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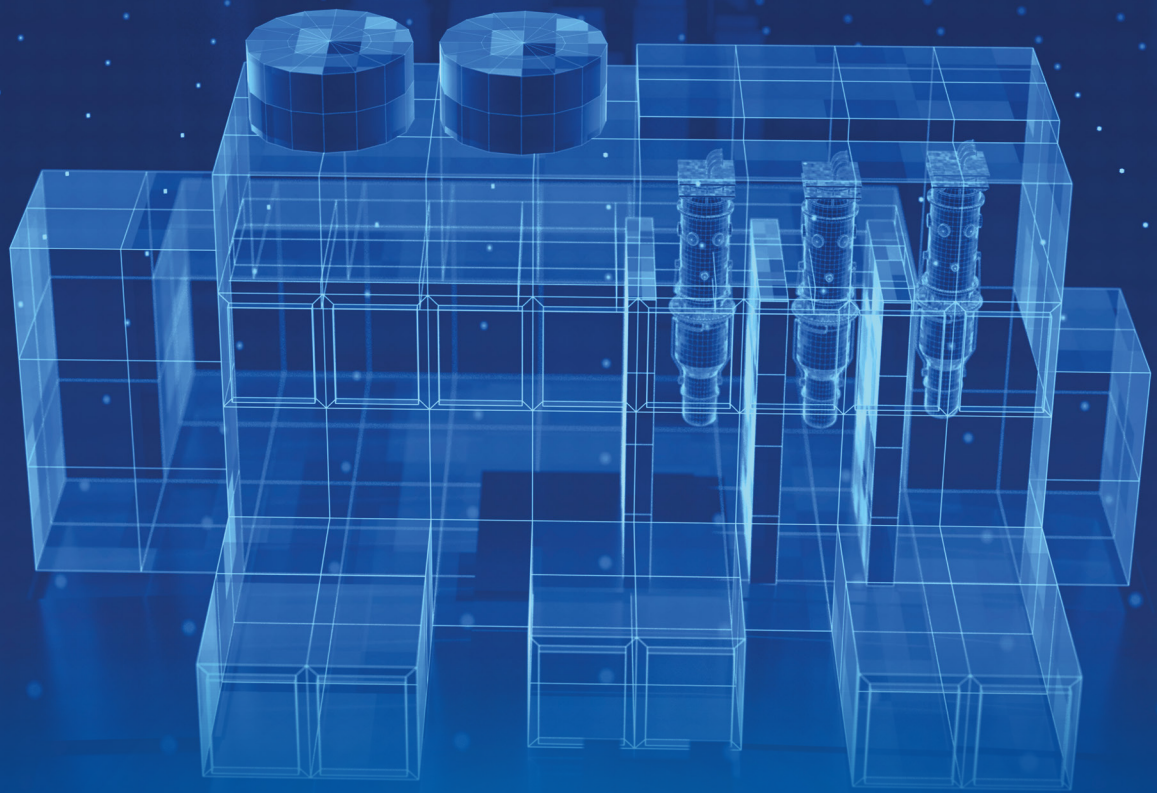
NUCLEAR HARMONIZATION & STANDARDIZATION INITIATIVE

Regulatory Cooperation Toolkit

Approaches for Addressing Areas of Regulatory Difference



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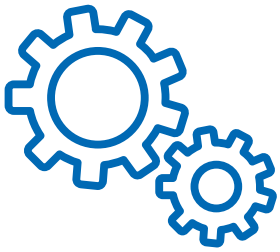
1. Introduction

1.1 Background

The Nuclear Harmonization and Standardization Initiative (NHSI) was established by the International Atomic Energy Agency (IAEA) in early 2022 in response to growing interest from Member States in advanced nuclear reactors. Under NHSI, governments, regulatory bodies, technical support organizations, designers, vendors, technology owners, operators and international organizations came together in a collaborative effort, consistent with their assigned roles and responsibilities, to harmonize and standardize regulatory and industrial approaches in support of the global deployment of safe and secure advanced nuclear reactors.

The NHSI consists of two interfacing tracks: the Industry Track and the Regulatory Track. The NHSI Industry Track aims to develop tools and industrial approaches for the effective large-scale deployment of advanced reactors, particularly small modular reactors (SMRs). The NHSI Regulatory Track supports the establishment of a global framework for regulatory reviews of advanced reactors with particular attention to SMRs. The framework will enable increased cooperation of regulatory bodies during assessments of advanced reactors, including SMRs and during leveraging of regulatory reviews and resources. This framework could be used as the basis for future regulatory harmonization in the licensing of new nuclear technologies.



During the first phase of NHSI from 2022–2024 (NHSI Phase I), the Regulatory Track developed approaches for three types of regulatory cooperation:

(a) Collaborative reviews: an independent review against national requirements, in discussion with other regulatory bodies but potentially reaching different decisions;

(b) Joint reviews: a team of regulatory bodies jointly review a design against common requirements and reaching joint decisions;

(c) Leveraging of regulatory reviews: a review against national requirements with the use of other regulatory bodies' reviews.

Each of the three approaches was addressed by a different working group. This work was captured in three technical documents: 1) *Information Sharing Framework for Regulatory Reviews of Advanced Reactors* [1]; 2) *Multinational Pre-licensing Joint Regulatory Review of Advanced Reactor Designs* [2]; and 3) *Collaborative Reviews and Effective Leveraging* [3].

