safety functions involving passive systems;
- Criteria for exclusion of events;
- New guidance for procedures may need to be developed for inspections of the manufacturer/producer of the module;
- Development of principles and requirements for the safety assessment of "multi-module" SMRs;
- Investigation or enhancement of methods to deal with passive features and with multi-module issues in PSAs; and
- Requirements and guidance for qualifying new materials and features applicable to SMRs designs, including the extent and scale of the testing, verification and validation of models, and fabrication processes.

It should be noted that the WG members found it difficult to establish a definitive list of common SMR features due to the early stage of their development and limited publicly available detailed design information. Subsequently, the group members identified potential opportunities and challenges related to the features and the application of DiD in a general way.

2.3 EMERGENCY PLANNING ZONE

The SMR Regulators' Forum Emergency Planning Zone Working Group was established to identify, understand and address key regulatory challenges with respect to EPZ sizes that may emerge in future SMRs regulatory activities. This will help enhance safety, efficiency in licensing, and enable regulators to inform changes, if necessary, to their requirements and regulatory practices.

Regarding the application of the concept of EPZ size to SMRs, this report:

- Shares regulatory experience and views amongst Forum members;
- Captures good practices and methods and strives to reach a common understanding; and
- Communicate the results of these discussions to the Forum Members.

The WG consensus positions are:

- SMRs encompass a variety of nuclear reactor designs;
- There is a need to consider that the EPZ size for SMRs can be scaled based on the technology, novel features and specific design characteristics; and
- The existing IAEA safety requirements and methodology, in general, for determining the EPZ size are effective in establishing emergency planning zones and distances. Specifically, IAEA Safety Standard Series No. GSR Part 7 and associated lower level publications.

3 CONCLUSIONS AND COMMON POSITIONS

3.1 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 NPPs (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. The report of the WG on GA (Appendix II, 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 NPPs that encompasses SMRs and that the GA-WG actively participates in the drafting of this document.

3.2 ADDRESSING OPERATING LICENCE 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 licence to load fuel into each reactor module, perform any testing and store the module prior to deployment in a guaranteed shutdown state. The operating licence 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 licence, 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?

3.3 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 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 SMRs 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; and
- 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 Forum considers that the existing IAEA safety framework for NPPs, 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 safety requirements. Paragraph 1.6 of Specific Safety Requirement (SSR) 2/1 (Rev.1) Safety of Nuclear Power Plants: Design, supports this point.

3.4 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; and

   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.

3.5 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:

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; and

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; and
7. Issuance of the licence/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.

3.6 COMMON POSITION ON ISSUES 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 licence. 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); and
5. Regulatory witnessing and technical assessment of commissioning activities.

Demonstration facilities and FOAK Plants may and often do present additional levels of uncertainties that may require additional regulatory effort to resolve. This impacts 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; and
4. Experience gained by both the regulator and the licensee.

3.7 COMMON POSITION REGARDING DEFENCE-IN-DEPTH FOR SMRs

As a fundamental principle for ensuring nuclear safety, the DiD concept is valid for SMRs and should be a fundamental basis of the design and safety demonstration of SMRs.

However, it was recognized that the DiD principles were developed for and applied mainly to large NPPs. Consequently, the design specifics and safety claims associated with SMRs as compared to large NPPs raise some questions for discussion regarding the application of DiD principles to SMRs. These SMR design specifics notably include facility size, modular design, the use of novel technologies, and SMRs applications.

It is not possible to express detailed requirements at this stage because the spectrum of SMRs is very large and because of the lack of information about SMR designs and designer intentions.

At this stage, the DiD WG identified some important issues for consideration in the evaluation of DiD for SMRs. The conclusions of the WG about the application of these issues to SMRs are presented in Section 7.1 of the Report from the WG on DiD (Appendix III).

Among these issues, the DiD WG identified safety areas for which the opportunity to further develop safety guidance to help the safety assessment of DiD applied to SMRs may be investigated. This is presented in Section 7.2 of the Report from the WG on DiD (Appendix III).

It could be desirable for future SMR Regulators' Forum activities to organize exchanges on safety information among SMR designers, regulatory bodies and their technical support organizations (TSOs) to better understand and frame SMR characteristics as mentioned in Section 7.2 of the Report from the WG on DiD (Appendix III).

3.8 CONCLUSIONS ABOUT THE APPLICATION OF DEFENCE IN DEPTH TO SMRs

3.8.1 Application of Defence-In-Depth levels

In general, all five DiD levels as defined for typical large Generation III NPPs and taking into account lessons learned from the Fukushima Daiichi Nuclear Power Plant accident are also applicable to SMRs. Appropriate features should be included in the SMRs design at each level.

In order to ensure the successive levels of DiD, and despite the efforts of SMR designers on DiD levels 1 and 2 reinforcement, it is important to get a clear demonstration of the effectiveness of the design safety features to mitigate PIE (level 3) and of the features to mitigate severe accidents (level 4) for all operating modes.

For DiD level 5, the DiD WG is in agreement with the NEA statement that, no matter how much other levels may be strengthened, effective emergency arrangements and other responses are essential to cover the unexpected.

3.8.2 Independence of the DiD levels

The independence among DiD levels, as far as practicable, is considered to be an important requirement to enhance the effectiveness of defence in depth in international and national standards and documents. The Fukushima Daiichi NPP accident has confirmed and reinforced this requirement. Therefore it should apply to SMRs as well. In the case of SMRs, it could be investigated whether the SMR specific features, in particular the compact design of the modules and the multi modules design, may particularly challenge the independence of DiD levels.

Some questions raised by the application of the independence concept in SMR design could be discussed. These include in particular the interpretation of "as far as practicable" and the acceptability of potential non-independent features that may be implemented by the designers.

3.8.3 Siting issues

Taking into account SMR specific features, selected site characteristics could be an important challenge for DiD reinforcement.

The design shall take due account of site-specific conditions to determine the maximum delay time by which offsite services need to be available.

Siting aspects may have important influence on SMR safety design and different DiD levels due to applicable range of suitable site for SMR installations, including underground, underwater or floating on water.

New site configurations may require the evaluation of additional specific external hazards and environmental phenomena. For multi-unit/module plant sites, designs shall take due account of the potential for specific hazards giving rise to simultaneous impacts on several units/modules on the site.

3.8.4 Design issues

Design activities

The DiD WG identified that the tendency of global standardization and certification of SMR designs desired by some designers and proposed by World Nuclear Association (WNA) may be challenging for current licensees and regulators. It may require significant changes in the national licensing process.

Inherent safety and passive systems

An important challenge for DiD in SMR designs is to achieve a well-balanced safety concept based on the use of optimal combination of active, passive and inherent safety features.

All inherent safety characteristics that are provided by the design and credited in the safety demonstration should be duly substantiated by SMR designers. The requirements and criteria for this demonstration should be defined beforehand and developed, which may need particular guidance. As many safety requirements are mostly oriented to DiD levels 3 and 4, it could be useful to further develop guidance and requirements for safety assessment of DiD levels 1 and 2. (See Section 7.2 of the Report for the WG on DiD, Appendix III).

SMR design with enhanced use of passive systems is required to develop safety criteria and requirements on the level of IAEA safety standards and safety guides, WENRA recommendations and national regulations. (See Section 7.2 of the Report for the WG on DiD, Appendix III).

The use of passive systems may induce new challenges: new innovative technologies without sufficient operational experiences, uncertainties related to qualification and reliability assessments, operational aspects as periodic testing, maintenance and in-service inspections. Particular attention should be paid to these issues at each of the design, construction and operation stages of SMRs. Further development of safety criteria and requirements may be necessary. This includes the application of failure criteria for safety functions involving passive systems. (See Section 7.2 of the Report for the WG on DiD, Appendix III.)

In case of uncertainties in passive features reliability or common cause failure mechanisms in active systems, a combination of active and passive safety systems may be desirable. Such a combination could even strengthen safety function performances at DiD levels 3 and 4 and improve the independence between those two levels.

Excluded events versus postulated initiating events

The designers should demonstrate that they have developed and applied a systematic approach for identifying postulated initiating events that may occur considering the design specifics of their SMRs and taking into account all plant states.

If some initiating events are considered to be "excluded" by SMR designers, without any safety features to mitigate their consequences, sufficient provisions (e.g., design, fabrication and operation) shall be implemented and duly justified.

Criteria for exclusion of events should be established. (See Section 7.2 of the Report for the WG on DiD, Appendix III).

Internal and external hazards

Common mode events due to internal hazards and their influence on DiD levels independence should be considered, taking into account SMR design specifics (e.g., modules, compact design and multi units/modules aspects).

Regarding the external hazards, because SMRs may be located remotely or in many different environments, a detailed analysis of all possible hazards and associated risks for SMRs should be performed for each specific SMR application. The IAEA, OECD NEA and WENRA international experiences and the lessons learned after the Fukushima Daiichi NPP accident should also be extensively used in the design of SMRs regarding the risks of external hazards.

Moreover, multi modules/units aspect should be considered in the safety assessment of internal and external hazards.

Practical elimination

The practical elimination concept should not be used to justify omission of a complete DiD level. For example, it should not be used to justify absence of severe accident management arrangements and capabilities that are expected at DiD level 4 or in the absence of offsite emergency response at level 5.

Multi-modules issues

As the concept of SMR “module” is not equivalent to the “unit” or “plant” concept for large reactors, the safety principles developed for the “multi-units” issue cannot be transposed to “multi-modules” in SMR facilities. Therefore, principles and requirements for the safety assessment of a “multi-module” SMR should be developed. (See Section 7.2. of the Report from the WG on DiD, Appendix III).

It is necessary to demonstrate that for “multi-modules” facilities, connections, shared features and dependencies among modules are not detrimental to DiD. A “multi-modules safety assessment” could contribute to verifying that all common features and dependencies don’t induce unacceptable effects.

Even if the SMR concept is based on modular design with small unique power on multi modules/units sites, the SMR design should take due account of the potential consequences of several – or even all – units failing simultaneously due to external hazards. It may affect the methodology for EPZ assessment.

Role of PSAs

As for large reactors, PSAs should be used for SMRs to complement the deterministic approach on which the design relies first.

PSAs could be used to check that DiD principles have been properly applied. PSA results could reflect the reliability of the features implemented at each DiD level and the sufficient independence of the levels. PSAs could also be used for the identification of so-called complex DEC sequences and for the assessment of the risks induced by multi-modules.

Methods to deal with passive features and with multi-module issues in PSAs should be investigated or enhanced. (See Appendix III, Section 7.2.)

3.8.5 Post-design issues

After the design phase, safety should be guaranteed during fabrication, construction, transportation, commissioning, operation and decommissioning of the installation.

The DiD WG focused the discussions on DiD application in siting and design activities. Post-design activities were not discussed in detail. However, the DiD WG has identified fabrication and transportation as specific aspects to focus on for many SMRs.

Since there is an increasing role of the manufacturer/producer of the main equipment of the module in the factory conditions, inspections performed in the factory are particularly important and new guidance for procedures for such inspections may need to be developed. (See Appendix III, Section 7.2.) A well planned and properly documented site acceptance testing and commissioning program should be prepared and carried out.

3.8.6 Novel technologies

Detailed assessments should be applied to innovative technologies of SMR designs that are without operational experiences. The new features and practices shall be adequately qualified through verifications, validations and testing before being brought into service to the extent practicable, and shall be monitored in service to verify that the behavior of the plant is as expected. Requirements and guidance are necessary for qualification programs of new materials and features applicable to SMR designs including the extent and scale of the testing, verification and validation of models, and fabrication processes. (See Appendix III, Section 7.2.)

3.9 CONCLUSIONS FOR EMERGENCY PLANNING ZONE FOR SMRs

The EPZ WG developed conclusions as listed below:

- SMRs encompass a variety of nuclear power plant designs. Managing SMR events involving the potential for releases of radioactive material that challenge public safety and the environment requires a coordinated response;
- There is a need to consider that the EPZ for SMRs is scalable depending on the results of a hazard assessment, the technology, novel features and specific design criteria, as well as for some, policy factors. The IAEA safety requirements and methodology for determining the EPZ size are effective in establishing an emergency preparedness and planning program, such that if a release does occur, protective actions will be implemented to protect the public and environment;
- A pre-application process may be considered to discuss the requirements and standards for siting and determining EPZs with potential applicants;
- For SMRs without on-site refueling capability, there is a need to consider the establishment of an EPZ at any intermediate stop and land-based maintenance facility used for the handling and the storage of the fuel assemblies;
- There is a need to consider some level of community emergency preparedness, for example, to receive public information and perform response drills, specifically when the size of the EPZs for SMRs are reduced to be in close proximity to densely populated centers;
- For SMR designs employing novel features and technology, there is a need to consider a mechanistic methods for determining relevant source terms, which may be considered in the determination of the size of the EPZ&Ds; and
- The same design of SMR implemented in different countries may result in different EPZ sizes depending on the regulation, protection strategy, dose criteria, policy factors, and public acceptance.

The IAEA Secretariat highlighted that:

- Existing IAEA Safety Standards already address EPZ&Ds and are applicable to new reactor designs (including SMRs);
- According to existing IAEA Safety Standards, it would not be appropriate to consider EPZ&D as a design issue (i.e. as being related/influenced by the design safety);
- EPR arrangements, including EPZ&D, need to be developed based on results of hazard assessment, accounting for events of very low probability and events not considered in the design;
- High uncertainties and the need for urgent response actions may persist for SMRs, hence the need for an emergency classification system and pre-established response plans;
- The timing may be positively affected by new reactor designs. The possible failure of additional safety functions needs to be considered nonetheless;
- The duration of the release may be impacted by new reactor designs, but response actions may still be required in all directions; and
- The size of the release may be affected by new reactor designs, having an effect on the size of the EPZ&D. The impact may not be the same for all EPZ&D.

4 RECOMMENDATIONS FOR FUTURE FORUM ACTIVITIES

Project participants made several recommendations with regard to the follow-up of the project. These are presented below:

4.1 RECOMMENDATIONS FOR FUTURE ACTIVITIES FROM GRADED APPROACH WORKING GROUP

From a safety perspective, member regulators in the SMR Regulators Forum agree that SMRs should be treated as NPPs and that the starting point in the 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.

The concept of Graded Approach is widely discussed in the IAEA safety framework and is mentioned in documents applicable to nuclear power plants. Appendix 1 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 Graded Approach 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.

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).

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.

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 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 first of a kind (FOAK)/demonstration facilities to gather operational experience and information needed to support safety cases for a future fleet of reactor facilities referencing that design3. 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; and
- Single operator, multiple reactor interface architectures.

4.2. RECOMMENDATIONS FOR FUTURE ACTIVITIES FROM DEFENSE-IN-DEPTH WORKING GROUP

The DiD WG identified safety areas for which the opportunity to further develop safety guidance to help the safety assessment of DiD applied to SMRs may be investigated. These include:

- Demonstration of reinforcement of DiD levels 1 and 2;
- Development of safety criteria and requirements for passive safety systems and inherent safety features;
- Application of single failure criteria for safety functions involving passive systems;
- Criteria for exclusion of identified initiating events from the design;
- New guidance for procedures may need to be developed for inspections of the manufacturer/producer of the module;
- Development of principles and requirements for the safety assessment of "multi-module" SMRs;
- Investigation or enhancement of methods to deal with passive features and with multi-module issues in PSAs; and
- Requirements and guidance for qualifying new materials and features applicable to SMRs designs, including the extent and scale of the testing, verification and validation of models, and fabrication processes.

The following activities are recommendations for possible future Forum activities:

- Organize exchanges on safety information among designers, regulators and their TSOs to better understand and frame the SMR characteristics; and
- Exchange information and share common positions on DiD with Member States in an effort to enhance harmonization on national and international levels of the licensing process.

4.3 RECOMMENDATIONS FOR FUTURE ACTIVITIES FROM EMERGENCY PLANNING ZONE WORKING GROUP

The WG members had a variety of discussions and insights while writing this document. Many of the discussions pertained to the following topics, which were determined to beyond the scope of the WG's purpose. Therefore, the WG makes the following suggestions for the future work of the SMR Regulators Forum:

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[3] 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.

- Explore further the necessity to develop publications addressing in further detail the technical basis for developing EPZ&Ds based on existing IAEA Safety Standards;
- Examine the safety culture with respect to SMR industry. This topic arises from new designers and operators entering the industry, as well as, creating a culture from the beginning to not become complacent by "safety by design";
- Examine the physical security requirements for SMRs. Do SMRs adopt a "security by design" philosophy?
- Examine the elements for community emergency preparedness or off-site response planning;
- Examine the licensing of materials, reactors and irradiated fuel while in transit and among transit state;
- Explore further the "One design, one review" concept;
- Define a "Prudent proven" technology; and
- Examine the advances in "human factors engineering" and how novel features of SMRs expand leverage HFE.

ACRONYMS

DiD	Defence-in-Depth
EPD	Extended Planning Distance
EPR	Emergency Preparedness and Response
EPZ	Emergency Planning Zone
FOAK	First of a Kind
GA	Graded Approach
HFE	Human Factors Engineering
HTGR	High Temperature Gas Reactor
ICPD	Ingestion and Commodities Planning Distance
INPRO	International Project on Innovative Nuclear Reactors and Fuel Cycles
MDEP	Multinational Design Evaluation Program
NPP	Nuclear Power Plant
NSCA	Nuclear Safety and Control Act
OECD	Organisation for Economic Co-operation and Development
OPEX	Operational Experience
PAZ	Precautionary Action Zone
PEPZ	Plume Emergency Planning Zone
PIE	Postulated Initiating Event
PSA	Probabilistic Safety Assessment
PSAR	Preliminary Safety Analysis Report
SC	Steering Committee
SSC	Structures, Systems and Components
SMR	Small Modular Reactor
TRISO	Tristructural-isotropic
TSO	Technical Support Organization
UPZ	Urgent Protective Action Planning Zone
WENRA	Western European Nuclear Regulators Association
WG	Working Group
WNA	World Nuclear Association

APPENDIX I - SMR PROJECT STATUS AND ISSUES IN FORUM MEMBER STATES

Canada

In the Canadian regulatory framework, the regulations along with associated requirements and guidance provide for sufficient flexibility for a proponent to propose how they are, in the opinion of the Commission of the CNSC:

a) qualified to carry on the activity that the licence 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.

Over the past several years, the Canadian Nuclear Safety Commission (CNSC) has worked diligently to ensure that Canadian requirements are technology-neutral to the extent practicable and can be met in different ways commensurate with the risks presented by the proposed activities. This work continues as a normal part of the regulatory document review and update cycle.

Stakeholders are encouraged to engage with CNSC early to understand the requirements that would apply for specific applications and the processes that would be used to authorize activities to proceed. For example, CNSC has implemented a Pre-Licensing Vendor Design Review Process to help vendors anticipate and resolve potential regulatory risks that a future licensee would need to address in a project proposal. A number of technology vendors are using this process to further inform their future activities in Canada. CNSC does not certify reactor designs at present because the need to do so has not arisen.

Canada has a licensing process that is suitable for projects of different types of SMRs but recognizes the need to improve process clarity as experience from projects is accumulated. As discussed above, the licensing process is focused on the proponent’s safety and control measures for the project which takes into account design features of the reactor facility (note: a reactor facility can be one or more modules/units). A licence can be established to encompass a range of activities (e.g. construction and operation) depending on the proposal submitted. The applicant will need to demonstrate, with quality submissions, that all of the safety and control measures will be in place for the proposed activities. CNSC has committed to fixed review timelines but this is heavily dependent on high quality submissions and community acceptance.

China

China started its research and development program on high temperature gas cooled reactors in the 1970s. In 1992, the Chinese Government approved the construction of the 10MW pebble bed high temperature gas cooled test reactor (HTR-10) and in January 2003 the reactor reached full power (10MWth) operation. In 2001 China launched its High Temperature Gas-cooled Reactor-Pebble-bed Module (HTR-PM) reactor development project. The HTR-PM will be a commercial demonstration plant for electricity production. The preliminary safety analysis report (PSAR) was accepted by the licensing authorities in 2012. First concrete of the HTR-PM demonstration power plant was poured in December 2012 and construction is progressing at present. The FSAR (Final SAR) assessment is expected in 2017 with operation towards the end of 2018.

In addition, the China National Nuclear Corporation (CNNC) is developing the ACP-100 design. ACP-100 is producing power of 100 MW(e) and based on existing PWR technology. The ACP-100 engineering design is close to completion, CNNC and IAEA signed an agreement to conduct a generic safety review for ACP100 in April 2015. It is expected to start the demonstration project with the first two units for Changjiang, Hainan Province on the south of China in the near future. Some Chinese corporations or nuclear research institutions, such as CNNC, China General Nuclear Power Corporation (CGN) and China Shipbuilding Industry Corporation (CSIC),Tsinghua University, are working for researching and developing of Low Temperature Nuclear District Heating Reactor Plant and Offshore Nuclear Plant.

Finland

Finland currently has three major reactor sites, one in the north of the country, and two more in southeast with conventional NPPs. The Licensee has expressed interest, but not yet shown any concrete signs of ambition to deploy SMR designs at this point. However, STUK is interested to prepare itself to be able to adequately review any future license application

France

The French regulatory body currently has no submitted license application for an SMR design. Preliminary discussions have been held between the IRSN, French TSO, and DCNS on the Flexblue concept and then with the French safety authority. Flexblue is a subsea small modular power plant with an output capacity of 160 MW(e) with a target deployment by 2025.

Recently, a French-UK partnership has been conclude to develop a new project of SMR, named iSMR, to be submitted to the UK and French government. The licensing process may start in 2021.

More generically, France sees challenges for multi-licensing process for worldwide deployment and for particular issues linked with SMR specific features like modular manufacturing, integrated design, multi-reactors architecture, human factors.

Republic of Korea

Korean nuclear industry is developing three SMR designs, which are currently at different stages of development. While not yet under construction, the Korean Nuclear Safety and Security Commission issued a Standard Design Approval for the 100MW(e) System Integrated Modular Advanced Reactor (SMART) in July 2012. This is the first integral type PWR design to receive an official design certification and in September 2015, South Korea and Saudi Arabia signed contracts to support their cooperation in furthering the reactors development.

Also there are sodium fast reactor, a government driven initiative and high temperature reactor, which is mainly driven by industry. Although interest in SMRs from Southeast Asian countries remains low for the moment, the Korean regulator wishes to prepare itself to address emerging challenges.

Russian Federation

In Russia, there are discussions around two different types of SMR designs. In 2003, the Russian Federation's nuclear regulator, Rostekhnadzor, issued the first construction license for KLT-40 which is a barrage mounted floating power unit (FPU) "Akademic Lomonosov" containing two reactor modules. Each reactor module is rated to 35MW(e) for a total of 70MW(e). Construction of the FPU began in 2007. It is planned that the FPU will be operational in 2017 in Pevek and will be fully operational in 2021.

Furthermore, a license application for a 100 MWe lead-cooled commercial reactor BREST-OD-300 was submitted in 2012, but it was denied by Rostekhnadzor. The vendor is expected to submit a second, improved application in 2018.

United Kingdom

The UK Government announced in March 2016 Phase One of a competition to identify which SMR could feasibly be deployed in the UK. Phase One of competition was open to technology developers, utilities, potential investors, funders and other parties interested in developing, commercialising and financing SMRs in the UK. One of the objectives of the competition was to give those in industry an opportunity to discuss their views on SMRs, to inform the UK Government policy going forward. The UK Government have considered a variety of options using the information gathered from eligible participants. The Office for Nuclear Regulation (ONR) has provided technical and regulatory input during Phase One of the SMR competition in 2016. ONR has also developed a strategy to ensure the regulatory framework in the UK is fit for purpose for SMR regulation.

United States

In the U.S., there are a number of SMR light water reactor designs being developed by different vendors. Four integral pressurized water SMRs are under development in the USA: Babcock &Wilcox's mPower, NuScale, Holtec SMR-160 and the Westinghouse SMR. The mPower design consists of two 180 MW(e) modules. NuScale Power envisages a nuclear power plant made up of twelve modules producing more than 50MW(e) each and has a target commercial operation in 2023 for the first plant that is to be built in Idaho. The design certification application of NuScale to the NRC was submitted to the NRC on January 6, 2017. The Westinghouse SMR is a conceptual design with an electrical output of 225MW(e), incorporating passive safety systems and components of the AP1000. The SMR-160 design generates power of 160 MW(e) adopting passive safety features.

A number of non-light water reactor (non-LWR) designs are being developed by different companies in the U.S. These designs include liquid metal fast reactors (LMFR), high temperature gas-cooled reactors (HTGR), and molten salt cooled reactors (MSR). Several non-LWR developers plan to engage in pre-application interactions with the NRC between now and 2019, including OKLO, inc., who is developing a compact fast reactor which uses liquid metal heat transport; X-Energy who is developing a modular HTGR; Terrestrial Energy who is developing an integral MSR, Transatomic Power who is developing an MSR, and Terrapower who is developing a Molten Chloride Fast Reactor.

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[4] 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[5] 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

[4] Alternate terminologies such as "proportionality" are used in some Member States but the intent of the term is essentially the same.
[5] 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 SMR6 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 Approach7 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:

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[6] Refer to the Terms of Reference for the SMR Regulators' Forum for a definition of SMR.

[7] 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 risk8 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 consequences9, 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.

[8] 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

[9] 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:
  - o decide how to review the application (using risk insights) and conduct the review
  - o decide whether the application adequately demonstrates activities will be conducted safely and that they meet requirements
  - o 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 <u>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</u>. 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

- o Certification
- o Compliance (e.g. inspections, table top reviews)
- o 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
  - o 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.
  - o 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:
  - o Facility minimum complement (plant staffing)
  - o Extent of emergency planning measures (and zones)
  - o 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 environment[10]. 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.

[10] 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 representative[11] 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

[11] 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 State12. 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 case13. 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.

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

[13] 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 design14. 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

[14] 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

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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.

<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">Site Evaluation for Nuclear Installations Safety Requirements Series No. NS-R-3,

Development of successor document SSR1 is currently in progress</td><td>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</td></tr>
</table>

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)

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**
Safety of Nuclear Power Plants: Commissioning and Operation Specific Safety Requirements Series No. SSR-2/2			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.

APPENDIX III - REPORT FROM WORKING GROUP ON DEFENCE-IN-DEPTH

Executive Summary

The SMR Regulators' Forum Defence-in-Depth Working Group was established to identify, understand and address key regulatory challenges with respect to defence in depth (DiD) that may emerge in regulatory activities relating to small modular reactors (SMRs). This group's work will help enhance safety and efficiency in licensing, and enable regulators to inform changes to their requirements and regulatory practices.

The DiD WG agreed that, as a fundamental principle for ensuring nuclear safety, the DiD concept is valid for SMRs and should be a fundamental basis of the design and safety demonstration of SMRs. However, since it is recognized that the DiD principles were developed for and applied mainly to large NPPs, the WG discussed their application to SMRs considering the SMR design specifics.

The working group members issued several findings that were divided into three groups: WG common positions, WG recommendations and WG observations. Opportunities to further develop safety guidance to help with the safety assessment of DiD as applied to SMRs were identified and include:

- demonstration of reinforcement of DiD levels 1 and 2
- development of safety criteria and requirements for passive safety systems and inherent safety features
- application of failure criteria for safety functions involving passive systems
- criteria for exclusion of events
- new guidance for procedures may need to be developed for inspections of the manufacturer/producer of the module
- development of principles and requirements for the safety assessment of "multi-module" SMRs
- investigation or enhancement of methods to deal with passive features and with multi-module issues in PSAs
- requirements and guidance for qualifying new materials and features applicable to SMRs designs, including the extent and scale of the testing, verification and validation of models, and fabrication processes.

