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Licensing Study

Public Summary

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LICENSING STUDY – PUBLIC SUMMARY

This Licensing Study – Public Summary is based on chapters 1, 2 and 13 of the Licensing Study (NUCL-4428) dated December 2nd, 2020.

1 INTRODUCTION

The licensing study presents and discusses a possible general licensing process and the main licensing phases for the deployment of Small Modular Reactors (SMRs) in Estonia, accompanied with a proposed more detailed possible licensing model for obtaining a construction licence in practice. The licensing model covers and addresses the safety assessments to be performed for the construction licence from the point of view of the Estonian regulatory body. However, the safety assessments of the licence applicant[1] and plant designer[2] are also essential elements in the overall picture.

The main licensing areas and the general grouping used throughout the study are **site**, **technology** and **organisation**, including the licence applicant's competencies, resources, capabilities and management system etc.

The safety assessments related to the technology has been a particular focus in the licensing study, as it is an area in which SMRs may necessitate and enable an alternative approach than has been the norm in the case of large Nuclear Power Plants (NPP) and in which significant international cooperation is expected to be of specific importance.

In the licensing study, licensing is predominantly addressed from the point of view of nuclear legislation and regulations, accordingly, a consideration of conventional licences or permits is not included. In addition, as the main focus area of the study is the construction licence, a more detailed assessment of other licensing phases, such as regulatory oversight during construction, does not form a major part of the study.

The main goal of the licensing study is to seek and propose an optimal and efficient licensing model for obtaining a construction licence for a SMR in Estonia, from the starting point of a legislative and regulatory "blank canvas". The general idea is that the Estonian regulatory body would, to the extent possible, verify the technology related safety assessment of a foreign regulatory body and supplement it with its own safety assessment. This approach builds on the concept of "one design, one review".[3]

The aim of the licensing model is a 12 month regulatory body approval time and minimization of design changes. The foreign regulatory body could be from the country of origin of the SMR design or another experienced country which has licensed the SMR design in question. Collaboration with several regulatory bodies is also possible,

[1] Note: This study uses the term "licence applicant" to mean the organisation applying for authorization (or approval) to undertake specified activities and "licensee" to mean the holder of the relevant licence (in the context of the licensing study these are pre-dominantly connected with the construction licence). In practice, these entities may be the owner or a related entity, depending on the commercial structure for the project.
[2] Note: As the plant designer is not necessarily the same legal entity as the vendor, in the licensing study the safety assessment is specifically to be performed by the actual designer of the plant, having the overall responsibility of the plant safety design.
[3] SMR Regulators' Forum Pilot Project Report: Considering the Application of a Graded Approach, Defence-in-Depth and Emergency Planning Zone Size for Small Modular Reactors, January 2018, section 4.3.

but in the licensing study the basis is to utilize and leverage on an earlier safety assessment of only one foreign regulatory party.

In the licensing model, the scope and objects of the licence applicant's and the Estonian regulatory body's safety assessments are considered with regards to a graded approach, depending on the safety significance of the subject of the safety assessment as well as the scope of the existing safety assessment performed by the foreign regulatory body, which is connected with the extent of design changes compared to the standard or reference plant.

The licensing study covers as background information briefly the basics of nuclear licensing, presents different licensing approaches and identifies and discusses different licensing phases based on the practices in Finland, United States, Canada and the United Kingdom.

Design certification / assessment is considered in the licensing study so as to determine their relevance with respect to the development of the licensing model. Various international cooperation forums that can be utilized to support the licensing efforts in Estonia are also presented. Expectations regarding a licensee's capabilities and competencies are described as to provide a roadmap for further planning for organisation development. Finally, preliminary licensing related risks for project development are identified and discussed on a general level.

The main results of the licensing study, a possible general licensing process, a possible licensing model for SMR deployment in Estonia and the key findings, are summarized in this executive summary of the licensing study.

