Lappeenranta
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Kristiina Söderholm

LICENSING MODEL DEVELOPMENT FOR SMALL MODULAR REACTORS (SMRs) - FOCUSING ON THE FINNISH REGULATORY FRAMEWORK

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ABSTRACT

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Licensing Model Development for Small Modular Reactors (SMRs) - Focusing on the Finnish Regulatory Framework

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Recently, Small Modular Reactors (SMRs) have attracted increased public discussion. While large nuclear power plant new build projects are facing challenges, the focus of attention is turning to small modular reactors. One particular project challenge arises in the area of nuclear licensing, which plays a significant role in new build projects affecting their quality as well as costs and schedules.

This dissertation - positioned in the field of nuclear engineering but also with a significant section in the field of systems engineering - examines the nuclear licensing processes and their suitability for the characteristics of SMRs. The study investigates the licensing processes in selected countries, as well as other safety critical industry fields. Viewing the licensing processes and their separate licensing steps in terms of SMRs, the study adopts two different analysis theories for review and comparison. The primary data consists of a literature review, semi-structured interviews, and questionnaire responses concerning licensing processes and practices.

The result of the study is a recommendation for a new, optimized licensing process for SMRs. The most important SMR-specific feature, in terms of licensing, is the modularity of the design. Here the modularity indicates multi-module SMR designs, which creates new challenges in the licensing process. As this study focuses on Finland, the main features of the new licensing process are adapted to the current Finnish licensing process, aiming to achieve the main benefits with minimal modifications to the current process.

The application of the new licensing process is developed using Systems Engineering, Requirements Management, and Project Management practices and tools. Nuclear licensing includes a large amount of data and documentation which needs to be managed in a suitable manner throughout the new build project and then during the whole life cycle of the nuclear power plant. To enable a smooth licensing process and therefore ensure the success of the new build nuclear power plant project, management processes and practices play a significant role.

This study contributes to the theoretical understanding of how licensing processes are structured and how they are put into action in practice. The findings clarify the suitability of different licensing processes and their selected licensing steps for SMR licensing. The results combine the most suitable licensing steps into a new licensing process for SMRs. The results are also extended to the concept of licensing management practices and tools.

Keywords: nuclear power plants, nuclear licensing, licensing process, small modular reactors
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TIIVISTELMÄ

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Kristiina Söderholm

Lisensiointimallin Kehitys Pienille Modulaarisille Reaktoreille, Keskittyen Suomen Viranomaisympäristöön

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Pienet modulaariset reaktorit (tässä työssä SMR) ovat nousseet viime aikoina suurempaan rooliin julkisuudessa. Suurten ydinvoimalaitosprojektien haasteet ovat ohjanneet huomion pienempiin reaktoriyksiköihin. Ydinvoima-alan lisensiointi on yksi ydinvoimalaitosprojektien suurista haasteista vaikuttaen sekä laatunäkökulmiin, että projektin kustannuksiin ja aikatauluihin.

Tämä ydinvoimatekniikan alalle sijoittuva väitöskirja, joka kuitenkin sivuaa osaksi myös Systems Engineering osa-aluetta, tarkastelee ydinvoima-alan lisensiointikäytäntöjä ja niiden soveltumista SMR:ien erityispiirteisiin. Tutkimus keskittyy lisensiointiprosesseihin valituissa maissa ja myös muilla turvallisuuskriittisillä teollisuuden aloilla. Lisensiointiprosessien, sekä erillisten lisensiointivaiheiden tarkasteluun ja vertailuun käytetään kahta eri analyysiteorian lähestymistapaa. Pääasiallinen aineisto koostuu kirjallisuuden lisäksi puolistrukturoiduista haastatteluista, sekä lisensiointiprosesseihin ja -käytäntöihin liittyvän kyselykaavakkeen vastauksista.

Tutkimuksen tulokset luovat uudentyyppisen, paremmin SMR:ille soveltuvan lisensiointiprosessin. Tärkein SMR:ien erityispiirre, joka vaikuttaa lisensiointiin, on konseptin modulaarisuus. Modulaarisuus tässä yhteydessä viittaa useisiin reaktorimoduuleihin ydinvoimalaitoksessa. Koska Suomen lisensiointiprosessin kehitys on ollut tutkimuksen kohteena, yhdistetään uuden lisensiointiprosessin merkittävimmät kohdat Suomen nykyiseen lisensiointiprosessiin niin, että minimaalisin muutoksin saadaan maksimaalinen hyöty.

Uuden lisensiointiprosessin sovellus esitetään käyttäen Systems Engineering, vaatimusten hallinnan, sekä projektin johtamisen käytäntöjä ja työkaluja. Ydinvoimalaitoksen lisensiointi käsittää hyvin suuren määrän tietoa ja dokumentaatiota, jota tulee hallinnoida soveltuvin käytännöin koko projektin ajan, sekä projektin jälkeen koko ydinvoimalaitoksen käyttöiän ja käytöstä poiston ajan. Tässä työssä esitetyt prosessit muodostavat osan ydinvoimalaitoksen johtamiskäytännöistä. Jotta sujuva lisensiointi voitaisiin mahdollistaa ja näin ollen antaa pohja myös koko ydinvoimalaitosprojektin onnistumiselle, ovat johtamiskäytännöt tärkeässä asemassa.

Tutkimuksen löydökset lisäävät ymmärrystä lisensiointiprosesseista ja käytännöistä. Tulokset havainnollistavat eri lisensiointiprosessien, sekä niiden sisäisten lisensiointivaiheiden soveltuvuutta SMR:ien lisensiointiin. Tuloksissa yhdistyvät parhaiten soveltuvat lisensiointivaiheet muodostaen uuden optimoidun lisensiointiprosessin SMR:ille. Lisäksi tulokset täydentyvät lisensiointiin soveltuvilla johtamiskäytännöillä ja -työkaluilla.

Avainsanat: ydinvoimalaitokset, ydinvoimaloiden lisensiointi, lisensiointiprosessi, pienet modulaariset reaktorit
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Completing this study has been a great experience for me. During my studies I have had the chance to familiarize myself with many new licensing issues as well as many different opinions concerning nuclear licensing. The most valuable experience in the research has been the various discussions with experts and researchers from different countries, different industry fields and different stakeholders in nuclear energy industry. Without these conversations and opinions this study would not have been possible. Your knowledge, your opinions and your feedback have been priceless.

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Helsinki, September 2013

Kristiina Söderholm

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ABBREVIATIONS

ACRS - The Advisory Committee on Reactor Safeguards (USA)
AEA - Atomic Energy Act (USA)
AECB - Atomic Energy Control Board (Canada)
AFM - Aircraft Flight Manual
AHWR - Advanced Heavy Water Reactor
ALARA - As Low As Reasonably Achievable
ALARP - As Low As Reasonably Practicable
ASN - L'Autorité de sûreté nucléaire (France)
CDF - Core Damage Frequency
CEAA - Canadian Environmental Assessment Act
CFD - Computational Fluid Dynamics
CHP - Combined Heat and Power
CL - Construction License
CNSC - Canadian Nuclear Safety Division
COL - Combined License (USA)
CRDM - Control Rod Drive Mechanism
CS - Certification Specifications (aviation industry)
DAC - Design Acceptance Certificate (UK)
DAC - Décret d'autorisation de creation (France)
DC - Design Certificate
DECC - Department for Energy and Climate Change (UK)
DEM - Discrete Element Method
DfT - Department for Transport (UK)
DiD - Defence in Depth
DiP - Decision in Principle (Finland)
DOA - Design Organization Approval (aviation industry)
DOE - Department of Energy (USA)
EASA - European Aviation Safety Agency
EA - Environmental Assessment
EC - European Commission
EIA - Environmental Impact Assessment
ENEF - European Nuclear Energy Forum
ENISS - European Nuclear Installations Safety Standards
ERDA - European Reactor Design Acceptance
EUR - European Utility Requirements
FAA - Federal Aviation Administration
FIAC - First In A Country
FOA - Funding Opportunity Announcement
FOAK - First Of A Kind
FNR - Fast Neutron Reactor
FSA - Functional Safety Assessment
FSAR - Final Safety Analysis Report
GDA - Generic Design Assessment (UK)

GFR - Gas cooled fast reactors
GP - General Product (railway Industry)
GPE - ASN Standing advisory committees (France)
GTHTR - Gas Turbine High Temperature Reactor
GT-MHR - Gas Turbine - Modular Helium Reactor
HI-SMUR - Holtec Inherently Safe Modular Underground Reactor
HSE - Health and Safety Executive (UK)
HTGR - High-Temperature Gas cooled Reactor
HTR - High Temperature Reactor
HTTR - High Temperature Engineering Test Reactor
I&C - Instrumentation and Control
IAEA - International Atomic Energy Agency
ICAO - International Civil Aviation Organization
INCAS - INtegrated model for the Competitiveness Analysis of Small-medium sized reactors
INPRO - The International Project on Innovative Nuclear Reactors and Fuel Cycles (IAEA)
IRSN - Institute for radiation protection and nuclear safety (France)
ITAAC - Inspections, Tests, Analyses and Acceptance Criteria (USA)
JAA - Joint Aviation Authorities
LFR - Lead-cooled fast reactors
LLI - Long Lead Items
LTPS - Licence to Prepare Site (Canada)
LUEC - Levelized Unit Electricity Cost
MDEP - Multinational Design Evaluation Programme
MEL - Minimum Equipment List (aviation industry)
MPMO - Major Projects Management Office (Canada)
MSR - Molten Salt Reactor
NEA - Nuclear Energy Agency
NEI - Nuclear Energy Institute
NII - Nuclear Installations Inspectorate (UK)
NOAK - Nth Of A Kind
NPP - Nuclear Power Plant
NRC - Nuclear Regulatory Commission (USA)
NSCA - Nuclear Safety and Control Act (Canada)
O&M - Operation and Maintenance
OCNS - Office for Civil Nuclear Security (UK)
OECD - Organisation for Economic Cooperation and Development
OL - Operating License
ONR - Office for Nuclear Regulation (UK)
PCmSR - Pre-commissioning safety report (UK)
PCSR - Pre-construction safety report (UK)
PM - Project Management
POSR - Pre-operational safety report (UK)
PPI - Plan Pluriannual d'Investissement (France)

PRA - Probabilistic Risk Assessment
PRISM - Power Reactor Innovative Small Module
PSAR - Preliminary Fafety Analysis Report
PWR - Pressurized Water Reactor
RCP - Reactor Coolant Pump
RE - Requirements Engineering
RFS - Basic Safety Rules (France)
RM - Requirements Management
SA - Severe Accident
SARPS - Standards and Recommended Practices (aviation industry)
SCWR - Supercritical-water-cooled reactors
SDCM - Standard Design Certification of Module
SE - Systems Engineering
SFR - Sodium-cooled fast reactors
SMART - System-integrated Modular Advanced ReacTor
SMR - Small Modular Reactor
SoS - Secretaries of State (United Kingdom)
SSC - Systems, Structures and Components
STUK - Säteilyturvakeskus - Radiation and Nuclear Safety Authority (Finland)
TraFi - Finnish Transport Safety Agency
TRISO - Tristructural-isotropic
TSO - Technical Support Organization
YVA - Ympäristövaikutusten arviointi - Environmental Impact Assessment (Finland)
YVL - Ydinvoimalaitos - Nuclear Power Plant (Finland)
YVL guides - Finnish Regulatory Guides for NPPs
VDR - Vendor Design Review process (Canada)
VHTR - Very-high-temperature reactors
WBS - Work Breakdown Structure
WENRA - Western European Nuclear Regulators' Association

1 INTRODUCTION

The world, and therefore the nuclear industry, has gone through large changes during the last decades. As the nuclear industry is focused on good safety and quality, they are guaranteed by detailed control and management. When nuclear power plants (NPP) (in this thesis "plant" contains all nuclear units in a site) were built in the past in Western countries, the amount of information was limited by the functional competence of information technology. Nowadays, the amount of information is practically unlimited by technology, which means that nuclear power plants are documented in detail and by dividing each unit into systems, components, interfaces, working practices, and cross-references between every element. This creates a new kind of framework in the nuclear energy industry, which affects the magnitude of requirements and information, and creates a situation in which not all the information can be managed by human cognition. The magnitude of information also makes information management challenging, if not impossible, in dynamic nuclear power plant engineering and construction projects. This is one of the main reasons why licensing processes in different countries have been developed further in recent years.

The development process has focused on the licensing challenges and optimization of currently available large NPPs. Recently, however, Small Modular Reactors (SMRs) have become more common and SMRs are expected to become the next commercially available nuclear power plant type. As SMRs are smaller and more simplified in comparison with large NPPs, licensing challenges can be overcome more easily. However, the licensing process needs focused development and optimization to take into account the specific features of SMRs.

"Nuclear power is an inherently hazardous and costly technology," explains Ioannis N. Kessides [74]. There have been many studies lately concerning nuclear costs and cost profiles. All these studies show the significance of capital cost in the nuclear energy field. When the older generation (e.g. generation 2) reactor designs are seen as no longer feasible in terms of safety, the new large NPP designs are becoming increasingly more expensive to build. As an example of the project challenges, the cost overruns of selected nuclear new build projects are discussed in reference [82]. The challenges facing large NPP new build projects provide a reason to study Small Modular Reactors (SMRs) in general and also provide a reason to study SMR licensing.

Under the current framework of the nuclear energy industry, licensing has been found to be one of the main challenges in the successful completion of NPP projects. Nuclear licensing processes vary between countries, and the differences can be seen in the licensing process steps, in the approaches adopted by regulatory bodies, and in the roles of different licensing stakeholders. Licensing processes can be divided into two groups: two-step licensing, (including Preliminary Safety Analysis Report and Final Safety Analysis Report phases); and one-step licensing, consisting of a single combined licensing phase. The regulatory framework, including the approach used by a regulatory body, can also be divided into two groups: a goal setting approach and a prescriptive approach. The goal setting approach presents only high level regulatory requirements, allowing the licensee to determine how these requirements are met on a case-by-case basis. The prescriptive approach, on the other hand, requires very detailed regulatory requirements to be followed.

Licensing processes have attracted more and more attention with the latest new build nuclear projects around the world. International organizations such as the World Nuclear Association (WNA) have also initiated licensing process studies. The WNA published a report: "Licensing and Project Development of New Nuclear Plants", in which certain aspects of licensing processes were studied and presented [81]. The main conclusions of the WNA report raise the importance of a predictable and stable licensing system. Early vendor selection has been identified as important since increased commitment is dependent on the progressive reduction of licensing risks as the licensing procedure moves forward. A reasonable level of design maturity has to be reached before applying for a license for a First Of A Kind (FOAK) project and for First In A Country (FIAC) projects, and a formally binding positive decision on a nuclear plant project taken by the government (and possibly national parliament) are also important findings. The final conclusion of the WNA study is the importance of efficient and effective design documentation and manufacturing documentation review between all parties involved. More generally, the WNA report discusses international harmonization of safety requirements and standardization of reactor designs as factors that would greatly facilitate licensing.

Practically speaking, all the publications and discussions that have emerged during this research with regard to the licensing process concern the licensing challenges facing large NPPs. However, certain aspects and findings apply to both large and small reactors. Certain findings are even more important for SMR licensing, due to the specific features of SMRs, and these are described in Chapter 4 of this thesis.

In this study, the target is the licensing process, focusing on the duration of the licensing process and the probability of failure. Later in the study the licensing process is compared from different perspectives. The severity of the licensing risk is estimated based on the overall duration of a certain licensing process step, should it have to be repeated from the beginning. The likelihood of the hazard will be estimated based on a qualitative approximation.

I aim to answer the main research question: "How can SMRs be licensed in Finland functionally, economically and practically?"
This research question is elaborated through understanding of the licensing processes and practices in different countries and different industry fields. Together with an understanding of the SMR-specific features (focusing on the LWR SMR designs) that affect the licensing, the suitable parts and features of different licensing processes are indicated. The functional part of the research question is handled through the actual licensing process development. The economical approach is studied and described within the context of SMR economics and their execution project durations, which are compared with the current NPP licensing schedules. The practical part of the licensing is carried through the Systems Engineering (SE), Requirements Management (RM) and Project Management (PM) processes.

The thesis begins by explaining the importance of this study from the nuclear energy industry point of view. This is discussed in Chapter 2 Research Framework. The chapter also presents the relevant literature that is used as a basis for this study, data gathering methods, and background information of the countries that are included in the study. I have gathered data for this thesis widely, using interviews and questionnaires, since the publically available data concerning SMR licensing is very limited. Once the framework for the research has been presented, I move on to describe the research methodology and the research process adopted in Chapter 3.

I will divide the main research question into subquestions.
The first sub-question is:"Is the current NPP licensing process suitable for SMRs?"
To enable the analysis of the licensing processes, the specific features of SMRs need to be understood. In Chapter 4, I describe the specific features of SMRs and SMR development around the world. The chapter offers a good understanding of those features of SMRs that affect the licensing process. Once the needs of SMR licensing compared to those of large NPPs are understood, the evaluation of different licensing processes can begin. Section 5.2 answers the first sub-question, while comparing the SMR characteristics with the Finnish licensing process. Chapter 5 describes the licensing processes in the studied countries as well as the development and changes that have occurred in recent years in connection to new build NPP projects. The licensing processes are divided into licensing steps, and these steps are analyzed and compared in detail. Other safety critical industry fields and their licensing processes and practices are also studied. The aviation industry and railway industry are two fields that are regarded as having many similarities with the nuclear industry, so I have included their licensing and permitting processes in this study. The licensing process for an aircraft has many features in common with nuclear facility licensing, and even more so with SMRs than large NPPs. As aircrafts are constructed, and therefore licensed, in series, SMRs are expected to have similar characteristics from the PM perspective.

The second sub-question: "What parts of different licensing processes could be feasible for the SMR licensing process?" is answered through the comparison of the licensing processes and their different licensing steps. I present the comparison of the licensing processes in Chapter 6. The comparison is achieved by first dividing the licensing processes into defined licensing steps. This task is not easy to perform, since there is no straightforward way of bringing these licensing steps into line. However, there are similarities in certain licensing steps between different licensing processes. These similarities are indicated and the corresponding licensing steps are then determined and compared with each other. I have performed the comparison of the licensing steps using the specific characteristics of SMRs as a reference point. After this I analyze these characteristics using the methodology presented in Chapter 3, and describe each of the licensing steps individually, as each one has certain unique qualities.

The third sub-question: "How could these parts be integrated into a new feasible SMR licensing model?" is discussed and answered in Chapter 7. In the first phase, I create an optimized licensing model for SMRs, assuming that no regulatory framework exists to set limitations on the process. After this phase, I take the current Finnish licensing process and propose modifications to it so that the main benefits from the optimized licensing process are included. This new SMR licensing process for the Finnish regulatory framework is then reviewed against the current legislation. I indicate the possible needs for legislative modification, if this type of licensing process would be put into operation.

As the background for this whole study is set in the nuclear energy industry and the need for licensing modification lends itself to SMR characteristics, I present the new licensing model application in Chapter 8. This chapter takes the new SMR licensing process to a practical level, using SE and PM tools and practices. My aim throughout this study has been to develop an applicable tool for SMR licensing, enabling future SMR projects to be successful from the licensing point of view. Bringing the new practices and tools to the nuclear field, feasible and practicable SMR licensing can be assured. At the end of the thesis I describe my contribution to the study, the limitations experienced, and the possible topics for future research.

It is reasonable to argue that this research is important for the nuclear energy industry since licensing is one of the main financial risks in new build nuclear projects. There has not been a lot of research focused on the SMR licensing process as SMRs have not been licensed so far in Western countries. SMRs are seen as part of the nuclear renaissance that is expected to take place, and many studies have been begun taking different SMR aspects into account. SMR designs and their technical solutions are widely studied, as well as the commercial competitiveness aspects. However, the licensing process studies have only discussed the licensing of large NPPs, while SMRs are only included in the discussion in a subordinate clause. As the studies and documentation of SMR licensing is very limited, interviews and questionnaires make up a notable part of my research. No licensed SMRs exist in the studied countries at this point of time, and all of the licensing activities are just taking their first steps. This situation increases the novelty of this research, since there is no experience from earlier SMR licensing to be used as comparison material.

The key theoretical contribution of this research is in the combination of multiple research paths providing a cohesive whole in SMR licensing. The presented theory rests on combination of certain features from different licensing processes. The theory is extended by other safety critical industries' practices and by the SMR aspects.

The result of this research introduces a co-evolutionary approach adapting SE theory, RM practices, and PM tools. The presented theory is a simple and comprehensible model combining various levels of licensing aspects. The novelty of the RM approach in nuclear industry is the determined categorization of the licensing requirements and comprehensive follow-up of each requirement during the whole lifecycle of the plant.

The new features of SMRs require research of licensing requirements and licensing processes. The improved characteristics of SMRs can really make a difference in the nuclear industry if they are optimally utilized from the technical and licensing perspectives, as well as processes and practices.

2 RESEARCH FRAMEWORK

This chapter describes the background to the SMR licensing study, including the statement of reasons why this study is important for the nuclear industry. In this chapter I present the basic background information as well as the methods used for gathering information during the research.

2.1 Statement of reasons on the importance of the study for the nuclear industry

The nuclear industry is not only a technical business, it is highly political and affected by public acceptance. One way to increase public acceptance and also affect the political atmosphere concerning nuclear energy is an internationally accepted and open licensing process. This is a good and credible way to communicate with politicians and also with the public. Over the years, public acceptance has become an increasingly important part of nuclear industry policy and all the nuclear-related activities. Public acceptance has been included in various steps of the licensing process activities.

The nuclear industry is undergoing many changes. Primarily, a number of new NPP projects around the world have been started, creating new types of challenges. Second, the number of different types of NPPs is increasing dramatically in the field of large NPPs as well as SMRs. The future direction for nuclear power plant designs can be said to be more simple designs and natural convection-based solutions.

Large NPPs and small modular reactors have shown the same indications in developing complex designs in a more simple and intelligible direction. The object of this development is safety improvement through inherent safety features, described more in Chapter 4, as well as in costs downsizing through decreasing the number of Systems, Structures, and Components (SSC) in the design.

Safety issues that are the most fundamental indicators in nuclear industry have been under discussion in past years due to the new NPP projects. Concepts on the different safety designs vary greatly, from very complex active safety design to very simple passive solutions. The main ideas behind simplification of the designs is to enhance the safety level of power plants and lower the costs. Although the opinions of different stakeholders vary, the concept of passive safety design is seen as an improvement of overall safety. This improvement is based on the reduction of the possibility of a failure in the active safety systems function and slower transient and accident sequences. The simplified design also enables the operator to better understand the features of the operating transients and accidents in the plant. The Defense in Depth (DiD) philosophy suits SMRs as well as large NPPs, however some modification of the used DiD approach may be required.

The trend in NPP development is seen to focus on very large units (>1000MWe) and Small Modular Reactors (SMRs), that are determined by the OECD to be <300MWe in size [4]. It should be observed that 'SMR' is also used to mean Small and Medium Sized Reactors. This definition is used by the IAEA [60]. Modularity is one of the new design features of SMRs. Modularity can be seen in many different ways, the most visible being the modularity of several reactors on the same plant with possibly shared systems. Modularity can also be seen in systems or large parts of them manufactured in the factory and ready modules delivered to the site to reduce delays and construction costs [55]. Modular construction methods are already implemented in the plans of many large NPP projects; however, this approach cannot be compared with SMR modularity, which is embedded in the design from the early design phase. Modularity is one of the features that creates the need for licensing process modification in many countries. The modular construction of large NPPs requires certain types of modification in certain licensing processes, such as Finnish licensing, where regulatory acceptance follows the project development. In this case, it should be well understood how the module is designed. All the systems and components, which have any connection to this module (e.g. one room), should be approved before the manufacture of a module can begin. This challenge will not be discussed further in this thesis as the focus is on SMRs.

Other advantages, in addition to those mentioned above, are features that can make SMRs competitive in the nuclear field. These features are standardization (mass production), short construction times, and serial construction (enabling self-financing), and sustainability issues.

The licensing process for a nuclear installation has been discussed and determined by different organizations. The fundamental standard that deals with the licensing process is the IAEA Safety Guide SSG-12 [63]. The licensing process can be divided into different steps according to the lifetime stages (presented in Figure 1 below). Different license combinations of the lifetime stages are also possible and widely used. The licensing process study, evaluation, and comparison in this study are focused on the early phases of the licensing process, including the siting, design, and construction. Commissioning and operation are also discussed as part of the study, but only from the new power plant point of view.

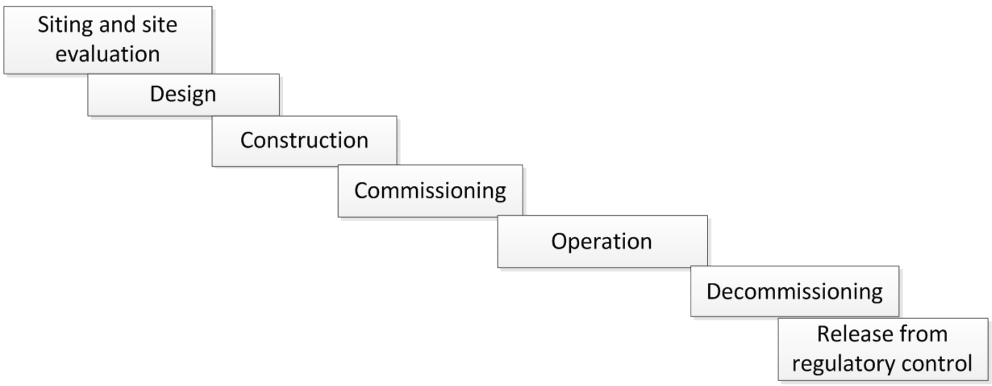


Figure 1 Stages in the lifetime of a nuclear installation in the IAEA SSG-12 [63]

The main focus of this thesis is to review and analyze the current licensing processes from the perspective of SMRs. This research focuses on the new situation that is provided by SMR designs, including many reactor modules in one specific unit. Also, the concept that many SMRs are to be built in series is included in the discussion. The current licensing framework has been built for units that contain only one reactor. This new modular approach, among many other new issues, makes it necessary to study and develop the licensing process. SMR licensing issues have been observed already in some countries and the discussion on the SMR approach has begun. European countries have not widely expressed their interest in SMR licensing studies and development at this point in time.

Licensing requirements in general have been under discussion in past years in many different forums, nationally as well as internationally. Many international organizations have discussed licensing requirements, as well as other technical requirements (standards and rules) and the harmonization of requirements. International organizations involved in nuclear licensing are described in section 5.1. This harmonization development has been emphasized in Europe, where there are many small nuclear countries with different national requirements. As the compatibility of nuclear energy against other energy production means has been under discussion, the costs of new NPP projects and cost distribution have been under many evaluations. One of the methods to reduce nuclear energy costs through new NPP projects is NPP standardization. The redesign of the NPP for each single European country is not the most competitive approach. It is possible that in one country there could be several NPPs built, each one with a different design. This would mean that every single unit would be redesigned, and therefore be unique. This might be the situation in Finland in the coming years.

The nuclear industry is quite a specific industry in terms of licensing. Having said that, there are many other industries that have similar or comparable safety features to deal with. This study investigates the features of different countries' nuclear licensing processes as well as those in the aviation and railway industries. The most suitable features will be acknowledged and selected for SMR licensing. As SMRs have more similarities with, for example, an aircraft than a large NPP, aviation industry licensing can be useful in several areas.

2.2 Data and data collection

This dissertation focuses on nuclear licensing processes and the characteristics of SMRs that affect the suitability of the licensing process. The background data is collected through research into and the study of relevant regulatory documentation, including nuclear legislation, nuclear regulations, and regulatory guides. The research data comprises semi-structured interviews with licensing experts in the utilities and regulatory bodies, as well as lawyers at the Ministry of Employment and the Economy and other nuclear law specialists in Finland. A questionnaire concerning the research questions and the main characteristics of the research was also used to gather data on licensing in the studied countries. This questionnaire was responded to by both industry utilities or designers and regulatory bodies.

The background data includes interviews, questionnaire responses as well as written documents, and observations. As the actual licensing processes and true practices are not always immediately apparent, only review of the regulatory documentation and many discussions with different stakeholders has improved the understanding of the subject. Semi-structured interviews provide one of the methods of data gathering. Interviews have been described as an efficient way of gather empirical data on phased events [33, p. 25-32]. The direct observation of licensing activities, so-called observation-based methods, as well as involvement in the Olkiluoto 3 and 4 projects' licensing activities, have resulted in an in-depth picture.

The interviews were guided by semi-structured interview outlines. This means that a prepared agenda was used for the interviews. However, there was still room for discussion, based on the interviewee's perspective and knowledge. Every interview was started with an explanation of the focus and purpose of the meeting. The suggestions by Miles and Huberman [86] are followed in presenting the results of the qualitative data, illustrative forms of data are utilized to summarize the results, including tables, crosstabulations, figures, and charts. To improve the transparency of the qualitative data results, the interview outlines are included in Appendix 1 and the questionnaire and responses are included in Appendix 2 of this thesis.

Over the course of the study I have presented the primary results to experts in the studied regulatory frameworks to get comments from the practical perspective.

During this study, it has been observed that relevant information is much more transparent in some countries and not so transparent in others. For example, the USA has an extensive public database at the regulator's website. Some countries have a much more restrictive policy in terms of public information. The direction of information publicity is towards a more open policy in many of the Western countries studied in the course of this research.

2.3 Basic background information on the nuclear power plants in the studied countries

Finland

In Finland, there are four NPP units at two sites:

- Two VVER units in Loviisa operated by Fortum (commissioned 1977–1980)
- Two BWR units in Olkiluoto operated by TVO (commissioned 1978–1980).

A fifth unit has been planned from the early 1980s. The first construction license application was withdrawn in 1986 (following the Chernobyl accident). In 1993, the decision in principle was granted by the Council of State but rejected by the Finnish Parliament. Finally, Parliament granted the decision in principle in 2002 and the Olkiluoto 3 project was started. The construction license was granted in 2005. [121, p 90] Two other decisions in principle were granted in 2010 - for TVO and Fennovoima, TVO is preparing the Olkiluoto 4 project and Fennovoima is preparing the Hanhikivi 1 project in Pyhäjoki. The decisions in principle are valid for five years.

USA

There are 103 reactors (PWR and BWR) at 31 different sites in the USA. The standardization is not at a high level and there are 80 different designs. The designs can be split roughly into four groups: one BWR design from General Electric and three PWR designs from different vendors.

In past years, design certificates have been granted for four designs and six designs are under review (2012). [153, p. 129]

Canada

Canada has 19 nuclear power reactors at four different sites. Shortly after the Second World War, Canada began development of its own line of nuclear power reactors, known as Canada Deuterium Uranium or CANDU reactors. The first CANDU to supply electricity to the Ontario grid was the 20 MWe Nuclear Power Demonstration (NPD) plant, followed by the first true commercial CANDU reactor, a 250 MWe design at Douglas Point, Ontario. The lessons learned from the Douglas Point project were used to construct and operate a larger commercial scale four unit CANDU station at Pickering, Ontario (500 MWe each) between 1971 and 1973. Multi-unit CANDU stations have characteristics that differ from traditional LWRs. For example, multi-unit stations share a common containment structure, connected to a common vacuum building to form a very large overall negative pressure containment volume. These stations do not share primary safety systems but do share some safety support systems, including some common backup power supplies, air systems, and emergency coolant systems (for coolant recovery phase). [17]
New nuclear reactors are planned to go into operation in the next decade. Some of these are likely be SMRs. [176]

France

In France, there are 58 PWR type NPPs at 19 different sites. The operator of all the plants is the state-owned Electricité de France (EDF). The units are highly standardized and only three different design generations exist:

- 34 CP0 and CPY units (900MWe) (licensed 1972–1982)
- 20 P4 and P'4 units (1300MWe) (licensed 1978–1985)
- 4 N4 units (1450MWe) (licensed 1984–1993)

The first EPR is under construction at the Flamanville site, and the licensing started in 2006. It needs to be mentioned that the single state-owned operator for all the plants and standardized fleet of reactors has influenced the regulatory system. [176, p 52]

UK

In Great Britain, there are 23 NPPs:

- 8 Magnox - operated until 2005 (into commercial operation 1976–1989)
- 14 Advanced Gas Reactors (into commercial operation 1976–1989)
- 1 PWR (into commercial operation 1995)

New PWR projects are on-going and AP 1000 and EPR are going through the licensing process in 2012. High standardization has not been the case in the UK. The licensing regime puts the focus on the licensee, while the responsibility for safety belongs to the licensee, not the regulator. The licensee establishes the safety case, which needs to be agreed formally by the Nuclear Installations Inspectorate (NII). A specific set of general regulations for nuclear safety does not exist in the UK. [121, p 106]

3 RESEARCH METHODOLOGY

The purpose of this chapter is to present the selected methodological approach to this research. I will describe the methodology and the research process used in this study. I will also describe the research methods and theories that have been adapted in this study.
The principles of the research methods used in this study are presented in the following sections.

3.1 Qualitative research method

A qualitative research method has been selected as suitable for many parts of this research. Since the character of the study is quite abstract and the results cannot be conventionally measured, the quantitative analysis approach, as an alternative to qualitative research, was not seen as a suitable method. The qualitative research method has many slightly different definitions, some of the determinations for the qualitative research method are presented here.

The qualitative research method is used for inquiry in many different academic disciplines. This method is a flexible and subjective research tool. Different types of research features and modes can be applied, such as interviews. If seen conventionally, qualitative methods produce information only on the particular cases studied. More general conclusions, in this sense, are only propositions. [127]

There are many considerations to decide when adopting a qualitative research method. Qualitative methods can be used to understand better any phenomenon if knowledge of the phenomenon is quite limited. Qualitative methods are also used to gain new perspectives on issues, or to gain more in-depth information that may be difficult to communicate quantitatively. [126]

Qualitative research can also be understood as research that produces findings not arrived at by means of quantification. "Where quantitative researchers seek causal determination, prediction, and generalization of findings, qualitative researchers seek instead illumination, understanding, and extrapolation to similar situations." [56]

3.2 Functional Safety Assessment

The Functional Safety Assessment (FSA) method has been applied to the comparison process of the different licensing processes within this study. The FSA approach has been selected for the comparison because it is difficult to compare the licensing processes and even more difficult to have any kind of quantitative measures as the comparison results. The FSA method provides a tool for comparing the licensing risks in different regulatory frameworks according to the probability of the risk to materialize and the severity of the influence on the licensing project in case the risk materializes. With the FSA method the quantification is done according to the risks in the licensing processes and the first risk evaluation is then approximated according to the suitability to the special features of SMRs.

"Storey (1996) identifies three aspects of system safety. The first is 'primary safety', which concerns such risks as electric shock and burns inflicted directly by hardware. The second is 'functional safety', which covers the safety of the equipment that depends on the risk-reduction measures in question, and is therefore related to the correct functioning of these measures. The third is 'indirect safety', which concerns the indirect consequences of a system not performing as required, such as the production of incorrect information by an information system such as a medical database." [90]

The FSA method is presented in different publications, such as the IEC 61508 Functional safety of electrical/electronic/programmable electronic safety-related systems [28]. Even though this study is not issuing technical systems, functionality is a comparable feature between programmable systems and the licensing process.

The IEC 61508 standard introduces safety management and safety engineering, including software and system engineering approach, as well as the management of all aspects of systems. [85] The FSA approach is traditionally used for technical systems and processes management; however, it is used also, for example, in the Project Management field. The FSA approach will be applied to the licensing process comparison in Chapter 6 of this thesis. The IEC 61508 grounds are based on the overall safety lifecycle (see Figure 2) that offers a model of the stages of safety management in the life of a system.

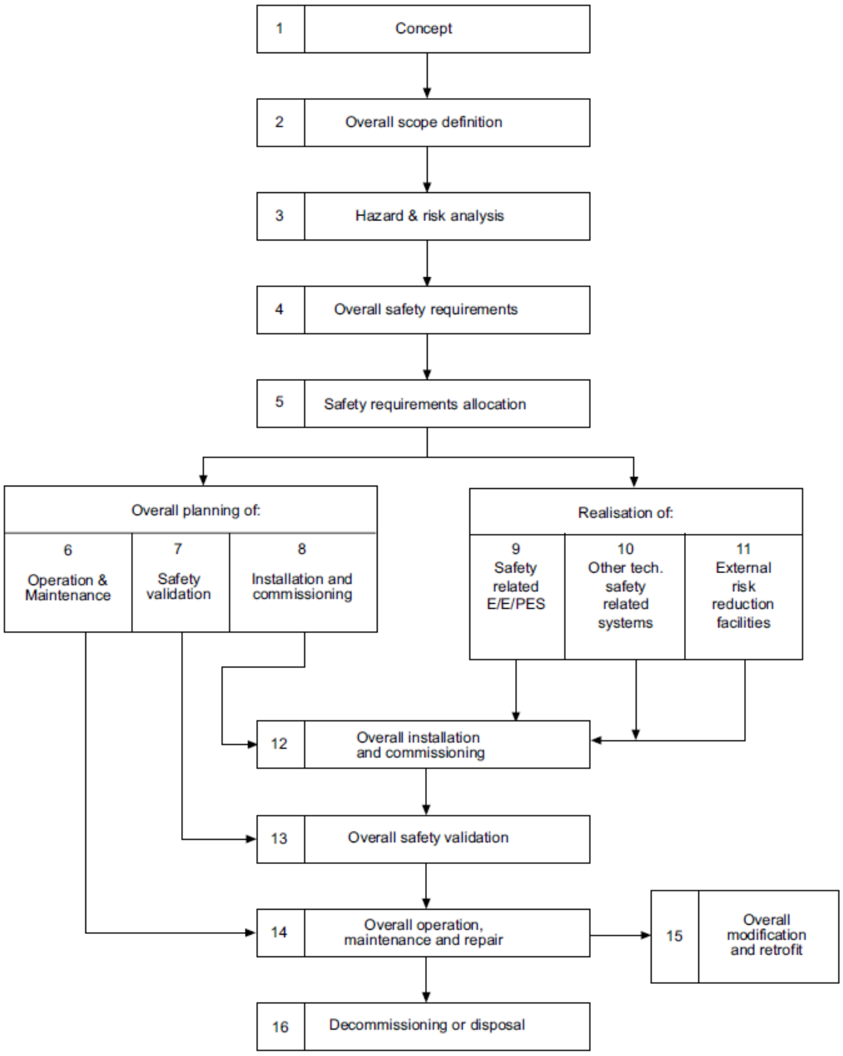


Figure 2 The overall safety lifecycle [69, EC 61508-1]

IEC 61508 requires a hazard and risk assessment. "The EUC (equipment under control) risk shall be evaluated, or estimated, for each determined hazardous event." [28]

The FSA process can be divided into three stages:

1. Establish the tolerable risk criteria
2. Assess the risk associated with the equipment under control

3. Determine the necessary risk reduction needed to meet the risk acceptance.

The first phase defines the tolerable risk criteria, which in this study is expressed in qualitative criteria. The example of tolerability of risk is presented in Figure 3 using risk band diagram.

Severity	Catastrophic 5	5	10	15	20	25
	Significant 4	4	8	12	16	20
	Moderate 3	3	6	9	12	15
	Low 2	2	4	6	8	10
	Negligible 1	1	2	3	4	5
		1	2	3	4	5
		Improbable	Remote	Occasional	Probable	Frequent
		Likelihood				

Figure 3 An example of risk band for tolerability of hazards [54]

It should be noted that the risk gradings are not used and the example figure is modified when used in this thesis. In the second phase the risk is assessed by questioning the probability of the failure, as well as the outcome of the assumed failure [69]. The likelihood and the consequences of the hazardous events is recognized and analyzed. In this study the target is the licensing process, and the licensing risks are focused on with the FSA. The likelihood of the hazard will be estimated based on qualitative analysis and the consequences are presented as "time lost".

The risk band has been adapted into the licensing steps comparison in Chapter 6 of this thesis. The risk bands present the comparison results to some extent in a qualitative manner. The risk band approach first raises the most important licensing phases to be developed further in terms of SMR licensing. After that indication, the risk bands also indicate the suitability of certain licensing process features for the special features of SMRs.

3.3 Value analysis

A value analysis has been applied in this study to analyze the responses to the questionnaire (presented in section 6.3). The value analysis method is therefore used to provide a validation of the FSA analysis results. . Value analysis is an approach to improve the value of a product or process. Value analysis is related to value engineering, which is a systematic method for improving the "value" of goods or products and services by using an examination of function. [86]

To use the value analysis method effectively, it is important to plan the study in detail, which is the way to get a more detailed understanding of the specific situations. Here are some examples of value analysis use. [10]

Table 1 An examples of value analysis use

Quick				X		Long
Logical	X					Psychological
Individual	X					Group

Value analysis can be divided into three parts [10]:

1. Identify and prioritize functions

   Identify the item to be analyzed and list the basic functions.

   Identify the secondary functions by determining the support functions for the basic functions.

   Determine the relative importance of each function.

2. Analyze contributing functions

   Find the components of the item being analyzed that are used to provide the key functions.

   Measure the cost of each component as accurately as possible.

3. Seek improvements

   Eliminate or reduce the cost of components that add little value.

   Enhance the value added by components that contribute significantly to the important functions.

Value analysis function is presented in the following figure (Figure 4).

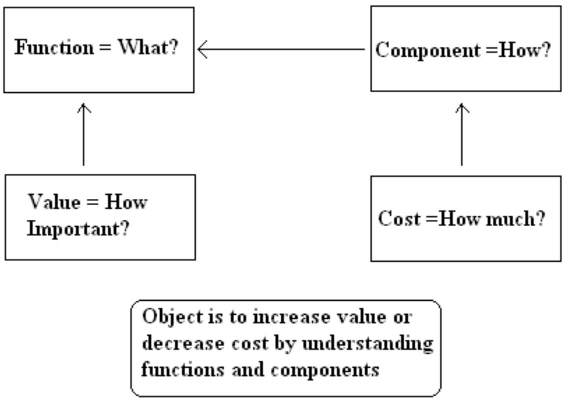


Figure 4 Value analysis process [10]

Value analysis is used in this study to understand the following features of the studied countries' licensing processes:

- Standardized process
- Comprehensive review
- Adjustable process
- Systems Engineering, Requirements Management and Verification and validations process

The evaluation of these features is carried out using a questionnaire that has been responded to by licensing experts in the studied countries. The object was to get responses to the questionnaire from each country's regulatory body and industry, as the responses could differ slightly depending on the point of view.
The questionnaire is presented in Appendix 2. The responses from each country are presented in Appendix 1.

A summary table of the responses has been produced to represent the studied features. The discussion of steps in licensing processes in connection to certain design maturity stage is also issued in order to understand the comparison at a more detailed level. According to the summary table, understanding the connection of the design stage, the value analysis method is used to evaluate the selected features in a more detailed manner. The value analysis study is presented in Chapter 6 of this thesis.

3.4 Systems Engineering (SE)

This section presents first the SE [51], RM [9] theory and the basis that is used with PM tools to bring the developed SMR licensing model to a practicable level.

SE is an engineering discipline that creates and executes an interdisciplinary process to ensure that the customer's and stakeholder's needs are satisfied in a high-quality, trustworthy, cost-efficient, and schedule compliant manner throughout a system's entire lifecycle. This process is usually comprised of the following seven tasks: **S**tate the problem, **I**nvestigate alternatives, **M**odel the system, **I**ntegrate, **L**aunch the system, **A**ssess performance, and **R**e-evaluate.

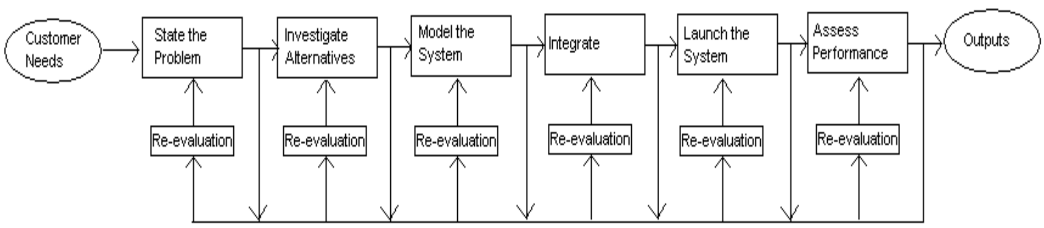


Figure 5 The Systems Engineering Process

SE as well as RM have been used and developed originally in software engineering, so mechanical engineering is far behind the development in these management fields. It can be stated that the process has been developed first for software engineering and later it has been adjusted for other industry fields as well. The approach in the mechanical engineering field is a little different from the software engineering field, as presented in the following figure (Figure 6).

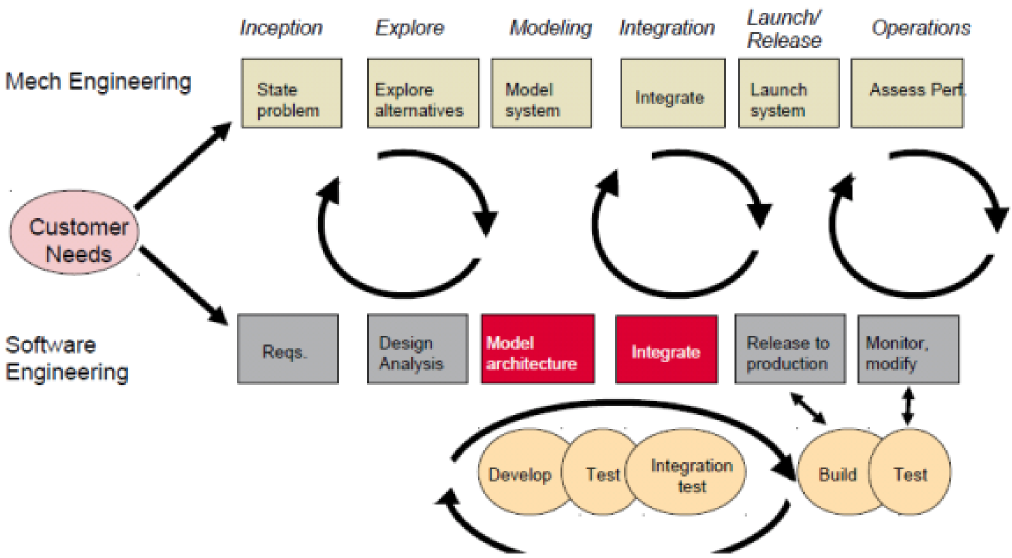


Figure 6 Systems Engineering Process in Mechanical Engineering vs. Software Engineering [50]

SE is handled in various standards, such as ANSI/EIA 632, ISO/IEC 15288 [71] and MIL-STD-499B. The SE processes and their interfaces are presented in the following figure (Figure 7).

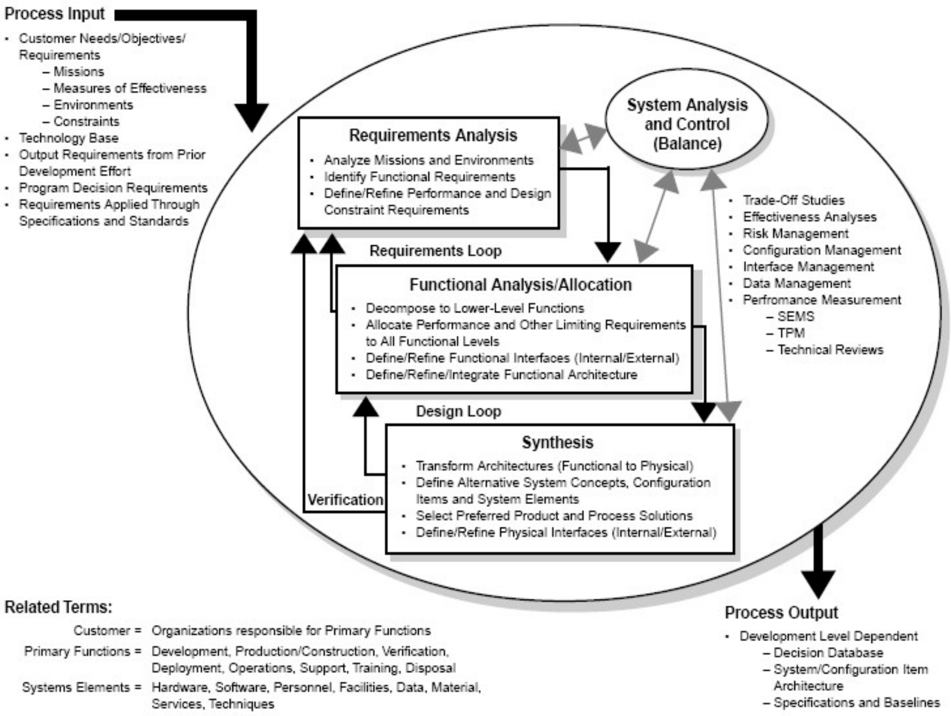


Figure 7 Systems Engineering Process [51]

The main SE standard used in this study is ISO/IEC 15288 [72]. This standard presents the System Life Cycle Processes as presented in Figure 8. The benefits of this approach in NPP projects are that the processes can be verified by an inspection organization and communication between different stakeholders is easier. The RM process is included in the Information Management Process in the Systems Life Cycle Processes.

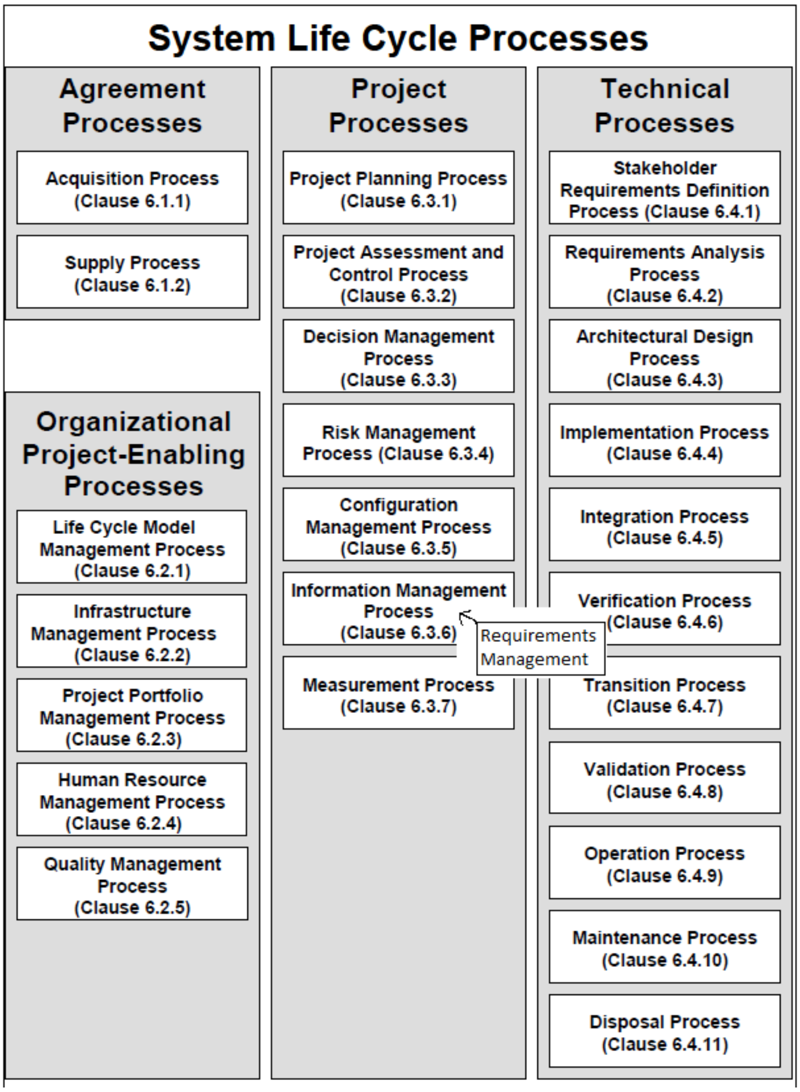


Figure 8 ISO/IEC 15288 System Life Cycle Processes

3.5 Requirements Management (RM) and Requirements Engineering (RE)

Terminology in the Requirements Management or Requirements Engineering fields can be used in many different ways. These terms are used differently in different publications and in different countries. In this study the term Requirements Management is used as a discipline that includes requirements development, requirements management (narrow scale) as well as Verification and Validation processes.

Requirements Development includes the following functions:

- Requirements Elicitation
- Requirements Analysis
  - Requirements Sourcing
  - Requirements Assignment
  - Requirements Decomposition and Derivation
  - Requirements Prioritization
- Requirements Documentation
- Requirements Evaluation

Requirements Management (narrow scale) includes the following functions:

- Requirements Change Management
- Requirements Tracing

Verification and Validation includes the following functions:

- Verification
  - Qualification
- Validation

Validation and Verification include different practices such as testing, analyzing, auditing, etc.

The phases of the RM (Requirement Definition and Analysis process, as presented in ISO/IEC 15288), can be divided into the following phases:

- Stakeholder requirement elicitation
- Stakeholder requirement definition
- Stakeholder requirements analysis and maintenance.

When these issues and phases are followed, the project has a good foundation and project communication is easier when all stakeholders understand the reasons for and targets of the project. Figure 9 presents an example of the Requirement Definition and Analysis process.

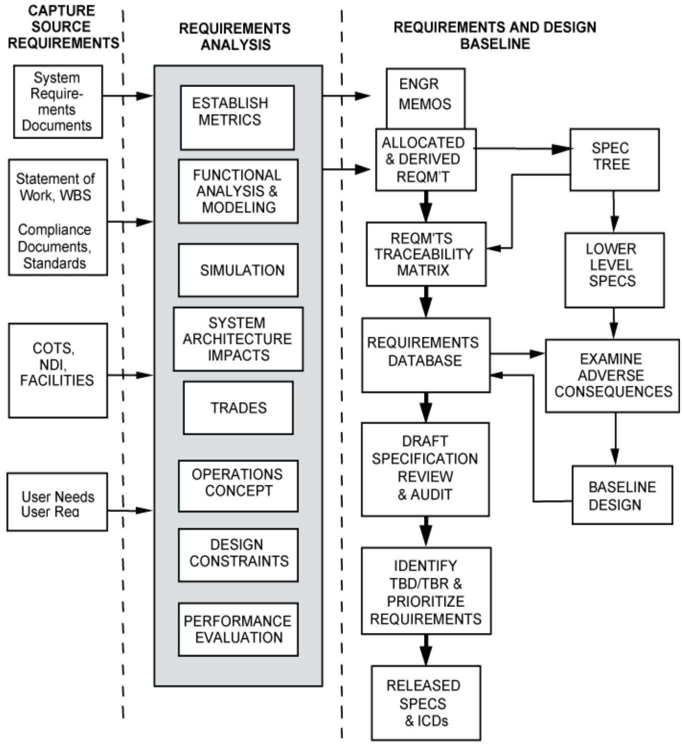


Figure 9 Requirements Derivation, Allocation, and Flowdown [51]

This shows the large amount of work that is needed in the Requirement Definition and Analysis phase. However, the benefits are realized in the later phases of the project.

3.6 The research process used in this study

The research process as well as the structure of this dissertation is presented in Figure 10. The process as a whole is explained later in detail.

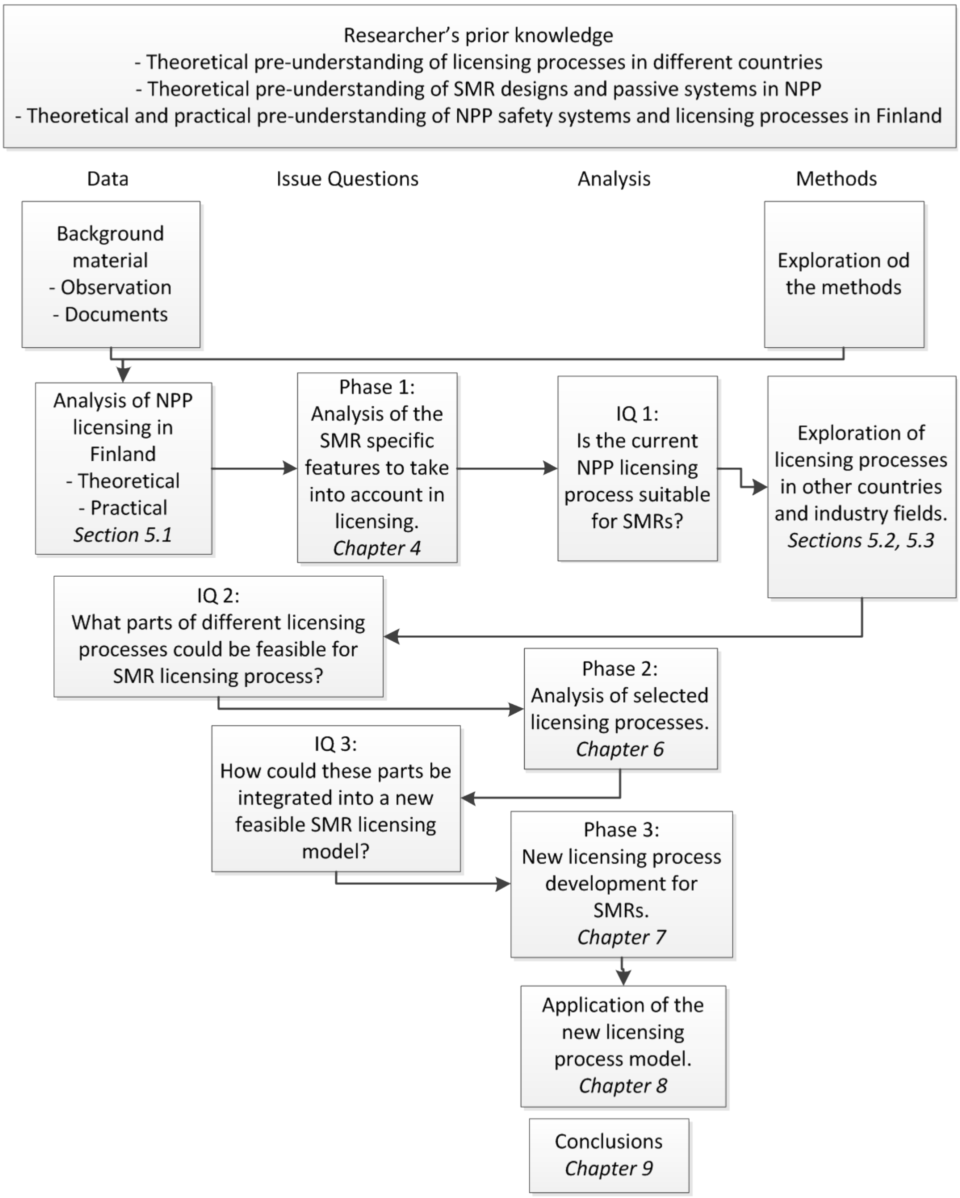


Figure 10 The research process used in the study

The research process presents the approach of the study. The aim of the study is to answer the main Research Question: How should SMRs in Finland be licensed functionally, economically, and practically?
The starting point of the research is based on the researcher's prior knowledge and experience in NPP licensing practices, particularly in Finland.

The background data observation and documentation has been developed for a long time before this study, and it has continued during the study. The researcher has been involved in large NPP licensing, prior to and during the study. This approach has been informative and useful practice to enable the comparison of the current licensing process with the specific features of SMRs.

