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NUWARD JOINT EARLY REVIEW – CLOSURE REPORT PHASE 2

Main lessons learned from the phase 2 of the Nuward JER – Regulators' perspectives

Report collaboratively written by

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EXECUTIVE SUMMARY

From June 2022 to June 2023, regulators from France (ASNR), Finland (STUK) and Czech Republic (SÚJB) have conducted a joint early review (JER) of the light water SMR developed by EDF, the NUWARD SMR, for which energy companies from these countries had expressed an interest.

After successfully completing its pilot phase, the NUWARD JER has been extended to address additional topics of particular significance for safety and its membership expanded to the regulators of the Netherlands (ANVS), Sweden (SSM) and Poland (PAA).

A catch-up process has been put in place for new members, in order for them to familiarize with the NUWARD SMR design and to contribute their insights on the topics discussed during the pilot phase. In addition, this second phase of the JER also incorporated feedback from the vendor on some regulators' review conclusions.

This second phase confirmed the benefits of such an initiative in enhancing regulators' effectiveness and responsiveness in licensing new reactors. In particular, it was a helpful input for members revising their regulatory framework.

It also confirmed that most of the identified divergences stem from differences at the guidance level and the way of implementing regulatory requirements but not really from differences in requirements as such.

While achieving consensus was not its primary goal, the JER identified opportunities for regulatory convergence, which are mentioned in this public report with the aim of generating discussion within international regulators' forums and seeking consensus within the regulatory community.

A dedicated forum where regulators can engage with a vendor on a specific reactor design is a highly effective tool for early interactions. It allows safety-related issues to be addressed at an early stage, minimizing findings later in the licensing process, while also enabling the deployment of a reactor design across multiple countries through joint regulatory evaluation. Furthermore, such cooperation facilitates practical, in-depth assessment of safety features, making the process both concrete and results-oriented.

After three years of collaboration, the JER has shown the importance for regulators to continuously reassess their practices. The licensing of new and innovative technologies presents an opportunity to develop new cooperative tools that will enhance the efficiency and responsiveness of regulatory assessments.

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1. A SECOND PHASE OF AN INNOVATIVE INITIATIVE

In September 2023, the nuclear safety regulator of France (ASN), Czechia (SÚJB) and Finland (STUK), with their Technical Support Organisations (IRSN for France and SÚRO for Czechia) shared the conclusions of the first phase of the Nuward Joint Early Review (JER) of the Nuward SMR in a public report 0.

Considering the very valuable outcomes, it was agreed not only to continue but also to expand the membership of the initiative. The regulators of Sweden (SSM), Netherlands (ANVS) and Poland (PAA), joined the JER. In November 2023, the six regulators signed a common Term of Reference and agreed on a mandate to rule the second phase, being driven by similar objectives than for phase 1, which means to enable participating regulators:

(a) to acquaint with a SMR design and identify the potential challenges that it raises prior to the beginning of their respective licensing process.
(b) to share their expectations, knowledge and practices about the identified topics.
(c) to increase knowledge transfer about regulatory practices and expectations.
(d) to provide EDF with early feedback about its design and possible associated regulatory challenges.

All the participating regulators agreed on the programme of work:

- a catch-up phase for new participating members to review the topics addressed in the first phase (see §2.1);
- review of additional technical topics;
- discuss feedback from Nuward on the impact of regulator's conclusion on their design and safety demonstration.

A significant design change of the Nuward SMR took place during the second phase of the JER. Indeed, Nuward decided to reconsider some key concepts of its SMR design. Although this shift had an impact on the JER, it was decided to maintain the programme of work considering the discussions were still very valuable for both the vendor and the regulators. The JER outcomes brought valuable insights comforting NUWARD in its decision to shift the design strategy, and will guide NUWARD in determining several critical choices for its new design.

This report highlights the main conclusions and lessons learned from the second phase of the JER.

In appendix, the context and a short description of the regulatory framework (including the licensing process) of the new members (Netherlands, Poland and Sweden) are provided. Similar content for Czechia, Finland and France is provided in the report from the phase 1 0.

2. PRESENTATION OF THE PHASE 2 OF THE JOINT EARLY REVIEW

2.1. SEQUENCE OF CATCH-UP

Three additional regulators joined the initiative for the second phase. It was decided to started this new phase by a catch-up sequence. During this sequence, the three new members were invited to share their regulatory framework and to conduct a streamlined review of the six topics addressed in phase one:

- topic 1: definition of safety objectives.
- topic 2: identification of DBC.
- topic 3: use of cooling passive systems.
- topic 4: development plan of scientific computing tools.
- topic 5: twin modules integration.
- topic 6: probabilistic safety assessment.

