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Collaborative Reviews and Effective Leveraging

The IAEA's Nuclear Harmonization and Standardization Initiative

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COLLABORATIVE REVIEWS AND EFFECTIVE LEVERAGING

THE IAEA'S NUCLEAR HARMONIZATION AND STANDARDIZATION INITIATIVE

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2025

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FOREWORD

In recent years, there has been growing interest in the global deployment of standardized advanced nuclear reactors, including small modular reactors. This trend has been accompanied by an increase in regulatory reviews and has placed greater demands on regulatory resources. At the same time, the current differences in regulatory and industrial approaches among countries have made the standardization of reactor designs across national borders challenging.

To address these challenges, the IAEA launched the Nuclear Harmonization and Standardization Initiative (NHSI) in 2022 to support the effective global deployment of safe and secure advanced nuclear reactors. The initiative is structured in two interfacing tracks: one for technology holders and operators (the Industry Track) and one for regulators (the Regulatory Track).

The NHSI Industry Track aims to develop tools and industrial approaches for the effective large scale deployment of advanced reactors, with particular emphasis on small modular reactors. In parallel, the NHSI Regulatory Track aims to develop a global framework for the regulatory review of advanced reactors, also with particular attention to small modular reactors. The framework is intended to outline common regulatory requirements and establish a shared understanding of how to meet them; to enhance national reviews by enabling regulatory bodies to take maximum advantage of international efforts and the work of other regulatory bodies; and to enable the sharing of regulatory resources and the implementation of joint reviews, without introducing additional regulatory steps or increasing the duration of national licensing processes.

To develop this global framework, a clear, staged approach was envisaged for the NHSI Regulatory Track, with three distinct phases of work. The first phase, completed in 2024, focused on the development of processes and tools to promote cooperation in regulatory reviews and increase alignment in review outcomes. It is envisaged that the second phase will focus on implementing the processes and tools developed during the first phase, as well as on gathering feedback to improve cooperation processes and to map the regulatory differences among Member States. The final phase may then focus on assembling the elements necessary to establish the global framework for regulatory reviews based on the feedback collected, in addition to building on the identified regulatory requirement commonalities and launching targeted efforts to address the differences.

During the first phase, the NHSI Regulatory Track collaborated with regulatory bodies and industry representatives through three dedicated working groups tasked with developing processes to enhance regulatory cooperation. Working Group 1 developed a framework to enable information sharing among regulatory bodies in order to facilitate cooperation in reviews of advanced reactors. Working Group 2 developed a multinational pre-licensing joint regulatory review process, in which a team of regulatory bodies conducts a design review against common requirements and reaches a joint decision. Working Group 3 focused on identifying practical approaches for leveraging existing regulatory reviews and international collaboration in the regulatory review process.

This publication, developed by Working Group 3, presents an approach for regulatory bodies to make effective use of the reviews of other regulatory bodies (leveraging of already completed regulatory reviews). In addition, it details a process for regulatory bodies to work together during ongoing regulatory reviews, referred to as collaborative reviews. A collaborative review involves multiple regulatory bodies conducting independent reviews against their national requirements, in discussion with one another during the process but ultimately reaching independent decisions. The approaches described in this publication have been informed by valuable insights from ongoing multinational and bilateral review activities, as well as previous international efforts to promote regulatory harmonization.

This publication is primarily intended for regulatory bodies and technical support organizations, but it is also relevant to industry stakeholders, such as advanced reactor vendors, because it provides insight into how regulatory collaboration and the leveraging of previously completed reviews might be done, facilitating the development of standardized reactor designs.

The IAEA is grateful to the Small Modular Reactors Regulators' Forum for its leadership of NHSI Regulatory Track Working Group 3, as well as to all the experts who participated in the consultancy meetings organized for the preparation of this publication and/or contributed to its review. Special thanks are extended to S. Belyea of the Canadian Nuclear Safety Commission, who served as the NHSI Regulatory Track Working Group 3 Chair. The IAEA officers responsible for this publication were P. Calle Vives, I.J. Botelho and V. Piotukh of the Division of Nuclear Installation Safety.

EDITORIAL NOTE

CONTENTS

1. INTRODUCTION

Various small modular reactor (SMR) designs are being considered for deployment by countries around the world [1]. When deploying an SMR design to several States, it is advantageous if the design changes arising from differences among States' regulations are minimized. This might be facilitated by cooperation during regulatory reviews, including collaborative reviews (covered in this publication) and joint reviews (covered in Ref. [2]), in which regulatory bodies from different States work together, and by 'leveraging' (making best use of) reviews previously performed by other regulatory bodies (see definitions in Section 2). Such cooperation between regulatory bodies has the potential to allow for easier international deployment of SMRs both to countries with nuclear experience and to embarking countries, without compromising safety.

In accordance with IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles [3] Principle 2, the regulatory body must "have adequate legal authority, technical and managerial competence, and human and financial resources to fulfil its responsibilities". One of the responsibilities of the regulatory body in the framework of regulatory reviews is to assess the suitability of the supplied information for its intended purpose. Regulatory cooperation does not diminish the responsibility of the regulatory body to competently perform its duties.

Cooperation during regulatory reviews of advanced reactors can enhance national reviews, potentially reduce time and resources needed for the review, increase safety through a more thorough review and the sharing of good practices, and provide a flexible way for regulatory bodies to work together. Regulatory cooperation can also provide useful experience to both experienced regulatory bodies and regulatory bodies in embarking countries. Furthermore, regulatory cooperation can reduce the time and costs of licensing 'nth of a kind' reactor designs.

1.1. BACKGROUND

The Nuclear Harmonization and Standardization Initiative (NHSI) was established by the IAEA Director General in early 2022 in response to growing interest in advanced nuclear reactors. Under NHSI, governments, regulatory bodies, technical support organizations (TSOs), designers, vendors, technology owners, operating organizations 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 [4]. NHSI consists of two tracks: an Industry Track and a Regulatory Track. This publication was developed under the Regulatory Track. It is applicable to any advanced reactor, including SMRs.

The NHSI Regulatory Track supports the establishment of an international framework that will enable increased cooperation of regulatory bodies during advanced reactor reviews 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 technologies. The key aspects of the NHSI Regulatory Track are:

- Minimizing repetition among regulatory reviews by different States;
- Minimizing the need for design changes arising from differences among regulations of States;
- Establishing a common basis for States' regulatory decisions while preserving States' sovereignty.

The approaches developed within this track are meant to enhance national reviews, enabling regulatory bodies to take maximum advantage of international work and efforts by other regulatory bodies. The implementation of these approaches is not expected to result in additional steps or increases in the duration of national licensing processes.

The approaches for regulatory cooperation developed within the NHSI Regulatory Track have focused on three types of cooperation:

- Collaborative review: an independent review against national requirements, discussing with other regulatory bodies but potentially reaching different decisions;
- Joint review: a team of regulatory bodies jointly reviews a design against common requirements and reaches a joint decision;
- Leveraging of regulatory reviews: a review against national requirements with the use of other regulatory bodies' reviews.

The work of the NHSI Regulatory Track was divided into three topics, each of which were addressed by a different working group:

- Working Group 1 - Information sharing framework for regulatory reviews of advanced reactors (see Ref. [5]);
- Working Group 2 - Multilateral pre-licensing joint regulatory review (see Ref. [2]);
- Working Group 3 - Collaborative reviews and effective leveraging of regulatory reviews (presented in this publication).

1.2. OBJECTIVE

This publication aims to describe possible approaches to cooperation between regulatory bodies from different States during pre-licensing (see e.g. Ref. [6]) and licensing reviews of advanced reactors. A particular focus is on collaborative reviews and on the sharing and leveraging of pre-licensing and licensing reviews performed by regulatory bodies in other States.

There are other forms of cooperation for regulatory reviews, as described in Refs [2] and [5].

1.3. SCOPE

This publication focuses on regulatory reviews carried out by States during the pre-licensing and licensing processes. These reviews can include safety, security and safeguards considerations.

This publication draws on IAEA experience in international cooperation and, more specifically, multinational and bilateral regulatory review activities and efforts to promote harmonization of regulatory approaches. These include the cooperation described in Appendix II: between the United States Nuclear Regulatory Commission (NRC) and the Canadian Nuclear Safety Commission (CNSC) (see Section II-1); between the United Arab Emirates and Republic of Korea (see Section II-2); the NUWARD Joint Early Review (see Section II-3); and between the Russian Federation and Belarus (see Section II-4).

The means by which proprietary and confidential information might be shared through such cooperation are discussed in Ref. [5]. For the purposes of this publication, it has been assumed that the necessary agreements to allow information sharing are already in place.

This publication is mainly targeted at regulatory bodies and their TSOs. Reactor proponents might also gain insight from how collaboration and leveraging might be done.

1.4. STRUCTURE

The publication consists of seven sections. Section 2 presents key concepts and influencing factors for regulatory collaboration. Section 3 describes different types of regulatory cooperation (collaborative reviews, joint reviews and leveraging) and explains how collaborative reviews might be established and operated. Section 4 describes a six-step process for leveraging information. Section 5 addresses the issue of differences in regulatory conclusions and how these might be resolved. Section 6 is devoted to risk management. Section 7 describes the roles of the organizations involved. Appendix I sets out preconditions for leveraging other regulatory reviews and Appendix II provides lessons learned from regulatory cooperation that has already taken place.

2. KEY CONCEPTS FOR REGULATORY COOPERATION

2.1. DESCRIPTIONS OF KEY CONCEPTS

The following concepts have been used throughout the report and are central to the approaches developed in Sections 3 to 5.

2.1.1. Cooperation

Regulatory bodies facing the review of the same reactor design might enter into cooperation. There are many different types of cooperation. As mentioned in Section 1, the NHSI framework is focused on three types of cooperation: joint review (see Section 3 and Ref. [2]), collaborative review (see Section 3) and leveraging approaches (see Section 4). The combination of these types of cooperation is possible, but not covered in detail in this publication.

The primary aims of regulatory cooperation are to widen the experience and improve the expertise of the parties, to reduce the burden on individual regulatory bodies by sharing the work, and to improve confidence in likely regulatory conclusions by obtaining a second opinion. All three of these aims may be assisted by leveraging, which involves using an already completed design review to inform and support a review by a different regulatory body.

2.1.2. Leveraging

When reviewing a reactor design, seeing another regulatory body's review of the same design could be very helpful. Nevertheless, when contemplating such leveraging, it is always necessary to demonstrate that the information to be leveraged is appropriate to the proposed task. Section 4 describes the steps in this due diligence process.

In the following paragraphs, the source that has already performed a review that can be leveraged is referred to as 'Regulator A' while the recipient that aims to take advantage of the information, is called 'Regulator B'. Because permissions may be required from more than one regulatory body, Regulator A and Regulator B may both represent more than one regulatory body.

2.1.3. Divergence

To make use of the results of an assessment performed by Regulator A, Regulator B needs to understand the context within which the work was conducted, to determine how to leverage the work for Regulator B's own system and purpose. Divergence in this context has several sources:

- Divergence in regulatory frameworks (i.e. the national laws, licences and regulations that stipulate the requirements to be met by an application) might or might not lead to country-specific design changes, or could require additional data in a safety demonstration. Further, the safety goals might differ, and there could be differences in assessment criteria, such as being performance-based or more prescriptive. The basic requirements for regulatory frameworks are established in IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [7];
- Divergence in licensing processes, for example, timing of the review in the process or depth of the review at different licensing stages;

— Divergence in Regulator A's and Regulator B's capacity and capability. This will determine how the regulatory bodies cooperate, for example, whether Regulator B is assisted by Regulator A in conducting the assessment, or whether they cooperate as more equal partners;
— Divergence in the timelines that different regulatory bodies follow. If the results of Regulator A's review are not yet available for leveraging, it could be more appropriate to perform a collaborative review, or else combine the two approaches;
— Divergence in design because of design changes (e.g. following an innovation or to meet a country-specific regulatory requirement), or because of site-specific features or bounding site characteristics used in the unified design development.

2.1.4. Informed customer capability

The IAEA Nuclear Safety and Security Glossary [8] states that 'informed customer' capability is "the capability of an organization to have a clear knowledge and understanding of the product being supplied or the service being provided." This concept is usually applied to applicants and authorization holders. IAEA Safety Standards Series No. GSG-12, Organization, Management and Staffing of the Regulatory Body for Safety [9], explains that this concept also applies in relation to regulatory bodies.

