Harmonization of Reactor Design Evaluation and Licensing: Lessons Learned from Transport

Cooperation in Reactor Design Evaluation and Licensing Working Group in cooperation with CANDU Owners Group

Title: Harmonization of Reactor Design Evaluation and Licensing:
Lessons Learned from Transport
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Published: December 2020
Report No. 2020/012

Cover image: Carem25, Comisión Nacional de Energía Atómica (CNEA), Argentina

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 the World Nuclear Association was created in January 2007 with the mission of establishing an international nuclear reactor design approval and certification process through the harmonization and worldwide convergence of safety standards and licensing approaches. CORDEL is currently working with its six task forces covering 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.

The CANDU Owners Group (COG) is a private, not-for-profit international corporation funded voluntarily by CANDU operating utilities worldwide, Canadian Nuclear Laboratories and supplier participants. COG facilitates research, joint projects, information exchange and industry alignment on industry standards, regulations and recent trends in CANDU and advanced nuclear technologies.

Contents

1 Introduction

Since its inception in 2007, the Cooperation in Reactor Design Evaluation and Licensing (CORDEL) Working Group of the World Nuclear Association has promoted a worldwide nuclear regulatory environment where internationally accepted standardized reactor designs can be widely deployed without major design changes at the national level. In practice, this would mean that safety evaluations of a reactor design and generic design certifications approved by a recognized competent authority would be acceptable by equivalent authorities in other countries.

The benefits of standardization – as advocated by CORDEL and its counterpart, the Multinational Design Evaluation Programme (MDEP)[1] – include:

- Improvements to safety through the sharing of monitoring, safety analysis, operating experience and best practices across a fleet.
- Boosting the investment attractiveness of nuclear new build through greater predictability of licensing and deployment time across countries.
- A positive impact on the perceptions of policy-makers, including in newcomer countries, and the general public as they see risks being managed consistently across borders.
- Enabling a strong supply chain and knowledge base that support long-term power plant operation.

Yet despite the broad acceptance of these benefits by governments, regulators and industry alike, and despite the good cooperation that has taken place under MDEP and CORDEL over the years, progress towards internationally-accepted standardized reactor designs has been limited. National regulations, while qualitatively consistent with the International Atomic Energy Agency (IAEA) safety standards, continue to apply different definitions, technical bases and interpretations in the implementation of basic safety principles.

In 2013, CORDEL published a report examining harmonization of design licensing and design change management procedures in the civil aviation industry – which has significantly increased safety and cost-effectiveness in that industry [1] – to learn lessons for nuclear regulation. However, CORDEL has not until now examined a successful example within its own industry: the regulatory harmonization of radioactive transport regulations. That process was driven by the interdependency of nations for the supply of radioactive material and development of international markets. The demand for reliable and scalable forms of low-carbon energy, the globalization of nuclear power, and the development of innovative technologies such as small modular reactors, arguably present a similar driver today for reactor design standardization and harmonized approaches to licensing.

This report presents the example of transport and extracts potential lessons to be drawn for international harmonization of reactor design and approaches to licensing. In so doing, the authors acknowledge that while there is significant complexity in designing a package to safely ship nuclear material in the public domain, the design of nuclear reactors is clearly of a higher order of complexity.

[1] After ten years of successful work, the Multinational Design Evaluation Programme (MDEP) decided to transfer the activities of its Digital I&C Working Group (DICWG) and the Codes and Standards Working Group (CSWG) to the Nuclear Energy Agency's (NEA's) Committee on Nuclear Regulatory Activities (CNRA), specifically to its Working Group on Digital I&C (WGDIC) and the Working Group on Codes and Standards (WGCS). Since this transfer in 2017-2018, CORDEL has maintained close collaboration with the respective NEA-CNRA working groups.

2 Development of Harmonized International Transport Regulations

The harmonization and standardization of the regulations for the transport of radioactive material entailed three steps:

- Development of an international model for the regulations.
- Adoption of these regulations into the legally-binding and non-binding instruments of international organizations.
- Incorporation into national regulations.

2.1 Development of an international model

The development of a set of regulations for the transport of radioactive material was one of the first tasks undertaken by the International Atomic Energy Agency (IAEA). Its Preparatory Commission had noted in 1957 that the IAEA "might be able to obtain information on the work which has been done in, and consider the formulation of, the regulations governing the transport of radioactive materials" [2], and further stated: "The transport of radioisotopes and radiation sources has brought to light many problems and involves the need for uniform packaging and shipping regulations … [to] facilitate the acceptance of such materials by sea and air carriers." Following the establishment of the IAEA later in 1957, two panels of experts were convened in 1959 – one for radioisotopes and materials of low specific activity and the other to consider large radioactive sources of fissile material. The US Interstate Commerce Commission regulations for dangerous goods were used as a model.

The literature consulted in writing this report does not specify what the problems encountered in international shipment in the 1950s were, but one can speculate that a combination of factors played a role, including:

- Packages being rejected on arrival at the consignee's country, because they did not meet local regulations.
- Transport workers receiving excessive doses during handling.
- Delays to the delivery of time-sensitive radiopharmaceuticals to the detriment of patient healthcare.