2 POSSIBLE SMR LICENSING APPROACH FOR ESTONIA

This chapter provides an overview of a possible SMR licensing approach for Estonia, including a possible general licensing process (section 2.1), a possible licensing model for obtaining the construction licence (section 2.2) and the key findings of the licensing study (section 2.3).

The different licensing phases that have been used as basis for the general licensing process have been addressed more in detail in the licensing study. The basis (safety assessment objectives and graded approach) and the actual details regarding the licensing model for obtaining the construction license are presented and discussed in the licensing study.

The proposed licensing model is based on extensive leverage of an existing safety assessment performed by the country of origin or another experiences regulatory body. In the licensing study, the licensing model is discussed considering the roles of various safety assessments carried out by different parties of a NPP project, i.e. the designer, the licence applicant and the regulatory body (Estonia).

The licensing model is based on one possible application of graded approach and it is technology neutral and generally applicable for any regulatory regime. Graded approach can be done in many different ways and another example of a licensing model and on the application of graded approach that have been applied in practice by the United Arab Emirates' (UAE) regulatory body for the Barakah project are presented

and discussed in the licensing study. However, the UAE licensing model is limited to the regulatory body point of view and thus, not directly comparable with the licensing model presented in the licensing study, which emphasises the licence applicant's role as an intelligent customer and where the licence applicant's and regulatory body's safety assessments are considered together for optimizing the use of resources.

As nuclear power is highly regulated and requires its own infrastructure, a wide political and public support as well as a clear endorsement by the Government are the basic pre-conditions for its use. Thus, in the licensing study it is assumed that the "National position" identified by the IAEA Milestone Approach (Milestone 1) has already been taken by the Estonian Government, and the focus of the licensing process is on a specific nuclear facility project taking place after the IAEA Milestone 1.

2.1 Licensing process

The possible general licensing process for SMRs in Estonia proposed in the licensing study and which is shown in Figure 1 encompasses the following licensing phases:

- **Decision-in-Principle**, which contains a political decision taken during phase 2 of the IAEA Milestone approach for a specific nuclear facility project based on a Strategic Environmental Assessment (SEA) and initial safety review[4] of site and technology.

  The role of the review of the site and technology during the Decision-in-Principle phase should be very limited (would not correspond to actual safety assessment neither in depth nor methods) and only to ensure that at least one potential site and generally acceptable technologies exist on the market. From the regulatory body perspective the review of the technology at this stage could only rely on the existence of a safety assessment performed by the country of origin or another experienced regulatory body for a standard design[5] or the reference plant. A brief general technology description, including designer's main safety justifications of the plant, potentially supplemented by the licence applicant's review of those could alternatively or also be an input for the regulatory body's safety review. For the actual Decision-in-Principle the focus should, however, not be on the technology and technical topics should be addressed only on a high level, not going into any details whatsoever.

  Due to the nature of the Decision-in-Principle, it is assumed to be issued by the national Government possibly followed by a Parliament ratification. It could also be considered whether a broader Decision-in-Principle, not limited to only a particular project, would be issued in advance of granting for example subsequent lighter Decision-in-Principles for individual projects.

  However, it would be valuable that the nuclear legislation would allow to apply from the regulator body, either in parallel with the Decision-in-Principle or

[4] Note: Safety review in the context of the licensing process and the licensing model for the Decision-in-Principle is a light safety assessment. Otherwise, due to different terminology used in different countries, safety review and safety assessment are mainly interchangeable in the licensing study when considering the construction licence.
[5] Note: Standard design is based on envelope site parameters, not a specific site.

separately even before and also after the Decision-in-Principle, conditional topical pre-approvals for certain design solutions which could play a fundamental role in the licensability of the nuclear facility. Handling of the topical pre-approvals would be separated from the Decision-in-Principle. This approach could resemble the practice in the United States, regarding the handling of Licensing Topical Reports (LTR) with the United States Nuclear Regulatory Commission (NRC), by which licensing risks can be mitigated early on in the project. This could also have a positive impact on the resources and time needed for the handling of the construction license application by the regulatory body.

