A Framework for International Regulatory Efficiency to Accelerate Nuclear Deployment

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Cover image: Barakah nuclear power plant units 1 and 2 (photo courtesy Emirates Nuclear Energy Cooperation)

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World Nuclear Association is the international organization that represents the global nuclear industry. Its mission is to promote a wider understanding of nuclear energy among key international influencers by producing authoritative information, developing common industry positions, and contributing to the energy debate.

The Cooperation in Reactor Design Evaluation and Licensing (CORDEL) Working Group of World Nuclear Association was created in January 2007 with the mission of establishing international standardization of individual reactor designs and harmonization of approaches to licensing. CORDEL activities cover a wide range of technical areas, while maintaining close cooperation with the OECD Nuclear Energy Agency, the International Atomic Energy Agency, and standards developing organizations (SDOs), in pursuit of the CORDEL goals.

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Acronyms

CNA	Canadian Nuclear Association
CORDEL	Cooperation in Reactor Design Evaluation and Licensing
DBA	Design Basis Accidents
DEC	Design Extension Conditions
DiD	Defence-in-depth
EASA	European Union Aviation Safety Agency
ECOSOC	Economic and Social Council of the United Nations
EPRI	Electric Power Research Institute
EPZ	Emergency Planning Zone
EU	European Union
FAA	Federal Aviation Administration
FOAK	First-of-a-kind
IAEA	International Atomic Energy Agency
IATA	International Air Transport Association
ICAO	International Civil Aviation Organization
ICH	International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
IMO	International Maritime Organization
INRA	International Nuclear Regulators Association
IPCC	Intergovernmental Panel on Climate Change
MDEP	Multi-national Design Evaluation Programme
MoC	Memorandum of Cooperation
NEA	Nuclear Energy Agency
NEI	Nuclear Energy Institute
NHSI	Nuclear Harmonization and Standardization Initiative
NOAK	Nth-of-a-kind
OECD	Organization for Economic Cooperation and Development
SARPs	Standards and Recommended Practices
SMR RF	IAEA SMR Regulators' Forum
SMR	Small Modular Reactor
UAE	United Arab Emirates
UNECE	United Nations Economic Commission for Europe
UPU	Universal Postal Union
WANO	World Association of Nuclear Operators
WENRA	Western European Nuclear Regulators Association

Executive summary

A new approach that defines and drives efficient international regulatory design review activities is required to enable a rapid increase in the production of nuclear energy to support increasingly urgent targets for global climate change mitigation and energy security. The success of the required ramp-up in clean and secure nuclear energy relies on the large-scale deployment of a fleet of standardized designs that are acceptable in multiple countries around the world. Such deployment relies on efficient project reviews, approvals, and licensing to achieve economies of scale across the supply chain and into operation, ultimately increasing the certainty in project reliability, deployment costs and schedules, while maintaining safety.

This paper builds upon previous work by the, Canadian Nuclear Association (CNA), the US Nuclear Energy Institute (NEI), and the World Nuclear Association Cooperation in Reactor Design Evaluation and Licensing (CORDEL) Working Group that explored the potential for international licensing of standard reactor designs and draws on lessons from previous harmonization activities and examples from other sectors, including international transport of nuclear materials and civil aviation.

The paper examines the potential to accelerate standardized reactor deployment through increased cooperation between national regulatory authorities and developing frameworks that involve all stakeholders.

This would involve a framework to gradually reach a high level of efficiency of regulatory design review and acceptance, primarily through:

The ability of one regulator to leverage all, or part, of the outcomes from reviews undertaken by other regulators to support their own regulatory process.

Based on the challenges associated with multiple diverse stakeholders, a review of other regulated industries, and previous and ongoing harmonization initiatives, this paper is recommending the following:

1. Increased support from governments and industry to facilitate increased collaborative regulatory design review activities including the enablement of groups of regulators working on specific designs.

2. Stakeholders to undertake activities to facilitate increased collaborative regulatory design reviews through a stepwise phased approach, which would allow near-term benefits through “low risk activities” while building a foundation for greater benefits that need a longer timeframe.

3. Increased coordination of existing harmonization activities to accelerate the progress through the stepwise phased approach and make most effective use of the resources available, through:
    - Developing a common vision for success and objectives.
    - Ensuring the involvement of key stakeholders from the outset.
    - Generating integrated project plans between different stakeholders.
    - Developing access to suitable resources over the long term.

This paper recognizes that while significant enhancements to streamline the reviews of a design already approved by another country are possible, there are differences in national legal and societal factors that may continue to require additional country-specific assessments.

A model is presented for gradually increasing collaboration between key stakeholders that is supported by multilateral agreements between technology vendors, regulators, and operators. Design review information would be exchanged between the regulatory bodies to accelerate regulatory review activities for second or n^{th}-of-a-kind (NOAK) deployment of the same reactor technology. Examples of previous and ongoing initiatives are used to illustrate how this objective can be achieved through effective cooperation. The goal of these approaches is to minimize regulatory burden that does not enhance safety, differences in national regulatory approaches, and unnecessary duplicative reviews.

1 The need for nuclear now

A climate emergency has been declared by multiple countries around the world who are adopting net zero targets with the aim of limiting global warming to 1.5°C. Nuclear energy is the second largest source of low-carbon electricity globally, and the largest in Organization for Economic Cooperation and Development (OECD) countries. Over the past 50 years, the use of nuclear power has prevented over 70 gigatonnes of CO_2 emissions, equivalent to nearly two years' worth of global energy-related emissions.

Dispatchable power sources are the foundation of electricity grids. Not all low-carbon electricity sources reliable produce power when it is needed.

In that regard, nuclear power is widely recognized as being a necessary part of the world's future energy portfolio. The percentage of that future portfolio which will be made up by nuclear will vary from region to region, and from country to country. All studies on the subject agree – if we are to achieve our environmental and energy security targets, we will need much more nuclear power than we have today.

In September 2022, the IAEA updated its nuclear power requirement estimates [1] identifying that the contribution of nuclear to the world electricity market could more than double to about 873GWe by 2050. The World Nuclear Association Harmony programme [2] and the median Intergovernmental Panel on Climate Change (IPCC) scenario [3] both indicate that nuclear capacity needs to rise to approximately 1,250GWe by 2050 to support a realistic and just transition (note these estimates do not account for use of nuclear energy in cogeneration and thermal heat for non-electrical applications).

Notably, the need for energy security has also recently increased in urgency, as both energy prices and availability have raised significant questions about the feasibility of a just transition to net zero. Through providing a dispatchable low-carbon energy form, nuclear power can greatly benefit the energy security of many nations, while also supporting wider environmental mitigation plans.

Some countries around the world are recognizing this increased need, with reinvigorated government support in established nuclear countries such as, but not limited to, France, South Korea, the UK and the USA, as well as increasing support in embarking countries such as Poland. One estimate in the USA has determined that the lowest cost reliable clean electricity system would require an additional 300GWe from nuclear by 2050 [4] – representing a three-fold increase in US nuclear operating capacity.

While evidence exists of the need for an urgent and rapid deployment of more nuclear power, progress is slow and currently behind the targets necessary to achieve net zero or energy security ambitions. To achieve the goal of a total of 1,250GWe of nuclear generation by 2050, accounting for planned closures, a total of 1,000GWe of new nuclear capacity will be required to be added to electrical grids worldwide by 2050. This equates to 40GWe every year for the next 25 years.