The second phase of NHSI is from 2025 to 2026 (NHSI Phase II). During this stage, the Regulatory Track focuses on the implementation of processes and tools developed during NHSI Phase I, as well as gathering feedback to improve cooperation processes and map differences among Member States. The *Regulatory Cooperation Toolkit* is one of the outcomes from NHSI Phase II.

1.2 Problem definition

In general, most regulatory bodies in all countries with a nuclear programme seek to follow the IAEA safety standards. This is evidenced, for instance, by the results of IAEA Integrated Regulatory Review Service (IRRS) missions [4] which aim to assess national regulatory frameworks against the IAEA safety standards. However, specific national regulations and guidance based on these standards vary between countries. These variations can result in significant design differences for reactors deployed across national borders.

These differences can stem from varying regulatory expectations regarding how fault scenarios are identified and acceptance criteria are defined, factors that ultimately shape the corresponding design provisions. The differences can be difficult to discern, as they are not always part of the written requirements, but may result from the deliberation of a group of individuals or be strongly influenced by the interpretations applied by the regulatory body's staff.

In addition to the differences in regulatory expectations related to acceptance criteria, the approaches and expectations for reviewing a safety case can vary widely among regulatory bodies, e.g. prescriptive versus non-prescriptive regulatory approaches. While the more flexible, non-prescriptive, approach is often seen as desirable, in practice it may be more liable to variations due to greater choice being available for vendors to meet the goals and the regulatory body's approach in implementing it, e.g. whether specific codes and standards are identified as recognized means to achieve the goals. Typically, the more prescriptive the nuclear regulations are, the less flexibility they offer. There is also potential for technology-dependencies or incompatibility as technology develops. Prescriptive approaches, however, do offer an increase in regulatory certainty for those technologies they were developed for, or are compatible with.

When a proponent seeks to license a reactor across countries with differing regulatory frameworks, variations in regulatory requirements and guidance may require reformulating the original safety case. This often demands substantial effort to develop new documentation tailored to each regulatory body, potentially leading to increased overall project costs, including the as-built plant. Even though regulatory bodies aim to assess reactor safety and compliance with regulatory requirements rather than limit design changes, deploying similar designs internationally can improve regulatory efficiency by supporting shared safety assessments and collaboration. Furthermore, standardized designs may help prevent safety issues occurring during the procurement, construction, operation, and maintenance of reactors.

Different requirements between countries also hamper regulatory cooperation and inhibit leveraging of prior safety assessments, adding to the effort and cost associated with licensing without a clear safety benefit. It is important to note that some regulatory jurisdictions encourage the use of submissions from other jurisdictions, and the proponent's development of a gap analysis to focus attention in the areas of greatest risk and/or difference, rather than requiring the complete reformulation of the safety case.

The variability in national regulation creates challenges that may present major barriers for new build projects. While it would be helpful if countries could rapidly adapt their nuclear regulatory frameworks to be more flexible and to easily accommodate novel safe designs, the reality is that these types of changes can take years or even decades.

1.3 Objective and scope

As one of the NHSI Regulatory Track Phase II activities, carried out in partnership with the SMR Regulators' Forum (SMR RF), experts from regulatory bodies and industries of 25 countries (Argentina, Armenia, Belgium, Brazil, Canada, China, Czech Republic, Finland, France, Germany, India, Japan, Republic of Korea, Kingdom of the Netherlands, Poland, Romania, the Russian Federation, Slovenia, South Africa, Sweden, Switzerland, Türkiye, United Arab Emirates, the United Kingdom, and the United States) participated in the development of a Regulatory Cooperation Toolkit. This work also involved the three permanent SMR RF observers: the European Commission, the Nuclear Energy Agency of the Organisation for Economic Co-operation and Development (OECD NEA) and the Cooperation in Reactor Design Evaluation and Licensing Working Group of the World Nuclear Association (WNA-CORDEL). The Toolkit covers two topics:

(a) Proven approaches to reach regulatory equivalency, focusing on areas of regulatory difference with examples of application;

(b) Resources for using leveraging approaches and for helping to draft regulatory reviews that can be more easily leveraged.

This document discusses the first topic *Approaches for Addressing Areas of Regulatory Difference.* It aims to improve understanding of why different requirements are applied to the same reactor design under different regulatory frameworks and to gather good practices to address these differences, so that design changes and licensing complexity between countries can be minimized.

The process and good practices captured in this document are aimed to support regulatory cooperation in design reviews, including all the types of cooperation described in the NHSI publications: collaborative reviews, joint reviews and leveraging of already completed regulatory reviews [1–3].

The second topic, *Resources for Leveraging Regulatory Review* [5], is addressed in the other document within this Toolkit. It builds upon the six-step approach, outlined in the publication *Collaborative Reviews and Effective Leveraging* [3]. This topic focuses on creating resources for each step — such as guidance documents, templates, and questionnaires — to support the Recipient Regulator in making effective use of the information provided by the Source Regulator.

2. Proposed approach

Regulatory bodies engaged in regulatory cooperation, such as the ones described in NHSI publications [1–3], may have differences in their regulatory approaches. According to the NHSI publication titled *Collaborative Reviews and Effective Leveraging* [3]:

- A regulatory difference refers to a divergence in the conclusions reached by different regulatory bodies regarding the same nuclear power plant design.
- The Source Regulator (Regulator A in Ref. [3]) is the regulatory body that originally performed the assessment.
- The Recipient Regulator (Regulator B in Ref. [3]) is the regulatory body seeking to leverage an existing assessment.