- **Construction Licence**, which would be based on detailed safety assessment of the site, technology (including site specific adaptations) as well as the organisations responsible for the project execution. All three safety assessments need to be in place and the regulatory body's safety assessment would strongly rely on the foreign regulatory body's safety assessment and the safety assessment of the licence applicant would also be credited. However, any design changes compared to the standard or reference plant design need to be assessed thoroughly by all the parties. However, design changes should be minimized and if any, they should be limited only to the local site and environmental conditions. The actual Environmental Impact Assessment (EIA) needs also to be conducted prior to the construction licence application. The construction licence could be issued directly by the regulatory body.
- **Operating Licence**, which contains the as-build safety assessment of the plant and the safety assessment of the operating organisation, including management systems and processes, resources and competencies. The operating licence could be issued directly by the regulatory body.
- **(Periodic Safety Review (PSR),** which contains assessment of plant safety for continued operation. The PSR process is in the responsibility of the regulatory body.)
- **Decommissioning Licence**, which contains safety assessment of the decommissioning plans and disposal of radioactive waste. The decommissioning licence could be issued directly by the regulatory body. However, potential permission to abandon site could be subject to separate Government decision.

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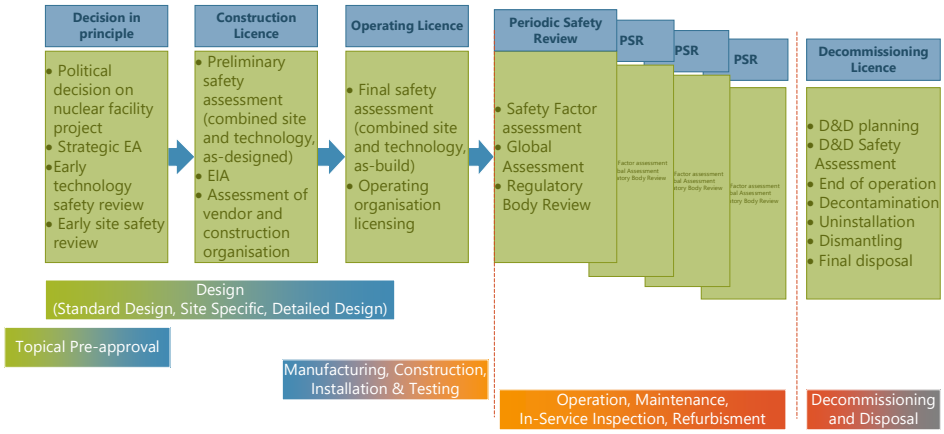

Figure 1. General licensing process for SMR deployment in Estonia.

The discrete steps licensing approach shown in Figure 1 enables thorough risk assessment for all the main project participants from both safety and economical point of view.

- The Decision-in-Principle phase ensures political commitment to the nuclear facility project.
- The construction licence phase gives the possibility for the licence applicant to assess the design more in detail. Site specific design is described and assessed by the designer. The licence applicant needs to perform its own safety assessment for the combined site and plant. The regulatory body will analyse the safety assessment processes of the designer and the licence applicant. The technical part of the safety assessment of the regulatory body would to a large extent be based on a foreign regulatory body's earlier safety assessment taking into account the site specific design changes. A prerequisite for this is that the earlier safety assessment by the foreign regulatory body is fully transparently available to the national regulator.

  The Preliminary Safety Analysis Report (PSAR)[6] most parts of which would be developed by the designer and supplemented by the licence applicant is the fundamental document for the safety assessment of the regulatory body. Licence applicant's safety assessment is also an essential input for this. In addition, plans for fuel supply, operation and maintenance as well as decommissioning and nuclear waste management need to be included on a general level. The licence applicant can make detailed investment analysis needed for the final investment decision.
- The construction licence would be granted based on the regulatory body's assessment of the safety of the project, including site, technology and organisation as well as environmental impacts. Final investment decision by the owner would be expected after the construction licence has been granted.

