European SMR pre-Partnership Reports

Workstream 2 – Licencing

ENSREG
European Nuclear Safety Regulators Group

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SNETP
Sustainable Nuclear Energy Technology Platform

European SMR pre-Partnership

Workstream 2

Licencing

Contents

ACRONYMS

Abbreviation	*Expansion*
ASN	Authorite de Surete Nucleaire - France
AGR	Advanced Gas Reactor
AMR	Advanced Modular Reactor
BWR	Boiling Water Reactor
CNCAN	Comisia Naţională pentru Controlul Activităţilor Nucleare - Romania
C&S	Codes and Standards
ELSMOR	Euratom R&I project "Towards European Licencing of Small MOdular Reactors"
ENISS	European Nuclear Installations Safety Standards Initiative
ENSREG	European Nuclear Safety Regulators Group
EPZ	Emergency Planning Zone
EUR	European Utility Requirements
HARMONISE	Euratom R&I project "Towards harmonisation in licensing of future nuclear power technologies in Europe"
HTGR	High Temperature Gas Reactor
IAEA	International Atomic Energy Agency
IAEA NHSI	IAEA Nuclear Harmonization and Standardization Initiative
IMS	Integrated Management System
IPWR	Integrated Pressurized Water Reactor
JRC	European Commission Joint Research Centre
LW-SMR	Light Water Small Modular Reactor
MSR	Molten Salt Reactor
NEA	OECD Nuclear Energy Agency
NEA CSNI	NEA Committee of Safety of Nuclear Installations
NEA EGSMR	NEA Expert Group on Small and Modular Reactors
NEA MDEP	NEA Multinational design Evaluation programme
NPP	Nuclear Power Plant
NRC	Nuclear Regulatory Commission – United States
NSSS	Nuclear steam supply system
PAA	National Atomic Energy Agency - Poland
PSAR	Preliminary Safety Analysis Report
PSA	Probabilistic Safety Assessment
PWR	Pressurized Water Reactor
SA	Severe Accident
SASPAM-SA	Euratom R&I project "Safety Analysis of SMR with PAssive Mitigation strategies – Severe Accident"
SMR	Small Modular Reactor
SSCs	Structures Systems and Components
SUJB	State Office for Nuclear Safety – Czech Republic
STUK	Radiation and Nuclear Safety Authority - Finland
WENRA	Western European Nuclear Regulators Association
WENRA SRLs	WENRA Safety Reference Levels
WNA-CORDEL	World Nuclear Association Cooperation in reactor Design evaluation and licensing (CORDEL) Working Group
WS	Workstream

Executive summary

In 2022, the main objective of the European SMR pre-Partnership WS2 was to identify the elements for establishing a European pre-licensing process based on commonly accepted safety assessments from different ENSREG [21] members interested in the licensing of the same SMR design.

ENSREG Members had nominated 20 experts from 15 EU countries to the WS2, one industry representative from ENISS also participated as member to this WS2 (See Appendix A).

In 2022, WS2 main activities were focused on:

- First review of NPPs licensing processes in different EU countries interested in SMR licensing (Czech Republic, France, Finland, Romania, Poland, Sweden)
- Establishing a clear state of play of activities in other fora (IAEA NHSI, SMR Regulatory Forum, NEA Committees, WENRA [20], EUR, ENISS, CORDEL, etc.) in relation to SMR licensing
- Interacting with WS4 on Codes & Standards
- Interacting with WS5 on different topics and reviewing the outcomes of some Euratom H2020 projects related to the licensing of SMRs and.

The main outcomes of this work are as follows:
Regarding nuclear installations pre licensing, a decision in principle is needed in some countries to start any project with an associated licensing process and in some other countries, a pre-licensing step is conducted if so-requested by the applicant. it was highlighted that in most of the countries, only a future licensee, that means the entity/organisation that will bear the prime responsibility for the installation is entitled to submit an application for a pre-licensing phase. Pre-licensing is an opportunity for the regulator to raise safety issues and for the licensee to have first feedback and therefore a better predictability regarding the construction licensing phase.

The importance of a preliminary regulatory assessment of new designs is widely recognised as a mean to allow early identification of potential regulatory issues, lack of specific requirements, needs for complementary experiments as well as to anticipate specific regulatory concerns, etc. In the light of the European Partnership for SMRs, even if the authorisation of nuclear installation remains the sovereign responsibility of the states, a cooperation between regulators on the pre-assessment of SMRs is an opportunity to share regulators' approach and expectations. Besides, it provides the SMR designer and the future licensees an idea of the licensability of such a design across several countries with different regulations**.** A collaboration among regulators of interested countries to conduct a preliminary joint safety assessment of selected designs, whose outcomes could then be used in the national licensing process as needed, is therefore suggested.

Many initiatives regarding SMRs have been launched at an international level in different fora (IAEA NHSI, SMR Regulatory Forum, NEA Committees, WENRA, EUR, ENISS, CORDEL) to address the challenges, risks and opportunities presented by SMRs. However, these reflections are usually conducted with very general perspectives. It illustrates the importance of focusing on concrete cases in the future steps of the European Partnership Initiative. The WS2 identified several areas of work that have been already done or are ongoing in these fora and that could support and complement WS2 activities: in particular, it highlights topics which would be interesting to consider when engaging early interaction and dialogue on licensing issues between the regulators and designers/licensees.

Regarding the IAEA NHSI initiative in particular, better coordination between EU countries would be recommended to influence the work performed in NHSI and ensure that the NHSI initiative provide outputs consistent with the European pre- Partnership approach**.**

The Codes and Standards (C&S) in a Nuclear Power Plant, large or small, contribute to prove that all the (safety related) Structure Systems and Components (SSC) will perform their safety function with a high level of reliability supporting the safety case of the installation. A (potential) licensee should prove that their proposed set of Codes and Standards achieve this goal comprehensively and completely.