The main objective of this sequence was to align the level of knowledge about the project before starting the second phase. The conclusions of the review raised during the first phase were shared with the new members.

This sequence, although very demanding for the regulators who carried it out, was not only very informative for all the members but it was also a challenge for the forum to perform a sequenced review with new members. To this end, the following recommendations have been identified to conduct such exercise:

- All the regulators should have a similar level of knowledge of the project;
- New members should have the opportunity to raise new findings;
- Conclusions raised during the different stages should be shared with all members;
- The additional workload for new members should be taken into account in the programme of work for the next phase.

The outcomes of new members' reviews were very valuable by providing more views in the discussion. Their reviews confirmed most of the divergences and common approaches identified during the first phase but it also raised new differences not identified in phase 1. For example, conclusions on topic 6 stressed difference regarding PSA level 3. Indeed, in application of a national regulation, not only applicable to nuclear installations, the Dutch framework requires PSA level 3 to be conducted by the applicant. Other members only require PSA level 1 and 2.

Besides, the catch-up sequence confirmed the large gaps between the six regulatory frameworks regarding the Defence-in-Depth matrix and DBC/DEC categorisation. In particular, the expected frequencies of occurrence and the radiological consequences limits associated with the different plant condition categories are very different from a country to another.

The divergences on the consideration of the boiling of the water in the spent fuel pool identified during phase 1 were also confirmed by the additional insight provided by the new members. Similarly, as pointed out during the phase 1, the approach regarding the application of a single failure criteria is different. Finland and the Netherlands have indeed more stringent requirement than the other members especially for DEC events.

2.2. REVIEW OF ADDITIONAL TECHNICAL TOPICS

In the same way as for the pilot phase, some additional topics of review have been selected. They were selected according to the following criteria:

1. It is a topic which brings answers on the level of safety that could be expected, and on the approach to meet this level;
2. It is a topic with SMR specificity on which there is no or very few safety requirements, recommendations or guidance, or significant information and experience feedback;
3. It is an important feature of the safety demonstration which requires a lot of time to be developed and assessed, due to its complexity or novelty. Starting the review of this topic as early as possible could help reducing the timeframe of the licensing process;
4. It is a key topic for the NUWARD SMR design, in a way that a late change on this topic would have an important impact on the design or the safety demonstration. Providing feedback as early as possible can enable the vendor to meet regulators' expectations more easily and timely.

For the second phase of the JER, the following topics have been discussed:

- Topic 7: Design extension conditions management strategies. Within this topic, the members discussed the strategy for the accident management of a first list of DEC-A scenarios and also the strategy for severe accident management (DEC-B). This topic complies with criteria 1, 3 and 4.

- Topic 8: Containment and radiological consequences assessment. This topic included the safety objectives in terms of radiological consequences limitation and the methodology retained for radiological consequences evaluations and calculations. It also covered the main safety features (including in

particular the definition of the barriers) retained for ensuring the confinement function, and respect of the safety objectives. This topic complies with criteria 1, 3 and 4.

- Topic 9: Criticality risk management. The members discussed the safety approach considered for criticality management (double contingency principle, keff criteria etc.). The main design options considered with regard to criticality management and the design choices made at the reactor and spent fuel levels. This topic complies with criteria 3 and 4.

- Topic 10: Electrical and I&C systems architecture. This topic covered the safety architecture of electrical and I&C systems, including a description of the overall electrical and I&C systems concept in the NUWARD SMR design. This topic complies with criteria 3 and 4.

The topics were selected based on the initial version of the Nuward SMR.

In addition to the initial programme of work, it was decided to address some specific topics of interest identified during the review.

For example, the exemption regime and the regulatory framework regarding aircraft crash were discussed.

The exemption regime can also be seen as an alternative for meeting various requirements through a standardized design. The discussion highlighted significant differences in the regulatory frameworks of the six member countries. While most members allow licensees to provide a justified rationale for non-compliance with regulations, all six regulators agreed that exemptions should only be granted on an exceptional basis.

The topic of aircraft crashes highlighted the limitations of the JER as a forum for openly discussing key issues related to design standardization. Much of the information is highly sensitive and confidential, while the conclusions drawn from this aspect of the licensee's application can have a significant impact on the design.

Centring the discussion on specific topics is an effective way to compare practices and should be considered as an approach for conducting a responsive review. While refocusing discussions can be effective, it remains necessary for the regulators to have a global vision of the concept.

2.3. VENDOR'S FEEDBACK ON REGULATORS REVIEW

The second phase was also the opportunity to conduct an iterative discussion with Nuward on possible methods of taking into account the feedback from the regulators' group. During this last step, Nuward shared vendor's perspectives on the impact of the conclusions raised by the regulators on a few selected topics.