It should be noted that the WG members found it difficult to establish a definitive list of common SMR features due to the early stage of their development and limited publicly available detailed design information. Subsequently, the group members identified potential opportunities and challenges related to the features and the application of DiD in a general way.

The International Atomic Energy Agency (IAEA) has seen a significant increase in interest in small modular reactors (SMR) from its Member States. These reactors are being developed to provide flexible power generation for a wider range of users with cogeneration and non-electric applications. The designs include but are not limited to water-cooled reactors, high temperature gas cooled reactors, liquid metal and molten salt cooled reactors. 15

SMR designers purport to have enhanced safety performance through inherent, passive and novel safety design features. There are design options for remote regions with less developed infrastructures, factory-builds, multiple-modules, transportable floating and seabed-based units. Any of these SMR features could challenge traditional licensing processes including legal and regulatory frameworks. Some SMR features have raised questions about how the principles of defence in depth (DiD) are being incorporated into SMR designs.

[15] https://www.iaea.org/NuclearPower/SMR/

As discussed in Section 2, the WG members found it difficult to establish a definitive list of common SMR features due to the early stage of their development and limited publicly available detailed design information. Subsequently, the group members identified potential opportunities and challenges related to the features and the application of DiD in a general way. Their judgment relies on a small set of available SMR documents, and is presented without feedback from SMR designers on how they intend to apply DiD principles to SMRs. For these reasons, the list of SMR features is non-exhaustive and their implications should be considered cautiously.

Purpose

The DiD Working Group (WG) is a sub-group of the IAEA's SMR Regulators' Forum.16 Its purpose is to identify, understand and recommend ways to address key regulatory challenges with respect to DiD that may emerge in future SMR regulatory activities.

Objectives

The group aims to ensure that the integrity of the safety concept of DiD is maintained and, if possible, enhanced for SMRs. It also works to identify efficiencies for licensing, and enable regulators to consider changes, if necessary, to their requirements and regulatory practices by:

- sharing Forum Members' views and regulatory experiences
- capturing best practices and methods, and creating common understandings
- identifying and discussing common safety issues that may challenge regulatory reviews associated with SMRs and, if possible, recommending approaches for resolution

1. Scope of the DiD WG activities

As a basis for its discussions, the DiD WG mainly referred to the IAEA five-level definition of DiD as described in several references. In particular, IAEA SSR-2/1 (Rev. 1), Safety of Nuclear Power Plants: Design [A1], IAEA INSAG-10, Defence in Depth in Nuclear Safety [A2], the Nuclear Energy Agency/Committee on Nuclear Regulatory Activities booklet, Implementation of Defence in Depth in Nuclear Power Plants [A5] and the Western European Nuclear Regulators Association Safety of new NPP designs [A3]. Other basic references for DiD information can be found in Section 8.

The scope of SMR design information was mainly limited to documents available through the IAEA. It also includes member experiences. The SMR design references are included in Section 8.

SMR features have also raised questions about revising traditional requirements in such areas as control room staffing, emergency planning (in light of reduced radioactive inventory) and other site related issues. The implications of SMR design features regarding these areas are not examined in this report.

Within the Forum, it was decided that physical security and safeguards would be considered out of scope.

2. Methodology

2.1. GENERAL APPROACH

To accomplish its objectives, the DiD WG:

- identified the design features typical to SMRs that raise questions about the application of DiD principles
- identified key DiD safety principles and investigated whether each applies to all types of reactors or if some may be adapted to SMRs

[16] The SMR Regulators' Forum emerged from resolutions 9 and 12 adopted at the IAEA 57th General Conference in September 2013. Member states agreed to add language related to improving cooperation and collaboration among SMR regulators.

- surveyed participating Member States about their SMR requirements and experiences

Since DiD is a very general concept that can generate a large set of principles and requirements, the WG selected a number of key safety issues of interest in each of the five levels of DiD. For each issue, and in consideration of the SMR features, the WG made an assessment of its applicability to a broad scope of SMR designs. Given the specific design options of SMRs and the DiD principles, the following questions were proposed to focus the DiD WG discussions:

- Are the definitions of the different levels of DiD for typical large generation III reactors including Fukushima lessons learned and related safety principles fully applicable to SMRs?
- Is there a need to adapt or extend the existing DiD safety principles?

In addition to the above, the WG reviewed the survey responses related to the regulation of SMRs and the expectations for DiD. The results of the survey are summarized in Section 6.

The working group members issued several findings that were divided into three groups: WG common positions, WG recommendations and WG observations. When the WG was not able to reach a consensus, all positions were documented. The results of the WG discussions are presented in Section 5. Section 3 provides background information on DiD and Section 4 discusses SMR-specific features as identified by the WG.

2.2. CONSTRAINTS AND LIMITATIONS

The working group experienced a number of constraints and limitations. It established its scope of work accordingly and implemented other appropriate mitigation measures to address these constraints and limitations. The major constraints and limitations are discussed below.

2.2.1. Limited time available for the WG to work together

The limitation of time available for face-to-face discussion is common among international working groups. This limitation was especially constraining for this WG. Achieving the group's main objective and reaching agreement on complex issues associated with DiD in SMR designs required significant discussion.

The WG limited its review to issues of DiD related to plant design. For example, DiD as it applies to plant operations was not in scope, although some issues associated with SMR deployment, such as remote operation and post-design issues, were considered in Sections 5.4 and 5.6. The WG also limited the extent of its consideration of reduced emergency planning zone size because this topic is the subject of another working group in the SMR Regulators' Forum (i.e., the SMR WG on emergency planning zones). To address communication constraints between in-person meetings, the WG used the IAEA website SharePoint interface, video conferencing, teleconferencing and frequent email communications.

2.2.2. Limited familiarity with SMR designs and availability of design information

The development and deployment of SMRs around the world is at a very early stage in terms of maturity of technologies and varying degrees of activity occurring in WG Member States. Many regulatory bodies of participating countries have exchanged limited information with SMR designers. Consequently, most WG members have limited personal knowledge and experience with SMR designs that could be brought to the Forum at the beginning of the project. Compounding this limitation is the fact that although IAEA has a number of initiatives to collect and disseminate information on SMR designs, most detailed design information is considered proprietary by SMR vendors and not available publicly. For example, limited design information was available on safety systems. Additionally, although one member had a significant amount of information on a design being developed in its country, it was unable to share such information.

To gain familiarity with many SMR designs, WG members identified a number of documents on SMR designs and safety issues. Members also researched their own files for publicly available information on SMR designs they had received from vendors. For studies like this in the future, it may fruitful to pursue interactions with SMR designers and vendors to see if they would be willing to discuss design details with the IAEA.

2.2.3. Limited information about application of existing DiD requirements to SMRs

Perhaps the biggest constraint for the WG was the lack of information from SMR design vendors on the implications of such things as new novel design principles and features (e.g., passive systems) and whether these challenged or complemented DiD principles. For example, to what extent does a multi-module facility design include coupling of modules and sharing of systems? Are designers concluding that provisions for DiD in levels 3 and 4 can be reduced in the presence of simple "inherently safe" design features normally associated with DiD level 1? The WG could address this limitation only by drawing on information available to them from their limited interactions with designers and regulatory bodies.

It could be desirable for future Regulatory Forum activities to organize exchanges on safety information between SMR designers and regulatory bodies with their Technical Support Organizations (TSOs) to better understand and frame future SMR Regulators' Forum activities.

3. Background on defence in depth.

3.1. THE CONCEPT OF DEFENCE IN DEPTH

Defence in depth (DiD) [A1, A2, C1] is the primary means of preventing accidents in a nuclear power plant and mitigating the consequences of accidents if they do occur. DiD is applied to all organizational, behavioural and design-related safety and security activities to ensure that they are subject to layers of provisions, so that if a failure should occur, it would be compensated for or corrected without causing harm to individuals or the public. This concept is applied throughout the design and operation of a reactor facility to provide a series of levels, as shown below, of defence aimed at preventing accidents and to ensure appropriate protection in the event that prevention fails.

Table 1: Levels of defence in depth

Level	Objective	Means for achieving the objective
1	Prevention of abnormal operation and failures	Conservative design and high quality in construction and operation
2	Control of abnormal operation and detection of failures	Control, limiting and protection systems and other surveillance features
3	Control of accidents within the design basis	Engineered safety features and accident procedures
4	Control of severe plant conditions including prevention of accident progression and mitigation of the consequences of severe accidents	Complementary measures and accident management
5	Mitigation of radiological consequences of significant releases of radioactive materials	Offsite emergency response (some onsite response may be included)

3.2. EVOLUTION OF DEFENCE IN DEPTH

DiD is based on an ancient military philosophy of providing multiple barriers of defence. Its application to nuclear power plant design appears to have been first articulated in documents published by the U.S. Atomic Energy Commission in the late 1950s and early 1960s. Indeed, WASH-740, Theoretical Possibilities and Consequences of Major Accidents in Large Nuclear Power Plants, published in 1957, stated that "the principle on which we have based our criteria for licensing nuclear power reactors is that we will require multiple lines of defence against accidents which might release fission products from the facility." The principle was applied in nuclear power plant design in the decades that followed and the term was better defined following the Chernobyl accident that occurred in 1986.

The definition of DiD in terms of five specific levels was first described in INSAG-3, Basic Safety Principles for Nuclear Power Plants (revised as INSAG-12 [C2]), published by IAEA in 1988. INSAG-10, Defence in Depth in Nuclear Safety [A2] was published in 1996. It presented a very detailed description of DiD including a table with the objective for each level of defence and the essential means of achieving each objective. INSAG-12 [C2] was published by IAEA in 1999. It elaborates on the table of INSAG-10 introducing a link between plant states and levels of DiD. The United States Nuclear Regulatory Commission (USNRC) published Regulatory Guide 1.174, An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis, in 1998. [A20] The guide established a risk-informed regulatory framework for evaluating proposed changes to a plant's licensing basis. This framework included the concept of maintaining adequate DiD as one of its five core principles governing the acceptability of risk-informed changes to the licensing basis. In 2000, the IAEA Safety Standard NS-R-1, Safety of Nuclear Power Plants: Design [A21], adopted the concepts and terminology of INSAG-10, and recognized that DiD is a main pillar for generating safety requirements for the design of nuclear power plants (NPPs), including several requirements that explicitly address DiD. This has continued to be the case as the safety standard has been updated and improved over the years.

Today, an international consensus exists that the DiD concept should be considered as a basis for systematic safety substantiations and safety demonstrations in support of nuclear facility licensing. DiD principles and requirements are addressed in many international documents. Most notable among these is IAEA Safety Standard SSR-2/1 (Rev. 1), Safety of Nuclear Power Plants: Design [A1], which is used primarily for land-based stationary nuclear power plants with water cooled reactors designed for electricity generation or for other heat production applications (such as district heating or desalination). However, as stated in SSR-2/1 (Rev. 1), it may also be applied, with judgment, to other reactor types to determine the requirements that have to be considered in developing the design.

DiD is a key concept of the safety objectives established by the Western European Nuclear Regulators Association (WENRA) for new nuclear power plants. [A3] These safety objectives call for the reinforcement of each level of the DiD concept and the improvement of the independence of the levels of DiD defined as one of the WENRA safety objectives. The objectives also ensure that the DiD capabilities intended in plant design are reflected in the as-built and as-operated plant and are maintained throughout the plant life time.

In particular, WENRA [A3] states that new situations, such as conditions from multiple failures and core melt accidents, should be taken into account in the design of new plants. These situations are identified as design extension conditions in IAEA SSR-2/1 (Rev. 1). This is a major evolution in the range of situations considered in the initial design to prevent and control accidents, and mitigate their consequences.

More recently, the Nuclear Energy Agency (NEA)/Committee on Nuclear Regulatory Activities (CNRA) green booklet on DiD [A5]:

- addresses the main issues related to DiD that were identified by a senior-level task group on DiD through an NEA/CNRA workshop as being of prime interest for further study and clarification in a regulatory context
- discusses how DiD has been further developed in response to lessons derived from the Fukushima Daiichi NPP accident
- provides an overall discussion of the use of DiD post-accident for regulators

Key issues derived from study of the Fukushima Daiichi NPP accident are discussed further below. In addition to the NEA work, the USNRC recently published NUREG/KM-0009, Historical Review and Observations of Defence-in-Depth [A22], which provides an historical review and observations of DiD for reactors, materials, waste, security, international and other United States federal agencies.

3.3. IMPLICATIONS OF THE FUKUSHIMA DAIICHI NPP ACCIDENT ON DEFENCE IN DEPTH

The 2011 accident in Fukushima Daiichi NPP provided unique insight into nuclear safety issues, and raised many questions about the tools used at nuclear power plants, including the effectiveness of the application of DiD. Since the accident occurred there have been extensive studies of the lessons learned by many organizations including the NEA/CNRA, WENRA and IAEA. The efforts of these organizations to improve DiD in light of the Fukushima Daiichi NPP accident are summarized below.

CNRA

The CNRA senior-level task group on DiD found that the use of the DiD concept remains valid despite the Fukushima Daiichi NPP accident. The impact of the accident on the use of DiD has reinforced its fundamental importance in ensuring adequate safety. In its report, the CNRA identifies several key issues related to DiD and provides additional guidance to regulators for addressing these issues.

WENRA

In its 2013 report on the safety of new NPP designs, WENRA discusses how insights gained from studying the Fukushima Daiichi NPP accident have informed the development of positions on the DiD approach, independence of the levels of DiD, and multiple failure events. They point to the Fukushima Daiichi NPP accident as a clear indicator of the importance of properly implementing the DiD principle to ensure the reliability of safety functions and to build provisions into the designs of new NPPs to address multiple failure events and events that involve core melt.

IAEA

The IAEA has studied the Fukushima Daiichi NPP accident extensively and, like other organizations, has gained considerable insight regarding potential improvements in the implementation of the DiD principles in NPP design. Such insights are reflected in a revised version of IAEA Safety Standard No. SSR-2/1 (Rev. 1). [A1] Major revisions being considered with regard to DiD were discussed recently at an IAEA consultancy meeting on the assessment of DiD for NPPs, held December 9–11, 2015 in Vienna, Austria. They include adding new requirements to ensure that provisions necessary for achieving each of the five levels of DiD have been incorporated into the design and that the provisions for each level are as independent from those of the other levels as reasonably achievable.

4. SMR specific features

Several IAEA publications [B1, B2] highlight the variety of SMR technologies and associated features that are being developed around the world. A recent report from the Word Nuclear Association (WNA) titled Facilitating International Licensing of Small Modular Reactors, Cooperation in Reactor Design Evaluation and Licensing (CORDEL) Working Group, Small Modular Reactors Ad-hoc Group [C4] summarizes the intentions of many SMR designers and vendors. The message of the WNA is that to facilitate moving towards international licensing for SMRs, it is necessary to understand the features of an SMR design.

Many SMR features have been developed to assist the reactor designs in fulfilling niche applications (e.g., their use in isolated electrical systems on islands, for mines or remote areas, as district heating units, and for chemical processes such as desalination or oil production). The WNA report [C4] notes that facilitation of changes in international licensing for SMRs will require an understanding of the features of SMR design. It also states that some of the features are not unique in themselves, and it is only when considered collectively that they provide an understanding of the reactor type.

Consistent with IAEA references [B2, B5], the SMR Regulators' Forum members have agreed to define SMRs as reactor facilities that:

- generate less than approximately 300 Megawatt electrical (1000 Megawatt thermal) per reactor

- are designed for commercial use (i.e., for power production, desalination or process heat rather than for research and test purposes)
- are designed to allow the addition of multiple reactors in close proximity to the same infrastructure
- may be light or non-light water cooled

It is important to note that the term modular has also been applied to new large reactors. When applied to these types of reactors, it is used to denote modular construction of the entire power plant – not to the production multiple reactor modules from a design template. The following sections discuss the approach to identifying specific SMR features for inclusion in the report.

4.1. APPROACH TO THE IDENTIFICATION OF SMR SPECIFIC FEATURES

In order to establish a comprehensive list of SMR specific features for comparison against the application of DiD, it was important to have sufficient information on SMR technologies. This includes the intentions of SMR designers and vendors regarding the integration of the DiD concept with design principles such as inherent safety features and with the mitigation of severe accidents.

As a starting point for the features identification, the DiD WG referred to available information on SMR designs as referenced in Section 8. The WG members used their judgment to determine those general design features that were typical to SMRs as compared to traditional large reactor features. Features that were common to several SMRs and not related to one particular design were considered in the selection process. For each of the SMR features identified, and to stimulate discussions, group members tried to specify the design implication and the main opportunities or challenges of the feature on the application of DiD. The results of this task are provided in the detailed table of appendix A. The development of this table is summarized below.

For each feature listed in appendix A, a short description of the implication of the feature on the design was provided in the second column to facilitate a judgment of its potential impact on DiD. The third column lists any opportunity that group members judged to be positive for the application of DiD. Similarly, the fourth column lists potential challenges to the application of DiD.

The last two columns assign the most appropriate DiD level that would be impacted by the implication of the feature. These were identified by comparing the objective of the DiD level and the means of achieving it against the implication of the design feature.

4.2. SMR SPECIFIC FEATURE CATEGORIES

The SMR specific features that were considered by the WG members have been grouped into four categories: facility size, use of novel technologies, modular design and applications. These categories are not mutually exclusive. They simply provide a useful framework for identifying important SMR specific features. The key SMR specific features are listed below and discussed briefly under their general categories. Key safety issues associated with these features are discussed in Section 5.

Facility size

- smaller plant footprint (as compared to a conventional NPP)
- small power of the core
    - reduced decay heat load
    - increased core stability
    - smaller inventory of radionuclides
    - passive safety

Use of novel technologies

- passive cooling mechanisms
    - natural circulation
    - gravity driven injection

- integral design (incorporation of primary system components into single vessel)
- non-traditional or different number of barriers to fission product release
- unique fuel designs (e.g., ceramic materials, molten salt fuel)

Modular design

- compact and simplified designs
    - practical elimination of some severe accidents
    - inherent safety features (e.g., longer grace periods)
    - fewer structures, systems and components (SSCs)
        - elimination of some traditional initiating events
    - introduction of new events
        - internal to single module
        - module to module interactions
        - new construction techniques
- production, assembly and testing in factory
- multi-module facilities
    - control room staffing
    - sharing of SSCs among modules
    - modules dependence/independence
    - multi-module failure in hazards conditions

Application (siting and transportation)

- siting
    - on ground
    - underground
    - on sea
    - under water
    - movable
    - in regions lacking in essential infrastructure (e.g., electrical grid, cooling water)
- module transportation
    - during construction
    - during the operation of other modules
    - for refueling purposes in some designs

As mentioned in Section 2, the WG members found it difficult to establish a definitive list of common SMR features due to the early stage of their development and limited publicly available detailed design information. Their judgment relies on a small set of available SMR documents, and is presented without feedback from SMR designers on how they intend to apply DiD principles to SMRs. For these reasons, the list of SMR features is non-exhaustive and their implications should be considered cautiously.

4.2.1. Facility size

As expected, designers emphasized SMR facility size as a unique and important safety feature. The WG identified lower power output, smaller reactor core size and smaller facility size as the main features. The main implications included smaller fuel load and radionuclide inventory, less decay heat and smaller facility footprint.

The WG noted that the implication of each feature was not straightforward and very design dependent. Opportunities for enhancing DiD were mostly in relation to the smaller facility size, lower radionuclide inventory and lower power load which could potentially be opportunities for DiD at levels 1, 2 and 3. The main challenge for DiD was identified to be designers' desire to lessen complementary measures, accident management and emergency response measures required at levels 4 and 5.

4.2.2. Novel features and technologies

Novel features and technologies represented the largest category of SMR specific features identified by the WG. These included non-conventional cooling methods (reactor vessel convection cooling with gas), novel vessel and component layout, non-traditional fission product barriers and unique fuel designs. Most of these features appear to be aimed at reducing challenges to DiD at levels 1 and 2. This is proposed to be done through, for example, reducing the number of SSCs available to fail, reduced reliance on active systems, and more failure-resistant fuel materials. One major challenge to DiD in this area is qualification of the novel features and technologies. Although the concept in principle could reduce challenges to DiD, design details and qualification programs were not readily available for discussion.

4.2.3. Modular design

Modular design for SMRs was purported to offer such features as compact and simplified design, improved fabrication, ease of transportability and additive modules for better power output flexibility to meet customer needs. Opportunities for DiD could be mainly related to improved fabrication and installation methods and optimized number of SSCs resulting in reduced potential for failures at levels 1 and 2. A modular design challenge to DiD could be independence between levels due to the proximity and sharing of SSCs, and the potential increase in common cause failures. The use of multiple modules could reduce the source term per module as compared to a larger plant, which could yield benefits at levels 4 and 5.

4.2.4. Facility application

SMRs can be autonomous and can be used to fill remote and isolated application niches for small communities and in industrial sites such as mines. Most challenges here are related to DiD levels 4 and 5, as local infrastructure is not likely to be in place. However, grid independence will force the SMR facility to be more self-reliant and therefore perhaps less prone to traditional initiating events such as loss of class IV power.

5. Consideration of key defence in depth safety issues for SMRs

Selection of key safety issues

Prior to the detailed discussions, WG members agreed that, as a fundamental principle for ensuring nuclear safety, the DiD concept is valid for SMRs, and should form an integral part of the design and safety demonstration. However, it was recognized that the DiD principles were developed for, and applied mainly to, large NPPs. Consequently, the design differences and safety claims associated with SMRs as compared to large NPPs raises some questions regarding the application of DiD principles to SMRs. The following discussions consider these principles in the context of SMR features to better understand if they are fully applicable to all types of reactors or if some adaptations may be desirable for SMRs.

As mentioned in Section 2, the WG members found it difficult to establish a definitive list of common SMR features due to the early stage of their development and limited publicly available detailed design information. Subsequently, the group members identified potential opportunities and challenges related to the features and the application of DiD in a general way. Their judgment relies on a small set of available SMR documents, and is presented without feedback from SMR designers on how they intend to apply DiD principles to SMRs. For these reasons, the list of SMR features is non-exhaustive and their implications should be considered cautiously.

WG members looked at the potential implications of SMR features as challenges or opportunities for the application of DiD. This allowed the group to analyze the applicability to SMRs of some DiD principles and requirements. These were selected on the basis of safety requirements, standards and guides published by international organizations (mostly the IAEA, WENRA and the Organization for Economic Co-operation and Development (OECD/NEA)). Since DiD is a very general concept that can generate a large set of principles and requirements, the WG members selected a number of key safety issues of interest in each of the five levels of DiD. For each selected safety issue and in consideration of the SMR features, the WG made an assessment of its applicability to a broad scope of SMR designs.

Application of defence in depth levels to SMRs

As described in Section 3, the application of the concept of DiD in the design of a nuclear power plant provides for five levels.

WG common position

Since SMRs will produce radioactive materials, it can be logically assumed that, in general, all five levels of DiD, as defined for typical large reactors in IAEA and WENRA documents, can be applied to SMRs.

The descriptions of the five levels in SSR-2/1 (Rev. 1) are very general. The point is to identify the general safety provisions expected for SMRs for each DiD level as compared to large reactors. Below are some key safety issues identified by the WG as particularly important for each DiD level. Some are valid for several DiD levels. These are further discussed in Sections 5.4, 5.5 and 5.6.

Level 1

For the first level of DiD, the objective is to prevent deviations from normal operation and the failure of items important to safety. SSR-2/1 (Rev. 1) states that to meet this objective, the plant must be soundly and conservatively sited, designed, constructed and maintained, and operated in accordance with quality management and appropriate and proven engineering practices.

The WG has identified some key issues for the application of DiD level 1 to SMRs. These include:

- site selection, as discussed in Section 5.4
- design and fabrication quality (see Section 5.5.1 for a discussion on design activities and Section 5.6 for a discussion of the importance of fabrication as it relates to post-design issues)
- the use of novel technologies and new materials as discussed in Section 4.2.2
- the role of inherent safety as discussed in Section 5.5.3
- exclusion of initiating events as discussed in Section 5.5.5
- the potential for hazards as discussed in Section 5.5.6

Note that some of these issues are traditionally discussed under level 1, but are also important for levels 2 to 4. Other cross cutting DiD issues, such as physical barriers, probabilistic safety assessments (PSAs) and multi-module issues are addressed in Sections 5.5.2, 5.5.9 and 5.5.10.

Level 2

For the second level of DiD, the objective is to detect and control deviations (postulated initiating events) from normal operational states in order to prevent anticipated operational occurrences (AOOs) at the plant from escalating to accident conditions. This second level of defence necessitates the provision of specific systems and features in the design, the confirmation of their effectiveness through safety analysis, and the establishment of operating procedures. SMR systems or features for level 2 that use novel technologies could pose a challenge for the safety analysis demonstration, as there could be limited information and qualification experience.

In addition to the issues already mentioned for DiD level 1, the WG has identified some key issues for the application of DiD level 2 to SMRs. In particular, the classification of events as AOOs as discussed in Section 5.5.5.2.

Level 3

In the third level of DiD, it is assumed that an accident could develop. This leads to the requirement that inherent and engineered safety features, safety systems and procedures be provided that are capable of preventing damage to the reactor core or significant offsite releases and returning the plant to a safe state.

In addition to the issues already mentioned for the previous DiD levels, the WG has identified some key issues for the application of DiD level 3 to SMRs:

- the role of inherent safety, passive and active systems as discussed in Section 5.5.3
- redundancy and diversification of safety systems and engineered safety features as discussed in Section 5.5.4
- design basis accidents (DBA) and design extension conditions (DEC) without core melt as discussed in Sections 5.5.5.3 and 5.5.5.4

Level 4

The main objective of the fourth level of DiD is to mitigate the consequences of severe accidents. The most important aspect for this level is to ensure the confinement function is successful. This ensures that radioactive releases are kept as low as reasonably achievable.

In addition, for level 4, all accidents with core melt which could lead to early or large releases must be practically eliminated.

In addition to the issues already mentioned for the previous DiD levels, the WG has identified some key issues for the application of DiD level 3 to SMRs:

- DEC with core melt as discussed in Section 5.5.5.4
- practical elimination as discussed in Section 5.5.7

Level 5

The final level of DiD, level 5, has to mitigate the radiological consequences of radioactive releases that could potentially result from accident conditions. This requires the provision of an adequately equipped emergency control centre, and emergency plans and procedures for onsite and offsite emergency responses. [A1]

For level 5, SMR designers may seek relaxations due to the claim of smaller source terms as compared to large reactors. Nevertheless, the importance of level 5 has to be determined on the basis of the confinement capabilities of the reactor. Moreover, as mentioned in the NEA green booklet on DiD [A5], the Fukushima Daiichi NPP accident provided several important lessons for the implementation of level 5. It demonstrated that no matter how much we seek to strengthen other levels and practically eliminate event scenarios, effective emergency arrangements and other responses are essential to cover what is not expected.