During the common WS2-WS4 meetings, it was highlighted that most regulators do not impose the use of particular Codes & Standards and have expressed readiness to accept those proposed by designers as part of a "full package". The designers should provide information to the regulatory body about what are the main differences in the C&S compared to the one commonly used in the country (or equivalences) and what are the design and safety implications of using a set of C&S instead of another one. It was stated that the designers should ensure that, whatever the C&S chosen for the design, the C&S will comply with the national regulations, being aware that some C&S or regulations not directly related to nuclear topics could have an impact (construction codes, health&safety, fire, etc.) on the designs.

In the field of research for safety and licensing of SMRs, a contribution is provided by projects like ELSMOR, HARMONISE, and SASPAM-SA funded under the Euratom Research And Training programme. However, many topics like Passive Systems, Severe Accident, Human Factor would still require significant research for SMRs. Collaboration between Regulatory Bodies and EU research organisations could be a mean for the regulators to get a common understanding of the challenges related to SMRs key safety.

In view of further supporting efforts to facilitate SMR pre-licensing in Europe several steps forward emerged:

- 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

To address these 3 main objectives WS2 identified several actions for further work (non-exhaustive list):

- Definition of the pre-requisites for an early dialogue (information needed from the future licensee, etc.).
- Agreement on the definition of what is the sufficient level of maturity for a designer-licensee to engage a joint safety pre-assessment.
- Definition, taking into account WENRA ongoing work, of commonly shared Safety Objectives for SMRs between the EU "interested" nuclear safety regulators.
- Agreement on the assessment criteria in a joint assessment: national requirements, a set of common criteria or decided case-by-case?
- Definition of a list of potential topics for consideration in the joint pre- assessment.
- Definition of the possible options and conditions for another regulator or licensee to join the pre-assessment after it has started and the necessary arrangements on the way how the reporting of the findings of one of these preassessments to 'third' parties should be done.
- Identification of potential blocking points in future licensing processes based on differences in nuclear safety or other types of regulations and on the outcomes of ongoing work in the different fora.

One element to further support WS2 activities will be the European Commission study ENER/D2/2022-82 "Benchmarking of the nuclear safety regulatory framework and regulatory practices for SMRs in different European countries" which started in January 2023 and should be able to identify several of these blocking points in SMR licensing through its "Stakeholders' Group".

1. Introduction

In 2022, the main objective of the European SMR pre-Partnership WS2 was to identify the elements for establishing a European pre-licensing process based on commonly accepted safety assessments from different ENSREG members interested in the licensing of the same SMR design.

ENSREG Members had nominated 20 experts to the WS2 from the following nuclear safety authorities (Austria, Belgium, Czech Republic, Finland, France, Germany, Hungary, Italy, Lithuania, Poland, Romania, Slovakia, Spain, Sweden, The Netherlands). One industry representative from ENISS also participated as member to this WorkStream.

The Chair of this WS2, who was nominated during the Kick-Off Meeting, is from ASN (France).

Main activities in 2022 were focused on:

- Developing a common understanding on NPPs licensing processes in different EU countries interested in SMR licensing (main milestones, etc.)
- Establishing a clear state of play of activities in other fora (IAEA, SMR Regulatory Forum, NEA Committees, WENRA, EUR, ENISS, CORDEL, etc.) in relation to SMR licensing
- Interacting with WS4 on potential issues related to Codes & Standards having relevance from a licensing perspective
- Interacting with WS5 on potential issues related to three topics: Human Factors, Severe Accidents, Passive Systems, having relevance from a licensing perspective
- Reviewing the outcomes of some Euratom H2020 projects related to the licensing of SMRs.

2. Main elements of NPPs licensing in Europe

WS2 has conducted a survey on the licensing processes in place in some of the member states represented in the group, on the bases of dedicated presentations and subsequent discussions taken during its meetings. In particular, the WS2 preliminary survey has covered the licensing process in France, Finland, Czech Republic, Romania, Poland, Sweden. In the following the main elements are briefly summarized and discussed for each country.

The main goal of this preliminary survey has been to develop a picture on the main elements and steps of the different licencing processes, with a special focus on a pre-licensing phase, where in place, with associated preliminary assessment. It has not been intended to perform any detailed comparison and analysis of existing communalities or differences among the licensing processes existing in the different countries, having relevance for possible future licensing activities of SMRs.

FRANCE [1]

1) The nuclear regulatory framework in France is the same for all nuclear installations.
2) The licensing process is initiated by the licensee (Applicant) who bears the prime responsibility for safety. The process cannot be initiated by the vendor or the designer. For SMRs, the same licencing process of other nuclear installations applies.
3) The licensing process comprises three main steps: a pre-licensing step, a construction licence step (Step 1), a commissioning licence step (Step 2):

- The pre-licensing step is:
  - optional (at the choice of the applicant)
  - related to a generic and conceptual design
  - not addressing site specific issues
  - conducted with the objective to state that a new design can be licensed
  - concluded with an official and public statement by ASN on the safety options of the project with a list of expected complements/evolutions for the «construction application».
- The construction licence step (Step 1) is:
  - related to a detailed design (in case of «first of a kind» applications, it may be necessary to complete the design assessment later during the commissioning phase)
  - addressing site specific issues
  - based on a safety demonstration as documented in the Preliminary Safety Analysis Report and on an Environmental Impact Assessment
  - including a public enquiry
  - concluded with a governmental authorization decree complemented with an ASN resolution with prescriptions on specific items.
- The commissioning licence step (Step 2) is:
  - related to the as built configuration of the design
  - based on an updated safety demonstration as in the Safety Analysis Report (SAR) and Operating documentation consistent with the SAR (i.e. General operating rules, periodic testing, maintenance, accident procedures; on-site emergency plan)
  - concluded with an ASN resolution with prescriptions on specific items.

4) The French licensing system does not include any type of design certification before the construction licensing step.

FINLAND [2]

1) For all nuclear facilities with thermal power exceeding 50 MW, including SMRs, a Political decision (Decision-in-Principle -DiP) is needed to start any project and associated licensing process. The DiP is a Government decision, ratified by the Parliament. It takes STUK's safety assessment into account. The application can concern several units. The application may include several reactor candidates or several alternative sites. STUK preliminary assessment is conducted on the bases of a conceptual design with the aim to identify major licensing challenges and modifications needed.