Phase 1: Study of the features of SMRs that are most important while planning the licensing process. This phase goes through SMR designs with their special features and the main differences with large NPPs. A qualitative research method has been used in phase 1. The features of SMRs are presented in Chapter 4.
The analysis of NPP licensing in Finland is mainly based on the background information and the current licensing activities in the Finnish NPP projects. The basis of nuclear licensing is presented in Chapter 5, and the Finnish licensing process is presented in section 5.2 .

IQ 1 is Sub-question 1: Is the current NPP licensing process suitable for SMRs?
This first sub-question is answered through a discussion of the Finnish licensing process and its suitability for SMRs in section 5.2.6 .
This sub-question raises the main challenges facing the current Finnish licensing process to be applied in SMR licensing. The discussion of the special features of SMRs is included within the scope of this sub-question.
The next phase of the study introduces the licensing processes in the USA, the UK, France, and Canada. Other safety critical industry fields are also studied, such as the aviation industry. The different licensing processes are analyzed and compared.

IQ 2 is Sub-question 2: What parts of different licensing processes could be feasible for the SMR licensing process?
This subquestion includes the licensing processes study. The selected countries' licensing processes and the features that are similar and different are discussed and compared. The licensing of other safety critical industry fields are also included in the study. The countries for this study are selected from Western Europe and America, because the information is available in these areas of the world. The regulatory body also has quite similar liability and independence in the studied countries; however, these features are not examined as part of this study. The studied countries have also been active in terms of nuclear licensing in past years, so the licensing processes have been developed and updated to fit the current licensing activities. The countries included within this study's scope are Finland, the USA, Canada, the UK, and France. The benefits and challenges of different licensing processes are indicated in terms of the specific features of SMRs.
This second sub-question is answered through Phase 2: Analysis of selected licensing processes. The analysis is conducted using first the Functional Safety Assessment (FSA) method, and second the Value Analysis method.

The FSA method is used to compare the different licensing steps of the countries that are included in this study. This is the basis of the selection of the certain licensing features from different licensing processes to suit the SMR licensing. This comparison also gives an indication of the most important licensing phases to be developed further for SMRs.
To justify the analysis results, increase the credibility of the analysis results, as well as deepen the understanding of the licensing process features, the value analysis is performed based on the questionnaires and the responses from the studied countries.

IQ 3 is Sub-question 3: How could these parts be integrated into a new feasible SMR licensing model?
This subquestion combines the studied licensing features building up an optimized licensing process model for SMRs. This optimized process is assumed to fit if there were no regulatory framework available in the country of SMR deployment. As reality needs to be taken into account, the optimized licensing model is not introduced to the Finnish regulatory framework as it is, but the most important features are selected and incorporated into the current Finnish licensing process.
This third sub-question is answered through Phase 3. The main features are introduced into the current Finnish licensing process, since the object of the new licensing model for SMRs is to minimize the changes needed in the current process, and have the most important features included in the licensing process.
Verification of the new licensing model's feasibility is presented using SE, RM, and PM processes and tools. This application phase gathers together the results of the study.
The conclusion then wraps up the findings of the study and discusses possible areas of further study and development.

The new licensing process application, in the Finnish regulatory framework, is then presented using the SE, RM, and PM practices and tools. This approach offers new features to the overall regulatory framework to be taken into consideration in the future.

After presenting the results of the study and their application, further actions and fields of study are discussed, together with the conclusions.

3.7 Summary of the research methodology

This study is very inter-disciplinary between nuclear technology as well as industrial engineering and management. There is no straightforward study process for the issues studied in this dissertation. This is why different techniques are applied in a wide range and from different engineering fields. The combination of the FSA and the value analysis has been selected because these methods together form a coherent whole where the different licensing processes and their parts can be placed and compared with each other. Even though the FSA method is primarily intended for technical objects, it contains features that are suitable for licensing process evaluation. The primary values of the risk bands are based on the failure rates (the experimental data from earlier projects). The final values of the risk bands are estimated according to the failure modes (indicated in the evaluation with each risk band) and effects (indicated in the evaluation with each risk band).

The FSA method is used for the comparison of the studied licensing processes and their suitability for the SMRs specific features, while the value analysis is used to verify the results. The industry and regulatory body responses for the questionnaire are analyzed through the value analysis, which also creates more confidence for the FSA analysis results. The SE approach is not widely used within the nuclear industry; however, it creates useful practice and tools for nuclear licensing. The nuclear industry has been quite a closed industry for a long time and the current challenges in licensing, as well as in other nuclear-related issues, have features similar to other fields of industry, where they might already have been solved. Suitable methods can also be found elsewhere; however, these methods are seen as best suited for this particular study. All the methods are applied in many stages of the study. The applications of different methods are presented in Chapters 6 and 8.

4 SMR CONCEPTS AND THEIR DESIGN FEATURES

There are two different definitions for the abbreviation SMR. In this study, SMR is defined as Small Modular Reactor, which is used widely in the nuclear industry. However, the International Atomic Energy Agency (IAEA) defines SMR as Small and Medium size Reactors. Many small and medium size NPPs have been built over the years, since the nuclear industry started with small reactor designs.

Small Modular Reactors (SMRs) are defined as reactors that produce electricity under 300MW_e [177]. Medium size reactors are units that produce power in the range of 300-700 MW_e [177]. SMRs vary greatly from very small (10-20MW_e) to near medium size (200-300MW_e) power units. SMRs have been designed for years in many countries and many of the current concepts are based on, for example, submarine types of reactors that have been built and operated for many decades. The concept of small modular reactor is not new, but the modularity has not been focused on the way it is done nowadays.
The new LWR based SMR design features include, almost without exception, integrated reactor pressure vessel, pressurizer, and steam generators. SMRs of such integral design have been under fast development in past years.

Technologies that depart from traditional LWR designs have been described within the framework of Generation IV. The Gen IV technologies include Gas cooled fast reactors (GFR), Very-high-temperature reactors (VHTR), Supercritical-water-cooled reactors (SCWR), Sodium-cooled fast reactors (SFR), Lead-cooled fast reactors (LFR), and Molten salt reactors (MSR)[48]. Some of these Gen IV technologies are included within the scope of SMRs.

The smallest SMRs (generally less than 25 MWe output) are clearly focused on remote areas with isolated electricity grids. The isolated areas are, for example, in northern Canada, Alaska, and many areas in Russia (Figure 12 shows an example of remote areas). Broader use may also appear in countries with very poor grids and the supporting infrastructure necessary to support larger NPPs. These concepts are primarily developed for different applications or a combination of applications, such as oil sands mining, hydrogen production (for energy storage), peaking support for renewables projects, and desalination. Figure 11 shows one possible application of very small SMRs within oil mining.

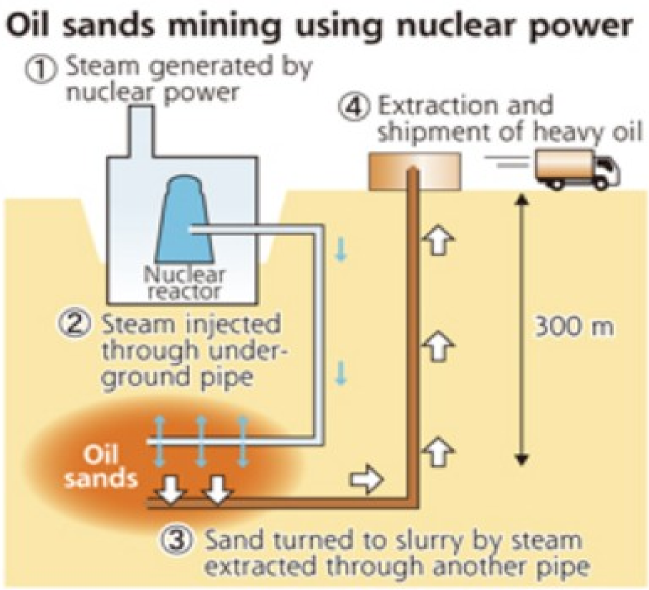


Figure 11 Oil sands mining as an application of small SMRs [94]

It should be observed that the above figure presents only the principle idea of SMR usage in the oil sands mining application.

Figure 12 Remote areas example in Canada [7]

Although the very small SMR designs are focused on utilization in remote areas, the medium size SMRs (200-300MWe) are planned in more traditional areas for either electricity or heat production, or Combined Heat and Power (CHP). It is predicted that these SMRs will be competitive for other power production means, such as natural gas [11, 75]. However such competitiveness can only be evaluated currently with no experience of the construction of SMRs. Only after acquiring some experience of SMR construction and licensing can a proper cost estimate be made.

The biggest investors and developers in the SMR field are the USA, Russia, and China. SMR designs are also developed in Korea, Japan, India, Argentina, and France [177].

<u>SMR design categories</u>

SMRs can be divided into different categories according to their design [100]:

Light Water SMRs

- o Use mostly fuel enriched to less than 5% U-235.
- o Relatively short refueling interval (mostly less than 6 years).
- o Integral PWR designs - steam supply system inside the reactor pressure vessel. Some designs, e.g. KLT and VBER, have conventional pressure vessels and steam generators.
- o Enhanced safety features relative to current LWRs
- o Either conventional land-based nuclear power units or floating nuclear power units
- o These would be classed as mainly Gen 3+ designs (integral LWR designs) because they utilize passive safety features.

- Lowest technological and licensing risk, similar to most currently operating power and naval reactors

Figure 13 presents LWR SMR designs. As can be seen from the LWR designs, there are both integrated LWR designs with the integrated steam supply system, as well as conventional LWR type SMRs with the primary coolant circuit. It should be observed that these figures are only examples, defined by the IAEA INPRO working group, and do not present a comprehensive overview of the SMR designs. [128]

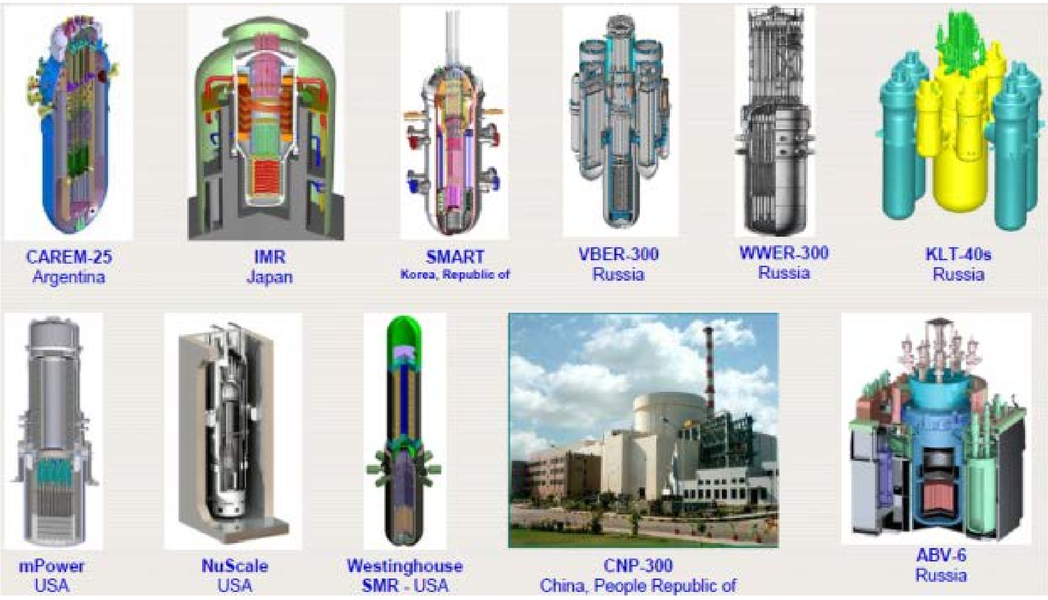


Figure 13 Examples of LWR type SMR designs in different countries [128]

High Temperature Gas Cooled Reactors (HTRs) as SMRs

- Typically graphite moderator
- Utilize helium as reactor coolant with temperatures up to about 1000°C
    - can generate heat for industrial applications via a heat exchanger
    - can be used to make steam conventionally via a steam generator
- Fuel for these reactors is typically in the form of tristructural-isotropic (TRISO) particles less than a millimeter in diameter.
    - Each has a kernel (*ca.* 0.5 mm) of uranium oxycarbide or uranium dioxide
    - Uranium enrichment up to 20% U-235, though normally less
    - This is surrounded by layers of carbon and silicon carbide, giving a containment for fission products which is stable to over 1600°C.
- The TRISO particles can be arranged in the following ways:
    - in blocks – hexagonal 'prisms' of graphite with about 15,000 fuel particles
    - in billiard ball-sized pebbles of graphite encased in silicon carbide with about 15,000 fuel particles
    - Less used fuel than from the same capacity in a light water reactor
- HTRs can potentially use thorium-based fuels
    - such as highly-enriched or low-enriched uranium with Th, U-233 with Th, and Pu with Th

Fast Neutron Reactors (FNR) as SMRs

- Na coolant, Pb-Bi-coolant, etc., HTRs
    - Most coolants are corrosive (Pb or lead-bismuth eutectic) or flammable (Na)
    - Possibility to produce new source terms (e.g. Po-210)
- Smaller and simpler than light water reactors
- More efficient fuel performance
    - Designed to use the full energy potential of uranium, rather than about the one percent that conventional power reactors use, but need reprocessing
- Longer refueling interval (up to 20 years)
- Fuels mostly 15-20% enriched
    - uranium nitride - UN, (U,Pu)N, (U,transuranic)N, U-Zr, or (U,Pu)Zr.

Molten Salt Reactors (MSR) as SMRs

- The fuel is a molten mixture of lithium and beryllium fluoride salts with dissolved enriched uranium, thorium or U-233 fluorides
- The core consists of an unclad graphite moderator arranged to allow the flow of salt
- Materials issues requiring R&D to be resolved
- Safeguards issues to be resolved by the IAEA (control of liquid fuel inventories)
- Temperatures around 700°C, low pressure
- Not fast neutron reactors
    - epithermal (intermediate neutron speed) with some moderation by the graphite

SMR Designs developed around the world

There are many SMR designs in different development stages in different parts of the world.

Table 1Table 2 presents a list of various SMR designs that are being developed globally [100]. The SMR designs are divided into groups according to their country of origin.

Table 2 List of SMR designs developed globally [100]

County/Design	Type of Reactor	Size
USA:		
mPower	PWR	180 MW_e
NuScale	PWR	12x45 MW_e
Westinghouse SMR	PWR	225 MW_e
HI-SMUR	PWR	145 MW_e
TRIGA	PWR	16,4 MW_e
GT-MHR	HTGR	285 MW_e
PRISM	Liquid Metal-Cooled Reactor	311 MW_e
Travelling Wave	Na-Cooled Reactor	100-1150 MW_e
Russia:		
ABV-6M	PWR	2x8,6 MW_e
VBER-150-300	PWR - Barge-Mounted	110-300 MW_e
VBER-300	PWR	340 MW_e
GT-MHR	HTGR	287 MW_e
VK-300	BWR - Cogeneration	250 MW_e
VKT-12	BWR - Transportable	12 MW_e
SVBR-100	Lead-Bismuth Fast Reactor	100 MW_e
KLT-40	PWR Icebreaker	38,5 MW_e
RITM-200	PWR Icebreaker	55 MW_e
VVER-640	PWR	645 MW_e
VVER-300	PWR	300 MW_e
Korea:		
SMART	PWR	90 MW_e
Japan:		

4S	Na-cooled fast reactor	10-50 MW_e
MRX	PWR	30MW_e
GTHTR	HTTR	300MW_e
India:		
AHWR	Advanced Heavy Water Reactor	300 MW_e
China:		
CAP 100	PWR	100-150MW_e
NHR-200	PWR - Nuclear Heating Reactor	200MW_{th}
HTR-PM	High-Temperature Gas-Cooled	2x105 MW_e
Argentina:		
CAREM-25	PWR	27 MW_e
France:		
NP-300	PWR	100-300MW_e
South Africa:		
PBMR	Pebble Bed Reactor	120MW_e

It should be observed that the presented SMR designs are in different design statuses. As can be seen from this table, the main SMR development, if compared with the number of SMR designs, is located in China, Russia, and the USA. It can also be indicated that the USA is focusing on LWR SMR designs. In the USA, the focus is on near future deployment, with the advantage of proven technologies providing greater certainty. Other countries are equally focused on LWR designs as well as other technologies, with a focus on closing their fuel cycles. In the USA, the development has been focused lately on LWR SMR designs; this issue might be partly caused by the DoE funding opportunity that has recently been supporting LWR SMR designs [29].

The various SMR technologies are treated differently in different countries. In the USA the SMR designs are seen as the first step towards the new nuclear technologies. Some other countries are planning to change straight to the other (developed) technologies. There are different politic positions concerning the deployment of SMRs. LWR SMR designs can be deployed mainly within the current regulatory framework, while closing the fuel cycle requires different technologies.

SMRs: advantages and challenges

SMR designs have certain claimed advantages, such as inherent safety features, when compared with conventional large NPPs. The main advantages arise from the small core inventory. However, the small size can also be a challenge, at least when considering economic competitiveness. New design features can also cause risks in SMR projects as well as licensing, even if the new features would approve the safety level of the power plant. With new reactor designs additional R&D is needed, new codes and models are required, and also materials sciences face new challenges. These issues, among others, require a large amount of work and study to become acceptable.

Below are some advantages and challenges that are based on a WNA study considering SMR features [128]. In Table 3, the advantages as well as challenges are divided into technological issues and non-technological issues.

Table 3 Claimed advantages and potential challenges of SMRs [128]

	Claimed Advantages	Potential Challenges
Technological issues	• Shorter construction period (modularization) • Potential for enhanced reliability and safety • Reduced complexity in design and human factor • Suitability for non-electrical application (i.e. process heat and desalination) • Tolerance to grid instabilities • Longer fuel cycles	• Licensability (delays due to design innovation) - "proven-ness" of specific design features (such as evidence to support passive behavior) - outstanding research and development activities - new codes and standards required for specific cases (lead-time issue) • Non-LWR technologies • Impact of innovative design and fuel cycle to proliferation resistance (e.g. molten salt fuels) • Operability and maintainability (not demonstrated) • Spent fuel management and waste handling policies • Post Fukushima action items on Design and Safety Analysis
Non-Technological issues	• Fitness for smaller electricity grids • Options to match demand growth by incremental capacity increase • Site Flexibility • Reduced emergency planning zone • Lower upfront investment capital cost per installed unit • Easier financing scheme	• Economic competitiveness (impact of economies of scale) • Regulation for fuel or NPP leasing (with new types of ownership) • First Of A Kind cost estimates • Availability of design for newcomers • Infrastructure requirements • Public Acceptance particularly around unconventional siting scenarios • Readiness of regulator to review safety cases using SMR technologies

Certain features can be both advantages as well as challenges. One example of such a feature could be the integral pressure vessel, with the steam supply circle inside the pressure vessel. This feature can contribute to improved safety, since large LOCAs are practically eliminated, but as a new design feature this may cause challenges in licensing and in operation. R&D supporting claims play a huge role in smooth licensing activities. For example, having thermal hydraulic demonstration loops is a significant contributor to proving the design. To provide some illustration of the requisite R&D, some examples are presented here. In the integral pressure vessel case, performing material degradation and aging inspections on vessels would be quite complex. In addition, the very large canned pumps still remain to be proven despite the fact that smaller canned pumps are used on submarines.

This thesis focuses on the LWR SMRs with integrated pressure vessel design. Most of the features described can be fit for other SMR technologies as well, but not in every case. The conventional steam supply circuit SMR designs are not included in this discussion.

4.1 Competitive strength of SMRs

The competitiveness of Small Modular Reactors compared with other power production means (large LWRs or conventional power production) is one of the main issues that is discussed while developing SMRs. In this section, the features of SMRs that affect competitiveness are described.

Scaling effects have been investigated widely in different SMR publications in order to understand the differences between large and small NPPs [55]. Scaling effects can be divided into soft scaling effects and hard scaling effects [177, p.8]. Soft scaling effects describe cost reduction by changing the management of construction (Figure 14). Hard scaling effects include changes of applicable technologies in the design when power decreases (Figure 17).

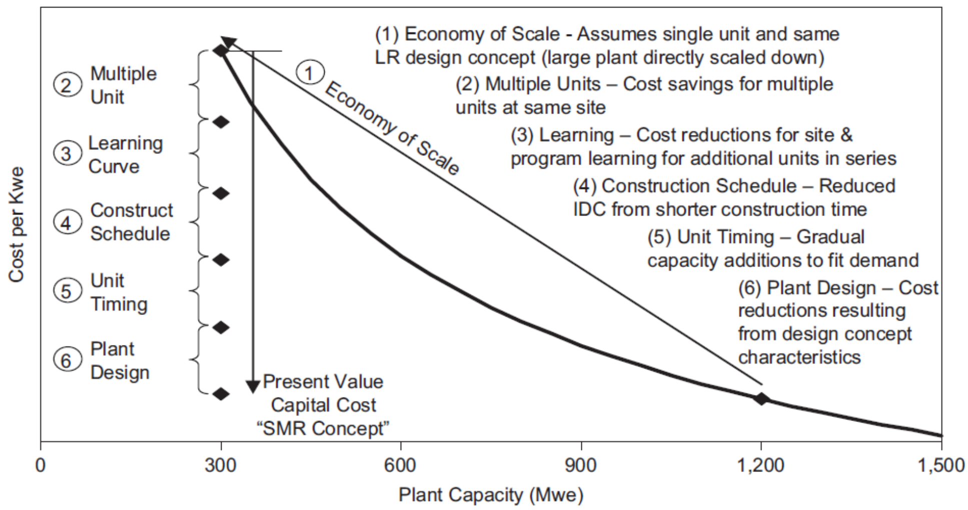


Figure 14 Soft scaling effect [91]

When assuming international deployment, it can be expected that a successful domestic deployment is a necessity to promote international confidence in the design. Only after domestic deployment can mass production with all its benefits and competitiveness in international markets be achieved.

Simplification

Most SMR designs are simplified compared to large reactors. In order to be competitive, SMRs need to be greatly simplified compared to large commercial power reactors without compromising safety.

Significant simplification can be achieved by using passive safety systems. Some passive safety systems are based on natural convection that can be used to cool down the reactor. However, significant R&D activities will be a necessity to prove the reliability of new types of passive safety systems. In a nuclear power unit, designs based on passive safety features require fewer systems and components. This feature of reducing systems and components raises a question about the used approach in terms of Defense-in-Depth (DiD). The DiD approach has become even more important lately in Europe, since WENRA has issued it as part of the Safety Objectives for New Power Reactors [169]. This approach, in terms of SMR features, is also discussed in reference [1].

In terms of SMR competitiveness, power unit expenses to a large extent consist of the cost of large components, structures, construction. In the case of an SMR, unit costs can be limited with the simplified design. The produced power can also be more effectively utilized, while the need for house load is much lower than in large NPPs, through the limited active components requiring power during operation.

Another typical feature of simplification, in light water type SMRs particularly, is the use of integrated components where pressurized and steam generators are integrated in the pressure vessel. The elimination of soluble boron use, which is the case in most of the light water SMR designs, simplifies the primary coolant chemical control requirements. This factor also removes the possibility of boron dilution as an initiating event of transient or accidental nature. As large NPPs with high core linear power need boron for power control, SMRs have been designed to have sufficient power control means with control rods and burnable poison. Operation and maintenance are also issues that must be taken into account in the simplification of SMRs, since the inspection strategies to support the longer fuel cycles have new features compared with conventional NPPs. The fuel cycles are planned to be longer and the outages are planned to be shorter than in conventional LWRs. Simplification is seen as a basis for safer and more competitive NPP design.

SMR Safety Features

In this section, safety features are discussed as part of the competitiveness feature. SMRs are based on safety concepts, which naturally differ from one SMR to another. However, certain generic features can be seen on the new type of LWR SMRs. These designs, with compact steam supply circuit design integrated into the pressure vessel, have excluded certain initiating events by the design. Advanced technologies in SMRs, new fuel types, as well as coolant and moderator materials also introduce different and, in many cases, inherent safety features. Overall, SMR designs are mostly based on passive safety features, with some exceptions. Passive safety features have been discussed in many publications, and passive systems categorization as well as other safety-related definitions are described further in, for example, IAEA TECDOC-626. [58] Passive safety features are executed with passive safety systems that do not need forced coolant flow and therefore do not require external power to function. Coolant circulation relies on natural circulation, which can be seen as inherently safe since they contain less parts that can fail.

Most SMR designs are based on a large coolant inventory and low power ranges so that the decay heat is relatively small and the large coolant (water) volume can remove the heat from the reactor with the passive function. In many cases, the need of external water is removed and all the water required for the cooling is located inside or near the reactor building.

The design of reactor needs to take into account the conditions required in natural circulation phenomena. The reactor, as the heat source, should be located at low elevation. Above the reactor are located the steam generators or turbines, the heat sink. In this way, natural circulation will ensure that the fluid will continue to flow as long as the reactor is hotter than the heat sink, even when the pumps are not producing the flow [95].
Passive functions can ensure the safety level with inherent safety features in self-contained manner [58].

An inherent safety characteristic has been described in reference [58] as follows: "fundamental property of a design concept that results from the basic choices in the materials used or in other aspects of the design which assures that a particular potential hazard can not become a safety concern in any way."

Potentially, passive safety features can be more reliable than active systems if they are designed properly. Also the need of many diverse systems for certain safety function can be reduced, if the failure of the safety system can be proved to be practically eliminated.
The Defence in Depth (DiD) approach, as it is used in this study, has been described by WENRA. The Figure 15 presents the Defence in Depth levels by WENRA. This approach varies from IAEA approach mainly in level 3, as the level 3 is divided in two parts in WENRA's approach. It is also required that different DiD levels should be separated as far as possible in NPP designs.

Levels of defence in depth		Objective	Essential means	Radiological consequences	Associated plant condition categories
Level 1		Prevention of abnormal operation and failures	Conservative design and high quality in construction and operation, control of main plant parameters inside defined limits	No off-site radiological impact (bounded by regulatory operating limits for discharge)	Normal operation
Level 2		Control of abnormal operation and failures	Control and limiting systems and other surveillance features		Anticipated operational occurrences
Level 3 (1)	3.a	Control of accident to limit radiological releases and prevent escalation to core melt conditions (2)	Reactor protection system, safety systems, accident procedures	No off-site radiological impact or only minor radiological impact (4)	Postulated single initiating events
	3.b		Additional safety features(3), accident procedures		Postulated multiple failure events
Level 4		Control of accidents with core melt to limit off-site releases	Complementary safety features(3) to mitigate core melt, Management of accidents with core melt (severe accidents)	Off-site radiological impact may imply limited protective measures in area and time	Postulated core melt accidents (short and long term)
Level 5		Mitigation of radiological consequences of significant releases of radioactive material	Off-site emergency response Intervention levels	Off site radiological impact necessitating protective measures(5)	-

Figure 15 Defence in Depth approach by WENRA [173, p.82]

One part of the DiD approach is practical elimination, discussed as Position 5 in reference [173]. All accident sequences which may lead to early or large radioactive releases must be practically eliminated. Objective O3 "Accidents with core melt" within the WENRA the Defence in Depth approach is required as follows: "It has to be shown that such accident scenarios are either practically eliminated or prevented and mitigated". Accident sequences that are practically eliminated are extremely unlikely, according to the DiD approach. This is a reason why the mitigation of their consequences does not need to be included in the design. [173, p.24]

Practical elimination can be quite challenging feature to demonstrate. The justification should be primarily based on design provisions. Certain strengthening can be handled by operational provisions, such as adequately frequent inspections [173]. Accident sequences can be considered to be practically eliminated if it is physically impossible for the accident sequence to occur. A demonstration of practical elimination should preferably rely on the criterion of physical impossibility. The demonstration should show sufficient knowledge of the accident condition and the phenomena substantiated by relevant evidence.

Also the practical elimination can be argued if the accident sequence can be considered as extremely unlikely with a high degree of confidence (from IAEA SSR-2/1). This extreme unlikelihood with high confidence is, however, more complex to be demonstrated.

The division of accident sequences, between practically eliminated sequences and the sequences taken into consideration in the design, are presented in the following Figure 16.

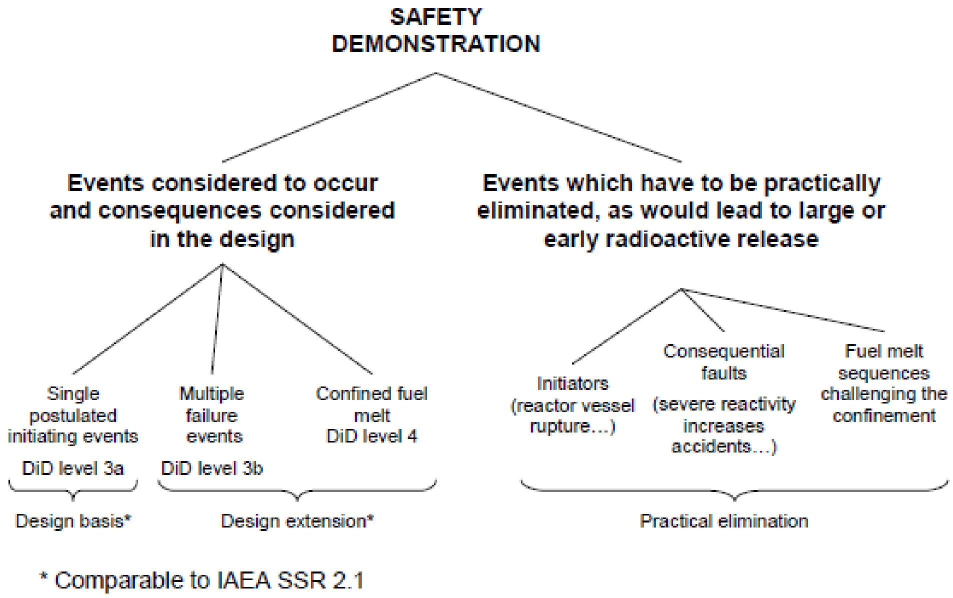


Figure 16 Accident sequences to be considered for Practical Elimination [173]

The demonstration of physical impossibility can be challenging, when based on engineered provisions. It must be recognized that some practical elimination claims may be based on assumptions, and the used assumptions shall be addressed. Accident sequence cut-off frequency, when excluding the certain feature from the design, can be used for engineered provisions. [173]

An example of a demonstration of physically impossible situation is an elimination of component features and/or failures from the design, which may initiate specific accident sequences. The spent fuel pools design in such a way that the coolant cannot escape the pools, is one simple example of the practical elimination. [173]

As well as engineered provisions, also the size of the reactor affects certain design features suitability. The dependency between reactor size and certain design features have been discussed in reference [47]. The limiting reactor size has been indicated for In-vessel Core Retention ~600MWe, Integral reactor ~300MWe and Natural convection ~50MWe [47, p.12]. The following figure presents the limitations in the economy scale diagram.

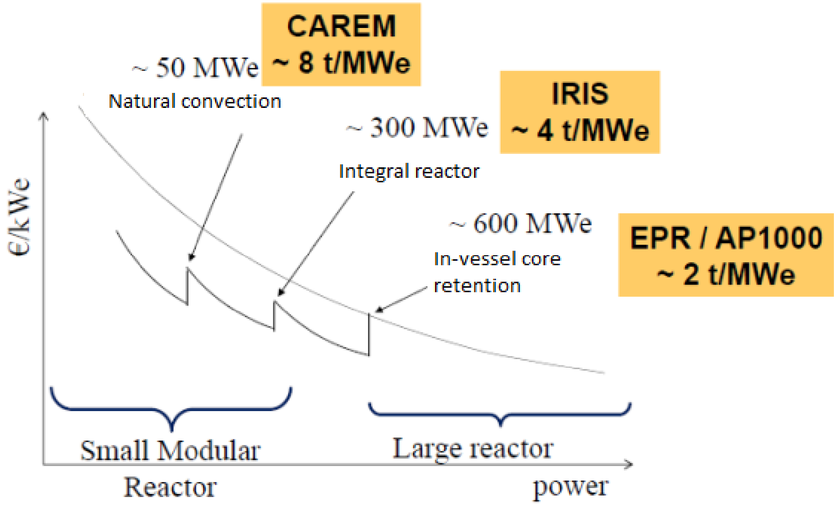


Figure 17 Hard scaling effect presenting dependencies of different size reactor designs [47, p. 12]

SMR design features and conventional large NPPs design features can be compared in terms of safety systems as well as support systems.

The following tables (Table 4 and Table 5) present the comparison of safety systems features and support systems features between SMRs and current large NPPs. These tables are based on World Nuclear Association study of SMRs [177].

Table 4 Comparison of current-generation NPP safety systems to potential, typical water-cooled SMR design

Current-generation safety-related systems	Claims for SMR safety systems
High-pressure injection system. Low-pressure injection system.	No active safety injection system. Core cooling executed using passive systems.
Emergency sump and associated net positive suction head for safety-related pumps.	No safety-related pumps for accident mitigation. No need for sumps or protection of their suction supply.
Emergency diesel generators.	Passive design, no need of emergency alternating current (ac) power for core cooling. Core heat removed by heat transfer through vessel all the way to the ultimate heat sink.
Active containmentcooling	Passive heat rejection out of containment.

Current-generation safety-related systems	Claims for SMR safety systems
systems.	
Containment spray system.	Spray systems not required to reduce steam pressure or to remove radioiodine from containment.
Emergency core cooling system initiation, instrumentation and control (I&C) systems. Complex systems require online testing for plant unreliability and safety systems inadvertent initiations.	Simpler and/or passive safety systems. Less testing, not prone to inadvertent initiation. Necessary measurements and state indications are needed (power required).
Emergency feedwater system, condensate storage tanks, and associated emergency cooling water supplies.	Ability to remove core heat without an emergency feedwater system.

Table 5 Comparison of current-generation NPP support systems to potential SMR design [177]

Current LWR support systems	Claims for SMR support systems
Reactor coolant pump seals, leakage of seals being a safety concern.	Integral designs, elimination of the need for seals.
Ultimate heat sink and associated interfacing systemsin case of extreme weather conditions and bio-fouling.	SMR designs are passive and reject heat by conduction and convection. Heat rejection to an external water heat sink not required under accident conditions.
Closed cooling water systems required to support safety-related systems.	No closed cooling water systems required for safety-related systems.
Heating, ventilating, and air-conditioning (HVAC) to support proper operation of safety-related systems.	Minimization or elimination of the need for safety-related room cooling, eliminating the HVAC and associated closed water cooling systems.

In addition to these overall SMR safety features, there can be seen certain country -specific SMR features can be seen. As an example of these, security issues can be mentioned. In the US SMR designs, this issue is resolved by locating the units below ground. In this manner, the APC and other external hazards are removed and the effects minimized. This means that the nuclear island must be reinforced against flooding and seismic events. Other issues such as mitigation against the reactor building buoyancy effects remain to be resolved. In Russian SMR designs, barge-based reactors have been issued. These SMRs present a number of safety and regulatory issues. Namely:

- How to perform siting and site related hazard analysis is not well understood
- Human induced (accidental or malevolent) events remain to be characterized and discussed (i.e. aircraft crash, ship collision).

Flooding in these designs functions quite differently than in traditional land-based designs. The benefits of these barge-based SMRs can be seen in factory building, always in the same place, as well as in delivery to the site, since the delivery can be handled as one piece.

In Russia, the ownership and licensee model will need more discussion as well in the future. For example, how can a recipient country accept a design that has been certified in Russia and run by a Russian company off the recipient country's coast? What would this kind of scenario mean in terms of licensing?

The SMR safety features are compared from the licensing perspective later in this section.

Modularity

Modularity is one of the main defining features of most SMRs. Modularity can be divided into two different categories: the first category is simply a single unit facility constructed of independently engineered modules (e.g. construction process for Westinghouse AP-1000 NPP), and the second is a facility structure composed of many reactor modules where modules are manufactured in factories and installed into the facility as needed (e.g. NuScale Power SMR design). [57]

Here the modularity of several reactors in one nuclear power unit is focused on.
Modularity is one of the main features that provides the need for licensing process modification in many countries.

The modularity of manufacturing is one area that needs more focus both in small and large NPPs. With a modular approach the costs of different components and parts of the unit can be reduced dramatically. For SMRs with factory production of a large amount of components, this would possibly be an even more effective approach that in large NPPs.

Standardization and Mass Production

Standardization is seen as critical to SMR competitiveness even if also beneficial to large NPPs. However, the benefits, just as in the case of modularity, can be even higher in SMRs compared with large NPPs. The benefits of standard designs can be, for example, easy execution at new construction sites. Standardized modules have the benefit of mass production and the possibility of a large part of production in factories, while diminishing the amount of work at the site. Some SMRs are designed to have the whole primary circuit, as integral design, produced at the factory and delivered to the site as a ready reactor module, while other SMRs plan to install the pressure vessel internals on site, as is the current practice with large reactors.

The supply chains are an important factor for a successful SMR project, as they are in large NPPs. However, with SMRs the importance of the supply chain might become even greater since SMRs are planned to be built in series, with high modularization. To make this approach competitive, a developed and available supply chain is a necessity. To ensure an effective and feasible supply chain, standardization in a large part of the unit is needed. The model for SMRs including many standardized units under construction almost simultaneously and operating for years promotes strong supply chain development and maintenance. Mass production also creates the possibility to develop better and more efficient construction techniques, which improves the competitiveness of SMRs.

Standardization combined with mass production and factory built components reduces production costs and construction time. Long lead items are not needed in many SMR designs and the work at the site may be performed simultaneously with modules production in factories. The standardization needs to be done internationally, following examples from other industries, such as the aviation industry.

The challenges of standardization need deeper study. It should be observed that the standardization of large LWRs has not been very successful. Standardization to date has been rare because of the time between builds. Quite often, SSCs may look similar, but they have certain differences, so that different versions of the same component are found in different NPPs. This means that the characteristics of those SSCs may be different. The standardization will continue to be a challenge for SMRs as well, until each design reaches the Nth Of A Kind (NOAK).

The standardization needs the harmonization of licensing requirements and codes and standards. The harmonization of requirements in Europe is a very slow and challenging process, not to mention requirements harmonization all around the world. In addition to the regulatory framework harmonization, the industry needs to recognize the benefits of standardization. As in current practice, every new build NPP in Western countries is customized, more or less. It should be observed on the industry side that standardization also means compromising in one way or another.

The scope of this study focuses on the licensing process and its effectiveness and suitability for SMRs. Technical issues and relevant requirements function are not included in the scope of thie dissertation.

Standardization has been selected from the findings also in the WNA report on Licensing and Project Development of New Nuclear Plants [81, p.4]:
"On a more general level, international harmonization of safety requirements and standardization of reactor designs could greatly facilitate licensing."
Standardization can be seen as at least as important in SMRs as it is in large NPPs.

Series Construction

As has been presented already in terms of standardization and mass production, the assumption in SMR development is to construct SMRs in series. Series construction and short construction times make the financing scheme very different from the case of large NPPs. As can be seen from this discussion, series construction is not a benefit in itself, but incorporated with other suitable features, series construction can be utilized effectively. Series construction in terms of investment and financing will be described next.

Construction time and investment model

One of the competitiveness issues and challenges in the case of large NPPs is the investment model. Due to long construction times for large NPPs with a large investment at the beginning of an NPP project, the investment is quite challenging for many companies. The costs of large investments with long-term liabilities can be crucial for many decision-makers. In terms of investment, SMRs can be seen as much more attractive.

Construction times for SMRs are typically estimated as less than for the construction times of large reactors. The short construction time can be achieved by using standardized components and simultaneous working practices. Long lead items (LLI) may need a different approach than for current NPP projects. Also, the SMR designs that are planned to be factory fabricated and delivered to a site as a whole, and to be installed on a pre-fabricated platform, need a new type of LLI approach. However, the work at the site may be done simultaneously with module production in factories, which affects the construction time and makes the construction more effective.

A short construction time with multiple units in construction in series enables self-financing. The first unit can produce power and finance a part of the next units' constructions costs. The OECD NEA has conducted a study with two different deployment schemes. Both of these are compared with a large NPP deployment. The assumption used for the SMR construction time is three years, and for a large NPP it is five years.

Figure 18 presents the two deployment schemes, the first one being four SMRs constructed in 11 years. The second scheme is four SMRs constructed in 15 years.

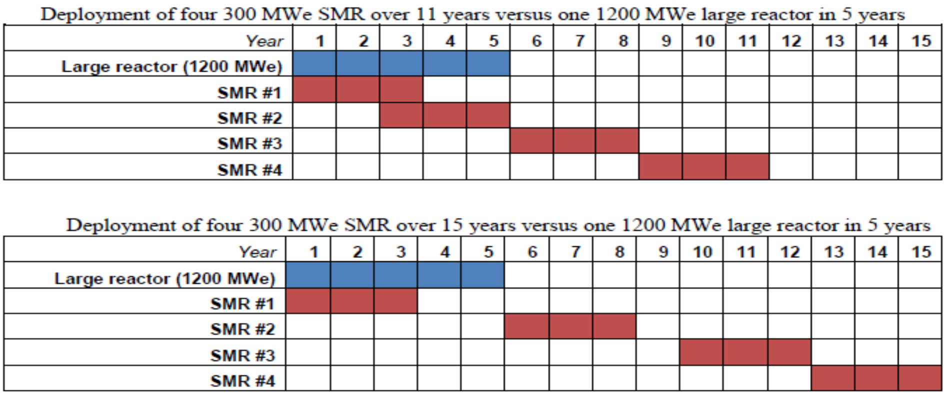


Figure 18 Construction schedules for the deployment of four 300MWe SMRs versus one 1200MWe large reactor [100]

The presented construction schedules for the deployment of four SMRs are then analyzaed in terms of financing. Figure 19 and Figure 20 present the sources of SMR financing and the cumulative cash flow for the deployment scenarios. These discussions shall be taken as estimates, since the actual costs of SMRs cannot be identified at this point in time.

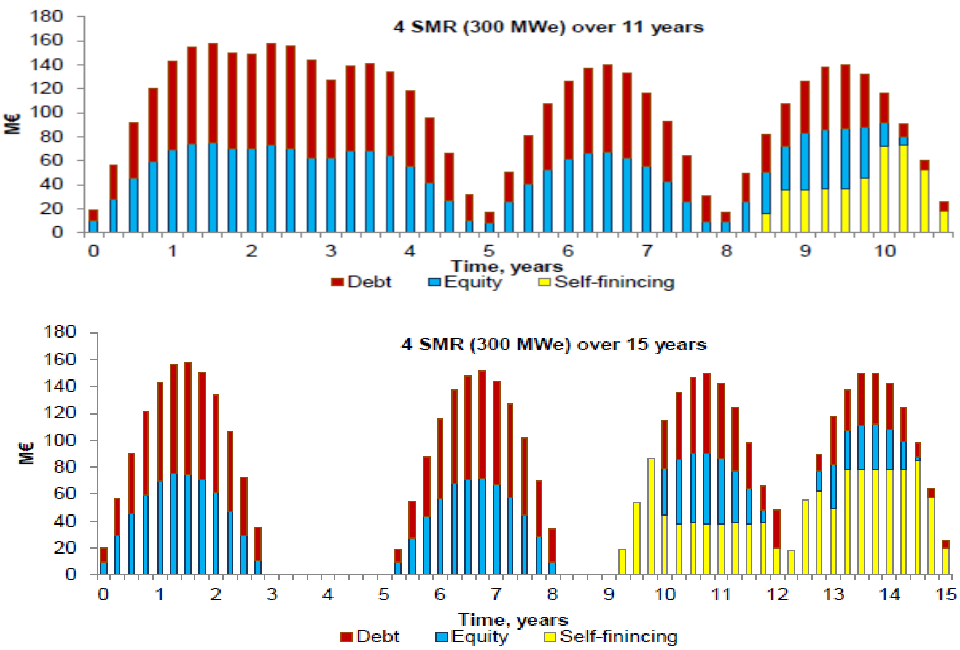


Figure 19 Sources of SMR financing for the deployment scenarios in Figure 18[100]

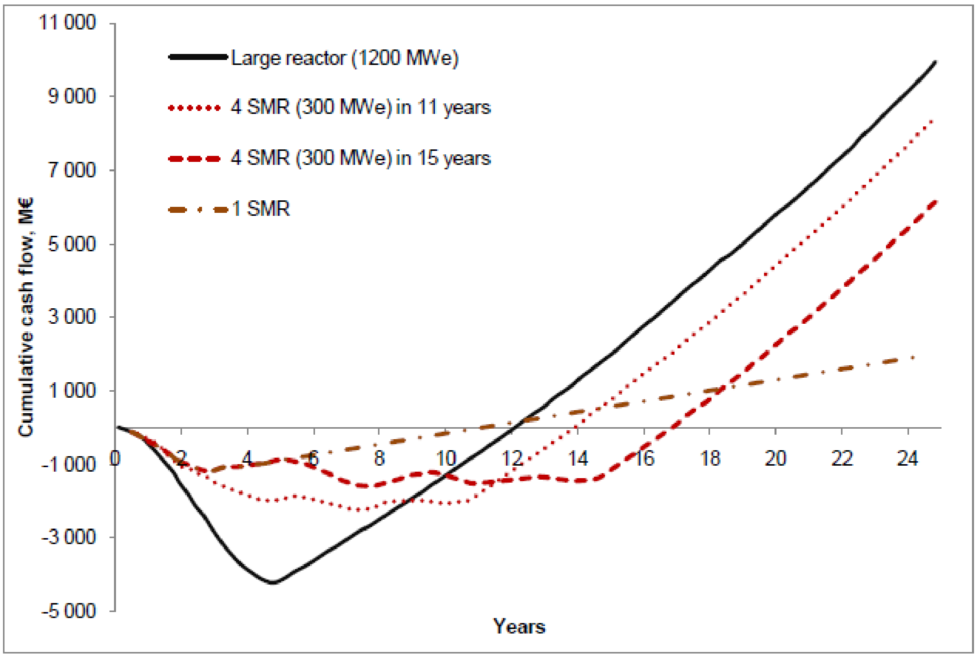


Figure 20 Cumulative cash flow for the deployment of four 300MWe SMRs versus one 1200MWe large reactor [100]

These make SMRs more competitive in the power production field, but it is still unclear if they will be truly competitive against large LWRs, because no SMRs have yet been constructed and the actual costs are unclear. Estimates and calculation models have been developed recently, and one of the calculation models in the INtegrated model for the Competitiveness Analysis of Small-medium sized reactors (INCAS), developed in Politecnico Di Milano in Italy [11].

4.2 The special features of SMRs affecting the licensing process

It has been observed that the licensing process is very important in the success of new NPP projects. [81] As the licensing process is very time consuming, it needs to be planned so it is suitable for the special features of SMRs to make it efficient. It should also be taken into account that the design maturity needs to be at a certain level in order to challenge the special features of SMRs as part of the licensing process. The framework is different from large NPPs in certain respects, and as most nuclear countries have developed their regulatory framework for large water cooled NPPs, the specific features of SMRs should be taken into account when modifying the licensing process.

For SMR licensing, the following areas may influence the need for differences from traditional large NPP licensing [132]:

- Smaller power output - lower decay heat, (increased use of graded approach to application of safety important mitigation measures)
- Passive safety features (different from most current NPPs),
- Modular design:
  - several reactor modules in one unit
  - modular construction with modules manufactured in factories
- Mass production (standardized design)
- Serial construction (many units in series)

Technical licensing challenges have been discussed in many publications and study reports, such as in reference [4]. Some examples that could be mentioned concern the technical licensing challenges in the SMR design. These examples have been identified by the IAEA INPRO Dialogue Forum on Licensing and Safety Issues for SMRs [113]:

- Non water-cooled SMR
- Long-lived cores and operation without on-site refueling
- Defense-in-Depth in plant design (functional defense levels)
- Reliability of passive safety systems
- Severe accident management
- Instrumentations and Control (remote operation applications)
- Control room operation (in case of many modules operated in one control room)
- Plant staffing
- Demonstration of innovative features
- in-vessel steam generators
- compact containment
- External hazards (underground designs)
- Fukushima lessons learned

The IAEA INPRO Dialogue Forum on Licensing and Safety Issues for SMRs [113] also identified a list of site-specific licensing challenge examples:

- New sites have not been licensed in many countries
- Public acceptance in case of many new sites
- Flexibility in emergency planning requirements, application of a graded approach
- Siting issues for SMRs including transportable NPPs
- Sites in remote areas (difficult to access)
- Environmental impact issues
- Transportation of fuelled-NPPs (modules)
- Safeguardability in case of many new sites

The presented issues are only examples and do not present a coherent whole of the technical challenges in terms of licensing. These issues are also described in other publications, such as reference [136]. This discusses, for example, the need for licensing requirements modification considering the use of station blackout emergency diesel generators.

One of the key features to keep in mind, while analyzing different licensing processes and their suitability for SMRs, is the modularity of SMR designs. Modularity provides the need for licensing process modification in many countries, since most of the current licensing processes are issued for single reactor units and many times they handle one unit at the time.

The licensing processes are not designed for SMR purposes, but a discussion on SMR licensing has been initiated already in the USA and some other countries. In Europe, licensing process development in the future has been studied by the European Reactor Design Acceptance (ERDA) Core Group [41] (see section 5.1). Therefore the experiences from other parts of the world can better be used with a certain amount of judgment on their suitability.

4.3 SMR concepts described in more detail

The current licensing process in Finland is based on large LWR licensing and, in the near future, it cannot be seen that other technologies would be licensed. Over the long-term things may change.

In the US, the DOE is funding SMR concepts for their licensing and design processes. The first Funding Opportunity Announcement (FOA) for SMRs was announced in 2012 to support FOAK engineering, design certification, and licensing through a cost-shared partnership [29]. The mPower design was awarded for the DOE funding with the goal of deploying the SMR by 2022. [179]

For the first round of DOE funding, only one SMR concept received an award; another round of funding was announced in 2013. [179]

The mPower concept is presented in some more detail to understand the special features of LWR SMR designs. The mPower design is probably the most mature in the design stage among the US SMR designs.

mPower 180MWe (PWR) - Babcock & Wilcox

The mPower 180MWe (PWR) is in the pre-licensing phase in the USA. Pre-licensing with the standard review plan process has been issued for mPower SMR, as presented in reference [151].

This is a modular design with a twin-module (two reactor modules) unit being the standard design. This below-grade design maximizes on proven concepts used in conventional LWR designs but introduces an Integrated LWR vessel, as well as a number of passive safety features. The Integrated PWR pressure vessel is known as an "Otto Hahn pressure vessel", which was designed a long time ago. [164]

The safety case for the design is based on passive safety systems and a large cooling water inventory that can be refilled periodically a long time post-accident. The pressure vessel has been designed to minimize penetrations and they are located high above the core. This design precludes the LB LOCA initiating events by design. The largest LOCA event as a design basis accident is therefore SB LOCA. Core uncovery is not predicted as a consequence of any initiating event; however, severe accident management is studied with the licensing. [49]

Design information [8, 80]:

- Designer: Babcock & Wilcox Modular Nuclear Energy, LLC (B&W), United States of America
- Reactor type: Integral Pressurized Water Reactor
- Coolant/Moderator: Light Water
- Neutron Spectrum: Thermal Neutrons
- Thermal Capacity (MWth): 540 (based on 180 MWe)
- Number of fuel assemblies: 69
- <5% 235U enrichment
- Gd2O3 spiked rods
- AlC and G4C control rods
- 3% shutdown margin
- Fuel Cycle: 48-month or more
- Design Features: 2 modules (2x180MWe) unit is planned with independent safety systems and turbines, reactor and spent fuel pool are placed under ground
- Burnable poison is used - no soluble boron
- Internal SRDM and RCPs
- Underground containment, fuel storage and ultimate heat sink
- Metal containment vessel
- Simultaneous refueling and NSSS equipment inspections
- Up to six B&W mPower reactors for TVA at the Clinch River site in Roane County, Tennessee

The mPower design is purposed as a twin-module design. See Figure 21.

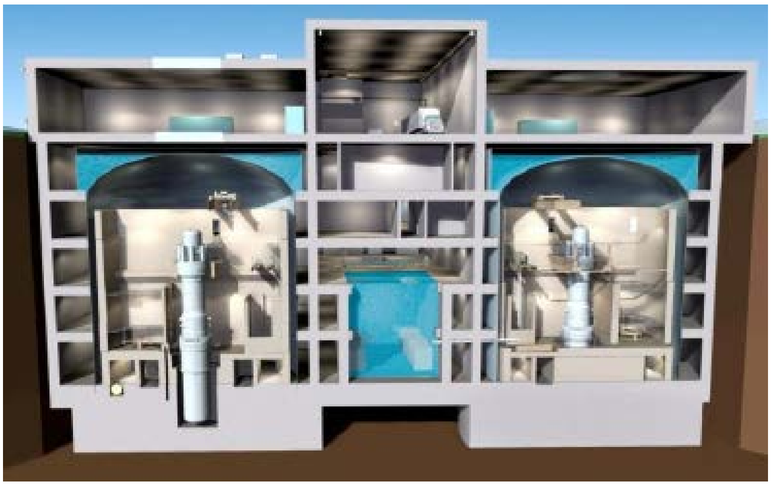


Figure 21 mPower SMR containment [80]

The cross-section of mPower, with the primary and secondary circuit flows inside the pressure vessel, is presented in Figure 22. This figure shows the design features that improve the natural circulation flow in the primary circuit. The low elevation of the core with quite high risers produces suitable conditions for the natural circulation phenomenon. Also, the secondary circuit within the once through steam generators can be seen.

The reactor coolant pumps are located in the upper part of the pressure vessel, in comparison with the conventional BWRs where the primary coolant pumps are in the bottom part of the pressure vessel. However, in the mPower design the reactor coolant pumps have no safety role in coolant circulation.

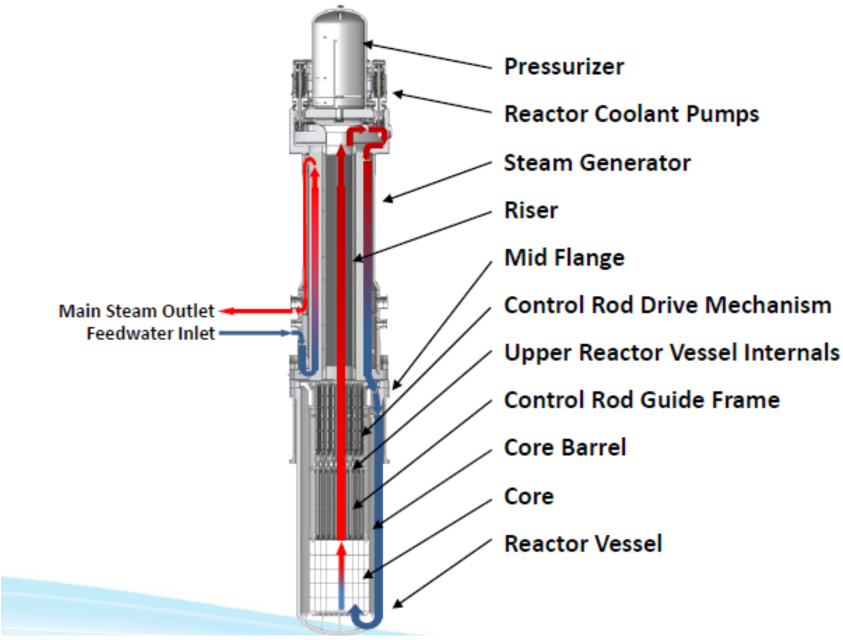


Figure 22 A cross-section of the mPower reactor [80]

The decay heat removal methods are presented in Figure 23. Here it can be seen that the passive cooling systems use both natural circulation and gravitation as a safety system actuator. The main safety features are implemented with passive safety systems, minimizing the need for active safety systems in the design. This cooling feature needs further analyses with regard to licensing requirements, at least in Europe, since the WENRA requirements indicate the need for diversity in safety systems (DiD level 3a versus 3b systems). However, in the case of passive safety systems, it needs to be discussed if this diversity is actually needed, or could the requirements be fulfilled with existing or other methods.

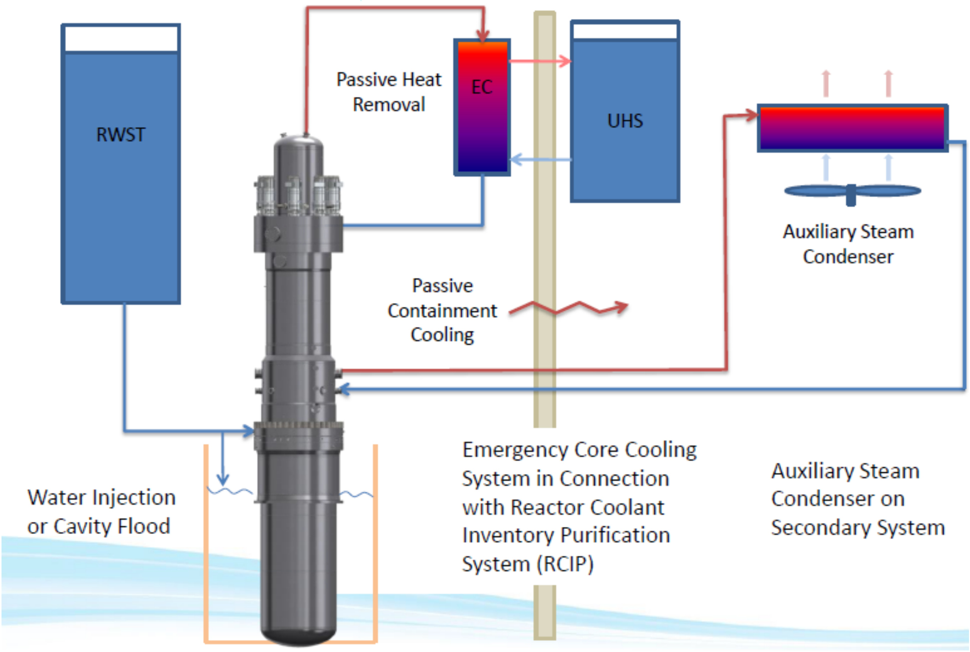


Figure 23 The decay heat removal strategy [80]

The licensing schedule at a high level is presented in Figure 24.