Independence of the defence in depth levels

In international and national standards and documents, the independence of the DiD levels is considered important for enhancing the effectiveness of DiD. Section 2.13 of SSR-2/1 (Rev. 1) states that the independent effectiveness of the different levels of defence is a necessary element of DiD. It helps to ensure that a single failure or combination of failures at one level does not jeopardize DiD at subsequent levels. The WENRA report, Safety of new NPP designs [A3], states that the levels of DiD shall be "independent as far as is practicable." Lessons learned from the Fukushima Daiichi NPP accident have confirmed and reinforced the need for such a requirement. Therefore it should be applicable to SMRs as well.

Under IAEA SSR-2/1 (Rev. 1) revision 1, requirement 7 for the application of DiD, Section 4.13A states the following:

The levels of defence in depth shall be independent as far as practicable to avoid the failure of one level reducing the effectiveness of other levels. In particular, safety features for design extension conditions (especially features for mitigating the consequences of accidents involving the melting of fuel) shall as far as is practicable be independent of safety systems.

The independent effectiveness of each of the different levels is achieved by incorporating measures to avoid the failure of one level of defence causing the failure of other levels. In particular in DEC, the safety features shall be independent, to the extent practicable, of those used in more frequent accidents such as DBA.

WENRA's Safety of new NPP designs [A3] provides some guidance on the independence principle application that could be used or adapted to SMRs. In particular, the report identifies the stronger independence requirement between features necessary to cope with accidents without core melt and those necessary in case of core melt accidents. "Complementary safety features specifically designed for fulfilling safety functions required in postulated core melt accidents (DiD level 4) should be independent to the extent reasonably practicable from the SSCs of the other levels of DiD."

If the independence of the DiD levels is simple to state, its application is not straightforward and may raise questions about:

- the way to apply the independence concept of two different levels
- the interpretation of "as far as practicable"
- the acceptability of potential non-independent features that may be implemented by the designers

However, these questions are not dedicated to SMRs only. They are also valid for large reactors.

In the case of SMRs, it could be also investigated whether the SMR specific features, in particular the compact design of the modules or some design constraints, may particularly challenge the independence of DiD levels or not.

Concerning the verification of the independence, WENRA indicates "The adequacy of the achieved independence shall be justified by an appropriate combination of deterministic and probabilistic safety analysis and engineering judgment." [A3] Probabilistic safety analyses, for all modes of operation, could also be developed and used for SMRs, in particular for the verification, to the extent practicable, of the independence of DiD levels.

WG common position

The WG believes that these issues are clearly applicable to all SMR designs and should be examined because of their importance in implementing the DiD philosophy.

In the case of SMRs, it could be investigated whether the SMR specific features, in particular the compact design of the modules, the simplicity of the design or some design constraints, may particularly challenge the independence of DiD levels or not.

WG recommendation

PSA is an important tool to assess the sufficiency of independence of the DiD levels and should also be used in SMR design.

PSA aspects are discussed in Section 5.5.10.

Key safety issues related to siting

The purpose of the first level of DiD leads to requirements that the plant be soundly and conservatively sited. It requires proper evaluation and selection of a suitable NPP site. These general issues are a major concern for SMRs, since the performed reviews for SMR development [B1, B2] show the ambitions of the designers and vendors to extend the range of suitable sites for SMR installations, including underground, underwater or floating on water. Siting aspects may have important influence on the SMR safety design and different DiD levels.

The scope and level of detail of the site assessment must be consistent with the possible radiation risks associated with the facility or activity, the type of facility to be operated or activity to be conducted, and the purpose of the assessment (e.g., to determine whether a new site is suitable for a facility or activity, to evaluate the safety of an existing site or to assess the long term suitability of a site for waste disposal) [A9].

Published IAEA standards and guides, and regulations of individual countries, cover land based stationary NPPs, research reactors and other nuclear facilities [C2]. Therefore, there is an interest in reviewing current international and national requirements and recommendations issued by groups such as the IAEA, WENRA and the USNRC concerning site evaluation and site selection to include designers' and vendors' ambitions for SMR locations and layouts. New site configurations may need to consider the evaluation of additional specific external hazards, environmental phenomena or human activities.

Some recommendations from the sixth International Project on Innovative Nuclear Reactors and Fuel Cycles (INPRO) Dialogue Forum [B5] are important to note.

- There is greater potential for SMR sites to be located where essential infrastructure is insufficient or does not exist. In this regard, site surveys and site characterizations are needed to address safety and security issues and establish plans for ensuring existing infrastructure. Guidance is needed on infrastructure considerations for reactor facilities sited in close proximity to hazardous industrial facilities. As the IAEA's NS-R-3, Site Evaluation for Nuclear Installations [B6] provides only high-level guidance, more details and associated safety guides may be useful to address the issue. Information should consider both policy-based infrastructure such as national emergency plans as well as physical infrastructure.
- Guidance from the IAEA to Member States might be useful to clarify the requirements that should address any difference between a transportable nuclear power plant and a fuel transport package. The IAEA also should facilitate a regulatory discussion to address the issue and whether to integrate shipment routes into site investigations as a basis for site acceptance or rejection. The country of origin of technology shall provide technical support in dealing with this issue.
- The report [B5] identifies "siting" related concepts "that require clarification for public understanding as follows: source term, core damage frequency, practical elimination, essential infrastructure, unacceptable potential effects of the nuclear installation on the regions (NS-R-3 § 2.25), inherently safe, and passive (safety) features. Clarification is also needed on the relationship between emergency planning and the term "inherently safe" – this is an important consideration for both the site survey and the site characterization steps. In this regard, the IAEA should consider adding this information to DS-433 and NS-R-3 to further clarify the guidance."

The question of SMR location in areas with low reliability electrical grids should also be addressed, with verification that this low reliability could be compensated by inherent safety, passive features, and very large autonomy in the design.

For multiple-unit/module plant sites, the design shall take due account of the potential for specific hazards giving rise to simultaneous impacts on several units/modules on the site.

New sites at atypical locations may require the evaluation of specific external hazards, environmental phenomena or human activities that could be important challenges for DiD level 1, (i.e., reinforcement for siting, design and plant operation).

External hazards are also discussed in Section 5.5.6.2.

WG common position

Particular attention should be paid to the characteristics of the selected sites for SMRs and to their impact on the effectiveness of DiD.

WG common position

The WG supports the positions and recommendations of sixth INPRO Dialogue Forum.

WG recommendation

The WG recommends that current international and national requirements and recommendations (such as those issued by the IAEA, WENRA and the USNRC) concerning site evaluation and site selection be reviewed and updated as necessary to include designers' and vendors' ambitions for SMR locations and layouts.

WG recommendation

Because of potential remote location of SMRs and possible different environments, a detailed analysis of possible external hazards and associated risks for SMRs should be performed for each specific SMR application and location.

Key safety issues related to design

Section 2.12 of IAEA SSR-2/1 (Rev. 1) states that the primary means of preventing accidents and mitigating their consequences is the application of defence in depth. This concept is applied to all safety related activities, whether organizational, behavioural or design related, and whether in full power, low power or various shutdown states. Note that the design activities themselves are also considered as an essential part of DiD. [A1]

More specifically for this report, Requirement 7 of IAEA SSR-2/1 (Rev. 1) [A1] clearly states that "The design of a nuclear power plant shall incorporate defence in depth." Accordingly, SMR designs should incorporate and demonstrate the effectiveness and reinforcement of all DiD levels.

Paragraph 4.11 of IAEA SSR-2/1 (Rev. 1) lists a number of design characteristics associated with DiD and design. In the following subsections, some important DiD issues related to design are selected and discussed with respect to their application to SMRs. It is recognized that the SSR-2/1 (Rev. 1) requirements were established mainly for large reactors (or without any consideration of the reactor size and type) but the WG felt that these would also apply to SMRs.

5.1. DESIGN ACTIVITIES

According to the IAEA's Fundamental Safety Principles [C1], "the prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risk." The licensee's responsibility includes in particular the verification of the appropriate design and of the adequate quality of facilities and activities. Requirements 2 and 3 of SSR-2/1 (Rev. 1) discuss the responsibilities of the plant designer and operating organization. While these requirements will apply to SMRs, the proposed concept of global standardization of SMR designs [C4] could make it more difficult for operating organizations to ensure these requirements are met.

The above is a well-established practice that could be an important challenge for the level and quality of the design considering the large spectra of countries and sites where SMRs may be implemented. There is an initiative by the WNA [C4], which represents most SMR designers and vendors, to optimize the licensing process by making it more international and involving the designer or vendor of the plant in the process. It is based on the application of standard design certification in which the design is assessed and verified by the regulatory body of the country of the designer or vendor with high level of competence.

In the case of a design change of the module after standard design approval (e.g., a change of the design after a large number of modules have been produced), an updated safety assessment may be required because a slight change in the design may have large effects on safety.

WG common position

Global standardization of SMR designs desired by some designers may be challenging for the licensee's responsibility.

5.2. PHYSICAL BARRIERS

Section 2.14 of SSR-2/1 (Rev. 1) states "A relevant aspect of the implementation of defence in depth for a nuclear power plant is the provision in the design of a series of physical barriers… The number of barriers that will be necessary will depend upon the initial source term in terms of the amount and isotopic composition of radionuclides, the effectiveness of the individual barriers, the possible internal and external hazards, and the potential consequences of failures."

DiD shall provide multiple levels for ensuring that each of the fundamental safety functions is performed, thereby ensuring the effectiveness of the barriers.

WG common position

The need for multiple barriers will also be required for SMRs, however, depending on the design and application of the facility, the barriers required and their effectiveness will be a discussion point in the licensing process.

For large reactors, a reactor containment structure is the main barrier for protecting the environment from the radioactive releases in case of accidents in particular severe accidents. In addition to the containment structure, complementary safety features are included in the design of the plant and procedures implemented to mitigate the consequences of core melt accidents.

WG common position

For SMRs, a main barrier for protecting the environment from the radioactive releases is also necessary to ensure the confinement function in case of accidents including severe accidents.

5.3. USE OF INHERENT, PASSIVE AND ACTIVE SAFETY FEATURES

As noted in Section 2.14 of SSR-2/1 (Rev. 1), "A relevant aspect of the implementation of defence in depth for a nuclear power plant is the provision in the design of a series of physical barriers, as well as a combination of active, passive and inherent safety features that contribute to the effectiveness of the physical barriers in confining radioactive material." [A1]

WG common position

DiD implementation requires a well-balanced safety concept that is based on the use of an optimal combination of active, passive and inherent safety features. This principle is also applicable to SMRs

Concerning the importance and role of each of these features, IAEA SSR-2/1 (Rev. 1) states that the expected behaviour of the plant in any postulated initiating event shall be such that the following conditions can be achieved, in order of priority:

(1) A postulated initiating event would produce no safety significant effects or would produce only a change towards safe plant conditions by means of inherent characteristics of the plant.
(2) Following a postulated initiating event, the plant would be rendered safe by means of passive safety features or by the action of systems that are operating continuously in the state necessary to control the postulated initiating event.
(3) Following a postulated initiating event, the plant would be rendered safe by the actuation of safety systems that need to be brought into operation in response to the postulated initiating event.
(4) Following a postulated initiating event, the plant would be rendered safe by following specified procedures.

SMRs that use extensively inherent characteristics and passive features may comply to a large extent with this statement. Indeed, SMRs designers seem to look for more extensive application of inherent and passive safety features and rely less on active safety systems in comparison with existing large reactors.

The impact of the extensive use of inherent characteristics and passive features on the relative importance of the different DiD levels for SMRs in comparison with current practice and requirements could be further investigated. In this regard, it is important to note that large nuclear power plants licensed in the United States that rely on passive safety systems also include back-up active systems capable of performing safety functions to account for the uncertainty in passive system reliability. The ability of these active systems to perform safety functions is subject to regulatory review during the licensing phase. These active systems are subject to some operational requirements to assure a satisfactory level of reliability and availability.

5.3.1. Inherent safety features

"Inherent safety" refers to the achievement of safety through the elimination or exclusion of inherent hazards through the fundamental conceptual design choice made for the nuclear plant. Potential inherent hazards in a nuclear power plant include radioactive fission products and their associated decay heat, excess reactivity and its associated potential for power excursions, and energy releases due to high temperatures, high pressures and energetic chemical reactions." [B3]

As already mentioned, SMRs designers seem to look for more extensive application of inherent safety and respectively less reliance on safety systems. [B1, B2, C4, C5] Examples of inherent characteristics could be:

- the use of natural circulation in place of reactor coolant pumps to eliminate the hazard of pump seal failure,
- low pressure and temperature of the cooling loops,
- low core power density,
- large coolant inventory providing grace periods,
- reduction in the number, size and location of pipes that penetrate the reactor vessel to reduce the frequency and severity of pipe ruptures and
- negative reactivity coefficients over the whole operating cycle. [B4]

Inherent safety characteristics can contribute to, and reinforce, DiD. Indeed, they can eliminate or limit inherent hazards and minimize the escalation of AOOs into accidents, and thus reinforce DiD levels 1 and 2. In addition, inherent safety characteristics could also minimize the escalation of postulated initiating events into more severe conditions and thus to reinforce DiD level 3 in the prevention of severe accidents.

However, all inherent safety characteristics that are provided by the design and credited in the safety demonstration should be duly substantiated by the designers. The requirements and criteria for this demonstration should be defined beforehand and developed, which may need particular guidance.

Safety assessments of SMR designs with enhanced inherent safety characteristics may require further development of safety requirements and guides for the safety demonstration of inherent features. As many safety requirements are mostly oriented to DiD levels 3 and 4, and as the requirements for these levels have been reinforced in the light of the lessons learned from Fukushima Daiichi NPP accident, it may also be useful to further develop guidance for safety assessment of DiD levels 1 and 2.

After design, inherent safety should be guaranteed during fabrication and construction phases of the nuclear installation. As the modules of the SMRs could be fabricated and assembled in the factory, the role of the manufacturer is essential in this demonstration.

The effectiveness of the passive systems and in some cases inherent safety characteristics will have to be periodically reconfirmed during the operation of the facility. As discussed in appendix II of IAEA NP-T-2.2, Design Features to Achieve Defence in Depth in Small and Medium Sized Reactors [B4], the performance of these features could degrade by some phenomena (e.g., ageing or clogging of passive equipment).

WG common position

The regulatory body needs to seek confidence in the effectiveness, over the life time of the facility, of the inherent safety characteristics of the SMR designs. It should be investigated how the effectiveness of each inherent safety characteristic credited in the safety demonstration is guaranteed over the facility lifetime. In this respect, the requirements for the justifications of this effectiveness expected from operators at each of the design, construction and operation stages of the SMR need to be discussed.

WG recommendation

All inherent safety characteristics provided by the design and credited in the safety demonstration should be duly substantiated by the designers. The requirements and criteria for this demonstration should be defined beforehand and developed, which may need particular guidance. As many safety requirements are mostly oriented to DiD levels 3 and 4, it is recommended to further develop guidance and requirements for safety assessment of DiD levels 1 and 2.

5.3.2. Passive systems

To achieve their safety function, passive safety systems rely on natural laws, properties of materials and internally stored energy. The concept of passivity as described in IAEA TECDOC-626, Safety related terms for advanced nuclear plants [B3] is considered in terms of four degrees or categories.

The passive safety systems concept assumes some advantages in comparison with so-called active safety systems:

- independence from external AC power supplies and safety function performance ensured in station blackout conditions
- a combination of diversified active and passive safety systems could strengthen DiD levels 3 and 4 or improve the independence of DiD levels
- passive systems are considered as less vulnerable to human error

However, the development and application of passive safety systems induces some challenges for the safety demonstration of levels 3 and 4 DiD principles:

- reliance on new innovative technologies without sufficient operational experience (see Section 5.5.8)
- challenges for the demonstration of passive systems performance and qualification, including:
    - assessment of the sensitivity of the small driving forces to uncertainties
    - methodologies and data for the quantification of the systems reliabilities
    - supporting research programs, performance tests and specific “acceptance criteria” for the qualification
    - assessment of passive system activation
    - assessment of proper function/performance of the Passive feature
- operational aspects such as periodic testing, maintenance and in-service inspections, which must be reconfirmed during facility operation to protect against degradation

WG recommendations

SMR design with enhanced use of passive safety systems requires further development of safety criteria and requirements on the level of IAEA safety standards and safety guides, WENRA recommendations and national regulations.

It should also be investigated how the effectiveness of each passive system credited in the safety demonstration is guaranteed over the facility lifetime. In this respect, the requirements for the justifications of this effectiveness expected from operators at each of the design, construction and operation stages of the SMR could be discussed.

5.3.3. Active systems

Active systems are those whose operation or function depends on an external source of power (e.g., air, electrical and hydraulic). The nuclear industry has a good history of important knowledge, practice and operational experience in the use of active safety systems for the limitation of the consequences of postulated initiating events in DBA conditions.

In nuclear energy development, preference is given to established engineering practices, and confirmation that the design has been proven in equivalent applications or operational experiences.

SMR designers wish to reinforce DiD levels 1 and 2 by design simplification, events exclusion, enhanced inherent safety and safety margins of nuclear installation, or modules. A well-balanced safety approach also requires an optimal use of innovative and proven technologies. This approach may lead to relying less on DiD level 3 and especially the role of active safety systems. However, a combination of diversified active and passive safety systems could strengthen DiD levels 3 and 4 or improve the independence of DiD levels.

WG common position

The well balanced safety approach requires further development and demonstration that postulated initiating events are reliably mitigated at DiD levels 3 and 4. For example, a combination of diversified active and passive safety systems could strengthen DiD levels 3 and 4 or improve the independence of DiD levels.

5.4. REDUNDANCY AND DIVERSIFICATION

According requirement 25 of SSR-2/1 (Rev. 1) "The single failure criterion shall be applied to each safety group incorporated in the plant design", where the term "safety group" is given the definition "the assembly of equipment designated to perform all actions required for a particular postulated initiating event." [A1]

According to the IAEA safety glossary, a postulated initiating event (PIE) is an event that can lead to anticipated operational occurrence or accident condition. Concerning passive components, Section 5.40 of SSR-2/1 (Rev. 1) requires that "The design shall take due account of the failure of a passive component, unless it has been justified in the single failure analysis with a high level of confidence that a failure of that component is very unlikely and that its function would remain unaffected by the postulated initiating event." [A1]

To fulfill these requirements, the single failure criterion must be applied for all safety systems used in DiD level 2 and, in particular, level 3 including passive safety systems. SSR-2/1 (Rev. 1) does not require application of the single failure criterion for level 4, only that the "features (used for DECs) shall have reliability commensurate with the function that they are required to fulfill." The WENRA report Safety of new NPP designs [A3] adds that this may require redundancy of the active parts.

Requirement 24 of SSR-2/1 (Rev. 1) states that "The design of equipment shall take due account of the potential for common cause failures of items important to safety, to determine how the concepts of diversity, redundancy, physical separation and functional independence have to be applied to achieve the necessary reliability." [A1]

Safety systems, in general, rely upon redundancy, functional independence, robust design and physical separation to ensure high reliability. Diversity is usually a measure applied to reduce the likelihood of common cause failures (CCFs) between different levels or sublevels (e.g., 3a and 3b) of DiD. [A8] Regulations in some countries include requirements for diversity. Functional diversity is for instance required in the generation of signals of the reactor protection system.

A plant deviation can escalate into a DEC due to multiple failures of safety systems. CCFs are probably the most important group for these types of failures. Diversification of safety features for DECs is a powerful tool to prevent the accident escalation into a core melt.

SMRs use passive safety systems at level 3 to a much greater extent compared to the current Generation III large reactors. Application of single failure criteria for the passive safety systems should be further developed on the level of the IAEA safety standards and safety guides. This is coupled with the passive system safety demonstration and lack of operating experience. Because of the uncertainties in the reliability and challenges of the safety demonstration of passive systems, it may be preferable to use a combination of passive and active systems to ensure a safety function. This would also provide additional diversification to cope with common cause failures.

Diverse features should be included in the design to prevent a design basis accident with a CCF from developing into a core melt accident.

WG recommendation

Application of single failure criteria for the passive safety systems should be further developed on the level of the IAEA safety standards and safety guides.

Diverse features should be considered in the design to prevent a design basis accident with a CCF to develop into a core melt accident.

5.5. PLANT STATES

Plants states currently covered in IAEA SSR-2/1 (Rev. 1) include:

- normal operation
- AOO
- accidental conditions (i.e., DBA and DEC)

For SMRs, similar categories of plant states are expected, however with specifics in terms of operation modes (e.g., module transportation) and list of postulated initiating events.

The normal operation is defined in IAEA Safety Reports Series No. 48, Development and Review of Plant Specific Emergency Operating Procedures [C7] as a plant operation within specified operational limits and conditions, such as the operation modes of power operation, reactor shutdown, shutdown operation, startup, maintenance, testing and refueling operation. For SMRs, all these operation modes may vary from current practices. In particular, specific refueling practices are expected for SMRs and could induce new risks.

The multi-module nature of some SMRs could affect refueling activities. For example, some designs may use the staggered refueling method in which the shutdown of a single module for refueling does not require shutdown of the other modules. This means that a module can be in refueling state while the other modules in very close proximity are still producing power.

WG recommendation

Due to novel operation and application of SMRs, operation modes should be completely characterized in terms of activities and performance of equipment and humans. During the safety assessment, particular attention should be paid to assuring that all the DiD levels are implemented adequately for all operation modes.

The WG also identified some issues for DBA and DEC that are presented in Sections 5.5.5.3 and 5.5.5.4.

5.5.1. Exclusion of events

SMR design options and features may reinforce the prevention of some incidents and accidents. The tendency of SMR designers seems to be to exclude or limit some initiating events (e.g., some types of loss-of-coolant accidents due to system and equipment design). It could be considered as important reinforcement of the DiD levels 1 and 2. Even if some initiating events are considered to be excluded by the designer, the exclusion should not be used to justify omission of a complete DiD level. This is also discussed in Section 5.5.7.

Requirement 16 of IAEA SSR-2/1 (Rev. 1) for selection of PIEs and Section 5.10 for exclusion of initiating events should also be applied for SMRs:

> IAEA SSR-2/1 (Rev. 1), Requirement 16 says “The design for the nuclear power plant shall apply a systematic approach to identifying a comprehensive set of postulated initiating events such that all foreseeable events with the potential for serious consequences and all foreseeable events with a significant frequency of occurrence are anticipated and are considered in the design.”

IAEA SSR-2/1 (Rev. 1), Section 5.10 says "A technically supported justification shall be provided for exclusion from the design of any initiating event that is identified in accordance with the comprehensive set of postulated initiating events."

The available information from the SMR designs [B1, B2, B4] does not present systematic selection of PIEs or technically supported justification of exclusion of some initiating events. Description of the plant operational states is limited, and the initiating events that occur in low power or shutdown states have not been presented in literature to date.

Demonstration of the integrity of the SMR module itself should be defined as first priority in this process, because the module is the critical component on which all the SMR safety functions rely. The assessment of the integrity of the primary coolant system should include a systematic approach in order to address/consider all the connections between the module and the safety systems as well as the systems for normal operation, and in the case of pressurized-water reactors (PWRs), the possibilities of steam generator tube ruptures. The publicly available SMR documentation is usually not detailed enough for review of the connections.

WG recommendation

Rules for excluding identified initiating events from the design are not established for SMRs. The IAEA should develop guidance on how to justify the exclusion of initiating events from the design. In particular such guidance should consider applications to SMRs.

5.5.2. Anticipated operational occurrences

The IAEA defines an AOO as an operational process deviating from normal operation which is expected to occur at least once during the operating lifetime of a facility but which, in view of appropriate design provisions, does not cause any significant damage to items important to safety nor lead to accident conditions.

Connections and shared systems between modules could lead to new types of AOOs (e.g., AOOs occurring at several modules at the same time, or an AOO at one module inducing an AOO or even a DBA at another module). The WG evaluation and recommendations regarding multi-modules issues are given in Section 5.5.9.

5.5.3. Design basis accidents

According to the DiD principle for the postulated events that cannot be considered as "excluded", safety features have to be implemented to mitigate their consequences at DiD level 3. PIEs are not described in detail in the available documents from SMR designers. These documents essentially point out the potential for excluding events. In the same way, the safety features that will be implemented to mitigate the postulated events are not described in detail in the available documentation on the module itself.

Despite the efforts on prevention of accidents for SMRs, designers should demonstrate that they have developed safety features to mitigate PIEs and provide justifications of their effectiveness.

Designers wish to create a module that envelopes all classical, well known primary circuits. For this approach, a classical PWR list of PIEs seems no longer applicable in its totality. This design should be verified against new possible internal initiating events inside the module and new types of initiating events in view of the module safety.

It is important that SMR designers demonstrate that they have developed and applied a systematic approach for identifying PIEs that may occur considering the design specifics of their SMRs and taking into account all the plant states. Reviewing the list of PIEs for other designs is necessary but not sufficient, since each SMR design is specific. Some techniques reported for some new designs in the U.S. include use of formal Failure Modes and Effects Analysis and system engineering studies of the failure modes on each system by the system engineer with lead for the system design.

Designers should demonstrate that they have developed safety features to mitigate PIEs and justify their effectiveness.

WG recommendation

Designers should demonstrate that they have developed and applied a systematic approach for identifying PIEs that may occur considering the design specifics of their SMRs and taking into account all the plant states.

Designers should demonstrate that they have developed safety features to mitigate PIE and provide justifications of their effectiveness.

5.5.4. Design extension conditions

DECs were introduced in international requirements in the 2000s and gained more focus after the Fukushima Daiichi NPP accident. [A1, A3] Several types of accidents are grouped as DECs, requiring different kind of measures. IAEA SSR-2/1 (Rev. 1), Rev.1 defines DECs as “Postulated accident conditions that are not considered for design basis accidents, but that are considered in the design process for the facility in accordance with best estimate methodology, and for which releases of radioactive material are kept within acceptable limits. Design extension conditions comprise conditions in events without significant fuel degradation and conditions in events with core melting.” [A1]

The definition of DEC is not yet universal. The CNRA green booklet [A5], for example, includes as one type of DECs internal and external events more severe than those considered in the design basis. In the IAEA terminology, a DEC is a postulated plant state that is determined by a postulated sequence of events [A8]. In this report, specific aspects related to internal and external hazards are described in Section 5.5.6.

Events without significant fuel degradation

Sequences involving a postulated initiating event that involves a common cause or common mode failure of and resulting in multiple failures in the safety system designed for coping with the event concerned are particularly important DECs.

The typical method to cope with initiating events that involve a common cause failure is to add diversity to the design. According to IAEA NP-T-2.2, all SMR designs have diverse reactor shutdowns. Most have diverse heat removal systems, some also have diverse heat sinks. Reactor shutdown is the most important safety function, because all safety systems are dimensioned assuming that the reactor shutdown succeeds. Therefore, SMRs must have diverse means for reactor shutdown. Additional diverse features should be considered in the design to prevent a design basis accident (level 3) with a CCF to develop into a core melt accident (see Section 5.5.4).

DECs also include events with combinations of failures selected on the basis of deterministic analysis, probabilistic risk assessment or engineering judgment.

For Generation III reactors, these so-called complex sequences include such initiating events as uncontrolled boron dilution in PWRs, multiple steam generator tube rupture or steam generator tube ruptures induced by main steam line breaks. [A8] These types of sequences should also be identified for SMRs and if significant, appropriate measures should be designed against them. The establishment of these sequences is plant specific and requires a PSA covering all operating states.