This feedback confirmed that most of the divergences are limited to the implementation of the regulation. It highlighted that no contradictory requirements have been identified. The divergences identified regarding the binding requirement at this stage were mostly due to difference in the level of conservatism.

The iterative dialogue with the vendor was very valuable for the regulators to guide their international dialogue and to prioritise their effort to align their views on some key topics with the regulators' community. The outcomes shared have been taken into account to identify potential topics to be addressed by international regulatory forums (see §3.3).

3. MAIN OUTCOMES FROM THE REVIEW OF THE DIFFERENT TOPICS

3.1. HIGH LEVEL CONCLUSIONS

All the 6 regulators are part of European Union (and therefore implement Euratom and ENSREG requirements) but are also members of Wenra. As a result, their regulatory frameworks (at the law and decree level) are already very similar. The review of the Nuward SMR highlighted that most of the divergences identified are not due to the regulatory requirements but mostly from the guidance level or even from their interpretation.

For instance, all regulators have very similar expectation on the isolation of containment penetration (two means, one outside and one inside). However, the views diverged on the consideration of a check valve as an isolation means. In a similar manner, all the regulators require the electrical and I&C equipment's to comply with diversification principle but there is no common approach on the criteria for achieving diversification.

The last sequence of the phase 2, including feedback from the vendor on the regulators' conclusion was very informative. Indeed, the regulators are not in a position to identify if their divergences would generate design changes. The vendor is the most appropriate stakeholders to conduct such assessment and to consider alternatives complying with all frameworks. Such an approach requires an assessment to be carried out very early on in the development of the design.

Among the divergences identified, some of them come from national regulation, not only applicable to nuclear installations. The requirement on PSA level 3 in the Netherlands (see 2.1) and the labour law affecting containment (see 3.2) are good examples.

3.2. EXAMPLE OF CONCLUSIONS ON PHASE 2 TECHNICAL TOPICS

Following statements are a sample of conclusions raised during the review.

- List of DEC-A
  There is a consensus in the member countries to consider the combination of DBC events with common cause failure as DEC-A events. However, the regulatory frameworks provide various approaches in the definition of complex sequences/multiple failures.

  All country members are expecting/requiring the support of Probabilistic Safety Assessment to establish the list of DEC-A accidents.

- Consideration of fuel melt in spent fuel pool
  Most of frameworks require/expect to make fuel melt in spent fuel pool a practically eliminated situation (STUK, ASNR, ANVS, SSM and SUJB). PAA expects the event to be considered in the safety demonstration.

- Containment
  All members require/expect to have two isolation means on penetration connected to the primary circuit or to the atmosphere of the containment (in series, one inside, one outside). In all other cases, only one means is accepted, outside the containment.

  Most members explicitly requires/expects to minimize the number of penetrations (ASNR, PAA, ANVS).

  All members require/expect isolation means to be located as close as possible of the containment.

  Most members expect/require diversification between the two isolation means. Criteria to define diversification should of course be discussed with the applicant. The regulation on containment is also affected by national regulation, not only applicable to nuclear installations. The labour law and more

specifically the regulation on health and safety of workers can have an impact on the exit routes and therefore the number of personal hatches in a nuclear plant.

- Combination of standards
  The review of I&C and electrical architecture revealed that none of the six regulators requires specific codes or standards within their frameworks. However, the regulators agreed on recommending that vendors avoid mixing different families of standards whenever a single standard can be used.

3.3. CHALLENGES TO BE ADDRESSED

The JER focused on identifying divergences, and possible convergence or harmonization were not discussed. During the review and discussion, the regulators have identified some divergences for which an international perspective would be helpful.

These topics may be addressed at international level among the regulators' community. The discussions may first help the regulator to better understand the different approaches and, potentially, to align the views and reach a common position.

- Application of best-estimate approach for DEC-A studies

The discussion within the JER highlighted that there are no harmonized practices on assuming best-estimate approach for DEC-A studies even if general recommendations/requirements in different regulation regimes are consistent.

Best estimate approach (or realistic approach) for DEC-A studies may be accepted by some regulators. Additional sensitivity studies may be expected, including a quantification of the uncertainties. While, for other regulators, the dominant parameters of DEC-A accident studies are expected to be penalized.

- Exclusion of large breaks

In order to justify the exclusion of large breaks, there are two main approaches:

i. Leak before break;
ii. Break Preclusion.

None of the regulators required a preferred approach. However, each regulator has a very different practice in how these two approaches are interpreted. This is mainly due to the legacy of the past experiences.

Regulators from the JER recommend the international community to first engage a dialogue to have a better understanding of the two approaches and then to try to raise recommendations for vendors to facilitate the demonstration of exclusion of large breaks.