To put this into context, over the last decade, the global industry has averaged approximately 6.7GWe (or approximately seven new reactors) connected to the grid every year. On the assumption that 50% of the 1,000GWe comes from Small Modular Reactors (SMRs) and the remaining 50% from GW-scale reactors, approximately twenty GW-scale reactors and seventy 300MW SMRs would need to be connected to electrical grids every year for the next 25 years – that is a total of 2,250 new nuclear reactors. Clearly a significant ramp-up in reactor deployments is needed to approach these ambitious targets.

1.1 The need for a new approach

To achieve the ambitious deployment targets discussed above, significant challenges must be overcome such as policy enablers, harmonized and efficient approaches between regulators, particularly safety assessment and reviews of reactor design, standardization of designs, development of a highly integrated supply chain, and human resource availability.

Frameworks to address these challenges are being developed in Europe under the European SMR Pre-partnership [5] and North America under the Advanced Reactor Roadmap [7].

This report focuses on efficiency in international regulatory design review activities[1], and how to transfer best practice and know-how related to such reviews from one country to another, including how to reduce the duplication of effort in regulatory reviews for national-level approvals of previously reviewed and accepted designs.

At the highest level, the design safety requirements of all countries with a civilian nuclear programme are consistent with those defined by the IAEA [6], which address the protection of people and the environment from radiation risks. Despite the high-level alignment, differences do exist between countries due the divergence in how their national approaches have developed.

The current deployment approaches of nuclear power plants, through which each deployment is essentially a new project, have led to a lack of timeliness and scalability in deployment. These approaches are not suited to providing the clean, safe, secure energy at the speed that the world needs it to support decarbonization and energy security, while also providing embarking nuclear countries the opportunity to eradicate energy poverty.

The current practice whereby each country's regulator establishes specific and often unique national requirements forces designers and licensees to support duplicative safety reviews and may result in country-specific design variations and inhibits the beneficial learning effects of NOAK projects/construction. Specific examples are detailed in World Nuclear Association report *Different Interpretations of Regulatory Requirements* [7].

Regulatory design review costs and durations vary from nation to nation as multiple factors are at play. Indicative costs have been estimated, however:

1. Fees paid to regulatory body – around USD60 million[2] per reactor per country.
2. Reactor vendor support costs – around USD180M-240 million[3] per design per country.

If four different countries review a reactor design independently, review costs of more than USD1 billion USD may result before considerations of how changes to the design will have consequential impacts on the supply chain, construction schedules, and fleet operational safety through continual improvement and experience sharing. The general trend over the last 15 years is for these costs to increase, on an inflation-adjusted basis.

It is also worth noting that in many countries, these costs are only for the regulatory design review. Additional costs and time will be required to achieve a construction and/or operating licence (possibly another 2-4 years or more) depending on the national licensing process for nuclear power plants[4]. There are also other costs throughout this process such as the cost of technology development, licensing application fees, and varying requirements on equipment qualification that further add to the overall cost for the reactor vendor and project developer.

As significant a factor as the costs of regulatory design reviews and licensing is, an even greater impediment is the impact on project schedules that current regulatory approaches pose. For GW-scale nuclear projects with average construction schedules of 6-10 years, an environmental assessment and initial licensing period in the range of 5-10 years is a significant hurdle to timely deployment. Such timescales are even more significant when considering the expected rapid deployment schedules of SMRs, with construction timelines on the order of 3 years. The current duration of design review and licensing activities essentially doubles the project deployment schedule, dramatically limiting interest from the financial community and hence hindering the ability of nuclear power to deploy quickly enough to significantly contribute to fighting climate change and delivering energy security. When reactor designs with entirely different deployment concepts, such as SMRs and micro-reactors, are considered, these design review and licensing timescales become a barrier to project initiation.

Considering the scale of the new reactor deployments needed in the next 25 years, these timescales and First-in-Country costs pose an unacceptable burden that should be reduced. Further, because differences in regulatory requirements drive design changes specific to each country, the ability of operators to compare operating experience is reduced.

A new approach is required, and the world needs it to be implemented now. However, the immediate implementation of such an approach may prove challenging in many countries. It is therefore considered that a stepwise approach would be more timely, allowing near-term benefits through "low risk activities" while building a foundation for greater benefits that need a longer timeframe.

[1] This report focuses on design review activities as it is considered an important starting point to increase regulatory cooperation – it is recognized that other aspects of licensing activities will also require increased optimization in order to take maximum value from regulatory cooperation.

[2] Represents typical fees based on multiple reactor vendor estimates and regulatory reports from US and UK. The actual cost to an applicant will depend on each country's cost recovery fee policy.

[3] Based on a ratio of 1:3-4 of regulatory fees to internal support costs.

[4] Some countries do not employ a pre-licensing step and therefore costs would be differently apportioned.

2 The vision

The long-term objective is to allow deployment of nuclear reactors measurably more efficiently than has been done in the past, while continuing to ensure the safety and security of nuclear power and the safeguarding of nuclear materials.

One of the most important factors required to support this will be minimizing the time and cost for approving a design that has already been approved by another competent regulatory authority. It is also important that embarking countries are supported through facilitating less experienced nuclear regulators and countries to benefit from the work done by a wide range of other competent authorities. These outcomes can be achieved without compromising national regulatory sovereignty.

To achieve the desired long-term objectives the following will need to be possible in relation to the regulatory design review process:

- One regulator leveraging all, or part of, the outputs from another regulator's review and incorporating them into its own review process – thus reducing the overall burden of regulatory review activities.
- Regulators collaborating to review different aspects of a new design in line with the agreed review model and criteria, incorporating the outputs from each other's review outputs into their own licensing processes.
- Regulators leveraging the resources of other regulators, and industry, to support their review processes, as far as possible.
- Newcomer country regulators acting as intelligent customers, accepting the regulatory design reviews from other nuclear regulators without the need to repeat the full analysis work, while being experienced and cognizant to regulate a reactor through its entire lifecycle.
- Suitable policy and mechanisms to enable multilateral regulatory reviews, such as funding to initiate early review activities prior to formal requests from governments.
- Industry have clarity with regard to regulators' expectations, including requirements and outputs from the design review phase. In addition, criteria to determine appropriate reactor design maturity to enter a multilateral review will be defined and well understood.

These activities will take time to develop and mature, and will require a framework to gradually reach a high level of efficiency of regulatory design review and acceptance.

To reach the desired high level of efficiency, it will be critical that the following four main stakeholder groups work together as they all have a vital role to play:

- Governments
  - Long-term energy policy that incorporates nuclear power and supports both industry and regulators.
  - Stable legal and market frameworks
  - Regulatory mandate to allow regulators to leverage outcomes from other regulators reviews without being perceived as not undertaking a full review,
  - Funding for resources required to support both increases in submissions and international collaborative efforts.

- Regulators
  - Processes and methodologies for joint review activities
  - Processes and methodologies for leveraging existing reviews
  - Updated regulatory frameworks
  - Continuous efforts towards the development of common safety objectives, requirements, and expectations.

- Industry (reactor vendors and licensees)
  - Ensure that their reactor designs are sufficiently mature so that the design substantiations submitted to national regulators are complete, enabling efficient application of the regulatory assessment process
  - Identify opportunities to enable regulators to start review activities as early as possible
  - Provide timely design submissions to national regulatory bodies to aid regulatory collaboration
  - Proactively gain a comprehensive understanding of national legal and regulatory frameworks
  - Support upskilling of regulators in new technologies and designs
  - Identify opportunities to enable the supply chain to facilitate n^{th}-of-a-kind deployment models
  - Technology demonstration to develop required justification.