When multiple regulatory bodies independently assess the same design, they may arrive at differing conclusions on its acceptability, even though the same level of safety is maintained. For example, the Recipient Regulator may find that a particular aspect of the design does not meet their own requirements, even though the Source Regulator — having completed its review earlier — determined that the design fully or largely satisfies their regulatory expectations. Similarly, when multiple regulatory bodies are assessing the same design jointly or collaboratively, differences in requirements could impact the conclusions of such reviews.

Such differences can arise from a range of factors, including variations in regulatory requirements, established review practices, or national legislative frameworks.

Figure 2.1 presents an illustrative process for identifying, categorizing, and addressing these regulatory differences, once two or more reviews have been completed. The objective is to enhance transparency, foster technical dialogue, support harmonization where feasible, and reduce unnecessary design changes or duplication of regulatory effort. Ultimately, the process aims to support the resolution of differing regulatory conclusions.

It is important to note that this process is intended as a general framework and not an exhaustive or prescriptive approach. Regulatory bodies are encouraged to adapt it to suit their specific circumstances, needs, and available resources.

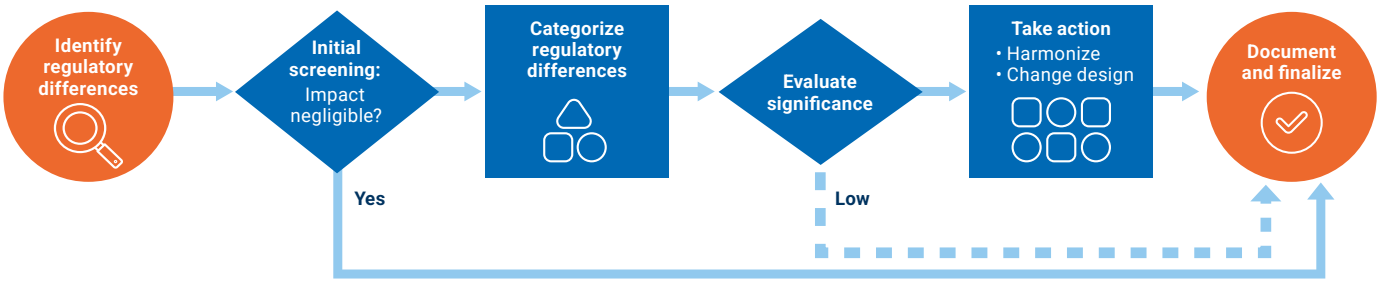


Figure 2.1 Flowchart for identifying, categorizing and addressing regulatory differences.

Step 1: Identify the topics/issues that have a regulatory difference

Step 1 for two or more regulatory bodies that intend to address one or more of their regulatory differences is to identify the specific topics or issues of difference. While some differences may have already been recognized during the early phases of regulatory cooperation, it is important to document them thoroughly and consistently. For instance, a table can be used to collect all identified differences.

The information necessary to initiate this step could be provided by the vendor and/or applicant (see Section 3 – All categories: Good practices for the vendor and/or applicant).

Step 2: Initial screening, do topics/issues have no or only a minor impact on risk and/or the design?

Step 2 in addressing regulatory differences is to identify those topics or issues that have a negligible impact on risk arising from the design. This step also considers the impact of the topics/issues on the design. To support this assessment, it is recommended that regulatory bodies consult with the vendor and/or applicant to identify which differences are truly minor (for example, those that have no impact on project timelines, costs, or key deliverables).

For such low-impact differences, it is good practice to document them in the review, even though no further action is necessary.

Step 3: Categorize topics based on the source of differences

Step 3 is to categorize the topics that have not yet been dealt with in earlier steps based on the source of differences. There could be four categories of topics that are further described in Section 3:

(a) Category A: Differences due to varying regulatory practices between regulatory bodies;

(b) Category B: Differences due to different legally binding regulatory requirements but sharing a similar intent. Although the exact rules, methods, or thresholds may differ, the overall objectives are aligned;

(c) Category C: Differences due to different legally binding regulatory requirements that are fundamentally incompatible, and regulatory bodies will not adjust their positions;

(d) Category D: Differences due to non-nuclear requirements.

Step 4: Evaluate the safety significance of the regulatory differences

Step 4 is to evaluate the safety significance of the differences identified, categorized and not previously screened out. If the safety significance is identified as low, regulatory bodies may be able to reconsider their position on the need for the requirement to be met or more easily be able to adapt their practices.

Step 5: Take action based on the category and safety significance of the differences

Based on Steps 4 and 5, the regulatory bodies can take action to address differences. The action may be a decision to harmonize approaches or to retain the regulatory difference. The latter may involve consideration of exceptions to rules/ requirements (no changes) where that is an option, or the consideration of practicable design changes that may accommodate both sets of regulatory requirements.

The consideration of design changes is a complex matter that depends on a multitude of factors, e.g. where the design originates from, the timing and scope of assessments across jurisdictions, and commercial aspects for broader stakeholders involved (i.e. developers/future operators). It is strongly recommended to engage vendors and/or applicants when considering whether design changes would be practicable or not. Furthermore, it is important to consider that changes which seem practicable in principle could become burdensome either in aggregation, or because of unforeseen, knock-on impacts later in the design, construction, operation or decommissioning.