- Regulation applied to containment

As seen during the JER for the Nuward SMR, some regulators may encounter innovative approaches to containment when licensing future SMRs. Discussions within the JER have highlighted that certain regulatory frameworks may need to be adapted. To anticipate this evolution, regulators could take steps to identify the best approach to address this challenge. The regulators recommend to pursue the work already conducted by the SMR Regulators' Forum in its report on "containment systems" [2]. In particular, the common position identified in the report should be disseminated within the regulators' community.

- Justification to be provided to support In-Vessel Retention (IVR) approach

For all the members, IVR strategy is to be assessed on a case-by-case basis: none of the members have requirements specifically developed regarding IVR. An IVR strategy has already been considered and assessed for mid-scaled reactors (<500MWe) by STUK, SUJB and ANVS.

4. LESSONS LEARNED ON THE INITIATIVE

4.1. KEY FEATURES TO MAKE THE JER A SUCCESS

The first public report issued in 2023 0 has already identified some feedbacks on the initiative. These included the followings, still applicable for the second phase of the JER:

- Reviewing a similar design helps to identify safety challenges for the licensing;
- Discussing with the vendor enable the regulators to better understand the design and the safety challenges;
- The scope of the review should be limited to the most important topics for safety or for the design;
- International standards (from IAEA or WENRA) are a very good harmonized reference but are not sufficient to provide a position other than an in-principle acceptability of a design or a safety approach.
- The JER initiative preserves each regulator's independence and sovereignty, as the joint synthesis enables to carry both common and individual views.
- As the JER initiative does not lead to regulatory binding decisions, it enables to have more open discussions between the regulators and the vendor;
- The JER initiative gives the working group useful insights on each other regulatory approaches and thus the opportunity to consider evolutions of their national regulatory framework including the regulatory safety guides.

The second phase of the JER also brought new lessons learned.

- Information sharing

  The ability to openly share technical information was a key prerequisite for the JER. To facilitate this, Nuward signed a non-disclosure agreement with all regulators, establishing a framework for information sharing.

  The discussions leading to the NDAs highlighted significant differences in transparency and public information-sharing regulations across various frameworks. As a consequence, the NDAs have been customised for each framework. This sequence should be anticipated and scheduled as a first step.

- Phase 2 challenges

  As described in section 2.1, the catch-up phase was a new challenge for the JER as it required to reconsider the sequence of work. In good harmony between all parties the planning and deadlines were adapted several times successfully to accommodate available resources, leading to limited delays of the JER.

- Flexibility

  The larger membership in phase two made the working process more challenging.

  To streamline the review, key subtopics were identified. It also made the material easier to compare.

  Besides, the number of meetings between regulators and experts was reduced, as organizing such meetings proved difficult due to the availability of multiple experts. Consequently, more interactions were conducted via email.

  In conclusion, phase two highlighted the need for flexibility to strike a balance between the ambitious goals of completeness and responsiveness.

- Creating a dialogue with the vendors
  The final phase of stage two, which involved iterative feedback from Nuward on the regulators' conclusions, was one of the key objectives of the JER. This dialogue is essential for regulators to understand whether regulatory divergences could lead to design changes. Additionally, it provides an opportunity for regulators to identify priority topics for discussion on potential areas of convergence.
  Furthermore, the conclusions raised by the regulator during the phase 1 and 2 will be taken into account for the new version of the Nuward SMR.

- Collaborative tools and knowledge management
  During phase 2, new collaborative tools were used to share documents and work collaboratively. However, their usefulness remained limited due to technical constraints such as language barriers, user interface issues, and the limitations of the online editing tool. In order to effectively support such international forum, a collaborative tool should:
    - Provide a high level of security;
    - Provide an interface in English;
    - Be available for all the members;
    - Be user friendly and easy to connect;
    - Be compatible with all digital environments.

  Furthermore, effective knowledge management is essential to maintain a structured and thoroughly documented repository.

4.2. LIMITS OF THE JER

The JER framework has been tailored to align with the objectives, needs, and constraints of all stakeholders involved in the Nuward SMR project.
Generating interest is the first prerequisite for establishing an initiative to review a design. In particular, the vendor must be actively seeking international development opportunities. From a regulatory standpoint, this also implies a willingness to review an SMR design.
The JER was limited to a review conducted at a very preliminary stage, which has advantages but also drawbacks. In particular, having sufficiently mature inputs is a challenge at this design stage.
The number of participants in the working groups is an additional constraint that should be considered when setting objectives and determining work methods. A broadly attended forum may have to adjust its ambitions to reflect the complexity of coordination.
Another key factor considered in the JER was the availability of resources, both for regulators and the vendor, to carry out this demanding review. The vendor must have sufficient financial and human resources to support the process, while regulators need adequate capacity to ensure a timely and effective review.
Given that the reviews were conducted jointly, synchronizing schedules was also essential. If stakeholders were at different stages of the project, a different approach and framework would have been required.
The second phase of the JER introduced the challenge of an expanded membership, adding complexity to the coordination of meetings with all stakeholders and causing delays in some discussions. Therefore, membership should be carefully structured, keeping in mind the constraints associated with a broad participation.