A PSA covering all operating states should be developed already in the design stage to identify those areas of the design in which the introduction of safety features for DEC may help to reduce the probability of core melt accidents, and balance the contribution to risk of different accident sequences. [A8]

Events with core melting

These events include severe reactor accidents (i.e., accidents involving core damage or fuel melt) and severe spent fuel storage accidents.

Sections 5.30 and 5.31 of IAEA SSR-2/1 (Rev. 1) state that “the containment and its safety features shall be able to withstand extreme scenarios that include, among other things, melting of the reactor core. These scenarios shall be selected by using engineering judgment and input from probabilistic safety assessments. The design shall be such that the possibility of conditions arising that could lead to an early radioactive release or a large radioactive release is practically eliminated.” [A1] Section 4.13A also states that “In particular, safety features for design extension conditions (especially features for mitigating the consequences of accidents involving the melting of fuel) shall as far as is practicable be independent of safety systems.” [A1]

Descriptions of current SMR designs [B1, B2, B4] indicate that designer efforts seem to be oriented towards severe accident prevention based on reinforcement of DiD levels 1, 2 and 3. Despite these efforts, independent features for severe accident mitigation (DiD level 4) should be included in the design of SMRs in order to ensure the successive levels of DiD remain.

WG recommendation

So-called complex DEC sequences should be identified for SMRs and if significant, appropriate measures should be designed against them. For this plant-specific identification, a PSA covering all operating states is necessary.

Despite the efforts to prevent severe accidents, independent features for severe-accident mitigation (level 4) should be included in the design of SMRs in order to ensure the successive levels of DiD.

5.5.6. Internal and external hazards

Internal and external hazards are important challenges for the DiD levels and for the independence of the levels. They can cause common mode failures that could impact the safety features involved at one DiD level and even simultaneously affect several DiD levels.

According to IAEA SSR-2/1 (Rev. 1), all foreseeable internal hazards and external hazards, including the potential for human induced events that could directly or indirectly affect the safety of the nuclear power plant shall be identified and their effects shall be evaluated. Hazards shall be considered for the determination of the postulated initiating events and of generated loadings for use in the design of relevant items important to safety for the plant. [A1]

The most recent revision of IAEA SSR-2/1 (Rev. 1) incorporates the lessons learned after the Fukushima Daiichi NPP accident especially in terms of reinforcement of safety in internal hazards and external hazards conditions.

The accident in Fukushima Daiichi NPP demonstrated that it is vital to consider the impact of common cause and common mode failures when implementing the concept of DiD, particularly from external hazards, as they can lead to a loss of several levels of DiD safety provisions or significantly reduce independent effectiveness. [A5]

WG common position

IAEA, OECD, NEA and WENRA experiences and lessons learned after the Fukushima Daiichi NPP accident with regard to the reinforcement of safety in view of internal and external hazards should be applied to SMR design.

5.5.6.1. Internal hazards

An NPP should be designed with adequate physical separation (e.g., by barriers, by distance or both) to protect the safety features implemented at each of the DiD levels against all potential internal hazards (such as fires, explosions and floods).

Internationally available documentation on SMRs [B1, B2, B4] does not present in detail the list of postulated internal hazards, how they are considered in the design and the provisions foreseen to protect the safety functions against such hazards.

WG recommendation

The list of internal hazards taken into account in the safety demonstration should be justified by SMR designers, considering all SMR design specifics. All potential internal hazards that may occur within the module or in areas common to multiple modules should be considered.

Provisions should then be defined to protect the safety functions against such hazards and avoid common cause failures (e.g., physical or geographical separation). As constraints may be induced for SMRs due to their small sizes and compact modular designs, particular attention should be paid to these provisions from the early stage of SMRs design.

Particular attention should be paid in SMR design to potential common mode failures due to internal hazards (such as fires, explosions, internal flooding and load drops) and to their influence on DiD levels effectiveness and independence, taking into account the SMR design specifics (e.g., modularity, compact design and multi-units).

As stated in IAEA SSR-2/1 (Rev. 1), for multiple unit plant sites, the design shall take due account of the potential for specific hazards to give rise to impacts on several or even all units on the site simultaneously. [A1] This statement is particularly applicable to multi modules/units SMRs.

WG recommendation

The multi modules/units aspect of SMRs should be considered in the internal hazard safety assessment, particularly in terms of:

- propagation of internal hazards from one module to another (e.g., fire propagation)
- the impact of operating activities of one module on the risk of internal hazard of other modules (e.g., the risk of load drop due to the refueling of one module)

These aspects are also addressed in Section 5.5.9.

5.5.6.2. External hazards

Like typical large reactors, SMRs could be threatened by their environments. Therefore, the risks of external hazards – natural or man-induced – should be taken into account in the safety assessment of SMRs, considering their specific location and environment.

WG recommendation

Because SMRs may be located remotely or in many different environments, a detailed analysis of possible external hazards and associated risks for SMRs should be performed for each specific application.

As stated in IAEA SSR-2/1 (Rev. 1), for multiple unit plant sites, the design shall take due account of the potential for specific hazards to give rise to impacts on several or even all units on the site simultaneously. [A1] Concerning the simultaneous impacts of external hazards on several units, WENRA states that "On multi-unit sites, the plant should be considered as a whole in safety assessments and interactions between different units need to be analyzed. Hazards that may affect several units need to be identified and included in the analysis." [A3]

These statements are particularly applicable to multi modules/units SMRs in case of external hazards. These aspects are also addressed in Section 5.5.9.

WG recommendation

The multi modules/units aspect should be considered in the external hazard safety assessment.

Taking into account the lessons learned from the Fukushima Daiichi NPP accident, IAEA [A1], OECD [A5] and WENRA [A3, A13] documents emphasize the reinforcement of DiD principles and in particular the need to address severe external hazards. IAEA SSR-2/1 (Rev. 1) requires that "The design of the plant shall also provide for an adequate margin to protect items ultimately necessary to prevent an early radioactive release or a large radioactive release in the event of levels of natural hazards exceeding those considered for design, derived from the hazard evaluation for the site." [A1]

WG common position

Considering the lessons learned from Fukushima, SMRs should include in their design adequate margins against external hazards as derived from the site evaluation to guard against uncertainties and to avoid cliff edge effects.

5.5.7. "Practical elimination" concept

WENRA's Safety of new NPP design [A3] includes that accidents with core melt which would lead to early or large releases have to be practically eliminated. Here "early release" means situations that would require offsite emergency measures, but with insufficient time to implement them. "Large release" situations would require protective measures for the public that could not be limited in area or time. The objective includes also nuclear fuel at fuel pools and storage locations and severe degradation mechanisms other than melting, (e.g., severe reactivity increase accidents). IAEA SSR-2/1 (Rev. 1) [A1] requires that the design shall be such that design extension conditions that could lead to significant radioactive releases are 'practically eliminated'. The OECD/NEA/CNRA Implementation of Defence in depth in Nuclear Power Plants following the Fukushima Daiichi NPP accident [A5] states that practical elimination of significant radioactive releases should be addressed in the design of new plants and can be applied to both prevention and mitigation safety measures. IAEA TECDOC-1791, Considerations on the Application of the IAEA Safety Requirements for the Design of Nuclear Power Plants [A8] has a chapter on the concept of practical elimination.

WG common position

SMRs, as well as other types of new reactors, must meet the IAEA SSR-2/1 (Rev. 1) requirement of practical elimination of accidents which would lead to significant releases.

According to IAEA SSR-2/1 (Rev. 1) [A1], the possibility of certain conditions arising may be considered to have been 'practically eliminated' if:

- it would be physically impossible for the conditions to arise, or
- these conditions could be considered with a high level of confidence to be extremely unlikely to arise

Practical elimination of an accident scenario or more than one scenario should not be claimed solely based on compliance with a probabilistic cut-off value. Practical elimination should be primarily justified by design provisions, in some cases also strengthened by operational provisions (e.g., adequately frequent inspections). The safety measures supporting practical elimination must be available throughout the life of the plant and for all fault sequences or circumstances that may affect them. This may be difficult where the form of the additional safety measure does not lend itself to inspection, testing or maintenance. To apply the concept, the phenomena must be well understood and the actions proposed must be adequately supported by experiments, testing, theory and analysis. Similarly, the development of the design must be adequately based on criteria such as appropriate design codes and choices of materials. [A5]

Accident sequences that are practically eliminated have a specific position in the DiD approach because mitigation of their consequences does not need to be included in the design. The IAEA TECDOC-1791 [A8] groups the events that should be practically eliminated into five categories:

1. events that could lead to prompt reactor core damage and consequent early containment failure
2. severe accident phenomena that could lead to early containment failure
3. severe accident phenomena that could lead to late containment failure
4. severe accident with containment bypass
5. significant fuel degradation in a storage pool

The practical elimination concept should not be used to justify omission of a complete DiD level. For example, the concept should not be used to justify absence of severe accident management arrangements and capabilities that are expected at DiD level 4 or absence of offsite emergency response at level 5.

The practical elimination requirements and criteria are widely discussed in nuclear safety regulations. They should be deeply assessed using deterministic and probabilistic approaches. Expert judgment is indispensable as well. Technical guidelines for the design and construction of nuclear power plants with pressurized water reactors [A10] emphasizes that if events cannot be considered as physically impossible, design provisions have to be taken to design them out. The above guidelines are applicable to SMRs as well as large reactors.

WG common position

The practical elimination concept should not be used to justify omission of a complete DiD level. For example, it should not be used to justify the absence of severe accident management arrangements and capabilities that are expected at DiD level 4 or the absence of offsite emergency response at level 5.

5.5.8. Proven technologies

The safety case will dictate requirements necessary for Systems, Structures and Components, and therefore, point to those SSCs that require robust and proven design, versus those that are not so important [A9].

Items important to nuclear safety shall preferably be of a design that has previously been proven in equivalent applications, and if not, these items shall be of high quality and be derived from a technology that has been qualified and tested. [A1] The preference is given to the established engineering practice, which uses the design that has previously been proven in the equivalent applications or the so-called operational experience.

SMR designs are considered to be innovative technologies, since they feature many safety aspects that are not yet supported by established engineering practices and operational experiences.

Requirement 9 of IAEA SSR-2/1 (Rev. 1) states that where an unproven design or feature is introduced, or where there is a departure from an established engineering practice, safety shall be demonstrated by means of appropriate supporting research programs, performance tests with specific acceptance criteria or the examination of operating experiences from other relevant applications. The new design or feature or new practice shall also be adequately tested to the extent practicable before being brought into service, and shall be monitored in service to verify that the behavior of the plant is as expected.

As most of the proposed SMR concepts are new innovative technologies without sufficient operational experience, these requirements are very important for SMRs. Special attention should be paid to how the technologies will be qualified and tested.

Where innovative improvements beyond current practices have been incorporated into the design, it has to be determined in the safety assessment whether compliance with the safety requirements has been demonstrated by an appropriate program of research, analysis and testing complemented by a subsequent program of monitoring during operation. [A9]

WG common position

Regulatory bodies should focus attention on the proposed innovative technologies that are without operational experiences. The new features and practices shall be adequately tested before being brought into service to the extent practicable to demonstrate their qualification, and shall be monitored in service to verify that the behaviour of the plant is as expected.

WG recommendation

Requirements and guidance be established for qualification programs of new materials and features applicable to SMR designs including the extent and scale of the testing, verification and validation of models, and fabrication processes.

5.5.9. Multi-module issues

The concept of multi-modules is specific to SMRs, and thus should be considered as an important safety issue to be investigated, particularly in comparison with current practices on nuclear safety for large reactors.

5.5.9.1. Application of defence in depth for multi-unit nuclear power plants

Historically, the safety assessment and safety demonstration for large reactors are based on a single-unit safety concept. This safety assessment approach does not assume any interaction between units and only single-unit impact for consequences. For the majority of participating countries in this project, according to the survey questions, a license is given for a single unit without specific regulatory requirements for multi-units issues. However, in the United States and Canada, there are requirements related to the sharing of structures, systems or components important to safety among nuclear units – unless it can be demonstrated that such sharing will not significantly impair each unit's ability to perform its safety functions. The issue of shared SSCs may be a challenge for the regulation of SMRs, as the smaller designs and the use additive reactor modules may lead to sharing that introduces risk significant vulnerabilities into the design.

There have been important evolutions over the last years in the expectations regarding safety assessment of multi-units, especially after the Fukushima Daiichi NPP accident. Safety considerations for sites with more than one unit are provided in several international documents. [A1, A3, A5]

Safety concerns about multi-units include the:

- impact of shared systems between several units on the site (such as for important, supporting or not important safety systems)
- simultaneous impacts of external hazards on several units on the site

Regarding the first point, in the current safety practice, each unit is fully autonomous. It features its own safety systems, safety support systems (e.g., heat sink and AC power) and control systems. IAEA SSR-2/1 (Rev. 1) Rev. 1 stipulates that "Each unit of a multiple unit nuclear power plant shall have its own safety systems and shall have its own safety features for design extension conditions." [A1]

Interconnections among the units of a multi-unit NPP are encouraged when they enhance safety. "To further enhance safety, means allowing interconnections between units of a multiple unit nuclear power plant shall be considered in the design". [A1] Further "For sites with multiple units, appropriate independence of them shall be ensured. The possibility of one unit supporting another could be considered as far as this is not detrimental for safety." [A13]

Concerning the simultaneous impacts of external hazards on several units, IAEA SSR-2/1 (Rev. 1) requires "For multiple unit plant sites, the design shall take due account of the potential for specific hazards to give rise to impacts on several or even all units on the site simultaneously." [A1] Additionally, WENRA states "On multi-unit sites, the plant should be considered as a whole in safety assessments and interactions between different units need to be analyzed. Hazards that may affect several units need to be identified and included in the analysis." [A3]

Multi-unit safety issues are also addressed with some interpretation in the recent NEA booklet on Implementation of Defence in depth in Nuclear Power Plants following the Fukushima Daiichi NPP accident. [A5]

5.5.9.2. "Multi-units" versus "multi-modules"

According to the limited publically available information on SMR designs, the WG observed that "multi-modules" could not be considered as equivalent to "multi-units", as with large reactors. Further, such concepts were not well defined for SMRs. For instance the "module" may or may not be autonomous and does not include individual safety systems and safety support systems such as separate heat sinks or AC power. It was observed in some designs that the control room, reactor building and ultimate heat sink, as examples, can be common to several modules. In addition, some SMRs may use a single confinement common to several modules. Therefore, the definition of SMR “module” may be better interpreted as “nuclear installation” or nuclear steam supply system (safety classified part of the primary and secondary circuit for PWR) than as “plant”.

The safety issues that should be investigated for multi-module facilities include:

- requirements for shared systems or interconnections between several modules
- impact of multi-module configurations on the risk of propagation of an AOO, a DBA or a DEC or an internal hazard from one module to other modules
- simultaneous impact of external hazards on several modules of the facility
- confinement function
- common spent fuel pool
- human and organizational aspects
- a single control room common to several modules

At this stage, the list of potential safety issues for multi-modules facilities remains open and cannot be completed until more detailed SMR design information is available.

WG observation

As the concept of SMR “module” is not equivalent to the “unit” or “plant” concept for large reactors, the safety principles developed for the “multi-units” issue cannot be transposed to “multi-modules” in SMR facilities. Therefore, the principles and requirements for the safety assessment of a “multi-module” SMR must be developed.

WG recommendation

It is necessary to demonstrate that for “multi-module” facilities, all connections, shared features and dependencies between modules/units are not detrimental to DiD.

The safety issues to be included in the safety demonstration for “multi-module” facilities should be investigated and completed as further SMR design information becomes available. The impact of the common features and dependencies between modules on each of the DiD levels and on the independence of them should be investigated.

Even though the SMR concept is based on module design with small unique power, on multi module/unit sites, the SMR design should take due account of the potential consequences on several or even all units on the site simultaneously caused by specific external hazards. It may affect the methodology for EPZ assessment.

WG common position

A “multi-module safety assessment” could contribute to verifying that all common features and dependencies do not induce unacceptable effects. As discussed in Section 4.6.8, PSA methods will need to be developed in order to model the simultaneous occurrence of accident sequences leading to severe accidents involving multiple modules.

In the absence of PSA methods, the USNRC has recently established high-level guidance and qualitative criteria [B7] that applicants with small, modular integral pressurized water reactor designs may use to show that the risk from multi-module accidents is acceptably low. This guidance does not assume the availability of a PSA that can model multi-module accidents nor provide numerical acceptance criteria. Rather, it directs applicants to conduct systematic assessments to identify accident sequences that could lead to multi-module core damage and large release events. Such assessments can then be used to demonstrate that a facility has been designed so that any such accident sequences are not significant contributors to risk (e.g., practically eliminated).

5.5.10. Role of probabilistic approach

Even if the design relies firstly on deterministic bases, probabilistic safety assessments could bring about many insights about the safety of SMRs, as they have for large reactors. Experience gained from the use of PSAs has revealed that, even when carried out from the very early design stage of a reactor, PSAs are very beneficial to evaluate the application of DiD, to check that the DiD principles have been properly applied and to identify potential weak points in the design not revealed by deterministic analyses.

Indeed, relying on a systematic investigation and assessment of a large set of initiating events and sequences, PSA results help identify the dominant contributors to the risk and thus to point out key safety issues. In particular, PSA results reflect the reliability of the features implemented at each of the DiD levels and the independence of the DiD levels. They are also useful to check the sufficiency of the redundant and diversified features implemented and to verify that the risks of common cause failures are limited. PSAs could also contribute to the identification of the postulated initiating events and of the set of design extension conditions to be considered in the design.

For all these reasons, the WG position is that for SMRs, PSAs should be used to complement the deterministic approach on which the design first relies – just as they are for large reactors.

Another specific issue to be considered for SMRs is the multi-modules configuration. As mentioned in Section 5.5.9, a “multi-module safety assessment” could be needed to assess the impact on safety of the connections and shared systems among modules. The role of the probabilistic approach in this safety assessment and the methods that could be applied to carry out a site risk assessment could be investigated.

WG recommendation

For SMRs, PSAs should be used to complement the deterministic approach on which the design first relies – just as they are for large reactors.

WG observation

The methods to deal with passive features and with multi-module issues in the PSA could be enhanced (or investigated) in the context of PSA developments for SMRs.

5.6. POST-DESIGN ISSUES – IMPORTANCE OF FABRICATION

After the design phase, safety should be guaranteed during fabrication, construction, transportation, commissioning, operation and decommissioning of the installation.

The WG focused the discussions on DiD application in siting and design activities. Post-design activities were not discussed in detail. The WG has identified fabrication and transportation as specific features of many SMRs. High-quality fabrication is an important element in the success of DiD. It is noteworthy that INSAG-12 states: “A primary safety requirement is that a nuclear power plant be manufactured and constructed according to the design intent. The plant manufacturers and constructors discharge their responsibilities for the provision of equipment and construction of high quality by using well proven and established techniques and procedures supported by quality assurance practices.” [C2]

For SMRs, a lot of the work is expected to be done at the factory (i.e., the fabrication of the whole module) and less on site. Therefore, there is an increasing role of the manufacturer/producer of the main equipment of the module in the factory conditions. In this context, inspections performed in the factory are particularly important and new procedures for such inspections may need to be developed.

According to international conventions and IAEA safety standards, regulating safety is a national responsibility and the prime responsibility for safety rests with the person or organization responsible for facilities. This well-established practice could be an important challenge for the level and quality of the design taking into account the large spectra of countries and sites where SMRs may be implemented.

During commissioning, it is necessary to demonstrate that the completed plant is satisfactory for service before it is made operational. This may pose specific challenges in the case of factory fueled SMRs. A well planned and properly documented site acceptance testing and commissioning program should be prepared and carried out.

WG common position

Since there is an increasing role of the manufacturer/producer of the main equipment of the module in the factory conditions, inspections performed in the factory are particularly important and new guidance for procedures for such inspections may need to be developed. A well planned and properly documented site acceptance testing and commissioning program should be prepared and carried out.

6. Sharing regulatory experiences with defence in depth among Forum Members

6.1. SURVEY OBJECTIVE

The DiD WG Member State regulators are either engaging or preparing to engage with proponents who are preparing safety cases for SMR deployment. These SMRs are anticipated to contain unique safety claims due to the inclusion of novel approaches and technologies. Some of these claims are expected to propose alternate interpretations of existing regulatory requirements as compared to large nuclear power plants. It is also possible that the proposals will contain new safety approaches where regulatory requirements may not yet exist.

This survey attempted to understand how, in each Member State, DiD requirements can be applied to alternative approaches being developed by SMR designers such that the safety principles of DiD are maintained. Alternative approaches being employed by SMR developers (for example passive and inherent features) can be similar to those being employed for larger nuclear power plants (generations III, III+ and IV). However, the use of these approaches is expected to be more intense for SMR designs with a goal by developers being to drive improvements both in efficiency of maintenance and operation and in overall safety. Of particular interest to the DiD WG is finding out where similarities and differences in practices exist in application to alternative approaches.

The results of this survey are presented to highlight similarities, differences and challenges in the application of DiD in each Member State, and to illustrate what this might mean for future SMR projects. The survey questions and Member State responses are summarized in appendix C.

6.2. RELATIONSHIP TO CNRA GREEN BOOK SURVEY

The OECD/NEA CNRA green booklet [A5] described survey results on the use of DiD among the regulatory bodies represented at CNRA. These results cover the main regulatory activities applicable to existing reactors and new large reactors, such as regulations, codes of practice and guidance, assessments of design/safety case/events/etc., inspections, enforcement/regulatory decisions and training of regulatory staff.

The DiD WG survey was concerned with regulatory framework and the industry's application of requirements focused on the SMR application. It was not clear if all countries have incorporated the lessons learned of Fukushima Daiichi NPP accident in their regulations related to DiD. The industry's application of the requirement is covered in the design management/control assessment in the green booklet survey, however, most WG Member States have not responded to the survey yet.

6.3. SURVEY RESULTS

The survey shows that all Member States apply the DiD concept to some extent in the regulations but the level of detail varies. Some use the five levels in the way specified by IAEA; others use the DiD concept as a general legislative framework.

All Member States require that NPPs are designed against external events. IAEA SSR-2/1 (Rev. 1) [A1] also requires that the design of the plant shall provide for an adequate margin to protect items ultimately necessary to prevent an early radioactive release or a large radioactive release in the event of levels of natural hazards exceeding those considered for design, derived from the hazard evaluation for the site (hazards exceeding the design basis).

None of the Member States is currently developing DiD requirements specific to SMR applications. A need is recognized to develop requirements concerning specific questions, such as passive safety features. Currently, there is no difference of design requirements between the research reactors and the commercial NPPs.

Very few responses were given to questions concerning application of DiD to specific SMR designs. This may reflect the fact that the DiD concept has not been the focus of discussion between the regulators and the designers in countries with active SMR projects. The DiD WG encourages the regulators to review the SMRs in the future by application of the DiD concept.

7. Findings, conclusions and recommendations

The DiD WG agreed that, as a fundamental principle for ensuring nuclear safety, the DiD concept is valid for SMRs and should be a fundamental basis of the design and safety demonstration of SMRs.

However, it was recognized that the DiD principles were developed for and applied mainly to large NPPs. Consequently, the design specifics and safety claims associated with SMRs as compared to large NPPs raise some questions for discussion regarding the application of DiD principles to SMRs. These SMR design specifics notably include facility size, modular design, the use of novel technologies, and SMRs applications.

It is not possible to express detailed requirements at this stage because the spectrum of SMRs is very large and because of the lack of information about SMR designs and designer intentions.

At this stage, the DiD WG identified some important issues for consideration in the evaluation of DiD for SMRs. The conclusions of the WG about the application of these issues to SMRs are presented in Section 7.1.

Among these issues, the DiD WG identified safety areas for which the opportunity to further develop safety guidance to help the safety assessment of DiD applied to SMRs may be investigated. This is presented in Section 7.2.

It could be desirable for future SMR Regulators' Forum activities to organize exchanges on safety information among SMR designers, regulatory bodies and their TSOs to better understand and frame SMR characteristics as mentioned in Section 7.2.

7.1. CONCLUSIONS ABOUT THE APPLICATION OF DEFENCE IN DEPTH TO SMRs

Application of defence in depth levels

In general, all five DiD levels as defined for typical large Generation III NPPs and taking into account lessons learned from the Fukushima Daiichi NPP accident are also applicable to SMRs. Appropriate features should be included in the SMRs design at each level.

In order to ensure the successive levels of DiD, and despite the efforts of SMR designers on DiD levels 1 and 2 reinforcement, it is important to get a clear demonstration of the effectiveness of the design safety features to mitigate PIE (level 3) and of the features to mitigate severe accidents (level 4) for all operating modes.

For DiD level 5, the DiD WG is in agreement with the NEA statement that, no matter how much other levels may be strengthened, effective emergency arrangements and other responses are essential to cover the unexpected.

Independence of the DiD levels

The independence among DiD levels, as far as practicable, is considered to be an important requirement to enhance the effectiveness of defence in depth in international and national standards and documents. The Fukushima Daiichi NPP accident has confirmed and reinforced this requirement. Therefore it should apply to SMRs as well. In the case of SMRs, it could be investigated whether the SMR specific features, in particular the compact design of the modules and the multi modules design, may particularly challenge the independence of DiD levels.

Some questions raised by the application of the independence concept in SMR design could be discussed. These include in particular the interpretation of “as far as practicable” and the acceptability of potential non-independent features that may be implemented by the designers.

Siting issues

Taking into account SMR specific features, selected site characteristics could be an important challenge for DiD reinforcement.

The design shall take due account of site-specific conditions to determine the maximum delay time by which offsite services need to be available.

Siting aspects may have important influence on SMR safety design and different DiD levels due to applicable range of suitable site for SMR installations, including underground, underwater or floating on water.

New site configurations may require the evaluation of additional specific external hazards and environmental phenomena. For multi-unit/module plant sites, designs shall take due account of the potential for specific hazards giving rise to simultaneous impacts on several units/modules on the site.

Design issues

Design activities

The DiD WG identified that the tendency of global standardization and certification of SMR designs desired by some designers and proposed by WNA may be challenging for current licensees and regulators. It may require significant changes in the national licensing process.

Inherent safety and passive systems

An important challenge for DiD in SMR design is to achieve a well-balanced safety concept based on the use of optimal combination of active, passive and inherent safety features.

All inherent safety characteristics that are provided by the design and credited in the safety demonstration should be duly substantiated by SMR designers. The requirements and criteria for this demonstration should be defined beforehand and developed, which may need particular guidance. As many safety requirements are mostly oriented to DiD levels 3 and 4, it could be useful to further develop guidance and requirements for safety assessment of DiD levels 1 and 2. (See Section 7.2.)

SMR design with enhanced use of passive systems is required to develop safety criteria and requirements on the level of IAEA safety standards and safety guides, WENRA recommendations and national regulations. (See Section 7.2.)

The use of passive systems may induce new challenges: new innovative technologies without sufficient operational experiences, uncertainties related to qualification and reliability assessments, operational aspects as periodic testing, maintenance and in-service inspections. Particular attention should be paid to these issues at each of the design, construction and operation stages of SMRs. Further development of safety criteria and requirements may be necessary. This includes the application of failure criteria for safety functions involving passive systems. (See Section 7.2.)

In case of uncertainties in passive features reliability or common cause failure mechanisms in active systems, a combination of active and passive safety systems may be desirable. Such a combination could even strengthen safety function performances at DiD levels 3 and 4 and improve the independence between those two levels.