Step 6: Document decisions and finalize activities

Step 6 is to document the decisions made and actions taken across the several steps in the process. This step would include documenting topics or differences which were judged to have a negligible impact and were therefore screened out in Step 2. It would also include documentation of differences that were categorized in Step 3 and evaluated in Step 4 but judged to have low significance. Importantly, efforts are to be made to accurately document the basis of the actions taken where differences were deemed to be significant in Step 4, and led to harmonization, retention of difference and/or design changes. Finally, the positions reached and their rationales are to be disseminated to all relevant stakeholders, e.g. regulatory bodies, vendors, applicants.

Section 3 lists good regulatory practices of relevance.

3. Examples and good practices

This section provides further explanation of the categories outlined in Step 3, along with illustrative examples. It also presents good practices for addressing each category.

Regulatory differences can arise during cooperation involving multiple countries. For simplification, this section will refer to two countries A and B that have engaged in regulatory cooperation, but the good practices identified are also applicable to larger cooperative arrangements.

A **Category A:** Differences due to varying regulatory practices

Category A refers to differences that arise from how regulatory bodies implement or apply their regulations, rather than from the regulations themselves. These differences reflect divergent regulatory philosophies, guidance and procedures, review approaches, or cultures between countries.

These are not incompatibilities at the level or involving specific regulatory requirements or/and fundamental goals of nuclear safety, but rather, stem from regulatory practices (assessment or oversight processes) or regulatory expectations (usually described in non-legally binding guides) to demonstrate compliance.

Examples of Category A

An illustrative example for Category A is the difference in hydrogen management systems for the same reactor design implemented in two different national contexts.

Regulatory Practice in Country A:

- The practice of the regulatory body in Country A requires hydrogen mitigation systems with an emphasis on passive autocatalytic recombiners and engineered safety features designed in accordance with national codes.
- Their approach focuses on demonstrating that the averaged hydrogen concentrations remain below flammability limits with sufficient margin under all postulated accident scenarios.

Regulatory Practice in Country B:

- The practice of the regulatory body in Country B requires more detailed analyses of hydrogen distribution and potential combustion phenomena. This may include experimental validation and computational fluid dynamics (CFD) simulations.
- Flammability criteria and hydrogen concentration thresholds are the same as in Country A, however, CFD can identify areas where localized concentrations may exceed flammability criteria or that simpler integral models may be conservative.

Outcome:

- The regulatory practices may lead to different results depending on the basis and tools used in the analyses. For example, detailed analysis may show simpler models were conservative, leading to the same or fewer measures, or the need for additional hydrogen igniters or enhanced ventilation systems due to greater resolution showing that localized volumes exceeded flammability criteria.
- This case illustrates how different regulatory practices can lead to variations in system design and safety demonstration methods for the same nuclear reactor design, even when both regulatory bodies share the objective of hydrogen risk mitigation.

Good practices

Have an internal discussion to clarify practices

An internal discussion within the respective regulatory body will help clarify one's own regulatory practices, including:

- What information is expected from the vendor and/or applicant?
- What assessment is needed from the regulatory body to be satisfied that the regulatory practice is met?
- What is the reason behind the use of the specific regulatory practice?

Establish communication teams with other regulatory bodies

Understanding regulatory practices of other regulatory bodies will likely require an exchange of information. The following arrangements can facilitate these exchanges:

- Designating liaison teams within each regulatory body for structured discussions on regulatory practices (if not already in place and assuming the other regulatory body is willing to cooperate);
- Using memoranda of understanding or joint working agreements to formalize collaboration, if not already in place.

Organize targeted technical workshops

Targeted technical workshops focusing on specific issues can help better understand the technical issues related to the regulatory difference:

- Focus each workshop on a single issue or theme (e.g. hydrogen management, seismic classification, safety analyses);
- Include technical staff and decision-makers from both regulatory bodies to ensure continuity and authority;
- Present side-by-side comparisons of each regulatory approach and the rationale behind it;
- Consider including external experts or experts from peer regulatory bodies to provide additional perspectives.

Identify underlying safety objectives (also relevant to Category B)

To facilitate regulatory alignment, it is important to look beyond surface-level differences and identify the underlying safety objectives through the following approaches:

- Going beyond the letter of the regulation to discuss the intent and safety goals behind it;
- Using this to create a shared understanding that can support aligned solutions (e.g. 'functional equivalence');
- Developing a 'requirements mapping table' to highlight how different rules address similar risks (this is somewhat similar to a requirements tree showing how lower-level requirements fulfil higher-level requirements).

Document and share precedents

Learning from past experiences can help streamline current and future regulatory discussions. Stakeholders can build a shared reference point for resolving similar issues by documenting relevant precedents, such as:

- Collecting examples of similar regulatory divergences and how they were resolved in other design reviews;
- Utilizing the SMR Regulation and Cooperation Hub as a central repository for regulatory precedents;
- Including rationale for past exemptions, harmonizations or compromises.

Involve the vendor and/or applicant

Engaging both the vendor and/or applicant early in the process helps ensure that technical solutions are aligned with different regulatory practices. Their involvement supports more effective problem-solving and promotes regulatory coherence:

- Facilitate technical presentations from the vendor and/or applicant demonstrating how their design meets the underlying objectives of both regulatory regimes;
- Ask the vendor and/or applicant to reconsider the design, where appropriate;
- Allow the vendor and/or applicant to propose alternative solutions that achieve at least equivalent outcomes.