[6] The PSAR contains design information and data regarding the proposed site and safety features of the plant, including hazard analysis, deterministic safety analysis and a probabilistic risk assessment.

- During the construction phase, construction, manufacturing, integration and installation will be performed, the operating organisation established by the licensee and commissioning plans finalised. The regulatory body will perform and organise inspections as part of the regulatory oversight during construction. After receiving the Final Safety Analysis Report (FSAR), licence applicant's safety assessment and other necessary plans the regulatory body will assess the safety of the plant and the operating organisation.
- Operating licence would be granted based on the results of the regulatory body's safety assessment. The operating licence may be given for rather long plant lifetime. However, the operating licence is usually bound to periodic safety reviews in one way or another.
- The safety of the plant needs to be assessed on a regular basis and the recommendation is that the interval of periodic safety review is no longer than 10 years. Periodic safety review focuses on the safety status of the plant based on 14 safety factors and global assessment.[7] Attention needs also to be put on the safety improvements planned for the next review period. IAEA SSG-25[8] gives more guidance on the performance of periodic safety reviews.
- In the end when the techno-economical lifetime of the plant is reached, the plant needs to be decommissioned. The licensee and the regulatory body need to assess the safety of the decommissioning. That would contain assessment of the decommissioning plan as well as it stages, such as decontamination, uninstallation, dismantling of the plant and final disposal of the waste. Abandoning the site is ultimately the final stage in the plant lifecycle, when the responsibility of the site is transferred from the licensee to the state.

2.2 Licensing model

In the licensing study, the flow of the main activities related to safety reviews during the Decision-in-Principle and especially, the safety assessments during the construction license phase are collectively called the "licensing model". The basic idea of the licensing model is that the licensing in Estonia would be carried out for a SMR design, which would have already been licensed in the country of origin, or by another experienced regulatory body, and which would then be adapted only to the local site and environmental conditions in Estonia. In accordance with the general licensing process summarized in section 2.1, the main points in the licensing model are:

- Existing safety assessment by a foreign regulatory body for the reference design could be sufficient for the Decision-in-Principle phase in order to ensure the availability of generally acceptable technologies. This could possibly be supplemented with designer's main safety justification for the standard design or the reference plant and the licence applicant's safety review of it.

[7] Periodic Safety Review for Nuclear Power Plants, IAEA Safety Standards Series No. SSG-25, 2013, paragraph 2.13 and Chapter 5.
[8] Periodic Safety Review for Nuclear Power Plants, IAEA Safety Standards Series No. SSG-25, 2013.

- Site specific safety assessment is required for the construction licence. Designer's safety justification and assessment should to a large extent follow the country of origin practices.
- The licence applicant needs to be able to take the role of an intelligent customer. This encompasses a possible safety review of the design for the Decision-in-Principle, but first and foremost the safety assessment of the site and the site specific design required for the construction licence. Licence applicant's safety assessment is an essential input for the regulatory body's safety assessment for the construction licence.
- The regulatory body carries out the safety assessment for the construction licence mandated in the Convention of Nuclear Safety (CNS)[9] or in the Nuclear Safety Directive[10]. This will be done in close cooperation with the foreign regulatory body utilizing the safety assessment already conducted for the standard design or the reference plant by the foreign regulatory body to the maximum extent.

The licensing model, focusing on the safety assessments of both the licence applicant and the regulatory body, applies graded approach. In the graded approach, when defining the depth of the safety assessment for a certain item, both the coverage of the safety assessment carried out by the foreign regulatory body and the safety significance of the items are considered as presented and discussed in detail in the licensing study. The main categorization with respect to technology is which parts of the design are affected by the local site and environmental conditions and which part is site independent. In more general terms this would mean deviations to the standard design or reference plant, due to any reason.