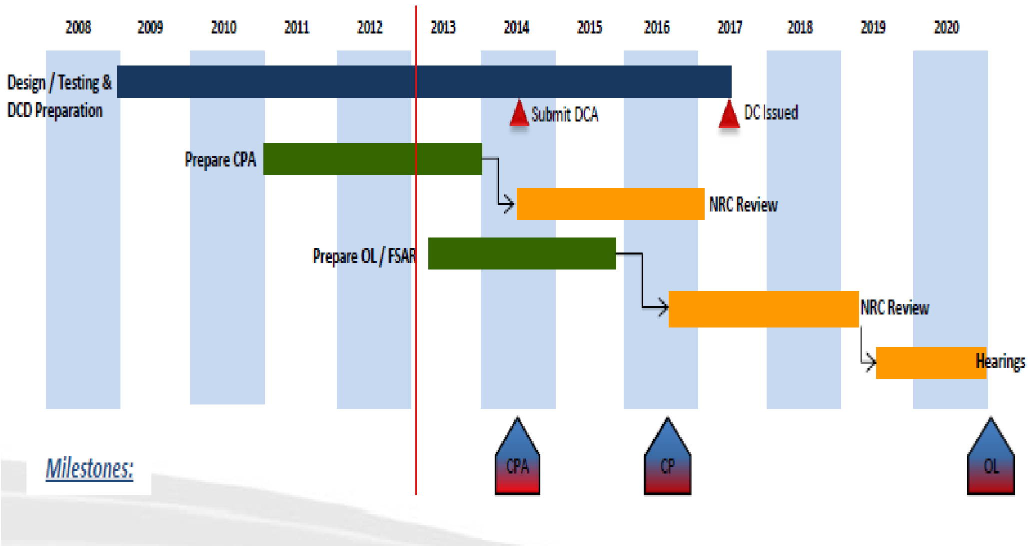


Figure 24 Licensing schedule for mPower SMR [87]

It has been decided that the Clinch River (TVA) project will be licensed under the 10CFR50 process [144] for the first two units, including separate construction license and operating license processes. This is no longer the preferred way of licensing in the USA but it is still useful for FOAK where certification has not yet been achieved. mPower is planning to apply for certification shortly following the start of construction of the first two units and the remaining units are planned to be built and put into service under the 10CFR52 process [144]. The certification will be used for all mPower projects in the USA from that point forward.

The mPower SMR design is a case in point for the SMR-specific issues presented in section 4.2. Namely:

- Small thermal inventory, with low decay heat, when compared with large NPPs. The graded approach usage will need discussion separately in every country as the licensing practice.
- Use of passive safety features, improve the design from the safety perspective. (Requirements for passive safety systems, at least in Europe, need more consideration in near future).

mPower's strategy is to ensure that a large number of components are designed to be factory produced and the work at site will be reduced to improve the efficiency of constructions and the quality of the design.

Mass production of standardized components is planned in the USA with the overall design being planned for most sites in the USA. For Europe, some modifications will probably be needed, but most parts of the design are expected to remain standardized.
Serial construction will likely occur at the TVA Clinch River project, starting with one twin-module unit, up to the planned six reactor modules (three twin-module units). [133]

5 LICENSING

Nuclear licensing is a process that demonstrates the required safety level fulfillment of a nuclear facility. In other industry fields, the corresponding process can be called, for example, a certification or permitting process. The licensing process varies greatly between different countries and is based on each country's legislation. The main focus and the basis of licensing remains the same between countries, but the process varies largely, as well as the approach to issuing licenses (prescriptive versus goal setting approach). The prescriptive approach is a licensing approach that sets very detailed regulations for a nuclear facility and operator to be licensed. Government inspectors confirm that the regulations have been correctly implemented. In this approach the level of safety is reviewed and ensured via requirements fulfillment [115]. One example of this type of approach is the US regulatory framework. Another approach is the goal setting approach, or performance regulations, which sets out a safety target usually in risk terms. In this approach, it must be shown that the design and operation achieves the set target. The requirements are set only at a high level and no specific technical solution is defined [115]. In this approach the level of safety is reviewed and ensured via a Safety Case, which demonstrates the safety features in a limiting event. The Safety Case approach has been developed in the UK since 1988, when a series of explosions and fires destroyed the Piper Alpha oil platform and killed 167 people [180]. One example of this type of approach is the UK or the Canadian regulatory framework. However no regulatory regime is purely performance-based, they all include some prescription.

Considering NPP licensing at a high level, the sectors can be divided into three main areas: organization, site, and the physical plant. These main areas are then divided into more detailed areas, which already differ somewhat between different countries' regulatory frameworks. The different areas then issue requirements at different levels of detail, depending on the regulatory framework approach. The licensing sectors are presented at a high level in Figure 25.

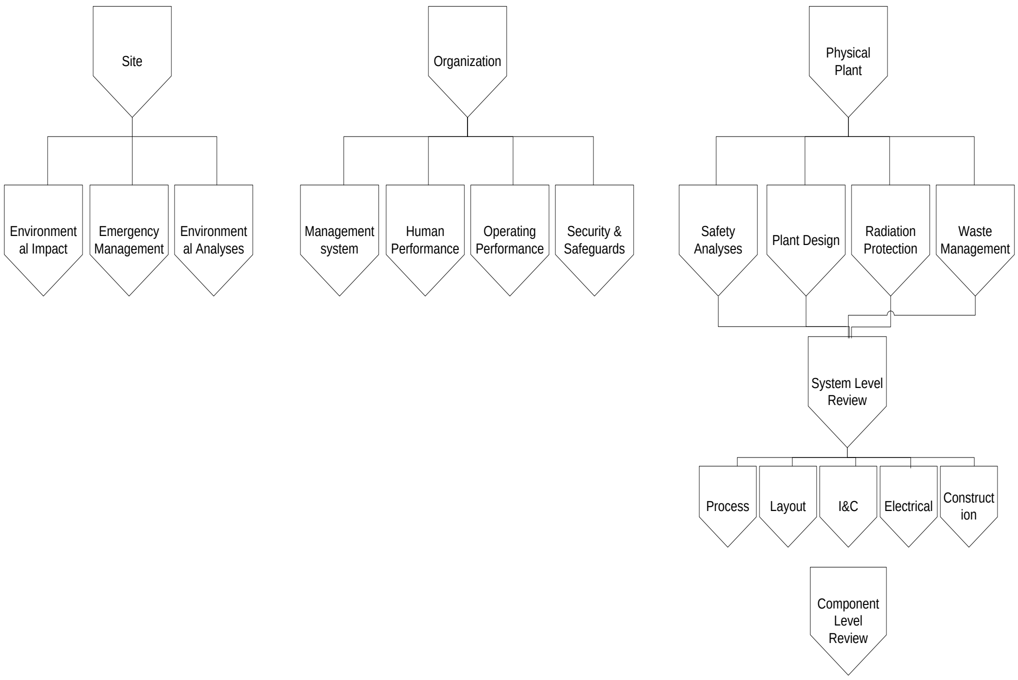


Figure 25 High level licensing areas for NPP licensing

The licensing process handles the above mentioned requirements, reviews, and approvals. The process is governed by the legislation, regulations, and customs in each country. Licensing processes are based on different documents on safety as well as other features and the validation and verification methods that regulate the documented characteristics. The licensing process comprises defined documents on different licensing steps and all steps together form a coherent whole concerning safety.

5.1 International organizations as stakeholders of licensing

Basically licensing is based on national and international legislation and safety standards; a general level regulatory pyramid. The International Conventions are legally binding, and therefore important in the nuclear industry. Here examples of International Conventions are presented:

- Convention on Nuclear Safety [64]
- Joint Convention (on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management) [60]
- Non-Proliferation Treaty [140]
- Vienna and Paris/Brussels conventions on nuclear liability [59]

Member states are obligated to incorporate these treaties into their national law.

At the international level the nuclear safety stakeholders are described in the following sections. Also the European level safety stakeholders are included in this discussion.

5.1.1 International Atomic Energy Agency (IAEA) [65]

IAEA is one of the main organizations at the international level to generate high level nuclear rules and regulations.
The IAEA shall be mentioned as being one of the main institutes in the nuclear field; its functions include [120]

- safeguards/non-proliferation
- Safety standards models/benchmarks for national regulations
- advice to newcomer countries for a nuclear regulatory framework
- IRRS (Integrated Regulatory Review Service) missions: peer reviews

Even if the international organizations' standards and requirements are not mandatory for the member states, in most cases they are however applied and followed.
IAEA safety standards are [66]

- Mandatory for the IAEA itself and for its activities
- Not mandatory for member states
    - member states are expected to take IAEA safety standards as a benchmark/model

5.1.2 Organisation for Economic Cooperation and Development (OECD) countries' nuclear energy agency [99]

At the international Regulator's level, a Multinational Design Evaluation Program (MDEP) was launched in 2006 between 10 national regulators and the Organisation for Economic Co-operation and Development (OECD) Nuclear Energy Agency (NEA) was set up. In the early years after the Second World War the Council of the OEEC (the predecessor of the OECD) set up the European Nuclear Energy Agency (ENEA), in February 1958. The agency’s name was changed in 1972 to the Nuclear Energy Agency (NEA) when the member countries grew beyond Europe’s boundaries.
The NEA's current membership consists of 31 countries in Europe, North America, and the Asia-Pacific region. [99]

5.1.3 The European Commission (EC)

In Europe, the European Commission has set directives to consider used nuclear fuel and radioactive waste [123], and to consider cooperation for safety at nuclear facilities [85], as well as nuclear safety [134]. These directives set the scope of nuclear energy in the member countries. The European Commission cooperates also with countries outside Europe. This cooperation has focused on neighboring countries and has then extended since 2007 to other countries as well. This international program is part of the Nuclear Safety Co-Operation Instrument (INSC) and it is presented in reference [40]. The European Commission has also founded an independent nuclear regulators' group, called the European Nuclear Regulators Group (ENSREG), in 2007. [35]

Lately the European Commission has paid attention to promoting and developing a harmonized licensing process for nuclear facilities at the EU level. The European Nuclear Energy Forum (ENEF) has created the European Rector Design Approval group (ERDA). [41]

5.1.4 Western European Nuclear Regulator's Association (WENRA)

An international regulatory framework within Europe is the Western European Nuclear Regulators' Association (WENRA) [171]. WENRA is a regulators' network for EU countries with nuclear power plants, and Switzerland. Also other interested European countries that have been granted observer status at WENRA [171]. As it is stated in reference [171]: "The main objectives of WENRA are to develop a common approach to nuclear safety, to provide an independent capability to examine nuclear safety in applicant countries and to be a network of chief nuclear safety regulators in Europe exchanging experience and discussing significant safety issues."

WENRA Members are: Belgium, Bulgaria, the Czech Republic, Finland, France, Germany, Hungary, Italy, Lithuania, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, the Netherlands and the United Kingdom, the Observers are: Armenia, Austria, Denmark, Ireland, Luxembourg, Norway, Poland, the Russian Federation and Ukraine. [172]

The Reactor Harmonization Working Group within WENRA has developed Safety reference levels for existing nuclear power plants as well as Safety objectives for new nuclear power plants. These guidelines are already used in Europe and they are incorporated stepwise into the regulatory frameworks of member countries.

WENRA Reference levels [168] and Safety objectives for new Power Reactors [169]

- Reference Levels are the basis for the harmonization of national safety requirements for operating NPPs
- Safety objectives are the basis for the harmonization of national safety requirements for new NPPs
- Voluntary implementation in national regulations (however, the members have agreed to implement these requirements into the national level regulations)

In Europe, WENRA [171] on the regulator side, and the European Nuclear Installations Safety Standards Initiative (ENISS) [34] and European Utility Requirements (EUR) [36] on the industry side, have been working for harmonized requirements on the European level.

5.1.5 Harmonization efforts of International Organizations

The regulatory framework in each nuclear country is handled according to each country's law and legislation. Implementation includes also national codes and standards (e.g. ASME, RCC-M, KTA, SIS…). Therefore there are differences which cause NPP design changes between countries, as well as changes to the mass of documentation for different regulatory regimes. Due to these challenges, the economical risks for NPP projects today are centered in many cases on regulatory and licensing issues. This situation is pronounced in Europe.

Standardization of NPP designs, simplification of the licensing process, and harmonization of the requirements in different countries, has become the goal in the nuclear industry. There are many international organizations working towards this goal. The World Nuclear Association (WNA) Cooperation in Reactor Design Evaluation and Licensing (CORDEL) Group can be given as an example, which is described in detail in references [175] and [174].

In Europe, with quite many small nuclear countries, the harmonization work has been seen as even more important than in other parts of the world. The current practice is that each country handles independently its own nuclear issues. It has been observed, and also learned from other industries, that certain coordination and standardization would help the nuclear industry to become more competitive as a power production mode.

Regulatory and licensing risks are presented in the following table. This table is based on reference [120], with some modifications and aspects from the Olkiluoto 3 experience.

Table 6 Regulatory and licensing risks

License(s) delayed	Delay in schedule, cost overrun (financing costs)
Substantial re-design required in licensing process	Cost overrun, delays, trouble with vendor, contract disagreement
Construction license not granted	Loss of investment incurred until then
Regulatory approvals during construction not granted	Cost overrun, delays
Operating permit not granted	Stranded investment
License(s) cancelled by court of law	Delay (if amended license is issued) loss of investment (if not)

There are some boundary conditions which make the harmonization process challenging. In each country the legislation, as well as codes and standards, is different to some extent, which set up the boundary conditions to national safety requirements and regulatory framework. The separation between legally binding regulations (parts of laws or decrees) and other safety requirements (from historical reasons, guidance, etc.) should be understood, and which parts of the licensing process can be modified, and which parts require changes in legislation. More information about the harmonization of licensing requirements can be found in references [26], [46], [170], [174] and [175].

The ERDA core group has generated a roadmap towards European Reactor Design Approval [41]. The concept is based on the approach that a nuclear reactor design should not be reviewed and approved independently by each national regulator in each EU Member State. The reactor design could, according to the ERDA approach, be licensed by an international review team in one European country, enabling this license to be used and approved within all the countries present in the review team. The Commission has also shown interest towards harmonization in the Commission Communication [26].
In addition to the harmonization of the regulatory requirements, the utilities must want the standardization, understanding that it also means that no optimization would be possible concerning the plant design.

To understand the licensing process and its suitability for SMR licensing, the current Finnish licensing process is presented in the following section 5.2. It also answers the first research sub-question: Is the current NPP licensing process suitable for SMRs?
The Finnish licensing process together with the specific features of SMRs, presented in Chapter 4, provide an answer to this question.

5.2 Current licensing process in Finland

Finnish nuclear energy history started gradually in the 1960s when a decision to buy the first NPP was made. The first decision concerned a Soviet designed VVER-440 and it was built in Loviisa. The currently operating NPPs started operation in Loviisa 1 (LO1) - 1977, Loviisa 2 (LO2) - 1980, Olkiluoto 1 (OL1) - 1978, and Olkiluoto 2 (OL2) - 1980. The Radiation and Nuclear Safety Authority (STUK) was founded in 1958, although then its responsibility was for the radioactive instruments of hospitals [119]. The original name was the Radiation Physics Department (Säteilyfysiikan laitos), then the Radiation Safety Department and, in 1984, it was changed to the Radiation and Nuclear Safety Authority. When STUK was also appointed as a regulatory body for nuclear safety, it was placed under the Ministry of Social Affairs and Health as an independent safety regulator. Today, STUK acts as an independent safety regulator under the Ministry of Social Affairs and Health.

The use of nuclear energy is highly regulated. The regulatory pyramid in the case of Finland is presented in Figure 26.

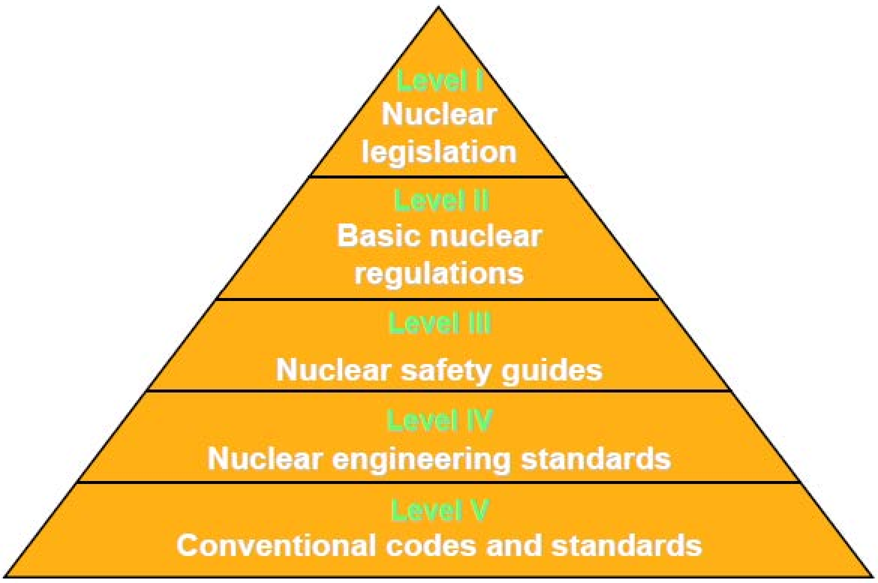


Figure 26 Finnish Regulatory Pyramid [125]

In the Finnish regulatory regime, nuclear-related legislation and regulations (Levels I and II in the pyramid) include among others the following:

- Nuclear Energy Act 990/1987
- Nuclear Energy Decree 12.2.1988/161
- Government Decrees
  - on safety of NPPs (733/2008)
  - on physical protection of NPPs (734/2008)
  - on emergency preparedness (735/2008)
  - on safety of the disposal of nuclear waste (736/2008)

Level III includes Regulatory Guides concerning the use of nuclear energy (YVL guides). From the licensee's point of view, these are the main requirements to be fulfilled. They also include many parts of the legislation and regulations. In the Finnish regulatory framework, these YVL guides play the main role.

Level IV includes the nuclear engineering standards, which in the Finnish regulatory framework is not a very straightforward issue. Since Finland does not have its own nuclear engineering standards, and the regulations do not define the set of acceptable standards, this discussion is necessary with every single NPP licensing process. In principle, certain international standards are applied in every single case, such as IAEA 75-INSAG-3 [61], etc.

Level V includes the Non-nuclear Codes and standards, in which the situation is the same, as with the nuclear engineering standards. The existing standards, such as construction standards are obligatory.

The importance of a good safety culture is a critical issue. Nuclear safety is not only based on technical issues, but also human and organizational performance. STUK and the responsible ministry have, since the beginning of nuclear energy use in Finland, developed and updated national safety regulations and legislation. Regulatory requirements are based on well established national and international practices and IAEA Safety Standards, as well as WENRA requirements, which are becoming increasingly important.

The Finnish licensing process includes three major steps. The licensing process begins with a Decision in Principle (DiP), which is a political process. This process determines if a new nuclear power plant would be an overall benefit for society. An Environmental Impact Assessment is required as background information for the DiP process. The DiP is issued first by the Government and ratified by the Parliament (as presented in the Figure 28 [78]. The second licensing step in the Finnish regulatory framework is a Construction License (CL) phase. This is basically similar to the US practice, defined as two steps licensing by 10CFR50 [148]. The CL phase can be seen as the most important licensing phase for the reactor design acceptance of new NPP licensing in the Finnish regulatory framework. This phase defines the acceptability of the NPP design and sets the limitations for all later phases of the project. The third phase of the Finish licensing process is an Operating License (OL) phase. The OL is issued for a determined time, and within this time frame it needs to be renewed, if applicable.

The main practical stakeholders in the Finnish regulatory framework are the license applicant, STUK, the Ministry of Employment and the Economy, and the Government. The role of the Ministry of Employment and the Economy is focused on the large licensing steps, issuing the DiP, CL, and OL. The role of STUK is preparing the safety statement in each stage of licensing for Ministry of Employment and the Economy's use. The Municipality of plant site has a veto right considering the siting within the DiP licensing phase. Current regulatory framework does not allow the designer organization be involved with the licensing other than through the license applicant. The license applicant is responsible for nuclear safety and therefore the overall licensing process. Different expert organizations or independent third parties/inspection organizations are used, but their use may become more focused in the future. The stakeholders in the licensing process are presented in Figure 27. There is no generic approval of designs in Finnish nuclear licensing.

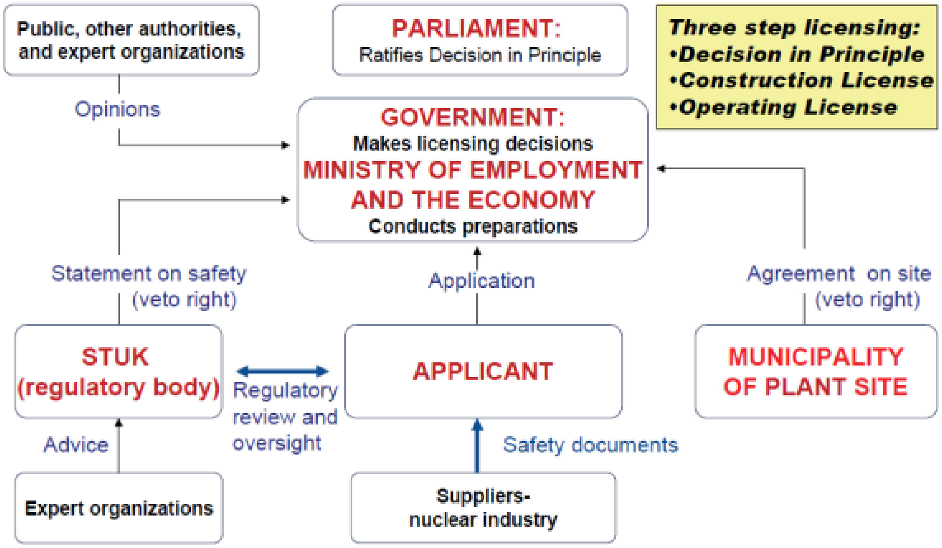


Figure 27 Main parties in licensing of nuclear facilities in Finland [78]

Licenses for nuclear facilities in Finland are issued by the Government

- Ministry of Employment and the Economy provides administrative support for processing license applications
- License can, in practise, be issued only after a positive statement by STUK

In the Finnish regulatory framework, STUK plays a main role in NPP licensing, because STUK must provide a positive statement before forwarding the application to the Government. Even if STUK is acting under the Ministry of Social Affairs and Health, the Ministry is not involved in any of STUK's decisions as a regulatory body. The actual costs of regulatory oversight are directly and fully charged from the licensed users of nuclear energy.

STUK's duties can be described as the following:

- Preparation of nuclear safety regulations
- Design and site evaluation
- Review and assessment of safety analysis
- Assessment of organizations involved in nuclear projects and their management
- Inspections to verify the quality of systems, structures, and components, including their manufacture, construction, and QA
- Inspections to verify maintaining the safety of facilities and materials
- Promotion of nuclear safety development

STUK is dedicated to nuclear safety and the main goal is to keep the **S**afety of nuclear facilities and waste management **A**s **H**igh **A**s **R**easonably **A**chievable (SAHARA). This principle is not affected by the political atmosphere with respect to the use of nuclear power.

The Nuclear Energy Decree gives STUK broad authority to ensure that nuclear power is produced in a safe manner, and to give the necessary orders for this purpose. In the case of a valid safety concern, there is no need to refer to any high level document but orders can be based on well argued and sound expert judgment. STUK's regulatory framework is seen as prescriptive, but it has certain flexibility. This flexibility in the licensing process has its benefits, as it can be modified according to the NPP design of a certain NPP project. However, this approach also has challenges, as the licensing requirements may be seen as unclear. As the YVL guides are not written in a very clear manner, they can be interpreted in many ways. Also the expert judgment may vary from one expert to another and, within the long time frames of NPP licensing, the changes in interpretation of the YVL guides make the risks in the licensing process higher.

The management processes become very important because the projects are so big and complex and durations are long.

The licensing steps in the Finnish regulatory framework are presented in Figure 28. As is stated in the figure, the energy policy is involved with the process until the DiP phase. After that phase, the licensing steps are relatively stable from the political point of view and the focus is put on nuclear safety questions. However, the main project risk, which has been learned from the Olkiluoto 3 project, is regulatory oversight during construction. This is not an official licensing step, but should be mentioned here as it is very time-consuming and an important part of the current licensing practice.

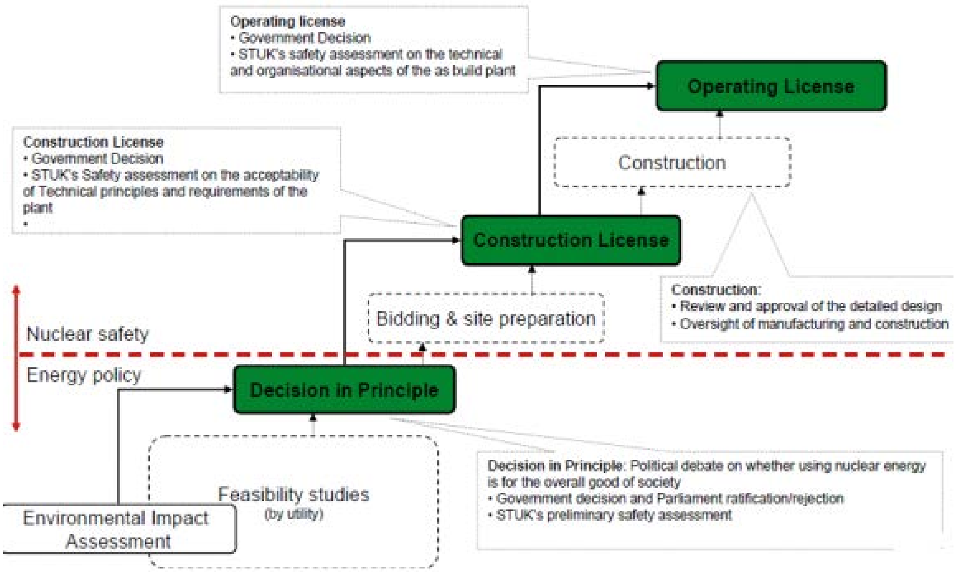


Figure 28 The licensing process in Finland [160]

5.2.1 Decision in Principle (DiP) contents and design maturity

The information required in the Decision in Principle phase is presented in the Nuclear Energy Act, and in the YVL guide B.1 [118]. The YVL B.1 requirements focus on the plant design information, and the YVL B.1 draft version is used here, since the final guide is not available at this point in time. The YVL guide states that STUK shall be able to prepare a preliminary safety assessment based on the information enclosed with the application for a Decision in Principle. An environmental impact assessment is also required before the DiP phase.

The description of safety principles implementation in the overall plant design is one of the key features included in the DiP phase. The design bases to be used in the design of the plant and its systems shall also be presented as well as references to the facilities that have served as models in the design.

Requirements concerning the organizations are also issued in the YVL guides, but these issues are not discussed here, since they do not have an influence on the design maturity.

5.2.2 Construction License (CL) contents and design maturity

In the new YVL guide, YVL B.1 requirements 608 and 609 (draft 4) discuss the issue of PSAR contents, which impacts directly the required design maturity in the CL stage [118]. YVL B.1 requirement 608 (draft 4) states the following: "The preliminary safety analysis report shall provide an overview of the plant-level design principles and the technical implementation of each safety-classified system and its relationship with the overall plant complex. When filing an application for a construction license, the systems' design shall be frozen to the extent that the detailed design will not necessitate any substantial changes to the information pertaining to the layout design of the plant, the location of main system components, or the systems listed in requirement 609, and that the requirement specification can be made for the purpose of procuring components and structures." [118]

Requirement 609 (draft 4) describes the information needed regarding safety class systems 1, 2, and 3. There are other requirements considering the CL application, but they do not have an impact on the required design maturity level.

The design majurity status in different licensing phases is one way to understand the licensing process better. In principle, the Finnish licensing steps can be connected with the design stages as shown in Figure 29 (presented in a STUK licensing seminar).

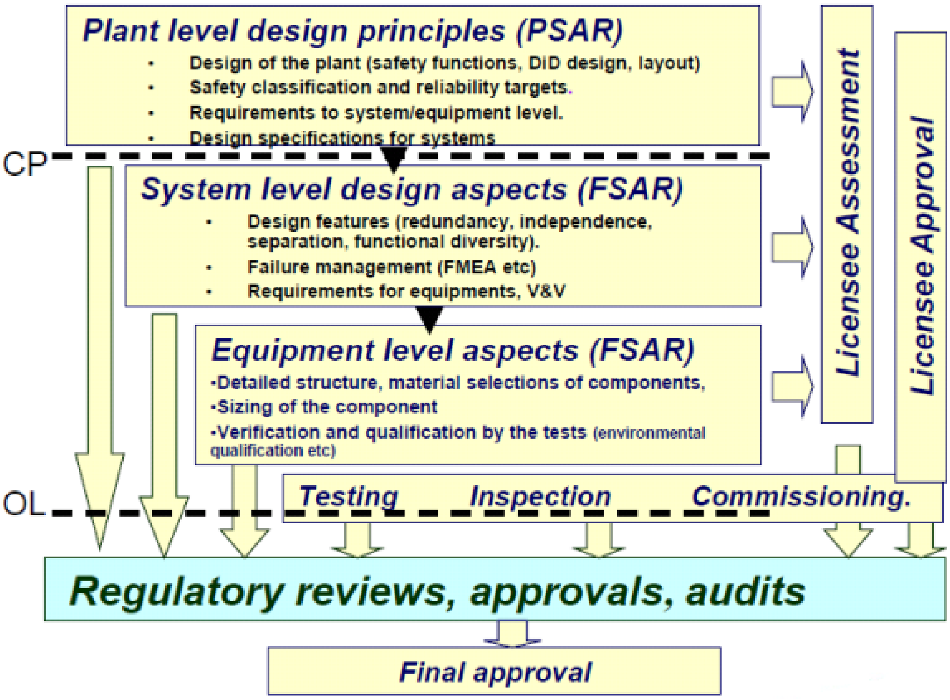


Figure 29 The design and licensing process for OL3 [161]

Figure 29 presents the approach that has been the case with the Olkiluoto 3 project. With this approach the plant level design would be represented in PSAR, included in the CL phase.

The lessons learned from Olkiluoto 3 project have been analyzed by different stakeholders. Here are some findings of Jukka Laaksonen, discussed in more detail in reference [79]:
"Main reasons for the delay are

- Too ambitious original schedule for a plant that is First Of A Kind (FOAK) and larger than any NPP built earlier,
- Inadequate completion of design and engineering work prior to start of construction,
- Shortage of experienced designers,
- Lack of experience of parties in managing a large construction project, and
- Worldwide shortage of qualified equipment manufacturers."

From this list of lessons learned, the second item can be selected as relevant to this research. This lesson was also one of the findings in the WNA Report on Licensing and Project Development of New Nuclear [81]. The WNA report did not include Finnish licensing, but the licensing processes of 10 other countries were discussed in that study.

To improve and accelerate the licensing process, and to lower the risk of licensing, the design should at least be at the systems level design when applying for the CL, as has been stated in the new YVL B.1 requirements.

5.2.3 Regulatory approvals as part of the regulatory framework

NPP licensing also includes, in addition to the three official licensing steps, regulatory approvals from every technical discipline. Disciplines are defined within each new NPP project including different technical fields, such as mechanical engineering, civil engineering, electrical engineering and I&C (Information and Control). Regulatory approvals are granted by STUK or other verified and approved inspection institutions (independent third party), depending on the safety classification.

Figure 30 presents the timely interphases between the design and regulatory approvals. This process is planned to suit the modification projects in the operating power plants. As the current licensing practices have been developed in past years to suit the operating NPP's needs, they may not be optimized for new NPP projects.

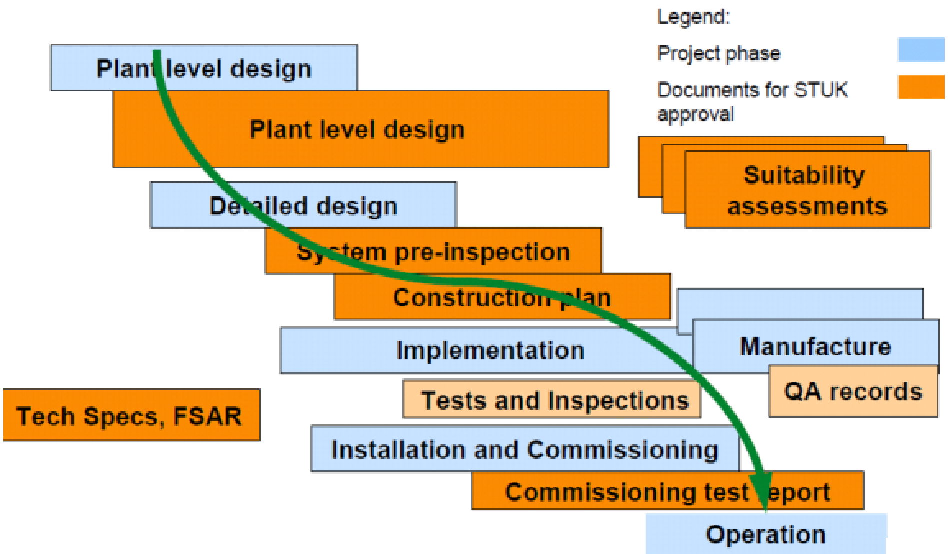


Figure 30 Compatible and timely interfaces between the design and regulatory approval process [161]

To understand this special feature of regulatory approvals in the Finnish licensing process, the background of the operating NPPs needs to be taken into consideration. In case of a new NPP project, the regulatory approvals are called the system pre-inspection phase or oversight during construction and this phase is issued between the CL and OL phases, situated within the construction phase of an NPP. As this licensing phase is not an official licensing phase, and in principle it is not required by the regulatory requirements, the documentation is approved by

STUK and it is not issued by the ministry. This phase handles partly the design issues that could be issued already during the CL phase, in case the design maturity level would be at a certain level.

The oversight during construction causes an extra review and inspection activities both from the licensee and regulatory body during the plant detailed design phase, if the design is not completed before CL. In order to intensify the process, this stage should be diminished and the relevant system inspections should be included in the CL phase.

Figure 31 attempts to represent the current licensing process phases and their contents from both the regulatory and designer points of view.

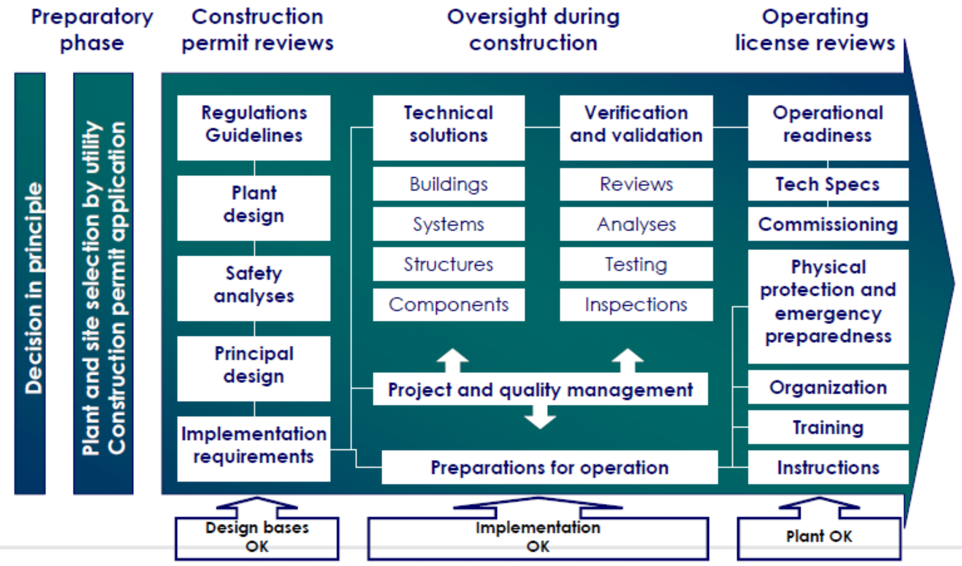


Figure 31 Regulatory supervision by STUK [77]

Regulatory approvals in mechanical engineering are presented here as an example. Mechanical engineering is approved in many design levels. The system level approval is granted based on the content of the Pre-Inspection Documentation. The regulatory approval for the mechanical component requires several different documents to be approved and procedures to be conducted in the different phases of the NPP construction. There is corresponding documentation for every plant delivery step: construction plan, installation construction plan, and commissioning plan. This step in licensing can be argued to mix the licensing and design processes. As the licensing process should not be combined with the design process, in this working method these two processes are mixed and the clear boundary between the two is missing. The procedures used for the evaluation, are regulatory control and regulatory inspections. Also the method for regulatory control in this phase can be argued to be something between a prescriptive approach and a goal setting approach. The trend has been towards an increasingly prescriptive approach in this phase, which needs a lot of resources and planning in the early licensing phases (as is the case in the USA). The other solution would be to take a more goal setting approach, using spot checks for the regulatory control in this licensing phase.

5.2.4 Operating License (OL) contents and design maturity

The operating license is presented in the nuclear legislation at a high level and is discussed in more detail in YVL guide B.1, starting from requirement 615. [118]
The final safety analysis report (FSAR) shall provide an as-built description of the unit prior to the loading of nuclear fuel into the reactor. The safety analysis report shall provide an overview of the principles applied in the design of the entire plant and in the design of each system contained in the unit.

Probabilistic risk assessment (PRA) and Classification documentation are also included in the operating license.

The information concerning the overall plant design is described in YVL B.1. The systems of different safety classification (SC 1, SC 2, SC 3 and EYT - not safety related) require different levels of information, using a graded approach principle. SC 1 is issued only for structures and components, as the highest SC for systems is SC 2.

It should be observed that the licensing approach in Finland concerning the safety analyses, within the CL and OL phases, focuses heavily on a deterministic approach. Deterministic analyses form the basis of NPP safety, while the probabilistic analyses are used only as verification. The balance between probabilistic safety analyses and the deterministic safety analyses is different in different regulatory frameworks.

In licensing principles, the fundamentals are not only technical requirements, but quality and safety culture also plays an important role. Licensee management needs to be committed to build and implement a strong quality management system and a high safety culture already during the NPP construction.

All the licensing steps and their connection with the design process are presented in Figure 32 below. This helps to understand the licensing process connection with design maturity and design process. A three-step design process, including plant design phase, system design phase, and component design phase are indicated on the left, while the Finnish licensing process is presented on the right.

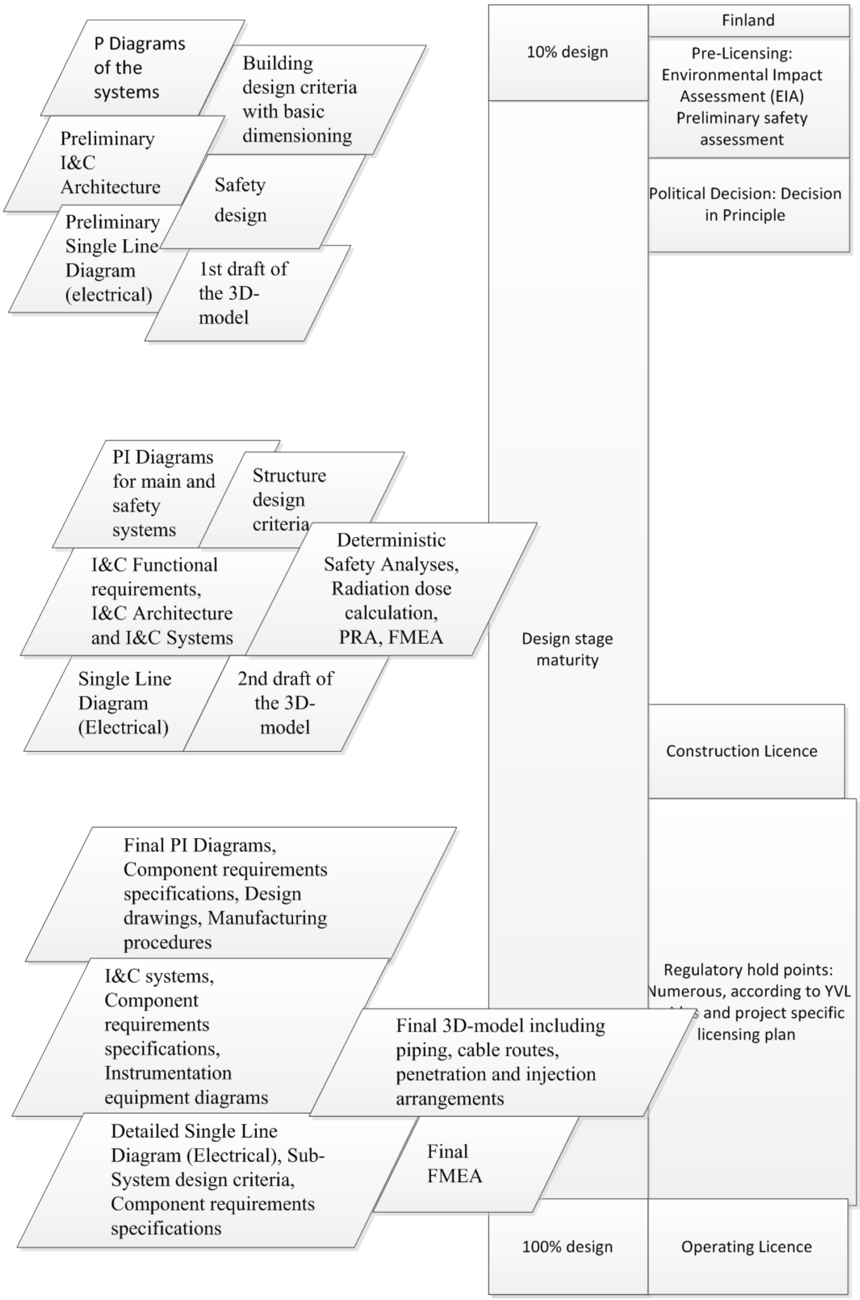


Figure 32 Design stages in connection with the licensing steps in the Finnish licensing process according to the new YVL guides (one interpretation of the approach)

As current Finnish licensing practice follows the NPP design phases, it is important to understand the overall processes in order to plan the licensing process in an optimal manner.

5.2.5 Information and Documents Management process

The current process of Finnish regulatory framework is based on document review and approval. The licensee in current practice handles all the licensing steps and submits all the relevant information to the regulator, while the plant designer does not have a direct connection with the regulator. This document based process can be time-consuming. Finnish licensing requirements require such detailed information that the vendors are not used to provide.

The approval of design documentation and the "once through" approach is presented in Figure 33. Clear and explicit design requirements and early interactions between the regulator and licensee are essential to achieving a common understanding and making the licensing process functional.

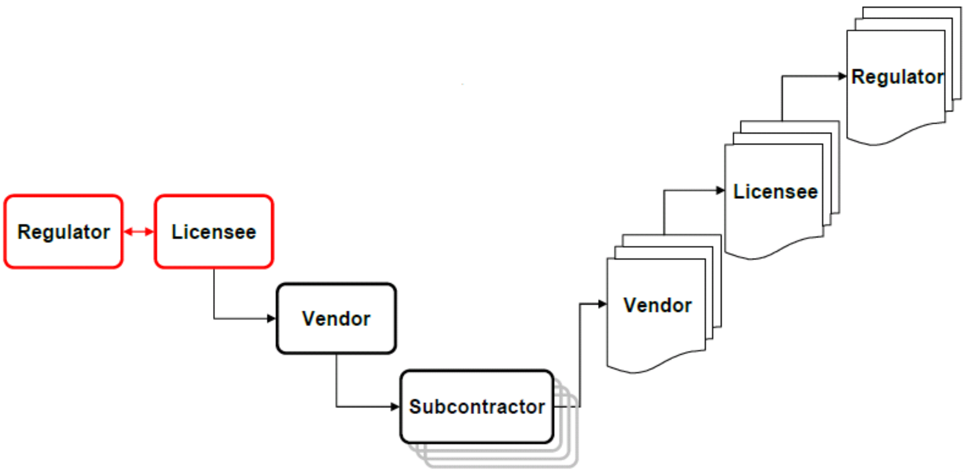


Figure 33 Goal - "once through" regulatory review and approval of the design documentation [162]

As the current NPP projects have thousands of requirements and many stakeholders in long subcontractor chains, the information management process has become more important than in the past. This is an issue to be agreed and a new approach shall be planned to handle both the large number of requirements and long subcontractor chains.
Since the long duration of the licensing documents handling is a problem, some modifications for the process can be suggested: the possibility of parallel review of the licensee and the regulator, and the possibility of the spot check type of review.

5.2.6 Is the current NPP licensing process suitable for SMRs?

This section aims to answer the first sub-question: "Is the current NPP licensing process suitable for SMRs?" The reasoning here is based on the large reactors licensing process study issued by the WNA [81]. The parts of those findings that also suit SMR licensing are presented here:

- "The licensing system must be predictable and stable. Pre-licensing of a design or a site is seen as an important feature of a regulatory system, reducing the risk of licensing and making the outcome of a licensing process more predictable.
- A reasonable level of design maturity should be reached before applying for a license for a FOAK project.
- A formally binding positive decision about a nuclear plant project taken by the government (and possibly parliament) at the outset would remove political considerations from the licensing process, which could then focus on safety issues.
- On a more general level, international harmonization of safety requirements and standardization of reactor designs could greatly facilitate licensing."

Using these findings to discuss the Finnish regulatory framework, the first three issues handle the pre-licensing of a design of a site (DiP in Finland) and the level of design maturity. Pre-licensing in the Finnish licensing process is compared with the DiP phase, with all its contents. It should be observed that the design acceptance is at a very general level included in the DiP process. The DiP process answers the requested formally binding positive decision and, in that manner, is suitable for licensing (both SMRs and large NPPs). The design maturity in this phase of licensing is at quite a low level, since currently every single NPP design needs redesigning to receive a license in Finland if built for the first time in Finland or if the regulatory requirements are modified between two deployments of the same design. As the SMRs are standardized designs, the design maturity is at a high level already during pre-licensing, causing unsuitability of the DiP process with SMR licensing. In other words, the DiP contents and function should be discussed if used for SMR licensing.

Within the Finnish regulatory framework, the safety requirements are partly different from other countries' safety requirements. This causes wide changes in the NPP designs preventing the standardization of the NPP design.

The specific features of SMRs are described in Chapter 4 and the main issues affecting licensing are presented here:

- Standardization
- Modularization
  Several reactor modules in one unit
  Modular construction with modules manufactured in factories
- Multiple units at same site
  Series production and prefabricated structure
- Simplicity of design (fully passive safety features)
- Short construction time
- Smaller front-end capital investment
  more flexible deployment according to power need

Lately in Finland licensing processes have been performed only one reactor at a time. This would mean that the process needs to be gone through every single time when licensing an SMR module. There would certainly be benefits from the earlier reviews, but the official process would still be required. When using the presented specific features of SMRs as a basis, the standardization (internationally) of the design is not an easy approach in the Finnish regulatory framework, with specific Finnish safety requirements.

Considering modularity, the licensing process should take into account the modular design with many reactor modules in one unit. In the Finnish regulatory framework, it is not set how many licenses for the reactor modules are required in the SMR case.

Also, the duration of the licensing process, being close to 10 years in the Olkiluoto 3 case [78], would not suit SMRs, since one of the main compatibility factors is the short construction schedule. The licensing practice in Finland directs the applicant to apply for the CL within a certain timeframe after the DiP acceptance. This forces the CL process to start in an early phase of the preparation process. Within the current regulatory framework, every NPP needs to be redesigned for Finland, causing a large amount of work and time between the DiP and CL phases. Within the current regulatory framework, the duration of the licensing process would cause SMR compatibility to be reduced substantially. The connection between the licensing process and the design process is not suitable for the SMR concept because SMRs are planned as standardized designs, and therefore the design would be quite well finished before starting the licensing process.

The regulatory approvals (or oversight during construction) between the CL and OL phases, is a licensing phase that should be omitted or at least minimized for SMR licensing.

The presented reasons cause the unsuitability of the current licensing process for SMRs. SMRs could probably be licensed according to the current process, but the feasibility of the project would become questionable.

The technical challenges in the current licensing regime are discussed in the Master's Thesis [1]. There are challenges in the fulfillment of certain regulatory requirements, such as the diversity principle in case of totally passive safety systems. Since one specific feature of SMRs is the simplicity of design, including passive safety features, the need for diversity and its scope need to be discussed in detail. It is important to understand the required safety level when handling the Defense in Depth (DiD) approach. The use of DiD levels [173] in the case of SMRs should be discussed, since the allocation of functions and systems in different defense levels may require a new kind of approach. The main challenge being the DiD level 3A versus 3B, since non-European countries do not acknowledge DiD level 3B. This is just an example of an open technical issue in the case of SMRs licensing within the current regulatory framework, and these issues should be agreed in Finland and in Europe in the near future. Since the technical licensing challenges are not part of this thesis, they will not be analyzed further here.

To understand better the Finnish regulatory framework, certain information considering the regulatory framework costs and schedules are described. The following information is based on STUK presentations in "Workshop on experience from construction and regulatory oversight of Nuclear Power Plants" Helsinki / Olkiluoto, Aug 30 - Sep 3, 2010.

Licensing costs, considering the regulatory body (STUK) and technical support organizations (TSO) costs are presented in the following figures.
The actual costs of the whole licensing process cannot be estimated in the current situation with the Finnish regulatory framework because the new NPP projects are not completed at this time (2013). Since the Olkiluoto 3 project is under construction and the Olkiluoto 4 and Fennovoima projects are in the preparation phase, there are no completed licensing processes that can be used as a reference.

When analyzing the licensing costs, it should be understood that the licensing itself does not cost much, when compared with the total costs of a new NPP project. However, the time used for licensing might extend the project schedule.

Figure 34 presents the level of regulatory oversight in the Finnish regulatory framework within a new NPP construction project (Olkiluoto 3). This figure indicates that the level of regulatory oversight is quite high with only one NPP project, and, if one considers SMRs with series construction and even overlapping construction schedules, a suitable approach for regulatory oversight needs to be discussed. The prescriptive versus goal setting approaches, with their benefits and challenges, should be analyzed and the most suitable approach for Finnish licensing decided

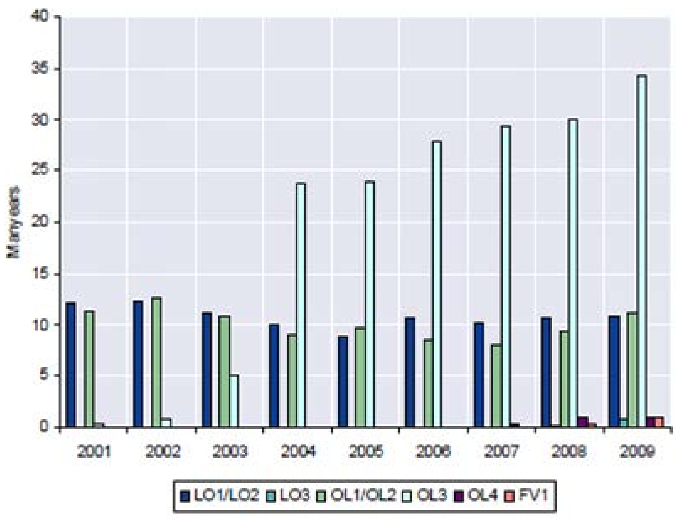


Figure 34 Regulatory Oversight of NPPs (man-years/NPP) [163]
In addition to the regulatory oversight, certain costs have been indicated for technical support organizations. As STUK is not competent in every area of expertise, technical support

organizations are used in certain areas. This approach is widely used in all nuclear countries. Figure 35 presents the annual costs of the technical support organizations, used by STUK, for the Olkiluoto 3 EPR project.

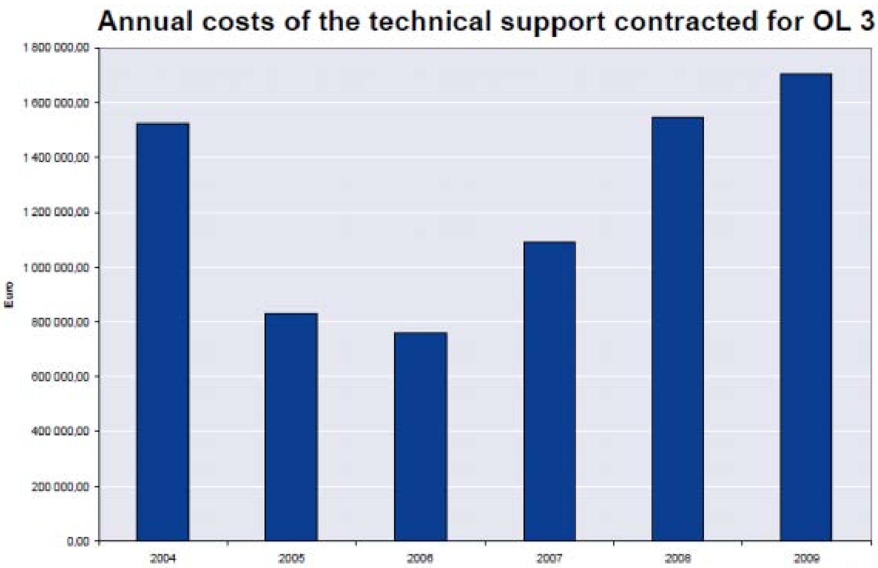


Figure 35 Information about annual costs of Technical support organizations [163]

Within these explanations, inspections, and considerations, it can be argued that the current NPP licensing process is not suitable for SMRs.
The non-suitable features of the Finnish licensing process in SMR approach are:

- Massive continuous regulatory supervision [77]
- Leads to adaptation of the design in Finnish requirements
    - The current licensing process aims for an approach in which at the beginning of the licensing process the design is at a conceptual level, which will not be the case with SMRs.
- The content of the necessary licensing documents have changed from project to project
    -
- Licensing and permitting of components is usually done case by case
    - The components of current NPPs are not standardized (differences between two similar components in different locations, or between the same components in different units)
    - The number of components in an NPP is huge (it is estimated that there are approximately 300,000 components in large LWRs)
- Takes around 10 years to license and construct an NPP [81]

This licensing process can be used for SMR licensing if so decided, but because of the specific features of SMRs, the current Finnish licensing process does not fulfill the requirements on functional, economical, and practical licensing. This argument is based on the experiences of the current projects, the characteristics of the licensing process that do not suit the features of SMRs, and the overall regulatory framework challenges found in the Finnish regulatory framework. It can be argued if the current regulatory framework is suitable for the licensing of large NPPs; however, that argument is not within the scope of this study.

5.3 Licensing processes in Selected Countries

The availability of information is seen as quite different in certain countries. As the study is mainly based on publicly available information, the studied countries are required to have information concerning their licensing processes publicly available.

As described in section 5.2, the Finnish licensing process should be developed to enable feasible licensing for SMRs. It is logical to start with other licensing processes to find features that are applicable to the Finnish licensing process. In this study, licensing processes in France and the United Kingdom have been selected as representative of Europe. These are selected as these countries have been active in the nuclear field (new built projects) in past years. The USA and Canada have also been included in the study. Other parts of the world are regarded as so very different in terms of licensing practices that they are not included in this study.

Table 7 presents the studied licensing processes and the comparative features between them. These features are evaluated and their suitability for SMR licensing is analyzed.

Table 7 Nuclear licensing processes in the example countries

<table>
<tr><th></th><th>Pre-Licensing</th><th>Political</th><th colspan="3">Licensing on new nuclear facilities</th><th>Regulatory hold points</th></tr>
<tr><td>FIN</td><td>Environmental Impact Assessment (EIA)</td><td>Decision in Principle</td><td colspan="2">Construction License</td><td>Operating License</td><td>Various hold points</td></tr>
<tr><td rowspan="2">USA</td><td>Early Site Permit</td><td rowspan="2"></td><td colspan="3" rowspan="2">Combined Construction and Operating License (COL)</td><td rowspan="2">Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)</td></tr>
<tr><td>Standard Design Certification</td></tr>
<tr><td rowspan="2">Canada</td><td rowspan="2">Vendor Design Review</td><td rowspan="2"></td><td>Licence to Prepare Site</td><td rowspan="2">Licence to Construct</td><td rowspan="2">Licence to Operate</td><td rowspan="2">Various hold points</td></tr>
<tr><td>Environmental Assessment</td></tr>
<tr><td>France</td><td>ASN opinion on safety options</td><td>Plan Pluriannual d'Investissement (PPI) - multiyear investment plan</td><td colspan="2">The authorization decree for NPP creation</td><td>License for the commissioning of the installation</td><td>Various hold points</td></tr>
<tr><td>UK</td><td>Generic Design Assessment (GDA)</td><td></td><td colspan="3">Nuclear Site Licence
(Environmental, Safety and Security review processes)</td><td>Established hold points: First nuclear concrete, First NI construction, First fuel to site, Commissioning</td></tr>
</table>

The features of the licensing processes in each country have been defined, and the connection between the design maturity status and licensing process phase has been identified.
It should be observed that the pre-licensing activities have one fundamental difference between the different countries.

5.3.1 The licensing process in the USA

US federal regulations are the basis of nuclear safety in the USA. Considering the legislation, the 1954 Atomic Energy Act (AEA) does not contain requirements concerning nuclear safety, but it does empower the Nuclear Regulatory Commission (NRC) to establish specific regulatory standards. The AEA only requires in section 182 an adequate protection for the health and safety of the public. [121, p 139] The NRC was formed in 1975 and it acts as a regulatory body. The NRC is totally independent from the government. The US President appoints the commission and its chairman, whose appointments are confirmed by the Senate. [148] The NRC makes rules and regulations that are necessary to carry out the purpose of the Atomic Energy Act (AEA). The NRC issues rules defining binding requirements. [121, p 139]

As in most countries, in the USA the legal pyramid is comprised of the fundamental law at the top at the top, the official collection of laws are enacted by the Congress. Although, these laws sometimes adopt specific requirements that must be applied by the NRC. In this case, they could be considered as a form of regulatory guidance.
The Code of Federal Regulations (CFR) comprises the regulatory enactments of all US Federal agencies. Title 10 of the CFR contains energy-related regulations. [65]
The main federal regulations in NPP licensing [148] are issued in 10CFR50 (Code of Federal Regulations, Title 10, Part 50) [155], 10CFR51 [156] and 10CFR52 [157].

The guidance documentation of the NRC is broad and forms a coherent whole for the basis of nuclear safety and licensing. The large volume of documentation is understandable since the NRC regulatory framework resembles a prescriptive licensing approach. NRC regulatory guidance is multifunctional and it applies to organizational issues, management procedures, standards, technical specifications, inspections, and enforcement requirements. Table 8 presents a list of NRC guidance documents to form a general overview of the NRC regulatory framework.

Table 8 NRC Guidance documents [65]

Code of Federal Regulations - Title 10
Regulatory Guides
NRC Legislation
NRC Inspection Manual
ADAMS
Federal Register Notices
Standard Programme
Enforcement Reports

Inspection and Assessment Reports
Operational Experience Reports
Part 21 Reports
SALP Reports
Technical Reports
Administrative Letters
NRC Bulletins
Generic Letters
Information Notices
Regulatory Issue Summaries
Inspector General Reports
Commission Meeting Transcripts
Preliminary Notifications
Speeches
Information Digest

NRC regulatory guides are designed to provide guidance to licensees on implementing specific NRC regulations. The regulatory guides are not strictly mandatory [121, p 139]. The NRC regulatory guides explain evaluation methodologies and techniques used for certain problems or accidents. These guides also explain the data needed for permits or licenses reviews. The regulatory guides can be divided into the following categories [65]:

- Power reactors
- Research and test reactors
- Fuels and materials facilities
- Environment and siting
- Materials and plant protection
- Products
- Transportation
- Occupational health
- Antitrust and financial protection
- General

The NRC inspection manual guides NRC inspection staff in regulatory activities. The inspection manual also gives guidance to licensees about NRC procedures.