Informed customer capability is embedded in the regulatory licensing processes and standards in order that regulatory bodies can independently and expertly review submissions made by the applicant and thus take ownership of their regulatory decisions. Leveraging the reviews of other regulatory bodies might lessen the workload, but it does not lessen the regulatory body's responsibilities. In undertaking a review, Regulator B does not rely solely on safety assessments conducted by the applicant, nor on those that it might have commissioned from external consultants. Instead, Regulator B has sufficient full-time staff capable of performing independent assessments, or evaluating assessments performed by others, including other regulatory bodies and, if applicable, TSOs. Informed customer capability is a prerequisite for leveraging (see also Appendix I).

It should be noted that an applicant for a regulatory review may be a designer, vendor, or future operating organization. Even though there may be differences between a designer and vendor organization, for simplification this publication will hereafter use 'vendor' as a general term to mean a designer and/or vendor organization.

2.2. FACTORS THAT INFLUENCE THE NATURE OF COOPERATION

There are a number of factors that can influence the structure of the cooperation and the working relationships involved. These are described in the following subsections.

2.2.1. Aims of cooperation

As described in Section 2.1.1, regulatory cooperation can support a number of aims and it is possible that cooperating parties will differ in this respect. An inexperienced regulatory body, for example, may have staff training as an important aim. In this case, the standards against which a review is to be judged are of particular relevance. Where regulatory bodies wish (or are obligated) to use their own national standards, this will limit opportunities for sharing tasks. Other regulatory bodies might be willing to agree on common standards for the purposes of the cooperation. The use, or not, of leveraged information will also affect the nature of the cooperation.

2.2.2. Number of participants

Regulatory cooperation normally involves a small number of States. Larger numbers bring added complexity and challenges: it might be difficult to share information and reach consensus, for example. The number of participants also determines the way leveraging is used.

2.2.3. Confidence in the information received

It is the responsibility of regulatory bodies taking part in cooperation to each apply their own due diligence to any information that might be received as part of the cooperation; they might also come to a view on the effectiveness of the cooperation as a whole. Where received information is assessed as being sufficiently reliable and appropriate to the task, regulatory bodies are able to take ownership and use it in their own reviews.

2.2.4. Involvement of the design information owner

NHSI Working Group 1 considered the permissions needed to exchange information as part of cooperation, recognizing that much of it is controlled information [5]. From this viewpoint, cooperation that is instigated by the design information owner (DIO) is usefully distinguished from cooperation between two or more regulatory bodies without the involvement of the DIO.

2.2.5. Impacts of divergence

Section 2.1.3 describes the sources of divergence in the context of leveraging, but these can also impact cooperation more generally. For example, where national frameworks differ significantly, this might hinder joint reviews unless the parties agree to use common standards; similarly, where country-specific designs are needed, the joint review might be limited to the common portions of the design. Regulatory timelines for review completion might also impact the form of cooperation and, in case of delays in completing tasks or delivering information, it might be helpful to have considered possible mitigating actions when establishing the cooperation.

In general, when divergence is small, cooperative working is easier; when large, more care is needed to reach optimum outcomes and, in some cases, cooperation might not be possible. Case studies of regulatory cooperation are presented in Appendix II.

3. COLLABORATIVE REVIEW: MULTIPLE REGULATORY BODIES WORKING TOGETHER

3.1. TYPES OF COOPERATION

In a situation where two or more regulatory bodies need to review the same design, multiple regulatory bodies can choose to cooperate in the review. This situation might arise, for example, when a regulatory body starts a licensing or pre-licensing process in one country and, soon after, a regulatory body in another country starts a licensing or pre-licensing process of the same design. A regulatory body might even want to join the cooperation or might simply ask to observe it if they see that it is probable that the same design is going to enter pre-licensing or licensing in their country.

While they might agree to cooperate, regulatory bodies retain their responsibility to make independent decisions on safety. The scope and depth of the cooperation needs to be agreed before starting the review, with the understanding that a broader scope involves a greater commitment from the parties.

Regulatory cooperation can take many forms, and the subsections that follow briefly describe the two examples or models used here. The distinguishing features of these are:

- Bilateral or multilateral collaborative review (hereafter referred to as 'collaborative review'), where technical topics are reviewed independently by all participating regulatory bodies against their country's regulatory requirements. In collaborative review, participating regulatory bodies come to their own independent conclusions then consult with other participants on their findings; it is likely that collaborative reviews will yield modest or even negative savings in regulatory effort compared to a non-collaborative review;
- Joint review, where topics are reviewed against an agreed common review framework by a team that is nominated by the participating regulatory bodies; here it is the team that draws the review conclusions. When the joint team works on behalf of three or more regulatory bodies, it is likely that joint reviews will yield significantly greater savings in effort than collaborative reviews. This is because not all the experts from the three or more regulatory bodies will need to review all the topics if there is a common review framework as explained in Ref. [2].

Figure 1 qualitatively illustrates the relative resource impacts of collaborative reviews and joint reviews.

By using the collaborative review model for some topics and the joint review model for others, both approaches could be used within the same cooperation. Similarly, the joint review model could easily encompass the review of a specific topic by a third party. The third party could be a team drawn from one or more TSOs or another external contractor. This indicates that there is enough flexibility in these models to design cooperation that meets the needs of the participants.

Leveraging of regulatory reviews that were completed prior to the establishment of the regulatory cooperation can be an input to both collaborative reviews and joint reviews and this could have a profound effect on the amount of effort needed to complete a review as illustrated in Fig. 1.

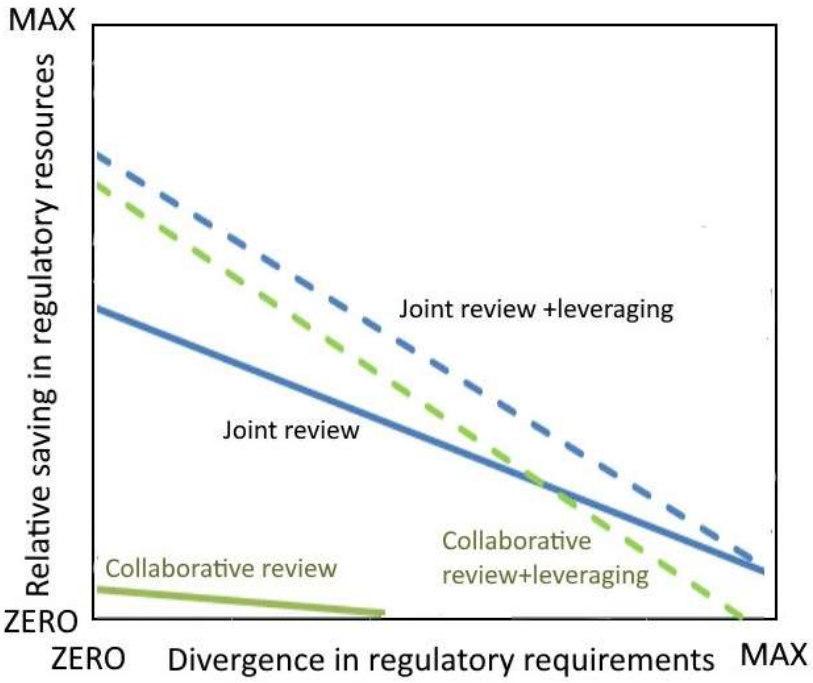

FIG. 1. Qualitative illustration of the types of regulatory cooperation.

3.1.1. Collaborative reviews

In a collaborative review, participating regulatory bodies review the topics simultaneously and independently but with varying degrees of consultation and exchange of views. In general, all participating regulatory bodies review all the topics against their own regulations, but the participating regulatory bodies can agree otherwise. In particular, they might decide to use a common review framework so that some tasks can be allocated to one or several participants - as in a joint review (see Section 3.1.2).

The advantages of this method include:

— Flexibility to agree on details;
— Opportunity for regulatory bodies to learn from each another;
— Each topic is reviewed multiple times independently, contributing to safety and trust;
— Each regulatory body is able to increase its knowledge of specific areas.

The disadvantages of this method include:

— Increased complexity, resources and a longer time to perform the review, as there are more administrative overheads with additional reviewers;
— Reduced support for the harmonization of regulatory approaches compared to the joint review approach.

3.1.2. Joint review

Like collaborative reviews, joint review tasks are agreed and addressed simultaneously but, rather than working independently, participating regulatory bodies agree to assign each review topic to one or several participants, with the others relying on their assessment. Alternatively, some tasks could be allocated, by agreement, to a third party. This might be appropriate if the

task is resource-intensive or highly specialized. The regulatory bodies also agree on a common review framework to be used in the review. The details of the review and topic distribution between regulatory bodies are agreed on a case-by-case basis. This arrangement works best if the parties have similar regulatory frameworks. Some participants might, nevertheless, decide to review certain topics independently. A potential approach to joint reviews is offered in Ref. [2].

The advantages of this method include:

- Optimization of time and resources as duplicate work is reduced;
- Specialists from different regulatory bodies can contribute where they are best suited;
- A learning opportunity for regulatory bodies with limited experience;
- Each regulatory body can increase its knowledge of specific areas;
- Harmonization of standards is supported;
- Independent assessment of specific topics against national criteria is still possible.

The disadvantages of this method include:

- Increased complexity as additional project management is needed to coordinate all the work;
- Increased demand for due diligence of the reviews performed by another party;
- Agreement on a common review framework and criteria might take time;
- Review against common criteria fosters harmonization but reduces usefulness with respect to assessment against a national framework;
- Need to avoid any misalignment between common decisions and sovereignty of national regulatory bodies.

Where a third party (e.g. TSO, contractor) is used to review part or all of the design against an agreed common framework, additional advantages and disadvantages can apply.

The advantages of this approach include:

- The ability to place specific tasks with contractors who have specialist knowledge and experience;
- Cost sharing.

The disadvantages of this approach include:

- Outsourcing increases the demand for due diligence;
- The need for agreements with both the contractor and the collaborating regulatory bodies brings added complexity;
- The use of common standards/design might make the outcome less useful with respect to national requirements;
- More limited scope for harmonization of regulatory approaches.

3.2. PROCESS FOR COLLABORATIVE REVIEWS

3.2.1. Examples of collaborative reviews and general considerations

One possible way for several regulatory bodies to collaborate during the review of the same design simultaneously and independently is the one that was used by the Czech, Finnish and

French regulatory bodies to review the NUWARD SMR reactor at an early stage of its development [10]. This collaborative review focused on key topics that presented high stakes for safety and for the design. The main objectives were to identify key issues that could challenge the potential licensing of the NUWARD reactor in the countries involved, and to identify areas of commonality and difference between the relevant regulatory frameworks and practices. See Section II-3 of Appendix II for information on the NUWARD collaboration.

Another example of a collaborative review is the CNSC and the NRC collaboration on regulatory and safety issues associated with licensing of the BWRX-300 small modular reactor [11]. The governing agreement allowed for both collaborative and joint reviews and the inclusion of TSOs. The regulatory bodies coordinated with the vendor and the utilities planning to deploy this reactor in Canada and the United States of America on topics for review. A work plan was written for each topic, and this included a description of the review approach to be used. The vendor supplied the technical information, which each regulatory body evaluated independently using their country's regulatory framework. A joint report provided common feedback as well as individual feedback from each regulatory body[1]. See Section II-1 of Appendix II for further information.

Another example of a recent collaborative review is the Multinational Design Evaluation Programme (MDEP)[2] established by the Nuclear Energy Agency (NEA) of the Organization for Economic Co-operation and Development (OECD). Since 2008, the MDEP has provided a platform for regulatory bodies reviewing the same design against their national expectations to exchange information on their work and, when possible, to develop common positions.

Collaborative reviews of a reactor design take time, and are usually composed of different steps, regardless of the targeted objectives. In general, reviews are regarded as projects and managed accordingly. The sections below describe these steps for a notional collaborative review inspired by that between the French Nuclear Safety Authority (ASN) in France, the Radiation and Nuclear Safety Authority (STUK) in Finland and the State Office for Nuclear Safety (SÚJB) in the Czech Republic and their TSOs [10], and that between the NRC and the CNSC [11].

Some of the steps and practices described below can also be used for joint reviews and leveraging of regulatory reviews. However, both joint reviews and leveraging of regulatory reviews need additional considerations and steps. These are presented in Section 4 for leveraging reviews and in Ref. [2] for joint reviews.