2) There are three steps of licences: construction, operation, decommissioning. Licences are granted by the Government based upon STUK safety assessment. The Ministry of Economic Affairs and Employment administrates the process.
   - For Construction Licence, the goal of STUK's safety assessment is to verify that the design and plans fulfil Finnish safety requirements. The STUK Regulations are used as assessment criteria (STUK's safety assessment report includes evaluation of each individual requirement);
   - For Operating Licence, the goal of STUK's safety assessment is to verify readiness for safe operation (although some activities may still be unfinished, their status will be inspected before fuel loading).

   Before starting the licensing process, unofficial discussions between the license applicant and STUK (also vendor can participate) are a practice.

3) The Finnish licensing system does not include any type of design certification before the construction licensing step.

4) A revision of Nuclear Energy Act and Nuclear Energy Decree is on-going. Optional pre-licence evaluation of reactor design is considered and as well separate site permit, which would be also applicable to SMRs. No specific licensing procedures or requirements will be drafted for SMRs. Some technologies specific requirements or guidance maybe needed.

CZECH REPUBLIC [3]

1) For all nuclear installations, the following licences are requested according to the Nuclear Act:
   - Siting of a nuclear installation;
   - Construction of a nuclear installation;
   - First physical start-up of a nuclear installation with nuclear reactor;
   - First power-generation start-up of a nuclear installation with nuclear reactor;
   - Commissioning of a nuclear installation without nuclear reactor:
   - Operation of a nuclear installation:
   - Individual phases of decommissioning of a nuclear installation;
   - Modifications affecting nuclear safety, technical safety and physical protection of a nuclear installation.

   Additional authorizations for siting (Planning Permission) and construction (Building Permit) are requested according to the Building Act.

2) Each of the main licensing steps implies a Safety assessment **(**Siting–Initial Safety Report, Construction-Preliminary Safety Report, Operation - Physical/power-generation start-up & operation-operational safety report).
   In the Initial Safety Analysis Report a description of the design in terms of compliance with the requirements for nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation extraordinary event management and security has to be included.
   For nuclear installations designs, proven methods, procedures and technology are required.

3) Design Certification or a pre-licensing step are not envisaged in the Czech regulatory system.

ROMANIA [4]

1) The nuclear regulation in Romania is generally technology-neutral.

2) The licensing requirements and licensing process are established in the regulation on the licensing of the nuclear installations (NSN-22) issued by the regulatory authority (CNCAN).

3) For a nuclear reactor, the licensing stage are:
   - design,
   - siting,
   - construction,
   - commissioning,
   - operation,
   - decommissioning.

   For each stage, a specific licence is granted by the regulatory authority.

4) The licensing for the design can be assimilated to a “design certification”. It is envisaged in the case of a new design that has not been constructed before in Romania. Before submitting an

application for licence, pre-licensing meetings with the potential applicant are organized, if so requested for clarification of the licensing process and requirements. A vendor can also apply for a design licence.

5) The main document that is submitted for a regulatory review is a safety analysis report whose content is adequate to the specific stage of the licensing process. The standard content of US NRC NUREG-0800-Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition is adopted as reference. Additional support documentation is requested on a case-by-case basis.

6) The regulatory body may make use of regulatory reviews performed in other countries that have licensed the same design or similar nuclear power plants.
Reviews performed in other countries are considered a useful input to the regulatory decision-making process in Romania but cannot and do not replace the regulatory review conducted by the national regulator.

POLAND [5]

1) For any new nuclear installation, there is a decision in principle made by the government.

2) Licensing process in Poland consists of three main steps: Construction licence, Commissioning licence and Operating licence.
   - *Construction Licence* is granted on the bases of a Siting Report, a Preliminary Safety Analysis Report (PSAR), and an Integrated Management System (IMS);
   - *Commissioning Licence* is based on an updated version of the PSAR and the IMS as well as a Commissioning Programme and related Procedures;
   - *Operating Licence* is the report of the implementation of Commissioning programme and consequent updating of PSAR and other documents.

   These licenses are granted by the regulatory body.
   On the bases of other documents related to non-nuclear aspects, a site permit and a Construction Permit are granted by the administration.

3) IAEA Safety Standards on NPPs Design and Safety Analyses are assumed as reference for the implementation of the licensing process.

4) The Polish legislation also offers the possibility for an applicant to apply for so called General Opinion and Preliminary Opinion on a specific new design. The applicant has however to be the future Licensee.
   - A General opinion addresses planned organizational and technical solutions or planned organizational drafts of documents. Scope of a General Opinion is defined by the Applicant. Results of the GO are not mandatory but can then be used in a possible future licensing process.
   - A Preliminary opinion addresses planned location of a nuclear facility

   General Opinion and Preliminary Opinion do not require a political decision to be applied for.

SWEDEN [6]

1) New nuclear installations and major modifications of existing installations are subject to licences under both the Act on Nuclear Activities and the Environmental Code. Licences is granted by the Government and the regulatory body (SSM) acts as a drafting authority according to the Act on Nuclear Activities.

If the activity requires a license under the Environmental Code, the Land and Environmental Court act as a drafting authority with SSM as a referral body and the Government decides on permissibility.

2) The licence application must be submitted to SSM who processes the matter under the Act on Nuclear Activities and to the Land and the Environment Court, who processes the matter under the Environmental Code. Both applications are to be accompanied by an environmental impact assessment.

3) SSM performs review and assessment of the licence application to check compliance with applicable requirements on nuclear safety and radiation protection so as to ensure the protection of people and the environment. If SSM finds that it provides an adequate demonstration of safety for the planned nuclear activity or facility SSM will propose that the Government grants a licence under the Act on Nuclear Activities and proposes licence conditions that enable a continued stepwise review process (SSM will review the licensees application for approval before start of construction, commissioning (test operation) and routine operation). The Government usually grant the operating licence with an indefinite term. Following a Government decision to grant a licence, SSM grant approvals according to the licence conditions that the Government have issued in a step-wise process. The licensee bears the prime responsibility for safety.