LIST OF ABBREVIATIONS AND ACRONYMS

ANVS	The Authority for Nuclear Safety and Radiation Protection
ASNR	French nuclear safety authority (formerly ASN)
BWR	Boiling Water Reactor
DBC	Design Basis Conditions
DEC	Design Extension Conditions
EDF	Electricité de France – French vendor and operator
ENSREG	The European Nuclear Safety Regulators Group
HTGR	High-Temperature Gas-cooled Reactor
I&C	Instrumentation and control
IAEA	International Atomic Energy Agency
IRSN	French technical support organization (now part of ASNR)
IVR	In-vessel retention
JER	Joint Early Review
NDA	Non-Disclosure Agreement
NPP	Nuclear Power Plant
PAA	Państwowa Agencja Atomistyki (Polish nuclear safety authority)
PSA	Probabilistic Safety Assessment
PWR	Pressurised Water Reactor
SAR	Safety Assessment Report
SMR	Small Modular Reactor
SSM	Strålsäkerhetsmyndigheten (Swedish Radiation Safety Authority)
STUK	Finnish radiation and nuclear safety authority
SÚJB	Czech state office for nuclear safety
SÚRO	Czech technical support organisation
TSO	Technical support organisation
WENRA	Western European Nuclear Regulators Association

REFERENCES

[1] NUWARD SMR Joint Early Review – Pilot phase closure report 2023

[2] SMR Regulators forum, Working Group on Design and Safety Analysis Phase 3 Report – Containment System December 2023

Appendix 1 Context, Licensing process and regulatory framework in the Netherlands

Context

The current Government is implementing a plan to introduce 4 new large NPPs, to extend the lifetime of the existing NPP and also supports the introduction of SMRs (both land- and marine based). Two Dutch companies are working on an initiative for one or more large SMRs, one PWR and the other BWR. Another foreign company is working on an initiative for one or more micro reactors. A startup company Thorizon is designing an MSR. It has now also an office in France. ANVS and ASNR cooperate in its regulation. It has been granted subsidies in both countries. Part of the research is done in the Netherlands. Further a maritime party has recently started to design a Dutch HGTR. The Dutch maritime sector has a goal to develop the maritime SMR fabrication industry. Based on all these plans ANVS is substantially expanding and professionalizing its staff. In 2023 a program New Initiatives Nuclear for a periode of 3-years was installed in order to prepare the ANVS for concrete upcoming projects, given the fact that there is high level of uncertainty on the timing and types of reactors.

One of the projects of preparation is the adaptation of the Dutch Safety Requirements.

Licensing process and regulatory framework

The Nuclear Energy Act stipulates that a licence must be obtained to construct, commission, operate, significantly modify or decommission a nuclear power plant or another nuclear facility.

In the current situation there is no separate site licence or a site permit. This means that the ANVS does not have a formal oversight possibility for a new nuclear power plant or another nuclear facility until a construction licence is given. Review of the site related issues will be part of the SAR review for the construction licence.

It is customary for initiators of larger licensing procedures (e.g., for a construction licence) to enter into preliminary consultation with the ANVS prior to submitting an application. In the preliminary consultation, the initiator announces the plans and the ANVS provides insight into the assessment frameworks and other conditions for the licence. The ANVS will conduct a preliminary review of the Safety Documentation. This preliminary consultation period can take up to a few years. Ultimately, the intention is for the preliminary consultation to be concluded with a draft permit application that has been assessed on essential components (e.g., the Preliminary SAR for a construction licence). The application may be expected to be complete and to be processed. The preliminary consultation has no formal legal status and legal term (or deadline).

Overview of the licensing process under Nuclear Energy Act, observing procedures mentioned in the General Administrative Act (Abw), variant with Environmental Impact Assessment:

- Informal discussions applicant and ANVS about application and EIA.
- Although the EIA legislation under the Environmental Act allows skipping the following steps, ANVS prefers the following:
    - To start the EIA procedure as well as the procedure for licence application simultaneously with applicant submitting ‘Mededeling m.e.r.’, a document stating the intention to submit an application for which an EIA is required;
    - The ANVS notifies the general public of the ‘Mededeling m.e.r.’ by publication in the Dutch
    - Government Gazette, one or more national and local newspapers, and on the website of the ANVS.
    - The notification also mentions that (1) all members of the public are free to lodge opinions on the ‘Mededeling m.e.r.’ and (2) advice will be requested from the Commission for the Environmental Assessment (‘Commissie voor de m.e.r.’, Cmer).