3.2.2. Launching a collaborative review

When reviewing the same design for a project, the idea of a collaborative review might be suggested by the DIO, vendor, future operating organization or another applicant. The project might be a mere prospect (i.e. pre-licensing discussions), or it might be a concrete licensing project for which governments or utilities have shown interest or even provided guarantees. The regulatory bodies of the countries concerned are candidates for such a collaborative

[1] A set of Joint Reports issued by NRC and CNSC are available at https://www.nrc.gov/reactors/new-reactors/advanced/who-were-working-with/international-cooperation/nrc-cnsc-moc/joint-reports.html

[2] https://www.oecd-nea.org/mdep

initiative. The applicant for the collaborative review is expected to identify potential relevant regulatory bodies for participating in such an initiative.

It is also possible that the idea of such a collaborative review could be raised by a regulator itself. As previously mentioned, the review could be suggested by another organization that might not be the DIO. If this is the case, involving the DIO from the outset will be beneficial.

What constitutes a relevant regulatory body for a collaborative review depends on criteria, such as:

- The regulatory body's experience in licensing and regulating nuclear reactors, and in international collaboration;
- The regulatory body's available resources;
- The regulatory framework, as large divergences could lead to better learning, but also additional effort;
- The legal framework, which, in some countries, might impose conditions on a regulatory body's ability to commit resources to a design review;
- The compatibility of regulatory bodies' timelines for national reviews.

The applicant, on the other hand, will likely be swayed to suggest a collaborative review to specific regulatory bodies by the interest in SMRs shown by the government of a regulatory body's State.

Whatever the scenario, the constitution of the team that will conduct the collaborative review needs to be agreed by consensus between regulatory bodies, the applicant, and potentially the utilities, operating organizations and possible future licence in each country.

Once the relevant regulatory bodies have been identified, the applicant and/or the regulatory body that originated the initiative might propose an international collaboration to the interested parties, specifying the form of collaboration and the expected outcomes. Before engaging in a collaborative review, the applicant and regulatory bodies involved in the initiative need to have a common understanding of the underlying objectives.

If an agreement in-principle is reached between the interested parties, the review team (comprising the regulatory bodies and possibly their TSOs) could draft Terms of Reference to define the collaborative review. A good practice is to share this document with the applicant and operating organizations (if applicable) before its adoption by the review team.

The Terms of Reference could, for example, address questions related to:

- The objectives of the collaborative review;
- The participation and the expected commitment from the participants, noting that the review will not succeed without adequate resources. If different levels of participation are accepted (e.g. active member, observer), the Terms of Reference could define them;
- The type(s) of collaboration expected to be used during the review, noting that more than one type of collaboration could be included;
- The expected outcomes of the collaborative review, especially the nature and significance of the deliverables;
- The overall review schedule, costs and funding;
- The possibility to withdraw or to welcome additional members;
- The number of regulatory bodies participating, noting that this has a direct impact on the volume of work.

The Terms of Reference can be complemented with an ad hoc document (e.g. a mandate), endorsed by the review team, that details the structure of the team, the programme of work and the working methodology. Some good practices regarding these aspects are provided in the following paragraphs.

Finally, non-disclosure agreements or other similar arrangements need to be in place between the applicant, the regulatory bodies and their TSO before the beginning of the collaborative review.

3.2.3. Establishing a programme of work

Once the review team is established, and before beginning the review, the review team and applicant need to agree on a programme of work. Ideally, this is defined before the agreement on the Terms of Reference, as the programme of work has a strong influence on the resources (quantity and quality) and the timeline of the initiative. The scope and depth of the review are defined to be consistent with the agreed project objectives.

Dividing the programme of work into single topics such as specific technical areas or design features (as independent as possible) has a number of advantages: it enables the work to proceed in parallel and thus more quickly; it diminishes the risk that difficulties on a single topic might delay the overall programme; it allows the type of collaboration to be topic-dependent (e.g. a collaborative review might be selected for a new or novel feature that all regulatory bodies want to understand, while a joint review might be preferred for familiar topics); finally, it enables interested parties to select the topics of greatest importance to them. However, single topic reviews might have limitations owing to interdependencies with other topics, especially since some of these interdependencies might become apparent during the review. In defining the programme of work, it might be helpful to group topics according to the objective that they serve. When selecting topics, the following aspects could be considered:

- The importance of the topic or feature for the safety demonstration. Highly important topics are expected to take more time to consider, so an early review of these topics could help with reducing the duration of the licensing process;
- Whether the topic's relationship to the reactor design is such that a late change to the safety arguments would have an important impact on the design or on the safety demonstration, and therefore early feedback from the regulatory bodies would be beneficial;
- Whether the topic is related to the expectations on the level of safety and how to meet them;
- Whether it is a novel design feature or regulatory approach on which there is no, or very little, information (e.g. no relevant safety requirements or recommendations, little or no guidance or experience).

In some circumstances it might be considered that a topic is too immature and the related documentation too underdeveloped to allow the topic to be included in the review.

Finally, as discussions throughout the review can increase knowledge on the design and the related challenges, it might be decided to include a new topic in the scope of the collaborative review, if the above aspects are met and if agreed by consensus between the interested parties. The programme of work and the overarching agreements need to be sufficiently flexible to allow this.

3.2.4. Organizational aspects of conducting a collaborative review

It is important to consider organizational aspects when defining the composition of the review team and the working methodology, especially when topics are to be addressed simultaneously by different experts. A clear understanding is needed of each person's role in the collaboration and of the inward and outward flows of information. The following structure could be adopted:

- A coordinator could be selected at the beginning of the collaborative review to lead the effort;
- Team leaders from each participating organization that would bring experience on project management and licensing. Team leaders from participating TSOs could also be appointed if relevant;
- Experts, from regulatory bodies and their TSOs participating in the review of topics.

The vendor may also identify a project manager to coordinate its inputs to the collaborative review.

3.2.5. Process for conducting a collaborative review

Prior to starting the review, a clear process for conducting the review is defined and agreed between the review team members and the applicant. Following a process brings clarity to the work performed and remaining. It also facilitates the integration of experts who are expected to participate only in the topics of their area of expertise.

The guiding documents define the working methodology while retaining enough flexibility to make improvements as experience is gained.

Holding a kick-off meeting with all interested parties is a good opportunity to:

- Remind the participants of the review's objectives, programme of work, expected outcomes and schedule;
- Present the structure of the review team and the working methodology;
- Present the general design and safety approach of the reactor under review, to ensure every participant has the same basic level of knowledge.

To conduct its work efficiently, the review team defines a systematic process, such as:

1. The applicant provides technical documentation to all regulatory bodies;
2. The regulatory bodies meet to assign the work and align on the review framework. In a collaborative review, all regulatory bodies are likely to review all topics against their own criteria. Nevertheless, collaboration will be more efficient if the work is broken down into agreed topics and a regulatory body with appropriate expertise is assigned to lead on each one;
3. Establish how and when the regulatory bodies will meet to share results (periodically or when topic is complete) and set up internal meetings between them as appropriate;
4. Each regulatory body performs a preliminary analysis of the technical documentation and generates a list of questions. These are sent to the topic-leading regulatory body that reviews the entire list to identify and resolve any overlap or conflicts. When this has been done, the questions are sent to the applicant, who provides written responses for a technical meeting where they are discussed. If necessary, this step is repeated until all the information needs are met. All regulatory bodies are invited to the technical

meetings and receive the written responses, but the team leaders are the most active participants;

5. Once the technical review is completed, a regulatory bodies-only discussion can start. It is the occasion for each regulatory body to share their conclusions. In particular, the regulatory bodies could discuss their regulatory practices and expectations related to the addressed topics and then present their positions on the acceptability of the applicant's proposition. The conclusions from this second step are drawn up in a joint report. Once validated by all regulatory bodies, this report is shared with the applicant. An optional additional step is to allow the applicant to provide feedback on the report;
6. All regulatory bodies perform due diligence on the final assessment. This includes confirming that the criteria used are consistent with their guidance or identifying the impact of any differences;
7. Differences in regulatory conclusions might be addressed using the procedure described in Section 5.

All exchanges with the applicant, whatever the format (e.g. meetings, written exchanges), are to be shared with all regulatory bodies. A single working language is to be agreed and information is to flow through the identified channels. The preferred channels of information could be the coordinator of the review team. During and after the review, the process can be enriched with feedback on the experience that was built throughout the process.

It is important to consider, for each meeting, whether it is to be held in person or remotely. Consideration will be given to holding technical meetings and most review team meetings in person, with the opportunity to participate remotely. For some short review team meetings, remote meetings might be appropriate.

3.2.6. Reduced scope joint reviews as part of collaborative reviews

For collaborative reviews including the joint review of a limited number of technical topics, there are some additional considerations to account for in the review process.

A joint review is usually divided into several topics, each of which might have its own agreed review framework. For each topic, one or more regulatory bodies or a suitable contractor is assigned to perform the review. In a joint review, the regulatory body performing the review is naturally the lead for that topic; where the review is performed by a third party, one of the participating regulatory bodies might be appointed to this role. Regardless, the lead regulatory body for each topic needs to have appropriate expertise. For joint reviews, it is the lead regulatory body for each topic that performs a preliminary analysis of the technical documentation and generates a list of questions that are then sent to the applicant who provides written responses.

If the collaboration takes place at a pre-licensing stage with more than two regulatory bodies involved, and a larger scope of topics for joint review, the process developed by NHSI Working Group 2 in Ref. [2] might improve the efficiency and structure of the review.

3.3. LEVERAGING AS PART OF COLLABORATIVE REVIEWS AND JOINT REVIEWS

When Regulator A has already performed a pre-licensing or licensing design review, it might be possible to use this existing review in subsequent regulatory cooperation. The cooperation could be structured along the lines of either of the models (collaborative or joint review) described in Section 3.1, or a combination of the two. In any event, the existing review is

divided into topics and topic leaders are appointed. The participants in the cooperation then decide the model to be applied when addressing each topic. Whichever model is used, it is important for all regulatory bodies assigned as ‘Regulator B’ to properly leverage the results of the cooperation into their own regulatory frameworks. In doing so, the information can be used for decision making by all regulatory bodies involved. Again, due diligence is applied, and Section 4 provides good practices that might be adapted for this purpose. Whichever model is used, the role of Regulator A is limited to provision of additional explanation wherever needed.

With a fully collaborative review approach, all the participating Regulator B bodies address all the topics, leveraging the existing review into their new review against their own review frameworks. In the context of Section 2.1.2, each participating regulatory body is regarded as Regulator B.

In a joint review approach, suitably experienced subteams are appointed to perform the review of each topic on behalf of the other members of the cooperation. For each topic, the existing review is leveraged into a new review that uses the common review framework that was agreed previously. In this case, each subteam and the review team as a whole take the role of Regulator B which, having informed customer capability, applies due diligence by following the steps described in Section 4.

Section 5 on addressing differences in regulatory conclusions can be used to deal with any differences in regulatory conclusions that arise from the cooperation.

4. APPROACH TO LEVERAGING INFORMATION

This section outlines a process for a regulatory body (defined as Regulator B) who wants to leverage information from an existing assessment already performed by another regulatory body (defined as Regulator A).

For regulatory bodies to be able to leverage other regulatory reviews it is important to know that nuclear safety infrastructure is in place and that Regulator B can demonstrate an informed customer capability. The regulatory framework of Regulator B needs to be established and implemented before the leveraging process can start (see Appendix I). The regulatory framework includes the national laws, licences and regulations that stipulate requirements to be met for an application. Then the regulatory process of review and assessment is followed in compliance with national requirements. Appendix I describes preconditions with respect to legal and regulatory infrastructure and other important considerations in relation to the risks associated with leveraging the reviews of other regulatory bodies.

Once all the preconditions identified in Appendix I are in place, leveraged information from Regulator A could, for instance, be used to complement engineering judgement, or could be accepted to a large extent by Regulator B to avoid duplicating the assessments carried out by the Regulator A.

The scope of this cooperation between regulatory bodies can encompass an entire design or can be limited to specific areas; for example, those which are the most safety significant, those for which the Regulator A has less experience and knowledge, or even those for which the assessment takes significant time and resources.

A step-wise process by which Regulator B can identify and determine the extent to which it might wish to leverage information from Regulator A is presented in Fig. 2 below. This step-by-step approach enables Regulator B to reassess the objectives, scope and efforts throughout the process, as the applicability of Regulator A's work is clarified. The process aims to provide a progressive understanding of the potential benefits and costs of the collaboration.