- International organizations
  - Support industry and regulators through timely production of relevant information and increasing awareness of the need for support to governments.
  - Coordination of both existing activities and future workstreams seeking for harmonisation and efficiency.

Regulatory groups such as the Western European Nuclear Regulators Association (WENRA) and the International Nuclear Regulators Association (INRA) have recently

confirmed their support of a more global approach to new reactor evaluation with statements [9][10] outlining the need to continue with and expand collaboration on joint assessments of new reactor designs through bilateral and multilateral agreements.

Success in increasing the efficiency of these new reactor evaluation activities is a prerequisite to increased deployment of nuclear reactors. The following are considered as indicators that significant progress towards the long-term objectives is being made:

- National regulators have sufficient resources and effective processes to support collaborative multilateral activities.
- National regulators are leveraging outcomes from the design review completed by another regulator with minimum additional effort.
- There is evidence of regulatory efficiency in terms of duration of design review activities
- Synergies among countries' regulatory frameworks increase to promote design standardization and to reduce the amount of reanalysis required by regulators of countries deploying the same technology.
- Embarking nuclear countries develop the ability to knowledgeably utilize competent authorities' review outputs to support safety case demonstration for reactor designs originally licensed in multiple different countries.
- Industry develops the ability to deploy the same standard design across multiple countries with no significant changes.
- Industry develops the ability to utilize large parts of the same supply chain across multiple countries.
- Nuclear safety, security, and safeguards are not compromised.

Achieving these objectives will not be easy and will require many stakeholders working together over an extended period. This will require a stepwise approach that maximises the benefits to stakeholders at each stage, while remaining sufficiently flexible to ensure national regulators maintain their sovereignty throughout.

To be successful, initial tangible joint actions between key stakeholders to facilitate increased cooperation will be required. The initial proposed steps in the development of this approach would be:

- Define what success looks like – possibly through a harmonization or efficiency charter
  - Long term vision
  - Mutually agreed objectives / outcomes
- Establish mechanisms to build trust between national regulators to facilitate common design reviews or mutual recognition of assessments, *e.g.* joint working, personnel exchanges *etc.*
- Increase communication and engagement between key stakeholders and dissemination of information to international organizations and governments
- Engagement with governments to support enablement of regulatory activities.

2.1 What are efficiency and harmonization?

Often when the subject of deploying standard reactor designs throughout the world is discussed, the word "harmonization" is used to describe the need in relation to regulatory requirements or codes and standards. However, there are many different ideas about what harmonization means, and so this paper introduces the term of efficiency to ensure alignment of perspectives.

Efficiency refers to the continuous improvement that is desired to be achieved through bi- and multi-lateral regulatory design review activities. This efficiency will ultimately decrease the burden on regulatory review activities, facilitate the deployment of standardized reactor designs, and increase the speed at which these reviews occur.

As introduced in more detail in Chapter 3, international or multinational approaches from other industries such as aviation [11], the pharmaceutical industry [12], and the harmonization of nuclear transport regulations [13] are often cited as good examples from which the reactor design review process could benefit learning from.

It is however worth noting that even these examples do not fully harmonize all requirements, but rather allow for reliance on the review of another competent authority's outcomes through validation and peer checking, with options to apply additional requirements if deemed necessary.

It is this form of efficiency between regulatory approaches that we seek to achieve in the review of nuclear reactor designs, and to do so we will need to increase the cooperation between regulators, from bilateral joint reviews to multinational leveraging of available reviews, including longer-term opportunities of regulators' convergence on design acceptance.

2.2 Known challenges

Nuclear reactor design evaluation is a well understood process with multiple differing stakeholders in each country. Collaboration between regulators and industry has the potential to increase this already large set of stakeholders and lead to conflicting demands. This could result in overcomplicating or adding additional steps to an already well-defined process, increasing duration and costs, rather than decreasing them.

It is also recognized that gaining widespread alignment on safety objectives, requirements, and expectations will be a difficult task. Some regulators may be concerned about how a specific safety issue is addressed, and industry may be concerned about regulatory cooperations resulting in layering of safety requirements leading to overdesign to meet highest common denominators.

Many of the new designs aiming to be deployed will have first-of-a-kind (FOAK) technological challenges, and regulators will have FOAK challenges in reviewing these new technologies – a subject discussed in detail in the World Nuclear Association publication *Design maturity and regulatory expectations for Small Modular Reactors* [14]. Adding increased collaboration with other regulators may slow the review process and achieving efficiencies in FOAK review activities may be difficult.

3 Lessons learnt from previous experience

3.1 Background

The need for increased efficiency of regulatory design reviews is not a new concept or one being addressed solely by the organizations associated with this report. There are a multitude of other regulators' cooperation initiatives that have taken place previously, and others which have been recently initiated:

- Multinational Design Evaluation Programme (MDEP)
- Western European Nuclear Regulators Association (WENRA)
- IAEA SMR Regulators' Forum (SMR RF)
- International Nuclear Regulators Association (INRA)
- CNSC and NRC Memorandum of Cooperation (MoC)
- IAEA Nuclear Harmonization and Standardization Initiative (NHSI)
- European SMR Pre-Partnership
- Joint French, Finnish and Czech Republic joint early review of NUWARD
- Canadian and Polish regulator SMR collaboration.

A review of these initiatives and those from other regulated industries (aviation, pharmaceuticals, and nuclear transport), can be seen in Appendix 1, and highlights that much can, and has, been achieved through collaborative efforts between different national regulators and industry.

3.2 Key lessons and successes

Cooperation initiatives focused on reactor design review activities

The key lessons and best practice can be categorized into 6 main areas:

- Vision
  - A clear vision with strategic goals and common objectives should be defined at an early stage in harmonization initiatives.
  - This should be complemented with concrete, measurable, and achievable outcomes.
- Resources
  - It should be ensured that suitable resources are available and can be dedicated to collaborative activities as necessary through the duration of the initiative.
- Stakeholders
  - Key stakeholders, including governments, should be included from the start of the initiative.
  - A range of regulators should be involved.
- Scope
  - It is difficult to identify real challenges or roadblocks without undertaking assessment of specific designs.
  - Selection of areas to be jointly assessed should be carefully considered and utilize expertise in regulatory and industry organizations as much as possible.
  - Joint work plans should be developed with the goal of incrementally increasing collaborative review efforts.
- Management
  - A mechanism for incorporation of guidance and outputs into national regulatory frameworks should be developed.
- Outcomes
  - Groups of regulators can collaborate and develop common positions.
  - Small groups of regulators can collaborate on the review of specific designs.
  - Smaller groups of regulators may be able to achieve greater clarity in a shorter period of time.

Lessons from other regulated industries

Appendix 1 also illustrates how other industries have achieved varying degrees of harmonization:

- Aviation industry
  - Outlines a model of how countries with initially disparate requirements can collaborate through international agreements to streamline and simplify the review process.
- Pharmaceutical industry
  - Highlights the risks of moving too slowly which results in many requirements becoming impediments to international cooperation.
  - Despite this, progress can and has been made, particularly in regional areas *e.g.* the EU. Global cooperation to ensure the COVID vaccine roll out demonstrates what can be achieved with sufficient government level support for an industry that has different regulatory approaches in different countries and regions.
- Nuclear material transport
  - Outlines the ability of international organizations to coordinate multiple regulators and country-specific interests to develop a streamlined set of requirements that facilitates the validation of the outcomes from other countries reviews.
  - Demonstrates how national sovereignty can be maintained through an international framework.