Being able to utilise the safety assessment of a foreign regulatory body to the maximum extent requires that the licensing documentation is structured and set according to the regulations of the country in question. Therefore, the proposed licensing model and regulatory basis for Estonia need to allow that the licensing documentation, especially the PSAR, and the regulatory basis of the relevant foreign country would be applied.

This means that the Estonian legislation and regulations should set safety targets compatible with international practice (such as IAEA), but should avoid setting detailed, prescriptive requirements. By this, possible design changes can be minimized and limited mainly to the local site and environmental conditions. The overview of a possible licensing model is illustrated in Figure 2.

[9] Convention on Nuclear Safety 1996.
[10] Council Directive 2014/87/Euratom of 8 July 2014.

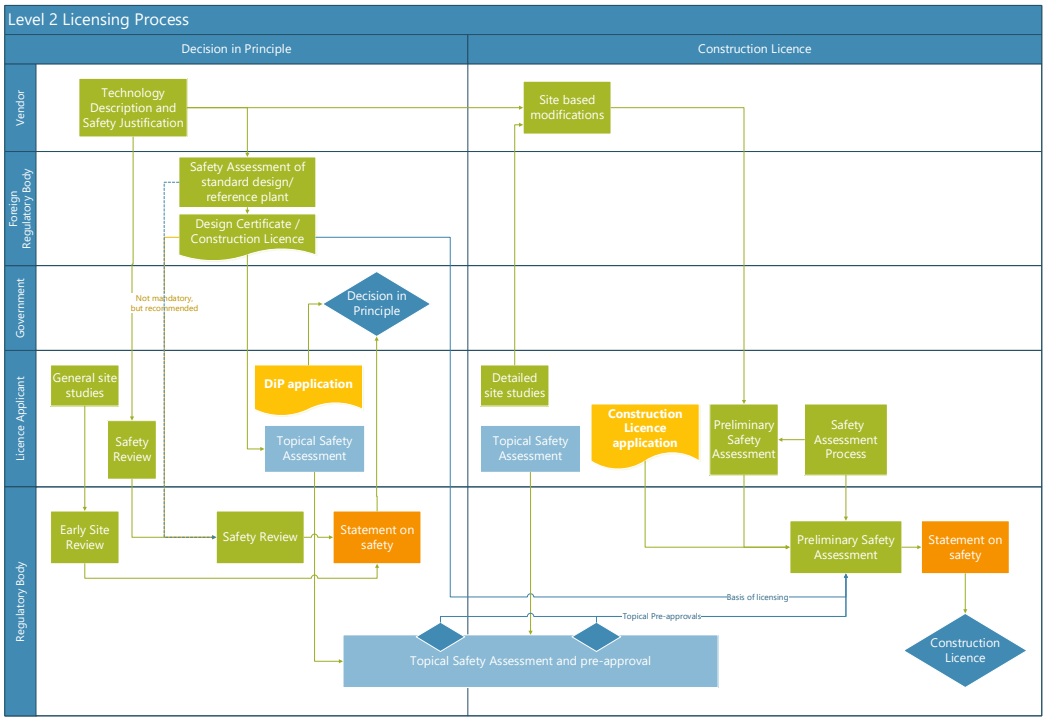

Figure 2. Schematic illustration of a possible licensing model for Decision-in-Principle and construction licence.

One fundamental assumption in the licensing model is that the plant design has already been assessed by the country of origin (or another experienced) regulatory body to an extent and depth that would enable granting a design certificate for the standard design or a construction licence for a reference plant.

This basically means that the design is mature enough for construction, but not necessarily for the specified construction site in Estonia. However, the main principles are known, such as application of Defence-in-Depth (DiD), diversity, physical and functional separation, autonomy and redundancy. Also primary circuit and the reactor core are well defined from neutronic and thermal-hydraulic viewpoints. Basic design of safety systems is also well advanced, the general arrangement is mostly established as well as most of the load bearing structures are defined. Preliminary Probabilistic Risk Assessment (PRA) as well as deterministic accident analysis and hazard analysis for internal events are performed.