    - Members of the public submit their opinions and Cmer gives advice on required scope and content of EIA.
    - Twelve weeks after receiving the 'Mededeling m.e.r.', ANVS gives advice to applicant on required scope and content of EIA report, taking notice of opinions and Cmer advice received.
- Applicant drafts its EIA and other documentation that will accompany the licence application.
- Applicant submits EIA report and other required documentation to the ANVS.
- ANVS determines if the application satisfies procedural requirements and expected completeness.
- ANVS notifies the applicant whether the application is admissible, or needs more work.
- Once the application is considered to be complete, ANVS notifies the general public, just like described above. In addition, during six weeks, the ANVS offers the public the opportunity to read printed versions of the documents at ANVS offices and at the town hall of the municipality in which the nuclear installation is (to be) located. In this phase it is not possible to submit opinions to the ANVS.
- ANVS starts evaluating the application and its documentation, to arrive at a draft decision. It will also judge if it is possible to do this in six months. With more complicated applications, ANVS may extend this period, although opinion of the applicant about this extension will be taken notice of.
- After concluding the evaluation, ANVS will send its draft decision to applicant and other authorities involved, as well as to the Cmer to ask its advice on the decision unless we judge that this is disproportionate given the nature and size of the initiative. Furthermore, the decision is made public, like described above, and during six weeks, anyone may submit opinions.
- Cmer gives advice on draft decision and on opinions submitted to the ANVS.
- ANVS formulates final decision, taking notice of advice of Cmer and opinions submitted and describing how this input has been used. ANVS sends the decision to applicant, Cmer and anyone who has sent an opinion on the final decision.
- The final decision is made public like described before. During six weeks, stakeholders that have objected to the draft decision are free to lodge an appeal with the Administrative Jurisdiction Division of the Council of State (the highest administrative court in the Netherlands) against the decision by which the licence is eventually granted, amended or withdrawn. The Council of State will issue a decision within one (or more) year(s).

The licences for nuclear installations are granted for an indefinite period. Modifications of licences are needed if the installation or the activity as described in the Safety Report (SR) is changed. For example, modifications have taken place in the past related to the implementation of safety improvements after the PSR.

An extensive body of legislation is based on the Nuclear Energy Act. This includes Governmental decrees, ministerial regulations, the regulations issued by the ANVS, and a number of general operating decisions. These include:

- Nuclear Facilities, Fissionable Materials and Ores Decree (Bkse): The Nuclear Installations, Fissionable Materials and Ores Decree (Bkse regulates all practices involving fissionable materials, including spent fuel, and nuclear facilities (including licensing).
- Fissionable Materials, Ores and Radioactive Materials Transport Decree (Bvser): The licensing system for the shipment of these materials has been elaborated in the Fissionable Materials, Ores and Radioactive Substances (Transport) Decree.
- Decree on Basic Safety Standards for Radiation Protection (Bbs): the Decree on Basic Safety Standards for Radiation Protection has been in force since 6 February 2018. The goal of this Decree is to protect the public, the environment, employees and patients against the adverse effects of ionizing radiation. This complies with the 2013/59/Euratom directive. The requirements set out in the Decree have been elaborated, in the associated regulations, published January 2018

An example of regulations and guidelines as issued and endorsed by ANVS relevant to licensing of SMRs is the VOBK, the non-binding Guidelines on the Safe Design and Operation of Nuclear Reactors - Safety Guidelines for short. These Guidelines provide new reactor licence applicants with detailed insight into what the ANVS considers to be the best available technology.

Appendix 2 Context, Licensing process and regulatory framework in Poland

Context

Poland is advancing its nuclear energy sector by incorporating Small Modular Reactors (SMRs) to enhance energy production and reduce carbon emissions. As a part of an update of the Polish Nuclear Power Programme (PNPP) in 2025, in addition to the construction of two large-scale nuclear power plants, further investment in nuclear energy is planned, which would include SMRs. As part of the PNPP, a road map for SMRs will be developed. There are few designs considered in Poland, among others BWRX-300, HTGR-POLA or LDR-50.

In 2023, the Advanced Reactor Assessment Division was established at the PAA, which is responsible for preparing the Agency for the SMRs licensing process. For several years, a review of Polish law has been carried out with a view to maintaining the greatest possible technological neutrality, which has resulted in the introduction of a number of amendments to the Atomic Law Act and a change to the Design Regulation and the Regulation on Safety Analyses planned for 2025. Work is also ongoing to update the remaining regulations in light of the introduction of nuclear power. The updated regulations will be in line with IAEA standards and best practices from leading nuclear countries.