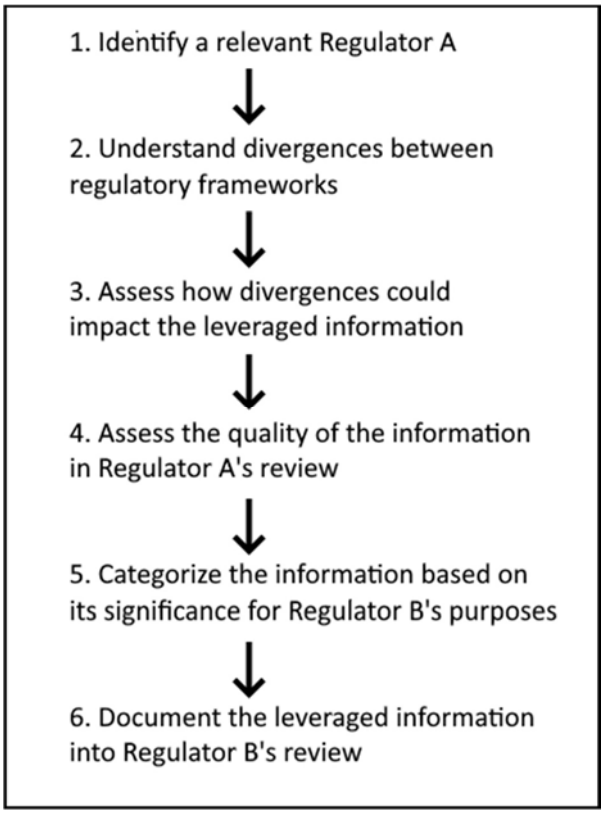

FIG. 2. Due diligence process for leveraging an existing design review.

4.1. STEP 1: IDENTIFY A RELEVANT REGULATOR A

Before Regulator B decides to leverage an existing design review performed by Regulator A, it first considers if it has sufficient confidence that leveraging will be beneficial. To aid this decision, it might be valuable to consider the experience and capability of Regulator A, for example:

- Whether Regulator A has already reviewed the same design being considered by Regulator B;
- Regulator A's experience of reviewing and licensing new nuclear power plants (NPPs), particularly technologies relevant to the design under consideration. This might include consideration of its strategy for the regulation of new NPPs, recent experience in design assessment, construction and operation of new NPPs, and publications relating to regulation of new NPPs;
- Regulator A's experience of regulating operating NPP and nuclear sites; particularly those sites hosting technologies relevant to the design under review. This might include consideration of the size of the regulatory body and the proportion of the organization devoted to regulating new NPPs, the maturity of the regulatory body, and the number and type of operating plants it regulates;
- Regulator A's involvement in international fora, initiatives and agencies; particularly involving technologies relevant to the design under consideration. This might include consideration of engagement in active programmes on the relevant technology, such as those organized by the IAEA, involvement in collaborative initiatives, such as the MDEP, known collaborations with other regulatory bodies, contributions to international guidance;

— The extent, scope and availability of published regulations, standards, guidance, criteria and processes produced by Regulator A, particularly those that are relevant to the assessment of the technologies under review. This might include consideration of how the standards and guidance have been benchmarked, and evidence of application to new reactor designs;
— The outcome of recent Integrated Regulatory Review Service missions to Regulator A.

Once the experience and capability of Regulator A has been considered, Regulator B might then wish to compare its own experience and capability to that of Regulator A. This comparison would allow Regulator B to determine areas of strength or where experience or capability is lacking, in either regulatory body.

Any perceived lack of experience or capability highlighted by the evaluation does not necessarily mean that a review cannot be leveraged. It might just mean that further activities or actions will be necessary to address these perceived shortcomings.

Overall, evaluating the experience and capability of both organizations can help Regulator B to decide whether to leverage all or part of Regulator A's review. A decision by Regulator B to proceed is contingent on an expectation of tangible and realizable benefits compared to conducting its own independent review.

4.2. STEP 2: UNDERSTAND DIVERGENCES BETWEEN REGULATORY FRAMEWORKS

The value of leveraging another regulatory body's review might vary depending on the divergence that exists between the regulatory frameworks or regulatory approaches. This divergence can have a significant impact on the effort needed to take advantage of another regulatory body's review and can also call into question the applicability of the existing review to the new assessment. To limit this risk and to better anticipate the benefits that can be derived from another regulatory body's review, it is essential to identify, but also to understand and assess, the extent and the significance of the divergence. This divergence can appear at several levels, as outlined in Section 2.1.3.

It is essential that Regulator B undertakes a rigorous analysis of any divergences with respect to the topics identified for leveraging, together with Regulator A. This rigorous analysis is necessary for Regulator B to be able to make its decisions in an independent and responsible manner, to have a properly critical view of the work carried out by the other regulatory body and to take ownership of the supplied information. This analysis can be carried out progressively and can utilize several information channels as outlined in the following paragraphs.

First, the work of international organizations might serve as an important source for understanding, at a high level, the regulatory processes and requirements of different countries. Some international multilateral initiatives, such as the MDEP, have focused on specific topics, and therefore provide more precise information, but always at a preliminary stage and at a lower cost, as Regulator A is not involved. Second, bilateral exchanges between the two regulatory bodies might take place to identify and assess the divergence between the authorization processes, the regulatory frameworks, the prescribed form of the application and the reactor design in the two countries. Such exchanges might take significant effort on the part of both regulatory bodies, and a formal cooperation agreement might be needed. Close interactions can be expected on multiple topics between the experts from each of the countries involved. A good

practice to optimize the efficiency of these bilateral exchanges could be to use questionnaires prior to a meeting. Sending a questionnaire in advance could bring a shared understanding of the issues, and holding a meeting, based on the responses to the questionnaire, could enable a focus on aspects that need further clarification. Furthermore, it is important to ensure that any information exchanged on the design and content of the dossier is complete and provides adequate detail, while complying with any agreements in relation to controlled information.

The vendor also has an important role to play, and a vested interest, in facilitating the identification of the level of divergence between the two regulatory bodies. Even if the designs to be deployed are identical, it is likely that the operating organizations will be different in the two countries concerned, and this could lead to differences in the mode of operation. However, the vendor is normally the same for both countries, so might identify a divergence or gap in the requirements for safety documentation between Regulator A and Regulator B. The vendor might also be able to identify any design changes arising from site specific aspects, design updates, change of operator, or other aspects. Such observations by the vendor would help Regulator B to more quickly determine differences in the applications submitted in the two countries, in particular the divergences related to the design and safety demonstration (e.g. structure, system and component design, site specificities, general operating rules).

Assessment reports drafted by Regulator A can also be an effective resource for identifying divergences. For example, these reports could highlight the arguments considered in Regulator A's decision making. These differences can be captured, for example, in a matrix listing the different topics to be reviewed and the identified divergences. This matrix might be more or less high level, depending on the needs, and might highlight design and safety demonstration differences and the basis on which both regulatory bodies have assessed the design. Such a matrix can help to develop the regulatory basis for assessing a nuclear reactor and can be completed in line with international standards, requirements and guidance (e.g. IAEA Safety Requirements or Ref. [12]) to facilitate the comparison of national regulatory requirements and to understand the rationale behind these requirements. Although these international standards are often implemented in national regulatory frameworks (sometimes, with different interpretations), they are not intended to help decide on the acceptability of a design and are, therefore, complemented with national regulatory requirements and expectations.

At the end of this step, Regulator B is expected to have identified and understood the areas where there are divergences between its application and the application submitted to Regulator A, and between the respective national regulatory frameworks and the corresponding expectations and practices.

4.3. STEP 3: ASSESS HOW DIVERGENCES COULD IMPACT THE LEVERAGED INFORMATION

With divergences identified, their impact on Regulator B's decision making is assessed. Here, a graded approach (see IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [13] and Ref. [14]) is key, especially when Regulator B intends to rely on Regulator A's review in a number of topics. Regulator B might need to categorize the identified divergences to anticipate the need for additional expertise or assessment.

4.3.1. Case of a divergence in the licensing process

Different licences or authorizations (e.g. for construction or commissioning) might require different levels of detail in the review. Therefore, the level of detail in the review performed by Regulator A for its licensing or authorization activities, might differ from that needed by Regulator B for its intended purpose.

If the divergences between the two licensing processes are such that Regulator A's review was not as detailed as needed for Regulator B, additional work and expertise might be needed from Regulator B.

On the other hand, if Regulator A's review was more detailed than needed by Regulator B, Regulator B will be able to obtain all the necessary information from Regulator A's review. Regulator B might also benefit from contacting Regulator A to obtain information on the reasons behind the level of detail in Regulator A's review.

It will be noted that a divergence in the licensing process is likely to have less impact than a divergence between the submitted applications or between the regulatory frameworks.

4.3.2. Case of a divergence between the submitted applications (design or safety demonstration)

In the case of a divergence between the submitted applications, it is worthwhile considering the following questions:

- Does this divergence involve a safety-related structure, system or component? Does it have an impact on the safety demonstration?
- What motivated the divergence (e.g. specific regulatory requirement, operational experience [15], operational optimization)?
- Is the divergence related to site-specific considerations? Which application has the most restrictive site-specific considerations?
- In the cases in which the impact of the divergence on safety can be qualitatively or quantitatively evaluated, Regulator A might consider whether this divergence has a negative impact on safety. Regulator A might also consider to what extent this divergence could impact Regulator A's assessment.

4.3.3. Case of a divergence between regulatory requirements, expectations and practices

In the case of a divergence between regulatory requirements, expectations and practices, it could be worthwhile to consider the questions set out below.

- Is Regulator A's regulatory framework similar to Regulator B's regulatory framework?

  In case of a positive answer, it is necessary to assess the differences between the national requirements (see next questions).

  In case of a negative answer, additional expertise might be needed, as the review conducted by Regulator A might not have covered some requirements of Regulator B.

- Are the requirements of Regulator A more stringent?

In case of a positive answer, the results of Regulator A's review might be taken into account without a need to perform an additional analysis.

In case of a negative answer, it might be necessary to carry out an analysis to determine if Regulator A's review enables Regulator B to conclude its review without any need for additional expertise.

— What is the level of divergence?

It is important to determine the level of any divergent requirement(s). Indeed, the level of a requirement provides insights into the effort needed to address such a divergence. If the requirement is legally binding, then the regulatory body might not be able to reassess its own requirement. If the requirement is not legally binding (e.g. a recommendation from a guide issued by the regulatory body), then Regulator B might reassess its approach or might accept a different approach with adequate justification.

Harmonization of requirements is a way to address regulatory divergence, but it is not the only one. Indeed, some regulatory differences can be addressed by a single design or safety case, or by a modification of that design or safety case.

— Does Regulator B have experience and knowledge of the approach and tools used by Regulator A to verify that regulatory requirements are met? And are these approaches and tools acceptable to Regulator B?

If Regulator B does not have any experience or knowledge of the approach and tools used by Regulator A to perform its review, additional effort will be needed from Regulator B to ensure that the approach and tools can be used. Ultimately, Regulator A might need to facilitate the understanding of the review.

Based on the answers to these questions, the expected impact on the effort to leverage information is presented in the flow chart of Fig. 3.