Below the regulations and regulatory guides there is a series of NUREG Documents. NUREG Documents are technical reports on different subjects. They are not regulations, or even mandatory documents. NUREG Documents include directories, manuals, and procedural guides for the NRC. Proceedings of meetings or conferences, international agreements, generic environmental impact reports, and contract reports between NRC and other organizations are also included in this series. [65]

The main areas of NRC regulatory activities are rulemaking (or standard setting), licensing, inspection, enforcement, regulatory research, and public information.
The rulemaking process in the US regulatory framework is the activity that issues regulatory standards. The NRC rulemaking process is initiated by technical staff, but the process is very open, with wide public participation. Within rules drafting, public meetings are held, and the rules are publicly commented on before implementation. The rulemaking process preferably starts with a notice of a proposed rule in the Federal Register, where stakeholders can comment on the proposed rule within a period of time.
NRC staff develops the text of the proposed rule, using the Federal Register for a commenting period. Depending on the significance of the issue or on the comments, the need for a public hearing is determined by the NRC. The final rule is published in the Federal Register.
The Commission has a website, "NRC Rulemaking Forum", giving advance notice to the public of rulemaking. This approach has been seen as a more stable regulatory process, since it can be demonstrated that the public has been involved at every stage and therefore the Commission's decisions are less likely to be challenged. [65]

The inspection function includes a wide range of different types of inspections of nuclear reactors, fuel cycle facilities, and other users of nuclear material. The NRC has assigned at least two resident inspectors to each site, with additional inspectors for sites with multiple reactors. Specific reactor inspection programmes for the major licensing phases are issued, such as NPP pre-construction activity, Construction Permit activity, pre-operational phase, start-up phase, operations phase, and decommissioning phase. The NRC has implemented a reactor oversight process utilizing a risk-informed, performance-based approach focusing on safety issues of the greatest importance. [6]

The enforcement regulatory function's objective is to prevent licensees from failing to comply with NRC regulatory requirements and to encourage licensees to identify and correct any deficiency in safety requirements. There are three types of enforcement actions: notice of violation, civil monetary penalties, and orders to modify, suspend or revoke licenses. [65]

The NRC licensing process has been streamlined and updated in past years. Through the licensing process, the NRC authorizes an applicant to conduct the following activities [148]:
"Construct, operate, and decommission commercial reactors and fuel cycle facilities. Possess, use, process, export, and import nuclear materials and waste, and handle certain aspects of their transportation.
Site, design, construct, operate, and close waste disposal sites."

To be licensed for any of the activities presented above, an application shall be submitted to the NRC. The NRC staff review the application using standard review plans. The NRC is therefore satisfied that the assumptions used are technically correct and that there will not be any adverse affects for the environment. [158]

The traditional approach to licensing a new power plant has been a two-step process involving a separate Construction Permit (CP) and an Operating License (OL). This process is represented in Part 50 of the NRC's rules (in Title 10 of the Code of Federal Regulations). The evaluation of the

licensing process convinced the NRC that the two-step process was burdensome and inefficient, and a streamlined process was developed by combining the CP/OL licensing process (Part 52 of the CFR). [65]
Other licensing alternatives, in addition to Combined Construction and Operating License (COL), established in 1989 are early site permits and certified standard plant designs. [154]

Public involvement is one of the key elements in all of the NRC's reactor licensing processes. The NRC holds numerous public meetings during the licensing process, and the law requires a public hearing before issuing a construction permit, early site permit, or combined license. [157]

The two-step licensing process (10 CFR Part 50) is presented in NUREG/BR-0298 [144]. This is also presented here, even though it is the "old" licensing process, since SMRs might decide to use this licensing process for their licensing.

Two-Step Licensing Process [144]
The two-step licensing process involves a construction permit and an operating license.
The NRC reviews the safety of the preliminary plant design and the suitability of the prospective site. When satisfied, the NRC issues a construction permit that allows an applicant to begin construction activities. During construction, the utility submits an application for an operating license. The NRC issues an operating license if all safety and environmental requirements are fulfilled.

For a Construction Permit application, three pieces of information must be included:

- Preliminary safety analyses
- An environmental review
- Financial and antitrust statements

In addition, an assessment of the need for the power plant must be included in the application.

The NRC performs an acceptance review for the application. If the construction permit application includes the required information, a notice of receipt in the Federal Register is published. The application is then reviewed and the findings on the site safety characteristics and emergency planning are documented in the safety evaluation report.

Public meetings near the proposed site are held to familiarize the public with the safety and environmental aspects, the planned location and type of unit, the NRC's licensing process, and the opportunities for public participation. In addition, frequent public meetings are held throughout the licensing process.

The Advisory Committee on Reactor Safeguards (ACRS), an independent advisory group, reviews the construction permit application and the NRC's safety evaluation in a public meeting and reports the results to the NRC's five-member Commission.

An environmental review is conducted by the NRC, to evaluate the potential environmental impacts and benefits of the proposed plant. This includes impacts on:

- air
- water
- animal life
- vegetation
- natural resources
- property of historic, archaeological, or architectural significance
- Other items (economic, social, and cultural impacts)

After completion of the review a draft environmental impact statement is issued for comments. Addressing the comments, a final environmental impact statement (FEIS) is issued and published by the NRC.

The plant design is finalized during the construction of the nuclear plant. With the finalized design an operating license is applied for from the NRC. The application contains a final safety analysis report and an updated environmental report.
The safety analysis report describes [142]:

- The plant's final design
- Safety evaluation
- Operational limits
- Anticipated response of the unit to postulated accidents
- Plans for coping with emergencies

An operating license application and the NRC's related final safety evaluation report are reviewed by the ACRS in a public meeting.

Additional Licensing Processes - Single step process (10 CFR Part 52) [144]
A new alternative for nuclear licensing was established in 1989. This alternative utilizes a combined licensing process, an early site permit process, and a standard plant design certification process. This licensing process is described in 10 CFR Part 52. The benefit is proactivity in licensing, allowing early resolution of safety and environmental issues. Those issues, which are resolved in the design certification process and during the early site permit process, are not reconsidered during the combined license review. In addition, there is also a possibility for a pre-application review before licensing activities. The pre-application process is optional and the review is informal. The new licensing process is described in Figure 36.

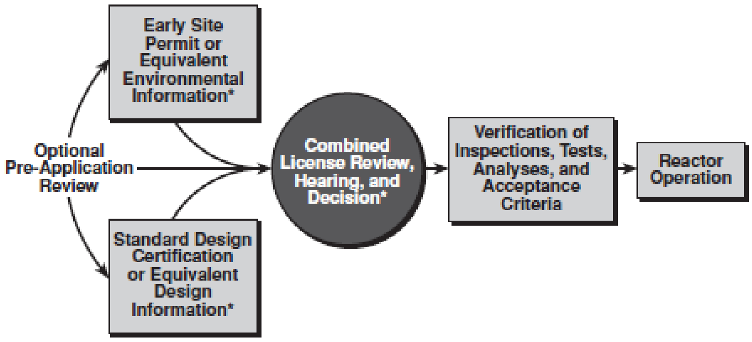


Figure 36 Relationships between Combined Licenses (COL), Early Site Permits, and Standard Design Certifications [144]

A combined license application can use an early site permit, a standard design certification, both, or neither as a reference. If an early site permit and standard design certification are not used as a reference, equivalent information shall be provided for the combined license application.

Even the new licensing process is lengthy and complex. The major steps of the process are [65]:

- Submittal of Safety Analysis Report (SAR) including
    - design criteria and information
    - comprehensive site data
    - safety features to prevent and mitigate hypothetical accidents
    - an environmental report on potential impacts
    - economic information for purposes of an antitrust review
- Commission's independent Advisory Commission on Reactor Safeguards (ACRS) review.
- An environmental statement by NRC that is issued for public comment.
- A public hearing is required before the NRC's atomic safety and licensing boards (ASLB) review. An ASLB is comprised of three members, two technical experts, and one lawyer.
    - During this process a Limited Work Authorization (LWA), to permit certain site preparation and initial construction activities, may be issued.
- Final Safety Analysis Report (FSAR) is prepared after the public process.
- Under the Part 52 process, an early site permit (valid for 10-20 years) and a standard plant design certification (valid for 15 years) may be issued. An important benefit of the COL is that issues resolved in early site permit or design certification proceedings cannot be reconsidered at the combined license stage.

Early Site Permits [144]

Under the NRC's regulations in 10 CFR Part 52, an early site permit for approval of one or more sites can be issued. This process is separate from a construction permit or combined license processes. An Early Site Permit application must contain the following information [144]:

- boundaries of the site
  - including a discussion of the exclusion area, where persons or property can be removed or excluded
- characteristics of the site
  - including seismic, meteorologic, hydrologic, and geologic data
- location and description of any nearby industrial, military, or transportation facilities and routes
- existing and projected future population of the area surrounding the site
  - including a discussion of the expected low-population zone around the site and the locations of the nearest population centers
- evaluation of alternative sites determining whether there is any obviously superior alternative sites
- proposed location of each unit on the site
- number, type, and power level of the units, or a range of possible units planned for the site
- maximum radiological and thermal effluents expected
- expected type of cooling system
- radiological dose consequences of hypothetical accidents
- plans for coping with emergencies

As has been described, public involvement plays a big role in the US licensing process. The public involvement possibilities are presented in Figure 37.

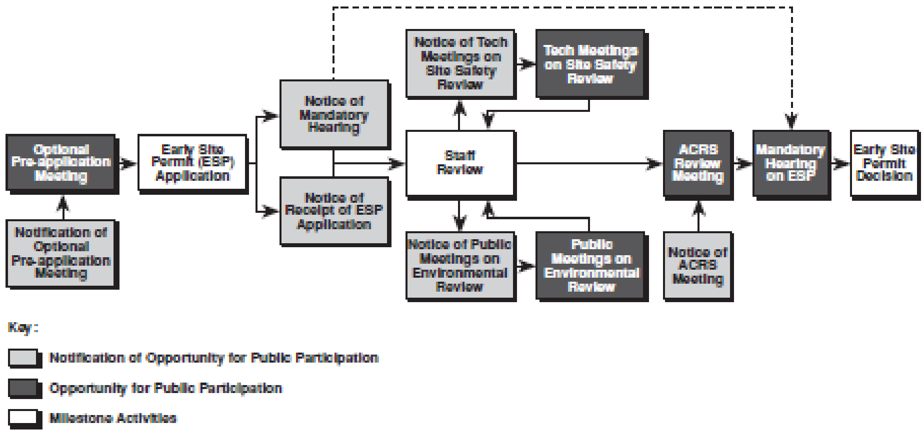


Figure 37 Opportunities for public involvement during the review of Early Site Permits [144]

Standard Design Certification [144]

The NRC can certify a reactor design for 15 years through Standard Design Certification process, through the rulemaking process. This process is independent of a specific site. An application for Standard Design Certification must contain the following information:

- proposed tests, inspections, analyses
- acceptance criteria for the standard design

A public meeting is organized for the Advisory Committee on Reactor Safeguards (ACRS) to review each application for a Standard Design Certification. A safety evaluation report written by NRC staff is also issued at the public meeting. If the design is accepted, it can be certified by the NRC through rulemaking. Under this process, the NRC publishes a public notice of the proposed rule in the Federal Register for public comments, as presented earlier in the public participation process. The NRC reviews the comments and finalizes the rule, which is then published in the Federal Register and becomes an appendix to 10 CFR 52.

Combined License [144]

A combined license authorizes construction and conditional operation of an NPP. The application for a Combined License (COL) must contain the same information as required for an Operating License application. The information includes financial and antitrust information and an assessment of the need for power. [143]

One main piece of information and activity for the COL is the inspections, tests, analyses, and acceptance criteria (ITAAC). The application must describe the ITAAC necessary to ensure the proper construction of the NPP and its safe operation. An ITAAC process flowchart is presented in Figure 38.

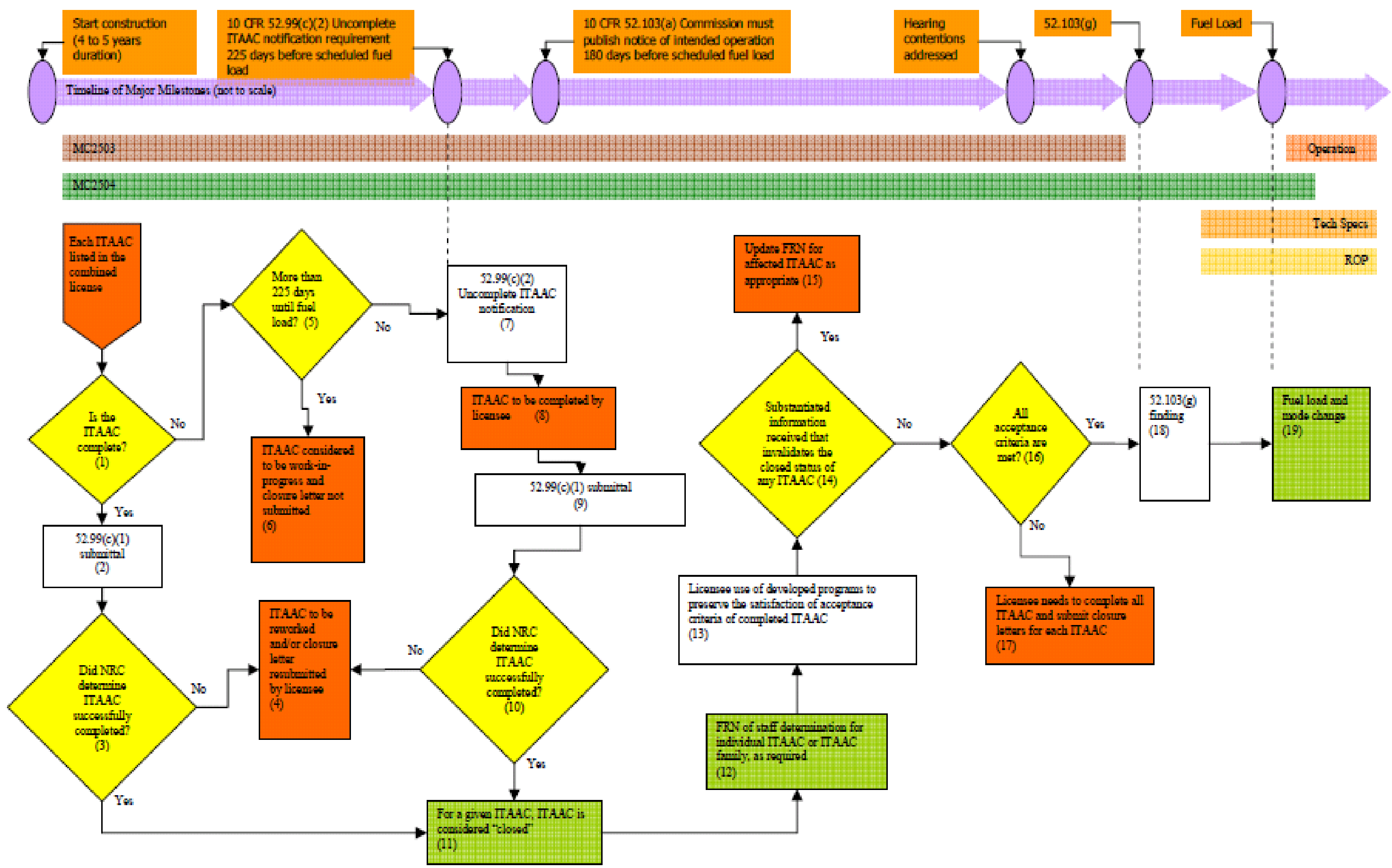


Figure 38 ITAAC process implementation under 10 CFR 52.99 and 10 CFR 52.103 [145]

The ITAAC process has defined milestones. The process begins with the start of construction, and the milestones are followed 225 days and 180 days prior to the scheduled fuel loading. The hearing contentions are addressed as a milestone before the 10 CFR 52.103 approval, after which the fuel can be loaded into the reactor. [150]

The ITAAC process follows each ITAAC listed in the COL. The ITAACs can be processed separately or they can be grouped as ITAAC families. The licensee needs to complete all ITAAC criteria and submit the closure letters for each ITAAC to the NRC. After the closure of each ITAAC, permission for fuel loading will be granted. [150]

If Standard Design Certification is used as a reference for the COL, the applicant must perform the ITAAC for the certified design and the site-specific design features. If Standard Design Certification is not used as a reference, the applicant must provide complete design information.

If an Early Site Permit is used as a reference, it must be demonstrated that the design of the plant is compatible with the Early Site Permit. In addition, the application must include information on issues not required with the Early Site Permit, such as the proposed plant's required power.
If an Early Site Permit is not used as a reference, the applicant must provide all the relevant site information, including a complete emergency plan.

The ACRS reviews the COL application and the NRC staff's safety evaluation report in a public meeting, as is the case also in other licensing steps. After issuing a COL, the NRC verifies that the required inspections, tests, and analyses are completed, and that the acceptance criteria are met. Only then can the unit start operations.

Figure 39 helps to understand the licensing process connection with design maturity and design process. A three-step design process, including plant design phase, system design phase, and component design phase are indicated on the left, while the US licensing process is presented on the right.

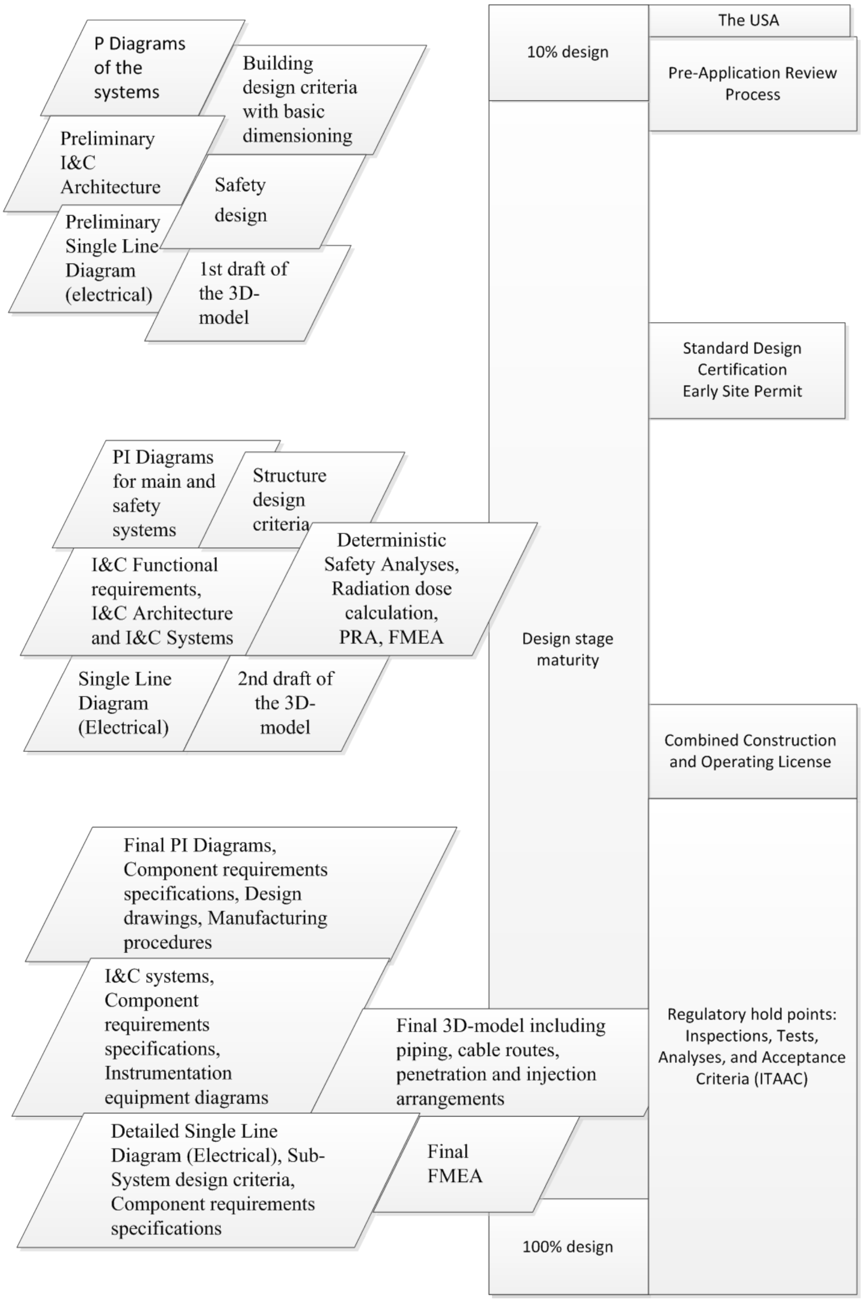


Figure 39 Design stages in connection with the US licensing steps defined in the 10 CFR 52

Other Licensing Processes

The regulations in 10 CFR Part 52 also include several appendices describing the processes for a manufacturing license, a duplicate plant license, preliminary and final design approvals, and site suitability reviews.

When considering licensing activities within the NRC, one of main activities issues license renewals. Nuclear plants in the USA were originally licensed for 40 years [141]. Another licensing issue confronting the NRC is license transfer. Since companies are changing over time, a new legal entity might take over an existing nuclear plant. The continuation of operations will require a transfer of the current NRC operating license. For this license transfer to happen, the NRC reviews the new operating organization for its technical, management, and financial capabilities to operate the reactor safely. [65]

SMR Licensing within the NRC

In the USA, SMRs are taken into account in licensing process development. The issues relating to the licensing of advanced reactors are presented in reference [149].

The NRC has developed its regulations on the basis of light-water reactors (LWRs). The Office of Nuclear Regulatory Researches in the NRC has developed an extensive program to support the licensing reviews of advanced reactors.
The research program focuses on the following nine key areas, each one addresses multiple technical topics [146]:

1. framework
    - including the development of regulatory decision making tools based on risk-informed, performance-based principles
2. accident analysis
    - including probabilistic risk assessment (PRA) methods and assessments, human factors, and instrumentation and control
3. reactor/plant systems analysis
    - including thermal-fluid dynamics, nuclear analysis, and severe accident and source term analysis
4. fuels analysis and testing
5. materials analysis
    - including graphite behavior and high-temperature metal performance
6. structural analysis
    - including containment/confinement performance and external challenges
7. consequence analysis
    - including dose calculations and environmental impact studies
8. nuclear materials safety
    - including enrichment, fabrication, and transport
9. waste safety
    - including storage, transport, and disposal

10. nuclear safeguards and security

There have also been wide discussions considering the following issues within SMR licensing [14]:

- "Implementation of the Defense-In-Depth Philosophy for Advanced Reactors
- Appropriate Source Term, Dose Calculations, and Siting for SMRs
- Appropriate Requirements for Operator Staffing for Small or Multi-Module Facilities
- Security and Safeguards Requirements for SMRs"

The NRC is developing detailed resolution plans for these issues, taking into account the following factors [14]:

- criticality of the issue in terms of the development of the New Generation Nuclear Plans or integral LWR designs
- number of affected technology groups and designer organizations
- potential effect on the design
- need for changes in legislation, rulemaking, or policy
- need for confirmatory research
- the participation and cooperation of applicants and other stakeholders
- effect on the schedules for prototype plants or commercial deployment
- the dependencies on other policy or technical issues.

Suggested three possible license scenarios, considering the number of licenses to be issued, are presented for SMRs or multi-module facilities licensing [12]. These licensing scenarios present the operating license scenarios and do not concern the actual licensing process. The alternatives are presented here.

Alternative 1: Single Facility License [12]

The single facility license would consider all the reactor modules under one license. This approach would possibly reduce the lifetimes for subsequent modules if the modules were constructed in staggered projects, because the license would be granted based on the first module schedule. The staggered addition and operation of reactor modules would not be feasible for a single operating facility license.

Other disadvantages could be, for example, with the following issues:

- individual power reactor modules' license shall involve verification of ITAAC
- individual modules may involve unique operating cycles
- module-specific operating problems might occur

A single license for an entire facility consisting of multiple reactors would probably present challenges in practical implementation and daily interactions in licensing or technical issues.

This alternative is not quite suitable for the USA regulatory framework. It should be observed that this type of regulatory framework is used in, for example, Canada with CANDU reactors.

<u>Alternative 2: Master Facility License and Individual Reactor Module Licenses [12]</u>

This approach has been applied in the NRC regulatory framework in the case of byproduct materials licenses.
In this approach, the Master Facility License (MFS) could include performance-based criteria and aging management requirements for common SSCs. In addition, the requirements and limitations affecting all modules would be issued within the MFS.
The individual licenses for each reactor module would be issued for operation. Each of these individual reactor licenses would reference the Master Facility License for site or facility requirements.
The main challenge for implementation of the Master Facility License approach is that the NRC would need to develop processes and new regulations. This approach would not fit directly within the existing technical and legal regulatory framework.

<u>Alternative 3: Individual Reactor Module Licenses [12]</u>

In reference [12] the following positions are stated:

- "A single application for a Part 52 COL can include multiple, essentially identical reactor modules, regardless of the size of the reactors."
- "The single application with multiple, essentially identical reactor modules…can undergo a single NRC review, SER, and NRC hearing."
- "The license duration for each module within a single license authorization is a period not exceeding 40 years from the date the Commission finds that the acceptance criteria in the license are met, in accordance with §52.103(g), for that module."

This licensing approach could be issued in the same way with large LWR licensing, according the 10 CFR Part 52. One challenge in this approach is addressed with common structures and components, when a license is issued to each module separately.
Two possible approaches for handling common SSCs have been introduced.

<u>Alternative 3a [12]</u>
An approach that might suit this issue is to address common SSCs primarily in the license for the first module. This approach is relatively simple, but it raises the same challenges related to the license term for common SSCs, as does Alternative 1.

<u>Alternative 3b [12]</u>
An alternate approach that would define license conditions for common SSCs in a license appendix. The appendix would ensure that the common SSCs remain functional and meet the necessary requirements for each module. This approach has similar features with the Master Facility License concept described under Alternative 2.

It has been suggested that each module would be separately licensed within the USA regulatory framework, but an official decision concerning this issue has not been issued at this point in time (February 2013).

5.3.2 The licensing process in Canada

The Canadian Nuclear Safety Commission (CNSC) is mandated, under the Nuclear Safety and Control Act (NSCA), to regulate all the nuclear-related activities in Canada. The Canadian regulatory framework is based on nuclear activities that go into the facility, so a plant does not get a license, but a licensee (utility) gets a Licence to Construct and operate a plant. The Parliament of Canada first established legislative control and federal jurisdiction over the development and use of nuclear energy and nuclear substances in 1946. The Canadian Nuclear Safety Commission was established as the successor to the Atomic Energy Control Board (AECB), when the NSCA came into force in May 2000. The CNSC is currently updating its regulatory framework for licensing new nuclear power plants. The Government of Canada has recently created the Major Projects Management Office (MPMO) that will coordinate an integrated federal project plan development and implementation, including the environmental assessment, the licensing and permitting processes, and the aboriginal consultation phases. [83]

The regulations, issued under the NSCA that apply to nuclear power plants are the following [88]:

- The General Nuclear Safety and Control Regulations
- The Radiation Protection Regulations
- The Class I Nuclear Facilities Regulations
- The Nuclear Substances and Radiation Devices Regulations
- The Packaging and Transport of Nuclear Substances Regulations
- The Nuclear Non-Proliferation Import and Export Control Regulations
- The Nuclear Security Regulations

These regulations stipulate regulatory requirements at a high level including mandatory information to be supplied in an application for a license. Further discussions of these regulations are provided in regulatory documents and regulatory guides which support the regulations.

Other legislation, enacted by Parliament, applying to nuclear power plants includes the following (but is not limited to) [88]:

- Nuclear Liability Act
- Nuclear Fuel Waste Management Act
- Canadian Environmental Assessment Act
- Canadian Environmental Protection Act
- Fisheries Act
- Species at Risk Act
- Migratory Bird Convention Act
- Canada Water Act

In the Canadian licensing framework the applicant's submissions are expected to address regulatory requirements as well as codes and standards applicable to the proposed licensing activities. The applicant's role is to propose a safety case and licensing basis according to the particular reactor design. Although licenses are based on a common license template, licenses are issued case by case for each licensee. CNSC licensing is a goal setting process or a performance-based process and differs greatly from the NRC's prescriptive practice.

Once the actual licensing process is triggered by an applicant, CNSC staff use defined Safety and Control Areas as the basis of their licensing review and at a later stage their compliance activities. The licensing basis comprises the following areas [88]:

- Physical Design
- Safety Analysis
- Fitness for Service
- Siting & EA
- Informing the Public
- Packaging and Transport
- Security & Safeguards
- Waste Management
- Emergency Management + Fire Protection
- Environmental Protection
- Conventional Occupational Health and Safety
- Radiation Protection
- Management System Framework
- Human Performance Management
- Operating Performance

For each of the Safety and Control Areas, the licensee is expected to address the corresponding regulatory requirements.

A large portion of the licensing basis is composed of the licensee's management systems, which demonstrate how the licensee meets requirements and is qualified to conduct licensed activities. Every licensee has its own management system structure, although they can share common characteristics. Applicable codes and standards as well as applicable regulatory framework documents are to be considered, addressed, and referenced in management system documents. When directly referenced, these codes and standards and regulatory framework documents then become part of the licensing basis. Although licenses have a common structure or template, they are specified according to the proposed licensing basis. [88]

In Canada, the licensing process, considering the whole NPP lifecycle, contains the following licensing steps [20]:

1. Licence to Prepare Site - LTPS (no SSC construction permitted)
2. Licence to Construct – Construction and Fuel-Out Commissioning
3. Licence to Operate – Fuel-in commissioning into commercial operation phase
4. Licence to Decommission – self explanatory
5. Licence to Abandon – Post decommissioning – releases site from regulatory control

For the scope of this thesis, only the first three steps are further discussed. In the LTPS the aim is to ensure that the site is suitable, and with this license the excavation may be started if the technology has been chosen and factored into the siting case. A comprehensive Environmental Assessment (EA) is required as a prerequisite to the LTPS. Environmental Assessments (EAs) are carried out to meet the requirements of the Canadian Environmental Assessment Act (CEAA). EAs identify the possibility of a specific project causing significant environmental effects. EAs also determine whether those effects can be mitigated. For each licensing phase after the LTPS, environmental determination is issued to confirm the original environmental assessment basis is being maintained. [20]

The Licensing Basis for a regulated facility or activity is a set of requirements and documents comprising [19]:

- the regulatory requirements within the applicable legislation and regulations;
- the conditions or safety and control measures, described in a license, and in documents directly referenced in a corresponding license;
- the safety and control measures described in a license application, and in documents directly referenced in a corresponding license.

The licensing steps Licence to Prepare Site, Licence to Construct, and Licence to Operate can be conducted in series or in a parallel staggered fashion. This is the decision of the licensee and depends on their applied licensing schedule and the maturity of the proposed design. As of November 2012, the EA process has been merged into the LTPS licensing step. [19]

Pre-licensing

The Vendor Design Review (VDR) is a pre-licensing process between the CNSC and a vendor/designer organization to verify, at a high level, the acceptability of a design with respect to Canadian regulatory requirements. It does not result in a license or certification but enables discussions between a vendor and a potential license applicant. The VDR is not a comprehensive review of the design but a sampling of typical areas that can negatively impact on the licensing process. A vendor design review should be applied when the vendor's conceptual design is complete and the basic engineering ongoing. [21]

The VDR process is divided into two main phases, with the third phase as a follow-up option on focus areas of interest. The first phase focuses on the vendor's processes and procedures. The second phase focuses on specific design activities being conducted by the vendor. At the end of phase two, the CNSC is able to make statements on whether or not the design, as reviewed, presents potential barriers to licensing in Canada. [21]

The three phases of the VDR process[21]:

1. Phase 1 examines whether vendor's documentation addresses how it will meet the regulatory requirements.
2. Phase 2 reviews whether there are any fundamental barriers to licensing.
3. Phase 3 gives the vendor the option to follow-up on any focus areas of interest.

The 19 focus areas are defined as follows [21]:

1. General plant description, Defense in Depth, safety goals and objectives, dose acceptance criteria
2. Classification of structures systems, and components (SSCs)
3. Reactor core nuclear design
4. Fuel design and qualification
5. Control system and facilities
6. Means of reactor shutdown
7. Emergency core cooling and emergency heat removal systems
8. Containment / Confinement and safety important civil structures
9. Beyond design basis accidents (BDBAs) and severe accidents (SA)
10. Safety analysis - deterministic safety analysis probabilistic safety analysis - internal and external hazards
11. Pressure boundary design
12. Fire protection
13. Radiation protection
14. Out-of-core criticality
15. (A) Robustness, (B) Safeguards (C) Security
16. Vendor research and development program
17. Management system of design process and quality assurance in design and safety analysis
18. Human factors
19. Incorporation of decommissioning in design considerations

The Nuclear Safety and Control Act does not have specific provisions for combined licenses and the licenses are normally granted for each phase separately. However, applications to prepare a site, to construct and to operate a new nuclear power plant could be assessed in parallel. This approach is dependent on the design maturity of the power plant design, as well as the project schedule and licensing plan. It should be noted that it is theoretically possible for an applicant to apply directly for a Licence to Operate and include activities for site preparation and construction. However, this kind of approach is very unlikely. The possible licensing schedule is presented in Figure 40.

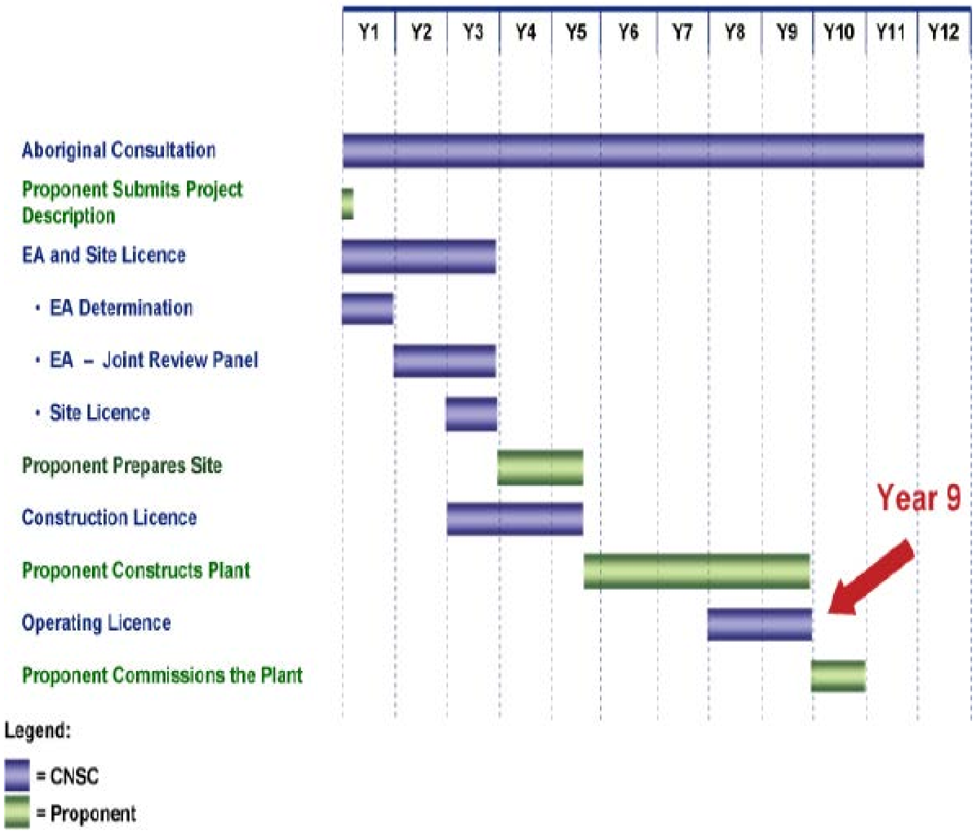


Figure 40 EA and Licensing Process for a New Nuclear Power Plant in Canada [88]

The CNSC has presented estimates on the duration of the licensing steps for a FOAK NPP. The total licensing time, from the receipt of application to the issuance of a Licence to Operate, is estimated to be nine years. A smaller FOAK SMR could theoretically be licensed to operate in about six to seven years. [30]

To understand the Canadian licensing process steps in connection to the plant design process, Figure 41 was developed to present the connection between the two. A three-step design process, including plant design phase, system design phase, and component design phase are indicated on the left, while the Canadian licensing process is presented on the right.

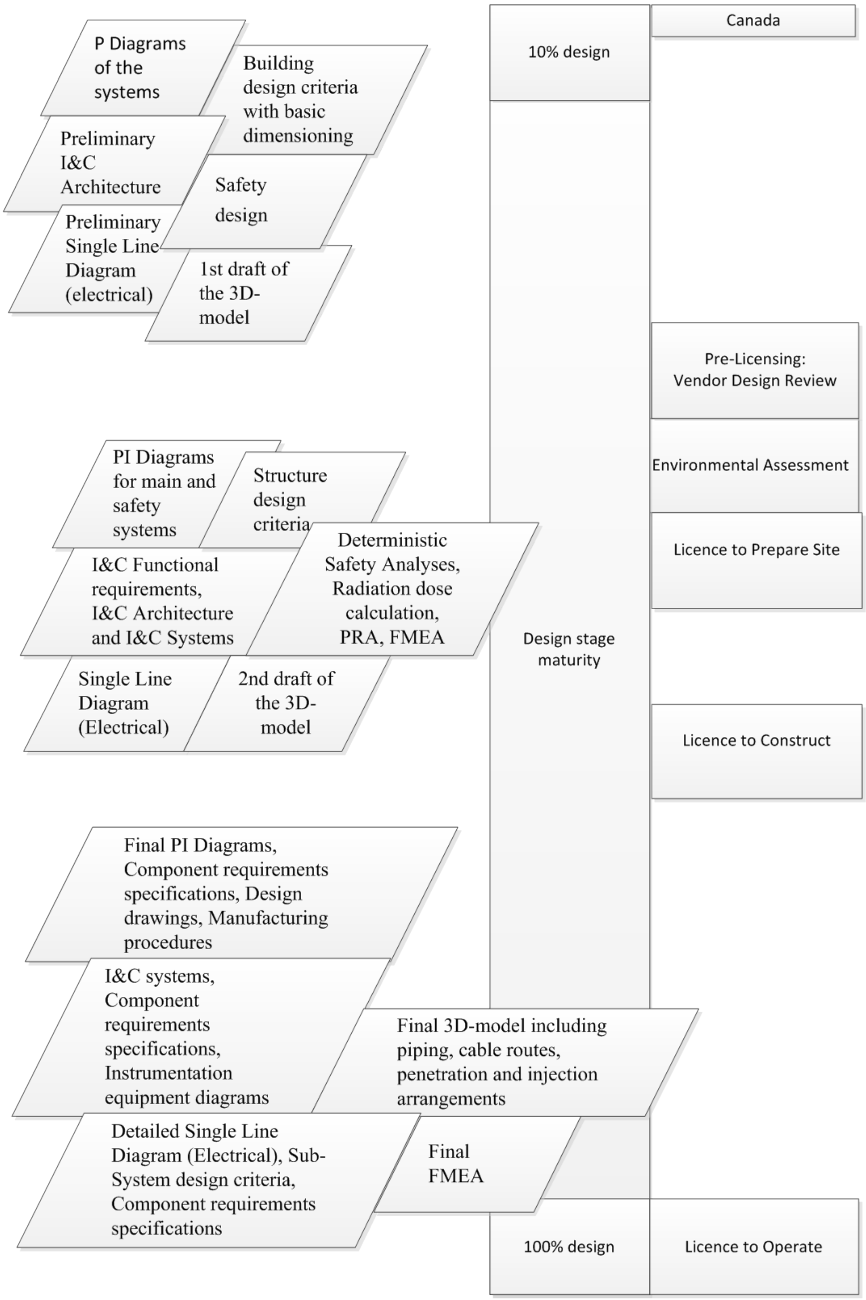


Figure 41 Design stages in connection with the Canadian licensing steps

There are potentially two focus areas for SMR development in Canada [31]:

1. Conventional SMR designs (e.g. B&W mPower) in southern provinces with grid infrastructure that cannot accommodate traditional NPPs (replacement for coal plants)
2. Micro-SMR designs (2-25 MWe) in northern parts of Canada where there are isolated grids in small communities, many of which are aboriginal communities.

The consideration of license applications for new NPPs follows the public hearing process, as set out in the CNSC Rules of Procedure. The public hearings for licensing applications for nuclear power plants take place over two hearing days, which are typically held over a ninety-day period. [88]

SMR Licensing

The CNSC permits an applicant to make licensing based arguments against regulatory requirements on a risk-informed approach (graded approach). More grading is likely to be possible for very small designs of output less than approximately 200MWt, based on a very small core inventory [21]. This threshold is not a firm fixed number but rather a guideline, but most of the LWR SMRs do not fall into this category, since they are closer to the SMR upper limit (300MWe). The limit applies to the whole unit with all the modules in it. So, for example, NuScale [98] with only one module would be quite close to this limit, but with a multimodule unit this kind of graded approach would not be applicable.

A discussion of the number of licenses is not as necessary in Canada as it is in other countries such as the USA. Canada has a lot of experience with Candus [23] with many reactors with connecting containment system. Candus operates under one Operating license (all the reactors in one unit). This approach would also be applied to SMRs in Canada.

Canada has already issued the pre-licensing phases 1 and 2 for Enhanced CANDU 6 (EC6), a 720 MWe CANDU Energy design [31]. This design does not fall into the SMR category, but is still quite small compared with the large NPPs being built in other parts of the world. Also, mPower [49] and NuScale [98] have started discussions to start pre-licensing activity in 2013 [31].

5.3.3 The licensing process in France

In France, reform of the regulator's status was modified in 2006. This reform has transformed the regulator's status into an independent authority. L'Autorité de sûreté nucléaire (ASN) used to be a cross-ministerial service under the joint responsibility of the Ministers for the Environment, Health, and Industry. The reform set up the ASN as an independent regulatory body. [16]

The ASN consults other bodies extensively. It mainly consults competent authorities: technical bodies, responsible ministers (Health, Environment, and Industry), competent ministers (Transport, Home Affairs, Agriculture, etc.) and other competent independent third parties. [16]

The ASN has a wide range of responsibilities, such as nuclear transparency and safety. The main responsibilities of the ASN can be divided into regulations, inspection, and information activities.

The ASN contributes to drafting regulations in two ways: by submitting its opinions to the Government on draft decrees and ministerial orders, and by issuing regulatory decisions.

The inspection activities are compliance checks against rules and specifications. Inspection is one of the primary means of verification available to the ASN, which also has appropriate powers of enforcement and punishment.

The information task of the ASN is particularly dealt with through its website (www.asn.fr) and the magazine Contrôle. The ASN informs the public and other stakeholders, such as local information committees, environmental protection associations, etc., about its activities and the state of nuclear safety and radiation protection in France.

In civilian nuclear activities, the ASN acts as a regulator, including the following nuclear activities [16]:

- nuclear power plants
- radioactive waste management
- nuclear fuel
- transport
- consignments of radioactive materials
- research laboratories
- industrial activities
- medical installations.

The roles and responsibilities of different actors are presented in Figure 42. This figure presents the regulatory framework's structure. As with Canada and the UK, the French regulatory framework can be defined as goal setting, the comparison being a prescriptive practice as is the case in the USA.

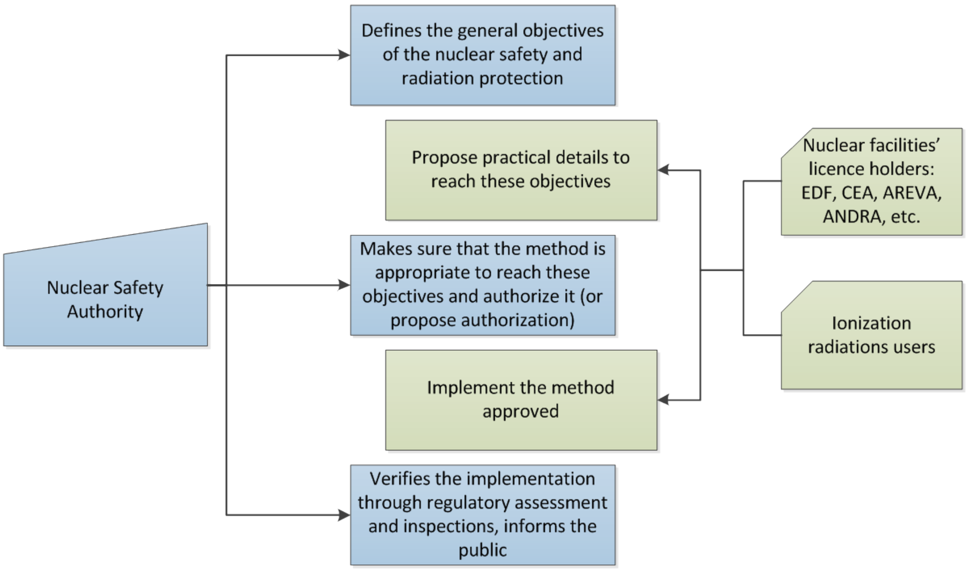


Figure 42 Responsibilities among stakeholders in the French regulatory framework [97]

The form of regulations in France can be presented in the legal pyramid. Figure 43 presents the legal pyramid for the French regulatory framework.

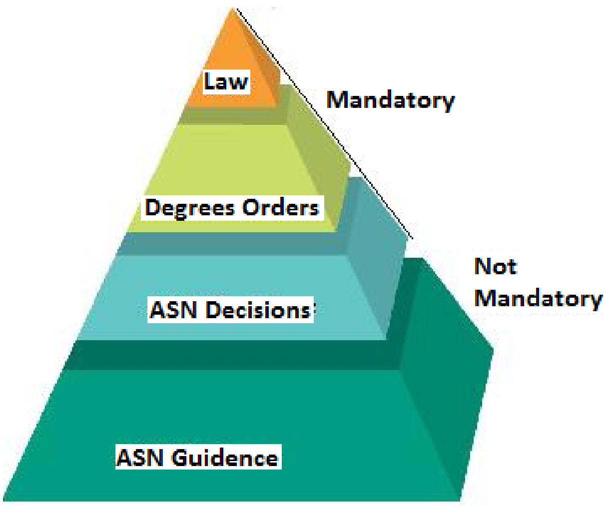


Figure 43 The French regulatory pyramid [97]

This pyramid deals with the mandatory as well as non-mandatory requirements. The regulatory framework in France is more goal setting than prescriptive, which can also be seen in this regulatory pyramid, since the number of mandatory requirements presented is quite small. After legislation, the mandatory requirements are ASN Decisions, and these are followed by non-mandatory ASN Guidance. [97]

The legislation, safety standards and regulatory requirements, which have been discussed and partly updated in past years, are they are presented here [97]:

- Legislation in the Environment Code
- Several governmental decrees
    - Decree dated November 2, 2007
    - Nuclear pressure equipment regulations
- A few ministerial orders
    - Order on general safety expectations (February 7, 2012)
    - Quality order (August 10, 1984)
    - Risk management protection order
- Nonbinding documents published by the ASN
    - Basic safety rules (RFS) and guides

In France, the licensing process for a new nuclear power plant includes two official licensing steps: Autorisation de Création and Operating Permit. In the French regulatory framework, this process handles only the NPP design and construction within the existing sites. Licensing for new sites is described in section 6.1.4 . However, the two official licensing steps presented do not represent the actual licensing process as a whole. In addition, there is pre-licensing activity, the ASN opinion on safety options [25]. This pre-licensing activity goes through the high level safety objectives and their fulfillment without going into details of the design. This pre-licensing step can be compared to the Finnish licensing process, the STUK safety evaluation in the Decision in Principle phase.

Another addition to the two-step licensing process can be seen in a political decision to build a new NPP. In the new law (implemented in 2006) the political decision, known as the Plan Pluriannual d'Investissement (PPI), meaning a multiyear investment plan, has been introduced as part of NPP licensing [101]. This multiyear investment plan is supposed to be prepared by the Government every five years when a new Parliament is elected. This step is not nuclear-specific, but is applied also to other large non-nuclear investments in France. The aim of the document is to provide the orientation for the new investment of the major electricity production means to be decided during the next five years.

An additional step is needed for each important investment project. This step deals with public participation, which has been getting more attention in many nuclear countries in recent years. In the French licensing process, the public participation step is dealt with by "public debate", which needs to be organized for each important investment project. This is not exclusive to the nuclear field, but relates to large investments, as the EIA in Finland. This "public debate" is a consultation phase without blocking rights. However, from the point of view of the project, this step should be considered, since it may take several months or even up to one year to organize and conclude. [27]

The overall licensing process can then be described in the following stages, without determining which belong to the official licensing process in France [97]:

1. ASN opinion on safety options
    - Pre-licensing activity
2. Multiyear investment plan
    - Political decision taken by the Government
    - Not a nuclear-specific activity
3. The authorization decree for NPP creation
    - Delivered by the Government on the basis of the ASN position
    - Aim of the authorization decree
    - Process linked with other administrative authorization
    - ASN can enact requirements for detail design of the NPP
4. The commissioning and operation authorization
    - Delivered by the ASN
    - The ASN can enact requirements for the NPP commissioning and operation

Concerning the regulatory framework in France, public hearings are required during the creation process. In addition, the administratively independent National Commission for Public Debate (CNDP) can order public hearings on any subject independently from the ASN decisions and process. [16]

The process of the authorization decree for NPP creation, with the different stakeholders and activities, are presented in Figure 44.

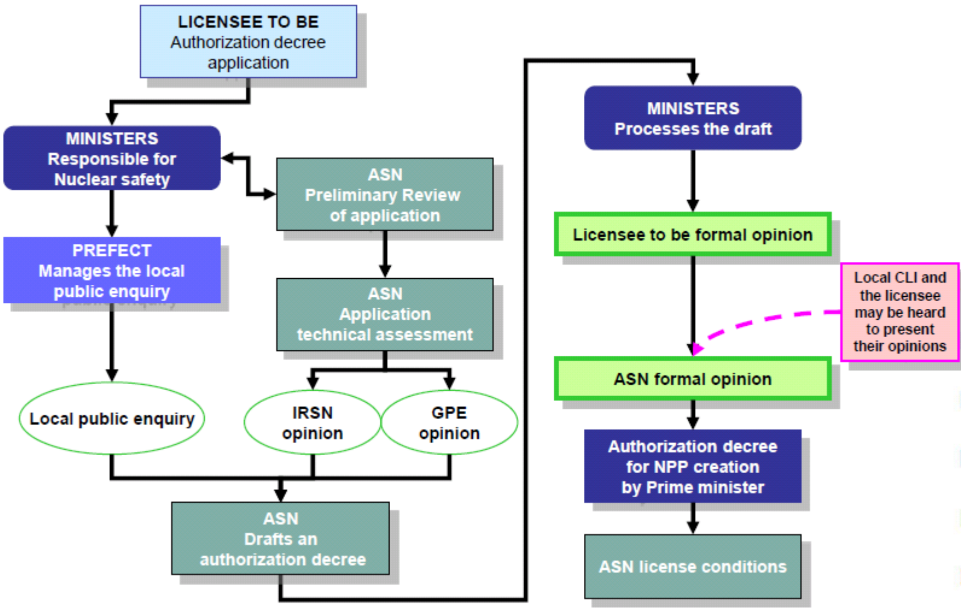


Figure 44 The authorization decree for the NPP creation process (since 2007) [97]

This authorization decree for NPP creation is the main licensing step in the French regulatory framework, which is why it is presented here in more detail than the other licensing steps.

As well as the overall licensing process, the authorization decree for NPP creation has also been further developed in recent years. Figure 44 presents the responsibilities of the licensee, the ministry, and the ASN. Also, the different actions, such as public participation, license application, reviews, assessments, and license granting are presented.

To understand the French licensing process steps in connection to the plant design process, Figure 45 was developed to present the situation. A three-step design process, including plant design phase, system design phase, and component design phase are indicated on the left, while the French licensing process is presented on the right.

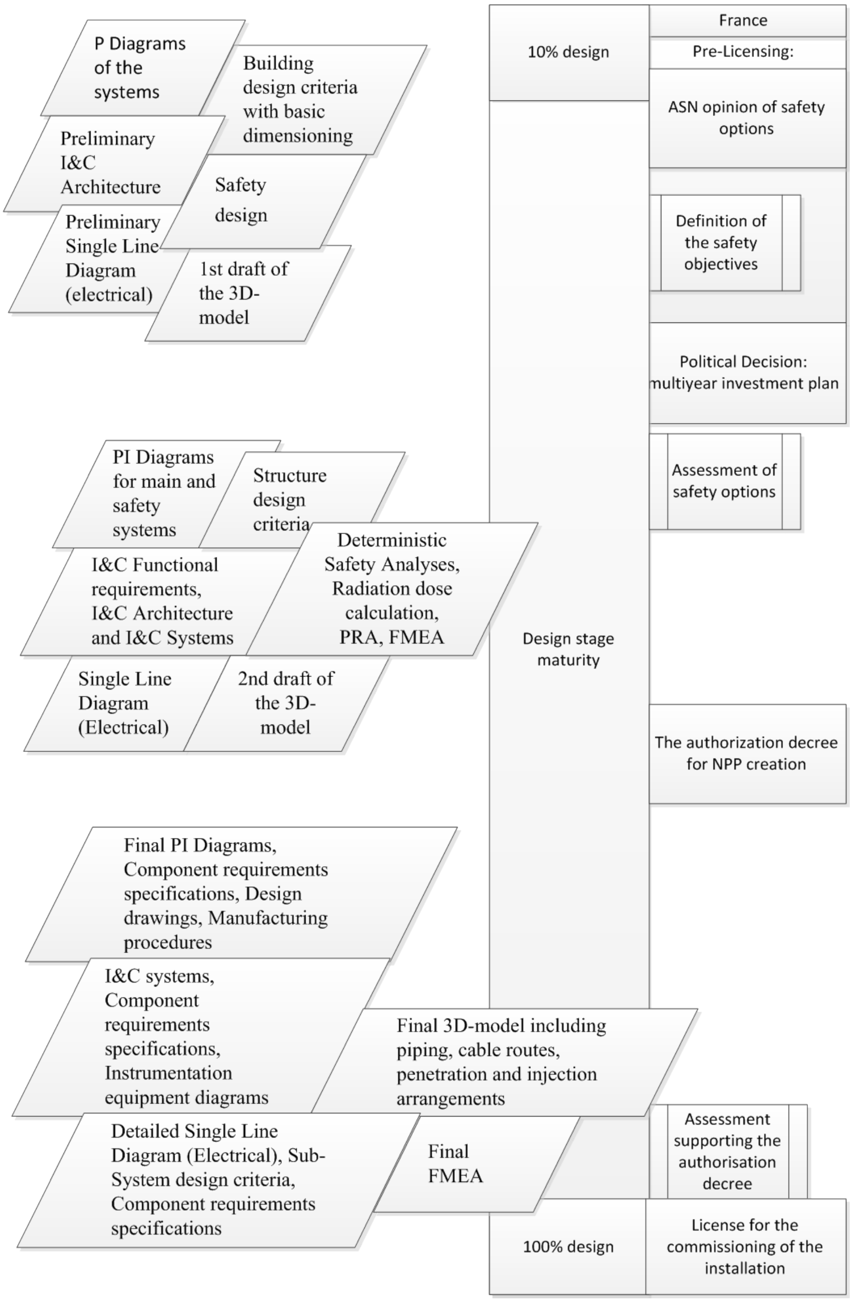


Figure 45 Design stages in connection with French licensing steps

Figure 45 presents the licensing steps and the corresponding design phases and gives an overview of the whole process. A general view of the licensing steps can be seen and the corresponding licensing steps in other countries can be compared.

The site approval process in the French regulatory framework would be handled well before applying for an authorization decree. As new sites have not been licensed in France lately, the experience of the site approval process with the current regulatory framework is not available. With the site approval, the licensee must inform the public authorities of its intention to build an NPP at a specific site. The review concerns mainly the socio-economic and safety aspects. The site approval process is divided into two different parts [97]:

- The ASN analyses the safety-related characteristics of the site: seismicity, hydrogeology, industrial environment, cooling water resources, etc.
- Other aspects are also part of the review, such as the consequences of the installation on natural life are included in the site approval process concluded by a decision of statement of public usefulness ("Déclaration d'utilité publique").

The site approval process and DUP ("Déclaration d'utilité publique" = statement of public usefulness) also involves a public inquiry, which allows the involvement of the general public. [97]

Overall, it can be stated that the French regulatory framework has been developed broadly in recent years, mainly due to the experience of the Flamanville new power plant project [97]. This development has also been seen in other nuclear countries with new NPP projects. All the projects in recent years have been FOAK projects and their licensing schedules have been quite long. As the lessons learned are to be implemented in the regulatory framework, the future NPP licensing processes might be quite different from the current ones.

5.3.4 The licensing process in the United Kingdom

The UK regulatory framework has been developed in recent years due to new NPP projects. The Office for Nuclear Regulation (ONR), an agency of the Health & Safety Executive (HSE), regulates nuclear safety in the UK. The HSE is sponsored by the Department of Work and Pensions. This ensures independence from the Department of Energy and Climate Change (DECC), the department which promotes nuclear energy within the UK. However, plans and legislation are in place to set up the ONR as a statutory company separate from the Government. This arrangement seeks to increase independence and allow more flexible arrangements. [52]

In the UK, there are many different regulators acting in different roles to regulate the activities of the UK nuclear industry. The licensing of a nuclear installation is the responsibility of the HSE, which is performed by the Office for Nuclear Regulation (ONR) (an agency of the HSE), and this is done under the Nuclear Installations Act 1965. However, other regulators are actively involved in controlling the activities of the UK nuclear industry. [109]
The different permissions, before construction or operation of any nuclear installation, are granted by different regulators. Presented here are the regulators with their respective roles in

nuclear regulation. The regulatory framework has gone through some changes lately and this represents the situation in 2013 [100]:

- The HSE's ONR grants Site Licences to the operators of nuclear power plants. The HSE reviews and approves the safety aspects of the design, manufacture, construction, commissioning, operation, maintenance, and decommissioning of the power plant. The management of radioactive waste at the site is also reviewed and needs approval before granting a license. ONR's responsibility in nuclear licensing is to grant a license to allow certain nuclear operations (including the operation of a nuclear reactor) on a specified site
- HSE's Office for Civil Nuclear Security (OCNS) (now also part of the ONR) regulates security issues in the UK. It is a responsible regulator concerninig physical security of nuclear material, IT security and security of nuclear material in transit. One of the OCNS reqponsibilities lies in inspection of people who access nuclear sites. OCNS requires and approves a site security plan, delivered by the licensee, before nuclear material arrival on site.
- The Environment Agency (in England and Wales) and the Scottish Environment Protection Agency (SEPA), regulate the following issues:
    - radioactive waste disposal, including discharges
    - abstraction from and discharges to controlled waters
    - operation of specific 'conventional' plant
    - assessment and, where necessary, clean-up of contaminated land
    - disposal of conventional waste
    - certain flood risk management matters

It also has wider responsibilities considering environmental permissions, with regard to Euratom Article 37 [96] requirements concerning the impact of nuclear sites on other EU Member States.