The industries discussed above and the successes they have achieved are acknowledged to operate generally in different markets with different drivers or are less complex by nature than reactor design reviews. It is also true that the collaborative activities that led to the successes in these industries typically started many decades ago with fewer stakeholders and simpler regulatory processes, yet in some cases still took decades to achieve the desired outcomes.

The opportunity nonetheless remains to learn lessons from these activities, and this report will use these lessons and those from previous initiatives to propose an approach that will drive increased cooperation between stakeholders, as well as interacting with and best utilizing the relevant aspects of ongoing activities. The aim of this approach is to facilitate and enable regulators to be able to recognize and leverage regulatory reviews from other countries, and define the roles that national governments, nuclear regulators, the nuclear industry, and international organizations will need to fulfil.

3.3 The need for coordination

Recognizing the need for increased collaboration, several multilateral regulatory review activities have recently started, namely:

- US and Canadian joint regulatory review activities for the GE-Hitachi BWRX-300 reactor design[5]
- France, Finland, and Czech Republic joint review activities for EDF's NUWARD reactor design.[6]

There are also many examples of bilateral cooperation such as those between the UAE and Korea, Russia and Bangladesh, and China and Pakistan (among others), all of which have valuable lessons and best practice to contribute towards more efficient regulatory design review approaches.

As identified in section 3.1, there is a wide range of international efforts and activities aimed at advancing towards a level of "harmonization" generally through increasing cooperation, which have all added value and made different levels of progress.

However, at times the scope of these activities has not been well aligned with each other, resulting in levels of duplication and /or gaps. In addition, these activities have generally suffered from a lack of resource, with a small pool of individuals contributing to most of them. This has helped facilitate communication between the activities, but greater efforts in coordinating this communication to align on objectives and scope is required if we are to achieve the outcomes set out in this report.

Building upon the lessons identified in section 3.2 specifically around vision, resources, and scope, it is considered that suitable coordination of these activities at an international level, to the extent possible, would reduce the timescales required to achieve the objectives set out in Chapter 2.

While not specifically required to achieve the actions defined in section 2, coordination of activities across organizations could enhance these actions to include:

- Development of a "harmonization charter" that sets out the objectives which key stakeholders agree to. Some progress has been made towards this with the statements from WENRA [9] and INRA [10] relating to SMR cooperation, but further involvement and alignment with other stakeholders is necessary.
- Development of a coordination mechanism that would:
  - Develop and provide input to a lessons learnt/best practice repository.
  - Identify gaps in existing activities.
  - Joint industry and regulatory activities to identify next steps such as:
    - Identify design/safety areas for specific focus, develop and drive an implementation plan to foster greater harmonization across these areas of focus.
    - Build upon work already carried out in assessing equivalency of codes and standards, identify areas of codes and standards to be focused on to allow increased multi-national use. For example, there may be aspects of certain codes used for light water reactors, that if demonstrated to be equivalent, or the differences better understood, could support aspects of regulatory reviews.
  - Identification of who is best placed to do what.
- Develop integrated work plans based on gaps and next steps involving key stakeholders.

A level of coordination and collaboration does exist between ongoing activities, and while not necessary to undertake the stepwise phased approach outlined in the section 4 of this report, an increased level of coordination would accelerate the progress through this approach while making most effective use of the resources available.

[5] Agreements also exist between CNSC and the UK and Polish regulators for collaboration on SMR design reviews.

[6] Countries such as the Netherlands and Sweden have expressed interest in joining these review activities.

4 A stepwise approach

In one of its first publications [15], CORDEL introduced the concept of an integrated stepwise approach to standardization with three distinct phases:

- Phase 1: Share design assessment.
- Phase 2: Validate and accept design approval.
- Phase 3: Issue international design certification.

Building upon the lessons and best practice outlined in section 3, the need to maintain national regulatory sovereignty, and the fact that other industries have taken many decades to achieve much greater global alignment in terms of regulatory approvals and yet have still not achieved the issuance of an international design certification, it would appear that setting a similar target of an international regulator or design certification for reactor design evaluation is an unrealistic goal, at least in the short term.

The concept of the stepwise phased approach is, however, in line with many of the best practices outlined in section 3 (*e.g.* starting with small groups of regulators, incrementally increasing collaborative review efforts). In terms of increasing efficiency in regulatory reviews, the three phases would therefore be better defined as:

- Phase 1: Technical cooperation and recognition
- Phase 2: Safety recognition with increased efficiency
- Phase 3: Full efficiency (which remains aspirational)

The goals, key activities, inputs from industry and desired outcomes for each of these three phases is outlined in Table 1. This is also diagrammatically represented in Figure 1.

The proposed three-phase framework could be further broken down into multiple steps when being implemented by cooperating regulators, and will have differing routes depending on the types of regulators involved, *i.e.* cooperation between regulators with experience of multiple technologies will be different than that between a regulator with one technology and an aspiring country regulator.

Previous experience has also shown that the approach should initially focus on bilateral or several small groups of regulators that have a common interest in reviewing the same design.

In Phase 1 it is therefore expected that activities could take place within a framework of bilateral or multilateral regulatory cooperation between regulators reviewing the same design, with opportunities for immediate, beneficial, "low risk" outcomes. Some such examples of these initial frameworks exist today:

- Bilateral joint early design review activities of the Canadian and US regulators for the BWRX-300.
- Multilateral early design review activities of between France, Finland, and the Czech Republic for the NUWARD design.
- Multiple examples of regulators supporting other country regulators, *e.g.* China supporting Pakistan, and Russia supporting Bangladesh, among others.

As these activities have already started with their own objectives and goals, it is important that the early lessons and best practices from these initiatives be understood at the earliest possible opportunity, to benefit future similar activities and understand how to effectively move into Phase 2.

All regulatory design certification or pre-licensing activities have different scopes and depths. The objective of Phase 2 is not to define or agree on a process, rather Phase 2 will aim to develop collaborative activities in such a way that the regulators know what they can use from the outcomes of another regulatory process (and vice versa) to support their own review activities. It is envisaged that this would lead towards a pathway that could be used by regulators to translate outputs from one regulatory review process into their own review process (like a "Rosetta stone"). The technical cooperation and collaborative efforts of small groups of regulators developed in Phase 1 would be the starting point for Phase 2 and would enable the increased collaboration required and the expansion of the group to other regulators interested in the review of a specific design.

One such example of when a similar process has occurred in regulatory design review is through the bilateral agreement between the UAE and Korea. While this activity did not get to the levels of efficiency anticipated during Phase 2, its lessons and those from the ongoing multilateral activities could be a useful starting point for Phase 2. This may also be a useful reference for considering the approach to support embarking countries. However, it should be recognized that the UAE approach may not be practical in all embarking countries due to the associated cost and resource availability considerations.

It may also be useful during Phase 2 to re-examine the certification approach utilized effectively within the aviation industry as an approach that could be used to efficiently validate the same design in multiple countries, while maintaining sovereign responsibility. Further discussion on this can be found in Appendix 1.

Phase 3 will build upon the lessons, best practices, and approaches developed during Phase 2 with the aim of developing greater alignment between national regulators on safety objectives, requirements, and expectations and which would allow one regulator to validate the outcomes of another regulator's design reviews.