Discuss through international fora

If bilateral dialogue stalls, international fora can provide a neutral platform for constructive exchange. These discussions are not intended to assess other regulatory bodies or critique divergent approaches, but to gather insights that can inform a regulatory body's own practices:

- Consult international bodies, such as the SMR Regulators' Forum (SMR RF), when bilateral efforts stall. SMR RF Members can use special technical sessions during the Forum's biannual meetings to discuss challenging regulatory topics and share experiences;
- Focus discussions on gathering information and perspectives to support national decision-making processes.

Category B: Differences due to different regulatory requirements but sharing a similar intent

Category B refers to cases where regulatory bodies have different regulatory requirements, rules, or standards, but these differences are driven by a common safety or regulatory objective. Although the specific methods, thresholds, or criteria may differ, the intent behind the regulations is aligned — for example, to ensure reactor safety, protect public health, or prevent environmental harm.

These differences usually stem from historical, legal, or technical development paths unique to each country, but they do not reflect a disagreement over the fundamental goals of nuclear safety. Regulatory bodies can seek a reasonable path forward that does not involve a change to the design being reviewed. Regulatory flexibility is key to achieving consensus on accommodating a design in multiple countries, for example, by considering harmonization or granting exemptions.

Good practices

Early planning for multinational inputs

To minimize challenges associated with differences in regulatory requirements, the vendor and/or applicant can plan early, identifying the range of regulatory jurisdictions they will seek to deploy the design in, seek multinational reviews, or develop a set of design principles that is inclusive of requirements across those jurisdictions. Gap analyses to inform early engagement with regulators, as documented in Section 3 – All categories: Good practices for the vendor and/or applicant, is also encouraged.

Consider undertaking benchmarking exercises for selected topics with selected countries

As an example, a benchmarking exercise was undertaken by the Belgium nuclear regulatory body, Federal Agency for Nuclear Control (FANC), upon request of the Belgian Government. To identify suitable reference countries, FANC selected four — Germany, France, Kingdom of the Netherlands, and Switzerland — based on the following criteria:

- Presence of reactors with similar technology, i.e. pressurized water reactors built in the same period as the first generation of Belgian reactors;
- Availability of publicly accessible information on safety requirements;
- Membership in the Western European Nuclear Regulators' Association (WENRA).

The benchmarking exercise, which focused on four key topics — aircraft crashes, earthquake, shared systems, and automatic/autonomous operation — is described in the FANC's report *Benchmark Nuclear Safety Requirements in Belgium and Abroad* [6].

Examples of Category B

An illustrative example is the difference in how 'severe accident' is defined and applied to non-water-cooled reactors, such as molten salt reactors or high temperature gas cooled reactors, across different regulatory jurisdictions.

Regulatory Requirements in Country A:

- Core damage is used as part of the definition of severe accident based on assumptions developed for conventional water-cooled reactors, typically involving fuel cladding failure and core geometry disruption.
- For some non-water-cooled reactors, such as those using liquid fuel without a traditional solid core, or TRISO fuel with gas coolant, there needs to be a reinterpretation of the existing definition or the establishment of a new one appropriate to these technologies.

Regulatory Requirements in Country B:

- A more flexible and technology-inclusive regulatory framework exists, allowing for the definition of severe accident to be applicable to different reactor types.
- This approach supports alternative safety justifications, provided that safety objectives are clearly demonstrated.

Shared Intent:

- Both regulatory bodies aim to ensure the containment of radioactive materials, protect public and environmental health, and uphold robust defence-in-depth principles.
- While their specific definitions may differ, their fundamental safety goals remain aligned.

In the first stage of the exercise, the regulatory requirements of each country were compared with the WENRA Reference Levels for each key topic. In the second stage, attention was focused on the implementation status of these requirements, as many were introduced after the commissioning of the first generation of reactors.

Consider the hierarchy of requirements (see also good practice for Category A)

A good practice would be to map the hierarchy of requirements — from high-level legislation and safety principles down to detailed regulatory guides. When a requirement is not met, it is crucial to identify its level (e.g. guidance vs. rule vs. law) and assess whether the design still fulfils the overarching safety objectives. This forms the basis for approaches, such as seeking and justifying harmonization of requirements or granting exemptions.

Establish clear criteria for granting exemptions

Regulatory bodies may have the ability to grant exemptions to regulatory requirements. Granting exemptions allows for flexibility, ensuring that safety is maintained through alternative means. It is important that the regulatory bodies establish clear criteria for exemptions, for example:

- The level of safety is not lowered.
- The design achieves equivalent or higher safety through a different means.
- The exemption would not compromise defence-in-depth or core safety functions.
- The exemption does not present an undue risk to the public health and safety.
- The requirement that will not be met is not a fundamental principle or similar.

Exemption requests need to be structured and may include technical justifications, risk assessments, operational impacts, and references to international precedents.

Assess that the exemption criteria are met and that all the necessary information has been provided

To determine whether granting the exemption would still satisfy the underlying basis of the regulation, the reviewer must have a clear understanding of the rule from which the exemption is requested.

Ensure transparency and documentation for granting exemptions

Ensure transparency by clearly documenting the rationale for any exemption in the regulatory decision record. It is expected that this includes: the safety objectives met, a summary of the differences, the justification for the exemption, and any compensatory measures or conditions applied. Where appropriate, the regulatory bodies may share information publicly to support stakeholder trust and serve as a reference for future decisions.