In the UK the safety regulatory framework is primarily goal setting, as has been discussed with regard to the Canadian regulatory framework as well. This indicates that no specific set of detailed regulations for the design of NPPs exists, and the general regulations set out targets in the form of risk targets. Basically, the licensee sets out how safety is to be ensured via safety documentation (the safety case), which is assessed by the ONR as deemed appropriate. Once approved by the ONR they cannot be modified without the ONR's approval. The licensees' activities are subsequently inspected to ensure compliance with this safety documentation. The basis of a safety case exists in a risk assessment and low dose rate due to the application of the ALARP (" As Low As Reasonably Practicable") principle. [121, p 115]

The UK regulatory framework is based on a one-stage licensing process. The nuclear license is called the Nuclear Site Licence in the UK. [110]

The design of new civil power reactors in the UK has adopted a new approach called Generic Design Assessment (GDA), which assesses the design of a proposed NPP prior to a site being selected or potentially could be located at multiple sites. This is not part of the licensing arrangement but it enables design assessment by the regulator prior to a Site Licence being issued. [52]

The GDA process is aimed at new power reactor designs and it will be undertaken before a site-specific license application is made. The outcome of the GDA is a statement of Design Acceptance Confirmation (DAC). The GDA does not replace the licensing process, but it will be an important factor in the HSE's licensing decision. Requests for a GDA will normally originate from a reactor vendor and operator partnership.
If the GDA process is completed, the licensing process would be expected to take around one year from the Site Licence application to the completion of the licensing process (depending on various factors). [52]

The Site Licence in the UK can be compared with the construction license in Finland, as the Site Licence approval gives permission to start the construction activities for an NPP. The Nuclear Site Licence sets additional requirements in the form of License Conditions, which once the Site Licence is issued the Licensee must comply with.

The basis of the GDA process, the interfaces between different parts, and the timelines are presented in Figure 46.

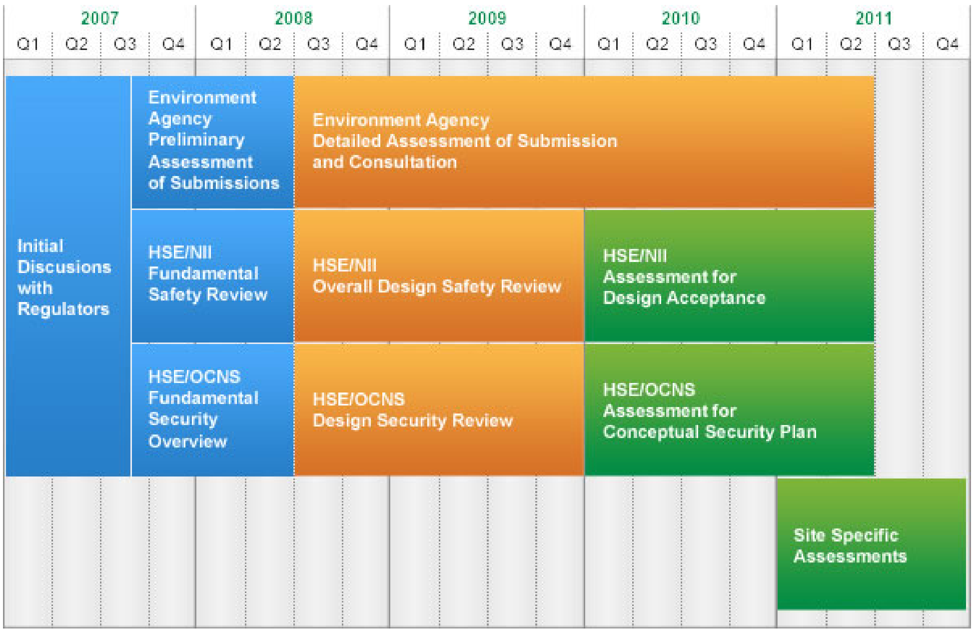


Figure 46 Generic Design Assessment timeline for the first GDA processes in the UK [103]

The regulators work together to provide an integrated approach to the GDA, but they each have a different legislative regime which will lead to some necessary differences in approaches.

Figure 47 outlines how the regulatory process within different regulators fits together.

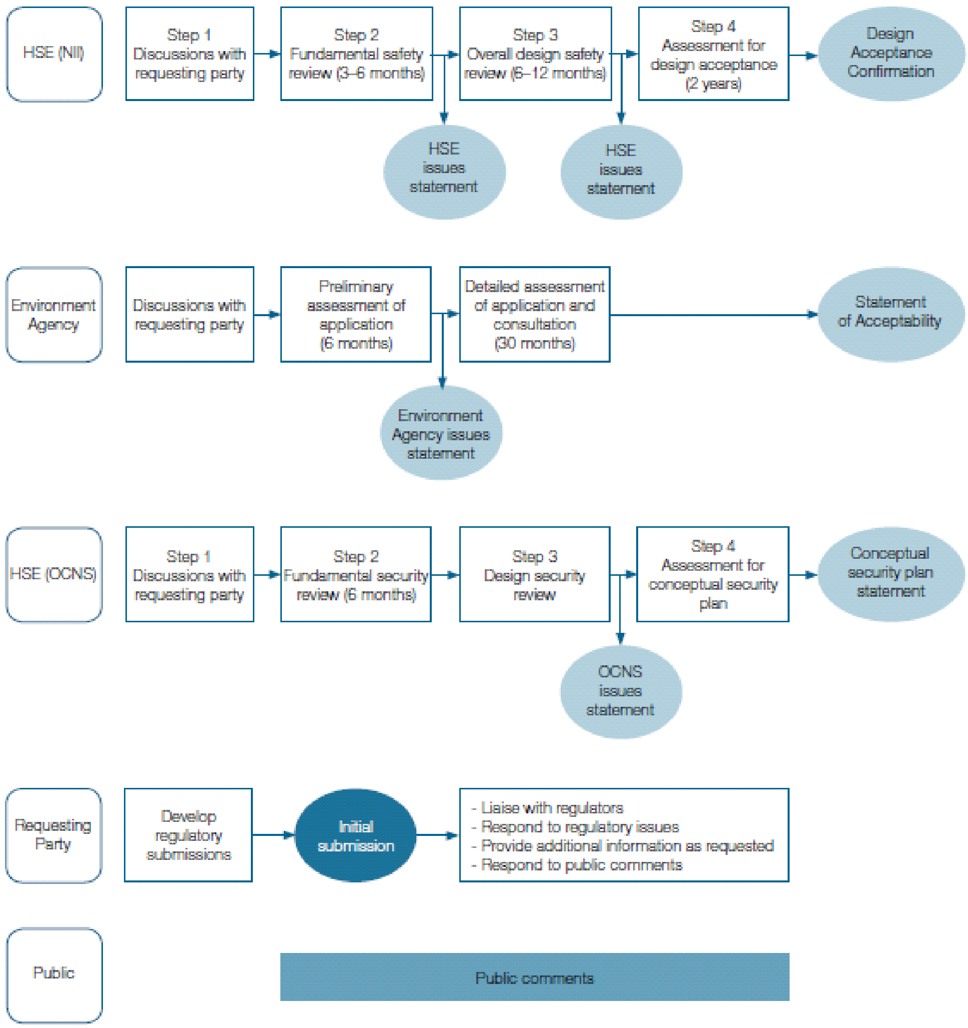


Figure 47 Outline timetable: Generic Design Assessment [105]

The figure presents the different steps included in the GDA process. The review within the HSE ONR, as well as the HSE OCNS, can be divided into four steps. Statements are also issued by the regulators after certain steps, which can be understood as hold points for the regulatory reviews.

As it has already been stated, the requests for a GDA will normally originate from a reactor vendor/operator partnerships. For example, in the UK, the EPR was submitted for GDA by EdF Energy (as the prospective operators) and AREVA jointly, and the Hinkley Point C Site Licence application was subsequently submitted by the EdF Energy NNB Generation Company Ltd. The DAC was granted for the UK EPR in December 2012. The Site Licence was granted on November 26, 2012, for Hinkley Point C in Somerset, to build two EPRs [112]. The AP1000 was submitted for GDA by Westinghouse in partnership with Horizon Nuclear Power. The GDA process on the AP1000 is still on-going; however, the proposed operating company was sold to Hitachi GE who is now requesting the GDA for the Advanced Boiling Water Reactor (ABWR) which will start during 2013.

During the GDA process, the ONR will carry out a detailed assessment of the safety elements of the design, based on a submission made by the Requesting Party. More information on this is set out in the Nuclear Power Station Generic Design Assessment (GDA): Guidance to Requesting Parties in reference. [105]

The intention of the regulators is to handle the GDA process in a transparent and open manner. To ensure that transparency, the following requirements have been set [52]:

- the Safety, Security and Environment Report provided for GDA shall be made available to the public by the Requesting Party
    - Exceptions are sensitive nuclear information, and commercially confidential information
- Comments from the public to the Requesting Party during the GDA process shall be invited and responded to
- The public comments, as well as response from the Requesting Party, shall be considered during the assessment of the design
- The licensing process shall be monitored and views on the main issues shall be published
- The process shall be developed for more general public and stakeholder engagement

Previously, public hearings on the design of a new nuclear power station did not take place during the licensing process. This is a change from the process that was undertaken for the Sizewell B power plant in the 1980s . However, some public hearings are held as part of the awarding of Planning Permission. [52]

Where applications are made for site-specific permissions (nuclear Site Licence, environmental authorizations and permits, and security plan approval) the regulators will follow their existing procedures. Where these site-specific applications are based on a design that has undergone GDA, the regulators will take full account of the work that they have already carried out and the advice that they have provided. [104]

Figure 48 outlines how these processes fit together.

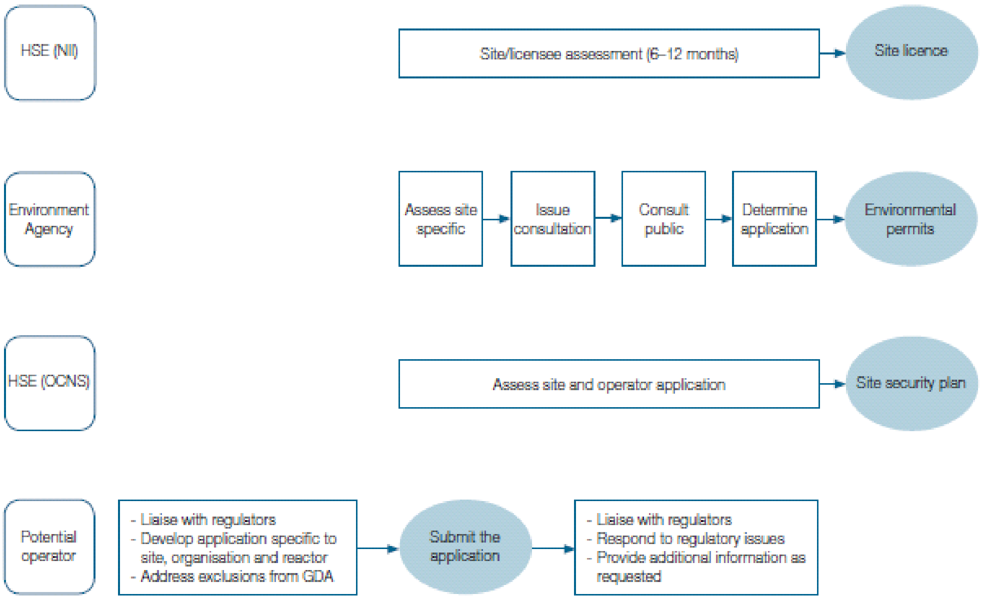


Figure 48 Outline timetable: Site assessment/licensing [104]

The GDA process is separate from the official licensing process, however, the different licensing steps are related. After the completion of the GDA the following are needed in connection with the Nuclear Site Licence process, since these cannot be handled during the GDA process [52]:

- site-specific aspects not covered by the generic site envelope
- other site-specific aspects
- any other changes to the design or safety documentation since the GDA
- assessment of the license applicant's organization
- consideration of any exclusions in the HSE's statement of DAC.

It is anticipated by the HSE that most potential nuclear power station operators will prefer the design to have completed the GDA process before submitting a Site Licence application. This is likely to make the process more efficient. If the GDA process is not completed, the licensing process will take longer to complete. However, it is still possible to apply directly for a Site Licence without the GDA.

It is estimated that the licensing process would take around one year from the Site Licence application to the completion of the licensing process (on the assumption that the GDA process has been completed) [52]. However, the duration of the licensing process depends on various factors, including:

- the adequacy of the Step 2 license application documentation (see Table 11)
- the number and type of exclusions in the HSE's statement of DAC

- the novelty of the licensee applicant's organizational structure
- the number of Site Licence applications that the HSE is considering in parallel.

The stepwise Site Licence process in the UK is presented in Table 9. A detailed representation of the step-wise licensing process in the UK can be found in reference [52].

Table 9 Stepwise licensing process in the UK [108]

1. Preparing to be a licensable organisation	Establish corporate body Develop organisational capability Develop management arrangements	Advise applicant
2. Creation and collation of licence application dossier	Identify activities to be licensed Address the following: > site safety documentation and proposal to deliver a schedule of safety submissions leading to pre-construction safety report (PCSR) > develop organisational capability, company structures, governance and procedures, including: – safety management prospectus – company manual – nuclear baseline – intelligent customer – design authority – internal challenge – procurement – licence condition compliance arrangements – emergency arrangements – nuclear safety committee terms of reference – definition of site and arrangements to demonstrate security of tenure	Advise applicant
3. Licence application	Submit application to ONR Notify DECC Secretary of State	Acknowledge receipt
4A. Nuclear site licence assessment	Continue to develop organisational capability, arrangements and safety case Agree position on nuclear liability insurance with DECC Prepare funded decommissioning plan	Assess site, organisation, facility safety case and adequacy of licence condition compliance arrangements Decide whether public body notification is required prior to grant of licence (NB not required for new power station sites). If yes, issue NIA65 section 3(3) direction to licence applicant

4B. Consultation	Respond to ONR direction under NIA65 section 3(3) to notify public bodies having duties in relation to the site (not applicable to civil power reactors)	Consider responses from public bodies Formally consult relevant environment agency as required by NIA65 section 3(6A) Consult DECC on applicant's financial standing and nuclear liability insurance
5. Granting of licence	Formally confirm readiness to receive licence	Produce licensing report Grant nuclear site licence
6A. Regulation under the licence – Construction	Continue developing PCSR to support stages of construction Maintain control and oversight of all safety significant matters Sustain adequate organisational capability to manage for safety Implement licence condition compliance arrangements and ensure continued adequacy Manage construction activities and modifications to design and organisation Prepare pre-commissioning safety report (PCmSR)	Licence instruments to permission progress from one stage of construction to the next using primary powers or derived powers under licensee arrangements as necessary Confirm FDP is in place before permission to commence nuclear safety-related construction Continued inspection and regulatory oversight of the plant, the licensee organisation, the development and implementation of the safety case and compliance with the conditions attached to the nuclear site licence
6B. Regulation under the licence – Commissioning	Maintain control and oversight of all safety significant matters Sustain adequate organisational capability to manage for safety Implement licence condition compliance arrangements and ensure continued adequacy Manage commissioning activities Prepare pre-operational safety report (POSR)	Licence instruments to permission progress from one stage of commissioning to the next using primary powers or derived powers under licensee arrangements as necessary Continued inspection and regulatory oversight of the plant, the licensee organisation, the development and implementation of the safety case and compliance with the conditions attached to the nuclear site licence
6C. Regulation under the licence – Operation	Safe operation and maintenance of the plant Maintain control and oversight of all safety significant matters Sustain adequate organisational capability to manage for safety Implement licence condition compliance arrangements and ensure continued relevance	Licence instruments to permission start of operations using primary powers or derived powers under licensee arrangements as necessary Continued inspection and regulatory oversight of the plant, the licensee organisation, the implementation of the safety case and compliance with the conditions attached to the nuclear site licence

Before granting the Site Licence the HSE will need to examine the Pre-Construction Safety Report (PCSR) to assess whether the operations at the site will be adequately safe. A PCSR can reference a safety case considered in a prior Generic Design Assessment, but will need to include additional information relating to the site-specific application. The construction of the plant may start after granting the Site Licence. Currently, the ONR has granted the Site Licence for Hinkley Point C; however, the licensee is not able to pour the first nuclear safety-related concrete until a number of design issues have been resolved.

Once the nuclear Site Licence has been granted, the licensee must comply with the relevant provisions of the Nuclear Installations Act 1965 and all the conditions that the HSE has attached to the license. It should be noted that the term ‘operation’ in the UK covers construction, commissioning, operation, maintenance, modifications, decommissioning, etc. The license, as well as the license conditions, applies at all time. The licensing process continues after granting the Site Licence due to regulation. As presented in the Table 9. there are licensing steps or regulatory hold points: 6A Regulation under the License - Construction, 6B Regulation under the License - Commissioning, 6C Regulation under the License - Operation.

During the construction, when acting according the license, the HSE may agree a set of hold points with the licensee. These hold points allow the HSE to oversee the progress throughout the construction.
The licensee will not be allowed to proceed past a hold point without the HSE issuing the corresponding permission.
An example of a set of possible hold points that might be applied during the construction phase includes [52]:

- pouring of foundation concrete
- first permanent concrete structure
- installation of reactor pressure vessel
- installation of reactor coolant pump support legs
- start of pre-stressing of primary containment
- start of primary safety system functional tests
- primary circuit hydrostatic test
- delivery of fuel to the site.

There may also be hold points related to the licensee’s organizational structure and organizational development. An adequate organization ensuring safety throughout the construction and commissioning period must be demonstrated.

When the permission to start the commissioning has been issued, commissioning may start. The licensee must comply with all license conditions.
When proceeding to operation, all the issues arising from the assessment of the Pre-Operational Safety Report as well as issues from commissioning shall be inspected and resolved satisfactorily.

Figure 49 helps to understand the UK licensing process steps in connection to the plant design process. A three step design process, including plant design phase, system design phase, and component design phase are indicated on the left, while the UK licensing process is presented on the right. The figure shows the licensing steps are connected with the design phases and provides an example set of regulatory holdpoints, giving an overview of the whole process. It also gives a general view to be compared with other countries' corresponding licensing steps and the design maturity in corresponding licensing stages.

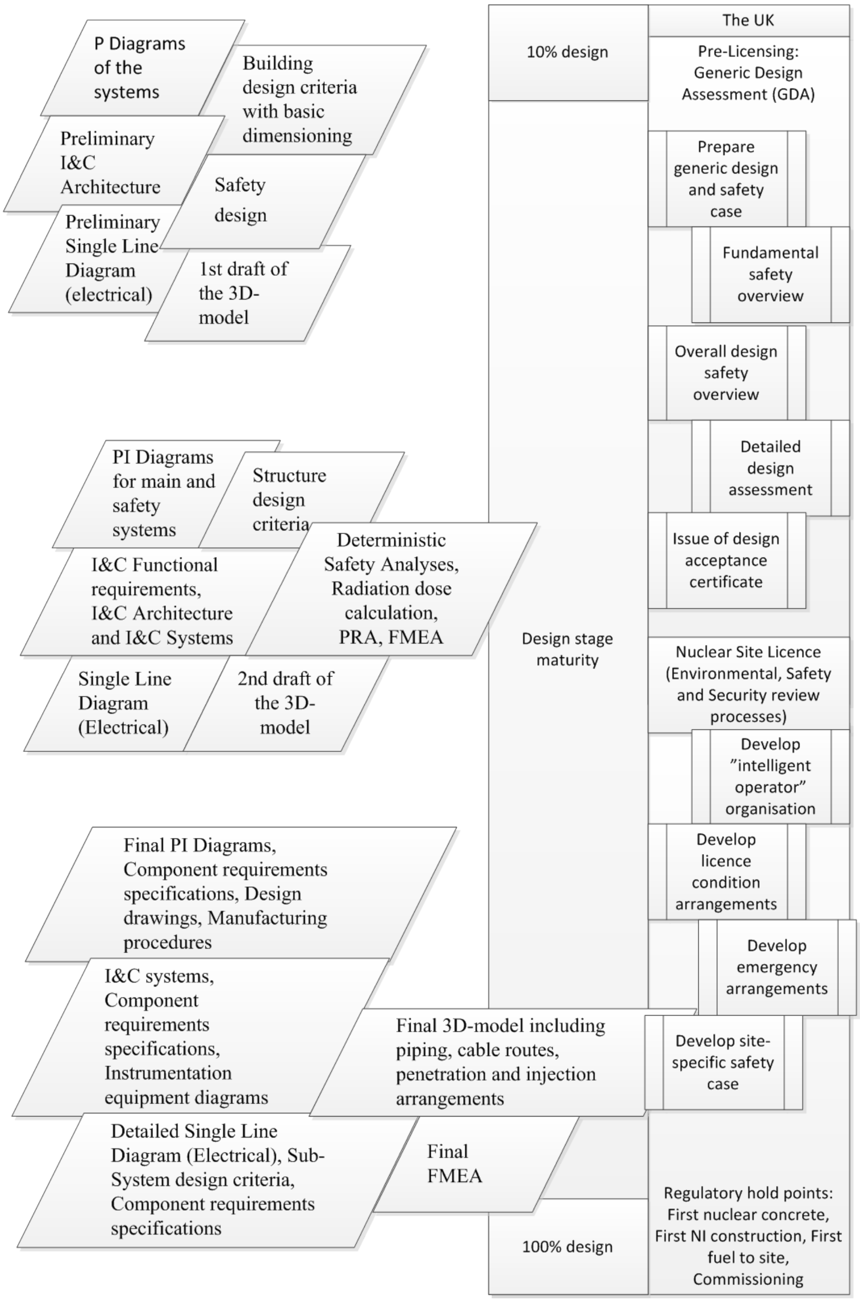


Figure 49 Design stages in connection with the UK licensing steps as well as regulatory holdpoints as an example

The nuclear licensing process in the UK has been developed widely in recent years. The overall functionality of the process cannot be evaluated at this point since the experience is quite limited. In the near future, with new licensing activities in the UK, it can probably be seen how this licensing process responds to the challenges of contemporary nuclear licensing.

5.4 Licensing and permitting in other safety critical industries

Licensing and permitting processes in other selected industry fields have been studied. The chosen fields of industry are the aviation and railway industries. These fields have been selected because of their safety critical nature and the availability of public information. The licensing and permitting principles are presented in international framework. However, the examples of the stakeholders are selected from Finland.

There are similar types of licensing and permitting processes in the aviation and railway industries with certain restrictions. For the aviation industry, the military (Finnish defense forces) and commercial (Finnair) aviation, including Finnish regulator TraFi (Finnish Transport Safety Agency), have been studied.

In the military field the licensing is quite different from the nuclear field, and the availability of relevant information is not that wide. In the defense forces the regulator is an internal organization and their processes are quite unique. After careful consideration it was decided that the focus of this study should be directed towards the commercial aviation field. It is clear that due to the development in the commercial aviation industry in past decades, the nuclear industry may learn from the regulatory processes in the aviation industry.

In the railway industry the main stakeholders in Finland are TraFi (Finnish Transport Safety Agency), the Finnish Transport Agency, and VR Group. Trafi is the National Safety Authority (NSA) and functions also as the Regulatory Body for the railway system. The Finnish Transport Agency is responsible for the organization of the maintenance and construction of the state railway network. VR Group is one of the responsible organizations for operation and maintenance activities.

The stakeholders in the aviation and railway industries have been studied using public data for the licensing issues, as well as outlined interviews with licensing specialists from the selected organizations. The interviews with some of the main questions are presented in Appendix 2.

5.4.1 Commercial aviation industry licensing and permitting

Aviation industry licensing is comparable with nuclear licensing, since both industries operate within global and highly regulated regimes. Both industries also share a goal of excellence in safety and reliability. There are, however, differences to be acknowledged. The transportation of objects is the basis of the aviation industry, but this is not the case in the nuclear field. This brings the need of international acceptance of the aircrafts to enable flights from one country to another. Another major difference is the issue of public perception that plays a great role in the nuclear industry, but less so in the aviation sector. Even if not all aspects of aviation industry licensing are eligible for transfer to the nuclear field, some of them are.

In the civil aviation industry, safety has been improved in the last decades. The rate of fatal accidents has decreased as indicated by the EASA [38]. International standardization and the harmonization of design approval have played a central role in this development, as well as the change of management procedures. In the aviation industry, safety requirements are set by an international organization, the ICAO (International Civil Aviation Organization) [68], which is the main stakeholder in licensing. The ICAO is based on the 1944 Chicago Convention on International Civil Aviation [42]. A set of binding international minimum standards are defined in Annex 8 of the Convention. These minimum standards are supplemented by national airworthiness regulations.

The ICAO makes political decisions, referred to as SARPS (Standards and Recommended Practices). The decision making process in the ICAO is quite long and slow. ICAO requirements are transferred to European and national level regulations.
When comparing the aviation industry with the nuclear industry, the ICAO can be compared, for example, with the IAEA. The main difference in the processes is that in the nuclear field countries are responsible for the licensing having a high level of independence for their licensing practices, while in the aviation filed there are certain international and national organizations under the ICAO that handle part of the licensing process.

The licensing of an aircraft is based on Type Certification and registration. A Type Certificate is issued by the state of origin for the aircraft design. In addition, an airworthiness certificate is issued for each aircraft in the state in which the aircraft is registered. Type Certification is not automatically valid internationally, but the authorities collaborate through bilateral agreements. The corresponding authority finds a group of experts from the aviation authorities of other major countries for the design review. This process provides for a Type Certificate in all the involved countries simultaneously. [42]
The original designer is involved in the response to events and safety-relevant findings throughout the lifetime of an aircraft design. Further design work concentrates on design improvements that are required due to the experience of severe events, these are introduced as Airworthiness Directives.

Certificates in the aviation industry can roughly be compared with nuclear licenses. A Type Certificate can be compared with Design Certification (used in some nuclear countries) and Airworthiness Certification can be compared with a specific NPP operating license. The difference is that in the nuclear industry these licensing steps and certificates are nation-specific, they are not internationally valid.

The regulatory level below the ICAO in Europe is the EASA (European Aviation Safety Agency), established in 2002 [37]. The EASA is an agency of the European Union, whose function is to provide regulatory and executive tasks in the field of civilian aviation safety. In the USA, the corresponding organization is the FAA (Federal Aviation Administration).

The EASA is competent to issue Type Certificates valid in all EU Member States. The EASA also sets, for example, the operating criteria for airlines and European airworthiness requirements.

The agency's responsibilities include:

- Expert advice to the EU for drafting new legislation;
- Implementing and monitoring safety rules, including inspections in the Member States;
- Type-certification of aircraft and components across all EU Member States, as well as the approval of organizations involved in the design, manufacture, and maintenance of aeronautical products;
- Authorization of third-country (non-EU) operators;
- Safety analysis and research.

International cooperation issues also include bilateral airworthiness agreements. These agreements enable national authorities to accept the design review work done by the regulator of the state of design. If necessary, they only assess compliance with the requirements, which differ from those of the state of design. Even with such an agreement, the authorities may still choose to perform a full review.

The background of the EASA lies in the JAA (Joint Aviation Authorities), which was an alliance of regulatory authorities of a number of European countries. The JAA had an agreement to cooperate in developing and implementing common safety regulatory standards and procedures [37]. In the nuclear industry field, the JAA could be compared to the current situation of WENRA, which is pursuing the harmonization of nuclear licensing requirements in Western European regulatory bodies.

The EASA and FAA have been harmonizing the safety requirements for commercial aircraft so that certifications in USA and in Europe are comparable. Certification Specifications (CS) set the requirements for different type of aircrafts, such as the CS-25, which is for large aircraft that are mainly in commercial use. The harmonization of the requirements is focused on the CS-25 because of the large number of this type of aircraft.
The focus of the development has shifted lately towards more integrated collaboration of regulators and a common approach to certification, which was included in the Cyprus arrangements in 1990. [39]

Lessons that can be learned from the aviation industry are described in the WNA Report: Aviation Licensing and Lifetime Management – What Can Nuclear Learn? [178] The following lessons have been indicated in the report:

- "Achievement of an UN-backed political agreement on the acceptance of basic safety requirements (Chicago Convention Annex 8).
- The design licensing (type certificate) process and bi- and multilateral acceptance agreements.

- Design change management and maintenance of type certificate throughout the lifetime of an aircraft design.
- Execution of the design authority role by manufacturers.
- Maintenance of the responsibility of national regulators within an internationally agreed framework." [178, p.3]

The requirements of the EASA are formulated in a way that the requirements are general and the declaration part gives more specific information of interpretation of the requirements. This is a good example of an approach that could be implemented also in nuclear licensing and has already been the trend in certain countries' nuclear regulation.

In aviation, each country has its own regulations (airworthiness codes), as well as its own regulatory authority (national aviation authority). In Finland TraFi monitors and controls the fulfillment of the requirements that are set mainly by the ICAO and the EASA. TraFi handles the licensing of airlines, registers aircraft, verifies the airworthiness of planes, handles inspections of airplanes and airline audits, etc. [44] It should be observed that the strong international framework for safety does not interfere with the authority of individual states [178, p.4]. It is stated in the Chicago Convention: "It was recognized that the ICAO standards of airworthiness would not replace national regulations and that national codes of airworthiness containing the full scope and extent of detail considered necessary by individual states would be necessary as the basis for the certification of individual aircraft. Each state would establish its own comprehensive and detailed code of airworthiness." [67] Possible deviations to ICAO standards must be published. The worldwide framework for aviation regulation does not transfer the responsibilities, but only sets a framework for regulators.

In the nuclear field, the international approach through the international agencies' recommendations does not differ that much from the aviation industry practice, but international cooperation should be more unified. The main difference is that there is no single convention in the nuclear industry that could be compared with the Chicago Convention. The Convention on Nuclear Safety does not include a real enforcement mechanism. Besides, the Convention on Nuclear Safety obligates states to implement regulatory systems which take into account safety issues. It does not establish any safety requirements in the same way as the Chicago Convention does in the aviation industry.

The comparison in Figure 50 was presented in the WNA Report [178, p. 6]. In the Aviation pyramid, only the ICAO Annex 8 is mentioned. However, many other standards also exist for this purpose.

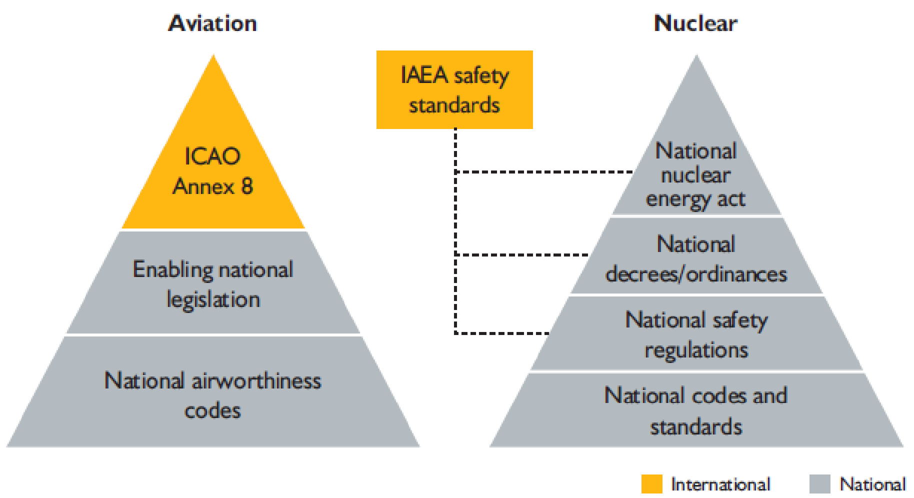


Figure 50 Hierarchy of the safety regulation system ('regulatory pyramid') in the aviation and nuclear industries [178, p. 6]

For each aircraft design approval, the designer must first apply for a Type Certificate from the state of design. In some countries, the design organization itself also needs an approval. In Europe, this is called a design organization approval (DOA).

In the nuclear field there are different approaches to design approval practices. In the USA, for example, design certification is applied for by the designer. In the UK, the practice is that a "requesting party" applies for the GDA. The "requesting party" can be either the designer alone (with certain indication of an interest from possible buyers), or the designer together with the possible buyer. In Finland, the owner/buyer (operating organization) is responsible for the licensing. Comparing this situation with the aviation industry, the designer issues the Type Certification. The regulatory body that approves the aircraft certification in Europe is the EASA and the certification process lasts typically about three years. This is also a different feature between the aviation and nuclear industries. The duration of the licensing process is much longer in the nuclear industry compared to the aviation industry (see section 5.4).

Similarities between the aviation and nuclear industries can also be found in the documentation. The airplane or plant designer produces documentation for certification/licensing. The aircraft is presented in the AFM (Aircraft Flight Manual). The AFM includes a description of the aircraft systems, operation, restrictions, etc. The AFM can be compared with the FSAR in the nuclear field. Other comparable documentation includes the Minimum Equipment List (MEL) in the aviation industry and Technical Specifications (or Operating Limits and Conditions, OLC) in the nuclear field, which includes the operational limitations, single-failures, common cause failures, and the operating principles in case of failures. The MEL presents the minimum functions with which an aircraft can be flown.

5.4.2 Commercial railway industry licensing and permitting

The railway industry's licensing process can also be used as a comparison because the safety criticality of the railway industry can be compared with the nuclear field. There are, however, differences similar to those in the aviation industry. The transportation of objects is again the basis of the railway industry, which is not the case in the nuclear field. As in the aviation industry, the railway industry also does not have to deal with public perception as an issue to the same extent as the nuclear industry. However, even with certain differences, there are many similarities in these fields of industry.

In the railway industry the licensing process in less complicated than that in the aviation or nuclear fields. In the railway industry all the components (railway engine, railway carriage, etc.) are licensed separately, as well as the related infrastructure. The interest groups in the railway licensing process are the licensee (owner or manufacturer organization), National Regulator, Notified Body (on European level) and Independent Safety Assessor. This framework can also be seen in the nuclear industry, depending on the country and the licensing practices. However, the regulatory body in nuclear field is always a nation level actor. A European level regulatory body does not exist.

In Finland, the National Regulator (TraFi) has a central task to monitor and develop railway safety and the interoperability of the railway system. TraFi prepares new national regulations, and estimates the need and also grants an authorization for placing into service. TraFi works in close cooperation with the European Railway Agency, the European Commission, and the national safety authorities of other EU Member States.

The requirements in the railway industry are divided into harmonizing EU requirements (for harmonizing the railway industry within Europe) and specific technical requirements in Finland. With the production of new safety systems, TraFi requests CENELEC standards to be used, which means in practice the use of EN 50126,50128 and 50129 standards.

The requirements are divided in the Finnish Transport Agency into different levels according to Figure 51.

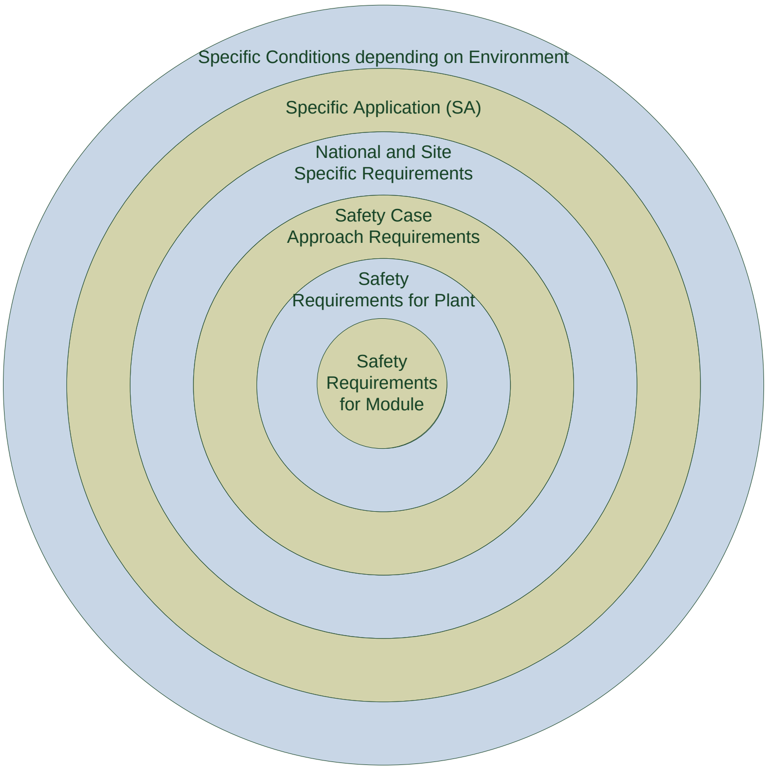


Figure 51 Requirements division into six levels in the railway licensing process in Finland

Different levels of requirements have been discussed in interviews with railway licensing professionals, carried out as semi-structured interviews. The interview outline is presented in Appendix 2. The licensing of the different levels can be done separately or as the specific application only if it covers "all the circles". The General Product (GP) is a component or a certain part of the system that can be licensed separately. After this GP licensing, the requirements on the European level, EN Requirements, are issued. These requirements are at a quite general level and they are issued first in the licensing process. After this phase, the Generic Application is applied. After the Generic Application, only the country-specific requirements are issued. These country-specific requirements take into account the special conditions and requirements in a single country. For example, in Finland the ambient conditions are quite different from Spain or other countries in Southern Europe due to the different environmental limitations and climate.

The licensing process in the railway industry is based on Authorization for Placing into Service. The Finnish licensing process is presented in Figure 52.

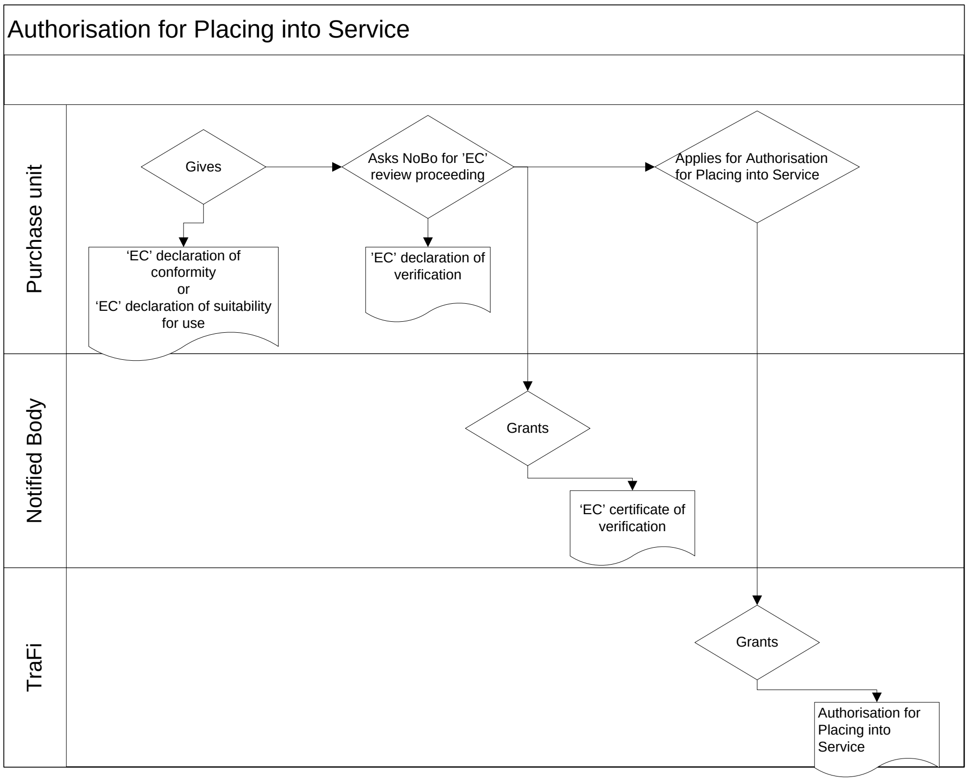


Figure 52 The Finnish process for Authorization for Placing into Service in the railway industry

The process for Authorization for Placing into Service in the railway industry has been discussed in semi-structured interviews with licensing specialists. The basis of these interviews is presented in Appendix 2. The European level approvals are getting more importance in railway industry and the direction is towards similar approach with the aviation industry (EASA). The licensing process used in the railway industry does not have that many common features with the nuclear industry that it could be used to improve the nuclear licensing process. However, the requirements architecture does have corresponding features.

5.4.3 Applicable features to implement to the SMR licensing process

European licensing practices, being the focus of this study, can learn certain suitable practices from the aviation and railway industries.

In the aviation industry, a high degree of trust has been achieved between the USA, Europe, and a few other countries. This is one feature that could be adopted by the nuclear industry licensing process. To make it possible, the development of more harmonized licensing processes is required. The countries could then recognize and even accept licensing conclusions from other licensing jurisdictions. It is recognized that this needs to be done by recognizing a country’s sovereign right to perform an independent licensing review. Some initial steps towards this have been taken in, for example, the MDEP framework, in which the UK, Finland, and France have shared their high level assessments of the same design.

Harmonization of European standards has been seen in the aviation industry. The international harmonization efforts of the nuclear energy area are described in section 5.2.
The nuclear licensing process has been studied in the ERDA working group, which is developing parts of the licensing process in a more harmonized direction. The aviation industry has already reached standardized requirements between Europe, the USA, and some other countries. The actual aviation licensing process in different countries does not play that big a role in licensing, even if the liability for licensing remains within the countries because of the international approval of a certain country's certification of an aircraft. This is a very encouraging development to apply at a certain level also in the nuclear industry.

One lesson to be learned from the aviation industry concentrates on the requirements based licensing. The licensing requirements split into two separate parts that are applied also in certain countries' nuclear licensing and could be even more beneficial in the nuclear industry. The two parts are: a general requirement part and a declaration part. This approach is also used in certain international requirements in the nuclear field. The situation though in the nuclear field is that these international requirements (such as IAEA requirements) are not used as licensing requirements, but as references behind the nation-specific licensing requirements. If every nuclear country had similar approach to licensing requirements, it would formulate the licensing requirements into a more standardized format, making them easier to be compared. This approach has the benefit of keeping the actual requirements at a general level and not pushing the design in a certain direction.

The distribution of requirements at different levels, as presented in Figure 51, could be applied also in the nuclear field, to some extent. This is done in the following. Requirements for the reactor module (Nuclear safety requirements), Requirements for the unit (parts other than the reactor module and safety systems), Safety Case approach, National (site) specific requirements, can be applied.

1. Safety Requirements for Module
   The inner part of the requirements is targeted at the reactor module and connected safety systems (which are independent in SMRs). These requirements would build the basis of nuclear safety. Requirements in this level do not have many differences internationally, since the differences from, for example, the site and safety classification are mainly focused on other parts of the design.
2. Safety Requirements for Unit
   The second layer would focus on the unit parts other than the module. These requirements might differ from one country to another, but they would not influence the Design Certification of Module. These requirements could be applied with a graded approach, using a risk-based consideration.
3. Safety Case Approach Requirements

The third layer would consist of the requirements for a safety case, representing the most limiting initiating events for transient events and accidents in different categories. This means the confidence of the plant design would be approved. Since the approach in different countries differs quite extensively when applying licensing analyses, which are one of the main indicators of successful licensing, there is a long way to go to standardize these requirements.

4. National- and Site-Specific Requirements
   The outer layer could concentrate on the site-specific issues and country-specific requirements. This would cause the main differences both in licensing process and in regulatory requirements. The site-specific issues could be handled at this level, with necessary interface analyses to the other layers' requirements.

It can be seen that both the aviation and railway industries have the same kinds of features with the nuclear industry. With SMRs the similarities are even wider when an SMR module can be compared with, for example, an aircraft or a train. In all the cases, the target is a complex ensemble with independent safety features.

6 FINDINGS

The object of this chapter is to answer the second sub-question: "What parts of different licensing processes could be feasible for the SMR licensing process?" This chapter presents a comparison of different countries' licensing process features across selected licensing process phases, giving indications of suitable licensing practices for SMR licensing.

6.1 Comparison of the licensing processes in the studied countries

There are many similarities as well as differences in the licensing practices in different countries. All of the studied licensing processes have been under review and further development in recent years. The USA has developed a standardized process that is relatively similar for each licensee; however, the process is still very long and cumbersome. US practice, with separate licenses for a standard design (Design Certification) and Early Site Permit for a specific site, with COL (Combined License) to operate and construct at a specific site, is designed specifically for large nuclear countries, with many copies of a single design. The UK is moving in the same direction as the US, by introducing the GDA process. In Finland, the licensing processes for nuclear facilities are issued on a project by project basis. There is no license or certification for a standard design. This is a suitable way to handle licensing in a country with a small number of NPPs, or many different NPP designs.

The licensing process development in the studied countries emphasizes early conversations with the regulatory body. Public involvement has also been increasing in the process; in the USA, it has played a big role for a long time. The USA has begun to focus on SMR licensing issues, generating Standard Review Plans for the mPower LWR SMR design [73] and planning for SMR licensing within the current regulatory framework. Basically, SMRs in the USA are to go through the same licensing processes currently in use for large NPPs (CFR Part 50 or CFR Part 52).

This licensing process comparison study is focused on the early phases of the licensing as already described in section 2.1 and presented in Figure 1. From the lifecycle stages, the siting and site evaluation, design, and construction are dealt within this study. To a certain extent, the operation stage is also discussed, in terms of the operating license. The information that has been used to estimate different licensing process steps is gathered from different documents, from interviews with selected licensing professionals in the studied countries, and through questionnaires sent to the studied countries, to professionals from both the industry and regulatory sides. The questionnaires as well as research methodologies are introduced in Chapter 3.

The features, which are compared between the regulatory frameworks in different countries, are: licensing steps and their similar features, as well as durations of different licensing steps. The justification of the comparison is based on the realized NPP projects or presented estimation of the durations by regulatory bodies.

6.1.1 The licensing process in Finland for comparison

The approval processes for a site in Finland essentially starts with the Environmental Impact Assessment (EIA or, in Finnish, YVA - Ympäristövaikutusanalyysi). The EIA is not a permission or license itself, but only an assessment of the impacts. The EIA and the preliminary safety assessment are the basis for the Decision in Principle in Finnish nuclear licensing. This part of the decision making process in Finland has been quite well standardized, because this process has been gone through four times in past years (Fin5 for OL3 and OL4, FV1 and Loviisa 3 in 2010). The political part of the Decision in Principle process, including government and parliament decision making process, take formally about one year. For example, Fennovoima has presented its project schedule in reference [69]. The preparation of the EIA has been estimated to take two years. For example, the EIA process for TVO's OL4 project started at the beginning of 2007 and the Decision in Principle was applied for in 2009. [138]

In this dissertation, the Olkiluoto 3 (OL3) case has been used as a basis for the schedule and duration of different licensing steps in Finland. Approximations about the duration of the Olkiluoto 4 (OL4) [139] and Fennovoima 1 (FV1) [44] projects have also been used to estimate the duration of different licensing phases. Figure 53 presents the Olkiluoto 3 licensing steps as they have been described by STUK [78].

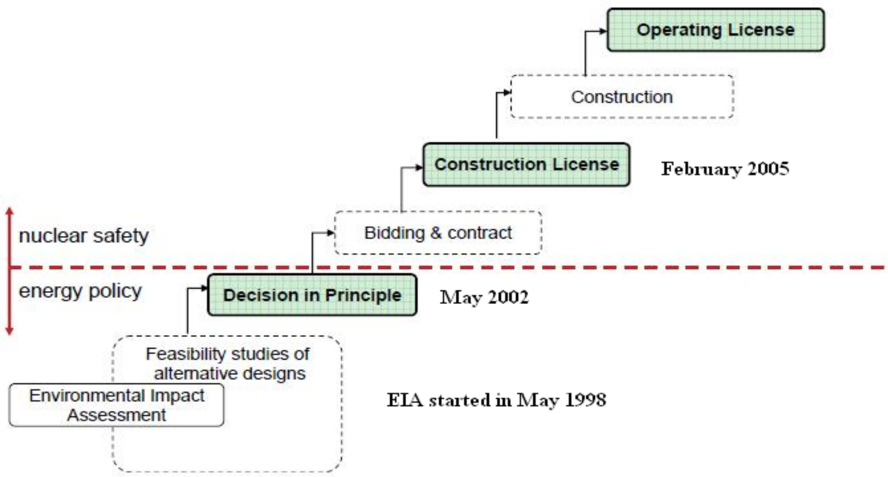


Figure 53 Licensing steps of the OL3 project [78]

The construction license phase needs to be estimated not only based on the OL3 experience, but also using the OL4 and FV1 estimated licensing schedules. For OL3, the construction license phase was very short and it took only one year (01/2004-02/2005) [137]. This CL process can be claimed to have been situated too early in terms of design stage and, in future projects, the design stage is expected to be much further advanced when applying for the construction license. The CL process has also been developed since the OL3 experience lessons learned and for future projects (and OL4 and FV1) the process will be more standardized and the process will take at least 18 months to go through.

The oversight during construction is the phase in the Finnish licensing process between the construction license and the operating license. This phase is not a formal licensing step in the Finnish regulatory framework, but it is defined as a regulatory approval phase. This phase was presented in section 5.2.3 . As an example of the duration of this regulatory approval phase, in the OL3 project this phase has lasted since February 2005 until the application for the operating license (which has not been applied for in June 2013). The duration of this phase cannot be precisely defined, but an approximation of six to seven years would be close.

The operating license phase cannot be estimated because this process has not been dealt with in Finland yet for a new built NPPs.

6.1.2 The licensing process in the USA for comparison

The projects that are going through or are scheduled for the licensing process in the USA are used as a reference for this study. These schedules are presented in reference [147]. Figure 54 presents the NRC licensing schedules of AP1000 (Westinghouse design), EPR (Areva design), and ESBWR (GE design).

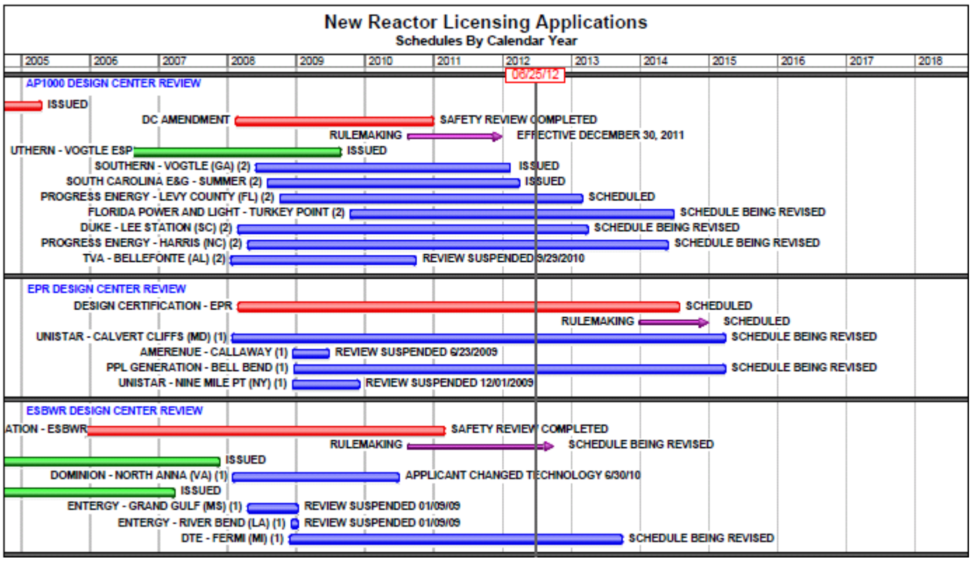


Figure 54 The expected licensing schedules of AP1000, EPR, and ESBWR by NRC [147]

The colors in the figure represent the different licensing and certification processes, Blue is the COL process, green is the ESP process, and red is the DC process. Rulemaking is marked with purple arrows.

For this study, approximations of the duration of licensing steps in USA are based on these as well as NRC licensing schedules for other designs. The Nuclear Energy Institute (NEI) [92] has participated in the development of these timelines. For the Early Site Permit (ESP), it typically takes between 12 and 24 months to develop an application, depending on whether it is a "greenfield" (uncharacterized) site or a site adjacent to an existing facility with existing site characterization data. Once the applicant submits the application, the process of NRC review and approval takes approximately 33 months (including the public hearing). [92] For the Design Certification (DC) process, it takes the NRC between 36 and 60 months to complete the review and rulemaking, depending on whether the agency has previously reviewed and approved the technology [92]. The rulemaking process is a process that develops NRC regulations, by revising or rescinding existing rules or developing new ones. Through this process, the use of DC as a reference of COL is reviewed, and, if appropriate, approved. This definition phase for the licensing requirements interpretation, takes approximately one year, including public hearings. A combined construction and operating license (COL) application may reference a certified design, an ESP or both. All issues resolved in connection with earlier proceedings associated with a standard design or site will be considered resolved for purposes of the COL proceeding. This makes the process more effective allowing the NRC to focus on remaining issues related to plant ownership, design issues not resolved earlier, and organization and operational programs. The number of open issues affects the duration of the COL process. According to the schedules presented in the reference [147], it can be estimated that the COL process can take between four and five years. In addition to these licensing processes, the defined regulatory approvals are issued via the ITAAC (Inspections, Tests, Analyses and Acceptance Criteria) process that ensures the realization of the approved/decided issues. This process accompanies the licensing steps and its duration is approximated to be around four to five years.

The US licensing process presents the prescriptive approach of licensing, presenting detailed rules and regulations for nuclear facilities. The prescriptive approach in the US licensing is described in more detail in section 5.2.1.

6.1.3 The licensing process in Canada for comparison

In Canada the Canadian Nuclear Safety Commission (CNSC) has prepared for licensing SMRs of various sizes. The only recent licensing experience in Canada for new build is a Licence to Prepare Site for Darlington site (a conventional NPP project). This experience is not used as a basis in this study, because the site characterization is still not finished and therefore the licensing process cannot be assumed to be completed. Instead the estimated schedules from the regulatory point of view are used as a basis in this study. The following table represents an approximate timeline for a FOAK NPP or larger SMR (e.g. B&W mPower). As can be seen from the Table 10, the entire process up to issuance of a Licence to Operate is anticipated to take approximately nine years. However, this timeline may differ depending on project-specific issues, as well as use of parallel license applications.

Table 10 Duration estimates in the Canadian licensing process [88]

Approximate Duration of the Environmental Assessment and Licensing Steps

Activity	Duration
Aboriginal Consultation	ongoing
Environmental Assessment and Licence to Prepare Site *(includes development of Joint Review Panel Agreement and EIS Guidelines)*	~36 months
Applicant prepares site	~18 months
Licence to Construct – at least 6 months overlap with the previous activities	~30 months
Licence to Operate	~24 months
Applicant's activities, e.g. plant construction	~48-54 months
Total duration from the application for the Licence to Prepare Site to Licence to Operate, taking into account overlapping environmental assessment/licensing and applicant's activities, which may run in parallel	~9 years

The following factors may influence the licensing process schedule [88]:

- The EA process could take up to 36 months, depending on whether the EA is carried out as a comprehensive study or by a panel. This estimate is based on past experience.
- The comprehensiveness and completeness of the applicant's submissions and supporting information.
- The time required for the applicant to carry out its activities.
- The possible open major safety issues that require resolution before the CNSC statement.
- CNSC resources available for the review.

The licensing process in Canada is a goal setting approach, enabling flexibility in the licensing process according to the project-specific plans. The process is flexible from the schedule point of view and can be handled in shorter or longer time periods, depending on the case.
Below are three postulated licensing scenarios.

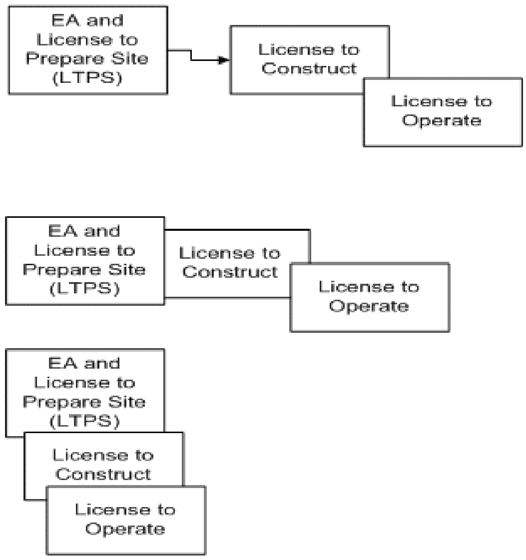


Figure 55 Possibilities for Canadian licensing process handling [21]

The different licensing options can be selected according to the status of the licensee's readiness. The first option is a deferred construction process where construction decision making can be deferred until after the environmental assessment is completed and a site preparation license has been granted. This might be the case in a new utility with a FOAK design. The second alternative, being the standard licensing process, is being used for the Darlington New Build project [22]. This option is also used to estimate the duration of the licensing process (in Figure 55). Third option is typically used if expanding a site with identical technology to what is already there or for identical copies of the reactor design (NOAK) to be placed on new sites where the applicant has all of the information necessary to develop a safety case for operation immediately following construction.

The advantage of the Canadian licensing process is its flexibility. There are many similarities in the Canadian licensing process with the UK process, where a performance-based approach is used, and the licensing basis is based on the licensee’s proposed safety case built up by the licensee. No detailed requirements are issued in the regulatory framework, but the responsibility of licensing is shifted heavily onto licensees. The licensee is expected to demonstrate how it will meet national requirements following the accepted principles, codes, and standards.

The US NRC and the CNSC have a history of cooperative dialog on common regulatory issues and this is continuing for SMRs proposed for deployment in both countries.

6.1.4 The licensing process in France for comparison

In France, the Flamanville 3 (FLA3) case has been used as a basis of the schedule and duration of different licensing steps. These licensing steps and durations are presented in Figures 59, 60, and 61 below. This project is the only new build project in France that can be used as a basis, but in the future projects the durations might be quite different from it. Flamanville 3 can be treated as a FOAK project for EDF Group. The project was authorized in the previous legal context. The new French law was enacted in 2006 and this may result in a different timeframe for licensing.