In parallel to the developments at the IAEA, the Economic and Social Council of the United Nations (ECOSOC), was advised by its Committee of Experts for the Carriage of Dangerous Goods to explore the possibility of finding mutually acceptable performance tests for outer packages for certain classes or groups of dangerous substances, and to request that the IAEA be entrusted with the drafting of recommendations on the transport of radioactive substances.

An ECOSOC resolution was passed in 1959 supporting the request to the IAEA on the proviso that its recommendations "are consistent with the framework and general principles of recommendations of the Committee of Experts on the Transport of Dangerous Goods of the United Nations, and that they are established in consultation with the United Nations and the specialized agencies concerned."

The outputs from the two IAEA panels were woven into a single set of regulations and these were approved by the IAEA Board of Governors in September 1960. The Board of Governors "recommended them to Member States and other international organisations as a basis for their own regulations" [3], and proposed to have the UN Committee of Experts on the Transport of Dangerous Goods include the recommendations in its future efforts on the transport of dangerous goods.

The first Regulations for the Safe Transport of Radioactive Material [4] issued in 1961 were largely qualitative, but – with a view to their practical implementation – early revisions provided specific quantitative performance, test requirements and acceptance criteria for containment, radiation control, prevention of criticality and managing heat. An important principle in designing the regulations was to describe *what* is required for safety, not *how* regulatory requirements are to be satisfied.

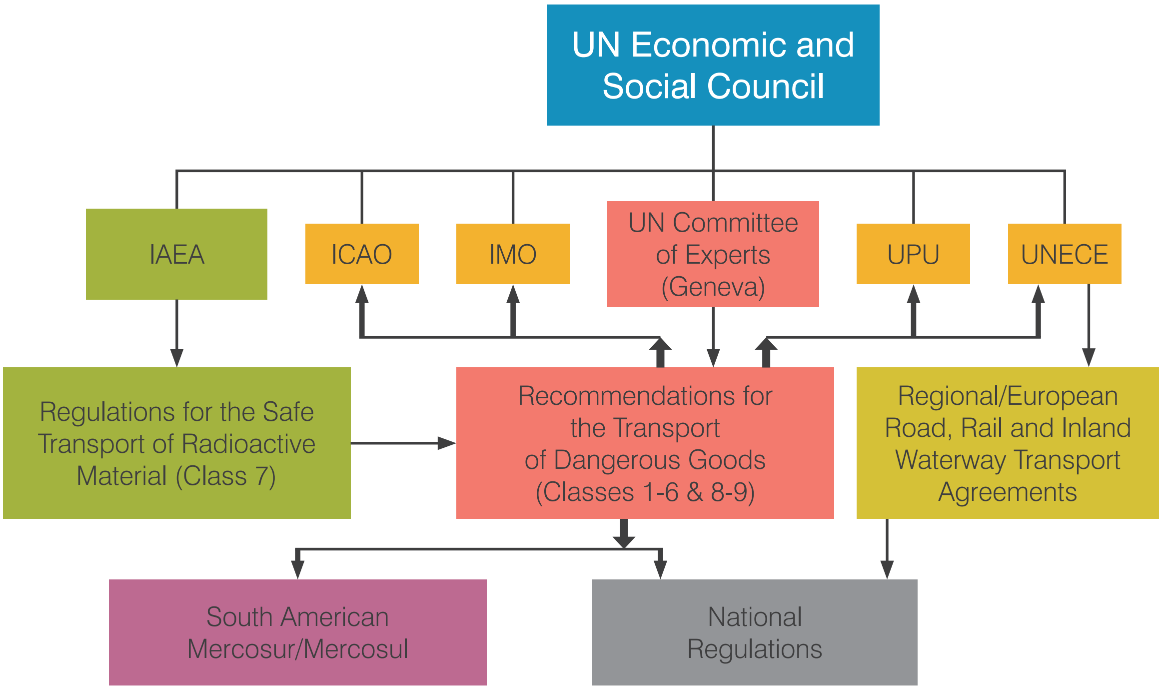
The 1963 revision of the regulations was an important milestone as it replaced the requirement for Type B packages to withstand the "maximum credible accident", interpretation of which had been the subject of much argument. The group of experts were able to agree to a series of tests and acceptance criteria that represent a large portion of the design basis accident environments that a Type B package might encounter during transport (see Appendix 1).

It would be wrong to assume that the emergence of a harmonized system of regulations for transport was inevitable. Compromises by all sides to forge the common rules were necessary. As Roy Gibson of the UK Atomic Energy Authority wrote in 1962 ahead of the important 1963 IAEA revision meeting: "It is true to say, however, that UK support for the IAEA regulations derives not from pride of partial authorship, but rather from an early recognition that compatibility between national and international regulations is a necessity for the atomic energy industry." He added: "Our delegation will not be going as a national delegation at all. We will do our very best to subordinate any national tendencies we may have." [3]

Since the 1963 revision, there have been regular changes to the regulations to address problems encountered during their use and new knowledge. The IAEA regulations are now reviewed according to the same two-year cycle as the UN Recommendations on the Transport of Dangerous Goods. Members of the IAEA Transport Safety Standards Committee, recognizing the importance of regulatory stability, apply the principle of not changing the regulations unless there is a real need to do so. This established the set of model regulations.