Licensing process and regulatory framework

Licensing of nuclear facilities in Poland consists of three steps: construction license, commissioning license and operation license. Before submitting an application for the construction of a nuclear power plant, it is advisable to undertake non-mandatory pre-licensing activities, such as meetings with the regulator or the submission an application for a general opinion of the President of the PAA.
The purpose of the general opinion is to enable the investor, before applying for a license, to seek the opinion of the President of PAA regarding compliance with the nuclear safety requirements of nuclear facilities in the scope of:

• organizational and technical solutions that the investor plans to apply in future operations;

• draft documents that should be submitted together with the application for a license.

In addition, before submitting an application for a construction license, a Decision in Principle must be obtained. It represents the initial approval from the government to proceed with a nuclear energy project, such as the construction of a nuclear power plant or the deployment of Small Modular Reactors (SMRs). The Decision is not a final construction or operational license, but it serves as a foundational approval that allows the project to move forward with more detailed planning, design, and regulatory processes.

Moreover, an environmental decision must be obtained prior to submitting the application for a construction license. This decision is issued by the General Director for Environmental Protection (GDOŚ) and is not part of the licensing procedure conducted by the President of the PAA.

The site assessment process, including detailed investigations of seismic, geological, hydrological and population-related conditions, is regulated under the Atomic Law itself. Based on the results of this assessment, the investor prepares a site report, which is assessed by the President of the PAA as part of the review process for the construction license.

Documents attached to the application for the construction, commissioning, and operation licenses are outlined in the Atomic Law and accompanying regulations. The President of PAA is required to review and issue a decision within specific timeframes – 24 months for a construction license, 9 months for a commissioning license, and 6

months for an operational license – provided that the application is complete. The Atomic Law also specifies the one-time fees associated with each application.

Applications are assessed against the provisions of the Atomic Law Act and implementing regulations and in accordance with the process established therein and in the Administrative Procedure Code. In addition, the President of the PAA publishes organizational and technical recommendations, which are not legally binding, but are guidelines that describe selected requirements in detail. During the process of assessing the documents submitted together with the application for the construction, commissioning and operation of a nuclear power plant, PAA inspectors also carry out inspections of both the facility or its construction and the suppliers of components.

An administrative decision which constitutes a license for construction, commission and operation may be appealed to court by a party to the proceedings.

Appendix 3 Context, Licensing process and regulatory framework in Sweden

Context

Since 2022, there has been significant interest in new nuclear power in Sweden from both the government and industry. Against this background, SSM is conducting extensive work to be prepared when a license application is submitted. Over 50 years have passed since the first Swedish nuclear power plants were commissioned, and now various new nuclear initiatives are beginning to emerge. Although it is still uncertain which initiatives will lead to a license application, it is essential for SSM to be prepared for them. In order to meet these challenges as effectively as possible, several prerequisites are important to establish. Among other things, SSM have established collaborations with appropriate regulatory authorities internationally. Furthermore, SSM is working, both nationally and internationally, to gain knowledge and expertise about new reactor technology and to identify and investigate the new safety issues that require special attention. In addition, SSM is updating and adapting the regulatory requirements with respect to new nuclear technologies, as well as reviewing the processes and routines that ensure that safety issues are handled robustly.

Both Sweden's Vattenfall and Finland's Fortum have conducted feasibility studies that include both SMR and LSR. One of the technologies considered was NUWARD and SSM were positive to have the opportunity to participate in the Joint Early Review.

Swedish regulatory framework

The Swedish legal framework consists of legally binding acts, ordinances and regulations. The following six Acts constitute the basic nuclear legislation:

- The Environmental Code (entered into force 1 January 1999)
- The Radiation Protection Act (2018:396)
- The Act (1984:3) on Nuclear Activities
- Protective Security Act (2018:585)
- The Act (2006:647) on Financing of the Management of Residual Products from Nuclear Activities
- The Act (2010:950) on Liability and Compensation for Radiological Accidents

The acts and the code are all supplemented by a number of ordinances and other secondary legislation, which contain more detailed provisions for particular aspects of the regime.

With reference to its legal mandate, SSM issues legally binding regulations for nuclear facilities in its Code of Statutes – SSMFS. Regulations may include non-binding general advice, which give strong recommendations on how to implement specific requirements. The regulations are also supported by non-binding guidance documents provided for comprehension of the implications of the regulations, with explanations and examples of application. The Swedish legal and regulatory framework is depicted in figure 1.