Excluded events versus postulated initiating events

The designers should demonstrate that they have developed and applied a systematic approach for identifying postulated initiating events that may occur considering the design specifics of their SMRs and taking into account all plant states.

If some initiating events are considered to be "excluded" by SMR designers, without any safety features to mitigate their consequences, sufficient provisions (e.g., design, fabrication and operation) shall be implemented and duly justified.

Criteria for exclusion of events should be established. (See Section 7.2.)

Internal and external hazards

Common mode events due to internal hazards and their influence on DiD levels independence should be considered, taking into account SMR design specifics (e.g., modules, compact design and multi units/modules aspects).

Regarding the external hazards, because SMRs may be located remotely or in many different environments, a detailed analysis of all possible hazards and associated risks for SMRs should be performed for each specific SMR application. The IAEA, OECD NEA and WENRA international experiences and the lessons learned after the Fukushima Daiichi NPP accident should also be extensively used in the design of SMRs regarding the risks of external hazards.

Moreover, multi modules/units aspect should be considered in the safety assessment of internal and external hazards.

Practical elimination

The practical elimination concept should not be used to justify omission of a complete DiD level. For example, it should not be used to justify absence of severe accident management arrangements and capabilities that are expected at DiD level 4 or in the absence of offsite emergency response at level 5.

Multi-modules issues

As the concept of SMR "module" is not equivalent to the "unit" or "plant" concept for large reactors, the safety principles developed for the "multi-units" issue cannot be transposed to "multi-modules" in SMR facilities. Therefore, principles and requirements for the safety assessment of a "multi-module" SMR should be developed. (See Section 7.2.)

It is necessary to demonstrate that for "multi-modules" facilities, connections, shared features and dependencies among modules are not detrimental to DiD. A "multi-modules safety assessment" could contribute to verifying that all common features and dependencies don't induce unacceptable effects.

Even if the SMR concept is based on modular design with small unique power on multi modules/units sites, the SMR design shall take due account of the potential consequences of several – or even all – units failing simultaneously due to external hazards. It may affect the methodology for EPZ assessment.

Role of PSAs

As for large reactors, PSAs should be used for SMRs to complement the deterministic approach on which the design relies first.

PSAs could be used to check that DiD principles have been properly applied. PSA results could reflect the reliability of the features implemented at each DiD level and the sufficient independence of the levels. PSAs could also be used for the identification of so-called complex DEC sequences and for the assessment of the risks induced by multi-modules.

Methods to deal with passive features and with multi-module issues in PSAs should be investigated or enhanced. (See Section 7.2.)

Post-design issues

After the design phase, safety should be guaranteed during fabrication, construction, transportation, commissioning, operation and decommissioning of the installation.

The DiD WG focused the discussions on DiD application in siting and design activities. Post-design activities were not discussed in detail. However, the DiD WG has identified fabrication and transportation as specific aspects to focus on for many SMRs.

Since there is an increasing role of the manufacturer/producer of the main equipment of the module in the factory conditions, inspections performed in the factory are particularly important and new guidance for procedures for such inspections may need to be developed. (See Section 7.2.) A well planned and properly documented site acceptance testing and commissioning program should be prepared and carried out.

Novel technologies

Detailed assessments should be applied to innovative technologies of SMR designs that are without operational experiences. The new features and practices shall be adequately qualified through verifications, validations and testing before being brought into service to the extent practicable, and shall be monitored in service to verify that the behavior of the plant is as expected. Requirements and guidance are necessary for qualification programs of new materials and features applicable to SMR designs including the extent and scale of the testing, verification and validation of models, and fabrication processes. (See Section 7.2.)

7.2. RECOMMENDATIONS FOR THE IAEA

The DiD WG identified safety areas for which the opportunity to further develop safety guidance to help the safety assessment of DiD applied to SMRs may be investigated. These include:

- demonstration of reinforcement of DiD levels 1 and 2
- development of safety criteria and requirements for passive safety systems and inherent safety features
- application of single failure criteria for safety functions involving passive systems
- criteria for exclusion of identified initiating events from the design
- new guidance for procedures may need to be developed for inspections of the manufacturer/producer of the module
- development of principles and requirements for the safety assessment of “multi-module” SMRs
- investigation or enhancement of methods to deal with passive features and with multi-module issues in PSAs
- requirements and guidance for qualifying new materials and features applicable to SMRs designs, including the extent and scale of the testing, verification and validation of models, and fabrication processes.

The following activities could be desirable for the next SMR Regulators’ Forum:

- organize exchanges on safety information among designers, regulators and their TSOs to better understand and frame the SMR characteristics
- exchange information and share common positions on DiD with Member States in an effort to enhance harmonization on national and international levels of the licensing process

Such a report could be published by the IAEA.

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Appendix A: Defence-in-Depth Working Group Members

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Appendix B: Typical SMR specific features

Facility size			
SMR feature	Implications of the feature	Opportunities for DiD application	Challenge for DiD application
Low thermal power output	Smaller fuel load required to sustain the output	Impact of this characteristic has to be assessed considering the features below	Levels 4 and 5 – Vendor desire for reduced barriers (e.g., confinement or containment requirements)
	Proportionally lower decay heat power	Level 1 – Equilibrium power can be removed to environment without fuel damage Levels 2 and 3 – Lower decay heat can lead to longer grace periods; less heat sink capacity required Level 4 – Reduced risk of fuel damage and consequential release of fission products	Levels 2 and 3 – Vendor desire to reduce heat sink capability; demonstration of decay removal capability still required
	Smaller radionuclide inventory	Levels 4 and 5 – Reduction in the dominant radiation hazard as the radiation hazard is roughly proportional to power level	Levels 4 and 5 – Vendor desire for reduced barriers (e.g., confinement or containment requirements)
	Smaller core power density	Levels 1 and 2 – Better safety margins and inherent safety Level 3 – better safety	Depends on the ratio between thermal power and core volume

		margins and inherent safety	
Small reactor core size	Smaller core volume	Level 1 – possibly better control stability; depending on design, the core could be less sensitive to minor perturbations due to lower quantities of fissile material	Level 1 – Control may be more sensitive depending on the percent enrichment of fissile material; small volume could lead to high core power density
	Larger coolant-to-fuel thermal power ratio	Levels 2 and 3 – Greater inventory of water per unit of power allows increase in thermal inertia due to heat capacity of water; slower temperature rise on loss of flow	See comments for modular section
	Better neutronic spatial control	Levels 1 and 2 – A smaller spatial design of the core would result in less control challenges from flux tilts	
	Larger surface to volume ratio	Level 3 – Facilitates easier decay heat removal with single phase coolant	
Small reactor facility size	Smaller plant footprint		
	Less space in facility	Level 1 – reduced complexity; reduced number of structures, systems and components	Level 1 – More common cause possibilities; reduced space for maintenance activities Levels 3 and 4 – Fewer possibilities for physical separation from internal and external hazards

			Level 3 – Reduced redundancy
Novel features and technologies			
Non-conventional cooling methods	Reliance on natural circulation	Levels 1 and 2 – Main pump failures and therefore associated loss-of-cooling initiating events are eliminated; reactor can be started without class IV power	Levels 1, 2, 3 and 4 – Uncertainties in natural circulation (cooling) performance in certain conditions; increased aspect ratio required; possibility of power oscillations Levels 2 and 3 – Main circuit depressurization may be required before sufficient thermosyphoning can be established
	Reliance on air cooling as a final heat sink	Levels 3 and 4 – Air is readily available	Levels 3 and 4 – Heat loads must be adequately understood in accident conditions
	Reliance on other non-water cooling media	Level 1 – May allow operation just above atmospheric pressure so no pressure vessel required therefore fewer design implications for the coolant pressure boundary piping	Levels 3 and 4 – Less operating experience available for non-water cooling media Level 1 – New novel designs have not been proven
		Level 2 – Higher boiling point of coolant allows more margin to overheat the fuel	
		Level 1 – Less operating	

		experience (e.g., chemistry, aging effects)	
Novel vessel and component layout	Incorporation of primary system components into a single vessel	Level 1 – Design simplification feature Level 1 – Reduces size and number of vessel penetrations Level 3 – Eliminates large break loss of cooling	Levels 1 and 2 – Limited volume within the vessel for mechanical equipment; loss of inherent safety, safety margins and grace periods; uncertainty in models used for design and assessment; applicability of current codes and standards Level 1 – New novel designs have not been proven
Emphasis on passive safety features	Reduced reliance on electrical power	Level 1 – De-emphasizes systems requiring large amounts of electricity and therefore eliminates failure possibilities Redundancy requirements for passive safety systems involved in DiD Level 3.	Levels 3 and 4 – Functional failure is possible without mechanical failure (e.g., small driving forces, higher level of uncertainties, etc.); no rules for safety assessments, no reliability data, no statistics Level 1 – Problems for periodical testing, inspections and maintenance; unclear how to guarantee the capability during the lifetime of the plant

	Purported to have higher reliability	Levels 2, 3 and 4 – Can remove heat in all operating plant states and accident conditions; stored energy is not required	Level 1 – Harder to test, model and operate manually Levels 3 and 4 – Less operating experience with passive safety systems; passive system may need active component initiation
	Use of natural forces such as gravity	Level 1 – Natural forces are readily available	Levels 3 and 4 – Weak driving force may lead to lower reliability under harsher environmental conditions; passive system needs to be activated; activation is important for system reliability
	Reduction in complex logic	Level 1 – Fewer failure possibilities; lower event frequency	
	Failure modes are more subtle		Level 1 – Active components have more obvious failure modes; passive systems maybe a challenge to test and qualify
	Less reliance on operator	Level 2 – Rapid response is not required from the operator for initial shutdown, reach control state and long term safe shut down	Levels 3 and 4 – Information for the operator for safety function performance
Non-traditional or different number of barriers to fission product release	New types of barriers to release of radioactivity (e.g., ceramic	Levels 3 and 4 – Barrier performance may be enhanced (e.g., lead-bismuth – lead will solidify when released so	Levels 1 and 2 – Uncertainty in safety margins; applicability of current codes and

	materials, molten salt fuel)	fission products are contained in lead) Enhanced safety margin resilience	standards Level 1 – New novel designs have not been proven
	Higher temperature fuel sheath integrity	Levels 3 and 4 – No fuel melt and therefore a reduction in accident scenarios rated as potentially severe	Levels 3 and 4 – How will the qualification be done?
	Designer claims containment not required		
Unique fuel design	Good neutron economy	Level 1 – Smaller amounts of fissile material are required	
	Higher melting temperature	Level 3 – Greater margin to prevent fuel failure	
	More efficient heat transfer	Level 3 – Design allows long-term passive decay heat removal	
	Higher heat capacity	Levels 2 and 3 – Slower progression of transients	Levels 3 and 4 – A high temperature gas-cooled reactor unit capacity below ~600 MWt is a necessary condition to ensure long-term passive decay heat removal from the core
		Level 1 – Achievement of a large temperature margin between the operation limit and the safe operation limit	

	Higher critical heat flux	Level 3 – Allows fuel to withstand higher temperatures	
	New materials for better barrier to fission product release	Levels 3 and 4 – Allows inherent fission product confinement properties at high temperatures and fuel burnups; enhanced safety margins	Level 1 - Qualification demonstration is a challenge
Modular design			
Compact/simplified design	Fewer structures, systems and components (SSCs)	Level 3 – Reduction in accident frequency (e.g., loss-of-coolant accident, steam line break or boron dilution)	Level 3: New initiating event for module; reduction of redundancy and diversity?
		Level 1 – Less piping, fewer penetrations, less maintenance burden; elimination of some Initiating events	Levels 1, 2 and 3 – May increase susceptibility to common cause multi-module events (e.g., internal fire, flood)
Module fabrication	Standardization (modular)	Level 1 – Predictability of product; simplified construction and installation	Level 1, 2,3 Slight design changes may progressively evolve the design; introduces a new possibility for common cause failure between modules
	Factory produced		Level 1 – Multiple construction interfaces between module constructors could lead to weaknesses; common codes and standards between countries may not exist
	Multiple organizations		Level 1 – Configuration control

	involved		issues
Transportability			Level 1 – Potential damage to module during transport; size limitation for transport
Module dependence and independence	Sharing of SSCs among modules	Levels 1,2,3 - Shared SSCs can be designed with additional DiD to enhance DiD for overall facility	Levels 1, 2, 3 and 4 – Increase common cause failures
Number of modules	Staffing		Level 1 – Multiple modules operated by single operator
			Levels 2, 3 and 4 – Control room staffing; operator may need to perform emergency response simultaneously on multiple modules
			Level 2 - Lack of operational data
	Radionuclide inventory	Levels 3 and 4 – Reduction in potential source term for single unit accident sequences	Level 3,4 and 5 Accumulative radionuclide inventory
	Accident analysis		Levels 3 and 4 – Increased complexity in accident sequences and responses
	Fuel storage requirements		Level 5 – Additional source term requires fuel cooling
Application			
Siting closer to populations			Level 5 – Emergency planning zone
Grid independence	Operation in island mode, site	Level 2 – Improved resistance to loss-of-grid	Level 4 – Less external response

	autonomy	events	capability
Novel locations (e.g., shipyard, mines, northern communities)	Lack of local infrastructure		Level 4
	Remote operation		Level 4
	External hazards change with environment		
Floating reactor assembly	Subject to the pitch and roll of the medium		Level 1 – More potential stressors leading to failure modes
Submerged reactor	Access to facility is restricted		All levels – Facility is not easily accessible

Appendix C: Survey results summary

A. **Regulatory framework responses**

Question 4.1

(a) Please describe how the use of DiD is articulated in your regulations, supplementary regulatory requirements (if applicable) and guidance.

Country	Regulations/guidance	Remarks
Canada	RD/GD-369, *Licence to Construct a Nuclear Power Plant* and REGDOC-1.1.3, *Licence Application Guide: Licence to Operate a Nuclear Power Plant*	
Finland	Nuclear energy act, Sec.7b, Radiation and Nuclear Safety Authority Regulation on the Safety of a Nuclear Power Plant, 1/Y/2016, Sec. 9 and 10	
France	DiD is addressed in the Technical Guidelines for Generation III reactors. These TG don't explicitly mention the size of reactors under scope, but assume large NPP. DiD is addressed in some Basic Safety Rules, in particular BSR I.3.a related to the SFC. DiD is interpreted in some ASN Guides, as draft ASN Guide 22 "Safety requirements and recommendations for the conception of PWR".	
Korea	Regulations on technical standards for nuclear reactor facilities, etc. Article 26	
Russia	OPB-88/97, par. 1.2.3	
United States	No explicit DiD requirements in regulation. To implement DiD level, the following rules are illustrated; Level 1: 10CFR 50, App. A and B Level 2: 10CFR 50, App. A, 10CFR 50.36, 10CFR 50.49, 10CFR 50.65 Level 3: 10CFR 50.44, 10CFR 50.46, 10CFR 50.48 Level 4: 10CFR 50.62, 10CFR 50.63, 10CFR 50.54(h)(h)(2), 10CFR 50.150, 10CFR 52.47(a)(27), 10CFR 52.47(a)(23) Level 5: 10CFR 100, 10CFR 50.47, 10CFR 50, App. E, 10CFR 50.54(h)(h)(2)	

Question 4.1

(b) When comparing research reactor design requirements to NPPs, how do the above requirements differ (if at all) and why are they different? (Note: SMRs occupy a spectrum of core inventories and power outputs in between research reactors and NPPs.)

Country	Regulations/guidance	Remarks
Canada	No difference in requirements, but application to SMR may differ	
Finland	Requirements for NPPs are applicable to research reactors on a case-by-case basis. No difference in requirements or guidance for reactors intended for production of heat or electricity.	
France	No difference in requirements or guidance	
Korea	No difference in requirements	

Russia	No difference in requirements	
United States	Due to the large difference of thermal power generated, the implementation of DiD for non-power reactors differ from commercial nuclear reactors – such as emergency planning zones	

Question 4.2

Does your country have any specific requirements related to the independence of the DiD levels?

Country	Regulations/guidance	Remarks
Canada	REGDOC-2.5.2, *Design of Reactor Facilities: Nuclear Power Plants*, sections 4.3.1 and 6.1	
Finland	Radiation and Nuclear Safety Authority Regulation on the Safety of a Nuclear Power Plant, 1/Y/2016, Sec 9,Guide YVL B.1 Safety design of a nuclear power plant, section 4	
France	The draft ASN Guide 22 "Safety requirements and recommendations for the conception of PWR" focus on safety requirements related to the independence of the DiD levels. It refers to WENRA Reference Levels for existing NPPs (September 2014) and the WENRA Report "Safety of new NPP designs" (March 2013) including insights from Fukushima Daiichi NPP accident. It is in good agreement with IAEA SSR 1/2 (Rev. 1) as well.	
Korea	No specific requirements, but Article 2, Article 27 of Regulations on Technical Standards for Nuclear Reactor Facilities, etc. applies	
Russia	OPB-88/97	
United States	10CFR 50, App. A (GDC), Reg. Guide 1.174 and 1.177	

Question 4.3

In your regulation, supplementary regulatory requirements and guidance for new reactor (any size and output), please describe any specific requirements for the design of features for each of the following:

(a) Level 1 normal operation.
(b) Level 2 anticipated operational occurrences.
(c) Level 3 design basis accidents (e.g. single failure criteria).
(d) Level 3 multiple failure accidents or for other design extension conditions.
(e) Level 4 severe (core melt) accidents.
(f) A "practical elimination" approach.
(g) Extreme hazards.

Country	Regulations/guidance	Remarks
Canada	REGDOC-2.5.2 (INSAG-10, SRS #46) Levels 1 to 4: REGDOC-2.5.2, sections 6.1 and 7.3.2 "Practical elimination" approach: RECDOC-2.5.2, section 7.3.4 Extreme hazard: RECDOC-2.5.2, section 7.4.2	
Finland	Guide YVL B.1 Level 1: Comply with high standards of quality and reliability with adequate safety margin Level 2: Provisions for deviations from normal operation	

	Level 3 (DBA): N+2 failure criterion, Remove the decay heat within 72 hours Level 3 (DEC): Comply with diversity principle with N+1 criterion and remove the decay heat within 72 hours Level 4: Independent systems from other levels Practical elimination: Deterministic analysis with PRA and expert assessments Extreme hazard: Decay heat removal within 72 hours and control of reactivity without relying on power supply at least eight hours	
France	Technical Guidelines for Generation III reactors, some examples: Level 1: Quality must be obtained and demonstrated notably by an adequate set of requirements for design, manufacturing, construction, commissioning and operation, as well as by quality assurance. Level 2: The inherent reactor behavior is stable (e.g. negative moderator feedback). To reduce the number of significant incidents and accidents by improvements of the equipment and systems used in normal operation Level 3 : DBA: Physical and spatial separation, SFC. Minimize the possibility of common cause failure. DEC: Assess the multiple failures condition deterministically, independence and diversification requirements. Level 4: Substantial improvement of the containment function. No containment venting. Maximum conceivable releases would necessitate only very limited protective measures in area and in time for the public. Practical elimination: Accident with large early release frequency is a matter of judgment. Practical elimination cannot be demonstrated by the compliance with a general "cut-off" probability. Hazard: Possible links between internal and external hazards and single initiating events have also to be considered. The improvements in the "defence-in-depth" should lead to the achievement of a global frequency of core melt less that 10-5 per plant operating year, uncertainties and all types of failures and hazards being taken into account.	
Korea	Levels 1 to 4 and extreme hazard: Regulations on Technical Standards for Nuclear Reactors Facilities, etc. No description on "practical elimination"	
Russia	Levels 1 to 4: None Practical elimination: Not implemented Extreme hazard: not less than 0.1g of gravity and 1.5 hours in the standard fire, spatial and physical separation of safety systems	
United States	Levels 1 to 3 (DBA): Same requirements Levels 3 (DEC) and 4: 10CFR 52.79, 10CFR 50.44, 10CFR 50.71 Practical elimination: Extreme hazard: Order EA-12-049	

B. Industry's application of requirements – responses

Question 4.4

Have any difficulties been identified (in particular by the designers and utilities) in applying DiD principles defined for large reactors to SMRs? If so, please describe them.

(a) For DiD level 1?
(b) For DiD level 2?
(c) For DiD level 3?
(d) For DiD level 4?
(e) For DiD level 5?

Country	Regulations/guidance	Remarks
Canada	Information is not publicly available at this time	
Finland	Comparison to Finnish regulations and guidance is ongoing. Results are not yet available.	
France	No experience	
Korea	Awaiting Input	
Russia	Level 1: Siting and size of protection zone Levels 2 to 4: No difficulty Level 5: EPZ in remote districts	
United States	No specific difficulties but some of DiD level may be different from that of large NPPs	

Question 4.5

(a) Have designers requested up-front 'relief' from some DiD principles for SMRs? If so, which one and for what reasons? For example:

- e.g., Specific systems for mitigation for a an anticipated transient without scram accident are not required because unique design features make the probability of such an accident negligibly small; or
- reduction in emergency preparedness requirements based on the "smallness" of the reactor?

(b) Have compensatory measures or justifications been provided?

Country	Regulations/Guidance	Remarks
Canada	Information is not publicly available at this time	
Finland	There is no application for licensing submitted. Comparison to regulations and guidance is ongoing and possible challenges have not yet been identified.	
France	No experience	
Korea	Awaiting Input	
Russia	Not identified	
United States	(a) Functional containment performance, emergency planning. (b) Regulatory gap analysis	

Question 4.6

What types of events or situations generally addressed in the safety cases of typical large GEN III or GEN IV reactors are considered as eliminated or excluded by SMR designers and for what reasons? (ex.: some break sizes excluded because of limited pipe diameters, some events excluded thanks to inherent safety characteristics).

Country	Regulations/Guidance	Remarks
Canada	Information is not publicly available at this time	
Finland	There is no application for licensing submitted. Comparison to regulations and guidance is ongoing and possible challenges have not yet been identified.	
France	No experience	
Korea	Awaiting Input	
Russia	Large brakes in primary circuit piping	
United States	Large breaks in primary circuit piping of light water reactors; gross melting of fuel in high temperature gas reactors	

Question 4.7

What types of requirements do the SMRs designers use in terms of:

a) Redundancy for active or passive safety systems (for accident prevention / for core damage prevention / for core damage mitigation)?
b) Diversification between systems involved in different levels of DiD?
c) Geographical or physical separation regarding CCF and internal hazards?
d) Potential for an accident in one module affecting other modules in a multi-module plant?

Other significant issues you would like to point out?

Country	Regulations/Guidance	Remarks
Canada	Information is not publicly available at this time	
Finland	There is no application for licensing submitted. Comparison to regulations and guidance is ongoing and possible challenges have not yet been identified.	
France	No experience	
Korea	Awaiting Input	
Russia	Requirements for redundancy, diversity and physical separation for safety system	
United States	Passive and active systems performing safety functions include redundancy in design in a graded fashion based on their safety classification and level of risk significance; SMR applicants address multi-module risk in accordance with guidance in NRC Standard Review Plan 19.0, Revision 3. One SMR designer has developed a simplified approach for estimating the frequency of core damage events in multiple modules occurring within a short time of one another.	

APPENDIX IV. REPORT FROM WORKING GROUP ON EMERGENCY PLANNING ZONE

Executive Summary

The SMR Regulators' Forum Emergency Planning Zone Working Group was established to identify, understand and address key regulatory challenges with respect to emergency planning zone (EPZ) sizes that may emerge in future Small Modular Reactors (SMRs) regulatory activities. This will help enhance safety, efficiency in licensing, and enable regulators to inform changes, if necessary, to their requirements and regulatory practices.

Regarding the application of the concept of EPZ size to SMRs, this report:

- Shares regulatory experience and views amongst Forum members.
- Captures good practices and methods and strives to reach a common understanding.
- Communicate the results of these discussions to the Forum Members.

The Working Group (WG) consensus positions are:

- SMRs encompass a variety of nuclear reactor designs.
- There is a need to consider that the EPZ size for SMRs can be scaled based on the specific design characteristics and site specific considerations.
- The IAEA safety requirements and methodology, in general, for determining the EPZ size are effective in establishing emergency planning zones and distances.

1. BACKGROUND

The designers purport to have enhanced safety performance through inherent, passive, and novel safety design features. There are design options being developed for remote regions with less developed infrastructures, siting near urban regions, transportable floating or seabed-based facilities. Some of the SMR features and uses have raised questions regarding the sizes of the EPZ required around the sites, and how the design features can affect the size of the EPZs.

The SMR Regulators' Forum sought to document the bases that underpin decisions on EPZ extent around new SMR sites. The goal was to examine how the EPZ size might be flexible with respect to technological improvements and commensurate with the offsite consequences. The working group documented its conclusions drawn from the discussions and analysis in this paper.

SMR designers have incorporated over 60 years of experience into the proposed designs to improve operational and safety performance. As a result, designers are attempting to reduce the need for emergency planning by instituting additional design features based on the lessons learned from prior industry events. SMR designers and potential applicants raised questions about the need for offsite planning zones and distances, and they are approaching regulators in many countries to examine and revise existing requirements.

2. OBJECTIVES

The EPZ WG established objectives to guide the work. These included:

1. Share regulatory experience among Forum Members and strive to reach common understanding on EPZ size and scalability of EPZs
   a) Document and disseminate the results of the discussions.
   b) Interact with designers, regulators, emergency preparedness specialists, where possible, to effectively inform forum activities that would prompt further insights.
   c) Present conclusions on EPZ sizes.

2. Draft a document outlining the following:
    a) Common terminology.
    b) Technology-inclusive general principles for determining EPZs sizes.
    c) Cross-cutting EPZ-related issues derived from among member nations.
    d) Potential environmental impacts of scaled EPZ size.
    e) Methodology to determine EPZ size.
    f) Feedback to the IAEA on suggestions for future work regarding changes to IAEA general requirements and safety guide documents, international codes and standards with respect to EPZ sizes and scalability.

3. SCOPE OF THE ACTIVITIES

Within the 2-year pilot project, the EPZ WG endeavored to identify general principles related to the size of the EPZ and siting criteria for SMRs with novel design features.

The scope of SMR design information provided was mainly limited to documents available through the IAEA with the addition of information provided by member experience through their regulatory organizations.

The working group examined the implications of the SMR design features upon EPZ sizes. Furthermore, the EPZ WG did not examine the public and political policies of the host states. Also, the EPZ WG limited the extent of its consideration of defence in depth and Graded Approach (risk informed) topics because those topics are the subjects of other working groups in the SMR Regulators Forum. The WG used a perspective that EPZ sizes are only as large as the areas that would be reasonably required for protecting the public.

Unlike the Defence-in-Depth and Graded Approach Working Groups, the EPZ WG chose not to use a survey in order to collect relevant, state-specific approaches to the EPZ and Siting criteria. The EPZ WG relied upon input from the working group members to obtain the information at the first meeting of the working group and determined that between the members' and IAEA resources, sending a survey would provide no significant additional information.