Leverage functional equivalence and performance-based approaches

Regulatory bodies are encouraged to adopt performance-based approaches, focusing on outcomes rather than prescriptive rules. Functional equivalence matrices, risk insights and expert opinion, supported by evidence (e.g. simulation, tests, operating experience), can help demonstrate how alternative designs meet safety goals.

The following practices can be adopted to enable flexibility in regulatory framework in general:

- High-level regulations (in legislation) can often be difficult or time consuming to change. As such, this type of legislation needs to be general, not detailed in nature, as to ensure it does not present an unnecessary burden should changes be needed to enable new technology.
- Regulatory activity can be informed by the risk associated with the facilities under consideration and rely on a graded approach. Risk can be factored into a regulatory body's framework, as well as its licensing, compliance and enforcement activities. For example, this may involve [7]:
  - Applying risk information to the development of requirements across all regulated activities;
  - Ensuring risk-informed requirements are reflected in the planning, scoping and prioritization of oversight activities;
  - Using national and international standards to analyse and inform the assessment of risk for a specific activity or facility;
  - Applying requirements and guidance in a graded manner commensurate with the level of risk of the regulated activity;
  - Having a regulatory framework that allows applicants and licensees to propose alternative methods to meet regulatory requirements where appropriate.
- Facilities with greater risk require stronger risk mitigation measures. For example, where there is greater uncertainty regarding facility operation due to the lack of operating experience, more stringent measures for containment, control and cooling, additional instrumentation, increased inspection frequency or a more restrictive operating envelope may be needed.
- Conversely, where there is less risk, less stringent mitigation measures may be adequate to achieve desired outcomes of fulfilling fundamental safety functions. For example, the inherent risk levels between a small research reactor and a large reactor designed for electricity generation, are significantly different. The use of the graded approach to regulating results in the application of measures that are proportionate to the risk of the facility.

There are standards available to inform risk assessment methodologies, such as Refs [8], [9], [10] and [11].

Consider adopting a process to accept alternative approaches

Regulatory bodies need to acknowledge whether their regulatory framework has been developed based on experience with certain technologies and set out criteria for alternative approaches. Examples of alternative approaches that could be considered in the regulatory frameworks can be found in Ref. [12].

An expectation when alternative approaches are considered by regulatory bodies is that the applicants/licensees must demonstrate that the proposed alternative meets the overarching safety requirement. For example, the case of a new reactor design using emergency reactor cooling systems that are not water-based systems, such as passive air cooling, may be considered by some regulatory bodies as an alternative approach. Applicants/licensees in this case need to show that these methods can adequately cool the fuel and maintain its integrity as required by regulations.

In cases when the applicants/licensees may refer to practices accepted by regulatory bodies in other countries, such as approved technologies, codes, or standards, they need to document the basis for acceptance and demonstrate compliance with the regulatory requirements of the country where the application is made.

Consider harmonization via updating lower-level requirements

If an issue recurs, updating or reinterpreting lower-level requirements (e.g. guidance, technical codes) can promote harmonization without compromising safety:

- Establish feedback loops between licensing reviews and rule-making processes;
- Ensure that harmonization does not weaken safety or inadvertently create inconsistencies elsewhere.

Consider initiating harmonization on this issue internationally

Harmonization can build on the national efforts to interpret or update national requirements. Regulatory bodies can support harmonization by documenting and sharing their efforts internationally, particularly through international fora and platforms such as the SMR Regulation and Cooperation Hub, to promote broader regulatory alignment.

C **Category C:** Differences due to a conflict in regulations

Category C describes situations where regulatory requirements between countries are fundamentally incompatible or contradictory, creating a direct conflict that cannot be resolved by interpretation or compromise. In these cases, regulatory bodies will not adjust their positions, and as a result, compliance with both sets of regulations simultaneously is impossible without changes in the design and/or the safety documentation.

Such conflicts typically arise from differences in national laws, safety philosophies, or security requirements that reflect non-negotiable regulatory stances.

Good practices

Early planning for multinational inputs

To minimize challenges associated with differences in regulatory requirements, the vendor and/or applicant can plan early, identifying the range of regulatory jurisdictions they will seek to deploy the design in, seek multinational reviews, or develop a set of design principles that is inclusive of requirements across those jurisdictions. Gap analyses to inform early engagement with regulators, as documented in Section 3 – All categories: Good practices for the vendor and/or applicant, is also encouraged.

Standardized documentation format

To facilitate future work on regulatory harmonization, regulatory bodies could adopt a similar approach to recording their regulatory differences, including:

- Specific requirement(s) in question;
- Regulatory body's assessment and justification in Country A;
- Regulatory body's differing conclusion and justification in Country B;
- Impact on design and potential paths forward.

Justification and transparency

Regulatory bodies may also clearly document the rationale for not harmonizing, including the following considerations:

- Sharing the rationale publicly, where appropriate;
- Documenting alternative approaches considered and explaining why they were rejected;
- Maintaining close contact with other relevant regulatory bodies throughout the process to avoid surprises;
- Agreeing with other relevant regulatory bodies on how the difference is presented.

Lessons learned and continuous improvement

Capturing lessons learned and maintaining a repository of past cases — such as through the SMR Regulation and Cooperation Hub — can provide valuable guidance for future harmonization efforts and support continuous regulatory improvement.