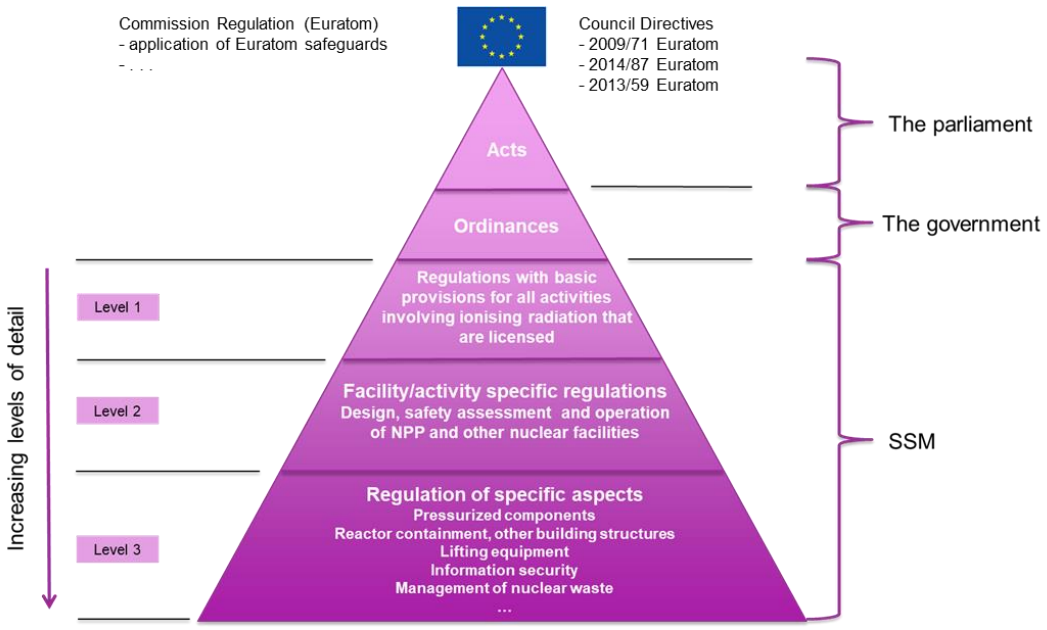

Figure 1. Swedish legal and regulatory framework

On level 1 nuclear power plants are covered by SSM:s regulations (SSMFS 2018:1) concerning basic provisions for licensable activities involving ionising radiation. Nuclear power plant specific regulations regarding design, safety assessment and operation on level 2 are:

- SSM:s regulations (SSMFS 2021:4) concerning the design of nuclear power plants
- SSM:s regulations (SSMFS 2021:5) concerning the assessment of safety and security for nuclear power plants
- SSM:s regulations (SSMFS 2021:6) concerning the operation of nuclear power plants

On level 3 there are regulations of specific equipment and activities at any nuclear facility. At the present there are level 3 regulations on safeguards, radioactive waste management and mechanical equipment, but more regulations are under development on e.g. reactor containment and other building structures, pressurized components and lifting equipment, that may be in force during a future licensing activity.

The regulations mainly include function oriented/performance based requirements complemented by prescriptive requirements. There is also a joint regulation of nuclear safety and security in the requirements.

Swedish licensing process

New nuclear facilities and major modifications of existing facilities that are subject to authorisation must be considered under both the Act on Nuclear Activities and the Environmental Code. As stipulated by the procedure for applications, a license application must be submitted to the Swedish Radiation Safety Authority, which processes the matter under the Act on Nuclear Activities, and to the Land and the Environment Court, which processes the case under the Environmental Code. Applications are to be accompanied by an Environmental Impact Assessment.

According to the Environmental Code, as a step of the licensing process, the Government is to consider the permissibility of certain activities, such as represented by facilities for nuclear activities under the Act on Nuclear Activities. An environmental impact statement must be submitted for the permissibility assessment. The Land and Environment Court reviews an application for permissibility, which is thereafter forwarded to the Government for

final consideration. The Government may decide on the permissibility only if the municipal council concerned agrees that the planned activities may be sited in the municipality (municipal veto). If the Government grants permissibility as per the Environmental Code, licensing approval needs to be issued for the nuclear activity according to the Act on Nuclear Activities, and for the environmentally hazardous activity according to the Environmental Code. The Government ultimately grants a possible licence in accordance with the Act on Nuclear Activities

In a case where SSM approves the application and proposes that the Government grant the license under the Act on Nuclear Activities, SSM must in these matters also propose that the Government take a decision on license conditions enabling a continued step-wise review process until such date that the planned facility may begin regular operation. As regards nuclear facilities, depending on the type of matter, one or more of the following license conditions are to be proposed:

- The facility may not commence construction prior to approval by SSM
- The facility may not commence test operation (commissioning) prior to approval by SSM
- The facility may not commence regular operation prior to approval by SSM

Based on these licence conditions a step-wise review process then follows, where SSM decides at each stage if the licensee is allowed to proceed to the next step.

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