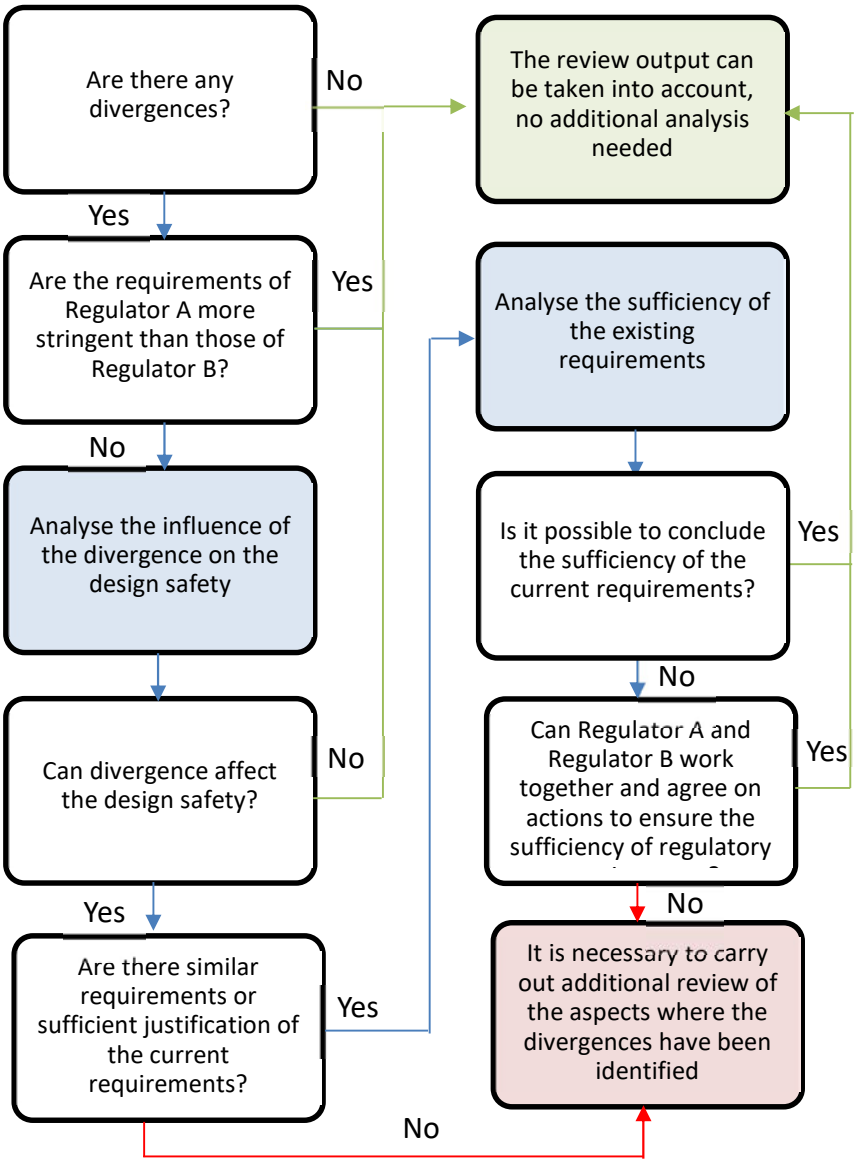

FIG. 3. Flow chart illustrating the analysis of divergence.

At the end of this step, Regulator B will have a good understanding of the usability of the analysis performed by Regulator A and the effort needed to leverage the information.

4.4. STEP 4: ASSESS THE QUALITY OF THE INFORMATION IN REGULATOR A'S REVIEW

This section provides information on preparing for and performing a quality assessment of the information provided by Regulator A. Regulator B first defines a basis for this assessment, aiming to clarify whether the information provided by Regulator A is of sufficient quality for Regulator B's purposes. This section outlines ways in which Regulator B can determine the necessary resources and methods needed for the quality assessment, establish and manage the relevant procedures and perform the assessment itself.

To assess the quality of the information provided by Regulator A, Regulator B utilizes the following elements already available from previous steps:

- Regulator B's purpose for leveraging Regulator A's review;
- Knowledge of Regulator A's level of experience and expertise, its procedures and management system;
- Understanding of upcoming review and assessment activities within the licensing framework and procedures of Regulator B;
- Identified differences in regulatory approaches and in national technical requirements and know-how;
- Understanding the scope and content of information needed from Regulator A.

The level of effort expended by Regulator B on the quality assessment is commensurate with the volume and the safety significance of the information being leveraged.

4.4.1. Preparatory steps for the quality assessment

In preparing a quality assessment of Regulator A's information, Regulator B undertakes a series of preparatory steps, including the following:

- Definition of the objectives of the quality assessment;
- Definition of a specific basis for quality assessment against which Regulator B will assess the information provided by Regulator A. The basis will most likely include the following:
  - Regulator B's national legal requirements related to inputs for review and assessment and licensing activities;
  - Outcomes from previous licensing review and assessment performed by Regulator B, including lessons learned and good practices;
  - Internal guides for Regulator B's own review and assessment procedures;
  - Regulator B's external guides regarding format and content of licensing and regulatory documentation;
  - Regulator B's quality assurance and management system methodologies and guidelines.
- Determination of a methodology for the quality assessment that has a clear scope and criteria, utilizes generally applicable and available assessment tools and covers clearly identified areas (e.g. siting, construction, commissioning, testing, operation, nuclear fuel, structures, instrumentation and control systems, radioactive waste management, security).

4.4.2. Scope of the quality assessment

The scope of the quality assessment carried out by Regulator B on Regulator A's information includes an assessment of clarity, accuracy, reliability, completeness, sufficiency, relevance and whether the information remains current.

4.4.2.1. Assessment of clarity, accuracy and reliability

Regulator B assesses:

- The overall clarity of the information (e.g. understandability and interpretability with respect to the terminology and language use, logical structure and coherence);

— The accuracy of information (e.g. identification of any errors, contradictions or inconsistencies);
— The reliability of information (e.g. whether the source(s) have been reviewed and approved, whether the source(s) have been suitably referenced, whether any supporting independent information has been supplied, cross-checking of references used to support key outcomes, evaluation of the strength of evidence and level of peer review).

4.4.2.2. Assessment of completeness, sufficiency and relevance

Regulator B assesses the completeness, sufficiency and relevance of the information obtained in relation to the purpose(s) determined by Regulator B, for example:

— Whether all the necessary information has been provided;
— Whether the information meets or exceeds all Regulator B's expectations based on the needs and purposes;
— Identification of possible gaps;
— Assessment of relevance.

To evaluate the relevance of the information supplied, Regulator B's purpose for leveraging needs to be compared to the purpose and outcomes of Regulator A's review.

4.4.2.3. Assessment of whether the information remains current

An important aspect of the quality of leveraged information is whether it remains current. Thus, Regulator B might determine if the design under consideration has significantly changed since Regulator A reviewed it. For example, Regulator B needs to consider:

— Whether any operational experience (including design changes during construction, which reduce the validity of the information) has become available or known;
— Whether features of Regulator B's site(s) need new evidence and arguments to support the available information;
— Whether the evidence underpinning the information has been superseded.

Within the assessment of the quality of information provided by Regulator A, Regulator B might also consider information and support from the SMR vendor, as this might assist in the understanding of Regulator A's information and help to overcome differences and specificities, making the quality assessment easier.

4.4.3. Performance of the quality assessment steps

Regulator B performs the quality assessment according to a well-defined plan that includes procedures for monitoring, adjusting (when necessary) and controlling the quality assessment activities as the quality assessment progresses.

4.4.4. Outcome of the quality assessment

Based on the outcomes of the assessments, Regulator B might decide:

— To ask for further information from Regulator A;
— To search for and use additional information resources;
— To adjust its own assessment, licensing or other procedures;
— To use applicable information for its own regulatory activities.

4.5. STEP 5: CATEGORIZE THE INFORMATION BASED ON ITS SIGNIFICANCE FOR REGULATOR B'S PURPOSES

4.5.1. Analyse the information to be leveraged

Regulator B, when considering the use of information from other regulatory bodies, needs to have the ability:

- To understand the information itself (i.e. be an informed customer);
- To understand the criteria against which the information was assessed (i.e. the regulations, policies and safety standards used by Regulator A);
- To understand the criteria against which it will be assessed (i.e. the regulations, policies and safety standards to be used by Regulator B).

The previous steps indicate the thoroughness of Regulator A's review, identified divergences and their significance for safety and assessed the quality of the information contained within Regulator A's review. Where gaps are discovered, ways of bridging these might need to be found to allow the information to be effectively leveraged.

When evaluating how readily information can be leveraged, one approach could be to divide it into at least two categories (e.g. Type 1 and Type 2) as illustrated in Fig. 4 below. Type 1 information needs additional work or detailed assessment to be successfully leveraged. This might be because it does not fully match the purposes of Regulator B or because the circumstances warrant more detailed assessment (most likely when the information relates to activities or components with a high safety significance), or both. Type 2 information is sufficient to be leveraged into Regulator B's framework with minimal additional information needed, perhaps because it has a low safety significance.

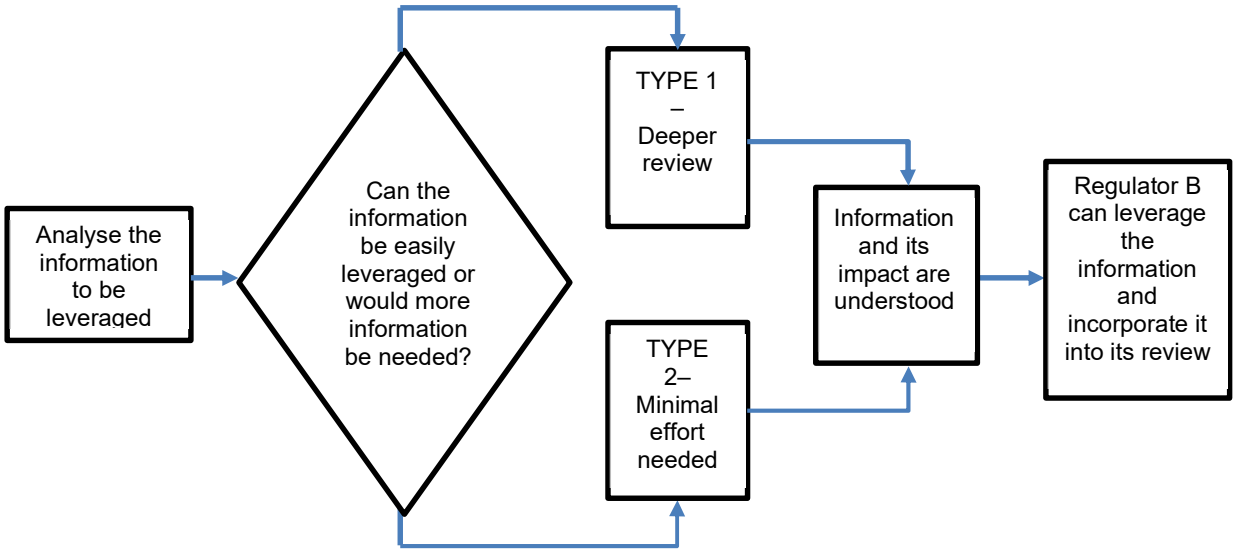

FIG. 4. Procedure for categorizing information with respect to the amount of effort needed for leveraging.

4.5.2. Deeper review needed – Type 1 information review

Regulator B categorizes information as Type 1 on account of its being inadequate for Regulator B's purpose. While the category refers, in effect, to the significance of the missing information, Type 1 is most likely to be applied when it concerns something that is important to safety. Possible reasons for a Type 1 categorization might include:

- Regulator B determines that the information it wishes to leverage from Regulator A has a significant impact on nuclear safety and is an area of new technology where the safety arguments are insufficient in some way;
- Since the review of information performed by Regulator A, new findings have emerged (e.g. from operating experience or research) with significant implications for nuclear safety;
- Conditions (e.g. mode of reactor operation, environmental, external hazards, AC voltage frequency) that are specific to Regulator B have not been adequately taken into consideration.

Alternatively, Regulator B might determine that, for its purposes, the information needed differs significantly from that supplied by Regulator A (e.g. owing to differences in regulatory framework or the necessary evidence threshold), such that a gap exists that needs to be bridged. This might consist of:

- Understanding Regulator A's regulatory requirements and how the information was used in the context of those requirements, including performance of in-depth and/or independent reviews where necessary;
- Further quality assurance and/or additional verification by Regulator B to raise confidence in the information up to the expected level and thus bridge a perceived gap;
- The drafting of a 'request for information' (see Section 4.5.4).

4.5.3. Minimal review needed – Type 2 information review

In this case, the documentation received by Regulator B is adequate to the extent that it contains sufficient information to demonstrate that:

- The information to be leveraged is consistent with the regulatory requirements in Regulator B's country;
- The technical basis used by Regulator A to perform its review and assessment is clearly described, explained, understood and adequate;
- There is no design change from one country to another with significant impact on nuclear safety;
- There is no change in operational activities with significant impact on nuclear safety.

In general, it is expected that Regulator B will be able to use Type 2 information to reach a conclusion independently, but in full awareness of the analysis performed by Regulator A. The extent and depth of all reviews is commensurate with the safety importance of the item, (i.e. a graded approach).

4.5.4. Requests for information

Throughout the leveraging process, Regulator B might need more information to support its review. When additional information is needed to help support Regulator B's decisions, there

are several options available. Regulator B might, for example, seek additional information or clarification from Regulator A when needing to understand how the latter reached its conclusion.

If the information is not available from Regulator A, Regulator B can seek the information from other sources. This is done transparently with Regulator A, and the results of the request for information are shared with Regulator A. The sources of this information might include:

- The licence or pre-licence applicant or the DIO (via the applicant);
- Research and development organizations, local or international TSOs or other regulatory bodies for information on research and development.