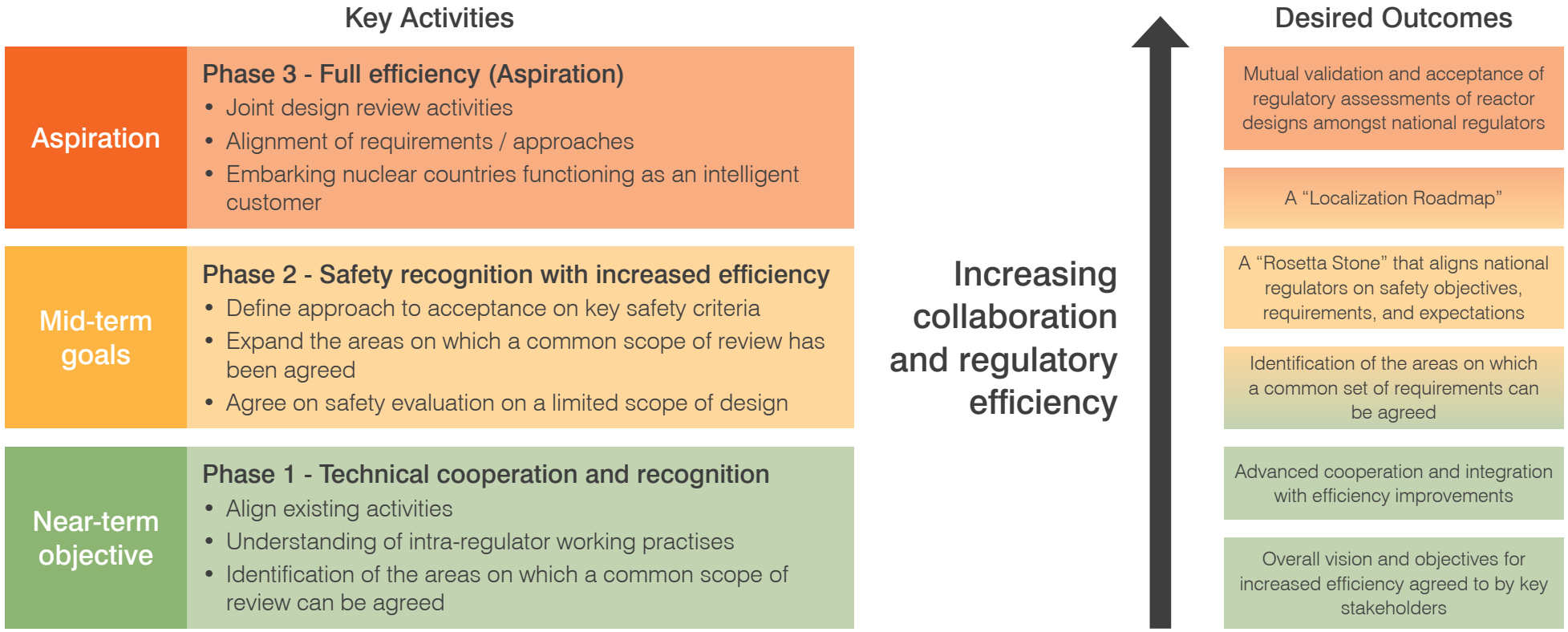

Figure 1. Three-phase approach to increasing collaboration and regulatory efficiency

Table 1. Three-phase approach to increase collaboration and regulatory efficiency

	Goal	Key activities	Industry input	Government support	Desired outcomes
Phase 1: Technical cooperation and recognition	Build upon the existing collaborative relationships and multilateral design assessments between groups of national regulators to identify opportunities to increase efficiency. Increase acceptance of work performed by other regulators and minimize the need for duplicative reviews.	Share technical insights on designs in each country. Perform joint technical reviews and issue joint documents of results. Build confidence in the competency of peers. Understand similarities and differences in regulatory frameworks. Identification of the areas on which a common scope of review can be agreed.	Timely and high-quality submissions to regulators. Identify opportunities to enable early regulatory review activities. Encourage regulators and governments to support joint regulatory review activities. Design specific training materials to upskill regulators in new designs. Input to goals and objectives. Coordinated input to international fora regarding regulatory streamlining.	Adequate funding to support regulatory resource engaging in structured collaborative activities with other regulators.	Overall vision and objectives for increased efficiency in design reviews agreed to by all stakeholders. Advanced cooperation and integration leading to increased efficiency such as regulators using design and analysis output without re-confirmation that it is correct.

	Goal	Key activities	Industry input	Government support	Desired outcomes
Phase 2: Safety recognition with increased efficiency	Further enhance relationships between groups of regulators/ owner operators/vendors. Increased convergence on acceptance criteria and safety demonstration approaches. Expand the numbers of regulators involved in joint design review activities. Propose an approach that can be used by emerging countries.	Expand the areas on which a common scope of review has been agreed. Accept part of certain peers' validation that a design meets safety objectives, and requirements. Agree on safety evaluation on a limited scope of design (*e.g.* Topical Report) where requirements can be demonstrated to be the same across the groups of regulators involved in the process. Development of an approach to support embarking nuclear countries with efficient adoption of reactor designs.	Identify major showstoppers in the joint design review activities between regulatory frameworks for specific technology. Undertake targeted codes and standards equivalency activities to support regulatory review outcomes or known challenges. Share experience between reactor vendors and licensees to allow for increased efficiency in document production when producing safety case. Generate increased support from governments to increase extent of and participation in collaborative efforts, including increased enablement of regulatory review activities.	Removal of any existing legislative barriers which may prevent national regulators adopting outcomes form other reviews. Active support in resolving information sharing challenges such as export control and security. Development of a mandate for regulators to allow them to leverage other regulatory outputs.	Identification of the areas on which a common set of safety objectives and requirements can be agreed. A defined pathway that aligns national regulators on safety objectives, requirements, and expectations to allow the translation of regulatory review outcomes from one country to another (like a "Rosetta Stone") A national approach (or "localization roadmap") which defines the scope of design that needs reviewed country by country to confirm compliance with different requirements, including cases studies on how this would be done.

	Goal	Key activities	Industry input	Government support	Desired outcomes
Phase 3: Full efficiency (aspirational)	Alignment of efficient regulatory frameworks (regulations, laws, requirements, and expectations) that do not layer each country's existing requirements. Full efficiency in approval (not including site-specific aspects) from other regulatory reviews. Implementation of a plan to support embarking nuclear countries.	Joint design review activities with clear examples of challenges and proposed mitigation. Alignment of requirements/ approaches such that a nuclear country can leverage the review of another nuclear country's regulator to support their own licensing process – with clear examples of challenges and proposed mitigation. Embarking nuclear countries functioning as an intelligent customer to leverage the review of another nuclear country's regulator in support of their own licensing process – with clear examples of challenges and proposed mitigation.	Ongoing focused activities on codes and standards comparison to increase level of regulatory review efficiency. Develop mechanisms to maintain and share design knowledge (per reactor design). Design specific training materials to support upskilling embarking countries' regulators .	Continued support through funding and addressing legislative challenges. Amending regulatory mandate as necessary to support increased use of other regulatory reviews.	Mutual validation and acceptance (reciprocity) of regulatory assessments of reactor designs amongst national regulators. Multiple pathways to mutual validation developed and being actively used by a wide range of countries including established nuclear countries, re-embarking nuclear countries, and embarking nuclear countries.

5 Conclusions and recommendations

To achieve the ambitious nuclear deployment targets required to support climate and energy security goals, some significant challenges must be overcome. These challenges include policy enablers, harmonized and efficient approaches from and between regulators, particularly safety assessment and reviews of reactor design, standardization of designs, development of a highly integrated supply chain, and human resource availability. The scale of this challenge demands a new approach.