Furthermore, the idea is that the plant in Estonia would not be first-of-a-kind, i.e. the construction of the first plant would had at least begun in another country. Based on this, it is safe to assume that a significant part of the equipment and components for the reference plant have also been chosen, construction methods are known and at least the main contractors and sub-suppliers are agreed for the reference plant project. The site may have some impact e.g. on the dimensioning of structures and selection of equipment, but that should not change the conclusion on the availability of generally acceptable technologies in the review depth envisaged for the Decision-in-Principle.

An existing reference plant (under construction or in operation) is not a mandatory condition for the Decision-in-Principle. However, this would be important from risk management point of view, providing additional confidence regarding the safety and operation of the plant, but especially, on the schedule and budget of the project that should, instead of technology, be in focus in the Decision-in-Principle. For the construction licence, having the reference plant in place would, on the other hand, enable both the licence applicant and the regulatory body to perform the safety assessment of the technology on a very solid basis and the changes to the plant design can be limited to only those necessitated by the local site and environmental conditions, if the Estonian regulatory body endorses the foreign nuclear regulations and requirements.

It would be important from licensing risk mitigation point of view that the regulatory body could commit to the principle solutions of the plant design early on. If parts and main features of the design (excluding site specific features), for which acceptability or non-acceptability of could have significant impact on the design and on the feasibility of the project, could be approved before the construction licence application, the licence applicant could rely on the acceptability of the features in the construction license phase. Such topical pre-approvals would obviously need to be conditional and bound to certain assumptions and boundary conditions. However, it is essential that they could be binding. Topical pre-approvals could be requested for example as part of the Decision-in-Principle application or in parallel, but also separately both before and after the Decision-in-Principle.

For the construction licence, site specific design and in particular the site specific and local adaptations or any other changes compared to the standard design or reference plant need to be assessed by the licence applicant and the regulatory body. As the systemic features are only known when all interfaces of the system are known, the designer and the licence applicant need to have capable processes for configuration management and safety assessment in place, so that the systemic behaviour of the plant is maintained throughout the site specific changes.

One of the important questions is how much and for which items the regulatory body needs to carry out a fully independent, detailed safety assessment and for which areas it would be sufficient to oversee that the safety assessment carried out by the licence applicant (and the designer) is done appropriately.

The designer obviously performs its own safety justification and assessment for the actual site specific design. This is proposed to be done to a large extent based on the country of origin practices. Thereafter, the design needs to be assessed by the licence applicant. One possible way of doing this by applying graded approach is discussed in the licensing study.

It is to be noted that most of the objects of the safety assessment of the site specific design are still the same as in the standard design or reference plant. Therefore, the regulatory body may rely in most cases on the results of the safety assessment performed by the foreign regulatory body provided that the earlier safety assessment can be made fully transparently available to the national regulatory body. In addition, the regulatory body should put sufficient attention to the licence applicant’s safety

assessment process in order to ensure its effectiveness, i.e. that safety concerns are recognised and mitigated transparently and corrective actions are put in action. The licensing study discusses also a possible way of applying graded approach in the safety assessment by the regulatory body for a design that has been earlier licensed e.g. in the country of origin. The highest priority would be on the most safety significant features that have changed from the standard design or the reference plant.

2.3 Key findings

The key findings of the licensing study, including some essential issues to which the licensing study does not provide answers, are presented in the following. The provided detailed issues are subject to further considerations.

