

## **TOWARDS HARMONISATION IN LICENSING OF FUTURE NUCLEAR POWER TECHNOLOGIES IN EUROPE**

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Innovative fission and fusion installations encompass novel technologies that drive the need for developing new licensing procedures. To this end, the early involvement of safety regulators, TSOs, research organisations, industry and supply chain actors on qualification, standardisation, V&V as well as licensing will have a positive input to the evolution of the safety regulatory framework [1]. The current nuclear regulatory framework appeared in the 1960s for licensing early NPP designs and since then it has undergone substantial modifications because of major nuclear accidents and in response to challenges posed by the licensing of Generation III designs. There is a broad agreement on the need to review the existing regulatory framework, incorporate novel concepts and endow it with sufficient capabilities for assuring safety during design and enabling proper regulatory oversight during operation of innovative facilities. Departing from a prescriptive-based to a performance-based approach in nuclear regulatory regimes needs examination under the prism of conformity with the safety objectives of future fission and fusion reactors considering their distinctive properties based on their related “source terms”. While fusion devices are in an early development stage, they can be the subject of a study since the ITER safety demonstrations cover all accident scenarios and its top-level safety objectives are based on international guidelines similar to those adopted by nuclear fission facilities.

In the framework of the Euratom Research and Training Programme the HARMONISE project (expected to start in mid-2022) will study all relevant research and cooperation activities in standardization and nuclear safety considering also the lessons learnt from the stress tests performed in the EU.

While States opted for differing national regulatory frameworks, the Three Miles Island and Chernobyl accidents acted as catalysts for change mandating the need for international cooperation on nuclear safety and radiation protection leading to harmonised approaches notwithstanding that both are national responsibilities. Achieving harmonisation requires establishing internationally agreed safety standards and supporting their global adoption. As such, IAEA has recognized that: [2] *“Regulating safety is a national responsibility. However, radiation risks may transcend national borders, and international cooperation serves to promote and enhance safety globally by exchanging experience and by improving capabilities to control hazards, to prevent accidents, to respond to emergencies and to mitigate any harmful consequences.”* In this framework, one of the first tasks undertaken by IAEA was the development of a set of regulations for radioactive material transport.

In order to achieve political, scientific, technical and economic harmonisation [3] among the Member States, EC introduced in 2003 two joint directives identified as the “nuclear

package”. The former directive defined general principles regarding nuclear site safety while the latter dealt with the management of spent fuel and radioactive waste in a legally binding sense at EU level. Another directive on funds for NPP decommissioning and waste management until final storage was taken out and appeared as recommendations in 2006. The nuclear package did not reach majority in the Council and in 2008 the EC presented a new draft directive on nuclear safety with a focus on NPP safety [4]. In 2014, the Council Directive 2014/87/Euratom amended Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations [5].

Meanwhile, regulatory authorities and industry have been sharing experience and regulatory practices to not only maintain but also enhance the safe operation of nuclear installations. Construction projects, e.g. NPP Olkiluoto 3, allow nuclear regulators to share resources and knowledge while harmonising the safety requirements applied to the new builds. Challenges in adhering to safety regulatory frameworks that are similar in objective but different in composition led in 2011/2012 to an agreement among nuclear-related organisations and regulatory bodies to better align their safety culture models. This agreement initiated the harmonisation of the guidance issued by IAEA, WANO, INPO and the USNRC regarding the safety culture [6].

The nuclear industry has been advocating standardisation as a means for improving [7]:

- General perception on consistent risk management across States;
- Installation safety by sharing information on safety analysis, operation and best practices;
- Supply chain and knowledge base needed for long-term plant operation;
- Investment appealing of new facilities because of higher predictability of licensing and deployment time.

Despite the broad consensus on the above points, State legislations maintain diverse definitions and interpretations in their application of basic safety principles while being consistent with the IAEA Safety Standards. Taking as a basis the IAEA fundamental safety objective, the HARMONISE project has set five Objectives:

*Objective 1: To analyse preliminary safety assessments of innovative fission and fusion installations*

According to the IAEA General Safety Requirements No. GSR Part 4 (Rev. 1) [8]: “*Safety assessments are to be undertaken as a means of evaluating compliance with safety requirements (and thereby the application of the fundamental safety principles) for all facilities and activities and to determine the measures that need to be taken to ensure safety.*”

The first HARMONISE objective is to collect and examine preliminary safety assessments performed at innovative fission and fusion installations. The works performed for the ALFRED, SMR, ITER, DEMO and WX-7 projects will be considered through a graded approach for determining the safety assessment scope.

*Objective 2: To peruse the licensing needs for innovative nuclear installations*

The work of the Multinational Design Evaluation Programme [9] (MDEP) employs resources and knowledge drawn from regulatory authorities in need of reviewing the safety of novel reactor designs. The expected outcome of this cooperative work is to harmonise the safety standards applicable to new reactors, while allowing regulatory authorities to implement the

State licensing process. According to IAEA [10]: “... *The term ‘licensing process’ is often used for nuclear installations; it includes all licensing and authorization processes for a nuclear installation and its activities.*” Considering that the licensing process of novel reactor installations will pose significant challenges on the current licensing and authorization processes, the second HARMONISE objective is to identify the needs for licensing innovative nuclear infrastructures. Its gaps will be identified and portrayed for future consideration in a harmonised licensing environment taking as a reference point the current licensing process. A hierarchical approach is to be adopted focusing on the specific needs of the ALFRED and DEMO innovative designs.