Considering the scale and speed of new reactor deployments needed in the next 25 years, we need to find an approach that will minimize the time and cost for approving reactor designs through taking credit for work done by other competent regulatory authorities.

Given the complexity of the differences in regulations and standards, including technical, human, and cultural challenges, and how difficult this makes convergence of the requirements, this paper is proposing a stepwise framework that builds upon the efforts of small groups of regulators, and industry, jointly working on the review of specific reactor designs, to increase efficiency in the design reviews to:

Facilitate the ability of one regulator to leverage all, or part, of the outcomes from reviews undertaken by other regulators to support their own regulatory process.

Maximizing benefits from this approach will require long-term support from both governments and international organizations, to allow regulators to credit work done by others, and to ensure that it supports embarking countries.

The need for increased efficiency of regulatory design reviews is not a new concept or one that is being addressed solely by the organizations associated with this report. A multitude of other initiatives have taken place previously such as the Multi-national Design Evaluation Programmme (MDEP, and others have been recently initiated such as the IAEA's NHSI.

These initiatives and others, including from other industries, have demonstrated that there is much that can be, and has, been achieved through collaborative efforts between different regulators and with industry. What is clear from other industries and ongoing harmonization activities is that support from governments and early alignment among key stakeholders are important prerequisites for success.

It has also been demonstrated through previous activities that working with large groups of stakeholders makes alignment of requirements increasingly difficult, and that working generically on design safety issues makes it difficult to identify the real challenges to joint design reviews.

It is recommended that the following actions are taken:

1. Increased support from governments, regulators, and industry to facilitate increased collaborative regulatory design review activities including the **enablement of groups of regulators working on specific designs**.

2. Stakeholders to undertake activities to facilitate increased collaborative regulatory design reviews through **a stepwise phased approach**, which would allow near-term benefits through "low risk activities" while building a foundation for greater benefits that need a longer timeframe.

3. **Increase coordination of existing harmonization activities** to accelerate progress through the stepwise phased approach and make most effective use of the resources available, through:
    - Developing a common vision for success and objectives
    - Ensuring the involvement of key stakeholders from the outset
    - Generating integrated project plans between different stakeholders
    - Developing access to suitable resources over the long term.

It has been demonstrated from other regulated industries such as aviation and pharmaceuticals that progress can be made if appropriate multilateral agreements can be developed, and suitable governmental and policy support are put in place to enable these agreements to develop.

The collaboration efforts will require additional resources above and beyond what each national regulator already needs to support short-term regulatory activities in their own countries. The aim of committing resources and efforts to these international collaborative efforts now is to support increased export markets and facilitate national regulators being able in future to carry out more reviews more efficiently.

Achieving the environmental targets and energy security goals required by 2050, or sooner, will require an innovative approach. This approach will require all of us to work together and agree on the strategies required to enable much faster widespread deployment of nuclear power.

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Appendix

Inspiration from other regulated sectors and best practice from previous harmonization activities

Other regulated industries

The nuclear industry is not the only sector in which safety is mission-critical and in which licensing and regulations are an indelible part of the picture. In several other sectors, international alignment on regulatory requirements has progressed much further than in the nuclear power industry, namely aviation, pharmaceuticals, and nuclear material transport. The challenge of licensing emerging and innovative technologies in these sectors has been studied in many reports and workshops such as an OECD NEA Workshop in 2020 [16].

Aviation

Building on the CORDEL aviation report [11], it is broadly understood that both passenger and freight aircraft are allowed to travel and bring their passengers and goods relatively freely between essentially any country in the world. Does this mean there is a complete international harmonization of requirements, and can this be used as a model for nuclear reactors? In fact, the harmonization of aircraft regulatory requirements is not complete, and is complicated – but it works, in large part (recognizing that certain tragic accidents have occurred and there are identified opportunities for improvements in aircraft safety).

The International Civil Aviation Organization (ICAO), which has 193 member states, operates extensive and multiple safety programmes and other cooperative activities. ICAO is an agency of the UN established in 1944 (through the Chicago Convention). Through participation of contracting states, ICAO develops Standards and Recommended Practices (SARPs) to cover all aspects of aviation including safety, which are annexed to the Convention. By signing onto this Convention, states agree that adopted standards will be implemented in their territories and undertake to achieve the highest practical degree of uniformity in regulation and operating procedures in relation to aircraft, personnel, airways, and other services[7].

Even in the airline industry, the route to the standardization achieved to date has not always been smooth. National safety authorities recognized that differences continued to exist between nations, driving manufacturers to design different versions of their planes for different countries of use.

To address this, the European Union established mechanisms for mandatory common practices. Some national regulatory functions have been ceded to supra-national agencies such as the European Union Aviation Safety Agency (EASA), to ensure a high and uniform level of safety in civil aviation by the adoption of common safety rules and measures in line with ICAO standards and recommended practices. Below that, national regulatory arrangements and requirements may be established by designated State authorities, which are expected to comply with requirements established at global and regional levels.

In North America, US airline regulation is led by the Federal Aviation Administration (FAA) along with several other agencies, while in Canada, the lead agencies are Transport Canada and the Canadian Transportation Agency; these agencies ensure conformance to national and international standards. Regulatory modernization processes are periodically undertaken (*e.g.* in 2012 in Canada) to respond to evolving challenges and opportunities.

[7] More information can be found for those interested at Skybrary.aero and many other sources.

Many countries have established methods for regulatory approval or certification of imported aircraft and other aeronautical products. The certification of an imported product is normally carried out through the assessment of the type certification performed in the exporting state by the authority of the importing state. The aim of this assessment is to ensure that the imported product meets a level of safety equivalent to that provided by the applicable laws, regulations and requirements that would be effective for a similar product in the importing state. The result of this assessment is type certificate validation. Once the type certificate is validated, the national authority in the importing country may issue each individual aircraft with a certificate of airworthiness.

To simplify the validation process, many states have implemented bilateral agreements with other countries, supported by implementing procedures based on a high degree of mutual confidence in the technical competence and regulatory capacity of the exporting authority.

The methods used by the national civil aviation authorities in this area offer sound principles for greater regulatory cooperation in the nuclear field.

Today, a high degree of commonality has also been achieved in national technical requirements for aircraft and aeronautical products such as engines, propellors, instruments, and other components. For example, the Canadian Department of Transport has taken the approach of basing all its regulations for transport category aircraft on the corresponding US Federal Aviation Administration regulations with national variations as needed [17].

Despite this, it is recognized that collaboration must continue for aircraft safety and regulation (as also done for nuclear power). As a result, work continues to be ongoing on international regulatory harmonization, *e.g.* between Canada and US through an Action Plan, and participation at the ICAO where the participating countries work to develop better and more harmonized security practices.

Another example of regulatory cooperation and alignment in the aircraft industry is in airline liability. The International Air Transport Association (IATA) has Safety Audit programmes, somewhat like those of the World Association of Nuclear Operators (WANO). The Montreal Convention (1999) establishes airline liability, unifying all the different international treaty regimes that had developed haphazardly since 1929. To date something like 137 of 191 contracting states are Parties to it.

In terms of aircraft design and safety, the US had reciprocal bilateral safety agreements with 48 countries as of 2014.

Pharmaceuticals

Another example for potential consideration of applicability of approach to nuclear, is efficiency in the pharmaceutical industry. A preliminary review of this industry shows that, while some progress has been made on alignment of regulatory requirements and mutual acceptance of regulatory approvals, this has been slow.