- Review of technology and site during the **Decision-in-Principle** phase should be very limited and done mainly to ensure the availability of generally acceptable alternatives of different technologies and at least one potential site.
- **International or European design certification** would be an optimal way to support an Estonian licensing process and model, but cannot be expected in the near future (at least, not on a timeline considered for the first SMR in Estonia).
- The Estonian licence applicant should seek **maximum utilization of existing safety case and Preliminary Safety Analysis Report (PSAR)** prepared for the standard design or a reference plant.
- Since the licensee will eventually have prime responsibility for the safety of the plant, the licence applicant will need to demonstrate **intelligent customer** capability. The licence applicant needs to be competent enough to undertake independent safety review and assessment of the PSAR and other licensing documentation to be submitted to the Estonian regulatory body.
- The licensing model should seek to achieve **maximum utilization of the safety assessment of an experienced foreign regulatory body** (from the country of origin or from another experienced country).
    - The earlier safety assessment would need to be fully transparently available to the Estonian regulator.
    - It needs to be ensured that the output of the foreign regulatory body is transportable and exportable to Estonia considering confidentiality restrictions, export controls (e.g. Nuclear safeguards and security considerations, including handling and utilization of foreign Design Basis Threat (DBT)).
- Even if the safety assessment would rely heavily on the safety assessment of a foreign regulatory body, an **independent safety assessment of the Estonian regulatory body** is needed. The Estonian regulatory body would need to verify the completeness and adequacy of the safety assessment and to ensure that local or site specific features have been appropriately addressed.
- The utilization of the foreign regulatory body's **safety assessment should be based on graded approach**, with Estonian regulatory body's depth of safety assessment

prioritizing deviations from the standard or reference plant design, safety significant items, as well as site-specific and licence applicant-specific matters.

- **Endorsement of regulatory requirements of foreign country.** Utilisation of standard design or reference plant PSAR and foreign regulatory body's safety assessment is only possible if the regulatory basis and safety standards in Estonia and the relevant foreign country are harmonised. Estonian legislation and regulations should set safety targets compatible with international practice (such as IAEA), but should avoid setting detailed, prescriptive requirements. By this, design changes can also be limited only to the local site and environmental conditions.
- Regarding the use of **codes and standards**, it could be recommended to apply graded approach. For higher safety classes the codes and standards of the country of origin could be used. Whereas local codes and standards could be used in the lower safety classes.
- **Cooperation between the Estonian and foreign regulatory bodies**. Significant human resources may be needed from the foreign regulatory body to support the Estonian regulatory body. This requires government-to-government commitment and financial resources from the Estonian regulatory body.
  - It needs to be considered prior to the investment decision and plant supply contract how to ensure willingness and ability for the foreign regulatory body (most likely from the country-of-origin) to cooperate with the Estonian regulatory body.
  - It needs to be planned well in advance how to ensure maximum cooperation between the Estonian regulatory body and the foreign regulatory body (most importantly from the country-of-origin).
  - It needs to be considered in advance how the Estonian regulatory body verifies the safety assessment processes of the foreign regulatory body.
- The suitability (site envelope-based) and **availability of the PSAR** and other relevant licensing documentation, which may be developed/owned by a foreign licensee as opposed to the reactor vendor, must be ensured.
  - It needs to be clarified by whom all the relevant information such as PSAR etc. is owned , and how it can be shared to the Estonian project and whether it is possible to export the PSAR to Estonia considering commercial, intellectual property and confidentiality restrictions, as well as export controls (e.g. Nuclear safeguards and security considerations, including handling and utilization of foreign Design Basis Threat (DBT)).

3 CONCLUSIONS

A general licensing process and a licensing model for the deployment of Small Modular Reactors (SMRs) in Estonia has been presented in the licensing study. The licensing model covers and addresses in particular the safety assessments to be performed for the construction licence from the point of view of the Estonian regulatory body.

The general licensing process for Estonia could be based on a discrete steps licensing approach without separate licensing of the site, including the following main licensing phases:

- **Decision-in-Principle**
- **Construction Licence**
- **Operating Licence**
- **Decommissioning Licence**

For SMRs, simplification and standardization is the way to achieve safety and cost efficiency. Due to the standardization, country specific adaptations should be kept to minimum, limited only to local site and environmental conditions. Standardization is possible only if the nuclear safety requirements in different countries are harmonized. This also improves the possibilities in different countries to reuse the original safety case and to take maximum benefit of the safety assessment of the regulatory body of the country-of-origin or another competent regulatory body.

