



Harmonisation Position Paper

Multinational Design
Evaluation Programme – MDEP

September, 2026



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List of abbreviations and acronyms

FOAK	First of a Kind
IAEA	International Atomic Energy Agency
LWR	Light Water Reactors
MDEP	Multinational Design Evaluation Programme
NEA	Nuclear Energy Agency
NHSI	Nuclear Harmonization and Standardization Initiative
SMR	Small Modular Reactors

1. Introduction

Among the activities within the Programme, the Multinational Design Evaluation Programme (MDEP) Terms of Reference includes "Enhancing multilateral cooperation within existing regulatory frameworks, with a view to harmonisation of regulatory requirements and practices". The founding member countries of MDEP contemplated the need for a common approach to design evaluation, hence the formation and constitution of MDEP. However, the members expressed views in terms of themes such as codes and standards and issue specific design aspects that this is a difficult task. Other areas such as Fukushima Lessons learnt have been more amenable to common positions.

It showed that achieving progress should not revolve around striving for complete uniformity in requirements and practices or creating a single universal code or standard that all countries must adopt. Instead, it's more practical and advantageous to enhance harmonisation incrementally in specific areas.

As a result, MDEP has played a significant role in enabling the comparison of regulatory requirements and practices. It has aided regulators in comprehending the disparities between them and has offered an opportunity to explore their basis and application. Additionally, it has worked towards reducing the differences in technical requirements, so far as is reasonably practicable.

MDEP members agreed to understand by the term "harmonisation" the "process of bringing the requirements to a certain point where they do not contradict each other and reflect a similar view of safety". At the same time, MDEP should focus on cooperation on regulatory practices that might culminate in harmonisation of regulatory requirements. The international safety standards should be considered as they provide a general level of harmonisation and can both provide input to the work and benefit from the results. Yet, it is worth noting that even at this level, progress is complicated by the linguistic and conceptual confusion surrounding the International Atomic Energy Agency (IAEA) corpus: in several languages the English word standard has been translated as norm¹, blurring the essential distinction between high-level safety principles (standards²) and detailed rules or precepts (norms³). This inconsistent terminology has fostered the mistaken assumption that standards and norms are interchangeable, obscuring the critical difference between general safety principles and binding technical requirements. Thus adds a further layer of complexity to achieving alignment. And the progress towards harmonisation of regulatory approaches and requirements for new reactor designs is also expected as a natural outgrowth of MDEP.

¹ In official translations, the English term standard has often been rendered as norma in Spanish, norme in French, нормы in Russian, and similar equivalents in Arabic (معايير), while only Chinese (标准) maintains the distinction by translating it as standard.

² Standard, which derives from an old expression denoting a sign on a pole as a rallying point, generally means a **level of attainment**, ideally represented by that sign. Namely, standard is a generic concept expressing general principles of achievement rather than detailed rules; it is a strategic rather than a tactic concept.

³ Norm, on the other hand, directly derives from the Latin *norma*, (which originates in the 'carpenter's square') and clearly denotes a **rule or precept**. The norms contain the tactics to achieve that strategic level of attainment contained in International Standards.

An overriding consideration of international bodies such as Nuclear Energy Agency (NEA) and the IAEA is the globalization of nuclear technologies which results in a compelling case to adopt common approaches. Notwithstanding the drive for harmonisation, technology developers are differentiating designs of advanced reactors for performance advantages in operational safety.

Although harmonisation is a noble aspiration in a practical sense the application is still the prerogative of the national authority. The case for harmonisation remains a goal with benefits acknowledged by both regulators and the industry.

2. Discussion

In developing an understanding of harmonisation, an important consideration would be that regulators and technology developers have the same perspectives on this approach. Currently harmonisation is in its inception stages and does require the establishment of fundamental principles to achieve consistency. While the objectives are being developed, the uncertainties of the intended outcome should also be mapped out for all affected organisations. As international organisations like NEA and IAEA are leading out to pursue harmonisation, regulatory bodies have barriers to achieving this goal which are imbedded in policies and legislation. Furthermore, the regulatory framework of regulatory bodies has been developed independently as per the national conditions when regulation of nuclear safety and security was conceived nationally. The evolution of national regulatory frameworks from the early days of the nuclear industry did not have harmonisation from an international perspective as a goal. Given the resurgence of international collaboration among regulators, we now recognise that we lack a common approach to the supervision of nuclear safety and security. Hence from a historical point of view legislation and regulatory frameworks are not similar in structure and substance. Harmonisation is therefore an immense challenge for regulatory bodies and to arrive at agreed outcomes will be a major undertaking.