2.2 Adoption of model regulations by international organizations

Once the model regulations had been agreed, the next step towards a harmonized regulatory framework was their adoption 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) [4] were first incorporated into the UN Recommendations on the Transport of Dangerous Goods, and through that publication 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).



Key
IAEA – International Atomic Energy Agency
ICAO – International Civil Aviation Organization
IMO – International Maritime Organization
UPU – Universal Postal Union
UNECE – United Nations Economic Commission for Europe

Figure 1. Flow of IAEA Transport Regulations into International and National Transport Regulations

In the case of maritime transport, the use of the IAEA transport regulations within the International Maritime Dangerous Goods (IMDG) Code is underpinned by the International Convention for the Safety of Life at Sea (SOLAS). Since 1 January 2004, the IMDG Code has become mandatory for the contracting states to SOLAS.

In the case of aviation, the use of the IAEA transport regulations within the Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO TI) is underpinned by Annex 18 to the Convention on International Civil Aviation, known as the Chicago Convention.

The European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) [5] is a legally binding treaty for its contracting states. The provisions of the ADR concerning radioactive material are aligned with the IAEA Regulations for the Safe Transport of Radioactive Material, and are reviewed and updated as needed. Once a transport package has been certified to comply with the annexes to the ADR, the package is authorized for road transport on the territories of the contracting states. The lead competent authority approves the certificate, and other competent authorities validate the approval.

2.3 Incorporation into national regulations

Signatory states to conventions such as SOLAS and the Chicago Convention are obliged to implement the provisions of the IMDG Code and ICAO TI into their domestic regulations. Several IAEA member states have instituted policies whereby the latest version of the IAEA Regulations for the Safe Transport of Radioactive Material (SSR-6) is incorporated into their regulations within a certain time period.

This does not, however, lead to complete uniformity between regulations. The IMDG Code, ICAO TI and SSR-6 are a minimum set of regulations. Member states can and do add additional domestic provisions.

In the USA, for example, regulations for the acceleration factors that packages are required to meet are more stringent than those found in Europe. These regulations have implications for tie-down features.

3 Benefits from a Harmonized International Regulatory Approach for Transport

There is little doubt that the harmonized transport regulatory framework based on the quantitative performance and test criteria and terminology of the IAEA Regulations for the Safe Transport of Radioactive Material (SSR-6) has contributed to a safe and practical system for the transport of radioactive material over the last 60 years. It has enabled common understandings to be forged between regulators, allowing them to cooperate effectively. Requirements are sufficiently harmonized such that only minimal design changes to packages are needed to meet specific national regulations, and that the technical reviews of a lead competent authority can be validated – often in a straightforward way – by other competent authorities. Since the first publication of the IAEA regulations in 1961, during which time more than half a billion packages have been shipped worldwide, there has been no case of a transport incident that has caused a significant radiological hazard to people or the environment.

3.1 Case studies

Depending on the countries involved, different degrees of efficiency can be achieved in the multilateral licensing of a transport package. In the case of Canada and the USA, competent authorities review all foreign-certified package designs before issuing the competent authority approval. This process can be lengthy and complicated due to different national interpretations of IAEA transport regulations in some areas.

To ameliorate the situation, the Canadian Nuclear Safety Commission (CNSC), the US Nuclear Regulatory Commission (NRC), and the US Department of Transportation (DOT) cooperated in 2009 to produce a joint guide – NUREG-1886 in the USA, RD-364 in Canada – to be used for Canadian and US regulatory approvals of Type B (U) and fissile package designs [6]. The development of this joint guide was the result of a bilateral agreement which stemmed from the common instruments referred to by the regulators and good mutual understanding. The guide is intended to assist applicants in preparing applications that "thoroughly and completely demonstrate the ability of the given package to meet either Canadian or United States regulations," and to limit redundant technical reviews.

The guide has been used to certify the NAC International Legal Weight Truck Transport Package for the transport of highly enriched uranyl nitrate liquid (HEUNL) in Canada and the USA. Appendix 2 shows how the approval of this package was conducted in parallel between the two authorities. The process demonstrated that efficiencies could be gained for both the applicant and reviewers.

An example of multilateral licensing involving greater efficiencies relates to the DN30 protective structural packaging developed by Daher Nuclear Technologies. The DN30 package is designed to protect any standard 30B cylinder against the mechanical and thermal impacts considered under normal and accident conditions of transport according to the IAEA regulations.

Daher decided to license the package with the French Nuclear Safety Authority (ASN), which has considerable experience of uranium hexafluoride (UF_6) transport. The ASN licence was awarded on 26 December 2018.