Pharmaceuticals are amongst the most highly regulated of any consumer products, and a highly globalized industry exists with over 50% of sales outside the country of origin. Until the last 20 years, pharma regulation was virtually entirely national, with separate tests and applications and distinctive criteria applied for each national market. However, over the last 30 years this has started to evolve. Arguments have been made that by releasing some national sovereignty, the effectiveness and efficiency of government regulation has in fact improved.

Harmonization in pharma regulatory requirements was pioneered by the European Commission in the 1970s as Europe moved towards a single market for pharmaceuticals. Some degree of success eventually led to discussions beyond Europe - notably with the USA and Japan - on harmonization, and establishment of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH).

The ICH brings together the regulatory authorities and pharma industry to discuss scientific and technical aspects of pharma and develop ICH guidelines. From its inception in 1990, ICH currently has 20 members with 35 observers.

Part of the driver of the need for moving towards common regulation was the immense cost and thousands of regulator employees duplicating efforts. Prior to regulatory alignment efforts, the speed of regulatory approvals varied across Europe by a factor of five. Accessibility to certain drugs (*e.g.* to combat HIV, approved in the European Union (EU) at that time but not then in the US) was one of the drivers in the US. The EU first, in the mid-1970s, tried an intermediate approach of a "multi-state" application with strict time limits (4 months to review a submission already approved by another state) but this was not actually applied in practice. It then moved to a "Centralized Procedure" and pooled scientific expertise to create an EU-wide consensus on certain key regulatory focus areas. Progressively, over years, the EU pharma regulation then became more and more integrated and centralized, and also became faster. In addition, the process evolved such that once approved by one EU nation, approval must follow in other states rapidly or be referred for binding arbitration.

Some observers may point to the geographic and regional differences in locations for nuclear power deployment that require localization studies and reviews, unlike pharma. In fact, there is a parallel: in the early days of harmonization between the EU, US and Japan, Japanese concerns had to be managed about potential racial differences leading to different toxicity reactions to the same dose of drugs.

Nuclear Material Transport

A full review of the evolution of harmonized international regulations for the transport of nuclear materials, and potential lessons to be drawn for international harmonization of reactor design and approaches to licensing, appears in the World Nuclear Association report "Harmonization of Reactor Design Evaluation and Licensing: Lessons learnt from transport" [13].

The harmonization and standardization of the regulations for the transport of radioactive material involved three steps: the development of an international model for the regulations; the adoption of these regulations into the instruments of international organizations; and their incorporation into national regulations.

The need for regulations governing the transport of radioactive materials was noted in April 1957 by the United Nations' Preparatory Commission ahead of the establishment of the IAEA later the same year. The development of such a set of regulations was one of the first tasks undertaken by the agency, which in 1959 convened panels of experts to consider the issue using US Interstate Commerce Commission regulations for dangerous goods as a model [19].

The IAEA issued its first Regulations for the Safe Transport of Radioactive Material in 1961. Subsequent revisions to the regulations, and the development of a set of common rules, required compromises by all sides, and there was "an early recognition that compatibility between national and international regulations is a necessity for the atomic energy industry".

The next step towards a harmonized regulatory framework was the adoption of the regulations by governments and other international organizations through a combination of legally binding and non-binding instruments. The IAEA Regulations for the Safe Transport of Radioactive Material (SSR-6) were first incorporated into the UN Recommendations on the Transport of Dangerous Goods, and through that into the rules of the International Maritime Organization (IMO), the International Civil Aviation Organization (ICAO), the Universal Postal Union (UPU), as well as those of the United Nations Economic Commission for Europe (UNECE). This subsequently led to the incorporation of the IAEA Regulations into national regulations.

This does not, however, lead to complete uniformity between regulations. The IMO International Maritime Dangerous Goods (IMDG) Code, the ICAO Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO TI) and IAEA SSR-6 provide a minimum set of regulations. Member states can and do add additional domestic provisions.

International cooperation initiatives

To date, there have been several attempts at harmonizing international nuclear safety requirements. The complexity of regulations and standards, which includes technical, human, and cultural challenges, makes convergence between regulators and standard development organizations (SDO) difficult to achieve. While such regional and multinational initiatives have great value, they need to be intensified and systematized.

The following initiatives have been reviewed to understand what lessons can be learned and best practices to take forward.

- Multinational Design Evaluation Programme (MDEP)
- Western European Nuclear Regulators Association (WENRA)
- IAEA SMR Regulators' Forum (SMR RF)
- International Nuclear Regulators Association (INRA)
- CNSC and NRC Memorandum of Cooperation (MoC)
- IAEA Nuclear Harmonization and Standardization Initiative (NHSI)
- European SMR Pre-Partnership
- ASN/SUJB/STUK & NUWARD early joint review
- CNSC & Polish National Atomic Energy Agency SMR Collaboration

Table 2 provides a summary of the key findings and best practices from each of these initiatives.

Table 2. Overview of international cooperation initiatives

Initiative	Key findings	Best practice
Multinational Design Evaluation Programme (MDEP)	• Originally proposed as the Multi-nationalDesign Approval Programme (MDAP) with the intent to create a process where the certification of the design by one regulator could be used by another, thus negating the need for subsequent regulators to perform complete independent reviews of the design. • This goal was deemed unachievable in terms of both scope and available resource, so the focus of the programme was shifted to sharing insights on each regulator's independent review of reactor designs. • The review activities of the AP1000 design provided a good example of where insights on both high-level system issues as well as component specific issues were shared between the US, UK, and Chinese regulators. • The review of the EPR design provided a good example of where several areas have been reviewed and addressed by a large number of regulators. • In addition to sharing information on a reactor-specific basis, parallel efforts were also undertaken to form consensus positions in some non-design specific generic areas, primarily digital I/C, and vendor inspection. • There was wide membership that balanced diverse regulatory approaches and maturity. • Established effective Communication Protocol between regulators and industry and other stakeholders with the objective of maintaining regulatory independence, national sovereignty; demonstrating openness and transparency in decision making to stakeholders (*e.g.* public); and resolving conflict (control of proprietary information or intellectual property).	• National regulators are happy to engage with other participants, provide access to their independent confirmatory analysis, and were willing to share their assessment outcome in a transparent manner. • Active participation is necessary in building relationships between regulators, bringing greater benefits. • Define clear vision with concrete, measurable and achievable objectives. • Groups of regulators working together on specific designs yields positive outcomes. • Need access to suitably dedicated resource. • Clear actions and accountability. • Maintain regulatory independence and national sovereignty. • Require effective communication approaches allowing for openness and transparency while managing sensitive information. • Important to understand the context (environments, legal and regulatory frameworks) in which the various regulatory regimes operate. • Involving industry representatives is crucial in enabling specific issues to be worked through.

Initiative	Key findings	Best practice
Western European Nuclear Regulators Association (WENRA)	• Initially main objectives of WENRA were to develop a common approach to nuclear safety (this has led to the production of sets of Safety Reference Levels) and to provide an independent capability to examine nuclear safety in EU applicant countries. • This has subsequently been extended to also becoming a network of chief nuclear safety regulators in Europe exchanging experience and discussing significant safety issues. • The WENRA members commit themselves to incorporate the Safety Reference Levels into their national regulatory framework. • WENRA Reference Levels are 'European-centric' and light water reactor (LWR) technology specific.	• Government involvement is an important driver to initiate activities and when new participants join the activities. • Develop a mechanism for incorporation of guidance and outputs into national regulatory frameworks. • Wide range of regulators to be involved.
IAEA SMR Regulators' Forum	• SMR Regulators' Forum, created in March 2015, provides enabling discussions among Member States and other stakeholders to share SMR regulatory knowledge and experience. • The Forum enhances nuclear safety by identifying and resolving common safety issues that may challenge regulatory reviews associated with SMRs and by facilitating robust and thorough regulatory decisions. • The Forum's work is expected to result in: o Position statements on regulatory issues o Suggestions for revisions to or new IAEA documents o Information to help regulators enhance regulatory frameworks o Reports on regulatory challenges with discussion on paths forward o Suggestions for changes to international codes and standards.	• Groups of regulators can collaborate and develop common positions. • Smaller groups of regulators may be able to achieve greater clarity on some of the remaining challenges. • Difficult to identify real challenges or roadblocks without undertaking assessment on specific designs.