In addition, regulatory bodies have frameworks that are prescriptive, non-prescriptive, or a hybrid of these approaches. This may pose a barrier to the goal of harmonisation. A primary barrier is, in some cases, in the adoption of the trilogy of safety, security, and safeguards, namely 3S approach. Although the 3S approach is considered ideal, it may not be possible to implement these in member states in the near future. These two factors have an important bearing on the aspiration to bring about harmonisation. Furthermore, the approach to use qualitative and quantitative standards also impacts the approach to harmonisation. The IAEA standards, however, present the most feasible basis to implement and make harmonisation functional for siting, design, and operation of nuclear facilities and activities.

While it is necessary to accept the complexities of the current national regulatory frameworks, regulatory bodies should be able to adopt the principles and processes of harmonized nuclear regulation. This will serve as a starting point of harmonisation. The approach adopted by MDEP has created an important model for regulatory bodies to make progress with harmonisation. The importance of common positions has indeed

served as a basis to have consistent approaches, when evaluating different designs. However, the degree to which these have been adopted is an additional layer which could be evaluated. A global standard for design safety review would be the outcome that would signify that the intended degree of harmonisation has been achieved. If this can be cascaded down to the level of a standard regulation on design safety the objective has been achieved. In practice, once the normative regulation had been agreed, the next step towards standardisation of design safety would be the adoption by legislators and regulatory bodies to give them regulatory requirements, safety criteria, and common principles for design evaluation.

3. Factors Impacting on Harmonisation

Several factors have been identified that carry the potential to restrict the extent of harmonisation. Key factors that cannot be overlooked include:

1. A factor that may affect harmonisation is the role of differentiation in nuclear steam supply system and involving Light Water Reactors (LWRs) and non-LWRs.
2. A further factor is the application of common position in relation to country-specific conditions such as environmental compliance and standards.
3. In addition, utility user-requirements may differ from country to country.
4. While MDEP specifically looks at design safety there are interfaces between the design and site-specific factors of a nuclear facility that impact common positions.

4. Perspectives

MDEP members move towards harmonisation of regulatory requirements for new nuclear power plants and have experience of cooperation in design reviews and regulatory oversight at different stages of nuclear power plant construction up to early phase operation. Similar outcomes and the same movement towards harmonisation are expected in relation to disruptive technologies and, particularly, small modular reactors (SMRs). Those might appear to be more challenging as they are related to new requirements and national rulemaking, as well as licensing difficulties of SMRs with first-of-a-kind (FOAK) features and lack of operating experience. All these challenges might have negative effect on harmonisation activities. Plans of strengthening the regulatory framework are usually developed jointly by the regulator, industry, design and engineering organisations involved in the process of implementing innovative designs. Industry standards are also to be developed to support new rules and regulations in the field of nuclear energy use. However, these processes will likely occur differently across countries, as they must first account for country-specific conditions, all these documents are subjects to further joint efforts towards harmonisation and standardisation. After all, different technologies do not change the ultimate goal of the regulator: supervision of compliance with rules and regulations and, as a result, minimizing the risks of an accident.

At the same time, differences in SMRs and larger nuclear power plants technologies/designs may affect certain elements of regulatory approaches, for example, in terms of methods or scope of control. Issues of harmonisation in relation to SMRs are relevant in the light of activities within the framework of the IAEA, in particular Nuclear Harmonisation and Standardization Initiative (NHSI). Thus, the NHSI Regulatory Track has its goal to "facilitate the development of common regulatory positions without compromising nuclear safety and national sovereignty". It is important to maintain contact and exchange information with NHSI in the process of the preparation and subsequent implementation of work on SMRs within MDEP. MDEP may also consider some other less comprehensive SMR initiatives if necessary⁴.

A most important aspect of SMRs is the modularity and modular fabrication of the systems and equipment. Modular fabrication of nuclear reactors has the potential to support regulatory harmonisation by promoting consistent approaches to quality assurance, manufacturing oversight, and design verification across jurisdictions. At the same time, it introduces challenges, as national frameworks may differ in areas such as transport authorization, module interface control, and supply chain responsibilities. These factors suggest that while modular fabrication can facilitate greater alignment of regulatory practices, it also underscores the importance of addressing differences in national requirements to enable effective harmonisation and creating an environment where benefits of modularity can be utilized.

5. Conclusions

- National authorities must understand the barriers to harmonisation and look for ways to revise their regulatory frameworks to incorporate changes resulting from common positions.
- Constructs in the national legislation and regulatory hierarchy of documents may need to be enhanced or revised to include changes of harmonized requirements.
- Common positions developed by MDEP should be used as a reference when considering design safety standards for a particular reactor design.
- National authorities should also recognise different approaches in the application of common positions and harmonized approaches.
- The development of the new regulatory approaches and requirements for the disruptive technology should consider the results of the international efforts towards harmonisation, including the applicable common positions.
- Further information exchanges are needed to ensure consistency in the implementation of common positions and approaches to realize the intent of harmonisation.

⁴ SMR-forum, which now is merged with NHSI, ECC-SMART, HARMONISE etc.

www.oecd-nea.org/mdep



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