4) According to the Environmental Code, the preparation and review of an application as well as the issuing of a licence and conditions, take place in open court hearings at the Land and Environment Court.

Summary of licensing processes relevant for SMRs

The legislative and regulatory system in place in each Member State establishes a licensing process for nuclear installations, applicable also for SMRs (see above). In all cases, the licensing process is subdivided in different steps comprising construction, commissioning, operation.

In some countries, a decision in principle is needed to start any project with an associated licensing process. This phase can be concluded with the issue of a General/Preliminary opinion or a Statement by the national regulator. In some other countries, a pre-licensing step is conducted if so requested by the applicant. In most of the countries, only a future licensee, that means the entity/organisation that will bear the prime responsibility for the installation, is entitled to submit an application for a pre-licensing phase. Even if this step of pre-licensing is not in the regulation, this pre-licensing phase occurs in many countries. It is an opportunity for the regulator to raise safety issues and for the licensee to have first feedback and therefore a better predictability regarding the construction licensing phase.

A design certification process is in place only in Romania, where a process exists in which also a vendor can apply for a design licence in the case of a new design technology never built in the country.

All these processes have to be in compliance with the EU legislative framework[1] in general and to the Euratom[2] legislative framework in particular.

[1] such as assessments that may be required, in particular, under Directive 2011/92/EU on the assessment of the effects of certain public and private projects on the environment, as amended by Directive 2014/52/EU, Directive 2001/42/EC on the assessment of the effects of certain plans and programmes on the environment, Directive 92/43/EEC on the conservation of natural habitats and of wild fauna and flora, Directive 2000/60/EC establishing a framework for Community action in the field of water policy.

[2] The Euratom legislative framework consists of three key legislative acts, namely Directive 2009/71/Euratom, as amended by Directive 2014/87/Euratom (Nuclear Safety Directive), Directive 2011/70/Euratom on the responsible and safe management of spent fuel and radioactive waste, and Directive 2013/59/Euratom (revised Basic Safety Standards Directive).

Conclusion

The importance of a preliminary regulatory assessment of new designs is widely recognised as a mean to allow early identification of potential regulatory issues, lack of specific requirements, needs for complementary experiments as well as to anticipate specific regulatory concerns, etc. It indeed supports early familiarization of the national Regulator with the new designs and to identify questions raised in terms of safety. It provides as well predictability to the licensee.

In the light of the European Partnership for SMRs, even if the authorisation of nuclear installation remains the sovereign responsibility of the states, a cooperation between regulators on the pre-assessment of SMRs is an opportunity to share regulators' approach and expectations. Besides, it provides the SMR designer and the future licensees an idea of the licensability of such a design across several countries with different regulations. A collaboration among regulators of interested countries to conduct a preliminary joint safety assessment of selected designs, whose outcomes could then be used in the national licensing process as needed, is therefore suggested.

3. Summary of ongoing activities in different fora

SMR Regulators Forum [7]

The forum has 11 participating countries (Canada, China, Czech Republic, Finland, France, Japan, Republic of Korea, Russian Federation, South Africa, United Kingdom, United States of America) and 3 observers from international organisations (JRC, OECD NEA and WNA-CORDEL).

The objectives of the forum are:

- to share regulatory experience among members,
- to identify and discuss common safety issues that may challenge SMR related regulatory reviews and, if possible, recommend common approaches,
- to advise IAEA on the need to revise or develop new publications on safety of SMRs.

The main tasks during the first phase were rather related to technical topics (graded approach, defence-in-Depth, Emergency Planning Zone Size).

For the second phase, three working groups were defined dealing with:

- Licensing Issues,
- Design and Safety Analysis,
- Manufacturing, Commissioning and Operation.

In this phase, the licensing issues Working Group produced reports on Key Regulatory Interventions during a Small Modular Reactor Lifecycle, potential issues related to the licensing process for a First of a Kind vs Nth of a Kind design and Licensing of new build projects with multiple module/unit facilities.

During the phase 3 (2021-2023) no work related to licensing process has been completed, as SMR Regulators Forum agreed to serve as the main organisational modality for the NHSI-RT-WG3: Process for leveraging other regulatory bodies' reviews (see below NHSI initiative). Basically, this means that the licensing working group of the Forum and NHSI WG3 have been combined. Furthermore, this combined working group also includes participants from other IAEA Member States that are not members of the Forum.

IAEA NHSI [8]

The new IAEA "Nuclear Harmonization and Standardization Initiative (NHSI)" initiative has been launched by DG GROSSI in April 2022. The initiative aims to facilitate the safe and secure deployment of SMRs to maximize their contribution to reach net zero carbon emissions by 2050. This initiative had its KoM the 23-24 June 2022. There are two tracks (industry and regulatory) in this initiative.

The industry track includes 4 Topics with the following aims:

- **Topic 1 - Harmonization of high-level user requirements**: The focus of this topic is to create a high-level publication, harmonizing the utility associations to define their needs, especially for SMRs and their uses. It is intended to be a learning tool for non-nuclear utilities and will aim to save time and accelerate the deployment of nuclear power programmes. (Timeframe: 2.5 years)
- **Topic 2 - Common Approaches on Codes and Standards:** The focus of this topic is to create a database allowing for the high-level comparisons of: Quality and management related requirements and the component manufacturing related inspection information; Suitability assessment process used for industrial grade components; Engineering and design related C&S; Advanced manufacturing standards, etc. (timeframe: 3 years)
- **Topic 3 - Experimental Testing and Validation for Design and Safety Analysis Computer Codes:** The focus of this topic is to establish a global cooperation and resource sharing for experiments and code validation between entities operating experimental facilities, technology holders and potentially TSOs. (Timeframe: 2.5 years)
- **Topic 4 - Acceleration of nuclear infrastructure implementation for SMRs and Microreactors:** The focus of this topic is to develop a publication aimed at providing a forward-looking view on scenarios that may accelerate the deployment of SMRs and Microreactors in technology recipient countries. (Timeframe: 2.5 years)