4. TERMINOLOGY

The use of "emergency planning zones" within this document means the regions encapsulating the advanced planning areas [for prompt or urgent response areas] and the planning distances [designated during the response as a result of the evolving accidents]. Advanced emergency planning should be conducted in order to avoid or minimize severe deterministic effects17, reasonably reduce stochastic effects18 and mitigate the consequences of the accident at its source. The types of EPZs and recommended distances for each type of EPZ are found in IAEA Documents General Safety Requirements (No. GSR Part 7), "Preparedness and Response for a Nuclear or Radiological Emergency," and Emergency Preparedness and Response (EPR) Nuclear Power Plant (NPP) EPR-NPP Public Protective Actions 2013, "Actions to Protect the Public in an Emergency due to Severe Conditions at a Light Water Reactor," Section 4.

Additionally, safety related terms are defined in the IAEA Safety Glossary, which can be located at http://www-ns.iaea.org/standards/safety-glossary.htm.

5. OVERVIEW OF CURRENT IAEA METHODOLOGY

General Safety Requirements, Part 7, requirements 4.19, 4.20 and 5.38(a) contain the requirements to conduct a hazard assessment and its considerations, and the requirement to establish emergency planning zones and distances. The methodology presented in determining the EPZ extent and size can be found in IAEA document EPR-NPP PAA 2013, in Appendix I, "Basis for the Suggested Size and

[17] IAEA GSR Part 7, Item 5.38(i)
[18] IAEA GSR Part 7, Item 5.38 (ii)

Protective Actions within the Emergency Zones and Distances." The working group reviewed the requirements and methodology and found that they are sufficient in their scopes and practices to be used to determine the size of the emergency planning zones (PAZ and UPZ) around an SMR site. The WG developed a diagram that represents a generalized approach from EPR-NPP PAA 2013 and the participating Member States' own processes. The areas of the emergency planning distances (EPD and ICPD) are not determined by the use of the approach. Rather, the emergency planning distances are determined by surveys after a release. The following are design considerations and comments about applying an approach for SMR PAZ and UPZ that the authors thought would be informative.

The WG approach, which is considered to be a common position, is presented at a high level in figure 1 and allows for flexibility by the various states in applying each step in the process, taking into account differences in the national regulatory frameworks. An example of this is considering the effectiveness in applying protective actions (i.e. dose reduction factors) when determining dose consequences. The dose reduction factors applied from EPR-NPP PAA 2013 Appendix I are based on simple assumptions in regards to public behaviour. These assumptions can vary from state to state, and some states may choose not to incorporate any protective actions into the dose consequence calculations.

In the subsections following figure 1 the WG has provided text for each box in the diagram to describe differences that may exist between Member States and factors that should be considered in the step of the approach.

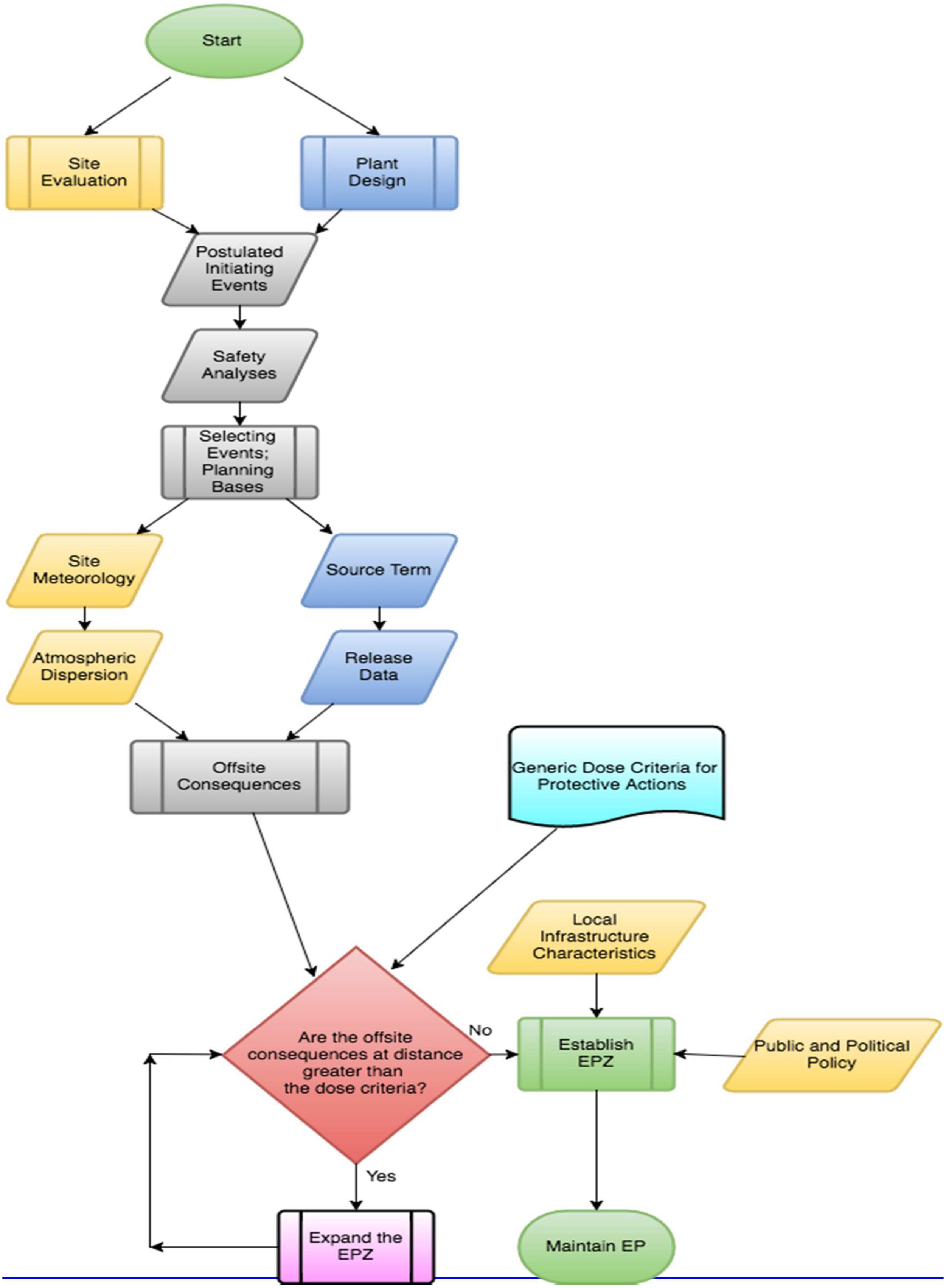

Figure 1 -- Generalized Approach to Determine EPZ Sizes

1. Start Generalized Approach to Determine EPZ Sizes
2. Site Evaluation for determining site suitability or for EPZ size determination. In some Member States, the siting requirements and the size of the EPZ are determined using different criteria as well as at differing times during a licensing process. In other Member States, the same criteria apply to siting and EPZ sizes.

    a) The site evaluation should identify those factors beyond the consideration of the plant design elements that could affect plant safety and any significant impediments to developing the emergency plans.

    b) The applicant should provide information that details the seismic, hydrological, geological, tidal, and other technically relevant subjects that support the site being suitable for the operation of a SMR. This would include the description of the uses of the surrounding land and waterways.

    c) The applicant should address the ability to return the site to a near-original condition at the end of plant life and the effects of long-term operation on the site.

    d) In determining the suitability of the site, the applicant should consider the ability to decontaminate and to have long-term storage of spent fuel.

    e) Population density and plans to maintain the population low such that the population itself does not become an impediment to implementing the emergency plan.

    f) Physical protection of the site

    g) Essential human assistance response means and times (fire, police, medical assistance, and so forth)

    h) Transportation routes (air, land, and waterways)

    i) Sensitive environmental characteristics for cultural, biological, societal impacts.

3. Plant Design
    a. The plant design should detail the planned number of operating reactors, power levels, electrical distribution, water sources and returns, emergency core cooling systems, spent fuel storage, and other design considerations.

    b. The plant design should provide a description of containment or the satisfaction of any containment function requirements.

    c. The EPZ WG considered major design features typical to SMRs that may affect the considerations and determinations of the sizes of the EPZ and the information and analysis that would be required to form the bases of the sizes of the EPZs. To determine the effect of each of the design features below, the EPZ WG members evaluated the feature without regard to another feature.

    d. Small reactors and low rated thermal power levels: The reactor core sizes and the low rated thermal power levels that are exhibited in the SMR designs work together to reduce the amount of radioactive materials for potential releases to the environment. Since the amounts of materials are reduced, the distances at which doses that exceed health or environmental limits resulting from any release could be lower. Therefore, an EPZ limited by the site boundary may be considered.

e. Modularity and Multiple Module Facilities: The use of "modularity" divides the source term into smaller, discrete reactors. A small modular reactor's core contains much less fuel than an existing large reactor core. The adding of the modules over time may allow the operator to obtain comparable power levels at the site as that provided by an existing power plant. However, the independent construction and operation of the modules makes a large-scale offsite consequence less possible as compared to a single, larger unit. Therefore, an EPZ limited by the site boundary may be considered.

f. Containment or Containment Function: Since the designers of SMRs are using different methods to contain any source term available for release, such as compact containment structures, high-pressure containment structures, double-wall construction, or water-immersed containment, the potential for offsite consequences is will be lower. Many factors will play a role in the effectiveness of the containment function, but with more robust the containment features, a large release is less possible. Therefore, an EPZ limited by the site boundary may be considered.

g. Subterranean Location: Some designers have designed plants for subterranean construction and operation. As such, any effluents would be at or near ground level. Hence, the effective extent of any release would be smaller than for a comparable release from an existing plant built above ground. Therefore, an EPZ limited by the site boundary may be considered.

h. Separate Operating and Maintenance Facilities: There are some small reactor designs without on-site refuelling capability. Rather the refuelling and maintenance of the reactor are done at another location. As those designs are deployed, separate emergency preparedness programs would need to be established around the operating site, maintenance site, and any port, depot or terminal during transit between the operating site and maintenance site.

i. Novel Features and Technologies: The use of novel features and technologies to lengthen the time between initiating event and the need for protective actions allows for additional time for accident prevention and mitigation. Therefore, an EPZ limited by the site boundary may be considered.

4. Postulated Initiating Events. The various Member States have differing processes in which to identify the postulated initiating events and to evaluate the impacts of the events. Some states employ a specific set of events to consider with the applicant supplementing any additional events required by regulations. Other Member States have set criteria for which an applicant evaluates the initiating events and determines the most severe set of events to include in the consideration of siting and EPZ sizes.

   a) The applicant should identify the postulated initiating events which could or does result in releases of radioactive material, referred to as source term, in accordance with the regulations and guidance provided by the licensing authority.

   b) The applicant should address how lessons learned from industry events are met through the design.

5. Safety Analyses. The type of analysis may differ from state to state depending on the systems involved, system integration, and safety-significance of the system. For example, a system that may have little to do with accident mitigation or prevention may not need extensive analysis to determine that system's function remains intact during an event. By contrast, the analysis required for a system relied upon for event prevention and mitigation may need redundant tests and analyses to deem its safety system function resilient during the event.

   a. Evaluating the plant's safety

b. Selecting Events and Establishing a Planning Bases

   i. Establish a list of credible accidents that would bound the analysis. (The use of probability risk analyses or probability safety analyses is meant to bound the analysis to determine a planning basis. It is not meant to bound the emergency preparedness and planning for the plant or site. The licensee and operator of the site would be required to respond to any emergency or event under its control.)

   ii. Practically eliminated accident sequences. As part of the analyses, the design would need to address which accident sequences were analysed and the results. The application should contain sufficient information for the technical staff to review the results and determine the appropriateness of the inclusion and exclusion of accident sequences. Those accident sequences that are subject to lessons learned, for example, Three-Mile Island, Browns Ferry Fire, Chernobyl, and Fukushima, should be included, or if not included, the basis for not including them.

c. Source Term

   i. Estimation of source terms for accident scenarios identified in safety analyses. The designers may use mechanistic source terms to account for the design-specific accident scenarios and accident progression. This use may form part of the applicant's or designer's request for a smaller EPZ than those which would granted to a large-light water reactor site. Additionally, the use of the mechanistic source terms to determine the suitability of a site may be considered.

d. Release Data

   i. Release height; stack or ground release.

   ii. Time before releases (hold-up)

   iii. Magnitude of releases (gross activity, isotopic activity, effluent flow rates)

   iv. Duration of releases

   v. Type of effluent (liquid, gas, metallic, and so forth)

e. Site Meteorology

   i. Wind direction

   ii. Wind speed

   iii. Stability Category

   iv. Precipitation

   v. Mixing height

   vi. Humidity

f. Atmospheric Dispersion Modelling

   i. Site specific meteorological data from nearest weather station

   ii. Recent data period of 1 year should be used

    iii. Weather data should be statistically analyzed to determine weather conditions used for planning purposes.

6. Determining Offsite Dose Consequence –Analyze the offsite dose consequences resulting from the postulated initiating events and the source term. Member states' approaches to determining the offsite dose consequences may vary.
7. Generic Dose Criteria— Among the differing Member States, the generic dose criteria may be determined by diverse levels of government and by differing ministries or agencies. For example, the dose criteria in one state may be a published by various ministries for the individual societal or industrial sectors regulated by the ministries. For example, the agricultural standards for dose may be under the oversight of one ministry and the human dose criteria may be under the oversight for health, and yet another for the environment or interior land dose criteria. Applicants or licensees should determine the distances at which the offsite dose consequences exceed the dose criteria. (Notes: The criteria are frequently called intervention levels, protective action levels, and protective action guides. The generic dose criteria may differ among the states.)
8. The EPZ size evaluation should identify those local infrastructure characteristics and factors that could affect plant safety and any significant impediments to implementing emergency planning and response. The infrastructure may provide familiar boundaries in setting the EPZ size.
9. Address public and political policy. In the various Member States, the public and political policies concerning energy and public health have differing degrees of influence into the decision making process. In some Member States, one policy may lean heavily in one direction, where in others, it may lean heavily in the other. A balance of the competing or complementary policies is found in the decision. Public and political policies could consider affected groups' input within the area of the proposed site, neighbouring states, and the states' public policies to determine minimum size of the EPZ. (Not all states use public or political policies in determining the EPZ sizes. The WG is neither recommending its adoption where it is not used nor the removal of the use of the policies.)
10. Establish EPZs. The decision making bodies may differ among Member States. In some states the local or provincial governments make a final decision as to the suitability of the site or the exact size and configuration, and in others, the national government makes the final determination.

    a) Evaluate the plant's safety, incorporating the hazard analysis, safety analysis, offsite dose consequences holistically.

    b) Compare the offsite dose consequences to the established dose criteria.

        i. If the offsite dose consequences exceed the dose criteria at a given distance, then expand the EPZs.

        ii. Continue to compare the offsite dose consequences to the dose criteria for a longer distance until the offsite dose consequences do not exceed the dose consequences.

        iii. States confirm the analysis and establish the EPZs.

        iv. Applicants and states establish and maintain emergency preparedness and planning within the EPZs.

6. CONCLUSIONS OF THE EPZ WG

- SMRs encompass a variety of nuclear power plant designs. Managing SMR events involving the potential for releases of radioactive material that challenge public safety and the environment requires a coordinated response
- There is a need to consider that the EPZ for SMRs is scalable depending on the results of a hazard assessment, the technology, novel features and specific design criteria, as well as for some, policy factors. The IAEA safety requirements and methodology for determining the EPZ size are effective in establishing an emergency preparedness and planning program, such that if a release does occur, protective actions will be implemented to protect the public and environment.
- A pre-application process may be considered to discuss the requirements and standards for siting and determining EPZs with potential applicants.
- For SMRs without on-site refueling capability, there is a need to consider the establishment of an EPZ at any intermediate stop and land-based maintenance facility used for the handling and the storage of the fuel assemblies.
- There is a need to consider some level of community emergency preparedness, for example, to receive public information and perform response drills, specifically when the size of the EPZs for SMRs are reduced to be in close proximity to densely populated centers.
- For SMR designs employing novel features and technology, there is a need to consider mechanistic methods for the approach for the determination of EPZ size. Operating feedback will help to reduce uncertainties and to determine future EPZ sizes for newer sites accordingly.
- The same design of SMR implemented in different countries may result in different EPZ sizes depending on dose criteria, policy factors, and public acceptance.

7.0 SUGGESTIONS FOR FUTURE WORK

The WG members had a variety of discussions and insights while writing this document. Many of the discussions pertained to the following topics, which were determined to beyond the scope of the WG's purpose. Therefore, the WG makes the following suggestions for the future work of the SMR Regulators Forum.

- Explore further the necessity to develop safety standards specific to establishing the necessary analyses, health or environmental standards for radiological releases, or public interactions for determining the EPZs.
- Examine the safety culture with respect to SMR industry. This topic arises from new designers and operators entering the industry, as well as, creating a culture from the beginning to not become complacent by "safety by design".
- Examine the physical security requirements for SMRs. Do SMRs adopt a "security by design" philosophy?
- Examine the elements for community emergency preparedness or off-site response planning.
- Examine the licensing of materials, reactors and irradiated fuel while in transit and among transit state.
- Explore further the "One design, one review" concept.
- Define a "Prudent proven" technology.
- Examine the advances in "human factors engineering" and how novel features of SMRs expand leverage HFE.

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Appendix A. Example of Member State approaches to determining EPZ

The following outline some Member State approaches used to determine the EPZs and EPDs.

	EPZ		EPD			Verification of Source Term/Offsite Consequences [see itemized list below]	
Country	PAZ	UAZ	EPD	ICPD			
Canada	Not pre-determined					(2)	
China	7-10 km		30-50 km			(5)	
France	20 km		20 km			(3)	
Korea							
Russian Federation	<25 km		<100 km			(4)	
USA	16 km (10 miles)		80 km(50 miles)			(1)	

1. The use of approved codes and methodology, the regulators require the input and output files for the verification of the source terms and offsite consequences. If the applicant uses a method or code other than an approved, the applicant must supply the input and output files and the source codes for the computer modelling that support the analysis and determination of source terms and offsite consequences with respect to the specific designs are part of an application.

2. The applicant needs to provide all relevant information for the offsite authorities assess or make an informed decision on the EPZ, such as the source term and accident sequences. The calculation is not required.

3. The applicant needs to provide all relevant information for the offsite authorities assess or make an informed decision on the EPZ, such as the source term and accident sequences. The calculations need to be included in the safety case.

4. Russian Federation – Offsite consequences are verified by using nuclear regulator guidance and safety review.

5. The applicant needs to provide all relevant information for determining the EPZ, such as source term and accident sequences. All above should be in accordance with nuclear safety regulations.

Canada

Definition of Nuclear Facility

The Class I Nuclear Facilities Regulations under the Nuclear Safety and Control Act [1] defines a nuclear facility as follows:

"Class I nuclear facility" means a Class IA nuclear facility and a Class IB nuclear facility.

"Class IA nuclear facility" means any of the following nuclear facilities:

a. a nuclear fission or fusion reactor or subcritical nuclear assembly; and
b. a vehicle that is equipped with a nuclear reactor.

"Class IB nuclear facility"

"Class IB nuclear facility" means any of the following nuclear facilities:

a. a facility that includes a particle accelerator, other than a particle accelerator described in paragraphs (d) and (e) of the definition "Class II prescribed equipment" in section 1 of the Class II Nuclear Facilities and Prescribed Equipment Regulations;
b. a plant for the processing, reprocessing or separation of an isotope of uranium, thorium or plutonium;
c. a plant for the manufacture of a product from uranium, thorium or plutonium;
d. a plant, other than a Class II nuclear facility as defined in section 1 of the Class II Nuclear Facilities and Prescribed Equipment Regulations, for the processing or use, in a quantity greater than 1015 Bq per calendar year, of nuclear substances other than uranium, thorium or plutonium;
e. a facility for the disposal of a nuclear substance generated at another nuclear facility; and
f. a facility prescribed by paragraph 19(a) or (b) of the General Nuclear Safety and Control Regulations.

Definition of Planning Zones

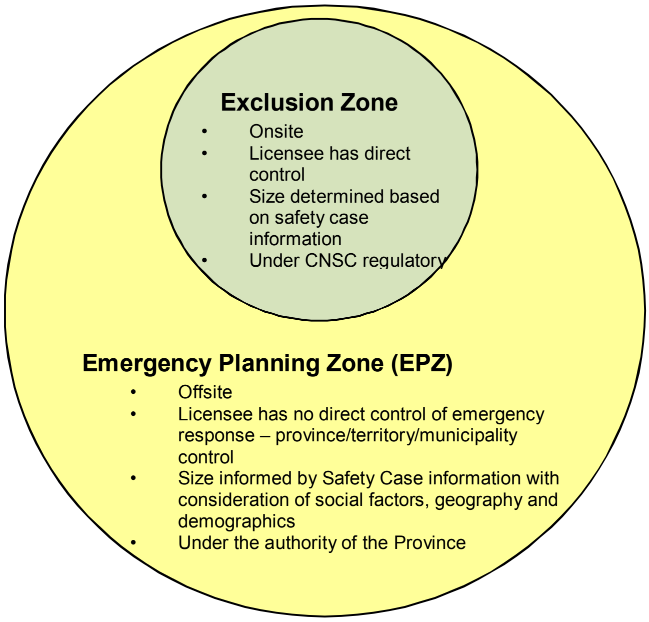
Exclusion Zone

Per section 1 of the Class I Nuclear Facilities Regulations, "Exclusion Zone" means a parcel of land within or surrounding a nuclear facility on which there is no permanent dwelling and over which a licensee has the legal authority to exercise control. Appendix A contains a summary of the Canadian process on determining the exclusion zone. Details on the exclusion zone are found in Regulatory Document RD-346 Site Evaluation for New Nuclear Power Plants.

Emergency Planning Zone

An Emergency Planning Zone (EPZ) is defined to be the area in which implementation of operational and protective actions might be required during a nuclear emergency, in order to protect public health, safety, and the environment. An EPZ addresses emergency measures to be utilized outside the licensee's exclusion zone and are normally controlled and executed by an external emergency planning authority.

Figure 1: Relationship between the EPZ and Exclusion Zone



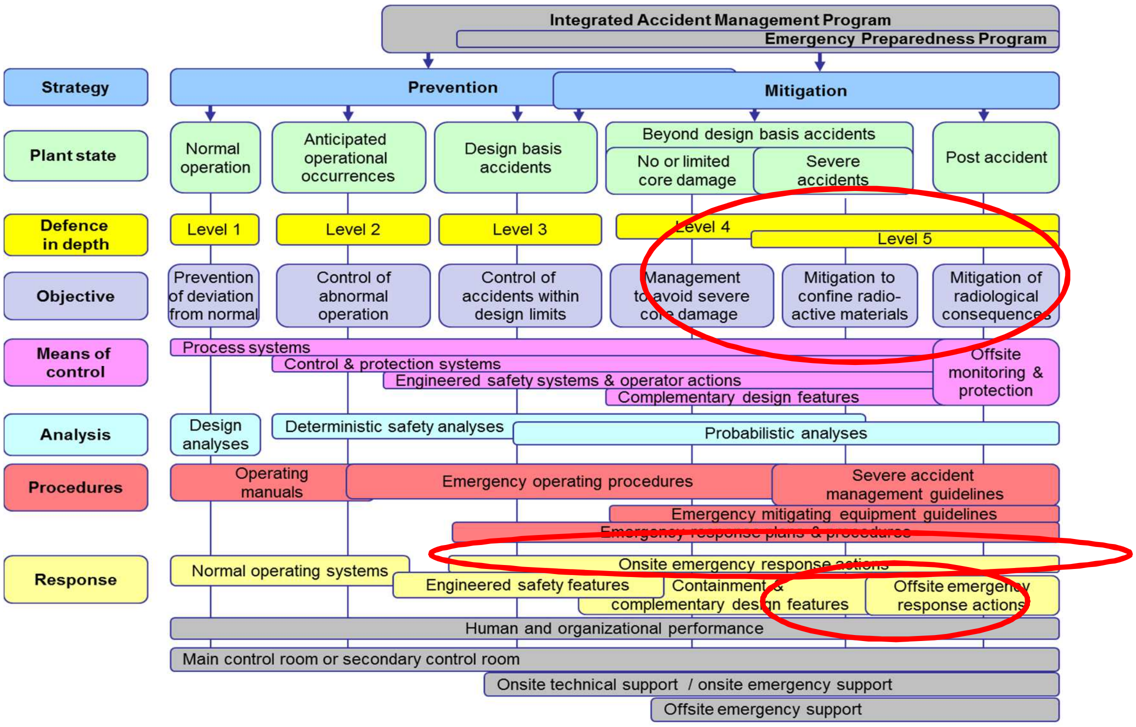
EPZ can be further broken down into additional sub-zones to address the following objectives (CSA N1600-General Requirements for Nuclear Emergency Management Programs):

- Provisions for automatic actions: A designated area (Automatic Actions Zone, AAZ) immediately surrounding a nuclear power plant (NPP) where pre-planned protective actions are implemented by default on the basis of NPP conditions with the aim of preventing or reducing the occurrence of severe deterministic effects. This includes licensee actions within the Exclusion Zone.
- Detailed planning: A designated area (Detailed Planning Zone, DPZ) surrounding a NPP, incorporating the AAZ, where pre-planned protective actions are implemented as needed on the basis of NPP conditions, dose modelling, and environmental monitoring, with the aim of preventing or reducing the occurrence of stochastic effects.
- Contingency planning: A designated area (Contingency Planning Zone, CPZ) surrounding a NPP, beyond the DPZ, where plans or arrangements are made in advance, so that during a nuclear emergency:
  - protective actions can be extended as required to reduce potential for exposure; and
  - dose rate monitoring of deposition is conducted to locate hotspots that could require protective actions following a release.
- Ingestion control planning: A designated area surrounding a NPP where plans or arrangements are made to
  a) protect the food chain;
  b) protect drinking water supplies;
  c) restrict consumption and distribution of potentially contaminated produce, wild-grown products, milk from grazing animals, rainwater, animal feed; and
  Note: Wild-grown products can include mushrooms and game.
  d) restrict distribution of non-food commodities until further assessments are performed

EPZ as Part of Defence in Depth

As illustrated in Figure 2 below, offsite emergency response measures, which are conducted in each of the EPZ, are considered to be Level 5 of Defence-in-Depth but, more importantly, are part of an integrated Accident Management Approach that works in concert with all five Defence in Depth levels.

Figure 2: Defence-in-Depth: Integrated Accident Management



Regulatory Requirements that address Planning Zone role in Class 1 Facility Activities

Regulations under the Nuclear Safety and Control Act

Specific requirements for EPZs are not explicitly stated in CNSC regulations such as the *Class I Facilities Regulations* as they are under the jurisdiction of the Province. However, information resulting from the licensing to construct and environmental assessment (EA) processes are used to support the EPZ requirements. In Canada, emergency measures are to be integrated into the overall facility safety case (that implements the defence-in-depth approach) (see Section 2.1.3 and Figure 2). That is, such measures are expected to be addressed in the following key *Class I Facilities Regulations* among others:

§3, *General Requirements*

"*An application for a licence in respect of a Class I nuclear facility, other than a licence to abandon, shall contain the following information in addition to the information required by section 3 of the General Nuclear Safety and Control Regulations*:

(a) a description of the site of the activity to be licensed, including the location of any exclusion zone and any structures within that zone;"

§4, *Licence to Prepare Site*

"*An application for a licence to prepare a site for a Class I nuclear facility shall contain the following information in addition to the information required by section 3*:

(a) a description of the site evaluation process and of the investigations and preparatory work that have been and will be done on the site and in the surrounding area;

(e) the effects on the environment and the health and safety of persons that may result from the activity to be licensed, and the measures that will be taken to prevent or mitigate those effects."