Examples of Category C

- In Country A, regulatory limits for occupational exposure are higher, including thresholds for sensitive organs such as the eye lens. Country B applies lower limits, requiring reduced average exposures over multiple years and stricter requirements for organ-specific protection. Public exposure requirements are broadly aligned, so the main differences concern worker protection and cumulative dose management.
- These differences could influence the design and licensing strategy for a nuclear facility. A design optimized for Country A might rely on administrative controls — such as limiting time in high-dose areas — rather than shielding or remote handling systems. However, the same design may not satisfy Country B's stricter requirements, which could necessitate additional engineering measures like enhanced shielding, robotic tools, or revised plant layouts to minimize exposure during maintenance activities.

Category D: Differences due to non-nuclear requirements

Category D describes situations where differences arise from regulatory requirements that are not generally established by nuclear regulatory bodies. These requirements originate from non-nuclear regulatory frameworks, such as building codes, fire protection standards for life safety, environmental regulations, or civil engineering requirements, and may therefore vary across jurisdictions independently of nuclear-specific safety regulations.

Good practices

Early issue identification

Vendors and/or applicants may proactively identify potential non-nuclear regulatory issues as early as at the pre-licensing phase. Early identification helps prevent delays later in the licensing process and allows sufficient time for design adjustments or risk mitigation.

Early regulatory coordination

Vendors and/or applicants in coordination with national nuclear regulatory bodies may engage early with other relevant authorities, such as the national grid authority, chemical safety authority and the civil engineering safety authority. Early coordination ensures that differences in requirements across sectors are recognized and addressed before they impact project design or licensing.

Examples of Category D

A few illustrative examples for Category D are discussed below:

Fire protection standards

Differences in fire protection standards, such as the use of National Fire Protection Association (NFPA) codes in Country A versus national building codes in Country B, may require vendors and/or applicants to modify building layouts, fire compartmentation, and evacuation routes, while ensuring that nuclear safety systems remain unaffected.

Civil engineering codes

Differences in civil engineering codes, such as the use of Eurocode in Country A versus American Society of Civil Engineers (ASCE) standards in Country B, can lead to variations in load combinations and may require structural reinforcements or redesign of buildings to meet country-specific requirements.

Environmental requirements

Differences in environmental requirements, such as stricter noise limits in Country A versus stricter chemical discharge controls in Country B, may require additional measures like enhanced noise insulation or water treatment systems to comply with country-specific regulations.

Rebar Sizing Standards

Differences in rebar sizing standards, such as the use of imperial units in the USA versus metric systems in Europe, require vendors and/or applicants to modify structural drawings and specifications, often necessitating design changes and recalculation of load capacity, spacing, and anchorage to comply with local building codes.

Flexible and risk-informed options

Countries may consider the development and acceptance of adaptable regulatory and design approaches within these non-nuclear requirements. These may range from strictly prescribed solutions to risk-informed choices that allow alternative methods while maintaining safety and compliance. Flexibility reduces the likelihood of conflicts between nuclear and non-nuclear requirements.

Structured assessment and resolution

Vendors, applicants and regulatory bodies can adopt structured methods to identify and resolve areas where a specific non-nuclear requirement cannot be met, ensuring they are assessed and then mitigated, if necessary, through alternative approaches.

All categories: Good practices for the vendor and/or applicant

A general good practice for the vendor and/or applicant, when introducing a design to a new Recipient Regulator that has been reviewed by a Source Regulator, is to start with a comparative analysis between the regulatory requirements and practices between the two regulatory bodies. To the extent practicable, this comparison should cover all applicable regulations (e.g. nuclear, environmental, industrial). The outcome of this comparison should help the vendor and/or applicant ensure that regulatory requirements will be met by the proposed reactor technology. An optimal licensing review in the recipient country would leverage the Source Regulator's review to the maximum extent possible and avoid duplication of efforts. Once it is known which regulatory requirements can be met and verified by using the Source Regulator's review, the focus of the Recipient Regulator would then be on ensuring that any unique or substantively different regulatory requirements are met.

Early engagement by the vendor and/or applicant with the Recipient Regulator may cover the attributes of the design, describing key elements like the safety case and the design margin. In addition to the technology overview, the focus of early engagement may also be on addressing any outstanding areas where regulatory requirements might not be fully addressed in the recipient country. This allows the vendor and/or applicant to identify closure strategies, which may include where the issue is addressed in the original review/application documents by the Source Regulator.

Other strategies may also include additional analysis or testing to demonstrate performance and meet the Recipient Regulator's requirements. The early engagement would also be an opportunity for the Recipient Regulator to identify areas related to the new technology that require acquiring new skills, updating existing guidance, resolving regulatory and policy issues that necessitate change, etc. Both the vendor and/or applicant, and the Recipient Regulator, may strive in the early engagement to agree on how to address any unique regulatory aspects that exist with the Recipient Regulator. It is recommended for the amount of effort put forward for addressing any unique regulatory aspects to reflect the safety and risk significance of the difference. This approach will help guide an efficient licensing process at the Recipient Regulator's country.

Appendix I: Examples of comparison tables for Category A topics

Design basis accident dose and safety objective assessment

Both the United States Nuclear Regulatory Commission (U.S. NRC) and Canadian Nuclear Safety Commission (CNSC) frameworks consider the frequency and consequences of postulated event sequences when setting performance objectives. In both cases, events with higher likelihood are expected to have lower consequences. Each regulatory body has independently defined risk-informed performance goals for new reactor licensing, including quantitative limits and methods to address uncertainties in frequency and consequence estimates for postulated licensing basis events.