4.6. STEP 6: DOCUMENT THE LEVERAGED INFORMATION INTO REGULATOR B'S REVIEW

A State has the responsibility to make its own regulatory decisions in relation to the adequacy of the safety and security of the designs proposed for construction in its own country. This is an international expectation reflected in the IAEA safety standards. It is therefore the responsibility of Regulator B to document its regulatory decisions and to show that an appropriate level of due diligence has been performed in leveraging the work of other regulatory bodies; this might be especially important in the case of an embarking country.

Other items to be documented in such cases include:

- The date of the assessment;
- The purpose of the assessment and the associated level of detail;
- Whether site specific assumptions in the leveraged information remain valid;
- Whether it can be demonstrated that the leveraged information can satisfy the regulatory requirements and framework of the leveraging country;
- That formal information exchange agreements have been established with the requisite parties and that their scope is appropriate;
- That the leveraging country has good knowledge of the regulatory framework of the leveraged country;
- The willingness of Regulator A to engage with the leveraging country, including the provision of access to detailed information.

There is value in Regulator B publishing as much information about its activities as possible to demonstrate its sovereign independence whilst leveraging information from Regulator A. This might include a statement of its country's own regulatory framework, its process for leveraging information, documented evidence of having undertaken and completed this process, and any additional work/engagement it has deemed necessary (including site specific differences) to gain assurance that the review meets its own regulatory framework, principles and legislation.

If possible, it could be useful to make available the information from Regulator A along with Regulator B's own reflections on this. Furthermore, if made publicly available, support from expert organizations used by Regulator A might further enhance the credibility of Regulator B's decision to leverage information and conclusions from another country.

Activities such as the above provide a high degree of transparency to local interested parties. However, the extent to which such activities are possible depends on several factors, including agreement by Regulator A and the applicant.

5. ADDRESSING DIFFERENCES IN REGULATORY CONCLUSIONS

5.1. HOW DIFFERENCES ARISE

Inevitably, when two or more regulatory bodies evaluate a common technology using different regulatory frameworks, there is potential for differences in regulatory conclusions. These could arise from:

- Different regulatory frameworks;
- New operational experience;
- Discovery of errors;
- New or differing codes or standards;
- Differences in site requirements.

In such circumstances, it is important to understand the different regulatory conclusions and their implications. In a leveraging scenario, it is the receiver of the information (i.e. Regulator B) who will need to take the lead and, perhaps, perform most of the work.

Differences can arise when one or both parties adopt an over-prescriptive approach to licensing. Here it needs to be remembered that safety, not process, is the overriding goal. Recognizing that safety can be achieved in different ways, differences can be reconciled when regulatory bodies utilize appropriate flexibility, in accordance with best practice.

5.2. PROCESS FOR ADDRESSING DIFFERENCES IN REGULATORY CONCLUSIONS

The first step is to analyze the differences in regulatory conclusions to determine their root cause and assess their safety significance. Where differences arise from safety assessment calculations, specialist expertise is usually needed to perform the analysis.

5.2.1. High safety impact

There is a general expectation that a reactor is capable of meeting the international expectations for safety. If an item with a high impact to safety is found, it needs further investigation and the involvement of other parties (e.g. the DIO). This is an urgent matter that needs the involvement of Regulator A if the issue is thought to affect an already operating design.

5.2.2. Moderate to low safety impact

Where a difference in regulatory conclusions arises from an issue that has a moderate to low impact on safety, a systematic process (e.g. risk informed decision making) could be used to determine the resolution path. In a leveraging exercise, Regulator B is expected to engage with the applicant and/or DIO to find an acceptable solution, but better practice is for both regulatory bodies to do this and to work together to find common ground. This approach recognizes that standardized global designs themselves bring safety benefits, because they are scrutinized by regulatory bodies from many countries, and safety improvements identified through operational experience are more likely to be directly transferable from one plant to another. These benefits are diminished when designs become country specific. In general, design changes are limited to those needed to accommodate the characteristics of the chosen site.

5.2.3. Difference arises primarily from regulatory framework

Where a difference in regulatory conclusions has little or no impact on safety but, instead, primarily arises from differences in the regulatory frameworks (or differences in interpretation of regulatory requirements), regulatory bodies might collaborate to see if changes can be made to align their frameworks more closely. This involves flexibility from both parties, but the preferred general approach is benchmarking against international standards (e.g. IAEA) or against the standards applied by regulatory bodies with appropriate experience.

If it is decided that the different regulatory conclusions cannot be reconciled, the countries jointly agree and document the difference. If design changes are needed to address the different regulatory conclusions, the aim is to keep those design changes as small as practicable recognizing the potentially greater benefits of universally applied designs (see Section 5.2.2).

6. MANAGING RISKS ASSOCIATED WITH SMR REGULATORY REVIEWS AND ENSURING EFFICIENCIES

To minimize the risks and maximize the efficiencies of the cooperation in regulatory reviews following the approaches presented in Sections 3 and 4, it is essential to follow standard project management and risk management processes. The expected outputs of such an approach are:

— A project management plan;
— A risk management plan;
— A live risk register that is reviewed and updated regularly;
— An information sharing site to enable interested parties to access all relevant documents.

It is assumed that all regulatory bodies involved, regardless of the cooperation model, can demonstrate an informed customer capability as defined in Section 2.1.3.

Table 1 and Table 2 below present non-exhaustive lists of risks that might impact the implementation of leveraging and collaborative reviews following the approaches described in Sections 4 and 3 respectively.

TABLE 1. RISKS ASSOCIATED WITH LEVERAGING OTHER REGULATORY REVIEWS

#	Risk	Risk description	Risk category	Risk response
1	Accessibility of information	Export control restrictions limit Regulator A sharing key information with Regulator B	Project management	Ensure government to government agreements are in place prior to initiating the review project (link to [5])
2	Translation of information (language or units of measurement)	Errors in the translation of information from Regulator A impact Regulator B's review schedule	Quality	Minimize translation errors by ensuring expert technical translators are available to support the review project from the beginning
3	Quality of information	Poor quality information provided by Regulator A impacts Regulator B's review schedule	Quality	Regulator B to complete due diligence of the information provided by Regulator A prior to starting the review project
4	Completeness of information	Regulator A provides incomplete information, which results in additional review burden for Regulator B	Quality	Regulator B to complete due diligence by assessing any divergence in the submitted documents prior to starting the review project, with any gaps addressed in the review plan
5	Timeliness of information	Delays in responses to requests for information impact the progress of review	Schedule	Holding regular meetings with Regulator A to clearly communicate what information is needed by when and tracking all requests on a shared system
6	Correctness of information	Errors in the information provided by Regulator A invalidate the review of Regulator B	Quality	Regulator B to conduct due diligence on information provided by Regulator A prior to starting the review project
7	Relevance of information	The information from Regulator A is not relevant to the review of Regulator B	Scope	Regulator B to conduct due diligence on the information provided prior to starting the review project

TABLE 2. RISKS ASSOCIATED WITH COLLABORATIVE REVIEWS BETWEEN ONE OR MORE REGULATORY BODIES

#	Risk	Risk description	Risk category	Risk response
1	Accessibility of information	Export control restrictions limit sharing key information between regulatory bodies	Project management	Ensure government to government agreements are in place prior to initiating the review project
2	Translation of information	Errors or delays in the translation of information between regulatory bodies impact the overall review schedule	Quality	Minimize translation errors by ensuring expert technical translators are available to support the review project from the beginning
3	Quality of information	Poor quality of information shared between regulatory bodies impacts the overall review schedule	Quality	Due diligence conducted by each regulatory body prior to initiating the review project, and requirements, expectations and standards communicated to all at the launch of the project
4	Gaps in expertise	The regulatory bodies collectively have insufficient expertise in one or more disciplines resulting in an incomplete review	Project scope	Review necessary expertise and hire TSOs or selected experts as needed prior to the start of the review project
5	Timeliness of information	Delays in responses to requests for information impact the progress of review	Schedule	Holding regular meetings between regulatory bodies and applicant to clearly communicate what information is needed by when and tracking all requests on a shared system
6	Correctness of information	Errors in the information shared between regulatory bodies invalidate the overall review project	Quality	Due diligence conducted by each regulatory body prior to initiating the review project, and requirements, expectations and standards communicated to all at the launch of the project
7	Timing to complete review	Regulatory bodies are working to their own review schedule, which might delay the overall review project	Schedule	One project manager leads the review across all regulatory bodies with one schedule and holds each regulatory body to account
8	Sharing information	A regulatory body is reluctant to share information in a timely manner, which impacts the project schedule	Schedule	Agreements are signed by all regulatory bodies involved at the beginning of the review project to address, amongst other things, sharing of information
9	Multiple requests for information	Requests for information between regulatory bodies and applicants get mixed up and are not well managed, which impacts the write-up of the review	Project management	One shared system to track all requests for information, which is managed and controlled by a dedicated project team
10	Differences in regulatory requirements	Differences in regulatory requirements lead to design changes	Requirements	Prior review by proposed members of the collaboration, the benefits of a universal design are highlighted
11	One regulatory body leaves or pauses its review	A regulatory body leaves or pauses its review, impacting the overall review project schedule and capability to finish the review in an adequate manner	Schedule, quality	Hire TSOs or other experts, as needed, to fill the knowledge gaps in the review project

It is up to the Regulator B's project manager to engage with all interested parties to review the risk tables and determine which risks are applicable, as well as any missing risks not identified. In the case of collaborative reviews, the development and review of the table could be done as part of the kick-off meeting.

Once determined, the risks are assessed and ranked highest to lowest in a risk register prior to the start of the project. During the implementation of the project, the agreed risk register needs to be reviewed on a regular basis and managed by a project manager.

The formal tool that summarizes risk management initiatives and the status of risks (active or retired) is the risk register in which identified, analysed, evaluated and treated risks are presented. The risk register identifies the active critical risks that need to be monitored and potentially escalated to senior interested parties and for which contingency plans need to be maintained.

7. SPECIFIC ROLES IN LEVERAGING INFORMATION AND IN COLLABORATING IN REGULATORY REVIEWS

The roles and activities of the various organizations in the implementation of the processes proposed in this document are described in Sections 3 to 5. This section provides some additional roles and activities of the regulatory body, TSO, vendors, future applicant/licence holder and international organizations.

The detailed roles and activities of the regulatory bodies have been described in Sections 3 to 5. An additional activity that could aid the leveraging process is to establish platforms (or to use existing platforms) where ideas, lessons learned, experience and information from a variety of sources are shared. These could be international platforms, such as the SMR Regulators' Forum[3], as well as ones established by bilateral or multilateral collaboration agreements.

7.1. THE ROLE OF THE TECHNICAL SUPPORT ORGANIZATION

The role of the TSO [16] in leveraging information can be substantial depending on the scenario and, more specifically, in the case where Regulator B is less experienced. Some specific activities of the TSO are summarized in the subsections below.

7.1.1. Review and assessment

The TSO performs technical reviews and assessments to evaluate whether the proposed design meets the stipulated safety objectives and requirements. The result of this assessment allows the regulatory body to determine if the facility is 'licensable', meaning that the facility complies with regulations and specific licence conditions. In case of a less experienced regulatory body or less competence in a specific domain, this review and assessment by the TSO is the most important source for information regarding safety for the regulatory body.

The TSO of Regulator B needs to be in close contact with Regulator A and/or Regulator A's TSO to gather all necessary information for the review and assessment.

In case of multilateral cooperation, the TSO could support one or several regulatory bodies, and hence play a crucial role in leveraging the information.

7.1.2. Development of safety regulatory documents

Leveraging of information between two regulatory bodies could lead to the development of specific requirements by Regulator B for the technology or design of a specific facility, where a TSO provides the scientific basis and information for Regulator B to develop regulations and associated guidance.

7.1.3. Training and knowledge management

Due to their nature and activities, TSOs might play an important role with respect to training and knowledge management. In the case of leveraging information, this might include specific topics related to the technology and the design of the facility and might explain how the

[3] https://www.iaea.org/topics/small-modular-reactors/smr-regulators-forum

fundamental safety functions are implemented and how defence in depth approach is applied; other areas covered include accident analysis or specific emergency measures [17].