The regulatory track includes 3 Working Groups with the following aims:

- **WG1: Framework for information exchange** which focus is on the identification of information sharing needs by regulators, potential obstacles, and potential solutions (timeframe: 1 year)
- **WG2: International prelicensing regulatory reviews** which focus is on the development of a process and criteria for international pre-licensing regulatory review of generic designs (timeframe: 2 years)
- **WG3: Leveraging other regulatory reviews** which focus is on how to leverage the reviews of other regulators and how regulators can work together during ongoing regulatory reviews (timeframe: 2 years)

OECD-NEA

CSNI Expert Group on Small and Modular Reactors (EGSMR) [9]

The Committee of Safety of Nuclear Installations (CNSI) established an expert group on SMRs in 2021 with the aim is to support safety demonstration for advanced nuclear technologies. The group is composed of 27 experts from 14 countries, IAEA and EC.

The main tasks of this group are:

- Assess CSNI past activities on water cooled NPP's safety relevant to SMRs and define work to be done to leverage this work for the need of SMRs safety demonstration,
- Identify safety knowledge gaps focusing on the mature technologies and provide recommendations to address these gaps,

- Identify new technical areas CNSI needs to develop,
- Identify necessary experimental programs and key facilities.

EGSMR has already identified challenges related to the implementation of defence in depth (DiD), the reliability of passive systems, the input for PSA when operational experience is limited and the applicability (and validation) of computer codes developed for LWR for other technologies.

At the end of 2022, a draft report is to be presented to CSNI focusing on the selection of mature technologies, the identification of the knowledge gaps and a proposal of areas for safety research to address these gaps.

In a second step, CSNI will:
- define knowledge gaps and propose effective SMR safety related research,
- define objective and scope of CSNI related activities to support safety demonstration of advanced reactors,
- define proposal for joint research projects to accelerate safety demonstration of novel SMR technologies,
- support knowledge preservation and competence building on a wide range of technical topics,
- develop technical opinion reports on safety issues of most relevance to safety demonstration of SMR to support regulatory decision making.

Multinational design Evaluation programme (MDEP) [10]

MDEP was established by NEA in 2006 as a multinational initiative taken by national safety authorities to develop innovative approaches to leverage the resources and knowledge of the national regulatory authorities involved in the review of new reactor nuclear power designs.

MDEP's main objectives were defined as follows:
- to enable increased cooperation within existing regulatory frameworks;
- to establish mutually agreed positions, influencing enhancements in the safety of new reactor designs.

Within MDEP, there are working groups dedicated to specific designs. Their members are national regulatory authorities of countries that already have commitments for new build or firm plans to have commitments in the near future for these reactor designs. Topics were selected based on the issues arising from regulatory activities in member countries, safety implications, or the general need to have a better understanding of the topic. This has facilitated sharing experiences and can be considered as a starting point for any further work on harmonisation between regulatory practices.

MDEP initiative has been enhancing co-operation among regulators and improving the effectiveness and efficiency of the regulatory design reviews, which are part of each country's licensing process.
One of the aims of MDEP is to work towards greater harmonisation of regulatory requirements. Co-operation amongst national regulators under MDEP has led to harmonization of regulatory positions and practices through the establishment of Common Positions, achieved through the activities of different design and issue-specific working groups.

EUR association [11]

In 1991 the major European electricity producers formed an organisation to develop common specifications for new designs to be proposed by designers in Europe and promote harmonisation across Europe and worldwide. The EUR Association nowadays brings together a dozen of Members representing companies involved in new nuclear projects or in electricity generation from nuclear power in Europe.

Since its creation, the EUR Organisation has developed and regularly updated common positions and harmonised requirements (the EUR Document) for the design of GEN III Light Water Reactors. The EUR Document:

- presents a comprehensive set of nuclear utility expectations for new LWR designs (including SMR) with respect to safety, performance, constructability, and economics,
- covers the entire plant up to the grid interface requirements. The requirements are grounded in proven technology with more than 50 years of commercial European and international LWR experience,
- has already been used as a technical basis for bidding purposes for new build projects in several countries in and outside Europe,
- has been independently benchmarked (Revision E) against the IAEA Safety Standards, WENRA SRLs and objectives/positions and EU NSD (EC funded report "Benchmarking of nuclear technical requirements against WENRA safety reference levels, EU regulatory framework and IAEA standard").

The EUR organisation has been working on SMRs since 2019, with its first outcome is a set of key positions on Light Water SMRs published in June 2021. Following this first step EUR has recently launched the Revision F project which main objective is to be fully applicable to the Light Water SMR designs, with a delivery target in 2024-2025.

ENISS [12]

ENISS is the European Nuclear Installations Safety Standards Initiative. Established in 2005, it represents nuclear installation licence holders from 14 European countries with nuclear program. ENISS is the common channel through which European nuclear licence holders interact with WENRA (nuclear regulators), the European Institutions and the International Atomic Energy Agency (IAEA). ENISS has observer sits at the IAEA safety standard committees.

The main missions of ENISS are:

- to develop common views and positions on the evolutions of the nuclear safety standards,
- to interact appropriately with the regulators and the key stakeholders to ensure that the licensee's positions are effectively given due consideration,
- to maintain an efficient information exchange platform between ENISS members with respect to nuclear safety matters.

As part of the first main mission, ENISS develops position papers resulting from consensus industry views on specific topics. A few have been published since 2018 (e.g. on practical elimination, on safety improvements in existing NPPs).

A task group was created in 2022 to address the topic "licensing of new designs", its first activity being essentially to support ENISS participation in this Work Stream 2 of the European SMR pre-Partnership.

World Nuclear Association Cooperation in reactor Design evaluation and licensing (CORDEL) Working Group [13]

CORDEL is World Nuclear Association's Working Group that promotes the standardization of nuclear reactor designs and harmonized approaches to licensing.