Validation for the French certificate was subsequently applied for in countries to which UF_6 is transported, namely Belgium, Brazil, Canada, Germany, Netherlands, Russia, South Korea, Sweden, the UK and the USA.

The process of validation has been efficient due to the respective national regulations being harmonized. For example, in Netherlands and Sweden the French certificate was validated within six weeks, under an ADR multilateral process which mainly involved administrative checks.

In the USA, the competent authority, the Department of Transportation (DOT), issued its validation of the French certificate on 17 October 2019. The DOT validation authorizes use of the DN30 package for import and export shipments. Because Daher also wanted to use the package for domestic transport within the USA, it submitted a package application to the US Nuclear Regulatory Commission (NRC) in August 2018 and received the NRC Certificate of Compliance in July 2019.

An example of the extent of cooperation and trust that can develop between regulators in the transport area is the memorandum of understanding (MoU) agreed between the UK and French regulators in 2006 regarding approval of certificates [7]. The MoU was put in place for the mutual recognition of package designs, such as fissile packages, that require multilateral approval. It was set up on the basis that both countries applied the same instruments for the safe transport of radioactive material, such as the ADR and the IMDG Code, that each country had a full understanding of the other's implementation of these instruments as a result of their membership of the IAEA, and that they both wanted to avoid duplicating work without increasing risks.

Under the MoU, each competent authority accepted the approvals issued by the other competent authority as "evidence that the design of a package meets the requirements for package design contained in the IAEA regulations." The agreement also provided for the lead competent authority to transfer a copy of the safety case to the validating competent authority. The basis of approvals was to be discussed at regular review meetings (required to be at least biannually) to ensure common understanding between the parties. When the requisite number of technical review meetings was not upheld, the MoU was rescinded. The authorities are considering reviving the cooperation between each other to improve efficiencies.

4 International Standardization of Reactor Designs and Harmonized Approaches to Licensing

As noted earlier, transport by its nature is international and this provided an important driver for the development of the harmonized regulatory framework that exists today. Consensus is building that the global share of nuclear energy must increase substantially to meet energy security and climate change targets. Together with traditional large-scale nuclear units, a new generation of advanced reactors, including small modular reactors (SMRs), sometimes factory-built, will need to be deployed for nuclear electricity generation as well as for non-power applications.

To support this new demand, the traditional model for nuclear deployment needs to be changed towards the international standardization of reactor designs and harmonization of approaches to licensing. The major benefits of such international standardization and harmonization are improved economics, regulatory efficiency, and enhanced design efficiency and safety.

Today's national approach to the licensing of reactors results in designs approved by a lead regulator being subjected to regulatory reviews in another country against different regulations. This leads to design changes being required, incurring additional costs, time and regulatory burden, as well as the complexities and loss of efficiencies associated with managing multiple designs of the same basic reactor model. A new regulatory paradigm is necessary to minimize duplication of certification effort and major design changes, and to improve nuclear power's competitiveness. Part of this competitiveness would derive from the enhanced investment attractiveness of nuclear new build through greater predictability of licensing and deployment time across countries.

Besides economic deployment, harmonization would allow consistent design change management, and improvements to safety through the sharing of monitoring, safety analysis and operating experience across a fleet. It should also produce an overall positive impact on the perceptions of policy-makers and the general public as they see risks being managed consistently across borders.

The international harmonization of transport regulations has been enabled by the following three-step process (see Section 2): development of an international model for the regulations; adoption of these regulations into the legally-binding and non-binding instruments of international organizations; and incorporation into national regulations.

In assessing whether a similar process can be applied in the reactor design domain, it is important to acknowledge that the governing framework for nuclear has evolved greatly in the last 60 years. Countries, whose nuclear industry was in its infancy in the 1960s, have reached a mature state with well-established systems for licensing reactors and protecting the environment, based on different standards and approaches. These systems are overseen today not by governments, but by independent regulators. It should also be acknowledged that there is an increased degree of complexity in licensing a reactor *vis-à-vis* a transport package.

The major challenges of international harmonization that need to be overcome include the different regulatory approaches, standards frameworks and nuclear policies used in various countries. In addition, there are other regulations that differ from nation to nation – such as environmental regulations – that impose requirements that can potentially affect nuclear reactor designs. In trying to achieve harmonization across the different regulatory approaches, the adoption of the most onerous requirements from each country, as well as adding new requirements on top of existing ones, should be avoided. Overcomplexity can undermine an effective nuclear safety system.

There are various efforts to address these challenges. On a regional level, the European Utility Requirements (EUR) constitutes a set of requirements jointly agreed upon by European operators of nuclear power plants. They do not have the function of regulations but, in practice, they play a vital role as they are used in tenders and contracts with vendors, and are considered by the industry to comply with IAEA SSR 2/1 Rev. 1 (*Safety of Nuclear Power Plants: Design*), the Western European Nuclear Regulators Association (WENRA) Safety Reference Levels, and national standards of European Union (EU) countries.