7.2. ROLE OF INTERESTED PARTIES

The vendor plays an important role in leveraging processes and is likely to be involved in them. The vendor has two major roles to fulfil. The first is as the information source. The necessary technical information for the review process (leveraging of information or multilateral review) comes from the vendor and informs the regulatory bodies' review. How this information and subsequent additional information is gathered and distributed is clearly defined early in the leveraging process. Communication between the regulatory bodies and the vendor is of key importance. The second role is to close the potential gap between the current and expected level of knowledge for the new technology (e.g. data acquisition and/or experimental results, codes and standards validation).

Similar to the vendor, the future applicant/licence holder can also play a role in leveraging information. In case the future applicant/licence holder is involved in the leveraging process, its roles and activities could be to:

- Participate in the leveraging process by establishing open communication channels with all interested parties;
- Share information from vendors and from research and development organizations;
- Support regulatory harmonization for licensing activities by sharing its perspectives.

International organizations provide mechanisms to share information and experiences within the nuclear community, including among regulatory bodies, operating organizations, vendors and research organizations. They can therefore play a very important role in establishing a harmonized approach on advanced reactor development.

Some relevant activities of international organizations include:

- Building of international consensus on key safety issues and good practices;
- Elaboration of recommendations that are widely used by their member countries to evaluate the need for change in national requirements, regulatory practices, and international codes and standards. International interactions organized by these organizations also support their members in evaluating and developing manufacturing capabilities and supporting construction of SMR first-of-a-kind demonstration projects to minimize construction risks;
- Organization of forums, working groups and technical meetings to exchange and evaluate information about lessons learned and best practices for all stages of a nuclear installation (e.g. design, construction, operation);
- Provision of training for their members;
- Development and maintenance of databases to collect, record and disseminate information;
- Administrative and project management support to the multinational pre-licensing joint regulatory review process [2].

Some examples of such international organizations and their activities are given below.

- The IAEA safety standards promote harmonization, and the IAEA has published several documents related to SMRs and advanced reactor designs. For instance, the

IAEA Safety Report No 123, Applicability of IAEA Safety Standards to Non-Water-Cooled Reactors and Small Modular Reactors [18], systematically identifies the novel features of these technologies and assess its impact on the applicability of the safety standards The IAEA also provides technical review services, for example, for evaluation of new designs;

— The SMR Regulators' Forum[4] provides interactions among its members and other interested parties to share knowledge and experience regarding SMRs. The SMR Regulators' Forum collaborated with NHSI by leading the activities of the Working Group 3 of the NHSI Regulatory Track, which developed this publication;
— The OECD/NEA contributes to the common evaluation of specific SMR designs through well-established mechanisms, such as the one used in the MDEP. The NEA has created specific working groups on regulation of new technologies and expert groups on SMRs, and has published technical opinion papers on key safety issues;
— The OECD/NEA Data Bank[5] includes computer codes, and nuclear and thermochemical data generated by the world nuclear research community, which is available to support validation and verification of computer models used for safety assessments;
— The IAEA and NEA jointly operate the International Reporting System for Operating Experience (IRS) that brings together lessons learned from operating experience ([19], [20]). This system is used for all reactor types;
— The World Nuclear Association's Cooperation in Reactor Design, Evaluation and Licensing Working Group established the Small Modular Reactor Ad-hoc Group in 2013 [21]. This group is developing a report on SMR technology and its potential for standardization and harmonization [22].

[4] https://gnssn.iaea.org/regnet/smr-forum/pages/default.aspx
[5] https://oecd-nea.org/jcms/rni_6525/data-bank

APPENDIX I.

PRECONDITIONS FOR LEVERAGING OTHER REGULATORY REVIEWS

I.1. REGULATORY FRAMEWORK AND THE REGULATORY BODY

Preconditions for leveraging other regulatory reviews include the existence of a sufficiently developed nuclear safety infrastructure and an adequate knowledge base in the respective countries. Nuclear safety infrastructure includes, amongst other things, an established, legally mandated and independent regulatory body and a regulatory framework with national laws, licences, and regulations that stipulate the requirements to be met by an application. The IAEA safety standards provide principles, requirements and recommendations on how to establish the regulatory framework (see Refs [3], [7], [23] and [24]).

The regulatory bodies involved need an established organization with sufficient resources to perform a critical appraisal of the information submitted by the applicant on all aspects of safety, commensurate with the licensing stage and process. Different licensing stages and different technologies involve different competencies. Before embarking on new projects, a resource analysis might be warranted and an approach to resourcing the project might be established, considering cost as well as in-house organizational capacities and sustainability. For example, siting of new facilities differs from the operation of existing nuclear power plants both from an expertise and numbers perspective. The regulatory bodies determine whether any additional expertise needed will be developed in-house or outsourced.

Countries involved in regulatory cooperation are expected to be Contracting Parties to the Convention on Nuclear Safety and, as such, to have been subject to relevant peer review missions such as Integrated Regulatory Review Service missions [25]. These missions provide independent insights into the overall organization, staffing and training of the regulatory body and its management systems.

I.2. ADMINISTRATIVE ASPECTS

Collaborative reviews and leveraging could entail the exchange of controlled information between regulatory bodies. To this end, formal arrangements need to be in place to permit such exchanges while maintaining confidentiality. The administrative measures needed to facilitate the exchange of information are covered in Ref. [26].

Regulatory bodies can expend significant resources and effort on reviews and it is therefore advisable for Regulator B to develop and implement a strategy that seeks to make best use of its resources in leveraging the information. Resource planning might include consideration of resources and skills needed for reviews of subsequent stages and long-term resource needs. Regulator B is likely to expend fewer resources than Regulator A, but these might still be significant when the initial agreements, data preparation and responses to requests for information are taken into account.

There might also be practical impediments to some regulatory bodies' ability to support the work of other regulatory bodies, including national policies and lack of funds for activities not related to their core activities. New nuclear projects need to be supported by both the vendor and the recipient country's national government, with associated financial commitments and resources.

I.3. REGULATOR B – INFORMED CUSTOMER CAPABILITY

As explained in Section 2.1.4, informed customer capability is also a prerequisite for leveraging, as it ensures that regulatory bodies can take ownership of their decisions.

I.4. RISKS ASSOCIATED WITH LEVERAGING OTHER REGULATORY REVIEWS

While leveraging information can have many advantages, it does not always result in a faster and more efficient review process: there are risks involved in too little or too much leveraging (see Fig. 5). To take maximum advantage of leveraging, the following aspects, among others, need to be considered:

- Potential inadequacy of the independent verification of safety, security and safeguards by Regulator B, not fulfilling its regulatory responsibility of review and assessment;
- Potential inadequacy of verification of compliance with the regulatory requirements, including relevant local, regional and federal laws;
- Potential undermining of the capacity building and competence of technical staff;
- Potential loss of public confidence as an independent regulatory body;
- Potential need to change the regulatory framework of Regulator B.

The risks of too little leveraging of the reviews of other regulatory bodies might include:

- Potential repetition of the same or similar reviews that were already conducted by other regulatory bodies;
- Potential overlooking of key safety issues that were already identified;
- Potential loss of regulatory efficiency in managing human resources for review and assessment activities of safety significance as the hosting regulatory body;
- Potential loss of regulatory effectiveness in making use of relevant information from other regulatory bodies as the hosting regulatory body.

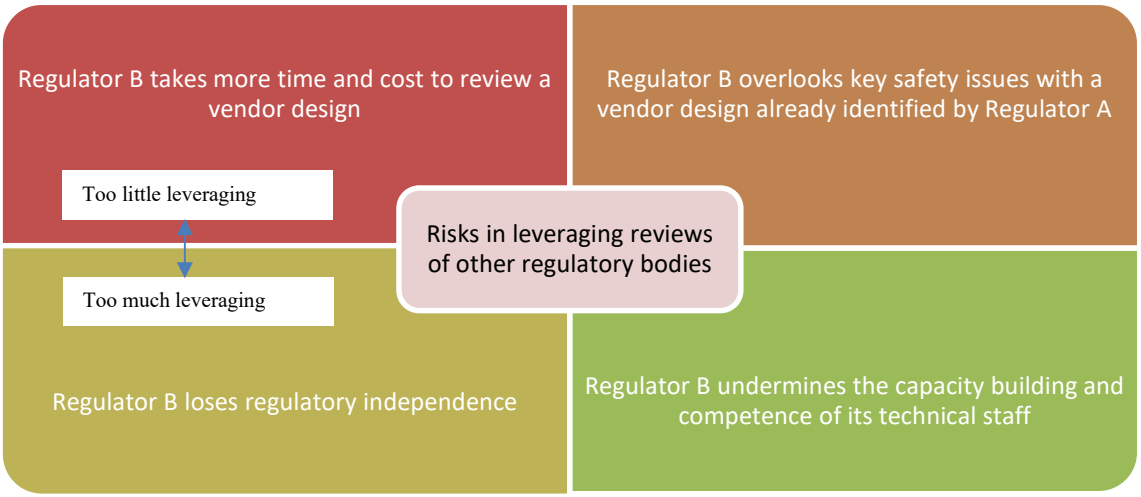

FIG. 5. Risks of leveraging the reviews of other regulatory bodies too little or too much.

APPENDIX II.

LESSONS LEARNED ON REGULATORY COOPERATION

II.1. COOPERATION BETWEEN THE UNITED STATES NUCLEAR REGULATORY COMMISSION AND THE CANADIAN NUCLEAR SAFETY COMMISSION

In June 2021, the Advanced Reactor Technologies and Small Modular Reactors Sub Committee [11] formed by the NRC and CNSC issued a report of lessons learned on the implementation of the Memorandum of Cooperation (MOC) that was signed in 2019 (non-public). That first report focused on challenges in identifying projects and drafting work plans, sharing proprietary information, and communications. In the two and a half years since that report was issued, the subcommittee has issued several joint reports, developed a charter for reviews of the BWRX-300 small modular reactor, and expanded cooperation. This review discusses some improvements made in response to the first lessons learned, efforts and feedback from external interested parties.

II.1.1. Improvements

(a) The subcommittee identified a need for more engagement with vendors/applicants during the development of work plans, and timely communication to remove barriers. To address this, the subcommittee holds planning meetings with vendors while developing the work plans. These meetings help align the scope and schedule before regulatory bodies commit resources. For example, discussions that led to development of the BWRX-300 charter were successful in defining the scope and timeline of these work plans. Routine meetings of the five parties (CNSC, NRC, GE Hitachi Nuclear Energy, Ontario Power Generation and Tennessee Valley Authority) are beneficial in ensuring clear communication throughout the work plans;
(b) The subcommittee created a Strategic Working Group that prepared a strategic plan defining the goals and priorities of the subcommittee collaboration for the NRC and CNSC. The strategic plan is evergreen and helps manage multiple projects at the same time while establishing the prioritization of future projects;
(c) The Strategic Working Group meets regularly to review the prioritization of current and future projects and assess whether additional projects should be added to the list;
(d) In response to requests from other regulatory bodies to participate in NRC and CNSC cooperation, the subcommittee developed criteria to determine whether a regulatory body could be invited to join as a participant or observer. The criteria are included in the strategic plan and include project timeline alignment, ability to share information and sufficient resources to effectively participate;
(e) The Strategic Working Group identified challenges related to applicant document access. In response, the subcommittee requested vendors to provide documents to both regulatory bodies. For example, the work plans for the BWRX-300 indicate that the information will be shared equally with the regulatory bodies and that the unique aspects of each country regulatory frameworks will be addressed or clarified by the applicant. In addition, the MOC collaboration desk guide highlights the vendor's responsibility for ensuring that each regulatory body has the information that is within the scope of the collaboration;
(f) A related challenge was uneven control of proprietary information between regulatory bodies. The subcommittee documented protocols to ensure that access controls implemented by each regulatory body for proprietary, export controlled and safeguards information are consistent;

(g) Initial experiences with writing joint reports identified that it would be more efficient to have administrative protocols and templates. The subcommittee developed administrative protocols and templates for preparation, approval, legal review, and publication of joint reports, and for public access via agency websites and/or accessed by public. The administrative protocols and templates are available in the MOC collaboration desk guide.

II.1.2. Areas of good practice

The subcommittee solicited feedback from the NRC and CNSC staff working on cooperative projects to identify the following suggestions for improving the process:

(a) Familiarization with the other country's requirements

Staff working on collaborative reviews are not always familiar with the regulatory requirements of the other country. Project leads need to develop an understanding of both regulatory frameworks and provide training to subject matter experts. This allows development of joint positions and minimizes the need to seek clarification.

The NRC and CNSC held training sessions on each other's regulatory processes. The regulatory frameworks were compared to understand how the decisions made in one country can be applied to the other.