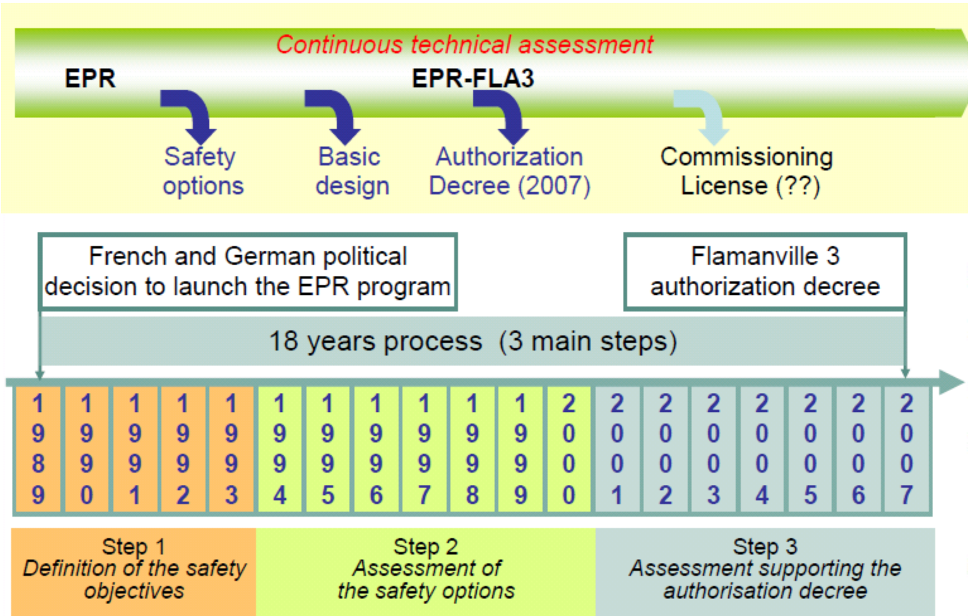


Figure 56 Licensing steps schedule for the Flamanville 3 project [97]

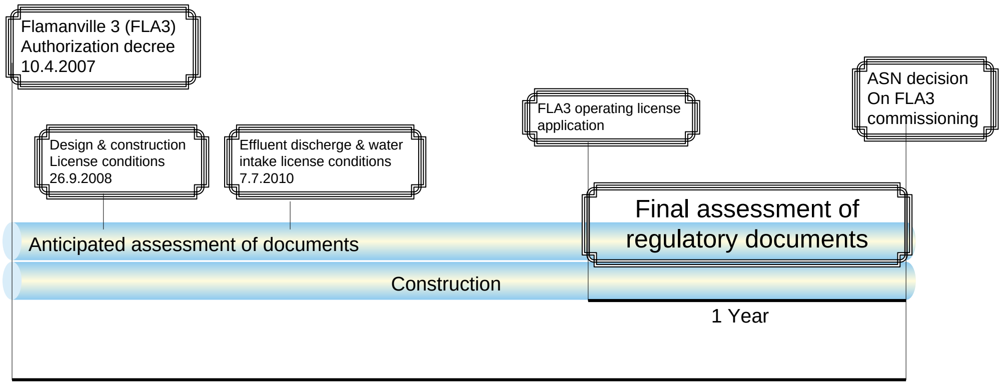


Figure 57 Licensing milestones for the commissioning of Flamanville 3 [97]

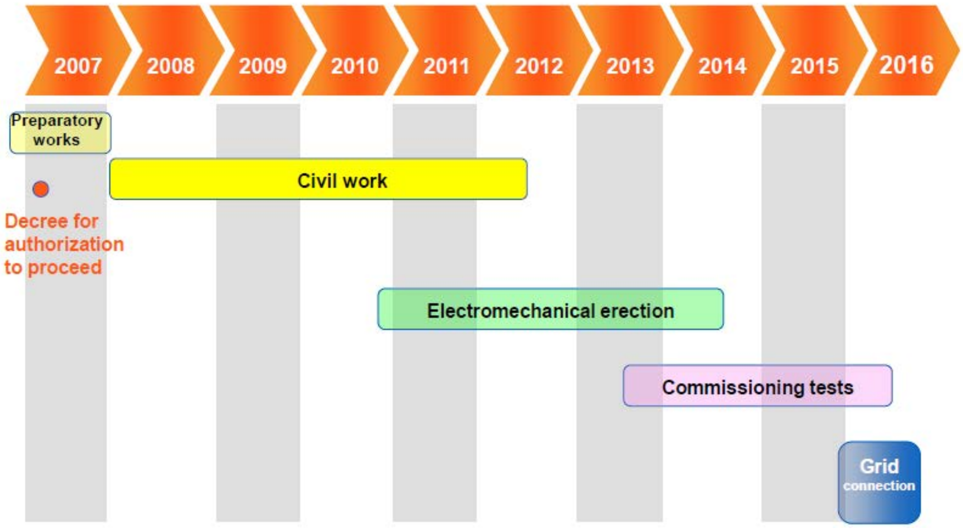


Figure 58 Flamanville 3 project schedule [114]

The future projects are to be implemented according to the new law. The process is analyzed more in section 5.2.3. The process presented takes different times depending on the project and political environment. The next French NPP project is the Penly 3 project.

The Penly 3 project has been "approved" by the previous parliament. However, the newly elected parliament (the election was in June 2012) will debate this matter and will probably organize "a national debate" on energy policy. The confirmation of the Penly 3 project is not assured in this context. An additional step, the so-called "public debate", needs to be organized for each important investment project. This public debate is only a consultation with no blocking rights.

This may take several months or up to one year to organize and conclude. [27] After all these steps, the investor can take the investment decision and start the actual licensing process.

6.1.5 The licensing process in the UK for comparison

In the UK, the estimate of the duration of the licensing steps is presented in Figure 59, with the regulatory framework of the UK. In the UK, the GDA (Generic Design Assessment) can be compared to Design Certification in this study.

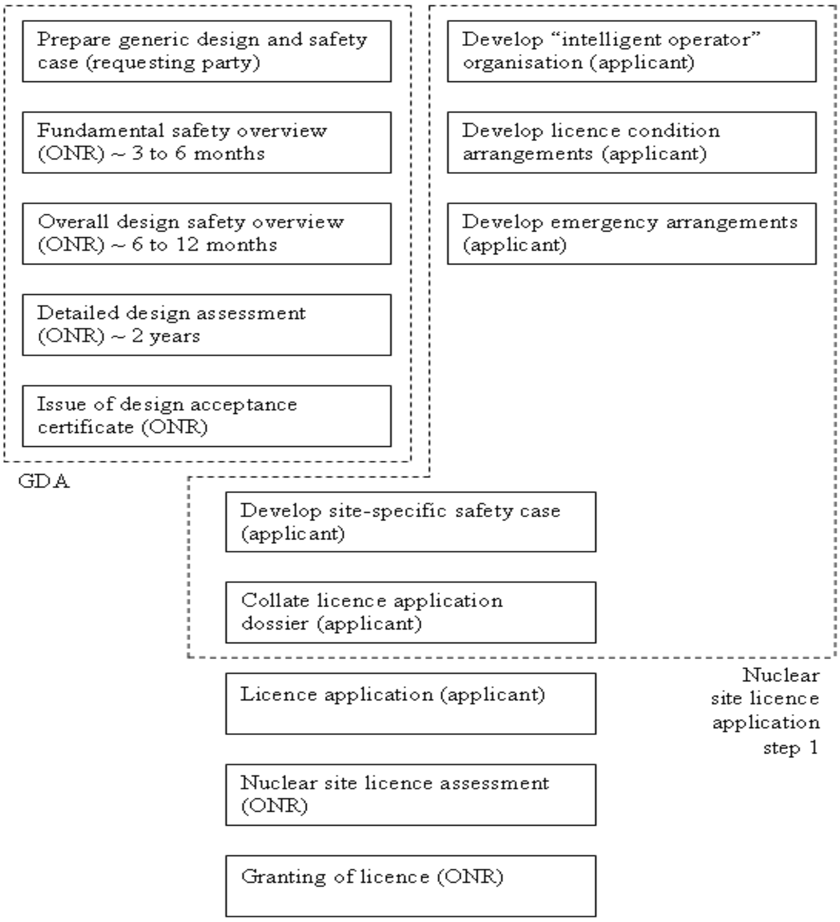


Figure 59 Duration of the different licensing steps in the UK [105].

The estimation of the duration of licensing in UK in this thesis is based on the on-going licensing processes of EPR and AP1000. The GDA process is estimated to take between two years and nine months and three years and six months, as presented in the above figure. For EPR and AP1000, the fundamental safety overview was commenced in September 2007. An interim DAC

(Design Acceptance Certificate) and a list of GDA issues were issued for both designs in December 2011. The GDA issues were closed and the (full) DAC was issued for UK-EPR. [111]

The licensing process has taken a great deal longer time than expected. In more detail [107]:

- The fundamental safety overview September 2007 - June 2008, taking nine months (about 50% longer than estimated).
- The overall safety design overview June 2008 - November 2009, taking 17 months (about 50% longer than estimated).
- The detailed design assessment began November 2009 - December 2012 for UK EPR
    - The interim DAC was issued in December 2011, after two years and one month
    - The whole process has taken three years and one month

It needs to be noted that this has been the first application of the GDA process in the UK, and so the lessons learned can affect the duration of the next GDA process.

The document describing the process for the GDA also suggests that the nuclear Site Licence application will take between six and twelve months. However, it has been seen through the Hinkley Point C licensing that the Nuclear Site Licence process takes around 20 months [102]. The Hinkley Point C Site Licence was applied for in July 2011 and it was granted in March 2013. [106]

The Site Licence includes licensing of the site, construction, commissioning, and operating, which are handled in different steps (as presented in 5.2.4). There is no information about the duration of these steps, since there have been no civil NPPs constructed in the UK recently. A general approximation from other countries can be used to evaluate the duration of NPP construction and commissioning. One example of a schedule would be the AP-1000 construction schedule to build two new nuclear units at the V.C. Summer nuclear station site near Jenkinsville, S.C. The construction schedule is five years for construction and start-up [124]. Because any well defined and suitable approximation cannot be given, this AP-1000 example schedule will be used as an example in this study.

6.2 Functional safety analysis (FSA) comparison of the licensing features

In this study, the target of the FSA comparison is the licensing process, focusing on the duration of the licensing process and the probability of failure. Later in the study the licensing process is compared from different perspectives. The FSA risk bands present the severity of the licensing risk, which is estimated based on the overall duration of a certain licensing process step. The assumption is that if the licensing phase fails, a certain part of the licensing would have to be repeated from the beginning. The likelihood of the hazard is estimated based on a qualitative approximation.

The FSA theory and process has been presented in Chapter 3. The question to be answered with the FSA approach is the relative importance of different licensing steps to be considered while developing the SMR licensing process. The suitability of the studied licensing steps in terms of

SMR licensing is also addressed. Within the FSA comparison, the main features from different licensing steps in the studied countries are compared and discussed. It will be noted that the licensing steps are not easily compared as the comparison needs to be handled in many stages.

The parameter for comparison is the efficiency of each process. Each of the licensing steps is analyzed according to the estimated duration and the process suitability to SMR (modular design) licensing.

For the FSA analysis, the licensing process is divided into three main phases:

1. Site approval (or Decision in Principle in Finland)
2. Design certification or Construction license (depending on the country)
3. Operating license (including the validation and verification that the power unit is built according to the approved design).

For every licensing step and each country, the following parameters are described:

- Duration of the licensing step
- Probability of failure
- Suitability for small modular reactor licensing.

The duration of each licensing step is taken from the studied background information. The probability of failure is estimated according to the experienced licensing practices. The suitability for SMR licensing is evaluated qualitatively according to the licensing step features and their capaility to handle modular design and their repeatability.

This analysis will provide a risk band in each country and in each licensing phase. The duration of different licensing processes is estimated and the limits of the risk bands are set within the average results. In Figure 60 the estimated duration of licensing processes in each of the studied countries is presented, assuming that the licensing would start at the beginning of 2013. For these approximations, the lengths of the recently issued licensing processes have been used as a basis, but it has to be observed that the designs have been First Of A Kind. This figure should not be used to compare the licensing process durations with each other, because of the differences of the licensing step contents and the uncertainties of the analysis. As can be seen in Figure 60, the licensing processes differ from one another, but certain similarities can be found, such as approving a site, approving the design, and allowing the operation.

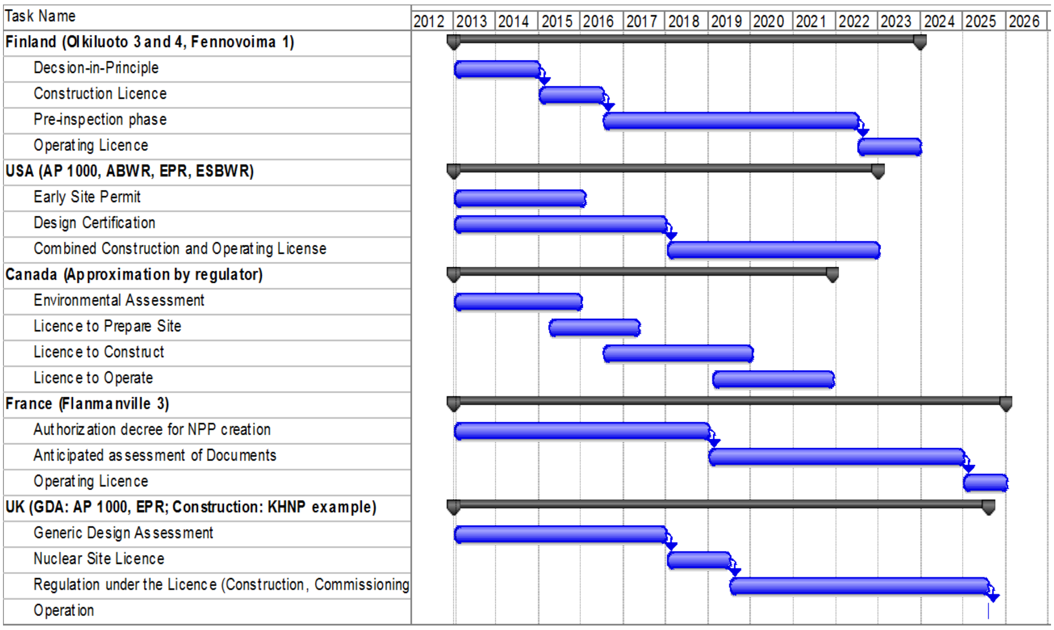


Figure 60 Overview of the duration of licensing processes in different countries

In the comparison of the licensing durations, the WNA Report on Licensing and Project Development for New Nuclear Plants [81, p.11] presents results of the study that includes the licensing processes in 10 countries. The WNA Report can be used as validation of the licensing schedules indicated here, since the scale of the licensing process duration is equal to this study. The WNA Report became public in January 2013, while the results of this study were already presented in the publication AECL Nuclear Review 2/2012 [132].

The risk severity associated with each licensing step is estimated with an approximation of certain licensing step failure. If the renewal of the licensing process would require many years, the risk severity was at a high level. The overall severity of the risk is dependent on the duration of each licensing step and also the configuration of the overall licensing process. When the single licensing step is independent of the overall licensing project, the failure of one licensing step has a smaller impact on the whole licensing project. When the licensing step is embedded with the licensing project, the failure of a single licensing step has a more severe impact on the overall licensing project. The suitability for SMR licensing is discussed separately while analyzing the licensing steps.

The site approval phase, the design certification or construction license phase and the operating license phase are compared according to the same principles. The risk bands in each licensing phase evaluation are similar, only the time scale in the risk bands is modified according to the corresponding licensing phase.

The principles of the comparison are presented first, see Figure 61, and then all the studied licensing phases in all the studied countries are handled one at the time.

Severity / Time				
6 Years				
4 Years				
2 Years				
	1-24%	25-49%	50-99%	Probability

Figure 61 The risk band of the licensing phase comparison

The definitions and representations for the parameters of the
Severity / Time (years)

- Time in this case represents the delay in the licensing schedule in case of the failure of this licensing step. The presumption is that the current licensing step would have to be started all over again.
- Estimation of the certain licensing step in a certain country is based on current experience and/or expectations for the future projects.

- Probability
  - The probability of the failure of the licensing step is estimated based on the previous experiences and also the features of the licensing step.
- Overall SMR risk also includes the following considerations
  - The independence of the particular licensing step, which influences the effects of the success or failure of the whole project overall.
  - The licensing step suitability for modular licensing (modular reactor design) and repeatable purpose (many SMRs in series).

The analysis of the licensing phases suitability for SMRs is performed in two parts. The risk bands are based on the failure rates. First the failure modes are assessed with each licensing phase. The failure rates are then assessd by the effects (severity / Time (years)). The probability parameters are evaluated based on the experimental data from earlier NPP projects. The result according to these valuables is marked in the figures with X1. Based on this baseline, the final evaluation of the result is adjusted according to the overall SMR licensing risk. This evaluation is performed using engineering judgement, keeping in mind the SMR-specific features, such as multi-module designs and series construction. This final result is marked in the figures with X2.

6.2.1 Site approval phase comparison

Site approval phase in Finland

Site approval in Finland is paralleled by the Decision in Principle in this study (see section 5.2.1). Here it must be mentioned that the caveat of some site issues are handled also in Construction License phase. This particular feature makes the site approval phase in Finland particularly challenging for new sites. However, in order to compare the site licensing in Finland, where the separate step for the site licensing does not exist, this has been seen as the best way to proceed.

According to the risk band's evaluations in Figure 62, the approximation can be made that the average values are the following:

- Severity / Time - 2 years
    - Estimate is based on the current experience and expectations for the future projects. [97]
- Probability
    - The probability of failure of the licensing step is in medium level. There are experiences in past years of failure in the DiP process (Fin5 application for TVO and Fortum in 1993 and Fortum application in 2010), however there have been quite many succesful DiP processes (TVO 2002 and 2010, Fennovoima 2010, Posiva)
- The X1 in the risk band is placed according to these assumptions.
- Overall SMR risk also includes the following considerations
    - The Site Approval (Decision in Principle) is crucial for the NPP project in Finland, which makes the risks higher.
    - The DiP suits modular licensing (modular reactor design) quite well, if it is modified to include the power level of the whole plant instead of indicating the number of reactors to be built. The DiP process is not well suited for repeatable purposes (many SMRs in series), because of the high political pressure and uncertainty facing the nuclear industry.
- The X2 is the adjusted indicator in the risk band, according to the consideration of the SMR-specific issues.

Severity / Time				
6 Years				
4 Years		X2		
2 Years		X1		
	1-24%	25-49%	50-99%	Probability

Figure 62 The risk band of the site permit phase in Finland

Site approval phase in the USA

Site Approval (Early Site Permit) in USA is an independent process and is not closely bound to the other parts of the licensing process.
According to the risk band's evaluations in Figure 63, the approximation can be made that the average values are the following:

- Severity / Time - 3 years
    - Estimate is based on the current experience and expectations for the future projects. [147]
- Probability
    - The probability of failure of the licensing step is average, since the site licensing has a pronounced connection with public acceptance. The impact of public acceptance on site licensing, in case of nuclear accidents somewhere in the world, such as Fukushima accident, might result in the whole licensing step failing. However, the probable result instead of failing the whole licensing process is the prolonging of the process by a number of years.
- The X1 in the risk band is placed according to these assumptions.
- Overall SMR risk also includes the following considerations
    - The Early Site Permit process is an independent process from the NPP project, site approval contents can be used as part of the initial data for COL. This makes the risk level of the project much lower, and the site can be separately licensed before the actual NPP project.
    - The Early Site Permit process is quite well suited for modular licensing (modular reactor design) as well as licensing many SMRs in series, if they can all be included in this site license. The only challenge is in a heavy change process, if the license needs modifications later on. The modification of a valid license is always a risk and needs a lot of work to be issued.
- The X2 is the adjusted indicator in the risk band, according to the consideration of the SMR-specific issues.

Severity / Time				
6 Years				
4 Years		X1		
2 Years		X2		
	1-24%	25-49%	50-99%	Probability

Figure 63 The risk band of the site permit phase in the USA

Site approval phase in Canada

Site approval, which is composed of the Environmental Assessment (EA) and Licence to Prepare Site in Canada, is a clearly defined process in the regulatory framework. Previously, the EA and Licence to Prepare site have actually been two separate processes that can be executed in sequence or in parallel, but they are done in parallel as a result of legislative changes made in late 2012, which requires the EA and first license to be issued by the CNSC within 24 project months. [31]
According to the risk bands evaluations in Figure 64, the approximation can be made that the average values are the following:

- Severity / Time **-** 3 years
  - Estimate is based on the current experience and expectations for the future projects. [88]
- Probability
  - The probability of failure of the licensing step is at a low level, which is one of the features of the licensee leading the licensing process (as the licensing is principally organized based on licensees' safety case in Canada and the UK). The public acceptance issue has a strong impact on the probability of failure of the site licensing segment. The situation and probability of failure might be different therefore in different parts of Canada, since the northern parts of Canada have different public acceptance issues compared to the southern parts.
- The X1 in the risk band is placed according to these assumptions.
- Overall SMR risk also includes the following considerations:
  - The site approval process can be an independent process from the NPP project, although this is not typically the case. This makes the risk level of the overall project quite low.
  - In Canada all the modules of the unit would be licensed at once as has been the custom for all multiple unit facilities. The licensing utilizes a graded approach extensively, which makes the process adaptable and easily repeatable in case of many SMRs in series.
  - Public hearings play significant role in the overall process. This would be especially true in northern parts of Canada, with isolated grids, where smaller SMR designs might be proposed. The aboriginal communities are dominant stakeholders and the public hearings play a significant role in the Site Approval phase in Canada.
- The X2 is the adjusted indicator in the risk band, according to the consideration of the SMR-specific issues.

Severity / Time				
6 Years				
4 Years	X1			
2 Years	X2			
	1-24%	25-49%	50-99%	Probability

Figure 64 The risk band of the site permit phase in Canada

<u>Site approval phase in France</u>

The site approval process is concluded by a decision of the so-called DUP ("Déclaration d'utilité publique" = statement of public usefulness). This process also involves a public inquiry which allows general public involvement. The site approval is within the licensee's responsibility. It can be a lengthy and difficult process in the present French socio-economic context. In the 1990s, the EDF tried to open a new NPP site on the Loire estuary (Le Carnet), but this process failed [43]. Presently, the EDF is using only existing nuclear sites for new builds (Flamanville, Penly). However, the issue of new sites may come under discussion in the future. For this evaluation, the site approval is estimated to take two years, as in Finland. There are some similar features in the Finnish and French licensing processes.

According to the risk bands evaluations in Figure 65, the approximation can be made that the average values are the following:

- Severity / Time - 2 years
  - Estimate is based on the current experience and expectations of the future projects in France, because of the lack of data of the French process. [97]
- Probability
  - The probability of failure of the licensing step is at a high level and it is not clear how new sites will be licensed in France in the future.
  - It should be observed that no successful site licensing processes for new nuclear sites have been established in France for more than 20 years. [43]
- The X1 in the risk band is placed according to these assumptions.
- Overall SMR risk also includes the following considerations
  - The site approval process can be an independent process from the NPP project.
  - The site approval process suitability for modular licensing (modular reactor design) is difficult to evaluate, because of the lack of experience. For licensing many SMRs in series (repeating the licensing step) this is probably not well suited, because of the high political pressure and uncertainty facing the nuclear industry.
- The X2 is the adjusted indicator in the risk band, according to the consideration of the SMR-specific issues.

Severity / Time				
6 Years				
4 Years			X2	
2 Years			X1	
	1-24%	25-49%	50-99%	Probability

Figure 65 The risk band of the site permit phase in France

<u>Site approval phase in the UK</u>

Site approval in the UK is part of the Nuclear Site Licence. The Nuclear Site Licence also includes other issues, as described in section 5.2.4. The Site Licence, being the main licensing step in the UK, where nuclear licensing is executed as one-step licensing, also includes many other issues in addition to site-specific issues. In this study, the site-specific issues are, however, analyzed within the Nuclear Site Licence handling, since more detailed distribution is not publicly available considering the UK regulatory framework. The approximation of the duration of site issues review is presented as six to twelve months. In this study, twelve months is used as the duration of handling site approval issues. It should be observed that in the UK the licensing is based on a safety case approach (as it is in Canada and France) and that differs largely from the licensing approach with set regulatory requirements used in the USA.
According to the risk bands evaluations in Figure 66, the approximation can be made that the average values are the following:

- Severity / Time **-** 1 years
    - Estimate is based on the regulatory documentation that evaluated the durations of the processes [104]
- Probability
    - The probability of failure of the licensing step is at a low level, which is one of the features of the licensee-led licensing process (as the licensing is principally organized based on the licensees' safety case). In this type of approach the site-specific issues, as well as unit-specific issues can be handled case by case, while detailed rules do not exist. The suitability of detailed rules is always questionable, while the site, design, and organizations change.
- The X1 in the risk band is placed according to these assumptions.
- Overall SMR risk also includes the following considerations
    - The NPP licensing is based on the Nuclear Site Licence. The site approval is coupled tightly with the overall licensing process and it is a crucial part of the NPP project.
    - The suitability of the UK licensing process for the modular reactor design, or repetition in case of many SMRs in series, is difficult to evaluate. Because this licensing step is one part of the larger complex, it might be

challenging to repeat only this part of the licensing separately from the other licensing process.

- The X2 is the adjusted indicator in the risk band, according to the consideration of the SMR-specific issues.

Severity / Time				
6 Years				
4 Years	X2			
2 Years	X1			
	1-24%	25-49%	50-99%	Probability

Figure 66 The risk band of the site permit phase in the UK

6.2.2 Design certification or Construction license phase comparison

<u>Design certification or Construction License phase in Finland</u>

In Finland, the Construction License is the official licensing step where the design is approved. The regulatory approvals between the CL and OL are also part of the design approval process, so in this study these two processes are combined to be considered together as design approval. The approval of the Construction License does not in Finland mean the approval of the design, since the license can be used only in the indicated NPP project and is not repeatable. The CL and regulatory approvals indicate a certain design stage (basic design or systems design, as described in section 5.2 , while in case of open issues, they might be solved later during the design and licensing processes. Even though the design approval is not strictly comparable with the Construction License, this has been indicated as the only suitable way to compare the Finnish regulatory framework.
According to the risk bands evaluations in Figure 67, the approximation can be made that the average values are the following:

- Time - 1.5 years for CL and 5.5 years for regulatory approvals
  - Estimate is based on the current experience and expectations for the future projects [97].
  - The CL handling is indicated to take about 1.5 years for future NPP projects. This phase in the OL3 project lasted approximately one year [78].
  - The regulatory approvals in the OL3 project have taken 5.5 years [78], the duration is relatively long. The length of the regulatory approvals phase is affected by the FOAK design-specific issues. The regulatory approval process in Finland, as well as its level of details, is quite different from the other countries, such as France (with a more goal setting approach to licensing).

    - It shall be noted that in case of another identical NPP licensing process, the duration would probably be shorter.
- Probability
    - The probability of failure of the licensing step is average. The probable result of failing the whole process is the prolonging of the process by years.
- The X1 in the risk band is placed according to these assumptions.
- Overall SMR risk also includes the following considerations
    - The CL is the center of the whole licensing process. If compared with other design approval processes that are somewhat independent from the actual NPP project, in Finnish licensing the whole project is very dependent on this licensing phase. The embedded feature of the CL in the Finnish regulatory framework makes this licensing step quite risky from the project perspective.
    - For modular licensing, the CL process is not well suited since this licensing step would be needed for either every single module, or every single SMR. It has not been discussed if this license is going to be for the whole unit or for a single reactor module. For the repeatable purpose (licensing many SMRs in series), i.e. the possibility of copying the CL needs to be discussed. This kind of repetition has not been executed in Finland.
- The X2 is the adjusted indicator in the risk band, according to the consideration of the SMR-specific issues.

Severity / Time				
7 Years		X1, X2		
5 Years				
3 Years				
	1-24%	25-49%	50-99%	Probability

Figure 67 The risk band of the design acceptance licensing phase in Finland

<u>Design certification or Construction License phase in the USA</u>

The Standard Design Certification in the USA is an independent process and is not closely bound to the other parts of the licensing process. There also exists a Pre-Application Review Process in the NRC where the design is reviewed prior to the official licensing process to see possible design flaws beforehand. The Design Certificate is applied by the plant designer and the certificate applies for a limited period of time. It should be noted that this design approval will be reviewed and revised due to the site-specific requirements in the COL.
According to the risk band's evaluations in Figure 68, the approximation can be made that the average values are the following:

- Time - 5 years
    - Estimate is based on the current experience and expectations for the future projects of the AP1000, ESBWR, EPR, and ABWR approvals.[147]
- Probability
    - The probability of failure of the licensing step is at an average level. The probable result instead of failing the whole process is the prolonging of the process by years.
- The X1 in the risk band is placed according to these assumptions.
- Overall SMR risk also includes the following considerations
    - The DC is an independent step from other licensing processes, and site approval contents can be used as part of the initial data for the COL. Design certification is applied separately from the actual NPP project and licensing.
    - The DC process suitability for modular licensing (modular reactor design) is not easy to estimate. For the repeatable purpose (many SMRs in series) the DC process suits very well, as long as the design is standardized up to a suitable design completion level. The license conditions are the key issue to be set in the way they apply for many siting conditions.
- The X2 is the adjusted indicator in the risk band, according to the consideration of the SMR-specific issues.

Severity / Time				
7 Years				
5 Years		X1		
3 Years		X2		
	1-24%	25-49%	50-99%	Probability

Figure 68 The risk band of the design acceptance licensing phase in the USA

<u>Design certification or Construction License phase in Canada</u>

In the Canadian licensing process there is an optional pre-licensing step called a Vendor Design Review (VDR). It can be compared with the UK GDA process, although its scope and depth of review is different. The VDR process in Canada is not design certification, but a pre-licensing activity to improve the readiness to enter the licensing process should the plant design be referenced in a specific site license application.

The official licensing step for the design approval is Licence to Construct, which is a clearly defined process in the regulatory framework. Licence to Construct can be handled in parallel with other licensing activities, which effects the total duration of the licensing process.

According to the risk bands evaluations in Figure 69, the approximation can be made that the average values are the following:

- Severity / Time - 2,5 years
    - Estimate is based on the regulatory documentation that estimated the durations of the processes [88]. The handling of Licence to Construct is overlapping the previous activities by at least six months and it can be handled also in parallel with the Licence to Operate. As presented in section 5.2.2 the schedule for licensing includes this 2.5 year process for Licence to Construct and then two years construction by the licensee, which is not included in the licensing duration but affects the overall licensing schedule.
- Probability
    - The probability of failure of the licensing step is at a low level, which is one of the features of the licensing leaded by licensee process (as the licensing is principally organized based on licensees' safety case in Canada and the UK).
- The X1 in the risk band is placed according to these assumptions.
- Overall SMR risk also includes the following considerations
    - The Licence to Construct process is highly dependent from the NPP project and its schedule.
    - In Canada all the modules of the unit are licensed at once (as has been the custom for all multiple unit facilities in Canada, such as certain Candu designs). The licensing utilizes a graded approach extensively, which makes the process adaptable and easily repeatable in the case of many SMRs in series.
- The X2 is the adjusted indicator in the risk band, according to the consideration of the SMR-specific issues.

Severity / Time				
7 Years				
5 Years		X1, X2		
3 Years				
	1-24%	25-49%	50-99%	Probability

Figure 69 The risk band of the design acceptance licensing phase in Canada

<u>Design certification or Construction License phase in France</u>

The authorization decree for NPP creation reviews the design at quite a detailed level. There are similarities between the authorization decree for NPP creation and CL (and authority approval) in the Finnish licensing.
According to the risk bands evaluations in Figure 70, the approximation can be made that the average values are the following:

- Severity / Time - 6 years
  - Estimate is based on the experience of the first EPR licensing. Because this is a FOAK plant, it is not clear what would be the duration of the licensing if it was applied to another design at a higher level of design completion at the beginning. [97]
- Probability
  - The probability of failure of the licensing step is estimated to be at an average level, because of the lack of information and experiences in recent years.
- The X1 in the risk band is placed according to these assumptions.
- Overall SMR risk also includes the following considerations
  - The authorization decree for the NPP phase is a crucial part of the NPP project. Parts of the NPP design are approved at a detailed design level due to the authorization decree for the NPP phase.
  - The authorization decree for NPP process suitability for modular licensing (modular reactor design) is difficult to evaluate because of the lack of experiences. For the repeatable purpose (many SMRs in series) in the authorization decree for the NPP could be copied with a lighter process, focusing on the specified features. This kind of repetition has not been executed in France.
- The X2 is the adjusted indicator in the risk band, according to the consideration of the SMR-specific issues.

Severity / Time				
7 Years		X2		
5 Years		X1		
3 Years				
	1-24%	25-49%	50-99%	Probability

Figure 70 The risk band of the design acceptance licensing phase in France

<u>Design certification or Construction License phase in the UK</u>

The GDA process in the UK can be compared to the Design Certification in the USA. The GDA process is quite new in the UK licensing system and it is not formally required for the Site Licence, but in practice it is an obligatory part of the licensing regime. Only a UK-EPR has gone through the GDA process, while the AP-1000 is still under review. The difference between the UK and USA licensing processes is the approach: while the NRC in the USA has quite a strict and clear set of regulatory requirements, in the UK, the approach is based on a safety case proposed by the licensee.
According to the risk bands evaluations in Figure 71, the approximation can be made that the average values are the following:

- Severity / Time - 5 years
    - Estimate is based on the regulatory documentation that estimated the durations of the processes [104]
- Probability
    - The probability of failure of the licensing step is at a low level, which is one of the features of the licensee-led licensing process (as the licensing is principally organized based on licensees' safety case in Canada and the UK).
- The X1 in the risk band is placed according to these assumptions.
- Overall SMR risk also includes the following considerations
    - The GDA is an independent step from other licensing processes. The GDA is applied separately from the actual NPP project and licensing. The GDA can be applied by the designer, licensee or both of them together.
    - The suitability of the GDA process for the modular reactor design is difficult to evaluate, because of the lack of experience. The repetition in case of many identical SMRs in series instead fits well with the GDA process, as long as the design is standardized.
- The X2 is the adjusted indicator in the risk band, according to the consideration of the SMR-specific issues.

Severity / Time				
7 Years				
5 Years	X1			
3 Years	X2			
	1-24%	25-49%	50-99%	Probability

Figure 71 The risk band of the design acceptance licensing phase in the UK

6.2.3 Operating license phase comparison

<u>Operating license phase in Finland</u>

In Finland, the Operating License phase has only been issued while reviewing and renewing the Operating Licenses for the operating units (OL1, OL2 in Olkiluoto and LO1, LO2 in Loviisa). The duration for the OL handling can only be estimated using the regulators' documentation.

According to the risk band's evaluations in Figure 72, the approximation can be made that the average values are the following:

- Time - 1,5 years
  - Estimate is based on the current experience and expectations for the future projects. [97]
- Probability
  - The probability of failure of the licensing step is at a low level. The probable result instead of failing the whole process is the prolonging of the process by years.
- The X1 in the risk band is placed according to these assumptions.
- Overall SMR risk also includes the following considerations
  - The OL is mainly a check of the 'as built' nuclear unit, verifying that the unit is built according to the accepted design features. This needs unit or modular specific inspections.
  - The OL process suitability for modular licensing (modular reactor design) is difficult to estimate, and it has not been discussed if this license is going to be for the whole unit or for a single reactor module. For the repeatable purpose (many SMRs in series), the OL could be copied focusing on the specific issues. This licensing step does not significantly differ from large NPPs and SMRs.
- The X2 is the adjusted indicator in the risk band, according to the consideration of the SMR-specific issues.

Severity / Time				
5 Years				
3 Years				
1 Years	X1, X2			
	1-24%	25-49%	50-99%	Probability

Figure 72 The risk band of the operating licensing phase in Finland

<u>Operating license phase in the USA</u>

The operating license is included in the COL process in the USA two-step licensing process (10 CFR Part 52). The operating license is just a part of the COL, the acceptable approach of the ITAAC process is also required to achieve the permission to operate.

According to the risk band's evaluations in Figure 73, the approximation can be made that the average values are the following:

- Time **-** 5 years for COL, for the operating license it is divided by 2 in order to get some estimate.
  - Estimate is based on the current experience and expectations for the future projects of the AP1000, ESBWR, EPR, and ABWR approvals.[147]
- Probability
  - The probability of failure of the licensing step is at a low level. Very standardized licensing process, with detailed rules, enables lowering the risk level. Instead, the risk of prolonging the process is quite high. The probable result instead of failing the whole process is the prolonging of the process by years.
  - Considering SMRs with a reactor module fabricated and transferred to the site, the licensing practices are not clear. This has been discussed within the NRC and some presentations indicate the open issues, such as presented in reference [122].
- The X1 in the risk band is placed according to these assumptions.
- Overall SMR risk also includes the following considerations
  - The COL is the center of the whole licensing process, the DC and ESP can be used as the initial data for the COL. There is no independence from the project, but in the USA licensing process the COL is embedded in the NPP project activities.
  - The COL process suitability for modular licensing (modular reactor design) is not easy to estimate. If every single module had to be licensed, the management of the licensing processes would be quite complex. For the repeatable purpose (many SMRs licensed in series), the COL could be copied focusing on the specified features.
- The X2 is the adjusted indicator in the risk band, according to the consideration of the SMR-specific issues.

Severity / Time				
5 Years				
3 Years	X1, X2			
1 Years				
	1-24%	25-49%	50-99%	Probability

Figure 73 The risk band of the operating licensing phase in the USA

Operating license phase in Canada

The Licence to Operate in the Canadian licensing process is specific to each project, the licensee proposes the licensing basis based on the used processes and procedures of the licensee. Permits for fuel loading, hot commissioning, and full-power commercial operation are issued. Hold points may be placed in the license to ensure the licensee has met technical and regulatory requirements at specific power milestones.
According to the risk bands evaluations in Figure 74, the approximation can be made that the average values are the following:

- Time - 3 years
    - Estimate is based on the regulatory documentation that estimated the durations of the processes [88]. The handling of Licence to Operate can be handled in parallel with the Licence to Construct.
- Probability
    - The probability of failure of the licensing step is at a low level, which is one of the features of the licensee-led licensing process (as the licensing is principally organized based on licensees' safety case in Canada and the UK).
- The X1 in the risk band is placed according to these assumptions.
- Overall SMR risk also includes the following considerations
    - The Licence to Operate process can be compared with OL process in Finnish licensing.
    - In Canada, all the modules of the unit are licensed at once (as it is the custom in Candus). The licensing utilizes a graded approach extensively, which makes the process adaptable and easily repeatable in case of many SMRs in series.
- The X2 is the adjusted indicator in the risk band, according to the consideration of the SMR-specific issues.

Severity / Time				
5 Years				
3 Years	X1, X2			
1 Years				
	1-24%	25-49%	50-99%	Probability

Figure 74 The risk band of the operating licensing phase in Canada

Operating license phase in France

The operating license in the French licensing process comprises final assessment of the regulatory documents. The operating license step is quite limited and short in French licensing

where the acceptance of the design and validation and verification is done already in earlier licensing steps.
According to the risk bands evaluations in Figure 75, the approximation can be made that the average values are the following:

- Severity / Time - 1 year
    - Estimate is based on the experience of the first EPR licensing and estimation of the Flamanville 3 NPP project. Because this is a FOAK plant, it is not clear what would be the duration of the licensing if it was executed to another design in a more mature design stage at the beginning of the licensing process. [97]
- Probability
    - The probable result instead of failing the whole process is the prolonging of the process by years.
- The X1 in the risk band is placed according to these assumptions.
- Overall SMR risk also includes the following considerations
    - The operating license process can be compared with OL process in Finnish licensing.
    - The operating license process suitability for modular licensing (modular reactor design) is difficult to estimate, and it has not been discussed if this license is going to be valid for the whole unit or for a single reactor module. For the repeatable purpose (many identical SMRs in series), the operating license could be copied focusing on the specific issues. This kind of repetition has not been executed in France.
- The X2 is the adjusted indicator in the risk band, according to the consideration of the SMR-specific issues.

Severity / Time				
5 Years				
3 Years				
1 Years	X1, X2			
	1-24%	25-49%	50-99%	Probability

Figure 75 The risk band of the operating licensing phase in France

<u>Operating license phase in the UK</u>

The licensing phase for operating license in UK is not a clearly separated phase in Site Licence process. The granting of the Site Licence also gives permission to operate the unit; however, hold points are often entered into the license condition requirements to seek permission at various phases of the construction and operation of the unit. This process has not been applied to an NPP in the UK in recent years, so the time needed for the licensing phase that can be compared with

the operating license phase, is estimated in this study according to the current trend in the other studied countries.
According to the risk band's evaluations in Figure 76, the approximation can be made that the average values are the following:

- Severity / Time - 2 years (approximation)
    - This process has not been applied in the UK yet (2012), so the time needed for the licensing phase that can be compared with the operating license phase is estimated in this study according to the current trend in the other studied countries.
- Probability
    - The probability of failure of the licensing step is at a low level, which is one of the features of the licensee leading licensing process (as the licensing is principally organized based on the licensees' safety case in Canada and the UK).
- The X1 in the risk band is placed according to these assumptions.
- Overall SMR risk also includes the following considerations
    - The operating license is part of the Nuclear Site Licence process.
    - The suitability of the UK licensing process for the modular reactor design or repetition in case of many SMRs in series is difficult to evaluate. Because this licensing step is one part of the larger complex, it might be challenging to repeat only this part of the licensing separately from the other licensing process.
- The X2 is the adjusted indicator in the risk band, according to the consideration of the SMR-specific issues.

Severity / Time				
5 Years				
3 Years				
1 Years	X1, X2			
	1-24%	25-49%	50-99%	Probability

Figure 76 The risk band of the operating licensing phase in the UK

6.2.4 Functional safety analysis (FSA) comparison results and discussion

The Functional safety analysis comparison, with its risk bands has clearly indicated that the operating license is not the challenge in terms of SMR licensing in the countries studied. Even if the project risks connected with the granting of the operating license are high, the process suits SMRs as well as large NPPs. The only question considering operating license is whether to use the approach of one license for the whole unit, or to obtain separate licenses for each reactor module.

The site approval and the design approval processes are shown to be important from the SMR point of view. The main safety and licensing features of an NPP design are based on the site approval and the design approval processes. This is why these two licensing steps are the focus areas of the next comparison.

In Figure 77 and Figure 78 the site permit phase and design acceptance phase comparison in the studied countries are presented. The results of the risk bands of the FSA show the difference between different countries' licensing processes in terms of licensing risk and suitability for SMR licensing. The FSA approach was selected to enable the comparison of the licensing processes phases, in spite of their qualitative features.

Severity / Time				
5 Years				
3 Years	UK	Fin	Fr	
1 Years	Can	US		
	1-24%	25-49%	50-99%	Probability

Figure 77 The studied countries in the risk band of the site permit phase

Severity / Time				
5 Years		Fin, Fr		
3 Years		Can		
1 Years	UK	US		
	1-24%	25-49%	50-99%	Probability

Figure 78 The studied countries in the risk band of the design acceptance phase

The processes can be divided into groups according to the results of the FSA results. The first feature that divides the licensing processes into two groups is the approach to determine the regulations. There are countries where an adjusted set of regulations for licensing is written by the regulator, while in other countries the licensee is responsible for setting up the rules and regulations, and preparing the safety case for regulatory approval. The first category, with the adjusted set of regulations set by the regulator, applies in the USA. While the second category, with the licensee setting the applicable rules and presenting the safety case, applies in the UK and Canada.

It is noted that the second category is more adjustable and therefore easier to be applied to SMRs with their special features. The adjustable process and licensing requirements enable the new features to be perceived and taken into account within the current regulatory framework. In this kind of approach the wide use of a graded approach is possible. Within the prescriptive licensing approach, the new features may need more consideration and modification of the detailed licensing requirements.

Another feature by which the licensing processes can be divided is the existence of the design approval as a separate process, versus approving the design within the overall NPP project execution. Basically, it can be noted that some countries follow a two-step licensing process (such as the USA's 10 CFR Part 50), while others have a process that can be compared to the USA's 10 CFR Part 52. The two-step licensing process follows the NPP execution process and is carried out and specified for a single NPP project. This approach is applied in Finland and Canada (where the licensing process can be modified according to the licensee's proposal). While in the USA and the UK there is a separate design certification process for the design. In France, the licensing approach is somewhere between the two groups. In principle, the French licensing process includes two steps, but the pre-licensing activity (ASN opinion on safety options) can be seen as a kind of design approval.

In the USA, the site permit is also an independent process, while in the UK it is integrated to the main licensing (Site Licence). The pre-licensing activities are already paid more attention, if compared with licensing methods and practices used in the past, to approve the efficiency of the licensing process due to early discussion of the design. Pre-licensing activities are used in all the studied countries. In Canada (VDR-process) the pre-licensing has been aimed in the design certification type direction, even though the VDR process does not grant the design any certification.

The FSA approach can be interpreted to show that the separate design certification would be well suited to SMRs with standardized design. The scope of the design certification is described further in Chapter 7.

6.3 Value analysis comparison of the licensing features

The value analysis method was presented in section 3.3. Using the value analysis method, licensing features in different countries' licensing processes are evaluated.

In this study, only two out of three functions of the value analysis method are used (1. Identify and prioritize functions, and 2. Analyze contributing functions). Improvements are looked for through the new licensing model, which is presented in Chapter 7.

The main function of nuclear licensing is the safety of the NPP, which can be divided into certain licensing areas, as presented in Figure 25. Another way to divide nuclear licensing, is the separation between requirements that target the physical plant and requirements that target the processes. More efficient licensing process implementation is crucial for successful SMR (as well as large NPP) project execution. Considering the licensing processes for large NPPs, there have been studies and publications lately, such as the WNA Report: Licensing and Project Development of New Nuclear Plants [81]. The importance of an efficient licensing process and even international harmonization of the different licensing processes, has been observed following prolonged NPP project schedules and increased prices. The specific features of SMRs are not dealt within the studies at the moment, but this is probably only a matter of time. This thesis is intended to provide such a contribution to this new field.

Figure 79 presents the categorization of the licensing functions into two groups. The Requirements for the processes (on the right hand side) present the aspect studied using the value analysis comparison method.

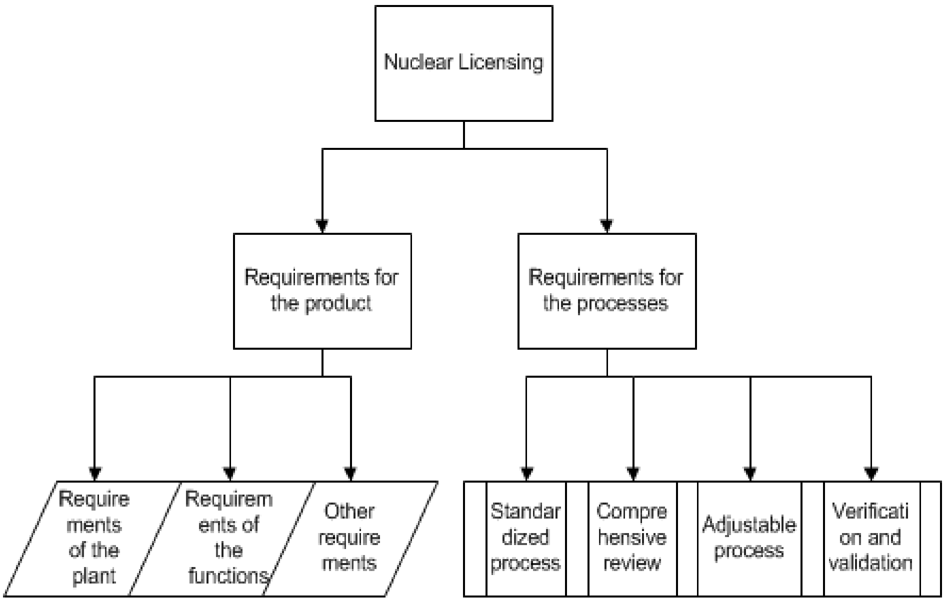


Figure 79 Licensing functions categorization in this study

It has been a very time-consuming and challenging task to develop harmonized licensing requirements for NPP licensing in Europe. The harmonization of both licensing processes and licensing requirements for the product has been successful in the aviation industry. There the harmonization has been even more necessary, since aircrafts fly between different countries; however, this kind of harmonization has been discovered to be necessary also in the nuclear industry.

The value analysis method has been used to analyze the following indicators:

- Standardized process for licensing, minimizing the licensing risk with a predictable approach
- Comprehensive review, including organization of regulations according to the importance and/or object
- Adjustable process for SMR features (including a graded approach)

- Systems Engineering, Requirements Management and Verification, and Validations process.

The value analysis is based on the responses to the questionnaire (presented in Appendix 1). The questionnaire tries to scrutinize the main issues of the licensing processes that represent the studied features: standardized process, comprehensive review, adjustable process, verification, and validation.

The questionnaire was sent to every studied country, to both regulatory bodies and industry representatives. The persons responding to the questionnaire were chosen so that they presented experienced licensing personnel in each country. Some cases indicated that the responses from the regulator and the industry representatives were different. These differences might be because of a different interpretation of the question or a different understanding of the regulatory framework. The differences were not discussed further, but were indicated in the responses table (Table 11).

The overview of the responses is included in Table 11 below. In the table the results of this part of the research are summarized. The "Nr of response" used in the Table 11, gives number for each question/response. These numbers are used later when refering to these questions and responses. When the responses of the questionaire (Appendix 1) are used as a basis for this summary table, the corresponding question is indicated (*in italics*) after the question in the table. It should be observed that the responses table also includes responses that are not included in the questionnaire, but have been answered according to the national reports of the IAEA's Convention on Nuclear Safety. [64]

Table 11 Questionnaire responses summary from the studied countries

Nr of	Response	Finland	USA	Canada	France	UK
1	Set of regulation determined by Regulator/Licensee - (R / L)	R	R	R (high level) / L (detailed)	R	R (high level) / L (detailed)
2	Used standards determined by Regulator/Licensee - (R / L)	R/L	R	L	R/L	R/L
3	Requlatory requirements organized according to their Importance or Object (plant/system/component) - (Y / N) - *question 1*	N	Y	N	N	N
4	Regulatory requirements deepness about plant / systems / components? (P / S / C / NP) - *question 2*	P/S/C	P/S/C	NP	NP	NP
5	Regulatory framework being active in past years for new NPPs (Y / N)	Y	Y	Y	Y	Y
6	Regulatory framework suitability for LWR SMRs? (Y / N) - *question 3*	N	Y	Y	Y	Y
7	Modularity taken into account in licensing process (Y / N) - *question 4*	N	Y	Y	N	Y
8	Licensing process planned to suit a repetition of licensing many identical power plants in series, shortening the licensing process dramatically? (Y/ N) - *question 5*	N	Y	N	N	Y - sampling
9	Possibility to use design licence granted in other country? (Y / N) - *question 6*	N	N	N	N	Y - if licensee approves
10	Possibility of graded approach applied in licensing process (Y / N) - *question 7*	N	Y	Y	N	Y
11	Licence for whole plant or licences for each reactor module? (1 license for all modules /Many licenses) - *question 8*	Not set	Many	1	Many/1 (different answers)	1 - need discussion
12	How many steps are included in systems approval in licensing process - *question 9*	3	1-2 (different answers)	2	3	NA
13	Safety classification approach assist in determining the applicable review organizations (IO/Regulator) (Y / N) - *question 10*	N	N	Y	N	NA
14	Regulatory requirements suitable for passive plants (Y / N) - *question 11*	N	Y and N (different answers)	Y	Y	Y
15	Is the I&C architecture/functional design of the plant being reviewed by the regulator, if yes in which stage? (Y / N) - *question 12*	Y-CL	Y-DC, COL	N	Many phases	Y-GDA
16	Requirements Management process and tools required for the licensee (Y / N) - *question 13*	Y	Y	Y	N	Y
17	How is licensee's Requirements Management process and tools reviewed? - *question 14*	No experience	Regular audits of QA program	Graded approach - sample review	Only Pre-licensing	Risk based approach
18	What stage of licensing is validation and verification process required? Who plans the V&V process? (R / L) - *question 15*	QA program, differs between disciplines	QA program, analytical methods and software before	No requirements - L	No requirements other than I&C	No set of requirements - Risk based approach
19	Are there set of regulatory requirements for validation and verification process or case by case approach? (Set / Case by case) - *question 15*	Set, mainly for I&C	Set, mainly for I&C	Case by case	Case by case	Case by case
20	Who does the planning of validation and verification? (V / L / R) - *question 17*	L, experts	V, L, experts	V/L	L	L
21	Existing a suitable licensing step for SMR module certificate (Y / N)	N	Y	N	N	N

The following abbreviations are used in the Table 11.

C	Component
L	Licensee
N	No
NA	Not Applicable
NP	NonPrescriptive
P	Plant
R	Regulator
S	System
V	Vendor
Y	Yes

In addition to these responses, an indication of the NPP design process phase connection to a certain licensing process phase is indicated in Figure 80. Due to this approach an overall understanding of licensing phases in different countries can be achieved. This approach will also be described in Chapter 8, where a case study of an SMR licensing project is presented.

The design maturity level is one of the key features to be discussed in each licensing phase. The corresponding design process phase is indicated in the left hand side, while the licensing processes are presented in the right hand side.

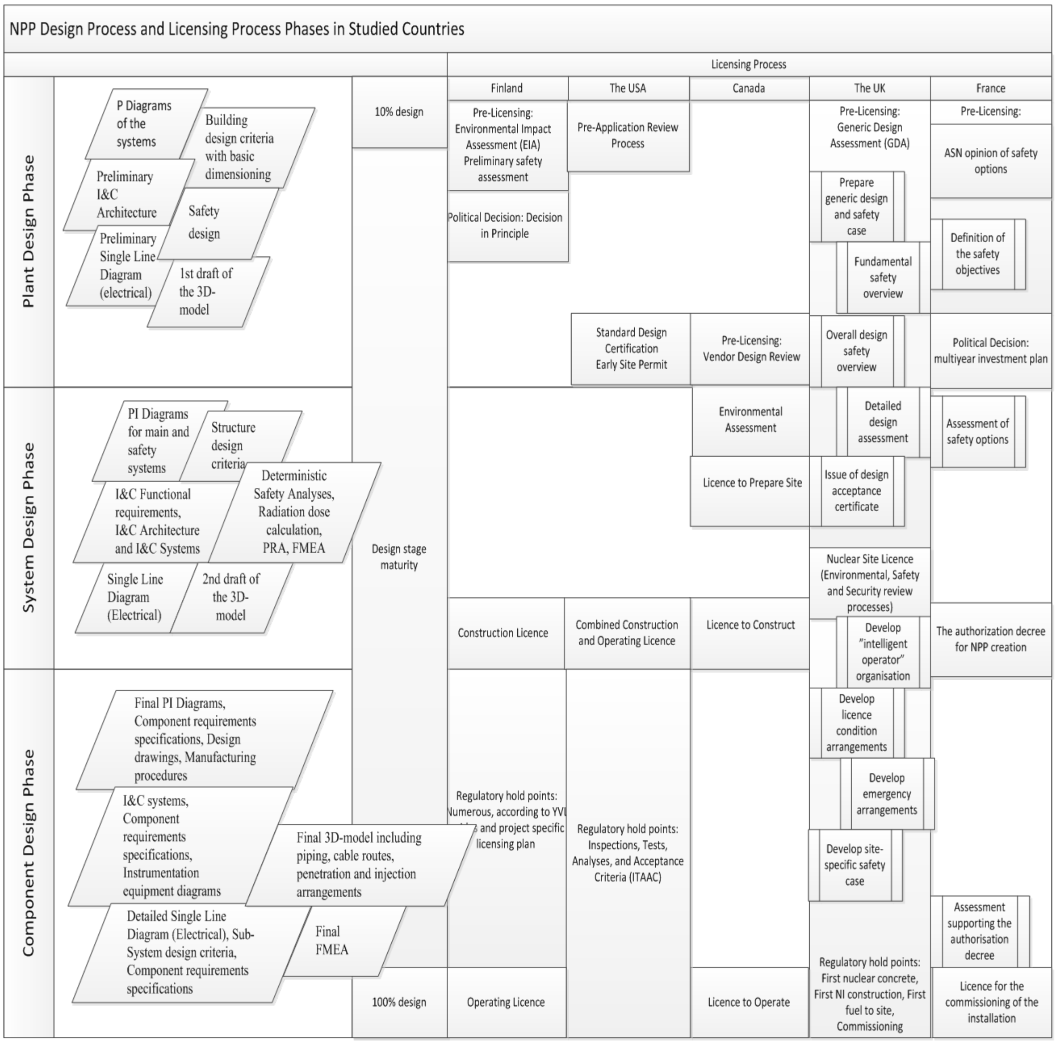


Figure 80 Connection between the NPP design process and different licensing process phases in the studied countries

According to the responses to the questionnaire, together with the licensing processes connection with the design phases, the value analysis variables have been selected. The licensing processes in Finland, the USA, Canada, France, and the UK have been analyzed according to the variables presented here.

The variables are selected to represent the licensing process standardization comprehensiveness and adjustability, which are key features to enable effective SMR licensing. Systems Engineering (including Requirements management and Validation and Verification) effective implementation in the studied countries' licensing processes, has been included in the analysis, as well as in the questionnaire. This kind of licensing approach makes the licensing process more predictable and transparent. These properties have been indicated as important also in the WNA Report on Licensing and Project Development of New Nuclear Plants. [81, p. 3]

The following comparison has been made for each of the studied countries based on the questionnaires results using the value analysis. The responses are used to implement the analysis results. The corresponding responses to define each value analysis result are indicated here.

Table 12 Example table of a standardized process
Responses 1, 2, and 5 in Table 11.

Standard						Variable
Established						New
Regulator determined requirements						Licensee determined requirements

Table 13 Example table of a Comprehensive review
Responses 3, 4, 6, 12, and 15 in Table 11.

Regulations organized according the importance						Not organized regulations
Detailed regulatory requirements						High level requirements
Regulations suitable for passive plants						Passive plants not fully considered

Table 14 Example table of an Adjustable process
Responses 7-11, 13, 14, and 21 in Table 11.

Modularity taken into account						Modularity not taken into account
Suitable for many identical NPPs in series						Not suitable for repetition
Graded approach available						No graded approach available

Table 15 Example table of Systems Engineering, Requirements Management, and Verification and validations process

Responses 16-20 in Table 11.