Moreover, in 2012, the European Commission formed the European Reactor Design Acceptance (ERDA) group under the auspices of the European Nuclear Energy Forum (ENEF) to achieve standardization of reactor designs in the EU in order to avoid potential delays in new nuclear build due to lack of consistency in terms of nuclear safety requirements. In line with this, the EU published a report on *Benchmarking of nuclear technical requirements against WENRA safety reference levels, EU regulatory framework and IAEA standards* in February 2019 [8] on the outcomes of four tasks, namely: 1. Benchmarking of the European Utility Requirements; 2. Possible application of the Franco German ETC [EPR Technical Codes]; 3. A common European pre-licensing process: scope, content, implementation; 4. Benchmarking of the national long term operation programmes.

The August 2019 memorandum of cooperation (MoC) [9] made between the Canadian Nuclear Safety Commission (CNSC) and the US Nuclear Regulatory Commission (NRC) to work together on advanced reactors provides a good example of how two national regulators can cooperate towards the harmonization of reactor design review and licensing processes. In December 2019, the CNSC and NRC, under an updated version of the previously agreed MoC, established a mechanism that allows an SMR design to be jointly reviewed by the two regulators. Vendors that are interested in such a review engage each regulatory body separately and request the initiation of joint review activities. Dedicated sub-teams are established to review the design against the required safety principles for each specific design. There are currently two SMR designs engaged in joint review activities by the CNSC and NRC.

Starting with such a smaller number of collaborators allows for timely and efficient cooperation to begin, and in principle, for progress to be achieved quicker than if a larger number of nations would be involved. However, such bilateral cooperation needs to be extended to a multilateral/international level to be able to fully realize the benefits of harmonizing requirements across national borders.

At the international level, the Multilateral Design Evaluation Programme (MDEP), composed of national regulators, has examined the equivalence of codes and standards – mechanical as well as digital instrumentation and control – through its working groups in close cooperation with the nuclear industry via entities such as CORDEL. As for reactor design evaluation and licensing, design specific working groups have brought together three or more regulators that are concurrently reviewing the same design to form a collaborative network, discuss their assessment methodology and share their assessment results. The endeavours made under MDEP have demonstrated the benefits of collaborative working in terms of safety and efficiency. They are a basis for a deeper and more concerted collaboration among regulators, which could extend, for example, to common design review and certification among interested countries and their national regulators for both SMRs and large-scale nuclear plants. The transport precedent demonstrates that if regulators are provided with a remit and resources, they are able to deliver ambitious harmonization.

As a way of measuring the progress made towards a more harmonized approach to licensing, it is instructive to look at the CORDEL roadmap (see Figure 2) [10], which suggests a pathway to international standardization of reactor designs. Using this gauge, the majority of efforts to date can be regarded as belonging to Phase 1. Today, regulators that have licensed a design share their assessments with other regulators that are assessing the same design. The MoC between the CNSC and US NRC represents the start of cooperation under Phase 2 in the CORDEL roadmap. During Phase 2 of the CORDEL roadmap, frameworks are set up to support competent authorities assessing particular designs, or validating the assessments and approvals of other authorities.

While such regional and multinational initiatives and efforts have great value, they need to be intensified and systematized. This will require the strong engagement and commitment of the three major enablers: governments (policy- and decision-makers); the national regulators; and the nuclear industry. The cooperation should be underpinned by an international agreement/framework, the principal elements of which would be:

- Sustained government engagement including sufficient funding to support a multinational regulatory advisory panel.
- Regulators to work towards the international harmonization of regulatory approaches and requirements, beginning with: common terms; harmonization of codes and standards; and quantitative safety requirements (technology-specific).
- Industry engagement to provide input and feedback.

As part of a new international framework, a process should be instituted to allow regulatory authorities to accept the approvals of a different country's regulator as evidence that safety requirements have been met. As is the case among transport regulators, this would involve the lead competent authority transferring a copy of the safety case to the validating competent authority, transparency over which instruments act as references for safety, and how those instruments are implemented. Mutual acceptance of assessments, which already occurs today, should evolve as trust and understanding develops between regulatory authorities. National regulatory independence would remain paramount so that a regulator would reserve the right not to validate another regulator's decision.

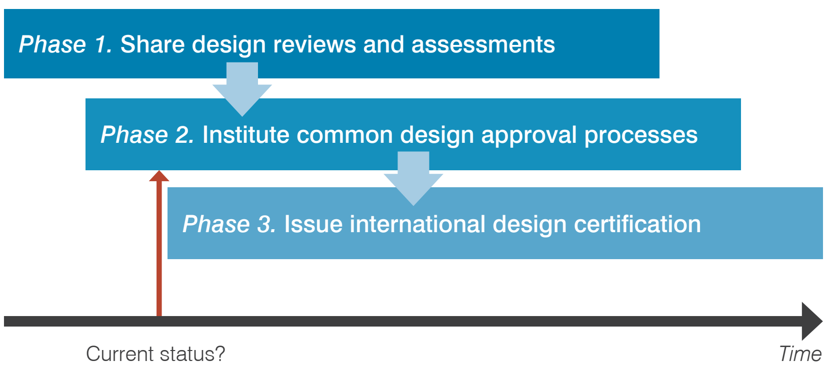


Figure 2: CORDEL Roadmap for International Standardization and Harmonization [10]