Initiative	Key findings	Best practice
	• Work is split across three groups: o Licensing Issues o Design and Safety Analysis o Manufacturing, Construction, Commissioning & Operations • To date, several common positions have been developed in relation to the general approach to take towards reviewing SMRs and what some of the key areas to address might be. • Some challenges remain, in part, due to the diversity of the regulators involved, particularly around definitions of passive systems, how to assess these systems and applicability of certain criteria. • No specific designs have been assessed.	
CNSC and NRC Memorandum of Cooperation (MoC)	• On August 15, 2019, the Canadian Nuclear Safety Commission (CNSC) and the United States Nuclear Regulatory Commission (NRC) signed an MoC to increase collaboration on the technical reviews of advanced reactor and small modular reactor technologies. • This resulted in several review activities for some reactor designs on specific subjects [20], as well as a comparative review of the Canadian and US regulatory frameworks. • Despite these being joint reports, limited joint review activities or assessments have taken place. • In September 2022, the USNRC and CNSC signed a charter [21] documenting collaboration on a new project under the MoC covering both countries' interest in the BWRX-300 small modular reactor design. • Joint work plans have been developed for three specific areas of the BWRX-300: o Safety demonstration o Fuel design o Steel-concrete composite construction. • At the time of writing this report no further information is available.	• Small groups of like-minded regulators can collaborate on the review of specific designs. • Selection of areas to be jointly assessed should be carefully considered and utilize prior expertise in regulatory organizations as much as possible. • Joint work plans should be developed with the goal of incrementally increasing collaborative review efforts

Initiative	Key findings	Best practice
IAEA Nuclear Harmonization and Standardization Initiative (NHSI)	• Launched in June 2022, the NHSI aims to facilitate the safe and secure deployment of SMRs to maximize their contribution to reach net zero carbon emissions by 2050. • Scope has been split into two tracks: o Regulatory and Government track ▪ Information sharing framework ▪ International pre-licensing regulatory design review ▪ Approaches to leverage other regulator's reviews. o Industry track ▪ Harmonization of high-level user requirements ▪ Information sharing on national standards and codes ▪ Experiments and validation of simulation computer codes to model SMRs ▪ Accelerating the implementation of a nuclear infrastructure for SMRs. • No formal reports or outputs have been produced at the time of writing this report. • It is not obvious how the scopes of the regulatory and industry tracks are connected. • The plan for involvement of governments remains unclear. • Resources appear constrained in certain areas.	• Set out strategic goals and common objectives from the start. • Include key stakeholders, including governments, from the start, or have a clear plan to involve them at a later stage. • Develop work plans that are linked to each other and to the overall plan. • Ensure adequate access to suitable resources.
European SMR Pre-Partnership	• Launched in June 2021, it focuses primarily on SMR technologies needed at the very beginning of the next decade to play a significant role in reaching the net zero goal by 2050 in Europe. • Aims to identify enabling conditions and constraints towards safe design, construction, and operation of SMRs in Europe in the next decade and beyond in compliance with the EU legislative framework in general and the Euratom legislative framework in particular. • There are five work-streams: o WS1: Market integration & deployment o WS2: Licensing o WS3: Financing & partnership o WS4: Supply chain adaptation o WS5: Innovation, research & development.	• Engage early dialogue between designers, licensees and regulators on main elements of the design options . • Promote cooperation of "interested" regulators to carry out a joint safety pre-assessment on a mature design and its dissemination with other regulators confronted with that design at a later stage. • Identify in an early phase potential blocking points in the safety requirements or licensing processes and arrangements for convergence.

Initiative	Key findings	Best practice
ASN/SUJB/STUK & NUWARD early joint review	• Launched in June 2022, the French, Finnish and Czech regulators, along with their respective technical support organisations, began the preliminary examination of the main safety options of the NUWARD SMR project sponsored by EDF. • Aims to carry out a joint assessment of the main safety options envisaged by EDF, notably the target safety objectives, the safety approach used in the design, the use of passive systems and the integration of two reactor modules within a single facility. • The experience and the conclusions of this multilateral examination of an advanced-design SMR project will lead to tangible progress in the harmonization and convergence of the licensing processes applicable to such reactors. • Six topics: o Safety objectives o List of design basis conditions o Use of passive cooling systems in the DBC/ DEC-A safety analysis o Development plan for scientific calculation tools o Multi-unit concept o Use of PSA. • Process: o Documents provided by EDF are reviewed by regulators' experts o Review results are documented in joint reports o After EDF feedback, reports are finished.	• Effectiveness of timely engagement (not too early, not too late) • Effective way to learn from the design, applicability of regulations and regulatory practices. • Differences between harmonizing requirements or harmonizing designs o Requirements differ, but design is considered acceptable. o Requirements are similar, but design is considered not acceptable.
CNSC and Polish National Atomic Energy Agency SMR collaboration	• Signed in February 2023, it aims to further expand the regulators' cooperation under the provisions of the Memorandum of Understanding on activities associated with advanced and small modular reactor technologies. • This cooperation may expand to facilitate a joint technical review of advanced and SMR designs, including the BWRX-300	• No formal output at time of writing this report.

It should be noted that some of these activities are ongoing. Lessons have been extracted from formal output from these activities available at the time of writing this report.

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Dispatchable power sources are the foundation of electricity grids. Not all low-carbon electricity sources reliable produce power when it is needed. In that regard, nuclear power is widely recognized as being a necessary part of the world's future energy portfolio. The percentage of that future portfolio which will be made up by nuclear will vary from region to region, and from country to country. All studies on the subject agree – if we are to achieve our environmental and energy security targets, we will need much more nuclear power than we have today.

The median Intergovernmental Panel on Climate Change (IPCC) scenario estimates that nuclear capacity needs to rise to approximately 1,250GWe by 2050 to support a realistic and just transition that would limit global warming to 1.5ºC.

The success of the required ramp-up in clean and secure nuclear energy relies on the large-scale deployment of a fleet of standardized designs that are acceptable in multiple countries around the world. Such deployment relies on efficient project reviews, approvals, and licensing to achieve economies of scale across the supply chain and into operation, ultimately increasing the certainty in project reliability, deployment costs and schedules, while maintaining safety.

This report outlines a new step-wise phased approach that could drive efficient international regulatory design review activities, facilitating the ability of one regulator to leverage all, or part, of the outcomes from reviews undertaken by other regulators to support their own regulatory process. For this to be successful it will require:

- Increased support from governments to enable of groups of regulators to collaboratively review on specific designs
- Stakeholders to engage with the stepwise phased approach
- Increased coordination between stakeholders of existing harmonization activities

This report has been produced by the Cooperation in Reactor Design Evaluation and Licensing (CORDEL) Working Group of the World Nuclear Association in cooperation with Canadian Nuclear Association (CNA) and the Nuclear Energy Institute (NEI).