RM process required for licensee						No regulations for RM
Regulations for overall V&V program						No regulations for V&V
Established V&V process for all the disciplines						No covering V&V process

6.3.1 Results of the value analysis in Finnish licensing

Table 16 Standardized process in Finnish licensing

Standard				x		Variable
Established		x				New
Regulator determined requirements	x					Licensee determined requirements

Table 17 Comprehensive review in Finnish licensing

Regulations organized according to importance				x		Not organized regulations
Detailed regulatory requirements		x				High level requirements
Regulations suitable for passive plants					x	Passive plants not fully considered

Table 18 Adjustable process in Finnish licensing

Modularity taken into account					x	Modularity not taken into account
Suitable for many identical NPPs in series					x	Not suitable for repetition
Graded approach available			x			No graded approach available

Table 19 Systems Engineering, Requirements Management, and Verification and validations process in Finnish licensing

RM process required for licensee	x					No regulations for RM
Regulations for overall V&V program				x		No regulations for V&V
Established V&V process for all the disciplines		x				No covering V&V process

6.3.2 Results of the value analysis in US licensing

Table 20 Standardized process in US licensing

Standard	x					Variable
Established	x					New
Regulator determined requirements	x					Licensee determined requirements

Table 21 Comprehensive review in US licensing

Regulations organized according to importance		x				Not organized regulations
Detailed regulatory requirements	x					High level requirements
Regulations suitable for passive plants	x					Passive plants not fully considered

Table 22 Adjustable process in US licensing

Modularity taken into account					x	Modularity not taken into account
Suitable for many identical NPPs in series			x			Not suitable for repetition

Graded approach available		x				No graded approach available

Table 23 Systems Engineering, Requirements Management, and Verification and validations process in US licensing

RM process required for licensee	x					No regulations for RM
Regulations for overall V&V program	x					No regulations for V&V
Established V&V process for all the disciplines		x				No covering V&V process

6.3.3 Results of the value analysis in Canadian licensing

Table 24 Standardized process in Canadian licensing

Standard					x	Variable
Established		x				New
Regulator determined requirements					x	Licensee determined requirements

Table 25 Comprehensive review in Canadian licensing

Regulations organized according to importance					x	Not organized regulations
Detailed regulatory requirements					x	High level requirements
Regulations suitable for passive plants	x					Passive plants not fully considered

Table 26 Adjustable process in Canadian licensing

Modularity taken into account	x					Modularity not taken into account
Suitable for many identical NPPs in	x					Not suitable for repetition

series						
Graded approach available	x					No graded approach available

Table 27 Systems Engineering, Requirements Management, and Verification and validations process in Canadian licensing

RM process required for licensee		x				No regulations for RM
Regulations for overall V&V program				x		No regulations for V&V
Established V&V process for all the disciplines				x		No covering V&V process

6.3.4 Results of the value analysis in French licensing

Table 28 Standardized process in French licensing

Standard				x		Variable
Established	x					New
Regulator determined requirements				x		Licensee determined requirements

Table 29 Comprehensive review in French licensing

Regulations organized according to importance					x	Not organized regulations
Detailed regulatory requirements					x	High level requirements
Regulations suitable for passive plants	x					Passive plants not fully considered

Table 30 Adjustable process in French licensing

Modularity taken into account			x			Modularity not taken into account
Suitable for many		x				Not suitable for

identical NPPs in series						repetition
Graded approach available				x		No graded approach available

Table 31 Systems Engineering, Requirements Management, and Verification and validations process in French licensing

RM process required for licensee				x		No regulations for RM
Regulations for overall V&V program					x	No regulations for V&V
Established V&V process for all the disciplines				x		No covering V&V process

6.3.5 Results of the value analysis in UK licensing

Table 32 Standardized process in UK licensing

Standard					x	Variable
Established	x					New
Regulator determined requirements					x	Licensee determined requirements

Table 33 Comprehensive review in UK licensing

Regulations organized according to importance					x	Not organized regulations
Detailed regulatory requirements					x	High level requirements
Regulations suitable for passive plants	x					Passive plants not fully considered

Table 34 Adjustable process in UK licensing

Modularity taken into account			x			Modularity not taken into account

Suitable for many identical NPPs in series	x					Not suitable for repetition
Graded approach available	x					No graded approach available

Table 35 Systems Engineering, Requirements Management, and Verification and validations process in the UK licensing

RM process required for licensee		x				No regulations for RM
Regulations for overall V&V program					x	No regulations for V&V
Established V&V process for all the disciplines					x	No covering V&V process

6.3.6 Value Analysis comparison results and discussion

In the value analysis comparison of the licensing features it has been noticed that generally the big nuclear countries (e.g. the USA) have standardized the process quite deeply. This kind of standardization is not at that high level in countries with small number of NPPs (e.g. Finland). This is understandable since the number of projects is much greater in large nuclear countries. Standardization becomes more important with a large number of NPP projects in order to enable predictable licensing. The level of detail in the review differs from one country to another. The differences might not go hand in hand with the number of NPPs in the country, but they vary due to the history and culture of the nuclear industry in different countries.

The value analysis, with the background information gathered from the questionnaire, provides a new perspective on the licensing process indicators:

- Standardized process
- Comprehensive review
- Adjustable process
- Systems Engineering, Requirements Management, and Verification and validations process.

These features of the different licensing processes are compared using the value analysis. Because of the differences in the licensing processes in the studied countries, the understanding of the licensing processes comparison has been formed using also the design stage as the variable for the comparison. Correlating the licensing stages with the corresponding design stage of the unit, the comparison can be conducted more consistently.

Findings of the value analysis

The adjustability of the licensing processes varies largely from one country to another. It can be seen that the UK and Canada have quite flexible processes, because the licensing is based on goal setting approach. In countries with a prescriptive approach to regulatory requirements (e.g. the USA), adjustability is not that well incorporated into the licensing process. Nevertheless, it can be seen that in a small nuclear country like Finland flexibility is quite easily achievable since the processes can be discussed and handled case by case.

There are benefits as well as challenges in an adjustable licensing process. As the WNA Report: Licensing and Project Development of New Nuclear Plants indicates in its main findings: "The licensing system must be predictable and stable." [81, p. 3]. A standardized licensing process is very predictable and stable; however, it can also make the licensing process quite heavy and inflexible. Predictability and stability should be combined with the adjustable features in the selected sectors. This is not an easy goal to achieve, but it should be set as a goal for the long term development.

One way to enable the predictability of the licensing process is a Systems Engineering approach and practices, including Requirements Management and a validation and verification process. The presented processes differ widely between different technical disciplines of the nuclear licensing as well as between different nuclear countries. SE has been used widely in I&C disciplines for some time, but, for example, process engineering has not been applied to the SE approach in most of the countries. Validation and verification is mainly planned and executed separately in different technical disciplines and the overall V&V planning is not seen in many countries.

It can be seen that the Systems Engineering approach is gaining more importance in the nuclear industry for the future, as has been the case also, for example, in the aviation industry. This issue is described further in Chapter 8.

7 DEVELOPMENT OF A NEW LICENSING PROCESS FOR SMRS

This study has shown clear indications that current licensing processes require some modifications to suit SMR licensing efficiently. The indications depend on the structure of the regulatory framework as well as the approach used in licensing. It has been demonstrated that the following features, presented in Table 36, in the corresponding countries require modification if optimizing the licensing of SMRs.

Table 36 Licensing features to be modified for SMRs in the studied countries

	Part of the licensing process to be modified for SMRs licensing	*Licensing methods and practices to be modified for SMRs licensing*	*Experience of the studied licensing process in terms of new NPP licensing*
Finland	Design approval and site permitting phases	Predictability of the licensing	Yes
The USA		Rigidity of the prescriptive licensing approach	Yes
Canada	Design approval phase	Predictability of the goal setting licensing approach	No
France	Design approval and site permitting phases		Yes
The UK		Predictability of the goal setting licensing approach	Yes

This chapter aims to answer the third sub-question: "How could these parts be integrated into a new feasible licensing model?"

From the SMR point of view, we are considering many identical modules (reactors) in one unit and probably many units constructed (and licensed) in at the same site. With this kind of approach the license needs to be multiplied in a very light process if the licenses of every module are separated.

The principles of the US licensing process 10CFR52 could suit SMRs in a small nuclear country like Finland, with certain modification and scoping. The independence of the site licensing as well as design certification make the licensing process adaptable, if compared with the project-specific two-step licensing with CL and OL. Also, the assumption that SMRs will be built in fleets, supports the design certification approach.

The Alternative 2: Master Facility License and Individual Reactor Module Licenses [12], from the USA, would probably be the most practicable option in the case of multimodule SMRs. The Canadian and the UK licensing practice, with a safety case and goal setting approach, could make the licensing process more adjustable to optimize the different SMR features.

A SE and especially RM approach should be implemented into the licensing process to make the process comprehensive and transparent. This approach would also help to make the validation and verification part of licensing easier to plan and execute in an effective manner. Since all the studied licensing processes include numerous requirements, it should be understood that the tools and practices for handling the licensing process play a very important role in successful licensing.

7.1 SMR licensing process optimization

The focus of the licensing process development should be on minimizing overlapping in the licensing process, since overlapping would be multiplied in case of SMRs with many units built in series. Modularity and serial construction indicate certain licensing features as more feasible for SMR licensing than others, as already discussed.

In this case there are two ways to make the process more effective: the modification of the process and the efficiency of the working methods. Process modification has already been discussed widely in this dissertation, and it is the main focus of the study. The working methods development will be described more in Chapter 8. The goal of the working methods development can be indicated as a reduction of the wide documentation-based licensing and replacing this with a requirements-based approach. The document-based approach is a traditional working method in the nuclear industry, and as the change of the working culture is a very difficult and slow process, it has not been discussed widely in the area. All the licensing processes are based on document reviews and depend significantly on personal knowledge of the regulatory requirements and the plant design. In many fields of industry, such as the aviation industry and the space industry, the SE approach has been implemented for licensing and PM purposes. With this approach the transparency of the process and the management of the requirements can be improved. At the same time, the dependence on the personal knowledge can also be decreased and, in the case of personnel changes, all the required information is available in a readable format. This working process development would not decrease the importance of the organization or personnel know-how, but it eases knowledge transfer to the next generation as well as the availability of information during a plant's lifecycle.

The modification of the process can be done by adapting the suitable features from the different countries' licensing processes, as well as using the selected features from licensing in the aviation and railway industries. The possible high level elements of a licensing process for SMRs are presented in Figure 81. Standard Design Certification for every module could be a practical approach for SMRs with more than one reactor module in one unit (e.g. 12 modules of NuScale design). While building many SMRs at the same site, only the necessary licensing steps could be selected and/or revised (as site approval), the other parts could be simply multiplied when necessary. The following results have already been shown in reference [132 - "Challenges on SMR Licensing Practices"] by the writer.

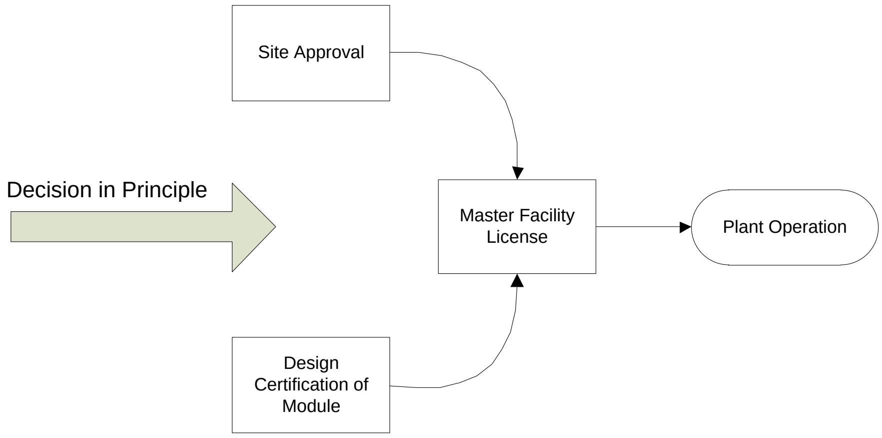


Figure 81 Possible elements of a licensing process for SMRs

Possible licensing steps that could be practical for SMR licensing include in any country:

- Decision in Principle

An upfront "political license" such as the current Decision in Principle in Finland has turned out to be a good practice in reducing the political risk during the later stages of a project. This kind of binding political decision has been indicated as one of the findings also in the WNA Report: Licensing and Project Development on New Nuclear Plants [81]. It is stated: "A formally binding positive decision about a nuclear plant project taken by the government (and possibly parliament) at the outset would remove political considerations from the licensing process, which could then focus on safety issues." [81, p.4] This approach could be expected to also work equally well for small modular reactors. Slight modifications to the current practice, such as conditions on the number of units, thermal power, and the validity of the permission, might be needed in the case of SMRs. The basis of this licensing step is taken from the Finnish licensing process.

- Site Approval

A site approval process similar to, for example, the Early Site Permit practices in the USA could be quite well suited to SMR licensing. It could be applied separately from other licensing steps. It should be noted that, in Finland, this process is currently included in other licensing steps and it has also been an effective practice in the Finnish case. Site approval challenges are not found in the licensing process, but there are public acceptance issues. Assuming the SMR case, there would be a need for many new sites and sites reasonably close to cities, thus the influence of public acceptance should not be underestimated. The basis of this licensing step is taken from the US licensing process.

- The Standard Design Certification of Module (SDCM)

The Standard Design Certification type of license has many features that suit SMRs well. Some modifications to the contents of the Standard Design Certification could be applied for SMRs, such as issuing a design certificate for a single module. The Design Certificate could be certification of the detailed design (almost 100% design of the module ready) of the SMR module. The modules are assumed to have independent safety systems and, from a safety point of view, they are not dependent on the other parts of the plant. The module and its safety systems are to be standardized and optimally they do not depend on the site features or other external features. Dusing the design phase the site envelope is assumed to be determined in a way that it suits most sites. The module safety issues or design would not be reviewed again as a single module during any specific NPP licensing.

The SDCM is the part of licensing that could be internationally valid or transferable from the country of origin to other countries. The licensing requirements of the module and its safety systems do not differ in practise from one country to another. The safety classification, which is quite different in different countries, does not have such differences in the area of primary circuit. The differences of safety classification are mainly focused on the next structural defense level, such as safety class 3 systems in Finland. The concept of this licensing step is new, since no modular license has been introduced in any of the studied licensing processes.

- Master Facility License

The Master Facility License (with similarities to the COL in the USA) also has many suitable features for SMR licensing. Some modification could be indicated if the Design Certificate contained only module certification, and then the Master Facility License would concentrate on safety issues that are common to the whole unit (e.g. external hazards and common cause failures). This approach would make this licensing step straightforward. The unit or project-specific part (Master Facility License) would be minimized to reduce repetition in the licensing process. The Master Facility License gives permission for operation when completed. As the SDCM also affects the other parts of nuclear power plant licensing, this licensing step can be seen either as a new concept, or as a modified concept from the US COL and ITAAC processes.

In this approach, a module would be licensed only once. When other identical modules were built, the same license application would be repeated and reviewed so that there are no changes in the design. Many modules of SMRs would only need to go through the module licensing process once, since the module and its safety systems were fully standardized. The limitation of this approach is the management of the possible changes of the design over the years as well as the design modifications over the lifetime of the unit. The modifications of the design and the modification of the SDCM shall be planned as part of the change management process. When applying SE principles efficiently, this change management process should be treatable.

It can also be proposed if the module license could be transferred from the country of origin of the SMR design, as is the practice in aircraft licensing. In the aviation industry, a high degree of confidence has been achieved between the USA, Europe, and a few other countries. This is one feature that could be adopted from the aviation industry. To make it possible, the development of more harmonized licensing processes, as well as licensing requirements, is required. The adequate protection of vendor and supplier intellectual property would be challenging in this approach, since openness of the design information would be the cornerstone of international acceptability.

The international standard certificate or at least European standard certificate has been mentioned in different studies over the years, but it has been found to be an almost impossible goal to achieve. For SMRs, this approach is seen as more achievable than in the case of large NPPs, since SMRs are planned as standardized designs, planned to be constructed as fleets, and the modular design enables modular standardization even if the other parts of the plant would differ from one site to another as well as from one country to another. Safety classification differences in different countries and their influence on SSC requirements, as well as validation and verification, are not dealt with in detail in this study. However, with the SDCM, the safety classification does not differ so much from one country to another, as the primary safety systems are safety classified in a similar manner in every nuclear country. The main differences between countries are found in lower safety classes with systems executing diverse safety features or being support systems for primary safety systems. Also codes and standards cost differences in requirements mainly in areas with lower safety classes. This is part of the reasoning why the SDCM could be applied internationally. This approach, of validating the design certificate from one country to another, is also proposed by ERDA [41] considering licensing process development for large NPPs in Europe. These issues should be included in further actions in SMR studies.

The same approach, of multiplying the license, which has been presented for modules, can be issued for the master facility license when only considering domestic nuclear licensing. Also in this case the licensing process could be handled only once when many identical SMRs are built at the same site or even different sites domestically, if the site characteristics would not differ too much from one another. In this case the license could be repeated reviewing for changes of the design required for a new site.

Lessons from the aviation industry and also from the railway industry include the division of requirements into parts. The aviation industry divides the requirements into two: general requirement and a declaration, which is also the case for certain nuclear countries as well as certain international requirements in the nuclear field. This licensing requirements approach would formulate the licensing requirements into a more standardized format. From the SMR point of view the railway industry approach would be even more beneficial, dividing requirements into different layers, as presented in Figure 51. The graded approach could be applied to SMR licensing through different requirements layers.

SE and RM processes are seen as tools to reduce the need for massive licensing documentation, which is currently inefficient and slow when reviewed. SE and RM will be further described in Chapter 8.

Development of the RM process will also affect large NPPs as SMRs. In the long term, the objectives of RM and SE are to reduce the need for paper documentation replacing the documentation with computerized data bases as the basis of licensing. Many functions could be handled in data bases including: issuing requirements, approving baselines in the RM tool, as well as reviewing and approving the validation and verification programmes and results. This process and work flows are used in other industries, such as the space industry, where the requirements approvals are handled within the RM tools.

In the new SMR licensing process the RM would be used both in SDCM and in Master Facility License. With a developed RM process and tools, the licensing requirements, design basis requirements, as well as configuration management could be handled using these processes and tools. The RM tool can be used for the whole plant lifecycle. Licensing requirements have to be satisfied over the whole plant lifetime.

7.2 The optimized licensing process adapted to the Finnish regulatory framework

As this research is focused on European regulatory challenges and especially on Finnish licensing practices, this chapter presents the suggested modifications to the Finnish regulatory framework implementing the suitable features for SMR licensing. The licensing environment in Finland has been under development in recent years, even though the main licensing steps have not been revised (see the current process in section 5.2 . The current Finnish licensing process is built to suit the current licensing framework for large NPP new build projects. The modification needs of the licensing process have been noted already in Finland, since the current process is heavy even for large NPP licensing and does not enable cost-efficient nuclear industry development in Finland. This section presents the minimal changes needed for the current Finnish licensing process to better take into account the SMR features.

In principle, the licensing process presented in 7.1 would be an optimal process for SMR licensing. However, the main improvements can be included in the licensing process with only small modifications to the current licensing process. The difficulty in Finland is that the industry and regulatory body are unfamiliar with this licensing approach, so a radical change is not feasible, at least in the short term. The modifications feasible for the short term are presented here. The current three steps (Decision in Principle, Construction License, and Operating License) are used as a basis when planning the SMR licensing process to Finland. The main modification would be the addition of the Standard Design Certification of Module into the licensing process. This addition would introduce the main benefits with minimum modification to the process.

As the optimized licensing process, the SDCM would be a certification of a standardized detailed design (almost 100% design stage of a module) of an SMR module. The modules are assumed to be independent units from a safety point of view, so most of the safety issues would be handled within the SDCM. This would change the contents of the CL and OL, which could concentrate on safety issues that are common to the whole plant (e.g. external hazards and common cause failures), as described in section 7.1 with the Master Facility License. This approach would make the CL and OL licensing step quite light and straightforward. The unit- or project-specific part of licensing (CL and OL) would be minimized to reduce the repetition in the licensing process for new SMR projects.

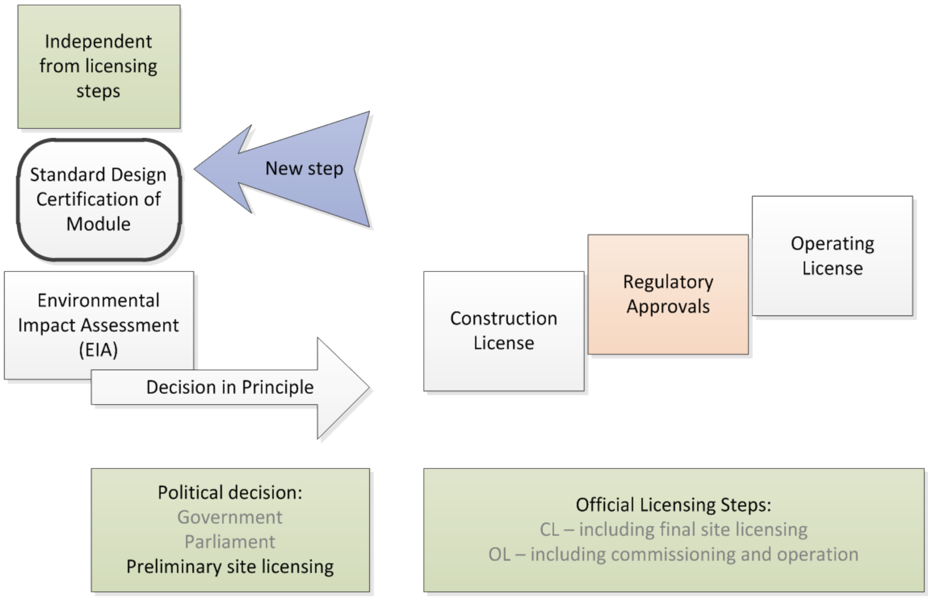


Figure 82 New, proposed licensing process for SMR licensing in Finland

With this approach the current licensing process would not necessarily change for large NPPs, but the SMRs could use the new approach including the SDCM to replace part of the CL work. The content of the DiP would be similar to what it is currently (2013), although the decision would not be made according to the number of reactors, but the power production level would be the set as a restriction. Also, discussion of the modules' construction, step by step, needs to take place, as well as the validity of the DiP. How could the growing power production be included in the DiP, as it could be justified as an overall benefit for society? This DiP decision statement would need very careful and thorough wording, since it is, in principle, quite challenging to write a binding decision that would also be flexible.

Pre-Licensing activities are seen as becoming even more important in the future in order to optimize the licensing process. The Pre-Licensing processes differ from country to country, since some licensing processes are legally binding, such as in the USA (design certification and early site permit), while other countries such as the UK and Canada have Pre-Licensing processes that are not very formal or legally binding. It has been observed that the terminology is not set when describing Pre-Licensing activities. Regardless of the differences of the approaches to Pre-Licensing, the importance of this licensing step is not questioned by the countries licensing new nuclear capasity.

The SDCM would cause changes to the CL contents, since the module and primary circuit approval, as well as primary safety systems, would be issued already in the SDCM. The SDCM would be issued separately from other licensing steps and from the construction project. It should be discussed if the SDCM could be issued during the Decision in Principle process. This approach would enable more detailed issuing of the module design already in the DiP phase.

The discussion of the distribution of costs for the SDCM is to be dealt with between the licensee and the designer organizations. Since the SDCM would be independent from the actual construction project, the benefit of this investment needs to be justified for both organizations. If it would be possible to get the Standard Design Certification of Module approved internationally within Europe, the interest in the designer organization would be at quite a high level. This would be a profitable approach for the designer organization in all other projects within European countries.

The Construction License Application would refer to the SDCM, dealing then only with the unit specific issues, turbine island issues, external hazards, common cause failures, etc., common issues for all the modules. However, these issues would not include the highest safety class structures, functions or systems, which would lighten the process remarkably.

The current content of the Construction License phase (defined in the regulatory guide YVL B.1, [118] and in the Nuclear Energy Decree [89]), and the changes to be proposed through the SDCM, are described here. The YVL B.1 is still a draft version, and it should be enforced during 2013. The YVL B.1 defines that the Construction license application shall include

1) The preliminary safety analysis report (PSAR)
2) A probabilistic risk assessment of the design stage
3) A proposal for a classification document

As the preliminary safety assessment report (PSAR) is seen as the main documentation for the safety review in the CL phase. The information shall provide STUK with sufficient grounds for preparing the safety assessment. The information may be presented to the required level of detail in the PSAR or, the information can be summarized in the PSAR and specified in more detail in separate topical reports.

As described in YVL B.1 [118] requirement 607 (draft 4):
"The following information concerning the overall plant design shall be provided:

1. A description of the safety principles and design bases used in the design of the plant and its systems.
2. A description of the key series of standards to be complied with in systems design
3. A description of the nuclear power plant and its safety-classified systems; overall architecture of systems
4. A description of how the following safety issues are observed in the overall plant design and in the design of principal safety-classified systems:
    a. the practical implementation of the defense in depth concept and independence between the levels of defense in the overall plant design
    b. the implementation of redundancy, physical separation, functional isolation and diversity principles in all plant systems performing safety functions, as required in the various operational facilities of the plant

c. the layout of the systems and related structures and equipment
d. protection against internal and external hazards
e. the plans to cope with an aircraft crash
f. the principles related to the avoidance of human error
g. a summary of the results of deterministic and probabilistic safety analyses, including estimated environmental consequences of severe accidents.

5. The principal organizations involved in the design of the plant and its systems, and information on how they satisfy the requirements set for a design organization in section 3 of the present Guide
6. The principal organizations involved in the implementation of the project and their plans for quality management
7. The license applicant’s own assessment on how the plant and the participating organizations satisfy Finnish safety and quality requirements."

In the new licensing process, including the Standard Design Certification of the Module phase in addition to the CL phase the YVL B.1 requirement 607 (draft 4), a list of necessary information can be divided into two parts. One part would be included in the Standard Design Certification of Module phase and the other part would be evaluated in the Construction License phase. It shall also be taken into account that some division can be done according to the plant design; the parts forming the module with its safety systems, and the other parts of the plant (outside of the independent safety systems of a module). The divisioning of the requirements are presented in the following table.

Table 37 YVL B.1 requirement 607 (draft 4) divisioning into SDCM and CL phases

YVL requirement B.1 (draft 4) 607	To be included in SDCM phase	To be included in CL phase
The following information concerning the overall plant design shall be provided:		
1. A description of the safety principles and design bases used in the design of the plant and its systems.	Included in SDCM	
2. A description of the key series of standards to be complied with in systems design	Module and primary safety systems (SC1 and SC2)	Other than module-related systems (SC 3 and EYT)
3. A description of the nuclear power plant and its safety-classified systems; overall architecture of	Included in SDCM	
4. A description of how the following safety issues are observed in the overall plant design and in the		
a. the practical implementation of the defense in depth concept and independence between the levels of defense in the overall plant design	Limiting the scope in the interfase between the module's safety systems and the next layer (e.g. the auxiliary systems) Focusing on the Defense lines 2 and 3, some parts of 4: • structural DiD approach: the structures of the module and its primary safety systems • functional DiD approach: the functions to control abnormal operation and failure, as well as control of	Starting from the interfase between the module's safety systems and the next layer (e.g. the auxiliary systems) Focusing on the Defense lines 4 and 5, some parts of 3: • structural DiD approach: the structures outer e.g. from the containment (depending on the design) • functional DiD approach: the functions to limit releases from the containment into the environment, external events and other common hazards (for all modules)
b. the implementation of redundancy, physical separation, functional isolation and diversity principles in all plant systems performing safety	Module and primary safety systems (SC1 and SC2)	Other than module-related systems (SC 3 and EYT), common parts for all modules of the unit
c. the layout of the systems and related structures	Module and primary safety systems	Common parts of the unit
d. protection against internal and external hazards	Module specific events (mainly internal hazards)	External hazards and common threats to all modules
e. the plans to cope with an aircraft crash		Included in CL phase
f. the principles related to the avoidance of human	Review of the design independency from operator actions	Included in CL phase
g. a summary of the results of deterministic and probabilistic safety analyses, including estimated environmental consequences of severe accidents.	Reactor related events, mainly DBC 2 and 3, only core retention issues in DBC 4	Unit specific events (common for every module), severe accident management
5. The principal organizations involved in the design of the plant and its systems, and information on how they satisfy the requirements set for a design	Included in SDCM	Included in CL phase, if differ from SDCM phase
6. The principal organizations involved in the implementation of the project and their plans for		Included in CL phase
7. The license applicant's own assessment on how the plant and the participating organizations satisfy		Included in CL phase

The design maturity level of the plant is described in YVL B.1 [118] requirement 608:
"The preliminary safety analysis report shall provide an overview of the plant-level design principles and the technical implementation of each safety-classified system and its relationship with the overall plant complex. When filing an application for a construction license, the systems' design shall have been frozen to the extent that the detailed design will not necessitate any substantial changes to the information pertaining to the layout design of the plant, the location of the main system components, or the systems listed in requirement 609, and that the requirement specification can be made for the purpose of procuring components and structures."

The design maturity level of the plant can be divided into two parts in the new licensing process. The unit-level design principles and the technical implementation of each system included within the scope of the Standard Design Certification of Module would be discussed within the corresponding phase. In this phase the design maturity level of the module and the safety systems shall be at a detailed level, while the other parts of the unit can still be at a system design maturity level. This phase would review all the SC 1 and SC 2 SSC of the unit, therefore the next licensing phase, the CL phase, would only include lower safety classified systems. However, discussion of the safety classification of some structures will be needed. The design principles and technical implementation of the common parts of the unit, safety class 3 and EYT systems, would be included in the CL phase. When applying for the construction license, the design maturity of the whole plant shall be at quite detailed design level, as described in the YVL B.1 requirements 608. The interface and relationship between the two parts shall be determined in detail already within the module design certification phase. In this new licensing approach the interface management is crucial for the success of licensing.

One demanding licensing step in the Finnish licensing practice has been the regulatory oversight during construction, which is an important regulatory interaction, even if formally is not an official licensing step in the Finnish regulatory framework. The proposed licensing approach could remove the need for this additional phase in the licensing, as the design stage would be so high at an early phase of the licensing that fewer additional regulatory reviews between CL and OL would be required. It shall be understood that certain regulatory review would still be required to monitor the construction and manufacturing. This could however be more spot check type monitoring by the regulator, shifting the responsibility for manufacturing and construction more onto the licensee.

The benefits, such as a reduction of the work load, become emphasized in the SMR case with many modules in a unit and many units at a site or separate sites as long as the module design is standardized. For large reactors, this kind of approach would not be suitable because large NPPs are not modular designs, they are almost every time customized according to the current requirements, and as they are rarely built as fleets. The issues of FOAK, NOAK, as well as FIAC licensing are discussed in the WNA Report on Licensing and Project Development of New Power Plants [81, p.7]; the benefits of the NOAK licensing cannot be fully employed when licensing the plant in a different country. Even if the design would be similar, the regulatory framework may differ. It is indicated in the report that: "However, many of the advantages of a NOAK may be weakened if the design is being built for the first time in a particular country – in this case, if the earlier licensing processes in the country (or countries) where the design has already been built are not taken into account, the project may be closer to a FOAK, at least for the licensing processes."

One focus when designing SMRs and planning their licensing should also be foreseeing the possible changes in the licensing requirements, so that there would be margins in the design. This means the changes in licensing requirements would not affect the standardized design, at least not in the near term.

A goal setting approach, as seen in the UK, is the development that should be applied to SMRs in Finland. The prescriptive approach, as is the trend of the current regulatory framework development, could be modified with a graded approach for SMRs.

7.3 Legislative modifications as a consequence of the licensing process modification in the Finnish regulatory framework

Nuclear legislation as the basis of the Finnish regulatory framework, including the Nuclear Energy Law and Decree, has been included within the scope of this thesis. The possible effects on legislation have been scrutinized and it has been discussed with legal experts. The framework of the study assumes that the needs for modifications in Nuclear Energy Law and/or Decree are minimized, since the process for law reform is very time consuming, hard, and precarious. The modification of the licensing process is designed mainly to deal with changes to YVL guides, and modifications of legislation are to be very limited. The aim of the licensing process modification is to enable the current licensing process approach, and, as an option, to enable the new approach as has been presented in section 7.2.

The legislation is dealt with through semi-structured interviews with lawyers at the Ministry of Employment and the Economy, as well as selected experts in Finnish Nuclear Law. The Ministry of Employment and the Economy was interviewed, because it is the responsible ministry for nuclear energy and therefore nuclear licensing in Finland. The interview questions, used in the interviews with the lawyers are presented in Appendix 2. The main modifications to the licensing process, which impacts the legislation, are the Decision in Principle modification and the Standard Design Certification of Module incorporation into the licensing process.

Legislative discussions concerning the Decision in Principle process

The DiP modification to suit SMR licensing does not need modification of legislation. This issue was discussed with the lawyers at the Ministry of Employment and the Economy using the interview questions (Appendix 1).
For SMRs, the number of reactors is not applicable to be included in the DiP application. The limitation would be connected with the produced power level, which is in fact the main issue to be described in the DiP, since the question in this phase is the overall benefit for society. Also, the Environmental Impact Assessment, which is required for the DiP, can be discussed and reviewed with the information of the technologies and the produced power level that impacts the environment directly. Legislation does not define the information for a number of reactors, for which the DiP is applied. This approach has become a practice due to the previous DiP processes. However, the whole project (including all the planned modules to be built in the unit) should be introduced to the ministry, as well as the municipality of the site (who has a veto right), to enable the decision making process. The overall information for the complete design of the execution project, even if modules are constructed in steps over time, is needed.

Another practise, which is not determined by the legislation, is the validity of the DiP. As it has been the custom in past DiP processes, the period of validity for the decision has been five years [44, 137]. Although, the validity is not set by legislation, and it can be seen as project-specific. The validity of the DiP for Posiva's Onkalo project, which is a deep fuel underground repository at the Olkiluoto site, is 16 years [129]. In the case of an SMR project, the DiP could be issued for a longer period, if needed, according to the project schedule.

Another question to be asked is the content of the CL application, which is usually required during the validity of the DiP. In a conventional process, the CL application includes the whole unit and is issued once. In the SMR case, if the reactor modules are to be constructed in steps, what should the contents of the CL application be? The CL application could be based on the unit configuration that is planned to be constructed in the first phase. Another approach could be to include all the planned modules in one CL application, even if constructing them in phases, a part of the modules first, the other modules later. The Nuclear Energy law can be interpreted so that the SMR unit can be issued as one nuclear facility, even if it includes many reactor modules. This issue, however, would probably not need a change in legislation, but would need evaluation and modification in the YVL guides since the content of the CL application should be modified. CL application contents are determined in the Nuclear Energy Decree at a high level; however, the process is not dealt with in detail in the legislation. Because of the high level treatment, the possibility for a step-wise process is not ruled out by law, and therefore can be discussed at a lower level of the process.

Legislative discussion considering the Standard Design Certification of Module

The need for legislative review and modification is raised with the Standard Design Certification of Module. Since the Nuclear Energy Law or Decree does not recognize the SDCM, this new approach should probably be included in the legislation.

The philosophy behind the Nuclear Energy Law in Finland is that it presents a comprehensive approach to nuclear licensing issues. This is why the new approach should be indicated also as a possible licensing approach. There are two possible alternatives to include the SDCM into the Finnish regulatory framework. These alternatives are described here.

The first alternative would include a principle idea of the SDCM that would be certification of the defined part of the unit. This certification would be issued by the regulator (STUK), and the Ministry of Employment and the Economy would not be involved in the process. Also, the current licensing practice would still be valid for large NPPs as well as for SMRs, but this new approach would become an alternative way of licensing in the SMR case. As the new approach would be limited to SMR licensing only, the legislative modification should be defined so that it would limit the use of a new licensing approach only for modular designs. It is not analyzed in this thesis how the legislation should be modified as only the principles are dealt with here. Also, the knowledge of the researcher is not wide enough to review and propose the necessary legislative modification.

The other approach to include the SDCM into the licensing process would be to include this step as a licensing feasibility study. This would not be defined by law, but the licensee would send an application of a licensing feasibility study to STUK to start the discussion. This application would not be based on the legislation. This approach would require a feasibility study by the licensee and according to the feasibility study results, a licensee could ask for a safety evaluation from STUK. The licensee (or licensee together with the designer organization) would be responsible for the costs of this pre-licensing process. As a result of this process, STUK could give a statement of the module safety issues. The statement could then scrutinize the selected YVL requirements, comparing them with the module design and stating how the YVL guides are fulfilled. The challenge with this process would be the final commitment of STUK. This statement should be indicated as a commitment and the statement would not be changed later if nothing was changed.

This licensing feasibility study has been performed in 1980–1990. At that time, a company called Perusvoima Oy, which coordinated IVO and TVO cooperation, conducted feasibility studies for six different NPP designs. STUK also studied these designs and the regulatory costs were paid by Perusvoima Oy. Although any certification was not issued then, the same type of activity was performed.

These two different solutions to the issue of the SDCM came up in the interviews with the lawyers. The responsibilities of the Ministry of Employment and the Economy and STUK need to be analyzed in the future to clarify the regulatory framework in Finland. The approach needs to be selected at some point of time if this licensing approach is to be applied to Finland. However, it is not within the scope of this dissertation to propose the approach.

8 SMR LICENSING PROCESS APPLICATION

This chapter presents the SMR licensing project model, which is based on the results of the licensing processes comparison and the developed licensing process for Finnish SMR licensing. The SMR licensing model has been developed using SE [51] and PM [67] processes, presented in sections 3.4 and 3.5, combining the processes presented in the corresponding standards with the Finnish licensing process for nuclear facilities. It should be observed that new build NPP projects have been successful in the past when many NPPs were built around the 1960s-1980s. The projects had many different features compared to current NPP projects, licensing being just one of them. However, the licensing changes have been massive, with a large number of requirements and long subcontracting chains. This is why the licensing process as well as PM features should be developed to enable successful NPP projects, both large and small reactors, in the future. As stated by Wang et al in reference [166] "In today's modern computing era, computer applications have become indispensable for engineers to do their work." This is indeed a relevant statement in nuclear projects. As a result of this study, an analysis of the SMR licensing project provides practical tools for an SMR licensing project in the Finnish regulatory framework. This PM and SE approach demonstrates the new licensing model's suitability and prospects in licensing.

8.1 Systems Engineering (SE) and Requirements Management (RM) based licensing

Requirements Management is one of the new development fields in the nuclear industry. The "conventional" management fields in the nuclear industry have been part of quality assurance (QA) and quality control (QC). Configuration Management, Project Management, as well as other management fields, have been issued in the nuclear industry, but the complete management system, as it is understood nowadays within the current regulatory framework, has only been under development recently. There may be exceptions to this somewhere in the world though. SE is an engineering field that has been developed in certain fields of industry to answer the need for overall management processes. RM is part of SE and is focused on requirements, their allocation and management, as well as validation and verification activities.

RM can be defined as activities which ensure requirements to be identified, documented, maintained, communicated, and traced throughout the lifecycle of a system, product, or service. The RM objective can be defined as keeping requirements in good order and being able to show complete traceability between stakeholder needs and regulatory requirements, and Validation and Verification activities and results. The argument for using RM and SE processes can be based on studies that deal with projects' success. These studies mainly focus on examining the time to market element, as part of product development projects. One example of such studies shows that investing 17% or more time in the requirements phase of the project, the reduction of the overall product development and employment time is between 30% and 50% [84]. Not to mention the number of design failures to be avoided using RM and SE methodology and tools.

SE or RM is not a solution for nuclear licensing issues, but they provide good tools for handling the broad licensing requirements-based licensing process. In a mature organization, with a developed PM culture, these tools can be fully taken advantage of. The presented tools can be used also for other technical and management issues, between many stakeholders, over the whole unit lifecycle.

8.2 Requirements Management usage in the Nuclear Energy field

The reason for moving towards requirements-based licensing is the simplification and transparency of the licensing process. The other objective in the long term would be a more streamlined licensing process and the reduction of the amount of documentation needed in nuclear licensing. In current nuclear projects, it has been realized that the amount of documentation to be managed with existing processes and tools is very large.
RM has been used for many years in certain fields of industry, such as the aviation industry, the military industry, and the space industry.

The need for this kind of process and tools can be justified with the complexity of different fields of industry. Figure 83 shows the complexity of certain fields of industry at a general level. As observed in the space, aviation, and military industries, the complexity of projects requires developed tools and processes for RM. As the figure indicates, nuclear projects are even more complex compared to the aviation, space, or military industries, which is one of the reasons justifying RM use in the nuclear industry.

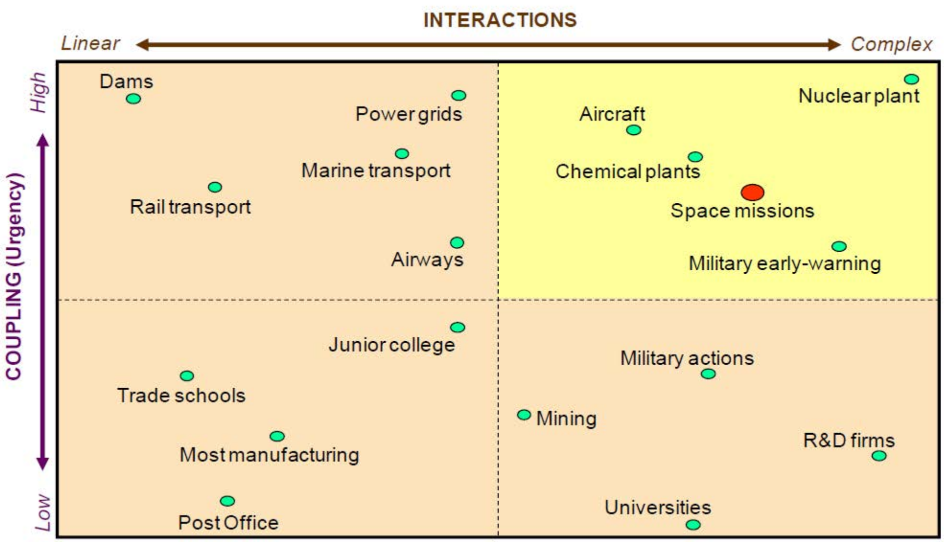


Figure 83 Systems that must manage complex interactions and high coupling are more prone to accidents, NASA study [167]

PM in the nuclear field, with long subcontractor/supply chains, makes the overall complexity of a new build project even higher, which was estimated in the NASA study [167]. The RM process is one way of handling the challenges that this kind of subcontractor/supply chains produces. RM in an NPP project can also be used to help the licensing process. The current documents-based licensing process is already based on the requirements fulfillment, but not in such a transparent manner. Regulatory requirements fulfillment is the fundamental issue for getting a nuclear plant licensed. In current practice the fulfillment of the requirements is not explicitly shown in the documents, but with good expertise they can be witnessed. The tracking of requirements fulfillment is not shown transparently in both directions (from requirements due to design steps until the end-product, and vise versa).

Usage of the RM tools and the developed SE processes for licensing would mean that every single requirement is explicitly tracked and their fulfillment is easily proven. This approach would make the approval process more transparent and clear. The approval would not be inspector's opinion of the issue in question, but the base lines would be settled in an early phase of the project, approving the requirements sets in selected freezing points.

The objective and also a challenge of this approach is to change the traditional documentation-based operation in the nuclear field into a more systematic, transparent practice. [159] The cultural change is a big step and it takes time and commitment at every level of the organization, both on the regulatory side and the industry side. The other challenge is the large number of requirements. This is an issue to be negotiated separately in every single nuclear project. The suitable level of requirements needs consideration case by case. This is one of the reasons why large NPPs currently do not use RM for licensing and in many cases are not very eager to go into this field.

The reasoning for RM usage is also the ISO 9001:2000 that is used for certification in many companies. In many cases, this kind of cultural change in an organization might be difficult to justify. Some justification are presented.
In the ISO 9001:2000 standard the following issues concerning RM are presented [70]:

- "Before submission of a tender, or the acceptance of a contract or order ... shall be reviewed by the supplier to ensure that:
    - The requirements are adequately defined and documented....
- The supplier shall establish and maintain documented procedures to control and verify the design of the product in order to ensure that the specified requirements are met.
- Design input requirements relating to the product, including applicable statutory and regulatory requirements, shall be identified, documented and their selection reviewed by the supplier for adequacy. Incomplete, ambiguous or conflicting requirements shall be resolved with those responsible for imposing these requirements.
- Design output shall be documented and expressed in terms that can be verified and validated against design input requirements.
- At appropriate stages of design, design verification shall be performed to ensure that the design stage output meets the design stage input requirements."

In Finnish nuclear projects, it has been observed that complexity, long subcontractor chains, and many specific nuclear-related components are obstacles to product development [165].

One of the critical phases of the process is the determination of the requirements. With the requirements determination, the fulfillment (validation/verification) method and the point of time should also be determined. A requirement is useful only if the fulfillment method is defined while determining the requirement. The fulfillment (validation/verification) can be an analysis, test, audit, etc. The phase of project, when the validation or verification can be generated, also needs to be estimated. In this manner, the RM process is comprehensive, transparent, and reduces the licensing risk.
Particularly in the I&C discipline, these issues have been under discussion in recent years (with the Olkiluoto 3 project) [165]. The requirements-based approach has been used in the I&C discipline longer and wider than in other technical disciplines.

Controlled procedures are even more important considering the validation of the I&C equipment and systems, compared with the validation of, for example, mechanical components. The V-model (Validation and Verification) concerning I&C [165] is presented in the following Figure 84. This is valid also in other technical disciplines in the nuclear industry, even though this type of modelling has not been used in other technical disciplines.

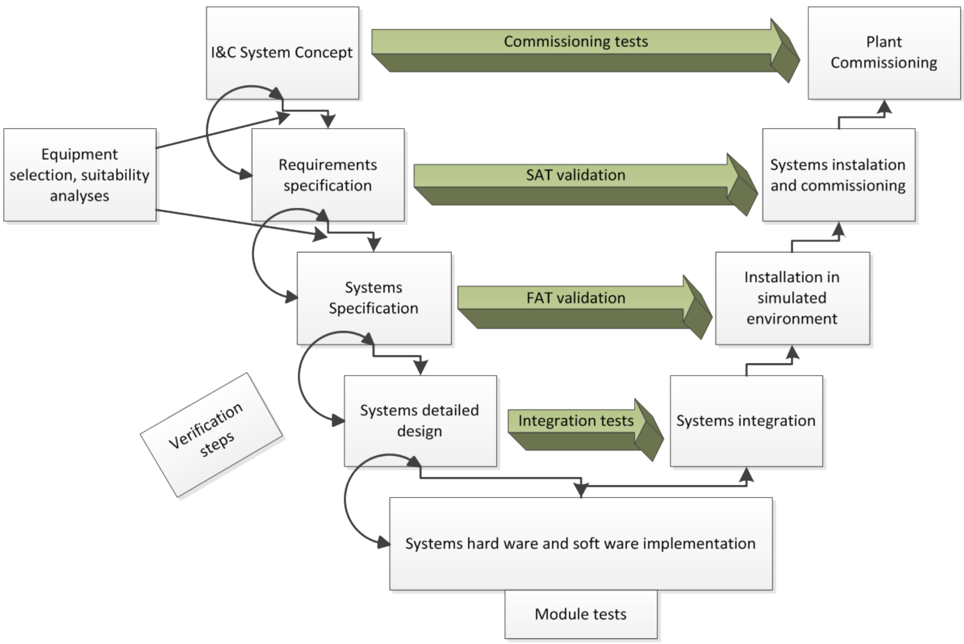


Figure 84 V-Model of I&C System Design Life Cycle

The left-hand side of the figure presents the requirements and the level of the requirements goes into a more detailed level (down-wards). For example, in process design, this could be unit level requirements - system level requirements - component level requirements (see also Figure 90). In every level of requirement, the verification step is needed to confirm that the process is going in the right direction. These freezing points could also be reviewed by the regulator approving the current level of the requirements set and giving permission to move forward with the design.

The right-hand side shows the fulfillment of the requirements. Validation & Verification processes and tests at a different level demonstrate that the valid requirements are fulfilled with the proposed solution.

With a suitable RM tool (such as Blueprint or IBM DOORS) the requirements structure can be handled and the fulfillment of the requirements can also be verified later, by tracking the solution path. This is the main idea of RM. An example of the SE and RM approach could be a model of the physical unit with its different parts, including information about the interfaces and requirements. An example of a requirements hierarchy can be seen in Figure 85.

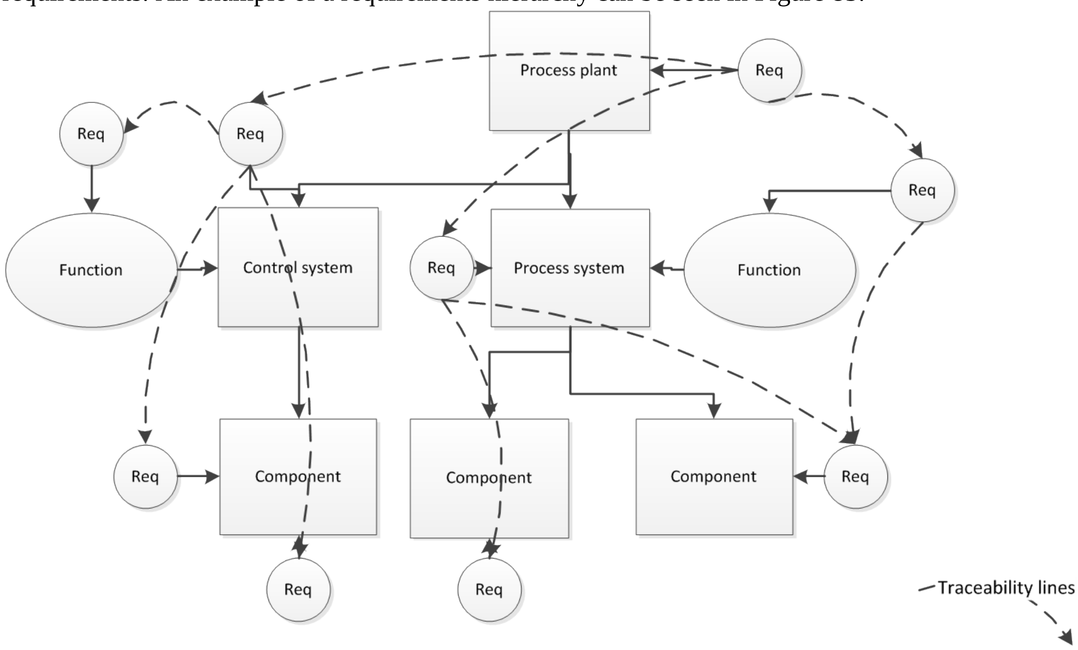


Figure 85 Requirements can be attached to all entity types at all levels of the unit hierarchy [135, p.8]

The RM tool can be built in many different ways. The most comprehensive way to use the RM tool is to have it as an integrated part of the intelligent plant design system (already in the design phase). In this approach there is a link between every requirement and corresponding system or component in the design system. The other approach is to use the RM tool separately from the design system. In this approach the requirements would also be linked to the systems and components, but the RM tool would not be integrated into the design system. The link could be implemented by reference or other suitable manner.

In SMRs with a simplified design and reduced systems and components, if compared with large NPPs, the total number of requirements can be reduced. Also, the fact that components are more standardized and the same requirements are suitable for many of them (the safety classification distinguishes the requirements, different requirements in different safety classes); makes the RM process somewhat easier to manage. Also, the factor that favors the RM approach in the case of SMRs is the series construction, which enables the same requirements basis application for all of them. The differences would comprise only the site and country-specific requirements, which are issued in the Master Facility License or the corresponding licensing step in the country of the construction project.

8.3 SMR licensing project model analyses and development using Project Management practices

Project and Project Management have many different definitions. For example, PMBOK, which is widely used guide book for PM, defines Project Management as "the applicable knowledge, skills, tools and techniques to project activities to meet the project requirements" [5, p.6]. PMBOK has also been used in this study as guidance in the background. Certain analysis methods are selected for an SMR licensing project. The ABC project model, stakeholder identification and analyses and risk analysis are described in this section. That being said, there also exist many other analysis methods that could be relevant for analyzing an SMR licensing project.

8.3.1 ABC Project model for SMR licensing project

The ABC Project Model [116] that is developed by Finnish Project Institute is used quite widely in Finland in different organizations. This project model is based on international Project Management standards, such as ISO 21500 [71] and PMBOK [5], and it represents the main project phases from the Project Management point of view.
The ABC Model basis is presented in Figure 86.

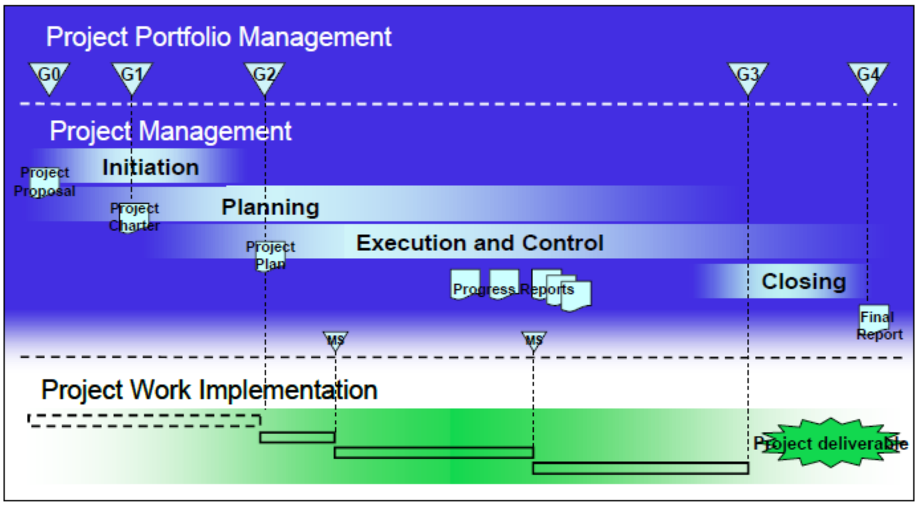


Figure 86 General ABC Project model [116]

The main gates (G0-G4) are the following:

- G0 is a decision to start the pre-studies of a project. Decision is based on a written project proposal
  - Approval of project proposal in G0 starts the initiation process until G1
- G1 is a decision to start the project planning process
- G2 is a decision to start the project execution, monitoring, and control process
- G3 **-** Project results (deliverables) are approved and a permission to start the project closing process is given with G3
- G4 is a decision to close the project

To apply this general ABC project model to an SMR licensing project, it has to be analyzed and interpreted. The main project phases can stay as they are presented, but the SMR licensing steps contribute to this project model. Figure 87 presents the SMR licensing project project model in the ABC Project Model terms.

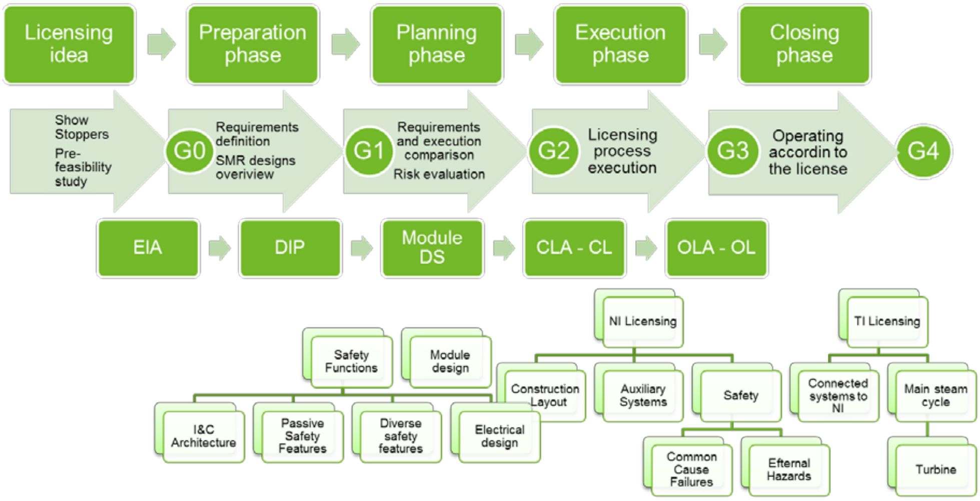


Figure 87 SMR licensing project built into the ABC Project Model

The general project model phases, as seen in the upper part of the figure, are used as a basis of this implementation. The gates G0-G4 and the main activities in each project step are presented below the main project steps. Below that the licensing phases of the new, proposed, licensing process for SMRs are presented. Parts of this, such as SDCM, CL and OL if needed, are still divided into discipline-specific licensing units. This level is not studied here, since it is closely connected to the technical licensing requirements and their usage. Different work breakdown structures (WBS) are available in many publications, such as presented by Amaba in reference [3]. With suitable modifications, the WBS structure can be created for an SMR licensing model. This is an area that needs to be studied further in future SMR studies.

8.3.2 Stakeholder identification and analyses

Stakeholder identification has been done using the Bryson technique [18] within the selected group. As the techniques of stakeholder analyses require group of people, inthis study, the group of participants for a Project Management training course (PM Master 2012 of Projekti-Instituutti [117]) was used for the stakeholder identification.
The technique uses the following steps [18]

- Brainstorm the list of potential stakeholders.
- Prepare a separate flip chart sheet for each stakeholder.
- Place a stakeholder's name at the top of each sheet.
- Create a narrow column down the right side of each sheet and leave the column blank.
- For each stakeholder, in the area to the left of the narrow column, list the criteria the stakeholder would use to judge the organization's performance (or list what the stakeholder's expectations are of the organization).

These steps were used with appropriate modifications for the purpose.

The stakeholders are discussed and analyzed by focusing on the SMR licensing project execution phase. Assuming that the DiP is already granted, which affects, for example, the power versus interest grid. Table 38 presents the identified stakeholders for the SMR licensing project.

Table 38 Stakeholders for the licensing project.

Internal stakeholders	*External stakeholders*
Licensee (project group)	Regulator (STUK in Finland)
Management of the owner organization	Government (policy maker)
Operators of the owner organization	Government (issuer of licenses)
Experts of the owner organization	Media
Designer organization	Environment (municipality, residents, etc.)
Subcontractors	

The identified stakeholders are analyzed using the power versus interest grid method. This method is described in detail by Eden and Ackernlann [32, p. 121]. This analysis identifies the status of each stakeholder group according to their level of interest and authority. This analysis gives good background for stakeholder management planning in the SMR licensing project. The results of the analysis applied to the groups in Table 38 is presented in Figure 88.

"Power versus interest grids typically help determine which players' interests and power bases must be taken into account in order to address the problem or issue at hand. They also help highlight coalitions to be encouraged or discouraged, what behavior should be fostered and whose 'buy in' should be sought or who should be 'co-opted'. Finally, they provide some information on how to convince stakeholders to change their views."[18, p. 31]

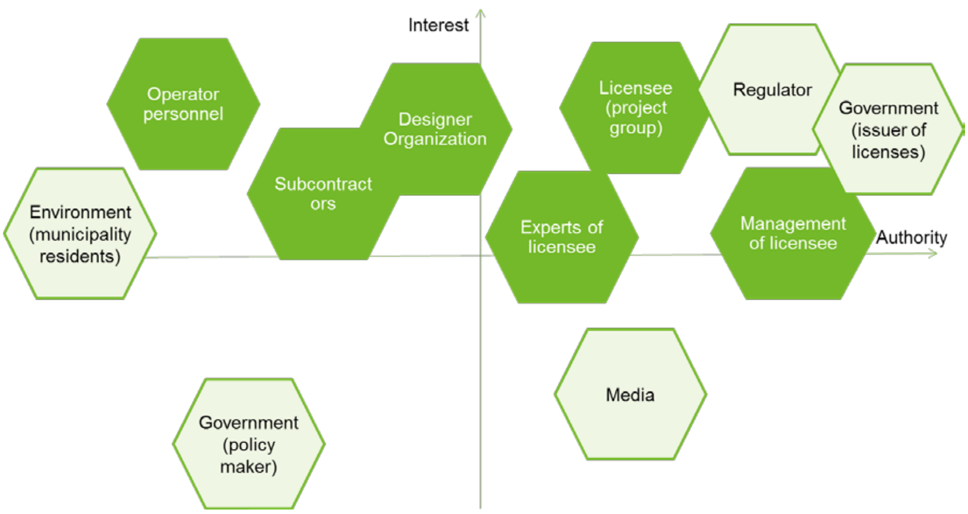


Figure 88 Stakeholder analysis - power versus interest grid

The power versus interest grid shows qualitatively the different authority levels of the identified stakeholders and also their interest in the licensing project. This analyses can be used as a tool while planning external licensing activities towards the stakeholders.

The next logical step, after the power versus interest grid analysis, is the stakeholder benefit map. The stakeholder benefit mapping is used widely in the PM field. The examples of the stakeholder benefit mapping usage can be found in the literature, such as in reference [15, p. 36]. The stakeholder benefit mapping gives a perspective on the selected features of the SMR licensing project influence and importance to the analyzed stakeholders.

Table 39 Stakeholders' benefit map for the SMR licensing project.