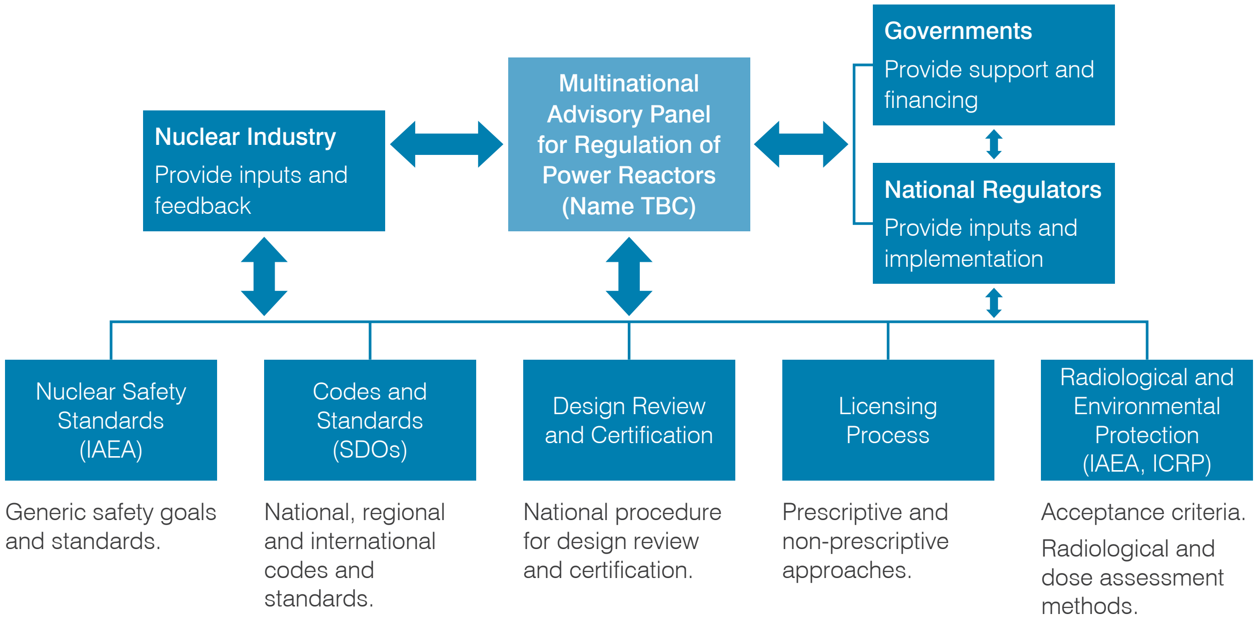


Figure 3. A Possible International Framework for Standardization of Reactor Designs and Harmonization of Approaches to Licensing

Figure 3 presents a possible international framework for harmonization of reactor design evaluation and licensing. At its heart would lie the proposed Multinational Advisory Panel for Regulation of Power Reactors, composed of experts from national regulatory bodies. The Advisory Panel could be a stand-alone body, or set up under the auspices of one or more already existing international organizations.

The structure of the Advisory Panel would change over time according to the requirements of the industry and marketplace but initially it could be established with two distinct sub-panels, one for SMRs and one for large-scale nuclear plants.

The functions of the Advisory Panel could be to:

- Provide recommendations to sovereign countries on reactor design evaluation and licensing.
- Define standardization boundaries (for example, the nuclear steam supply system for SMRs could be under common evaluation, while site-specific characteristics, such as seismic demands or cooling sources, remain under national regulations).
- Recommend detailed, quantitative technology-specific safety standards and requirements.
- Validate equivalency assessments of national and international codes and standards.
- Specify and undertake studies in order to steer the required level of harmonization across areas.
- Encourage harmonized regulatory requirements throughout the life-cycle of the reactor, including collection and implementation of experience during design, operation, maintenance, waste management and decommissioning.
- Provide a forum for collaboration on design review and licensing, and on developing a joint approach for design review and certification.

The nuclear industry would support the joint regulatory reviews leveraging the safety design knowledge and operational experience available across reactor vendors, utilities and owners groups. It is recommended that there is further analysis of the role of the nuclear industry within the framework, including an examination of the benefits of increased cooperation between utilities and owner-operators in the evaluation of a common reactor design.

5 Summary

This report draws on the experience of developing harmonized international nuclear transport regulations to inspire and inform the development of internationally accepted standardized reactor designs and a harmonized approach to licensing.

The harmonized regulatory framework for transport has contributed to a safe and practical system for the movement of radioactive material over the last 60 years. It has enabled common understandings to be forged between regulators, allowing them to cooperate effectively with one another. Requirements are sufficiently harmonized such that minimal design changes to packages are required to meet specific national regulations, and that the technical reviews of a lead competent authority can be straightforwardly validated by other competent authorities.