(b) Support for embarking countries

It is important to ensure that regulatory bodies joining the MOC as participants do not impact regulator timelines associated with work plans. Observing work plans prior to participating is one way to ensure that new participants are able to become valuable contributors.

(c) Effective communication with all parties before and throughout reviews

Effective communication and alignment through multi-party meetings that include utilities, vendors and regulatory bodies for a specific design prior to submission ensures that the topics chosen for reviews benefit all parties and that the same information is provided to each regulatory body. These meetings are held periodically throughout the collaborative review. For example, discussions that led to the development of the BWRX-300 charter were successful in defining the scope of the projects. In addition, routine meetings of the abovementioned five parties are beneficial in aligning all participants throughout project development and implementation.

(d) Documenting lessons learned

Continually seek feedback from participants and external interested parties. Best practices and actions to address challenges are documented in guidance and procedures to improve effectiveness of collaborative projects including the MOC collaboration desk guide).

II.1.3. Challenges faced/areas for improvement

The challenges below were identified by NRC and CNSC management and the staff working on the collaborative projects through a qualitative email and verbal survey. The industry also shared feedback through the meetings of senior management from NRC, CNSC, GE Hitachi Nuclear Energy, Ontario Power Generation and Tennessee Valley Authority.

(a) Lifetime collaboration in the strategic plan

Consensus among staff, management, and industry identified that the NRC and CNSC need to consider how to continue the collaboration throughout the entire lifetime of plants.

Action: Include in the MOC strategic plan issues to be addressed in the future as part of lifetime collaboration, such as construction and operation. Determine if any changes to the MOC processes are needed to collaborate during these phases.

(b) Work plan implementation

(i) Misaligned submissions to regulatory bodies by vendors can create inefficiencies and delay reviews.

Action: Increase communication and alignment through multi-party meetings that include utilities, vendors, regulatory bodies and other interested parties for a specific design prior to submission to ensure that vendors provide the same information to each regulatory body at the same time. Reinforce the role of independent sovereign regulatory bodies and expectations from utilities and vendors to facilitate reviews.

(ii) Differences in regulatory requirements can present challenges to reviews when a vendor proposes an alternative approach.

Action: Consider developing guidance and training for staff on assessing alternative approaches.

(c) Communications

(i) Each regulatory body maintains a separate repository of MOC documents (e.g. meeting minutes, guidance and process documents, work plans). Having a common place to store all documents will assist in knowledge management; providing guidance and training to staff working on collaborative projects makes it easier to track projects. The current method of sharing information (Box software) is only used to transmit and does not store documents long term.

Action: The subcommittee will explore other options for storing documents or determine if the use of Box software can be modified to allow this.

(ii) The subcommittee needs to develop a multi-year communications plan to better share the outputs of its collaboration and work plans.

Action: The Strategic Working Group will develop an evergreen communications plan to share the results of its collaboration with a broad audience.

(d) Issuing joint products

Products need to speak with one voice to increase their value and clarity on issue resolution. Joint reports need to include clear conclusions where appropriate, to provide clear guidance to vendors.

Action: The NRC and CNSC will improve their approach to developing joint reports. The subcommittee will consider developing standard language for report templates and guidance for contributors.

(e) Collaboration beyond joint products

Joint products serve as an important resource to future applicants and the international regulatory community. However, CNSC and NRC staff are learning to explore further

opportunities to collaborate beyond joint products to increase agility and harmonization.

Action: Document other activities which demonstrate collaboration such as hours saved by leveraging another regulatory body's review, and meeting logs showing staff effort toward a topic and the benefit to each regulatory body.

II.2. COOPERATION BETWEEN THE UNITED ARAB EMIRATES AND THE REPUBLIC OF KOREA

Within the context of the regulatory review of the application to construct Barakah NPP Units 1 and 2 in the United Arab Emirates, the regulatory body, the Federal Authority for Nuclear Regulation (FANR) considered the review carried out by the Korea Institute of Nuclear Safety as part of the licensing of the reference plant in the Republic of Korea.

Based on this cooperation, the following areas of good practice were identified by FANR during a review of the lessons learned from the construction licence application review project covering the views and opinions of 39 technical experts working on the project:

- Being managed as a project was key to success;
- Having different TSO experts to cover specific parts of the preliminary safety analysis report review was essential;
- Breaking the project down into discrete work packages improved the overall efficiency and effectiveness of the project;
- Leveraging from the regulatory review of the Korea Institute of Nuclear Safety and breaking the preliminary safety analysis report down into 223 safety evaluation reports and assigning each report as either Cat 1 or Cat 2 (consistent with the categories type 1 and type 2 outlined in subsection 4.5.1) saved time by minimizing number of requests for additional information;
- Having a secondee from the Korea Institute of Nuclear Safety helped facilitate the communication with the Korea Institute of Nuclear Safety;
- Having a SharePoint site enabled good management and control of all the documents and ensured access for all reviewers from FANR and the TSOs;
- Having standard safety evaluation report templates helped harmonize the final document when fully integrated into one report.

FANR also identified several challenges faced throughout the construction licence application review project. These included:

- Language barriers and misunderstandings which significantly slowed the closing of requests for additional information (translation from Korean to English was sometimes a slow process);
- Sharing of export control documents that FANR requested to be reviewed by TSOs delayed the review in some areas – this was overcome by having government to government agreements in place;
- Different regulatory requirements between the United Arab Emirates and the Republic of Korea made it more difficult to utilise the preliminary safety analysis report review.

As the project progressed, all the above challenges were overcome by utilizing a comprehensive risk register which was regularly reviewed and updated throughout the project.

II.3. THE NUWARD JOINT EARLY REVIEW

A detailed description of NUWARD collaboration can be found in the NUWARD SMR Joint Early Review Closure Report [10], which was jointly prepared by the regulatory bodies of France (ASN), Finland (STUK) and the Czech Republic (SÚJB), and published in 2023.

The main lessons learned from the first phase of the Joint Early Review were summarized in two public reports published in 2023. The first one [10] was developed by the aforementioned regulatory bodies and the second one [27] by NUWARD.

A second phase of the Joint Early Review was initiated in 2023 with the addition of the regulatory bodies of the Kingdom of Netherlands, Poland and Sweden. It is anticipated that this second phase will also be concluded with the release of a public report providing the main conclusions and lessons learned.

II.4. COOPERATION BETWEEN THE RUSSIAN FEDERATION AND BELARUS

The Russian Federation and Belarus established cooperation in 2011 in relation to the construction in Belarus of an NPP with two Generation 3+ VVER-1200 reactor units, each with an electrical capacity of 1200 MW. The cooperation included the following aspects:

- TSOs in both countries were responsible for conducting independent evaluations for regulatory bodies;
- There were bilateral discussions and agreement of the regulatory reference framework for the review;
- There were bilateral cooperation agreements and memoranda of understanding as well as bilateral discussions between TSOs on the review scope;
- The Federal Environmental, Industrial and Nuclear Supervision Service in the Russian Federation (Rostechnadzor) was responsible for transfer of experience in safety regulation and decision making;
- The Department of Nuclear and Radiation Safety in Belarus (Gosatomnadzor) was responsible for leveraging of the TSO review results and regulatory decision making.

Rostechnadzor and Gosatomnadzor interacted actively in the field of safety regulation. The bilateral cooperation also included transfer of Rostechnadzor experience in licensing of nuclear facilities and activities in the field of peaceful use of atomic energy and conducting a safety review of the VVER-1200.

At the different stages in Belarus's NPP licensing procedure and prior to its decision making, Gosatomnadzor involved its own TSO and authorized experts to conduct safety reviews.

As this was its first experience of reviewing a safety analysis report and other documents justifying safety for a licensing process, Gosatomnadzor authorized collaboration between its own TSO and the TSO of Rostechnadzor (Scientific and Engineering Centre for Nuclear and Radiation Safety (SEC NRS)). SEC NRS had been carrying out independent safety reviews on different safety related topical issues specified by Gosatomnadzor (based on the proposals of its own TSO). SEC NRS was chosen since it has extensive experience in carrying out safety reviews of a similar type of reactors being successfully operated in the Russian Federation.

For the independent safety review by SEC NRS, the following tasks and criteria were agreed on a bilateral basis):

— Compliance assessment of design, engineering and technological solutions with the requirements of safety rules and regulations in the field of atomic energy use (Russian Federation regulatory documents), the provisions of the IAEA and provisions of other international organizations in the field of the use of atomic energy and ionizing radiation sources (e.g. International Commission on Radiological Protection);
— Assessment of the completeness of technical and organizational measures to ensure safety during operation of the NPP;
— Assessment of quality assurance measures for compliance with the relevant safety requirements;
— Determination of the completeness, sufficiency and validity of organizational and technical approaches (solutions) aimed at ensuring that the limits and conditions of NPP safe operation do not exceed the established dose limits and the permissible levels of exposure of personnel and the public, as well as radiation effects on the environment;
— Preparation of unambiguous conclusions on the achievement of nuclear and radiation safety levels established by safety regulations in the context of each thematic issue of the review, as well as recommendations and proposals on ensuring nuclear and radiation safety during future NPP operation.

In the course of the safety reviews, the TSOs of Belarus and the Russian Federation held meetings with the NPP vendor (design organizations) to obtain clarifications regarding questions raised during reviews.

The NPP vendor also provided the Belarus TSO with results of the review made by the Russian Federation TSO for consideration during its own review.

All safety review results were discussed at several consultancy meetings attended by the experts of Gosatomnadzor, Rostechnadzor and both TSOs.

II.4.1. Areas of good practice

The cooperation approaches applied by the regulatory bodies of Belarus and the Russian Federation and the experience of conducting safety reviews by the TSOs of Belarus and the Russian Federation may be of interest to other States that have insufficient national experience in nuclear and radiation safety regulation.

The transfer of lessons learned from a more experienced to a less experienced regulatory body can be essential in establishing an effective nuclear and radiation safety regulatory framework. It is most effective if this transfer is done in real time either by sending specific questions or by holding special seminars and discussions. It is for this reason that scientific visits, technical meetings and training courses were arranged in the framework of cooperation activities between Rostechnadzor and Gosatomnadzor.

Training courses on safety regulation were organized for Gosatomnadzor personnel, including courses on rulemaking, safety requirements (including regulatory requirements and international guidance), regulatory decision making, inspections of nuclear facilities, conduct of safety reviews, application of computer software and other main activities of regulatory bodies and their TSOs. At the request of Gosatomnadzor several special technical meetings on some of the most interesting areas were also organized in accordance with the bilateral agreement.

The use of licensing approaches and a regulatory framework similar to those in the country of the NPP vendor can be helpful. Generally, the regulatory framework of the recipient country at the beginning of the nuclear technology implementation is imperfect and might contain some gaps. Such gaps can be mitigated by the vendor's experience with the national licensing process and requirements, even in the absence of relevant requirements in the recipient country's regulatory framework in the early stages of the project.

The usage of international requirements, such as the IAEA's General and Specific Safety Requirements, in addition to a national framework, could be useful for ensuring the quality of the review during leveraging and regulatory decision making.

The provision of support from a more experienced regulatory body with TSO involvement throughout the licensing process allows for the transfer of experience by demonstrating the practical application of regulatory approaches, and leads to a significant improvement in the understanding of personnel in the recipient regulatory body.

II.4.2. Challenges faced

At the time of the licensing procedure, there were no internationally agreed approaches to conducting safety reviews involving foreign regulatory authorities and TSOs. Therefore, it took considerable time to develop approaches to conducting such a review in the case of cooperation between the Russian Federation and Belarus. In particular, a significant number of issues arose concerning the roles and areas of responsibility of the participating organizations, both on the part of the regulatory bodies and on the part of the vendor and its design organizations.

All the issues that arose were resolved during discussions with all interested parties and stated in agreements and contracts. Issues of responsibility for safety were resolved based on the basic principles established in SF-1 [3] and the requirements established in GSR Part 1 (Rev. 1) [7].

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ABBREVIATIONS

CNSC	Canadian Nuclear Safety Commission (Canada)
DIO	design information owner
FANR	Federal Authority for Nuclear Regulation (United Arab Emirates)
MDEP	multinational design evaluation programme
MOC	memorandum of cooperation
NEA	Nuclear Energy Agency
NHSI	Nuclear Harmonization and Standardization Initiative
NPP	nuclear power plant
OECD	Organisation for Economic Co-operation and Development
SMR	small modular reactor
TSO	technical support organization
NRC	United States Nuclear Regulatory Commission (United States)

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