*Objective 3: To examine risk-informed, performance-based (RIPB) approaches in licensing reviews and regulatory decision-making*

A prescriptive-based regulatory approach establishes detailed requirements with acceptance criteria while prescriptive regulations define clear expectations for the regulatory body and the operating organisations. On the other hand, it is these regulations that place a high burden on the regulatory body and operating organisation and may not contribute to a safety culture development. The third objective of HARMONISE is to examine the departure from a prescriptive-based approach to a performance-based approach in nuclear regulatory regimes, under the prism of conformity with the safety objectives of innovative fusion and fission facilities. The regulatory infrastructures that currently use the RIPB approach to licensing will be reviewed to examine their capability to license innovative nuclear power technologies. In case of non-LWRs, the NRC Regulation Guide [11] has endorsed the NEI 18-04, Rev. 1 [12] report as a preferred method that non-LWR designers could follow when carrying out design assessment prior to license applications. HARMONISE will take advantage of the proposed in NEI 18-04 [12]: “... *systematic and reproducible process ...*” for licensing-basis event selection, SSC classification, defence-in-depth adequacy evaluation and identification of the proper description detail for SSCs. HARMONISE will review the steps that ought to be demonstrated during a design process leading to a RIPB safety basis.

*Objective 4: To delimit harmonisation and standardisation on component assessments, methodologies, codes and standards*

Nuclear installation workers and the public expect equivalent safety levels in facility operation without substantial differentiation – from the safety point of view – among State safety requirements and their implementation in nuclear infrastructures. There is a tendency to expect that the safety requirements ought to be independent not only of the regulatory regime, but also of the facility design. To this end, the fourth objective of HARMONISE will define the boundaries of harmonisation and standardisation on component assessments, methodologies, codes and standards pertinent to the safety of existing nuclear installations. The overall safety requirements will be examined in the absence of the technical idiosyncrasies characterising specific nuclear facilities. HARMONISE will adopt a stepwise “harmonisation” approach taking as a basis the IAEA Safety Standards and any recognized differentiations among practices adopted at State level.

*Objective 5: To learn from earlier experience in harmonisation efforts*

The Cooperation in Reactor Design Evaluation and Licensing (CORDEL) Working Group [13] has been advocating a nuclear regulatory environment suitable for adopting internationally accepted, standardised, reactor designs that should not be the subject of

significant design modifications because of State regulations. Subsequently, generic design certifications and safety evaluations of reactor designs approved by a regulatory authority would be applicable to other States, as well. In a parallel effort, the MDEP has worked on safety design reviews for new reactors and approaches for harmonising safety licensing review practices and requirements. Notwithstanding the consistency of State regulatory frameworks with the IAEA Safety Standards, they maintain different elucidations and materializations of basic safety principles. As a fifth objective, HARMONISE will draw lessons from earlier works in harmonising radioactive transport regulations [14] as well as the outcomes of harmonisation efforts in other industries such as the harmonisation of design licensing and design change management procedures in civil aviation.

The Council Directive 2014/87/Euratom recognizes that [5]: *“The concept of defence-in-depth is fundamental to the safety of nuclear installations and is the basis for implementing high level nuclear safety objectives. Application of the defence-in-depth principles, as recognised in international standards and guidance and by WENRA, ensures that safety activities are subject to, as far as reasonably practicable, independent layers of provisions, ...”* Furthermore: *“The stress tests demonstrated the key role of enhanced cooperation and coordination mechanisms between all parties that have responsibilities for nuclear safety.”* [5]. To this end, HARMONISE will factor into its approach the defence-in-depth concept and the progress made in standardisation and nuclear safety since *“... The peer-reviews have proved to be a good means of building confidence, with the aim of developing and exchanging experience and ensuring the common application of high nuclear safety standards.”* [5].

Identifying the licensing needs for innovative technologies incorporated in future fission and fusion reactors requires an exhaustive analysis to determine whether, or not, current codes and standards address these needs. New technologies need to be detailed and grouped into different categories depending on the qualification and licensing process. In order to ensure that this analysis is performed in a robust manner, HARMONISE will solicit the expertise of Standards Development Organisations responsible for code development.

HARMONISE will take advantage of the accomplishments achieved by current and earlier research and cooperation initiatives in standardisation and nuclear safety, in EURATOM and outside, considering also the outcomes of the EU stress tests. An extensive consultation process will take place with ENSREG, WENRA as well as ETSO to benefit from the progress made in cooperative initiatives such as the ENSREG National Action Plans, the WENRA RHWG, the NEA CNRA and the WNA CORDEL Working Group.

HARMONISE findings will be disseminated and reported to Member States’ nuclear safety regulators with the aim to facilitate their early involvement regarding safety verifications and licensing of future fission and fusion installations.

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