§5, *Licence to Construct*

"An application for a licence to construct a Class I nuclear facility shall contain the following information in addition to the information required by section 3:

(a) a description of the proposed design of the nuclear facility, including the manner in which the physical and environmental characteristics of the site are taken into account in the design;

(b) a description of the environmental baseline characteristics of the site and the surrounding area;

(f) a preliminary safety analysis report demonstrating the adequacy of the design of the nuclear facility;

(i) the effects on the environment and the health and safety of persons that may result from the construction, operation and decommissioning of the nuclear facility, and the measures that will be taken to prevent or mitigate those effects;

(k) the proposed measures to control releases of nuclear substances and hazardous substances into the environment;"

§6, *Licence to Operate*

"*An application for a licence to operate a Class I nuclear facility shall contain the following information in addition to the information required by section 3:*

(c) a final safety analysis report demonstrating the adequacy of the design of the nuclear facility;

(d) the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility;

(h) the effects on the environment and the health and safety of persons that may result from the operation and decommissioning of the nuclear facility, and the measures that will be taken to prevent or mitigate those effects;

(j) the proposed measures to control releases of nuclear substances and hazardous substances into the environment;

(k) the proposed measures to prevent or mitigate the effects of accidental releases of nuclear substances and hazardous substances on the environment, the health and safety of persons and the maintenance of national security, including measures to:

> *(i) assist off-site authorities in planning and preparing to limit the effects of an accidental release,*
>
> *(ii) notify off-site authorities of an accidental release or the imminence of an accidental release,*
>
> *(iii) report information to off-site authorities during and after an accidental release,*
>
> *(iv) assist off-site authorities in dealing with the effects of an accidental release, and*
>
> *(v) test the implementation of the measures to prevent or mitigate the effects of an accidental release;*

() the proposed measures to prevent acts of sabotage or attempted sabotage at the nuclear facility, including measures to alert the licensee to such acts;

§7, *Licence to Decommission*

"*An application for a licence to decommission a Class I nuclear facility shall contain the following information in addition to the information required by section 3:*

***(f)** the effects on the environment and the health and safety of persons that may result from the decommissioning, and the measures that will be taken to prevent or mitigate those effects;*

***(h)** the proposed measures to control releases of nuclear substances and hazardous substances into the environment;*

***(i)** the proposed measures to prevent or mitigate the effects of accidental releases of nuclear substances and hazardous substances on the environment, the health and safety of persons and the maintenance of national security, including an emergency response plan;*

Supporting requirements and guidance in CNSC Regulatory Documents

CNSC Licence Application Guides (LAG) identify information that should be submitted to support an application for a licence and address the submissions and level of detail needed to address the above regulations for each phase of licencing. For example, in RD/GD-369, Licence Application Guide, Licence to Construct a Nuclear Power Plant, addresses emergency planning considerations in:

- Chapter 4, Site Evaluation
- Chapter 12, Emergency Preparedness

The following key regulatory documents contain requirements and guidance that influence the information submitted by an applicant to support Exclusion Zone and EPZ decision-making:

- RD-346: Site Evaluation for New Nuclear Power Plants
- RD/GD-369: Licence Application Guide: Licence to Construct a Nuclear Power Plant
- REGDOC-2.3.2, Accident Management
- REGDOC-2.4.1: Deterministic Safety Analysis
- REGDOC-2.4.2: Probabilistic Safety Assessment (PSA) for Nuclear Power Plants
- REGDOC 2.5.2: Design of Reactor Facilities: Nuclear Power Plants
- RD-367: Design of Small Reactor Facilities
- REGDOC 2.10.1: Nuclear Emergency Preparedness and Response

Other regulatory documents under the following Safety and Control Areas further support the facility safety case, including evidence to support provisions in level 5 of Defence in Depth as well as confidence in the ongoing safe operation of the facility:

- Management System
- Human Performance Management
- Operating Performance
- Fitness For Service
- Radiation Protection
- Emergency Management – specifically Fire Protection
- Security

Supporting Requirements in CSA Standards

In addition to the above CNSC Regulatory Documents, the Canadian Standards Association (CSA) also maintains standards that support and address areas relevant to information used to support cases for Emergency Planning. The following published and draft standards are pertinent to post-accident conditions; however, many other CSA standards exist to support design and safety analysis activities that address preventative means:

- CSA-N288.2: Guidelines For Calculating The Radiological Consequences To The Public Of A Release Of Airborne Radioactive Material For Nuclear Reactor Accidents
- CSA-N290.15: Requirements for the Safe Operating Envelope of Nuclear Power Plants
- N290.16-16: Requirements for Beyond Design Basis Accidents
- CSA-N1600: General Requirements for Nuclear Emergency Management Programs

Overview of Process for Determining EPZ Extent in Canada

Roles and Responsibilities of Responsible Participants and Agencies

Provinces

Provincial governments have the primary responsibility for offsite emergency planning and response to protect public health, property and the environment. As such, the province prepares its provincial nuclear emergency response plans (PNERP) in coordination with the federal government, under the Federal Nuclear Emergency Plan (FNEP). For example, in the province of Ontario, where the majority of the nuclear power stations in Canada operate, the PNERP is described at the following web-link: Emergency Management Ontario: Emergency Response Plans.

Health Canada

Health Canada, as the lead department under the FNEP (Health Canada, 2002), provides Guidelines for intervention following a nuclear emergency in Canada or affecting Canadians Canadian Guidelines for Intervention During a Nuclear Emergency, November 2003.

These Guidelines are a key reference for provincial governments when preparing provincial nuclear emergency plans, as well as other responsible agencies and applicants for licences for activities regulated under the Nuclear Safety and Control Act.

CNSC

The CNSC is the regulatory authority for licensing, compliance and enforcement for nuclear reactor facilities in Canada. As part of the licensing process, CNSC takes into consideration the design basis accident dose limits and confirms the determined Exclusion Zone distance is appropriate to meet all required safety requirements. The CNSC works closely with the province to provide information regarding the nuclear facility safety case and licensing process to assist the province in determining the EPZ extent.

Applicants for Activities Involving New Reactor Facilities

Applicants and licensees for activities involving the use of reactor facilities are responsible for submitting complete applications outlining how the site evaluation and chosen technology will, through their safety analysis, result in appropriate Exclusion Zone and emergency response plans to meet the provincial requirements. In addition, in accordance with the REGDOC 2.10.1, the applicants and licensees are required to work with and support the province in determining the EPZ extent.

Considerations for Determining EPZ

Physical Design of Reactor Facility

Reactor vendors must consider the range of applications and environments as well as the regulatory requirements, for all countries of commercial interest, when developing their designs. The entire process of ensuring an appropriate Exclusion Zone starts with the design of the reactor facility and the design data that supports safety claims.

Vendors must ensure their designs are robust enough to meet their intended safety objectives, protective action limits and to address all these potential conditions.

CNSC provides requirements and guidance on key areas of importance to planning zones such as physical design of reactor facilities and safety analysis for applicants as well as to assist reactor vendors in the development of new reactor designs they are intending for Canadian applications.

The Class 1 Nuclear Facilities Regulations requires that an application for a licence for a reactor facility to demonstrate that the selected design has accommodated specific site and regional characteristics. Composite bounding designs submitted as a bounding approach are possible; however, the applicant is limited to the projected releases as set in the Environmental Assessment (EA) and confirmed at the time of the construction licence review.

Design requirements are provided in REGDOC-2.5.2, Design of Reactor Facilities: Nuclear Power Plants and RD-367, Design for Small Reactor Facilities. Safety analysis requirements are found in REGDOC-2.4.1, Deterministic Safety Analysis, and REGDOC-2.4.2, Probabilistic Safety Assessment (PSA) for Nuclear Power Plants.

Postulated Initiating Events (PIE)

PIEs are theoretical events that can cause one or more adverse effects on the facility. They form a key input to the safety analysis of a facility design in all of its potential environments.

These events consider internal events, such as the breaking of an installed component within the plant, or an electrical fire. They also consider external events such as a significant earthquake or flooding.

There is a significant body of ongoing knowledge capture, best practice and lessons learned in this field. Vendors, owners groups, regulators, researchers and other nuclear safety organizations are involved in developing and maintaining the body of practice around determination of PIEs.

Site evaluation also plays a key role in the identification of PIEs for the specific site. The CNSC provides requirements and guidance on site evaluation for new NPPs. Please refer to the following for further information RD-346, Site Evaluation for New Nuclear Power Plants. In addition, information on identification of PIEs can be found in REGDOC-2.4.1, Deterministic Safety Analysis and REGDOC-2.4.2, Probabilistic Safety Assessment (PSA) for Nuclear Power Plants.

Probabilistic Safety Assessment (PSA)

PSA is a comprehensive and integrated assessment of the safety of a reactor facility. The safety assessment considers the probability, progression and consequences of equipment failures or transient conditions to derive numerical estimates that provide a consistent measure of the safety of reactor facility, as follows:

A level 1 PSA identifies and quantifies the sequences of events that may lead to the loss of core structural integrity and massive fuel failures.

A level 2 PSA starts from the level 1 results, analyses the containment behaviour, evaluates the radionuclides released from the failed fuel, and quantifies the releases to the environment. A level 3 PSA starts from the level 2 results, and analyses the distribution of radionuclides in the environment and evaluates the resulting effect on public health.

In Canada, CNSC provides requirements and guidance on conducting a PSA which includes targeted requirements to address the lessons learned from the Fukushima event, allows for a Graded Approach, and commensurate with the risk. Please refer to the following for further information REGDOC-2.4.2, Probabilistic Safety Assessment (PSA) for Nuclear Power Plants.

Deterministic Safety Analysis (DSA)

DSA predicts the facility's response to a range of events based on the current state of the facility as well as operator actions. This analysis addresses a range of scenarios for which the acceptance criteria must be met. It is another tool for early identification and mitigation of potential risks.

A DSA of a reactor facility's responses to an event is performed by an applicant/licensee using predetermined rules and assumptions (such as those concerning the initial facility operational state, availability and performance of the facility systems and operator actions). DSA can use either conservative or best-estimate methods.

CNSC experts review licensee DSA as part of verification and compliance activities.

In Canada, CNSC provides requirements and guidance on conducting a DSA which includes targeted requirements to address the lessons learned from the Fukushima event and allows for a Graded Approach, and commensurate with the risk.

Requirements for DSA are articulated in REGDOC-2.4.1, Deterministic Safety Analysis.

Limiting Credible Accident and Criteria for Identification of the Planning Accident

Based on the safety analysis, the applicants/licensees would identify a list of limiting credible accidents. It is the responsibility of the applicants/licensees to propose the planning basis taking the guidance into account when selecting the limiting credible accidents. Requirements for planning basis are articulated in: REGDOC 2.10.1, Nuclear Emergency Preparedness and Response §2.1 as follows:

All licensees shall:

1. establish a planning basis for their EP program
2. ensure the planning basis considers the hazards that have, or could have, an adverse impact on the environment and the health and safety of onsite personnel or the public, and also consider:
    a. all accidents and internal or external events that have been analyzed as having an unacceptable impact on their facilities
    b. the inclusion of multi-unit accidents scenarios for multi-unit power reactor facilities
    c. extended loss of power
3. use the results from the planning basis to determine the scope and depth of EP program requirements

Additional requirements for licensees of reactor facilities with a thermal capacity greater than 10 MW. These licensees shall:

4. provide regional and provincial offsite authorities with necessary information to allow for effective emergency planning policies and procedures to be established and modified, if needed, periodically.

As stated in bullet 4, the applicants/licensees are required to provide the necessary information (credible limiting accidents and associated source terms) for the provincial and regional authorities to effectively establish their emergency planning policies and procedures. This includes the establishment of the provincial planning accident and the eventual establishment of the EPZ.

The Source Term and releases

The resulting source term is a list of all of the radionuclides that would be released to the environment for the selected accident, following the functioning of all the safety systems to their expected performance under the accident conditions. The source term also includes the release duration and other parameters such as stack height.

Considerations of Meteorology for Atmospheric Dispersion and Deposition Models

The sites meteorological characterization data and modelling is applied to the release to see how the types of isotopes would travel through the air and be deposited throughout the environment.

Dose Assessment and Distribution in consideration of pre-established dose criteria

Once the dispersion and deposition models have been characterized, the resulting exposure pathways and dose calculations are performed. These are assessed against pre-established dose criteria for emergency response measures to determine the distances to which certain protective actions such as sheltering and evacuation would be required (PALS).

Assessment of other external factors

Other external factors are then applied as they may have requirements for their proper consideration in the planning basis or for security reasons that may require adjustments to the EPZ. These considerations take into account for example, security, town limits, the emergency response plans, social factors as considered through the public EA and licensing process.

EPZ Determination Process Map

Figure 3 illustrates the overall process for determining EPZ extent in Canada. It is important to note that several responsible Federal and Provincial agencies are involved as indicated in Section 2.2.1, each according to their mandates and respective roles and responsibilities. A similar discussion on the establishment of the Exclusion Zone is described in Appendix A.

It is important to note that the applicants/licensees are required to provide regional and provincial offsite authorities with the necessary information to allow for effective emergency planning policies on a periodic basis. This requires the applicants/licensees to provide information to the provincial authorities that would assist the province to establish the appropriate EPZ around the nuclear facility. This information may include the limiting credible accidents and their associated source terms. From the list of limiting credible accidents, the province will determine the planning accident based on established criteria.

The resulting source term from the selected planning accident would be used with the sites meteorological characterization data and modelling to determine the isotopic dispersion. Once the dispersion and deposition models have been characterized, the resulting exposure pathways and dose calculations are performed. These are assessed against pre-established PALS. PALS are dose criteria for emergency response measures to determine the distances to which certain protective actions such as sheltering and evacuation would be required.

In addition, the provincial authorities would also consider social factors, geography and demographics in determining the EPZ around the nuclear facility. It is important to note that although the determination of the EPZ size is under the authority of the province, the province works with multiple supporting organizations to develop a technical planning basis which would be used to determine the EPZ.

In summary, the EPZ extent is based on the nuclear reactor’s technology, the resulting dose assessments against the provincial PALs, and various external factors such as social considerations, demographics and geography.

Licensing basis

A set of requirements and documents for a regulated facility or activity comprising:

- the regulatory requirements set out in the applicable laws and regulations
- the conditions and safety and control measures described in the facility's or activity's licence and the documents directly referenced in that licence
- the safety and control measures described in the licence application and the documents needed to support that licence application

Bounding Approach

A design approach used for developing a representative source term based on the design of a theoretical composite reactor facility derived from the weakest systems of multiple competing vendor designs. This bounded design represents the most conservative (worst case) source term, thereby ensuring the eventual selected technology will meet any requirements of the Environmental Assessment and is confirmed at the time of the Construction Licence review for new reactor facilities.

Exclusion Zone

Overview of Process for Determining Exclusion Zone in Canada

The information that informs discussions around Exclusion Zone extent for a specific nuclear reactor facility site is developed during the Environmental Assessment (EA) process19 and refined in the Construction Licence application process. In the EA process, the proponent may choose to consider a range of different reactor technologies being considered.

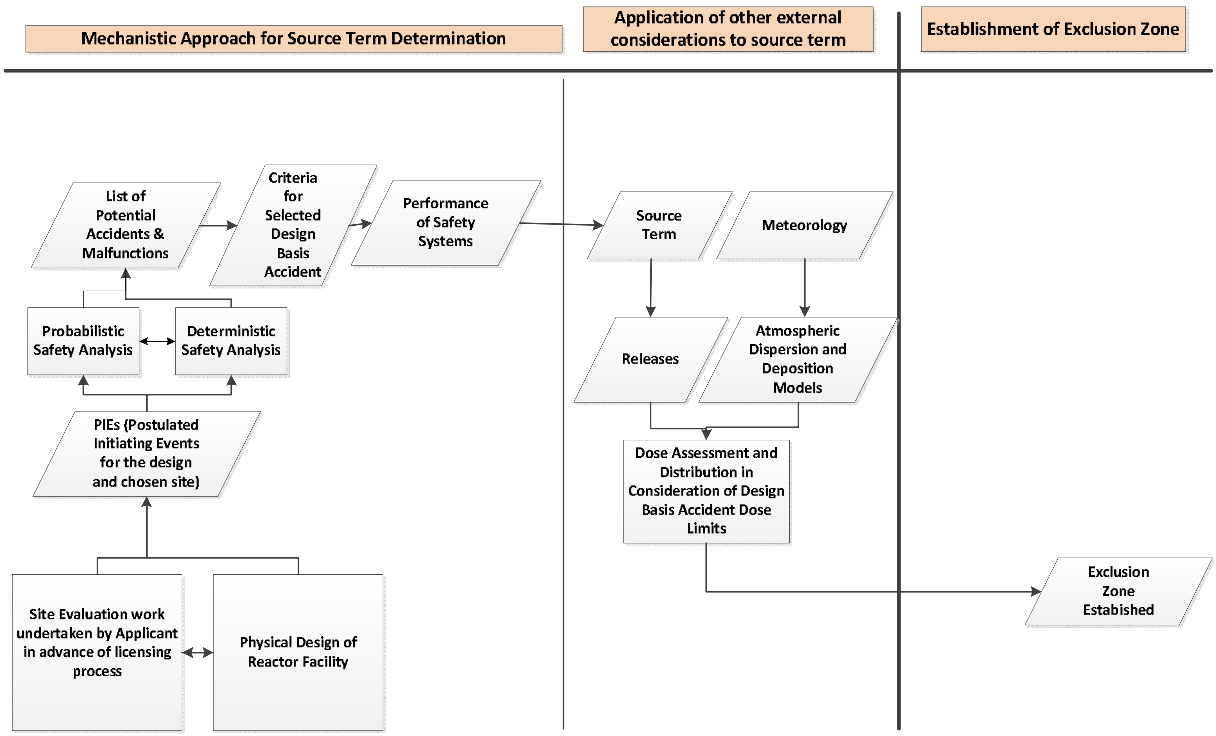
The applicant for a construction licence must demonstrate that:

- The selected Exclusion Zone distance meets the protective action limits set by the Province.
- The reactor facility design has demonstrated that it can, under the selected accidents, meet the pre-established dose criteria for its projected releases.
- That the selected Exclusion Zone distance has taken into consideration all necessary external considerations.

Figure 3 illustrates the overall process for determining the Exclusion Zone extent. The CNSC licensing process results in the acceptance of the Exclusion Zone for a given site. This approach ensures all required regulatory requirements for safety are met while maintaining flexibility to allow for various combinations of technologies and sites.

[19] Normally done in conjunction with an application for a Licence to Prepare Site

Figure 3: Overview of Canadian Process for Determining Exclusion Zone



Considerations for Determining Exclusion Zone

Physical Design of Reactor Facility

Reactor vendors must consider the range of applications and environments as well as the regulatory requirements, for all countries of commercial interest, when developing their designs. The entire process of ensuring appropriate Exclusion Zone starts with the design of the reactor facility and the design data that supports safety claims.

Vendors must ensure their designs are robust enough to meet their intended safety objectives to address all these potential conditions.

CNSC provides requirements and guidance on key areas of importance to Exclusion Zone such as physical design of reactor facilities and safety analysis for applicants as well as to assist reactor vendors in the development of new reactor designs they are intending for Canadian applications.

The Class 1 Nuclear Facilities Regulations requires that an application for a licence for a reactor facility demonstrate that the selected design has accommodated specific site and regional characteristics. Composite bounding designs submitted as a bounding approach are possible; however, the applicant is limited to the projected releases as set in the EA and confirmed at the time of the construction licence review.

Design requirements are provided in REGDOC-2.5.2, Design of Reactor Facilities: Nuclear Power Plants and RD-367, *Design for Small Reactor Facilities*. Safety analysis requirements are found in REGDOC-2.4.1, *Deterministic Safety Analysis,* and REGDOC-2.4.2, *Probabilistic Safety Assessment (PSA) for Nuclear Power Plants*.

Postulated Initiating Events (PIE)

PIE are theoretical events that can cause one or more adverse effects on the facility. They form a key input to the safety analysis of a facility design in all of its potential environments.

These events consider internal events, such as the breaking of an installed component within the plant, or an electrical fire. They also consider external events such as a significant earthquake or flooding.

There is a significant body of ongoing knowledge capture, best practice and lessons learned in this field. Vendors, owners groups, regulators, researchers and other nuclear safety organizations are involved in developing and maintaining the body of practice around PIE.

Site evaluation also plays a key role in the identification of PIE for the specific site. The CNSC provides requirements and guidance on site evaluation for new nuclear power plants. Please refer to the following for further information RD-346, Site Evaluation for New Nuclear Power Plants. In addition, information on identification of PIE can be found in REGDOC-2.4.1, Deterministic Safety Analysis and REGDOC-2.4.2, Probabilistic Safety Assessment (PSA) for Nuclear Power Plants.

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PSA is a comprehensive and integrated assessment of the safety of a reactor facility. The safety assessment considers the probability, progression and consequences of equipment failures or transient conditions to derive numerical estimates that provide a consistent measure of the safety of reactor facility, as follows:

- A level 1 PSA identifies and quantifies the sequences of events that may lead to the loss of core structural integrity and massive fuel failures.
- A level 2 PSA starts from the level 1 results, analyses the containment behaviour, evaluates the radionuclides released from the failed fuel, and quantifies the releases to the environment. A level 3 PSA starts from the level 2 results, and analyses the distribution of radionuclides in the environment and evaluates the resulting effect on public health.

In Canada, CNSC provides requirements and guidance on conducting a PSA which includes targeted requirements to address the lessons learned from the Fukushima event and allows for a Graded Approach, commensurate with risk. Please refer to the following for further information REGDOC-2.4.2, Probabilistic Safety Assessment (PSA) for Nuclear Power Plants.

Deterministic Safety Analysis (DSA)

DSA predicts the facility's response to a range of events based on the current state of the facility as well as operator actions. This analysis addresses a range of scenarios for which the acceptance criteria must be met. It is another tool for early identification and mitigation of potential risks.

A DSA of a reactor facility's responses to an event is performed by an applicant/licensee using predetermined rules and assumptions (such as those concerning the initial facility operational state, availability and performance of the facility systems and operator actions). DSA can use either conservative or best-estimate methods.

CNSC experts review licensee deterministic safety analyses as part of verification and compliance activities.

In Canada, CNSC provides requirements and guidance on conducting a DSSA which includes targeted requirements to address the lessons learned from the Fukushima event and allows for a Graded Approach, and commensurate with risk.

Requirements for DSA are articulated in REGDOC-2.4.1, Deterministic Safety Analysis.

List of Potential Accidents and Malfunctions

The list of potential accidents and malfunctions are derived from the analysis of the plant response to the PIE, and are an output of the safety analysis and are used to identify the limiting accident.

Criteria for Identification of the Limiting Credible Accident

The identification of the limiting accident is one of the most critical steps in the overall system of arriving at an appropriate Exclusion Zone extent; however, CNSC recognized that prescribing a limiting accident could place unnecessary constraints on the ability to apply new technological approaches to ensuring safety. As a result, the following approach is used to maintain a certain level of flexibility while ensuring safety:

From the list of accidents and malfunctions coming out of the safety analysis, a range of representative design basis accidents must be identified that appropriately represent criteria that are technically credible and acceptable from an emergency planning basis.

Performance of Safety Systems and Emergency Operating Procedures (EOPs) and Severe Accident Guidelines (SAMG)

Following the selection of the limiting credible design basis accident, an assessment of the reactor facility's ability to respond to the accident is performed in order to come up with the postulated source term. This includes the effectiveness of safety systems in limiting fuel damage, and preventing uncontrolled releases of radionuclides to the environment.

The Source Term and releases

The resulting source term is a list of all of the radionuclides that would be released to the environment for the selected accident, following the functioning of all the safety systems to their expected performance under the accident conditions. The source term also includes the release duration and other parameters such as stack height.

Considerations of Meteorology for Atmospheric Dispersion and Deposition Models

The sites meteorological characterization data and modelling is applied to the release to see how the types of isotopes would travel through the air and be deposited throughout the environment.

Dose Assessment in Consideration of Pre-Established Design Basis Accident Dose Limits

Once the dispersion and deposition models have been characterized, the resulting exposure pathways and dose calculations are performed. These are assessed against pre-established design basis accident dose limits.

China

EPZ regulation of NPP

Within China, EPZ should be set around the NPP. It contains Plume Emergency Planning Zone (PEPZ) and Ingestion Emergency Planning Zone (IEPZ). The set and size of EPZ for NPP normally refer to the national standard *emergency plan and preparedness criterion part I: the division of EPZ (*GB/T 17680.1*)*. According to the national standard, the PEPZ includes inner zone and outer zone. The size of PEPZ generally is about 7~10km and inner zone is about 3~5 km, considering heat power of reactor and radiological consequences of postulated accident sequences as well as political factors. IEPZ can be considered with results of accident radioactive consequence assessment in the stage of emergency plan and preparation.

Siting regulation of NPP

Exclusion Area (EA) and Planning Restricted Area (PRA) must be set around NPP. The size of both areas shall be determined with radioactive consequences of Postulated Siting Accident. Boundaries of EA is no less than 500m from reactor, can be made base on terrain, landform, weather and traffic of site. The radius of PRA must be no less than 5 km distant from the reactor.

NPP shall be built away from cities. Town with the population of 10,000 can’t be included in the PRA. Cities with the population of 100,000 can’t be in a radius 10 km of the site.

France

POST –ACCIDENT ZONING IN FRANCE[20]

Post-accident zoning is designed to provide a structuring framework within which actions to protect the population and manage contamination across the territories affected by the accident can be instituted.

The first post-accident zoning is established on the basis of a predictive model of future population exposure to the ambient radioactivity in the inhabited zones and contamination in the food chain, as a result of deposited radioactivity. The zoning is determined by the local authority on the basis of dosimetric guidance values taking into account the latest international references and European regulatory framework. The distinction is to be made between two zones each with a distinctive purpose:

- a public protection zone (ZPP) inside which action is needed in order to lower as much as possible population exposure to ambient radioactivity and ingestion of contaminated foods;
- a heightened territorial surveillance zone (ZST), which is broader and more focused on economic management, within which specific monitoring of foodstuffs and farmed crops is to be instituted.

Where applicable, within the public protection zone, a relocation perimeter determined in accordance with the ambient radioactivity (external exposure), is to be defined. Residents must be relocated for a duration that shall vary according to the level of exposure in their living environment.

The public protection zone (ZPP) is defined as the area within which actions designed to reduce exposure to ambient radioactivity for residents of the said areas as low as reasonably achievable are warranted. This area is defined for the purpose of providing radiation protection for the population living in the most contaminated territories, based on dosimetric guidance values. The initial definition of the ZPP will be made on the basis of assessment of projected doses likely to be received during the month following the end of release, without taking into account the effectiveness of the contamination reduction actions implemented in the area. The ZPP is in other words delineated based on the most disadvantageous of the two following exposure indicators:

- the projected effective dose received during the first month following the end of release, regardless of pathways of exposure, including ingestion of contaminated local foodstuffs, the guidance value used being approximately 10 mSv over the first month;
- the projected thyroid equivalent dose received over the course of the first month following the end of release, regardless of pathways of exposure, in particular ingestion of contaminated local foodstuffs, the selected guidance value being approximately 50 mSv over the first month.