SMRs are a particular area of focus for CORDEL, notably for its SMR and Licensing & Permitting Task Forces. CORDEL has proposed a path towards a harmonized and well-regulated global SMR deployment and has issued multiple reports supporting this objective which are publicly available on World Nuclear Association's website:

- Facilitating international licensing of SMRs
- Design maturity and regulatory expectations for SMRs
- Different interpretations of regulatory requirements
- Harmonization of reactor design evaluation and licensing: Lessons learned from transport

CORDEL has also issued reports to support reactor design standardization, notably:

- Safety classification for I&C systems in NPP – current status and difficulties
- International nuclear I&C and Electrical system standards Tables with URLs (update to be published in 2023)
- Safety classification for I&C systems in NPP – comparison of definitions of key concepts
- Advanced manufacturing of nuclear components

Conclusion

Many initiatives regarding SMRs have been launched at an international level in different fora to address the challenges, risks and opportunities presented by these reactors. However, these reflections are usually conducted with very general perspectives. This fact illustrates the importance of focusing on concrete cases in the future steps of the European Partnership Initiative.

From these different initiatives and regarding the objectives of the European SMR pre-Partnership, the main elements of attention concern:

- from OECD NEA EGSMR
    - their 2022 report should indicate the mature technologies. This assessment should be compared with the ones identified by the European SMR pre-Partnership to ensure consistency,
    - the topics identified by EGSMR as challenges should be considered when selecting the technical topics to raise when engaging early interaction and dialogue on licensing issues between the regulators and designers /licensees.
- from EUR
    - the topics addressed in the EUR key positions on LW SMRs should be considered when selecting the technical topics to raise when engaging early interaction and dialogue on licensing issues between the regulators and designers/licensees.
- from WNA/CORDEL
    - Two reports are of particular interest: “Design maturity and regulatory expectations for SMRs” and “Different interpretations of regulatory requirements”. The topics for which different interpretation of regulatory requirements were identified could be selected when engaging early interaction and dialogue on licensing issues between the regulators and designers /licensees.
- from OECD NEA MDEP,
    - The interest to develop cooperation between some national regulators on a given design rather than on principles. MDEP has as well highlighted the issue of different timeframe of regulator’s reviews.
- from NHSI (and SMR Regulatory forum)
    - the initiative launched by IAEA, which is focused on processes and doesn’t specifically address any specific SMR design, concerns:
        - on the one hand, the definition of a pre licensing process, including the definition of criteria on which the review would be performed, and how it should be documented,

- on the other hand, the definition of a process for mutual recognition/acceptance of other regulatory reviews.

To take maximum benefit from the IAEA NHSI initiative better coordination between EU countries would be recommended to influence the work performed in NHSI and ensure the NHSI initiative provide outputs consistent with the European pre-Partnership approach**.**

The various initiatives launched in the different fora highlight topics which would be interesting to consider when engaging early interaction and dialogue on licensing issues between the regulators and designers/licensees.

4. Codes and Standards

Survey among the WS2 members and interactions with WS4 [14]

The codes and standards applied in the design and construction of a Nuclear Power Plant, large or small, contribute to prove that all the (safety related) Structure Systems and Components (SSC) will perform their safety functions under the conditions (temperature, pressure, humidity, irradiation, earthquake, etc.) to which they are likely to be subjected with a high level of reliability supporting the safety case of the installation. The nuclear industry produces detailed rules on good engineering practice and industrial practice, which it compiles in "industrial codes". These rules make it possible to transpose the requirements of the general technical regulations into concrete terms while reflecting good industrial practice.

The question of the Codes&Standards (C&S) was addressed by WS2 members with a survey and common meetings with WS4 members.

A survey among the WS2 participants was performed about the use of the C&S, and in particular to know if specific C&S were defined in the regulation in their countries. The conclusion is that the national safety authorities generally[3] do not prescribe the use of particular codes or standards. Regulators also mentioned that they have experience with different C&S and it is possible to have different C&S used in a nuclear installation but that it should be avoided at the system level (only one set of C&S for an entire system), in particular for the higher safety class systems. The list of codes and standards used for the design is generally required in the safety report.

During common WS2-WS4 meetings, WS2 members have recalled that designers should ensure that, whatever the C&S chosen for the design, the C&S will comply with the national regulation. In particular, it should be distinguished between the C&S which are directly linked to national regulation (like the ones for pressure vessels) and the ones which are not linked to any national regulation. Some specific national regulations show indeed differences across the EU and this is an obstacle to standardisation. The need for mapping the differences in regulations between EU countries was emphasized.

From the designers survey performed by WS4, it appears that designers are open to use different C&S but that using different C&S could have an impact on the design of some SMRs components. To facilitate the licensing, the licensee should obtain the proper information from the designers in view of informing the regulatory body about what are the main differences in the C&S compared to the one commonly used in

[3] Romania recommends a list of industrial codes and standards but allows for the use of different codes and standards, provided that at least an equivalent level of safety is demonstrated.

the country of interest (or equivalences) and what are the design and safety implications of using a set of C&S instead of another one.

There are also some others C&S or regulations not directly related to nuclear topics, but which could have an impact (construction codes, health&safety, fire, etc.) on the designs.

Acceptability of high-quality industrial grade components used in safety classified systems, was brought up by WS4 but was not addressed by WS2. WENRA is planning to work on the subject to come up with a common understanding and possibly recommendations.

Conclusion

Most regulators do not impose the use of particular Codes & Standards and have expressed readiness to accept those proposed by designers as part of a "full package". The designers should ensure that, whatever the C&S chosen for the design, the C&S will comply with the national regulation. The designers should as well provide information to the regulatory body about what are the main differences in the C&S compared to the one commonly used in the country (or equivalences) and what are the design and safety implications of using a set of C&S instead of another one.

There is an interest that the designer mentions at an early stage the C&S it intends to use. This could be a topic to consider in the pre-licensing.