This report also examines the main drivers of harmonization of transport regulations, namely the interdependency of nations for the supply of radioactive material and the development of international markets. Enabling nuclear power to fulfil its potential as the world transitions to low-carbon energy systems, and realizing the benefits of innovative technologies such as small modular reactors (SMRs), present a similar driver today for reactor design standardization and harmonized approaches to licensing.

It is often cited that the sphere of nuclear reactor safety regulation is already harmonized through near-universal adherence to International Atomic Energy Agency (IAEA) safety standards. However, these qualitative standards are interpreted differently in national regulations resulting in non-uniform requirements and a lack of standardization. The transport example shows that those tasked with devising the early nuclear transport regulations were able to put aside national differences and agree on common quantitative performance and testing criteria and terminology. These laid the foundations for today's nuclear transport regulations, that define *what* needs to be achieved, rather than *how* to achieve it, leaving scope for national variation and innovation. In the reactor design sphere, with its greater complexity, quantitative criteria would need to be developed on a technology basis.

Efforts have been made for more than a decade, principally via the Multilateral Design Evaluation Programme (MDEP), to harmonize approaches to reactor licensing. This experience can serve as a basis for a deeper and more concerted collaboration among regulators, which could extend, for example, to common design review and certification among interested countries and their national regulators for both SMRs and large-scale nuclear plants. The transport precedent demonstrates that if regulators are provided with the mandate and the resources, they are able to deliver ambitious harmonization in the form of model regulations. While there would be an expectation that states participating in the process would implement the model, this would remain a sovereign decision. The transport example also demonstrates the need for ongoing commitment to the adoption and updating of the model regulations once they have been created.

Regulators today are more experienced and more independent than they were 60 years ago, and they are expected to play a central role in developing a harmonized framework for reactor design evaluation. Success, however, would require strong engagement and commitment of the two other major enablers: governments (policy- and decision-makers); and the nuclear industry.

Drawing on the lessons from the harmonization of international transport regulations, this report recommends that an international framework is established for the harmonization of reactor design evaluation and licensing. At the heart of this framework, would be a multinational regulatory advisory panel, composed of experts from national regulatory bodies and empowered by an international agreement to take steps towards international standardization of reactor designs and harmonization of approaches to licensing.

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Appendix 1 | Quantitative Requirements in the IAEA Transport Regulations

The range of conditions and events, *i.e.* the design basis, that underpins establishing the quantitative transport package requirements and acceptance criteria includes:

- Mishandling and tampering.
- Impacts due to large drops when loading or to collision during transport.
- Fire and damage by fire-fighting materials.
- Immersion in water.
- Smothering by debris or by other goods as a result of one of the above.

Impact and fire are considered to be the most likely to cause serious immediate damage.

The quantitative performance and test requirements and acceptance criteria for Type A (normal conditions of transport) and Type B (normal and accident conditions of transport) packages (see Figure A1) are based on conditions that would require very robust packages that can withstand all postulated accidents.

The transport regulations also include a graded approach by specifying quantitative radioactive content activity limits for:

- Controlling the quantity of radioactive material in a Type A package.
- Establishing content limits of excepted packages.
- Establishing release limits for Type B packages.
- Characterizing low-specific activity material.
- Establishing thresholds for requiring added tests such as the deep-water immersion test.

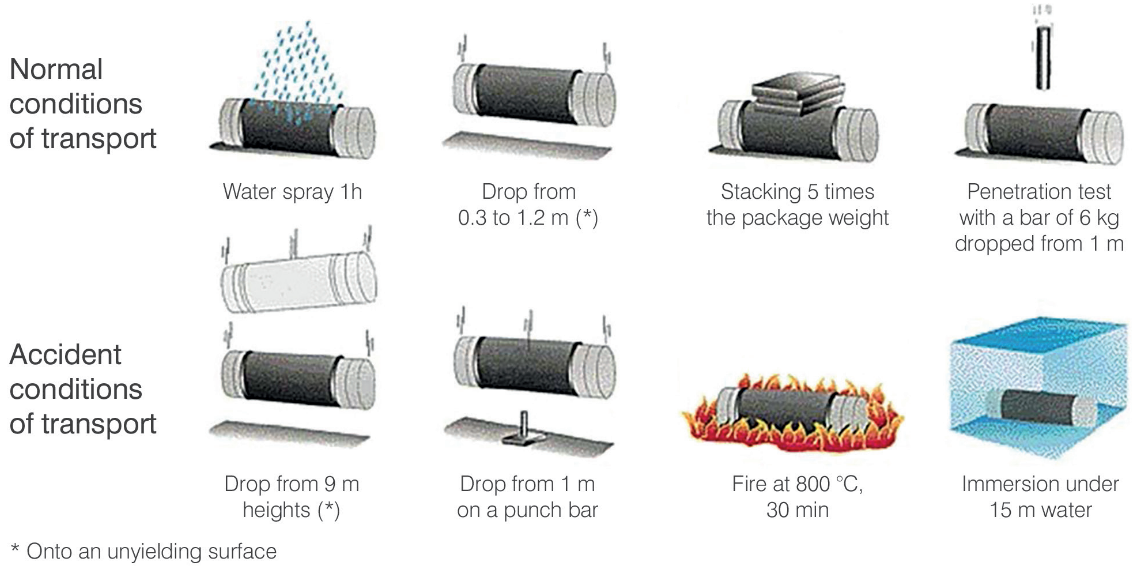

Figure A1. Test Requirements and Acceptance Criteria for Type B Transport Package Design
Source: Canadian Nuclear Safety Commission [11]