The dosimetric guidance values are not to be interpreted as thresholds or limits. The uncertainties on estimated dose are such that other factors than dose should be considered. These factors are connected with the conditions under which the actions envisioned are carried out in reality, and are best assessed at the local level.

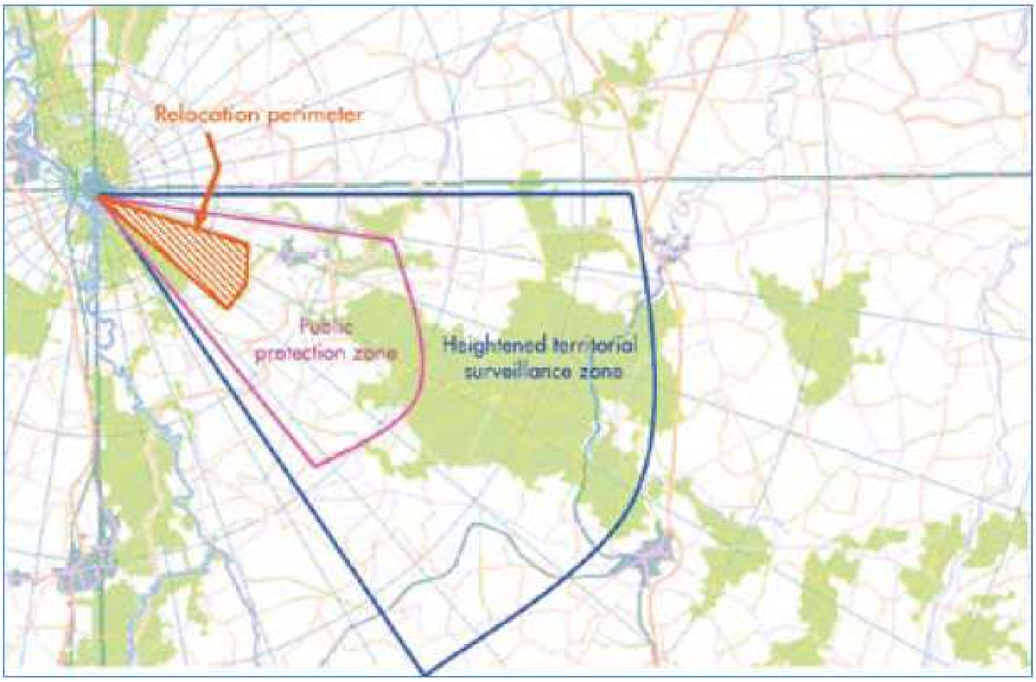
The relocation perimeter shall be delineated based on the results of an assessment showing the projected effective doses over the first month following release, not taking into account the contaminated foodstuffs of local origin ingested, comparing them to a guidance value on the order of 10 mSv over the first month.

The heightened territorial surveillance zone (ZST) extends beyond the borders of the public protection zone. As the emergency phase comes to an end, the ZST is also delineated, using forecast assessments derived from models of the transfers of radioactivity deposited in farming areas. It is characterized by

[20] Policy elements for post-accident management in the event of nuclear accident – Final version – ASN 5/10/2012

lower environmental contamination that does not require the automatic implementation of population protective actions.

This contamination is nonetheless significant and can affect in particular foodstuffs and agricultural products, substantiating the institution of specific systems to monitor the radiological quality of the relevant products. In some agricultural products and foodstuffs, contamination may exceed, albeit temporarily, the maximum permitted levels (NMA), considered of regulatory value and set at the European level to regulate the placing on the market of the said foodstuffs.



Rough depiction of post-accidental zoning

During the exit period from the emergency phase, an approach based on predictive modelling is the only way to provide the public authorities with dose assessments for the population and on agricultural foodstuff contamination, making it possible to define the ZPP and ZST.

In order to secure the most accurate assessment possible, the modelling-based approach requires a large amount of data and information on the characteristics of the affected facility and its environment (in particular on the agricultural production), as well as assumptions about the lifestyles and diet of the populations affected. It is important to emphasize that this method, even when applied using realistic data, yields results worked with significant uncertainties. These are due to the great variability of the phenomena in play, the partial or imprecise understanding of the data used for the assessments, as well as the imprecision intrinsic to the models used.

In such an environment, IRSN, in charge of the first predictive assessments used to define the zoning, uses the data and reasonably conservative assumptions to compute the consequences, in order to prevent the risk that the actions used when establishing the ZPP and ZST are "adjusted upward". The expression "reasonably conservative assumptions" here refers to assumptions leading to dose or foodstuff contamination estimates on the basis of which sufficiently-protective actions can be adopted, without the ZPP's or ZST's becoming oversized as a result, as this could put the populations and local economy at an unwarranted disadvantage. The first assessments are regularly updated, taking into account the new data gained on site, in particular the results of measurement campaigns on the actual environmental contamination gained using the existing resources (radiation monitors, measurement stations) and resources deployed to an exceptional extent (mobile laboratories, helicopter transported monitors, etc.) as well as the local environment (agricultural production, for example).

USA

Within the United States, the regulations for determining the size of the EPZ for large light-water reactors are for fixed distances around NPPs, and deviations from the fixed distances are allowed only by explicit permission of the Nuclear Regulatory Commission. Additionally, siting and emergency preparedness are separate regulations, and both have different bases and require different licensing actions.

The regulations that govern the size of the EPZ for large light-water reactors can be found in two separate locations within the Code of Federal Regulations. In Energy (Title 10 of the Code of Federal Regulations (CFR)), the EPZ sizes are defined to be at 10 miles (16 km) for the plume exposure pathway EPZ and 50 miles (80 km) for the ingestion exposure pathway EPZ. In Emergency Management and Assistance (Title 44 of the CFR), the same distances are defined. The Nuclear Regulatory Commission (NRC) regulates the nuclear licensees and the Federal Emergency Management Agency (FEMA) inspects and evaluates the radiological emergency preparedness for the offsite communities and governments. The relationship between the NRC and FEMA with respect to radiological emergency preparedness is described in a memorandum of understanding (Appendix A to 44 CFR 353) that defines the roles, responsibilities and the authorities that are shared between the two agencies.

The regulations that exist pertain to light-water reactor designs with a reactor power output of greater than 300 megawatts-electric. The NRC is developing a set of regulations for emergency preparedness for small modular reactors, advanced reactor designs and for medical isotope production and utilization facilities. Those efforts can be followed through the website http://www.regulations.gov/ and search for either the NRC rule identification number: 3150-AJ68 or the NRC docket identification number: NRC-2015-0225.

The current practice for the NRC is that if an application for a small reactor design or license were submitted to the NRC for evaluation, the applicant needs to provide such information and analysis to support its application and request for an exemption to the regulations. The NRC staff would evaluate the application, perform or confirm the safety and hazard analyses. After the staff completes its evaluation, the Commission would make a determination of the adequacy of the request. The NRC has granted exemptions to the EPZ regulations in the past.

Russia

Regulation of EPZ issues in Russia is implemented by two regulatory bodies i.e. by Rostechnadzor (nuclear regulatory body), who mainly regulates EPZ sizing and their implementation as early as on siting phase for site selection, and the Ministry of emergency situations (further - EMERCOM), who regulates the issues of the usage of EPZs for emergency planning.

1. **Setting of EPZ sizes based on Rostechnadzor regulations**

Rostechnadzor requirements on NPPs EPZs' sizes are established in [21]. Dose criteria (see tables 1 and 2) which shall be used as a basis for defining the EPZs' sizes are set in [22] are referenced in [21].

Table 1 - Generic intervention levels applicable for planning of response on initial phase of accident

Protective measures	Averted dose (10 days), mSv			
	Whole body		Thyroid, lungs, skin	
	A-level	Almost always justified	A-level	Almost always justified
Sheltering	5	50	50	500
Stable iodine administration: adults children	- -	- -	250* 100*	2500* 1000*
Evacuation	50	500	500	5000
* - thyroid only; If averted dose higher than A-level but lower than “Almost always justified”, than decision on intervention made based on optimization procedures				

It's notably that threat categorization is linked with the buffer zone concept. Buffer zone size in case of NPP (for all units which are in the design) is defined based on normal operation airborne radioactive discharges due to which dose constraint (set by Rospotrebnadzor) shall not be exceeded.

Table 2 - Generic intervention levels applicable for planning of response on intermediate and later phase of accident

Protective measures	Averted dose, mSv	
	A-level	Almost always justified
Restriction of food and drinking water consumption	5 for the first year 1 /y at following years	50 for the first year 10 /y at following years

[21]Baseline criteria and safety requirements on siting of NPPs” NP-032-01.

[22] Norms for radiation safety NRB-99/2009. Sanitary norms and rules SanPiN 2.6.1.2523-09. Approved 07.07.2009 by decree of Chief Medical Officer № 47.

Relocation	50 for the first year	500 for the first year
If averted dose higher than A-level but lower than “Almost always justified”, than decision on intervention made based on optimization procedures		

The application of EPZs partially depends on threat category of facility. Procedure for defining threat category is established in regulatory document OSPORB-99/2010 [23]. According to [23] facilities are categorized as shown in table 3.

Table 3 - Facilities threat categorization

I category	If worst-case accident can lead to exposure that exceeding 1 mSv for member of public (beyond the buffer zone) than this facility is I category
II category	If facility not related to I category and worst-case accident can lead to exposure of personnel that exceeding 5 mSv (in area that between buffer zone and facility site boundary) than this facility is II category
III category	If facility are neither related to I category nor to II category and if there is a possibility of workers exposure (in the site of facility, but not taking into account the rooms, where only group A personnel have access) that exceeding 5mSv than this facility is III category facility
IV category	remainder

This is the criterion for defining size of the buffer zone. In the buffer zone it's prohibited:

- permanent or temporary dwelling of members of public;
- deployment of child-care facilities;
- deployment of industrial and auxiliary facilities not related to facility.

Typical NPPs buffer zone radius is less than 4 km.

The off-site emergency response is necessary only for threat categories I and II. In case of threat category I facility protective measures shall be implemented with regard to public (i.e. beyond the buffer zone) and to the personnel of organizations which are not the facility workers, but which provide various services to facility (i.e. beyond the site boundary and inside the buffer zone). In case of threat category II protective measures shall be implemented only with regard to the personnel of organizations which are not the facility workers, but which provide various services to facility (i.e. inside the buffer zone).

According to [21] and to [24] for NPPs whose design was approved before the year 2003 projected dose shall not exceed "Almost always justified levels" (see table 1) beyond the site boundary in case of possible design basis accidents. This limitation is treated as acceptance criterion. According to [21] and [24] for NPPs whose design was approved after the year 2003 the acceptance criterion almost the same. The only difference from older designs is that more stringent acceptance criterion equal to level A (see table 1) shall not be exceeded. Thus EPZs sizes are defined only for beyond design basis accidents are taken into account.

The Rostechnadzor regulatory document OPB-88/97 [25] states that for purposes of emergency planning only BDBAs with release occurrence frequency of 10-7 per reactor per year are taken into account.

[23] Basic sanitary rules for radiation safety (OSPORB-99/2010). Sanitary norms and rules SP 2.6.1.2612-10 (as amended 16.09.2013). Approved 26.04.2010 by decree of Chief Medical Officer № 40.

[24] Sanitary rules for nuclear power plants design and operation (SP AS-03). SanPiN 2.6.1.24-03. Approved 28.04.2003 by decree of Chief Medical Officer № 69.

25 NP -001-97 (OPB-88/97) “General regulations on nuclear power plants safety”

In [21] there is two kinds of EPZs are subdivided:

- all-phase (initial, intermediate and later phase) emergency planning zone;
- obligatory evacuation emergency planning zone.

In NP-032-01 [21] it's established that all-phase emergency planning zone is defined based on generic intervention levels (see tables 1 and 2) as the zone of maximum radius of all the subzones, the radii of which are determined by the particular protective action (i.e. evacuation, ITB, sheltering, relocation and agricultural countermeasures). Subzone for restriction of food and drinking water consumption (see table 2) has the maximum radius, so all-phase EPZs' size are defined by size of this subzone.

The obligatory evacuation EPZs' size is defined based on "Almost always justified level" (see table 1). NP-032-01 [21] also regulates application of an obligatory evacuation EPZ for NPP site selection purposes. There are restriction imposed in [21] on population density and on presence of hardly evacuated organizations (prisons, hospitals, etc) in obligatory evacuation EPZ.

2. Setting of EPZ sizes based on EMERCOM recommendations

Basic EMERCOM document, which defines EPZs sizes is [26]. According to [26] EPZs of commercial reactors have sizes specified in table 4.

According to [26] in the precautionary protective actions planning zone for purposes of reduction of stochastic effects and eliminating of deterministic effects following measures should be planned:

- total evacuation during 4- 6 hours;
- sheltering;
- iodine prophylaxis.

Protective measures are to be planned within the urgent protective actions planning zone (for purposes reduction of stochastic effects) are: total evacuation within 6-8 hours, iodine prophylaxis and sheltering.

Table 4 - EPZs' sizes of commercial reactors

Thermal power, MWt	Radius of precautionary protective actions planning zone, km	Radius of urgent protective actions planning zone, km		Radius of intermediate and longer term protective actions planning zone, km	
		inner	outer	inner	outer
> 1000	5	5	25	25	100
100 - 1000	3	3	25	25	100
10 - 100	n.a.	0	5	5	50
2 - 10	n.a.	0	0,5	0,5	5

In intermediate and longer term protective actions planning zone a means should be planned for monitoring in order to impose or remove the restrictions on food and water consumption.

[26] Standard contents of off-site protection plan. Approved 14.05.2006 by Minister for emergency situations.

APPENDIX V - MEMBER STATE NUCLEAR REGULATOR SURVEY ON THE GRADED APPROACH AND DEFENCE IN DEPTH AS APPLICABLE TO SMR

Introduction and Purpose of the Survey:

The Small Modular Reactor (SMR) Regulators' Forum was established as a two year Pilot Project in early 2015 to identify, understand and address key regulatory challenges that may emerge in future SMR regulatory discussions. This will help enhance safety, efficiency in licensing, and enable regulators to inform changes, if necessary, to their requirements and regulatory practices. In the Terms of Reference for the Forum, the objectives for the project were identified as follows:

1. Share SMR regulatory knowledge and experience among the members and other stakeholders to:
    - o Facilitate robust and thorough regulatory decisions;
    - o Encourage enhanced nuclear safety.
2. Identify and discuss common safety issues that may challenge regulatory reviews associated with SMRs and, if possible, recommend common approaches for resolution.

This survey contains questions from two of the three Working Groups of the Forum.

1. Defence in Depth Working Group (DiD-WG)
2. Graded Approach Working Group (GA-WG)

These working groups were formed because the Member State regulators are either engaging or are preparing to engage with proponents who are preparing safety cases, for SMR deployment, that are anticipated to contain numerous safety claims based on the use of novel approaches and technologies. Some of these claims are expected to provide alternate interpretations of existing regulatory requirements. It is also possible that proposals will contain new safety approaches where regulatory requirements may not yet exist.

Member state regulators are expecting 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)

Proposals will likely drive a conversation between regulators and the regulated to consider applying a Graded Approach27 to confirm novel approaches or technologies being proposed will result in a level of safety commensurate with the risks presented by the proposed activities. This is expected to have an impact on how Defence-in-Depth will be applied to prevention and mitigation of accidents.

The SMR Regulators' Forum agreed that there is a need to share Member State information on the application of both the Graded Approach and Defence-in-Depth and to offer thoughts on what this means in the context of addressing novel approaches being proposed for SMRs. This survey is seeking to understand how, in each Member State:

- The Graded Approach has been or is being used by regulators, the regulated and the decision-making process (e.g. Commission or Board) for activities related to the lifecycle of nuclear reactor based facilities. Of particular interest to the Working Group is how Member States address the use of the Graded Approach in the face of novel technological approaches and safety claims. The survey is also seeking to understand how regulators are prepared or are preparing to address safety cases that may be presented for activities involving SMRs.
- Defence-in-Depth requirements can be applied to alternative approaches being developed by SMR designers such that the safety principles of DiD are maintained. Alternative approaches being employed by SMR developers (for example passive and inherent features) can be

[27] 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.

similar to those being employed for larger nuclear power plants (Gen 3, 3+ and 4). However, the use of these approaches is expected to be more intense for SMR designs with a goal by developers being to drive improvements both in efficiency of maintenance and operation and in overall safety. Of particular interest to the Working Group is finding out where similarities and differences in practices exist in application to alternative approaches.

What this Survey will be used for:

The working groups, as part of the Forum's two year work plan, are committed to produce working group pilot project reports that will document the results of project work and publish results on the Forum's website for public reference. The results of this survey will be presented, in tabular format, to showcase similarities, differences and challenges in the application of the Graded Approach and DiD in each Member State and illustrate what this might mean for future SMR projects.

The working groups will analyze the survey results to:

- identify and understand good practices and methods currently in use
- discuss where Common Position statements might be made by the Forum that encourage the use of these good practices and methods
- better understand regulatory challenges and promote discussions on possible paths forward
- identify possible revisions/enhancements to either existing or new IAEA documents

Regulators may choose to apply lessons learned from the survey results and related analyses to inform changes, if necessary, to their requirements and regulatory practices (including codes and standards).

What is an SMR in this survey?

The SMR Regulator's Forum members have agreed to define Small Modular Reactors as reactor facilities that typically have several of these features:

- Less than approximately 300 MWe (~1000 MW thermal) per reactor "unit"
- Designed for commercial use, i.e., power production, desalination, process heat (as opposed to research and test reactors)
- Designed to allow addition of multiple reactors in close proximity to the same infrastructure (modular "units")
- May be light or non-light water cooled
- Claims of preventive measures to reduce risk, e.g., inherently safe fuel, enhanced coolants, practical elimination of large releases has been achieved (EPZ size implications)

IAEA publications such as http://www.iaea.org/NuclearPower/SMR/ serve as references for the discussion to highlight the variety of technologies being developed. Appendix A of this survey provides a sample list of possible technologies.

Who should respond to this survey?

These survey questions are intended to be addressed by the regulatory body staff responsible for overseeing technical assessments, certification (if applicable) and licensing assessment activities of either existing or new facilities with a particular focus on SMRs. They are encouraged to discuss the questions with technical support staff (including Technical Support Organisations - TSO) to obtain a full picture of how application of regulatory requirements is addressed.

Part 1: General information about SMR development / deployment in your country

Question 1.1

Please describe any projects involving SMR concepts the regulatory body is involved in at present. Please include, as applicable:

- A general description of the technology (ies) (e.g. cooling type, neutron spectrum, land or marine-based) Please include a general description of where modules will be manufactured and how modules will be transported.
- A description of preliminary or pre-licensing efforts (high level description of efforts by designers of different types of SMRs to engage early with the regulatory body)
- Efforts to certify the design including a discussion about what status the design is expected to be at to achieve certification. (e.g. site generic preliminary safety analysis report?)
- Licensing efforts for specific sites within your state (construction, commissioning, operation)
- Discussion on involvement in regulatory cooperation efforts with other IAEA Member State regulators where your state is involved in technology export discussions.

Question 1.2

(a) Please describe the licensing approach for a multiple module (i.e. units) facility? (for example, is there one license per unit or a facility license applied to multiple-units?
(b) How do your regulatory requirements address interactions between the modules in the safety assessment?

Question 1.3

Do you have a particular set of safety goals (Ex: Are there specific requirements in terms of core damage frequency, releases…) for SMRs in your country? If so, are these goals for a single reactor module or a multi-module plant, or are there separate goals for each?

Question 1.4

Within all the actions and requirements implemented in your country as a result of the lessons learnt from the Fukushima Daiichi NPP accident, were any specifically applicable to SMRs? If so, please summarize them.

Question 1.5

Passive systems are extensively used in SMR designs. Please describe any specific requirements on the use of passive safety systems in your country for, for example:

- Design (including safety classification)
- Safety Analysis
- Verification and validation
- Reliability assurance

GRADED APPROACH SURVEY QUESTIONS

2. Use of the Graded Approach in Your National Regulatory Framework

> **Note:** IAEA definition of Graded Approach [Ref. 2007 Safety Glossary]:
>
> 1. For a system of *control*, such as a regulatory system or a *safety system*, a process or method in which the stringency of the *control* measures and conditions to be applied is commensurate, to the extent practicable, with the likelihood and possible consequences of, and the level of *risk* associated with a loss of *control*.
>
> An example of a *Graded Approach* in general would be a structured method by which the stringency of application of *requirements* is varied in accordance with the circumstances, the regulatory systems used, the *management systems* used, etc. For example, a method in which:
>
> (1) The significance and complexity of a product or service are determined:
> (2) The potential impacts of the product or service on health, *safety, security*, the environment, and the achieving of quality and the organizations objectives are determined;
> (3) The consequences if a product fails or if a service is carried out incorrectly are taken into account.
>
> 2. An application of *safety requirements* that is commensurate with the characteristics of the *practice* or *source* and with the magnitude and likelihood of the exposures.

Question 2.1

(a) What is your country's equivalent terminology (if different) and definition of Graded Approach?

(b) In what ways does your definition differ (legally) from the IAEA definition above?

Question 2.2

Please describe how the Graded Approach is integrated into your national regulatory framework (legislation, regulations, and supplemental requirements). In the description include details about:

(a) How the regulatory body is legally enabled to apply the Graded Approach in its regulatory activities (including decision-making). For example, how is the regulator accorded the flexibility to develop, interpret and apply requirements in a risk-informed manner to specific cases?

(b) How the licensee is legally enabled to interpret and apply requirements in a risk-informed manner to specific cases?

(b) How your regulatory framework addresses licensee activities of differing risk? (e.g. small research reactor operation, large research reactor operation, and nuclear power facility operation)

Question 2.3

IAEA has articulated that SMRs should be considered to be NPPs. In recognition of this, what is your organization's strategy for addressing potential novel features that will be proposed by SMRs? (e.g. use of inherent core characteristics, 'melt-resistant' fuels, passive heat sinks)

Do you have a methodology to classify different types of SMRs in your regulatory framework? If yes, please describe the methodology.

Question 2.4

Please describe efforts made by your agency to identify issues in regulations that may be needed to address the application of the Graded Approach to SMR specific cases.

Question 2.5 – For requirements and guidance that support the regulations, how will your organization address application of the Graded Approach in cases involving technological innovations and new approaches? In general, what possible enhancements or changes do you foresee to these requirements and guidance?

Examples to assist with interpreting these questions:

- How well would your requirements and guidance for Defence-in-Depth address the use of a Graded Approach in a proponent's proposal to use a novel nuclear fuel with significant advances in safety?
- How well would your requirements and guidance for addressing safety goals address multiple module/multiple plant sites?
- How might your approaches for emergency planning zone size definitions address a specific design's proposal for a unique emergency planning zone size for a site?

Question 2.6

a) If applicable in your case, does your organization have specific requirements for factory fueled and sealed transportable SMRs (also denoted by the IAEA as transportable NPP or TNPP)?
b) Do your existing transport requirements for nuclear substances (e.g. irradiated fuel) apply?
c) Please describe the requirements that would apply for transportation of such SMRs with fresh or spent fuel inside.

3. Actions by the Regulatory Body to assess application of or applying the grading approach

Question 3.1

(a) Please describe how the Graded Approach is integrated into your organization's management system processes and procedures for technical assessment and licensing (with a focus on licensed activities involving nuclear reactors).

(b) Please describe the various toolsets in management systems that are used by both the regulatory body and Technical Support Organizations to apply the Graded Approach (assessment, compliance, decision-making) and assess a proponent's use of the Graded Approach. Examples:

- Guides and procedures used by staff to perform assessments (guides on the use of expert judgement)
- Independent calculation tools (e.g. Probabilistic Safety insights)
- Operating feedback analysis/review
- Decision matrices
- Expert Panels
- Specific Risk Informed Decision Making (RIDM) procedures
- conservative methods
- Uncertainties assessment
- Cliff-edge effects characterization

(c) Please describe whether probabilistic tools are used by the regulatory body to justify/confirm the applicability of a Graded Approach. If so, how are they used?

Question 3.2 (specific technical or innovative approaches)

(a) How does the use of the regulator's toolsets described in Question 3.1 change in assessment and decision making involving demonstration prototypes of a technology or approach? (e.g. inherent / passive safety features, new arrangements of systems)

(b) How does the use of the regulator's toolsets described in Question 3.1 change in assessment and decision making involving First-of-a-kind build projects?

(c) For innovative approaches, what guidance do you provide to proponents to address the role of deterministic and probabilistic approaches in a Graded Approach proposal to be used in a safety case?

Question 3.3

What kind of additional/alternative/supplementary demonstration/evidence are you looking for from the proponent when making a case for the use of the Graded Approach? (e.g. code validation, margin assessments, analysis of code and standard applications under possible increased risk?)

Please describe the type of evidence required to demonstrate "transferability" of proven experience from other nuclear facilities. (i.e. evidence of where similarities and differences exist between the existing use of a feature and how it might be used in the future)

DEFENCE IN DEPTH (DiD) SURVEY QUESTIONS

REGULATORY FRAMEWORK

Question 4.1

(a) Please describe how the use of DiD is articulated in your regulations, supplementary regulatory requirements (if applicable) and guidance.

(b) When comparing research reactor design requirements to NPPs, how do the above requirements differ (if at all) and why are they different? (note: SMRs occupy a spectrum of core inventories and power outputs in between research reactors and NPPs)

(c) Do you foresee any special DiD requirements and/or guidance being developed specifically for SMR applications? If so, in which areas and why?

Question 4.2

Does your country have any specific requirements related to the independence of the DiD levels?

Question 4.3

In your regulations, supplementary regulatory requirements and guidance for new reactors (any size and output), please describe any specific requirements for the design of features for each of the following:

a. Level 1 of DiD.

b. Level 2 of DiD.

c. Level 3 design basis accidents (e.g. single failure criteria).

d. Level 3 multiple failure accidents or for other design extension conditions.

e. Level 4 severe (core melt) accidents.

f. A "practical elimination" approach.

g. Extreme hazards.

INDUSTRY'S APPLICATION OF REQUIREMENTS

Question 4.4

Have any difficulties been identified (in particular by the designers and utilities) in applying DiD principles defined for large reactors to SMRs? If so, please describe them.

a. For DiD level 1?
b. For DiD level 2?
c. For DiD level 3?
d. For DiD level 4?
e. For DiD level 5?

Question 4.5

(a) Have designers requested up-front 'relief' from some DiD principles for SMRs? If so, which one and for what reasons? For example:

- E.G., Specific systems for mitigation for a an anticipated transient without scram accident are not required because unique design features make the probability of such an accident negligibly small; or
- reduction in emergency preparedness requirements based on the "smallness" of the reactor?

(b) Have compensatory measures or justifications been provided?

Question 4.6

What types of events or situations generally addressed in the safety cases of typical large GEN III or GEN IV reactors are considered as eliminated or excluded by SMR designers and for what reasons? (i.e.: some break sizes excluded because of limited pipe diameters, some events excluded thanks to inherent safety characteristics).

Question 4.7

What types of requirements do the SMRs designers use in terms of:

a. Redundancy for safety active or passive systems (for accident prevention / for core damage prevention / for core damage mitigation)?
b. Diversification between systems involved in different levels of DiD?
c. Geographical or physical separation regarding CCF and internal hazards?
d. Potential for an accident in one module affecting other modules in a multi-module plant?
e. Other significant issues you would like to point out?

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