The NRC's traditional approach relies heavily on deterministic analysis. In contrast, the NRC's Licensing Modernization Project (LMP) incorporates probabilistic methods to identify key initiating events and safety functions aimed at preventing or mitigating event progression. The CNSC approach combines deterministic analysis with support from probabilistic methods, placing it between the two NRC approaches. Applying risk-informed safety classification to the NRC's traditional model would result in a framework similar to the CNSC's, incorporating probabilistic insights and a structured review of defence in depth.

Further information can be found in Ref. [13].

Table I.1 — Comparison of regulatory practices for the design basis accident dose and safety objective assessment in Canada and the USA

	Regulatory practice in Canada	Regulatory practice in USA
Regulatory practice	• Risk-informed performance goals; • Deterministic and probabilistic approach to evaluate how the goals are met.	• Risk-informed performance goals; • Two different approaches to evaluate how the goals are met: – Deterministic evaluations; – NRC LMP-probabilistic methods.
Differences	A detailed comparison was developed and summarized in Ref. [13]. Key differences include the following: • NRC uses licensing basis events (anticipated operational occurrences, design basis events, beyond design basis events) with risk-informed categorization. CNSC uses deterministic categories (anticipated operational occurrences, design basis accidents, design extension conditions) with fixed frequency thresholds. • NRC uses a continuous Frequency-Consequence (F-C) curve. CNSC uses discrete thresholds for event consequences.	
Potential impact on design	Reclassification of some events may be needed for some cases, which could result in additional safety features or analyses. In some cases, the differences could lead to more bounding conservative designs, possibly resulting in larger safety margins.	
Possible convergence	Regulatory body exchanges could be supported by a crosswalk of event categories for the specific design under evaluation to identify more detailed differences between the classification schemes. Probabilistic safety assessment and deterministic consequence analyses could be developed as part of the regulatory applications.	

Safety classification of SSCs

The CNSC regulatory framework allows for grading of the classification of structures, systems, and components (SSCs) that are important to safety. In contrast, the NRC framework identifies a designer-selected group of SSCs as safety-related (SR), meaning they can perform all functions defined under the safety-related category, based on either the traditional or LMP approach.

Other SSCs that are still significant for safety — because they help reduce risk, protect against specific hazards, or strengthen defence in depth — are classified differently. Under the NRC traditional approach, these are labelled as important to safety (but not safety-related), while under the LMP, they are designated as nonsafety-related with special treatment (NSRST) requirements.

Further information can be found in Ref. [13].

Table I.2 — Comparison of regulatory practices for the classification and assignment of engineering design rules to structures, systems and components

	Regulatory practice in Canada	Regulatory practice in USA
Regulatory practice	Grading of classification of important to safety SSCs	Classification of a designer-selected set of SSCs as safety-related, where the selected SSCs are capable of performing all functions captured within the definition of safety-related associated with the regulatory approach (either traditional or LMP)
Differences	NRC distinguishes SR, NSRST, and Non-Safety SSCs. CNSC uses a broader 'important to safety' classification.	
Potential impact on design	Additional SSCs may be required to be treated as safety-important, triggering design upgrades, redundancy, and quality assurance/quality control enhancements.	
Possible convergence	Regulatory exchanges could focus on how the specific design SSCs are classified using a combined matrix that includes both criteria. When inconsistencies occur, focused discussions could be held to determine whether the design of the SSCs needs to meet the stricter treatment.	

Appendix II: Examples of Category B topics

Differences in requirements for quality assurance

CSA N286 [14] and ASME NQA-1 [15] are both quality assurance standards used in the nuclear industry. The use of CSA N286 is a regulatory requirement in Canada, and the use of ASME NQA-1 is a regulatory requirement in the USA.

Table II.1 — Comparison of regulatory requirements for quality assurance standards

	Regulatory requirement in Canada	Regulatory requirement in USA
Regulatory requirements	CSA N286 is required for quality assurance.	ASME NQA-1 is required for quality assurance.
Differences	A detailed comparison of the Quality Assurance and Management System Attributes in both codes can be found in Ref. [13].	
Impact on design	Differences could lead to variations in how management systems are structured and implemented, particularly in areas like safety classification, documentation control, and lifecycle integration. In this specific case it was assessed that each regulatory body has the ability to use risk information to help lessen the impact of these differences.	
Possible convergence	The regulatory body can review the designs and processes developed under specific codes and request vendors and/or applicants to demonstrate that their management system processes meet regulatory requirements. The CNSC has observed that the use of ASME NQA-1 has been largely fit for purpose when assessing vendor management systems as part of its Vendor Design Review programme.	

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Abbreviations

ASME	American Society of Mechanical Engineers
CFD	computational fluid dynamics
CNSC	Canadian Nuclear Safety Commission (Canada)
CSA	Canadian Standards Association
FANC	Federal Agency for Nuclear Control (Belgium)
IAEA	International Atomic Energy Agency
LMP	Licensing Modernization Project
NHSI	Nuclear Harmonization and Standardization Initiative
NSRST	nonsafety-related with special treatment
SMR	small modular reactor
SMR RF	Small Modular Reactor Regulators' Forum
SR	safety-related
SSC	structure, system, and component
U.S. NRC	United States Nuclear Regulatory Commission (United States of America)
WENRA	Western European Nuclear Regulators' Association

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