Appendix 2 | Parallel Certification of Revised NAC Legal Weight Truck Transport Package for the Intended Transport of Highly Enriched Uranyl Nitrate Liquid

The NAC Legal Weight Truck (NAC-LWT) transport package is a lead-shielded Type B shipping package designed to transport various types of used nuclear fuel. It is designed to protect used fuel against all mechanical and thermal impacts under normal and accident conditions of transport, and has radiation and neutron shielding in compliance with the IAEA transport regulations.

For the transport of highly enriched uranyl nitrate liquid (HEUNL), NAC International modified the inner components of the NAC-LWT package to hold four inner containers filled with HEUNL within the package cavity. To safely transport HEUNL from Canada to the USA, NAC applied for parallel independent certification of the revised NAC-LWT transport package with the USA (both the Nuclear Regulatory Commission and the Department of Transportation), as country of origin, and with the Canadian Nuclear Safety Commission.

CNSC	NRC
28/12/2012: NAC application received as the validating competent authority.	**28/12/2012:** NAC application received as lead competent authority.
01/2013-12/2014: CNSC staff review followed RD-364. • CNSC staff requested additional information. • CNSC staff also reviewed NAC responses to NRC requests for additional information. • CNSC included an environmental assessment. • CNSC staff considered information in Supplement Analysis Savannah River Site Spent Nuclear Fuel Management.	**01/2013-12/2014:** NRC staff review followed Standard Review Plan for Transportation Packages for Radioactive Material, NUREG-1609. • Used guidance in NUREG-1886. • NRC staff issued three requests for additional information.
23/12/2014: CNSC issued for public comment technical assessment report: NAC-LWT Package Design for Transport of Highly Enriched Uranyl Nitrate Liquid. • CNSC staff performed independent criticality simulations to confirm NAC's criticality simulations. **23/12/2014-10/06/2015:** Public consultation and feedback on comments.	**24/12/2014:** NRC issued safety evaluation report, Docket No. 71-9225. • No independent criticality simulations were performed by the NRC staff.
10/07/2015: CNSC issued Package Design Safety Evaluation for Certificate Number CDN/E173/-96 (Rev. 9).	**24/12/2014:** NRC issued Rev. 61 of the Certificate of Compliance.
	DOT
	29/01/2015: DOT issued Competent Authority Certification USA/9225/B(U) F-96, Revision 54.

There are two main differences between the contents of the CNSC technical assessment and the NRC safety evaluation report:

- The CNSC technical assessment explicitly includes a review of the NAC management system, whereas the NRC safety evaluation report does not, because NUREG-1609 states: "The following areas of 10 CFR Part 71 are not within the scope of this review plan: Approval of a quality assurance program."
- The CNSC technical assessment explicitly includes an environmental assessment, which supports the CNSC's regulatory process by ensuring adequate provisions are in place for the protection of the environment and the health and safety of Canadians before an activity is carried out. The environmental assessment by the CNSC staff took into consideration the initial environmental assessment performed by the US Department of Energy (DOE) in 2013.[2]

This case study illustrates that efficiencies can be achieved from providing guidance for a harmonized approach:

- NAC, as the applicant, submitted the same information to the NRC and CNSC.
- NRC and CNSC reviews of the licensing application used the same guidance in NUREG-1886 and RD-364, although the reviews were performed against their respective regulations.
- CNSC, as required by its regulations, performed an environmental assessment and made use of the information in the DOE environmental assessment.

[2] In the USA, the DOE is responsible for performing an environmental assessment. The initial environmental assessment in 2013 was documented in DOE/EIS-0279-SA-01 and DOE/EIS 0218-SA-06, and subsequently updated in DOE/EIS-0218-SA-07.

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Harmonization of Reactor Design Evaluation and Licensing: Lessons Learned from Transport reviews the process of harmonizing the regulations for the transport of radioactive material begun over 60 years ago and its impact. It extracts potential lessons to be drawn for the international standardization of reactor designs and harmonized approaches to licensing, which is viewed as essential for the development and deployment of innovative nuclear technologies, such as small modular reactors.

Based on the transport experience, the report recommends that an international framework is established for the harmonization of reactor design evaluation and licensing. At the heart of the framework would be a multinational regulatory advisory panel, composed of experts from national regulatory bodies, empowered by an international agreement.

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 CANDU Owners Group (COG).