For the construction licence, which was the main focus in the licensing study, the safety assessment of the regulatory body can be considered to cover three basic licensing areas:

1. the **technology** of the nuclear facility,
2. acceptability of the **site**, and
3. the **organisation**, including the capabilities and competence of the licence applicant as well of the supply chain.

In order to make SMRs a realistic option in the future, it is necessary to strongly streamline the safety assessment process related to technology comparing to e.g. recent licensing experience for large newbuild reactors in Europe.

An European (or international) design certification or assessment would be the preferable option for the licensing model. However, whether it is politically realistic, is unclear and at least it cannot be expected in the short term.

Therefore, the licensing model presented in this study is based on the utilization to a large extent of an existing safety assessment by a foreign regulatory body and application of graded approach for the safety assessments of the licence applicant and the Estonian regulatory body. In the graded approach the depth of the safety assessment would depend on the scope of the existing safety assessment by the foreign regulatory body and on the safety significance of the safety assessment object in question. The main issues related to this approach identified in the licensing study are the following:

- Close cooperation between the Estonian regulatory body and the foreign regulatory body in which the same technology has been licensed is needed. Possibilities and commitment of the foreign regulatory body and the way and extent of the cooperation need to be investigated.

- The safety assessment of the Estonian regulatory body should be based as far possible on a previous safety assessment of a competent foreign regulatory body, e.g. from the country-of-origin of the technology. A prerequisite for this would be close cooperation with the foreign regulatory body and fully transparent availability of the earlier safety assessment. No unnecessary duplication of work for the safety case and for the safety assessment work. Possible limitations for export and disclosure of information (PSAR and results of the safety assessment of the foreign regulatory body) to Estonia needs to be investigated.
- The nuclear legislation and higher level safety targets in Estonia should be compatible with the international practice (such as IAEA), but for the lower level regulatory requirements, it should be made possible to adopt requirements of the foreign country where the reference plant has been licensed. This is a pre-condition for utilizing the safety assessment of a foreign regulatory body and to limit design changes only to the local site and environmental conditions. This issue is to be considered in the development and establishment of the Estonian nuclear legislation and regulatory regime. It would be desirable that the Estonian legislation and regulations would set safety targets compatible with international practice (such as IAEA), but would avoid setting detailed, prescriptive requirements in order to have sufficient flexibility to allow applying lower level requirements, guides and standards from the foreign country.
- Application of graded approach in the licensing model sets expectations on the licensing documentation. It needs to be assessed how existing PSAR and other licensing documentation can be categorized according to the safety assessment grades of the licensing model. The main question is, how easily the part related to technology independent of the site can be identified from the PSAR.
- Early dialogue between the regulatory body, the licence applicant and the vendor helps to minimise surprises and the licensing risk. It would be valuable that the nuclear legislation would allow to apply from the regulatory body, as a pre-licensing step, conditional pre-approvals for certain design solutions which could play a fundamental role in the licensability of the nuclear facility.

In addition, a question that is not addressed as part of this study is, what evidence, if any, is in the end needed by the Estonian regulatory body regarding the competencies of the foreign regulatory body and regarding the processes producing the safety assessment to be utilized as basis for the licensing of SMR in Estonia.

However, even if the safety assessment related to technology licensing area would be streamlined by efficiently utilizing the earlier safety assessment of a foreign regulatory body, it is emphasized that the licence applicant as well as the regulatory body need adequate key competences and need to have a comprehensive understanding of the fundamental aspects of the safety case.

In particular, the licensee will eventually be the one that bears ultimately the responsibility of nuclear safety. Therefore, the licence applicant needs to develop the capabilities to act as an intelligent customer from the beginning of the project, with the target to ensure that the organisation is ready and capable to take the plant in operation.

However, the size of the organisation both at the licence applicant/licensee and regulatory body can be compacted by smart utilisation of international cooperation, in particular, with the regulatory body of the country-of-origin.