5. Research and Innovation

Interaction with WS5 [15]

During a common WS2-WS5 meeting, three topics were discussed: Passive Systems, Severe Accident, Human Factor (it is important to highlight that WS5 members had, so far, no detailed discussions with SMRs designers on the above-mentioned topics).

The main elements which came out of the discussion were the following:

- A passive system needs to be a proven technology and its reliability in any condition is key. The discussions with WS2 highlighted the need to check all the possible bounding conditions for Passive Systems operation, to apply conservative deterministic analysis, thus also consider the Passive Systems failures. The need for R&D on instrumentation was also mentioned.

- In the field of Severe Accidents, it is important to note that the definition of Emergency Planning Zone (EPZ) is the responsibility of the public national authorities. The main point of discussion with the SMRs applicants (designers /licensees) should be Safety Objectives for SMRs. It is also well known that there are very different ways, in different countries, to calculate doses to the public in case of a nuclear accident. In this regard the importance to work on the development of a common approach was mentioned.

- For Advanced Modular Reactors like HTGR or MSR the definition of a severe accident should be adapted: it should correspond to cases where there is a failure of the level 3 of the Defence in Depth (DiD).

- The Human Factor part of the discussion was about the need or not to conduct research on this subject. Some NPPs in the world (AGR, CANDU) already operates with one Control Room (CR) for two units but how many units can be controlled from a single Control Room remains an open question.

Euratom projects

The projects ELSMOR, HARMONISE, and SASPAM-SA funded under the Euratom Research And Training programme have been presented as directly related to the licensing process and severe accident analysis of SMRs.

"ELSMOR" project [16]

ELSMOR aims to create methods and tools for the European stakeholders to assess and verify the safety of light water small modular reactors (LW-SMR) that would be deployed in Europe. It is gathering, analysing and disseminating information on LW-SMRs' potential and challenges to target audiences such as citizens, decision-makers and regulators.

ELSMOR advances the understanding and technological solutions pertaining to light water SMRs on several fronts:

- Collection, analysis, and dissemination of the information on the potential and challenges of Small Modular Reactors to various stakeholders, including the public, decision makers and regulators
- Development of the high-level methods to assess the safety of LW-SMRs
- Improvement of the European experimental research infrastructure to assist in the evaluation of the novel safety features of the future LW-SMRs.
- Improvement of the European nuclear safety analysis codes to demonstrate the capability to assess the safety of the future LW-SMRs

"HARMONISE" project [17]

HARMONISE has set five Objectives:

- Objective 1: To analyse preliminary safety assessments of innovative fission and fusion installations
- Objective 2: To peruse the licensing needs for innovative nuclear installations
- Objective 3: To examine risk-informed, performance-based (RIPB) approaches in licensing reviews and regulatory decision-making
- Objective 4: To delimit harmonisation and standardisation on component assessments, methodologies, codes and standards
- Objective 5: To learn from earlier experience in harmonisation efforts

One of the activities of the HARMONISE project is to communicate regularly with different stakeholders. The main tool of communication will be semi-annual workshops.

"SASPAM-SA" project [18]

SASPAM-SA Project has set four Objectives to transfer and adapt the knowledge and know-how of well-proven and established large Light Water Reactor (LWR) technology to SMRs iPWR, in view of the European SA and Emergency Planning Zone (EPZ) analyses:

- The identification of plausible SA scenarios for iPWRs with the related conditions in the vessel and in the containment,
- The study of the applicability of the existing experimental databases to iPWR and identify new experimental needs,
- The assessment of the capability of internationally recognized European and Non-European computational tools (largely used in Europe) to describe the behavior of the most promising iPWR designs during SA scenarios,

- The prediction of the resulting radiological impact on- and off-site, taking into account special SA mitigation/management strategies.

The expected outcomes of the project will help speeding up the licensing of iPWRs in Europe, as well as the siting processes of these reactors in light of their possible use near densely populated areas.

Conclusion

Collaboration between Regulatory Bodies and EU research organisations could be a mean for the regulators to get a common understanding of the challenges related to SMRs key safety issues. For a given design/technology, the discussions should further include designers and future licensees to focus further research and experiments on potential blocking points (lack of knowledge) for the licensing process

6. European Commission study "Benchmarking of the nuclear safety regulatory framework and regulatory practices for SMRs in different European countries" [19]

Over decades, nuclear safety standards have been developed and regularly updated on the global scale by the IAEA as well as within the EU, and by WENRA (Safety Reference Levels). Current regulatory framework found within established nuclear markets were designed for larger nuclear power plants and may be challenging for SMRs due to some SMRs features. In addition, the regulatory framework, or the regulatory practices already in place in countries using nuclear energy, while being consistent in terms of main objectives and principles, often follow very different approaches: this may include differences (scenario, criteria…) to demonstrate compliance with the requirements, with potential impact on design provisions.

With all these elements in mind, the European Commission (DG ENER) has launched a study to perform a "Benchmarking of the nuclear safety regulatory framework and regulatory practices for SMRs in different European countries". The study will mainly focused on EU countries which have expressed a clear interest for SMRs and the willingness to license SMRs on their soil. The proposed study will assess whether and how the differences in the nuclear regulatory framework or regulatory practices in different European countries could affect the licencing of SMRs in the European Union. The study should also present the regulatory framework and regulatory practices in some European and non-European SMR designers' country-of-origin, in particular those for which clear interest has been expressed by potential licensees in the EU.

This study has started in January 2023 and has a duration of 12 months. It will include collection and data, two workshops and preparation of intermediate and final reports on the topic.

It is foreseen that for the entire work, a representative "Stakeholders Group" should be established to support and supervise the selected Contractor. This SG should be mainly drawn from members of the European SMR pre-Partnership WS2, nuclear industry representatives (designers and operators) involved in the licensing of NPPs/SMRs and representatives from relevant international organisations like WENRA, ENISS, IAEA, OECD-NEA and EUR.

7. Actions for future steps to support pre-licensing of SMRs

During WS2 meetings as well as during the ENSREG conference in June 2022 and the European SMR pre-Partnership Workshop in October 2022, several challenges emerged. To address these challenges, the following objectives have been defined:

- 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

To address these three main objectives, some possible ways forward or pre-requisite activities are presented below.

1. Engage early dialogue between designers -licensees and regulators on main elements of the design options

The first action would be to create the necessary tools to enable an early dialogue between designers – licensees and EU regulators and that would facilitate performing thereafter joint assessments.

To do so, the following steps should be envisaged.

1. Establishing the way for one designer- licensee (or group of licensees) to initiate early dialogue with national regulators in the different EU countries of interest (e.g. as a group in the ENSREG context)
2. Definition of pre-requisite information for an early dialogue (file from licensee, etc.). Designers-licensees that wish to initiate this early dialogue would first prepare a report. This report would include a high-level description about their design philosophy, especially with regard to European legally binding requirements and WENRA SRLs. They should indicate, for example, how is their interpretation of DiD, what is their proposal to practically eliminate an early and large release? Etc.
3. Definition of the arrangements of the early dialog (e.g. selection of key topics, type/structure of the dialog, type of expected feedback).

Administrative support for implementing the actions needed should be arranged. It could be initiated in the frame of the WS2 but potential support from the European Commission should be investigated to ensure long term sustainability.

2. 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.

The benefit of a joint pre assessment would be that **"**interested" European regulators can jointly conduct a preliminary safety assessment of SMRs designs at an early stage of their development when safety options are still open, share their evaluations and give vendors/future licensees feedback and especially anticipate issues which would have to be addressed in the licensing.

Before a joint pre-assessment, the following points should be discussed/agreed first:

1. Agreement on the definition of what is the sufficient level of maturity for a designer-licensee to engage a joint safety pre-assessment (it is understood that the minimum level of detail roughly corresponds to a plant-level design).
2. Establishment of the kind of agreements which are needed (legal, financial, aspects of sharing information about the outcome and who can use it, secretariat support, etc.). Participation of the potential future licensees of the design to be assessed. Agreement on what should be the reasonable duration of such a pre-assessment.
3. Definition of the format and content of the submitted documentation by the designer-licensee.
4. Definition, taking into account WENRA ongoing work, of commonly shared Safety Objectives for SMRs between the EU "interested" nuclear safety regulators.
5. Agreement on the assessment criteria in a joint assessment: national requirements, a set of common criteria or decided case-by-case?
6. Definition of a list of potential topics for consideration in the joint pre- assessment.
7. Definition of the way to share and discuss the findings of these pre-assessments, (as a minimum to consider preparing a 'review report' accompanied by a workshop to actively discuss the findings among regulators and explain how these findings have been identified).
8. Definition of the possible options and conditions for another regulator or licensee to join the pre-assessment after it has started and the necessary arrangements on the way how the reporting of the findings of one of these preassessments to 'third' parties should be done.

3. Identify in an early phase potential blocking points in the safety requirements or licensing processes and arrangements for convergence

It should be useful for the designers and regulators to know, at the stage of conceptual or SMR basic design development, the main differences in the safety requirements and licensing processes in the EU member states in view of finding convergences an avoiding potential blocking points at a late stage of the licensing process.

Regarding the identification of the generic blocking points and convergence amongst the EU regulators, the following considerations and actions should support this:

1. Establish the main differences in the safety requirements, licensing processes in the "interested" EU member states in view of finding if convergence is needed to avoid blocking points.
2. Identify the potential blocking points related to SMR features and designs which are related to nuclear safety regulations.
3. Identify the potential blocking points outside of the nuclear safety regulations that could impact the standardisation (including all relevant legal matters, and environmental, emergency planning, fire safety and security aspects).
4. Define the arrangements to enter and complete (or not) a convergence phase considering the situations where:
    a. Convergence might be possible on the basis of the current requirements and expectations only (generic basis).
    b. Convergence might be possible only in the frame of a specific design assessment.

c. Convergence is not possible due to significant differences in the national legislations for example.

Work already performed in different fora and projects starting could also provide some information, such as:

- The European Commission study "Benchmarking of the nuclear safety regulatory framework and regulatory practices for SMRs in different European countries" that is just starting (see Chapter 6) should be able to identify several of these blocking points through the "Stakeholders' Group" that should be created in this frame. This should include blocking points due to different regulatory frameworks (e.g. US or Canada versus Europe).
- The SMR Regulators' forum, IAEA NHSI, IAEA TECDOC-1936, EUR Key Positions on SMLWR, Euratom Horizon project "ELSMOR" and "HARMONISE", etc. …

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Appendix A: European SMR pre-Partnership WS2 members and observers

Participants	Organisation	Country
Sylvie CADET-MERCIER (Chairperson)	**ASN**	France
Ghislain Pascal (secretariat)	**DG ENER**	EC
Sebastian Kuhn	**BMU**	Germany
Tamás Czerovszki	**HAEA**	Hungary
Karel Künzel	**SUJB**	Czech Republic
Štěpán Kochánek	**SUJB**	Czech Republic
Evaldas Kimtys	**VATESI**	Lituania
Minna Tuomainen	**STUK**	Finland
Eetu Ahonen	**STUK**	Finland
Daniel Kjellin	**SSM**	Sweden
Lamberto Matteocci	**ISIN**	Italy
Luca Cretara	**ISIN**	Italy
Philippe DUPUY	**ASN**	France
Cantemir Ciurea - Ercau	**CNCAN**	Romania
Madalina Coca	**CNCAN**	Romania
Marcela Karelová	**UJD**	Slovakia
Rick Bulk	**ANVS**	The Netherlands
Santiago Arenzana Romeo	**CSN**	Spain
Marcin Dabrowski	**PAA**	Poland
Gufler Klaus	**UG**	Austria
Simon COENEN	**FANC**	Belgium
William Ranval	**ENISS**	
European Commission (observers)		
Angelgiorgio Iorizzo	**DG RTD**	
Jesus ALQUEZAR SABADIE	**DG ENV**	
Luca Ammirabile	**DG JRC**	
Yvan Pouleur	**DG ENER**	