Stakeholders	Risk minimization	Design approval	Safety level	Predictable process	Schedule
Management of licensee	++	+	++	+	++
Licensee (project group)	+	++	++	++	++
Operator personnel		+	++	+	+
Experts of licensee		+	+	+	
Designer organization	++	++	++	++	+
Subcontractors	++	++	+	++	+
Regulator		++	++	++	+
Government	+		++		+
Media	+		++		+
Environment			++		+

The stakeholders benefit map shows the importance of the selected features of the SMR licensing project from different stakeholders' points of view. From this benefit map, it can be concluded that the licensee project group, designer organization, subcontractors, and regulator show most interest in design approval as well as a predictable licensing process.

8.3.3 Risk analysis of the SMR licensing project

The logical continuation of the project planning, after the stakeholders' analysis and the stakeholder benefit mapping, is the risk analysis. Before describing the risks of the SMR licensing project, it needs to be clarified what is meant by risk.
Risk can be defined in the following way [24, p. 6]:

- Risk **-** "an uncertain event or condition that, if it occurs, has a positive or negative effect on a project objective" **-** The US Project Management Institute (PMI)

- Risk - an uncertain event or set of circumstances that, should it accur, will have an effect on the achievement of the project's objectives - the UK Association for Project Management (APM)

Risks can be analyzed using different techniques provided in the literature; in this study, the group of participants for a Project Management course (PM Master 2012 of Projekti-Instituutti [117]) was used for a risk analysis control group. The risks of the SMR licensing process are analyzed qualitatively using the stakeholders and the selected features for stakeholder benefit mapping as background. The risks, their characteristics in terms of internal and external features, and their influence targets are determined and presented in Table 40.

Table 40 Risk analysis of the SMR licensing project

Number	Internal/External risk	Risk	Effect target
1	Int.	Current licensing process is not suitable for SMRs	Schedule
2	Ext.	Current regulatory requirements are not suitable for SMRs	Product
3	Int.	Short SMR construction schedule is challenging for current licensing process	Schedule
4	Int.	The design is not approvable (show-stoppers)	Product
5	Int.	Competent recourses are difficult to find	Expenses
6	Ext.	Media may attact to oppose SMRs	Product
7	Ext.	Political environment may change	Product
8	Ext.	Possible severe accident somewhere in the world	Product
9	Ext.	Regulatory requirements interpretation may change during the licensing project	Expenses
10	Int.	Design stage of the selected design may be lower than expected	Schedule

The identified risks are risks that may occur during the licensing project execution phase. The risks concerning the early SMR project phases are not handled here. The same assumptions as with the stakeholder analyses are also used in the risks analyses.
After identification of the risks, a qualitative risk analysis can be performed for the identified risks. A qualitative risk analysis presents the probability and the severity of the risk. This approach presents risk bands, as does the Functional Safety Assessment that is presented in 3.1.2 and used widely in this study. For an SMR project, the qualitative risk analysis is presented in Figure 89. The numbers of the identified risks from Table 40 are placed in the figure according to their effectiveness and probability.

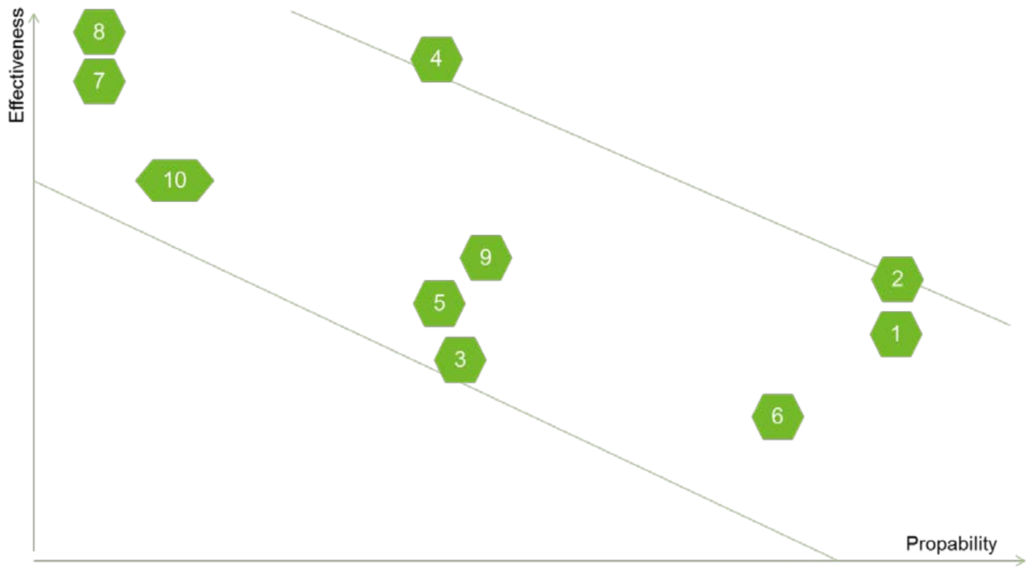


Figure 89 Qualitative risk analysis for an SMR project

This risk analysis provides visible risk bands and with this analysis it is easy to identify the most severe risks to take into account while planning the SMR licensing project. The SMR licensing project shows that the following risks are severe and should be focused on:

- 4 (The design is not approvable),
- 2 (Current regulatory requirements are not suitable for SMRs),
- 1 (Current licensing process is not suitable for SMRs)

This analysis result shows the importance of this study and its subject matter. The main risks can be dealt with while starting the project planning well before the SMR licensing project execution phase.

8.4 Systems Engineering processes and Project phases implementation in SMR licensing

SE and RM has been presented in sections 3.4 and 3.5 and it has been part of this study throughout as a practical tool to manage the licensing of a very complex ensemble.

It has been one of the lessons learned from current licensing activities in the Finnish nuclear industry that the management of licensing requirements is one of the key components for successful licensing. The complex and wide set of licensing requirements needs advanced management tools and methods to be well organized and taken care of systematically. Effort has been put into connecting the SE processes and Project phases with the licensing process steps. Figure 90 presents the interconnection of the processes [2, 51, 71 and 68].

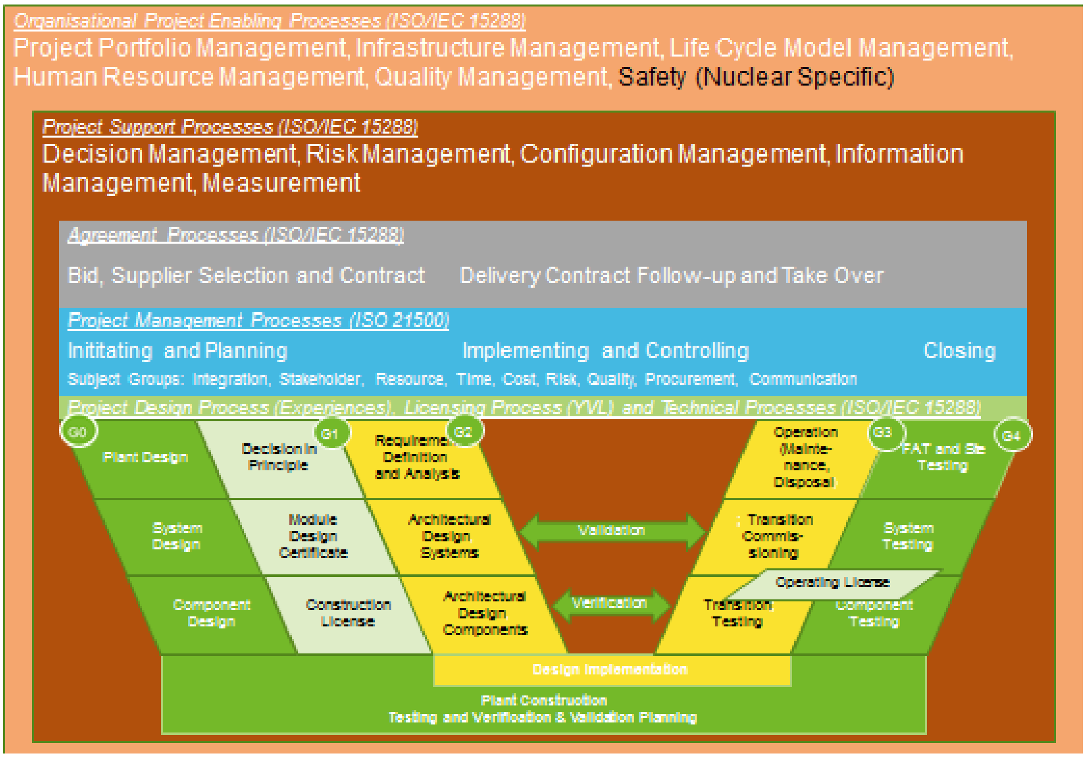


Figure 90 SMR licensing model using SE and PM tools

Figure 90 presents the PM and SE tools' suitability for the licensing project. The figure is divided into areas (indicated in different colors), starting with large entities, such as Organizational Project Enabling Processes. The next layer is Project Support Processes, moving to a smaller scale and to a specific project with PM Processes. The V-model presents the Project Design Process, Licensing Process, and Technical Processes, such as RM Process. The ABC Project Model Gates are indicated in the figure with circles of G0-G4.
The layers of the figure are presented in more detail in the following.

8.4.1 Organizational Project Enabling Processes.

The organizational project enabling processes are processes which give a company level background to the project execution. In this study, the following processes are included in this group:

- Life Cycle Model Management includes general policies and procedures for PM through the whole lifecycle of each project. It is necessary that the company has determined these in order to build-up a strong project culture in the company.

- Project Portfolio Management - especially with large projects, it is necessary that company already has a strong project culture, which includes practices in Project Portfolio Management
- Infrastructure Management ensures the benefits of similar features between different projects to be taken into account. This helps resourcing and PM at a general level between projects.
- Human Resource Management - company level process with strong input from the projects.
- Quality Management is responsible not only for the final product quality, but also design process quality. This is a highly important management field when considering licensing issues and the safety critical industry.
- Safety is a nuclear-specific addition to the ISO/IEC 15288 standard. In safety critical projects, safety is the result of a high quality design process and working culture with strong management level support in the company.

Quality and safety are not just issues for the project, but also issues for the management.

8.4.2 Project Support Processes

The project support processes have project-specific content, with company level aspects. These are indicated as management level processes assuming that they follow similar procedures in each project.

- Decision Management takes care of the project follow-up and helps to make the best solutions in the situations where alternatives exist.
- Risk Management is actually a project-specific process, with a company level aspect in the risk analyses, with strong link to the business and strategy of the company.
- Configuration Management is understood here from an administrative point of view. Configuration Management guarantees that project information, works, and outputs support each other throughout the project lifecycle, and necessary changes are made to requirements and targets. Change management is part of this process, but Configuration Management oversees projects from the wider point of view.
- Information Management includes practices to manage all project information, including tools used for information management.
- Measurement includes processes and tools which help both the project manager and decision makers to follow-up the project progress and needs. Measurement Process Input to this process comes from the projects.

8.4.3 Agreement Process

The Agreement Process includes two main phases:

- Supplier selection and contract
- Delivery contract follow-up and takeover.

In a large project, supplier selection can be very challenging, being treated almost as a separate project. However, it is important that at least the most important parts of the project organization

exist already during the supplier selection. A detailed understanding of technical questions and project progress is needed to perform successful supplier selection and contracting.
Even if the supplier selection and contract is probably the most important part of the Agreement Process, it continues until project takeover. Delivery contract follow-up is still an important part to help management in following up the projects.

8.4.4 Project Management Processes

The PM processes are project-specific processes, and are shared in a group according to the ISO 21500 standard.

- Initiating Process Group
- Planning Process Group
- Implementing Process Group
- Controlling Process Group
- Closing Process Group

These processes include all traditional PM tasks from the start of the project until project closing.

8.4.5 Project Design Processes

Project Design Processes are shown in the lower V-part. Design Process, Licensing Process, and Technical Process descriptions are included in the model. Licensing process has been discussed widely in this study, so it will not be handled here, as the main focus is to show the different process interfaces. Design process as well as technical process are described here.

Design Process
The design process starts with requirements specification (not presented in Figure 91), and continues with the first design phase. The design phase's contents are presented below. The Validation and Verification process in this study is included in the licensing process, even though it could be included in one of the design or licensing processes. It should be noted that this is only an example of what different design phases could contain and different design companies have slightly different design processes.

Plant Design phase:

- P Diagrams of the systems
- Preliminary I&C Architecture
- Preliminary Single Line Diagram (Electrical)
- Building design criteria with basic dimensioning
- 1st draft of the 3D model including main components, main piping routes, main walls and floors, support structures, access routes, and divisional separation
- Safety design of Defense in Depth concept and Safety Functions

System Design phase:

- PI Diagrams for main and safety systems

- I&C Functional requirements, I&C Architecture, and I&C Systems
- Single Line Diagram (Electrical)
- Structure design criteria
- 2nd draft of the 3D model including components, piping, walls, floors, room layout
- Deterministic Safety Analyses, Radiation dose calculation, Probabilistic Risk Assessment (PRA), Preliminary Failure Mode and Effect Analysis (FMEA)

Component Design phase:
- Final PI Diagrams, Component requirements specifications, Design drawings, Manufacturing procedures
- I&C systems, Component requirements specifications, Instrumentation equipment diagrams
- Detailed Single Line Diagram (Electrical), Sub-System design criteria, Component requirements specifications
- Final 3D model including piping, cable routes, penetration and injection arrangements
- Final FMEA

The nuclear power plant design process is quite a similar process to that used in many other industrial fields.

Technical Processes

The presented Technical Processes are in accordance with the ISO/IEC 15288 standard, including the whole lifecycle of the product. The processes are arranged according to the design and licensing processes. The technical processes are the following:
- Requirement Definition and Analysis
- Architectural Design of Systems
- Architectural Design of Components
- Design Implementation
- Transition: Testing
- Transition: Commissioning
- Verification and Validation
- Operation: Maintenance and Disposal

In the following section a short description of these processes is given.

<u>Requirement Definition and Analysis</u> is the basis for a project, and therefore basis for a whole lifecycle of a product, which is a result of the project.

Using traditional PM practices, the requirement definition and analysis is often at a very general level. With the requirement definition and analysis, the stakeholders can understand and approve the project targets. Requirement Definition and Analysis should include planning for Validation and Verification Processes. The challenge in requirement definition is to keep the requirements at such a level that they are not just a list of requirements, but the complete design can be understood through the requirement definition. With well-defined requirements, the requirement database is a good tool in the design verification and validation phases as well as in the testing and commissioning phases. The important issues in the Requirement Definition and Analysis Process are:

- To understand the targets of the project
- To understand the scope of the project
- To identify the stakeholders
- To understand the technical purpose and content of the product
- To identify the correct and essential requirements
- Capture requirement sources

Architectural Design of Systems and Components is the process which is strongly based on the Requirement Definition and Analysis Process. The character of the product and requirements of the design process are defined in the Requirement Definition and Analysis phase.

Design Implementation phase includes realization of the final product of the project, i.e. constructed in the case of an NPP.

Verification and Validation Processes are presented in the next phases, but actually they have an important role also in the Design Implementation phase of the project. The Verification Process should especially be applied before construction is started. The Validation Process has a stronger role in the testing and commissioning phases.

Transition: Testing is an important phase of the NPP project where validity of the systems and components as well as the whole final product is proven.
In NPP projects, tests can be shared in three general groups:

- Tests of the Supplier
- Tests of the Owner
- Test required by Authorities.

In the optimal case, the content of the tests would be included in the Requirement Definition and Analysis Process.

Transition: Commissioning is a phase where the final product is proven to be in accordance with the requirements and ready to be taken into commercial operation.
During this phase, the project requirements are transferred to the operational requirement database. During the unit operation it is important that the original design requirements and bases are available.

Verification and Validation are not separate individual phases of the project, but they should be understood as continuous processes throughout the project implementation.
According to ISO/IEC 15288 Verification and Validation are defined as the following [72]:

- "The purpose of the Verification Process is to confirm that the specified design requirements are fulfilled by the system

- The purpose of the Validation Process is to provide objective evidence that the services provided by a system when in use comply with stakeholder's requirements, achieving its intended use in its intended operational environment."

Both processes are essential for inclusion in the overall RM Process and they have a big role in guaranteeing that the final product is in accordance with the requirements.

Operation: Maintenance and Disposal. During the Maintenance, original design requirements and bases can be found from the unit database.
This means that a well working and efficient Requirement Definition and Analysis Process is needed through the whole lifecycle of the NPP.

8.5 Conclusions on the SMR licensing process application

The main findings of this study are concentrated into the special features of SMR licensing and Finnish licensing process development to suit SMR licensing. The SDCM has been proposed for addition to the Finnish licensing process. In this approach the SDCM is introduced and it has reduced the need for regulatory oversight during construction (Pre-Inspection phase) between the CL and OL phases. This is the way to develop the licensing process more proactive, emphasizing the early licensing (Pre-Licensing) activities in the SMR project. As Pre-Licensing has been indicated to receive increasing importance in licensing, this develops the licensing process more efficiently. In licensing SMRs, this approach is more effective and easier to execute if compared with large NPPs. The special features of SMRs, as presented in Chapter 4, enable the module and its independent safety systems at a high design stage to be standardized and licensed in an early project phase. With the possibility to develop an internationally applicable "Standard Design Certification of Module", this could be the first step towards international nuclear licensing, which is the long-term goal of the nuclear industry.

Some examples of the new SMR licensing and deployment project schedules can be presented. Using the two estimates of the OECD/NEA SMR construction schedules [100, p.88] Figure 91 presents the licensing schedules.

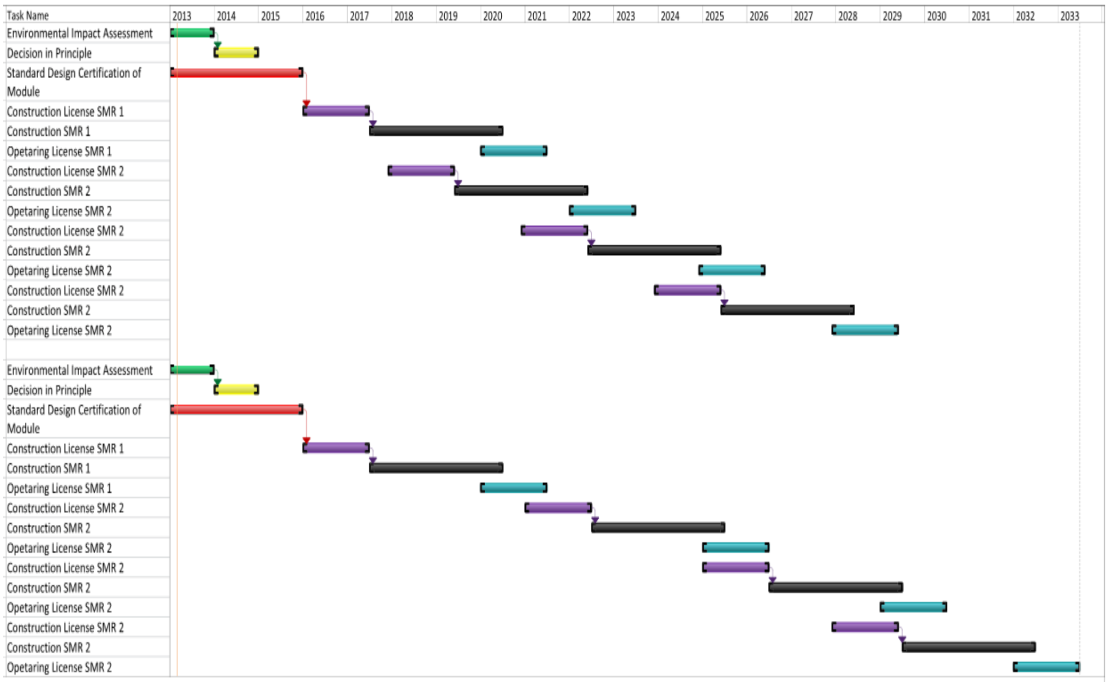
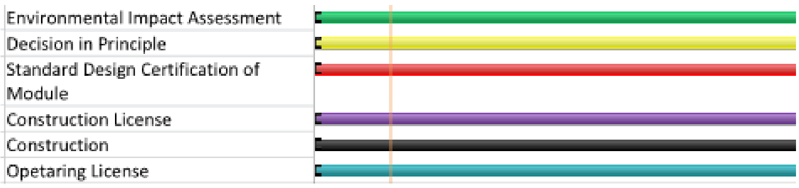


Figure 91 Licensing and deployment schedules with the OECD assumptions [100, p.88].

The first assumption used in the figure is deployment of four 300 MWe SMRs over 11 years, and the second assumption is deployment of four 300 MWe SMRs over 15 years.
The colors in the figure are coded to represent a certain licensing process step.



The licensing and deployment project schedule demonstrates the influence of the new licensing model on SMR licensing in series. The most benefits are gained, not with the first SMR deployment, but with the SMRs after the first one. It should be taken into account when planning SMRs that they should be planned to be built more than one in a series, in order to license them functionally, economically, and practically.

9 CONCLUSIONS

In this chapter I summarize the key contributions of the study. I also describe the limitations and potential avenues for future research in the field of SMR licensing.

9.1 Discussion and Contribution

Throughout this research my intention has been to develop an understanding of the licensing processes and practices in different countries. Together with an understanding of the specific features of SMRs that affect licensing, it has created a view of the most suitable licensing process features for SMR purposes. My aim has been to develop an optimized licensing process model assuming that the licensing country does not have an existing regulatory framework available. This optimized process model presents the results of this research and is described in Chapter 7. The optimized process has been fitted to the Finnish regulatory framework, incorporating the most beneficial features of the optimized model into the current Finnish licensing process in Chapter 8. The new licensing process, with the application model and discussions, answer my research question: "How can SMRs be licensed in Finland functionally, economically, and practically?"

Besides presenting theoretical contributions in this research, I intended to provide support and tools for SMR licensing and licensing planning. I also intended to open the discussion about the current regulatory framework, as well as the needs for the modification of legislation to enable a flowing licensing process and therefore enable the success of an SMR project.

To these ends I compared nuclear licensing processes to licensing processes in other fields of industry. The research setting was also chosen to reflect the SMR-specific issues and their influence on the licensing process. Nuclear regulatory frameworks, which have been active in new nuclear reactor licensing were included. Only Western countries were chosen for this research, as their regulatory frameworks are seen to have principles similar enough for the comparison to be performed.

My key aim has been to study the licensing processes and the licensing experiences in recent years, not including the former licensing practices from the 1960s to the 1980s within the scope of the research. The other focal point of my study has been to understand the SMR-specific characteristics from the licensing point of view.

All the studied countries have their own specific features in the licensing process and regulatory framework. The countries have also modified and developed their licensing processes since the new wave of new build nuclear reactors has been expected to begin. Certain lessons have already been learned from the current NPP projects. Many practices have also been included in this research through discussions and interviews with specialists, as certain aspects of licensing practices are not well defined in the documentation. Interviews and questionnaires compose a notable part of my research. This part of the research is based on experts' views from the regulatory frameworks of different countries. I tried to find experts in the studied countries who would also understand the specific features of SMRs and the needs in terms of licensing processes to gather reliable results. However, as this study has a qualitative nature, there may be some variation in the results arising out of the experts' views and knowledge of the studied subject. To minimize this possible variation, responses were requested from both the industry side and the regulatory side.

No licensed SMRs exist in the studied countries at this point in time, and all the licensing activities are just taking their first steps. This provided a good reason for this research and also increases the novelty of the research, since there are no experiences from earlier SMR licensing to be used as comparison material.

Many parts of the large NPP licensing process are relevant also for SMR licensing. However, the serial construction schedules, modular plant designs as well as mass production of components and systems set specific licensing process requirements.

9.2 Theoretical Contribution

The development of the approach used in this research was encouraged by many different studies and methods. Firstly, the NRC licensing process [152], which has been used as a basis for regulatory frameworks in many countries, emphasizes the predictable process. This prescriptive licensing process includes very detailed requirements, which can be seen as both beneficial and challenging. The benefit comes from the predictability of the process and requirements, while the challenge is the heavy and time consuming process in which the requirements are formulated, design by design. Secondly, at the other end can be seen the UK licensing process [103], which is also a widely known licensing process around the world. This licensing process focuses on a goal setting approach, which brings flexibility to the licensing process. This approach sets only the high level regulations, while the licensee is obligated to present the safety case and therefore the required safety level fulfillment. Furthermore, the Finnish regulatory framework is seen as a hybrid of the two regulatory framework approaches presented above. The Finnish regulatory framework has been developed towards a more prescriptive approach with regulations development, which has been under development in recent years, and is still ongoing at the time of writing. [93] This development has been under discussion and opinions vary from one end to another. The main concern about the regulatory framework development towards the prescriptive approach is the availability of the required resources for this type of licensing. One of the lessons learned from the Olkiluoto 3 NPP licensing process is that the regulatory approvals between the construction license and operating license, are massive and need a lot of resources for the review. This licensing practice is challenging to study, since it is not determined as a licensing step, but it is formed from the requirements of discipline-specific regulatory guides.

The role of the regulatory body in Finland, which is after all the focus of this research, has been discussed mainly in association with the Olkiluoto 3 project, both publicly [79] and internally within the stakeholders.

As already mentioned, the licensing approach suitable for the characteristics of SMRs has not been studied in European level at this point in time. As the SMR development and first SMR deployments will not most likely be situated in Europe, the licensing discussion in Europe is only taking its first steps.

The key theoretical contribution of this research is in the combination of multiple research paths, which provide a cohesive whole. The presented theory builds on combining the existing nuclear licensing processes, but expands the approach by other safety critical industries' licensing approaches and by the SMR aspects. The needed changes in the current nuclear regulatory framework are evaluated and discussed.

The theory also adapts the SE, RM, and PM features. The model, presented and discussed in Chapter 7 and applied to a practical model in Chapter 8, illustrates the SMR licensing model for the Finnish regulatory framework. Another theoretical contribution produced during this research is the comprehensive use of the RM process as the basis of licensing. This approach of using requirements as the licensing basis is not new as such. However, the novelty of this approach is the determined categorization of the requirements and comprehensive follow-up of each requirement during its whole lifecycle until the validation and verification phase. The theme of this approach lies in the determined freezing points forming base lines for the process. The methods to fulfill the requirements are set in advance, when the requirement or its application is formulated. This helps the validation and verification part of the process and sets rules for requirements fulfillment and closing.

9.3 Limitations and future research

In this research I have made multiple choices that are justifiable in the context of the research. Some choices could have been made otherwise, leading possibly to marginally different interpretations. However, I have tried to justify all the choices thoroughly and ensure the best possible quality in the outcome.

The selection of cases used herein could be open to criticism. Obviously the case selection could cause variation in the results and interpretations; for example, if the cases represent extreme cases and the researcher does not recognize the risk. After careful consideration, I settled on these particular cases, as described thoroughly above. My interpretation is that selecting other regulatory frameworks for this research could possibly have led to a slightly different nuance to the conclusions, but for the most part, to the same results. However, selecting other countries' regulatory frameworks could have proven to be challenging as the detailed information in certain countries is not publically available and the cultural differences might cause misunderstandings in the interpretations. However, selecting different types of regulatory frameworks from, for example, Asian countries as the basis for further research could prove to be interesting.

It shall be understood that the licensing process development does not resolve all the licensing challenges and problems, but the whole regulatory framework, including all the stakeholders, should have a common understanding of the situation. The management of licensing (in both regulatory body and the licensee organization) has a big role to enable the succesful nuclear licensing project. Every single country has its own specific features in terms of licensing, and therefore an overall analysis of the regulatory framework is necessary to understand the challenges and focus on them.

In terms of the future research focus points that have been brought up, the main interest seems to be in certain technical approaches and their application in terms of licensing. One of the important research areas is the safety classification that varies widely between countries. One part of the safety classification is also the use of codes and standards that also vary from one country to another. A lot of research has been accomplished concerning safety classification differences (mainly structural classification), but research focusing on functional classification and the Defense in Depth approach would be useful. An exclusive focus on SMR designs, determining the common functions of certain types of SMR designs, in terms of Defense in Depth and therefore functional safety classification is the research field I have discovered to be important in the future.

As all licensing is focused on risks in one way or another, and all the features are combined with each other, the other research field in terms of SMR licensing is a graded approach or risk-informed approach. A graded approach has a connection with the safety classification, as well as other approaches issuing risks, such as Probabilistic Risk Assessment (PRA). In the SMR case the graded approach should be studied thoroughly, since the small power level in the core, as well as other SMR-specific characteristics, are aimed at bringing the risk level down. This is why the grading in the licensing approach could play a more significant role, if compared with the large NPP licensing approach. A graded approach discussion has already begun in different international and national organizations; however, this field needs quite a lot of research to become commonly understood within different stakeholders in different countries. Also, to get the full benefit of this type of approach in SMR licensing, the approach and its application in the SMR case needs quite a lot of research.

Internationally approved certified design has been the goal of many organizations over many years. This goal seems to be quite far away, even if other safety critical industry fields, such as the aviation industry, provide a good example of achieving this goal. The aspiration to achieve this goal needs to be prioritized among all stakeholders, utilities, vendors, regulatory bodies, politicians, etc., to make it possible in the future. The harmonization of requirements would mean compromises in certain aspects, such as certain national practices. However, the overall safety level would rise due to operational experience, wider knowledge, and an understanding of the requirements in different countries among other benefits. The standardization would mean compromises in utility requirements, such as shutdown durations and optimizations of the design into a certain environment and site. However, the benefits would come from the standardized spare parts, availability of staff from other units, etc.

In the nuclear energy industry, international standardization is still seen as the long-term goal, and this study is proposing one possible step towards that goal. The presented model presents the Standard Design Certification of a Module, which could become an internationally accepted part of the SMR licensing process.

References

1. Alarotu, H., 2013, "Small Modular Reactors: Specific Safety Features", Master's Thesis, Aalto University School of Science, Degree Programme in Engineering Physics and Mathematics, Espoo, February 8, 2013

2. Alifrosti, K., 2012, "Project Governance framework for nuclear power plant project", MSc Thesis, Tampere University of Technology, Tampere, Finland

3. Amaba, B., 2013, "Process and Technology - Rational in Oil, Gas and Minerals", Presented at IBM Rational 2013, April 24, 2013, Orlando, USA

4. American Nuclear Society (ANS), 2010, "Interim Report of the American Nuclear Society President's Special Committee on Small and Medium Sized Reactor (SMR) Licensing Issues", July 2010, Available at: www.ans.org/pi/smr/ans-smr-report.pdf

5. ANSI/PMI, 2008, "A Guide to the Project Management Body of Knowledge", PMBOK Guide, Fourth Edition, ANSI/PMI 99-001-2008, ISBN: 978-1-933890-51-7

6. Apostolakis G., Lui C., Cunningham M., Pangburn G., Reckley W., 2012, "A Proposed Risk Management Regulatory Framework", U.S. NRC, NUREG-2150, Available at: http://pbadupws.nrc.gov/docs/ML1210/ML12109A277.pdf

7. Arctic Maps, 2013, "Northern Canada", Available at: www.threecordministries.org/ArcticMaps.htm

8. Babcock & Wilcox, 2009, "B&W introduces scalable, practical nuclear energy", Babcock & Wilcox press release, 10 June 2009, Available at: http://www.babcock.com/news_and_events/2009/20090610a.html

9. Bahill, A. T., Gissing, B., 1998, "Re-evaluating systems engineering concepts using systems thinking", IEEE Transaction on Systems, Man and Cybernetics, Part C: Applications and Reviews, Available at: www.sie.arizona.edu/sysengr/publishedPapers/Similar.pdf

10. Barlow, M. T., Rockar, H. M., 1982, "Value Analysis/Value Engineering Towards a Discipline", 1982 save Conference Proceedings, Available at: www.value-eng.org/knowledge_bank/attachments/VAVE%20towards%20a%20Discipline.pdf

11. Boerin, S., Ricotti, M., 2009, "Cost and Profitability Analysis of Modular SMRs in Different Deployment Scenarios", Presented at: Proceedings of the 17th International Conference on Nuclear Engineering (ICONE 17), 12-16 July 2009, Brussels, Belgium, Paper ICONE17-75741

12. Borchardt, R. W., 2011, "Licensing Structure for Multi-Module Facilities Related to Small Modular Nuclear Power Reactors", Policy Issue Information, SECY-11-0079, June 12, 2011

13. Borchardt R. W., 2011, "Use of Risk Insights to Enhance the Safety Focus of Small Modular Reactor Reviews", Policy Issue Information, SECY-11-0024, February 18, 2011

14. Borchardt, R. W., 2010, "Potential Policy, Licensing, and Key Technical Issues for Small Modular Nuclear Reactor Designs", Policy Issue Information, SECY-11-0034, March 28, 2010

15. Bradley, G., "Benefit Realisation Management, Second Edition, A Practical Guide to Achieve Benefits Through Change", ISBN 978-1-4094-0094-3 (hbk.)

16. Bredimas, A., William J. Nuttall, W. J., 2012," A Comparison of International Regulatory Organizations and Licensing Procedures for New Nuclear Power Plants", Judge Business School, University of Cambridge, Trumpington Street, Cambridge, CB2 1AG, UK

17. Brooks, G.L., 1993, "A Short History of the CANDU Nuclear Power System", Available at: https://canteach.candu.org/Content%20Library/19930101.pdf

18. Bryson, J., 2004, "What to do when stakeholders matter, Stakeholder Identification and Analysis Techniques", Routledge Taylor & Friends Group, Vol. 6 Issue 2004 21-53, Public Management Review ISSN 1471-9037 prin/iSSN 1471-9045, Available at: www.tandf.co.uk/journals

19. Canadian Environmental Assessment Agency, 2012, "Canadian Environmental Assessment Act", Date Modified: 2013-03-27, Available at: www.ceaa-acee.gc.ca/default.asp?lang=En&n=16254939-1

20. Canadian Nuclear Safety Commission (CNSC), 2010, "Licensing Basis Objective and Definition - INFO-0795", Minister of Public Works and Government Services Canada 2010, Catalogue number CC172-54/2010E-PDF, ISBN 978-1-100-14820-5, Available at: http://nuclearsafety.gc.ca/pubs_catalogue/uploads/INFO_0795_E.pdf

21. Canadian Nuclear Safety Commission (CNSC), 2012, "Pre-licensing Review of a Vendor’s Reactor Design”, Guidance Document, GD-385, 2012, Available at: www.nuclearsafety.gc.ca/eng/lawsregs/guidancedocuments/published/html/gd385/index.cfm

22. Canadian Nuclear Safety Commission (CNSC), 2012, "Darlington Nuclear Power Plant", Date Modified: 2012-11-16, Available at: http://nuclearsafety.gc.ca/eng/readingroom/newbuilds/opg_darlington/

23. CANDU Owners Group Inc - COG, 2013, "CANDU Reactors", Available at: www.candu.org/candu_reactors.html

24. Chaplin C., Ward S., 2003, "Project Risk Management, Processes, Techniques and Insights, Second Edition", School of Management, University of Southampton, UK, ISBN 0-470-85355-7

25. Comets, M-P., Jamet, P., Bourguignon, M., Dumont, J-J., 2012, "Nuclear Safety Authority (ASN) opinion n° 2012-AV-0143 of 31st January 2012 concerning safety options for the ATMEA1 reactor project", The Nuclear Safety Authority Commission, Paris, 31 January 2012

26. Commissioning Communication, 2010, "Energy 2020: A strategy for competitive, sustainable and secure energy", 16096/10, Published on: November 10, 2010.

27. Davis, M. B., 2010, " Plans for a second French EPR move forward ", Nuclear France, Available at: http://francenuc.wordpress.com/2010/02/14/plans-for-a-second-french-epr-move-forward/

28. Dean, S., 1999, "IEC 61508 - Understanding Functional Safety Assessment", Saul Consulting Ltd, July 1999

29. Department of Energy DoE, 2011, "Congressional Budget Request - DOE/CF-0063", Volume 7, Office of Chief Financial Officer, February 2011, Volume 7

30. DeVos, M., 2011, "Regulating iPWR “SMRs” - Canada is Ready", Presented in: American Nuclear Society 2011 Winter Meeting, Embedded Topical Meetings – SMR 2011 Conference, “iPWR SMR Design and Licensing Update Panel”, 2.11.2011

31. DeVos, M., 2012, "Consultancy to prepare an INPRO Dialogue Forum on Licensing and Safety Issues for SMRs - The Path Forward to Regulating SMRs in Canada", Presented at: 17-19 December 2012, IAEA INPRO, Vienna, Available at: www.iaea.org/INPRO/meetings/Meetings_in_2012.html

32. Eden, C., Ackermann, F., 1998, "Making Strategy - The Journey of Strategic Management", ISBN 13:978-0-7619-5224-4, ISBN 13:978-0-7619-5225-1

33. Eisenhardt, K. M., Graebner, M. E., 2007, "Theory Building from Cases: Opportunities and Challenges", Academy of Management Journal, 50: 25-32

34. ENISS, 2013, "European Nuclear Installations Safety Standards Initiative", Last update: 09 March 2013 Available at: www.eniss.eu/

35. ENSREG, 2012, "European Nuclear Regulators Group" Available at: www.ensreg.eu/

36. EUR, 2013, "European Utility Requirements for LWR nuclear power plants", Last update: February 26 2013, Available at: www.europeanutilityrequirements.org/eur.htm

37. European Aviation Safety Agency (EASA), 2007, "Certification Directorate", Available at: http://easa.europa.eu/certification/certification-directorate.php

38. European Aviation Safety Agency (EASA), 2011, "Annual Safety Review 2011", Figure 2-1, Available at: www.easa.europa.eu/communications/docs/annual-safety-review/2011/EASA-Annual-Safety-Review-2011.pdf

39. European Civil Aviation Conference (ECAC), 1990 "Concerning the Development, the Acceptance and the Implementation of Joint Aviation Requirements", Arrangements, Cyprus, 11 September 1990, Available at: www.easa.europa.eu/rulemaking/docs/international/archive/cyprus.pdf

40. European Commission, 2012, "Nuclear Safety Co-operation Instrument (NSCI)", Development and Cooperation - EUROPEAID, Last update: 12/06/2012, Available at: http://ec.europa.eu/europeaid/how/finance/nsci_en.htm

41. European Reactor Design Approval (ERDA), 2011, "Roadmap towards European Reactor Design Approval", Core Group, WG Risks/WG Opportunity, Presented at: European Nuclear Energy Forum, Bratislava, Prague, 12/2011

42. European Reactor Design Acceptance (ERDA), Core Group 2012, "Roadmap Towards European Reactor Design Acceptance", Presented at: European Nuclear Energy Forum, Bratislava - Prague, 31 July 2012

43. Fédération Antinucléaire 44, 1997, "France: The end of the Carnet project, finally", published by WISE News Communique on September 26, 1997, Available at: www10.antenna.nl/wise/index.html?http://www10.antenna.nl/wise/483-4/4798.html

44. Fennovoima, 2012, "Fennovoima Project Schedule", Available at: www.fennovoima.com/en/project/schedule

45. Finnish Transport Safety Agency (TraFi), 2011, "Ilma-alukset", Available at: www.trafi.fi/ilmailu/ilma-alukset

46. Fourest, B., 2009, "Towards Design Standardization and Safety Harmonization: European Nuclear Utility Initiatives", Eurelectric representative, Presented at: MDEP Conference Paris 10-11 September 2009

47. Gautier, G.-M., 2012, "Modular Water-cooled Systems for Electricity Generation, Process Heat, Seawater Desalination, Marine Propulsion, and Other Applications - Light-Water-Reactor Concepts", Presented at: FJOH 2012 on "Innovative Modular Nuclear Reactors: Concepts, Physics and State-of-the-art Analysis Methods", Aix-en-Provence, France, August 22-31, 2012

48. Gen IV International Forum, 2013, "Generation IV Technology : Evolution of Nuclear Energy Systems" Available at: www.gen-4.org/Technology/evolution.htm, AEN, NEA

49. Generation mPower, 2013, "Technology", Available at: www.generationmpower.com/technology/

50. Gorman G., 2012, "The Convergence of Engineering Disciplines in Modern Systems Engineering", Presented at IBM Innovate 2012 (SE-2070) 3.-7.6.2012, Orlando, USA.

51. Haskins, C., 2011, "Systems Engineering Handbook: A Guide for System Life Cycle Processes and Activities", Version 3.2.2., Revised by Krueger, M., Walden, D., Hamelin, R. D., San Diego, CA, US, INCOSE

52. Health and Safety Executive, 2012, "Applying for a nuclear site licence for new nuclear power stations - A step-by-step guide", 28.5.2012, Available at: www.hse.gov.uk/newreactors/guidance.htm

53. Health and Safety Executive, 2012, "Safety Assessment Principles for Nuclear Facilities ", Revision 1, Available at: www.hse.gov.uk/nuclear/saps

54. Henley, E. J., Kumamoto, H., 1891, " Reliability engineering and risk assessment", ISBN 0137722516

55. Hesketh, K., 2012, "Modular Water-cooled Systems for Electricity Generation, Process Heat, Seawater Desalination, Marine Propulsion, and Other Applications - Core Neutronics and Thermohydraulics: Overview of Physics and Solution Methods", Presented at: FJOH 2012 on "Innovative Modular Nuclear Reactors: Concepts, Physics and State-of-the-art Analysis Methods", Aix-en-Provence, France, August 22-31, 2012

56. Hoepfl, M. C., 1997, "Choosing Qualitative Research: A Primer for Technology Education Researchers", Journal of Technology Education, published on Volume 9, Number 1, Fall 1997.

57. Hwang, I. S., 2012, "Modular Water-cooled Systems for Electricity Generation, Process Heat, Seawater Desalination, Marine Propulsion, and Other Applications - Lead and Lead-bismuth Concepts", Presented at: FJOH 2012 on "Innovative Modular Nuclear

Reactors: Concepts, Physics and State-of-the-art Analysis Methods", Aix-en-Provence, France, August 22-31, 2012

58. International Atomic Energy Agency (IAEA), 1991, "Safety related terms for advanced nuclear plants", IAEA, VIENNA, 1991, IAEA-TECDOC-626, ISSN 1011-4289, Available at: www-pub.iaea.org/MTCD/publications/PDF/te_626_web.pdf

59. International Atomic Energy Agency (IAEA), 1991, "Joint Protocol Relating to the Application of the Vienna Convention and the Paris Convention", INFCIRC/402 , Available at: http://www.iaea.org/Publications/Documents/Infcircs/Others/inf402.shtml

60. International Atomic Energy Agency (IAEA), 1997, " Joint Convention on The Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management", INFCIRC/546, Available at: http://www.iaea.org/Publications/Documents/Infcircs/1997/infcirc546.pdf

61. International Atomic Energy Agency (IAEA), 1999, "Basic Safety Principles for Nuclear Power Plants 75-INSAG-3 Rev.1", INSAG-12, Available at: http://www-pub.iaea.org/MTCD/publications/PDF/P082_scr.pdf

62. International Atomic Energy Agency (IAEA), 2006, "Status of Innovative Small and Medium Sized Reactor Designs 2005: Reactors with Conventional Refuelling Schemes", IAEA-TECDOC-1485, Vienna, March 2006

63. International Atomic Energy Agency (IAEA), 2010, "Licensing Process for Nuclear Installations", Safety Standards, Specific Safety Guide No. SSG-12, Available at: www-pub.iaea.org/MTCD/publications/PDF/Pub1468_web.pdf

64. International Atomic Energy Agency (IAEA), 2012, " Convention on Nuclear Safety", Last update: March 12, 2013, Available at: www-ns.iaea.org/conventions/nuclear-safety.asp

65. International Atomic Energy Agency (IAEA), 2012, “Regulatory Body, Learning Objectives for Section 2”, Available at: http://www.iaea.org/ns/tutorials/regcontrol/chapters/regbody.pdf

66. International Atomic Energy Agency (IAEA), 2013, "IAEA Safety Standards - for protecting people and the environment", Last update: February 20, 2013, Available at: www-ns.iaea.org/standards/

67. International Civil Aviation Organization (ICAO), 1944, "Convention on International Civil Aviation - Doc 7300", 1944 Chicago Convention, Available at: http://www.icao.int/publications/pages/doc7300.aspx

68. International Civil Aviation Organization (ICAO), 2013, "ICAO in Brief", Available at: www.icao.int/about-icao/Pages/default.aspx

69. International Electrotechnical Commission (IEC), "IEC 61508, Functional safety", safety-related systems, 1.1.1999

70. International Organization for Standardization, 2008, "ISO 9001:2000 specifies requirements for a quality management system where an organization" Available at: www.iso.org/iso/catalogue_detail?csnumber=21823

71. ISO, 2012, "Guidance on project Management", International Organisation for Standardisation, ISO 21500

72. ISO and IEC, 2008, "Systems and software engineering - System life cycle processes", International Organisation for Standardisation and International Electrotechnical Commission, ISO/IEC 15288

73. Johnson M. R., 2011, " Feasibility of Including Risk Information in Categorizing Structures, Systems, and Components as Safety-Related or Nonsafety-Related", Policy Issue Information, SECY-11-0156, November 2, 2011

74. Kessides, I., N., 2012, "The future of the nuclear industry reconsidered: Risks, uncertainties, and continued promise", Energy Policy 48 (2012) 185–208

75. Koppes, S., 2011, "Small reactors could figure into U.S. energy future", The University of Chicago, December 13, 2011, Available at: http://news.uchicago.edu/article/2011/12/13/small-reactors-could-figure-us-energy-future

76. Koskinen, K., 2010, "Sustainable Capacity Building for Nuclear Programme - the Finnish Experience", Presented at: International Conference on Human Resource Development for Introducing and Expanding Nuclear Power Programmes, 14.-18.3.2010, Abu Dhabi

77. Kymäläinen, O., 2011, "Licensing process and status of new nuclear in Finland", Fortum, Presented at:PGE Warsaw, 27 January, 2011

78. Laaksonen, J., 2010, "Overview of Olkiluoto construction project and its regulatory oversight - Main lessons learned", Presented at: Workshop on experience from construction and regulatory oversight of Nuclear Power Plants, Helsinki/Olkiluoto, 30 Aug - 3 Sep 2010

79. Laaksonen, J., 2010, "Lessons Learned from Olkiluoto 3 Plant", Power Engineering, Presented in conference paper by Jukka Laaksonen at Nuclear Power Europe in Amsterdam in June 2010, Available at: www.power-eng.com/articles/npi/print/volume-3/issue-3/nucleus/lessons-learned-from-olkiluoto-3-plant.html

80. Lee, D., 2011, "B&W mPower Program", Presented at: IAEA SMR Technology Workshop, December 6, 2011, Vienna, Austria, Available at: http://www.uxc.com/smr/Library/Design%20Specific/mPower/Presentations/2011%20-%20Generation%20mPower.pdf

81. Licensing & Permitting Task Force of the World Nuclear Association, 2012, "Licensing and Project Development of New Nuclear Plants", WNA Report: A Report by the World Nuclear Association's Licensing & Permitting Task Force, Report No.: 2013/002

82. Little, A. D.,.2010, "Nuclear New Build Unveiled: Managing the Complexity Challenge", Available at: www.adl.com/uploads/tx_extthoughtleadership/ADL_Nuclear_New_Build_Unveiled.pdfS.

83. Major Projects Management Office (MPMO), 2008, "MPMO Mandate", Date updated: 2012-08-03, Available at: http://www.mpmo-bggp.gc.ca

84. Mansurov, N., Probert, R., 2001, "Scenario-based approach to evolution of communication software",

85. Mil, L., 2009, " Neuvoston Direktiivi 2009/71/EURATOM", L178/18 Euroopan Unionin Virallinen Lehti 2.8.2011, Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:172:0018:0022:FI:PDF

86. Miles, L. D., "Techniques of Value Analysis and Engineering", Wendt Library, 215 N. Randall Ave., Madison, WI 53706

87. Miles, M., 2013, "Generation mPower, FORATOM Small Modular Reactor Forum", Presented at: FORATOM SMR Seminar, Brussels, 28.2.2013, Available at: www.foratom.org/small-modular-reactors.html

88. Minister of Public Works and Government Services Canada, 2008, "Licensing Process for New Nuclear Power Plants in Canada", INFO-0756 (Revision 1), May 2008, Catalogue number CC172-38/2008E-PDF, ISBN 978-0-662-48658-9

89. Ministry of Deployment and the Economy, 2008, "Government Decree on the Safety of Nuclear Power Plants", 733/2008, Available at: www.edilex.fi/saadokset/smur/20080733

90. MTL Instruments, 2011, "An introduction to Functional Safety and IEC 61508", AN9025, Available at: www.mtl-inst.com/product/mtl_safety_related_sr_series_isolators

91. Mycoff, C., Carelli, M., Petrovic, B., Miller, K., 2010, "Strategies to Demonstrate Competitiveness of SMRs in World Markets"

92. NEI, 2010, "New Facilities, Licensing New Nuclear Power Plants", NEI Fact Sheet, Available at: www.nei.org/resourcesandstats/documentlibrary/newplants/factsheet/licensingnewnuclearpowerplants

93. Nevalainen, J., 2012, "Ydinvoiman rakentaminen, viranomaisnäkökulma- ja tehtävät", Presented at: Enterprise Forum 1/2012 15.2.2012, Available at: www.kotu.oulu.fi/ef20/esitykset/2012_1/Janne_Nevalainen_STUK_esitys.pdf

94. New Energy and Fuel, 2013, "Nuclear Reactors to Produce Oil", January 17, 2013, Available at: http://newenergyandfuel.com/http:/newenergyandfuel/com/2013/01/17/nuclear-reactors-to-produce-oil/

95. Ninokata, H., 2006, "A Comparative Overview of Thermal Hydraulic Characteristics of Integrated Primary System Nuclear Reactors", Tokyo Institute of Technology, Available at: www.kns.org/jknsfile/v38/JK0380033.pdf

96. Nocera, F., 1999, "The Legal Regime of Nuclear Energy, A Comprehensive Guide to International and European Union Law", ISBN 90-5095-490-1, D/2005/7849/62, NUR 828

97. Nuclear Power Plants Department, 2012, "Licensing approach in France - Autorité de sûreté nucléaire (France)", Presented at: Seminar on the evaluation of the sitting and on the licensing of a new NPP, Poland, February 16, 2012

98. NuScale Power, 2013, "Safe, Simple, Small, And Economical Nuclear Power", Available at: www.nuscalepower.com/

99. Organisation for Economic Cooperation and Development (OECD) Nuclear Energy Agency, 2010, "History of the OECD Nuclear Energy Agency", Last reviewed: 29 October 2010, Available at: www.oecd-nea.org/general/history/

100. Organisation of Economic Cooperation and Development (OECD) Nuclear Energy Agency, 2011 ,"Current Status, technical feasibility and economics of small nuclear reactors", V12, 26 April 2011

101. Organisation for Economic Cooperation and Development OECD, 2011, "OECD Economic Surveys: France", ISBN 978-92-64-09304-1 (print), ISBN 978-92-64-09305-8 (pdf), Available at: http://dx.doi.org/10.1787/eco_surveys-fra-2011-en

102. Office for Nuclear Regulation, An Agency of HSE, 2011, "Site licence application for Hinkley Point C received, 29 July 2011", Available at: www.hse.gov.uk/nuclear/hinkley-point-c/index.htm

103. Office for Nuclear Regulation, An Agency of HSE, 2012, "New Reactors Timeline", Available at: http://www.hse.gov.uk/newreactors/timeline.htm

104. Office for Nuclear Regulation, An Agency of HSE, 2012, "New nuclear power stations, Generic Design Assessment", A guide to the regulatory processes, Published by: the Health and Safety Executive and the Environmental Agency, NGN01, 08/08

105. Office for Nuclear Regulation, An Agency of HSE, 2012, "Nuclear power station Generic Design Assessment: Guidance to Requesting Parties", Available at: www.hse.gov.uk/newreactors/guidance.htm

106. Office for Nuclear Regulation, An Agency of HSE, 2012, "Hinkley point C licensing", Available at: www.hse.gov.uk/nuclear/hinkley-point-c/index.htm

107. Office for Nuclear Regulation, An Agency of HSE, 2012, "Milestones", Available at: www.hse.gov.uk/newreactors/key-milestones.htm

108. Office for Nuclear Regulation, An agency of HSE, 2012, "Licensing Nuclear Installations", Available at: www.hse.gov.uk/nuclear/licensing-nuclear-installations.pdf

109. Office for Nuclear Regulation, An Agency of HSE, 2012, "Internal operational instructions and guidance", Available at: www.hse.gov.uk/nuclear/operational/index.htm

110. Office for Nuclear Regulation, An Agency of HSE, 2012, "How we regulate", Available at: http://www.hse.gov.uk/nuclear/regulation-and-licensing.htm

111. Office for Nuclear Regulation, An Agency of HSE, 2012, "New nuclear power stations: Generic Design Assessment - Design Acceptance Confirmation for the UK EPR™ Reactor", 13 December 2012, Unique No: EPR01513R, Available at: www.hse.gov.uk/newreactors/reports/step-four/close-out/epr70475n.pdf

112. Office for Nuclear Regulation, An agency of HSE, 2012, "ONR grants nuclear site licence for new UK power station", Date: November 26, 2012, Available in: http://news.hse.gov.uk/onr/2012/11/onr-grants-nuclear-site-licence-for-new-uk-power-station/

113. Park, P., 1012, "Minutes on INPRO Dialogue Forum on Licensing and Safety Issues for SMRs", Meeting held 17-19 December 2012, IAEA INPRO, Vienna, Available at: www.iaea.org/INPRO/meetings/Meetings_in_2012.html

114. Pays, R., 2011, "EPR Flamanville 3 project", EDF Nuclear Engineering Division, Available at: www.iaea.org/NuclearPower/Downloads/Technology/meetings/2011-Dec-12-16-WS-Paris/1.09-R.PAYS-EDF-FA3.pdf

115. Pitblado, R., 2011, "Will the US warm up to the safety case approach?", DNV Managing risk, Available at: http://www.dnv.com/industry/maritime/publicationsanddownloads/publications/offshoreupdate/2011/01_2011/willtheuswarmuptothesafetycaseapproach.asp

116. Project Institute, 2012, "ABC Project Model TM", available at: www.projekti-instituutti.fi/files/622/ABC-project_model_esite_EN_15062011_lowres.pdf

117. Project Institute, 2012, "PM Master training course", Available at: www.projekti-instituutti.fi/en/personal_development

118. Radiation and Nuclear Safety Authority (STUK), 2013, "YVL B.1 Safety Design of a Nuclear Power Plant", YVL B.1, Draft 4, 7 March 2013, Available at: https://ohjeisto.stuk.fi/YVL/B.1-L4.pdf

119. Radiation and Nuclear Safety Authority (STUK), 2012, "Lyhyt Historia", Last update: 22.5.2012, Available at: www.stuk.fi/stuk/fi_FI/historia/

120. Raetzke, C., 2010, "Effective Nuclear Regulation from a Utility Perspective", Presented at: “Tuumaenergia efektiivne reguleerimine”, E.ON Kernkraft, Hannover (Tallinn, 26 February 2010), Available at: http://www.slideserve.com/fox/effective-nuclear-regulation-from-a-utility-perspective-seminar-tuumaenergia-efektiivne-reguleerimine-tallinn-26-f

121. Raetzke, C., Micklinghoff, M., 2006, "Existing Nuclear Power Plants and New Safety Requirements - An International Survey", publisher Carl Heymanns Verlag GmbH-Köln-Berlin-München 2006, ISBN 13:978-3-452-26453-4, ISBN 10:3-452-26453-X

122. Reckley, B., Kevern, T., Starefos, J, 2010, "NRC Licensing Experience", Presented at: United States Nuclear Regulatory Commission SMR Workshop, Available at: www.nrc.gov/NRR/OVERSIGHT/ASSESS/index.html

123. Sawickifi, M., 2011, "Neuvoston Direktiivi 2011/70/EURATOM", L199/48 Euroopan Unionin Virallinen Lehti, 2.8.2011, Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:199:0048:0056:FI:PDF

124. SCE&G’s new nuclear deployment group, 2012, "Nuclear Project Schedule", Building of two new nuclear units at the V.C. Summer nuclear station site near Jenkinsville, S.C., Available at: www.scnuclear.com/NR/rdonlyres/71518E07-1F7A-4293-A4D5-0501B322AF20/0/nnd_timeline.htm

125. Sjövall, H., 2010, "Feasibility studies and bidding process", Presented at: Workshop on experience from construction and regulatory oversight of Nuclear Power Plants, Helsinki/Olkiluoto, 30 Aug - 3 Sep 2010

126. Strauss, A., Corbin, J., 1990, "Basics of qualitative research: Grounded theory procedures and techniques", Newbury Park, CA, Sage Publications, Inc.

127. Strauss, A. L., Corbin, J. M., 1998, "Basics of Qualitative Research : Techniques and Procedures for Developing Grounded Theory", ISBN 0-8039-5939-7

128. Subki, H., 2011, "Update on SMR Technology Status and IAEA Programme on Common Technology and Issues for SMRs", Presented at: INPRO Dialogue Forum on NE Innovations: CUC for SMR, 10 – 14 October 2011, Available at: http://www.iaea.org/INPRO/3rd_Dialogue_Forum/03.Subki.pdf

129. Sundell, R., Äikäs, T., 2012, " Olkiluodon Kapselointi- ja Loppusijoituslaitoksen Rakentamislupahakemus", Available at: www.tem.fi/files/35285/Olkiluodon_kapselointi-_ja_loppusijoituslaitoksen_rakentamislupahakemus.pdf

130. Söderholm, K., 2012, "Challenges of SMR Licensing", Presented at the 2nd International Technical Meeting on Small Reactors, Ottawa, ON, Canada, November 7-9

131. Söderholm K., 2013, "Would the licensing for huge units fit for SMR?", Presented at: Presented at: FORATOM SMR Seminar, Brussels, 28.2.2013, Available at: www.foratom.org/small-modular-reactors.html

132. Söderholm K., 2012, "Challenges on SMR Licensing Practices", AECL Nuclear Review, Volume 1, Number 2, Special Issue on Small Reactors, Available at: www.aecl.ca/Assets/Nuclear_Review/ANR_1-2_ENG.pdf

133. Tennessee Valley Authority (TVA), 2010, "Key Assumptions Letter for the Possible Launching and Construction of Small Modular Reactor Modules at the Clinch River Site", TVA letter to the Nuclear Regulatory Commission, 5 November 2010, Available at: http://pbadupws.nrc.gov/docs/ML1031/ML103120558.pdf

134. The Council of the European Union, 2009, "Council Directive 2009/71/EURATOM of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations", Directives, Official Journal of the European Union, L 172/18

135. Tommila T., 2013, "A control engineer’s introduction to requirements engineering", Version 1, SAREMAN project, VTT

136. Trikouros, N. G., 2012, "A Perspective on Small Reactor Licensing and Implementation", U.S. Nuclear Regulatory Commission, Nuclear Technology, May 2012, Volume 178, Number 2, NUTYBB 178 (2) 125-240 (2012), ISSN:0029-5450

137. TVO, 2012, "Uuden ydinvoimalaitosyksikön rakentaminen etenee - Valtioneuvosto myönsi Olkiluoto 3 -ydinvoimalaitosyksikölle rakentamisluvan", Available at: www.tvo.fi/www/page/2547/

138. TVO, 2012, "Ympäristövaikutusten arviointiohjelma, Olkiluodon ydinvoimalaitoksen laajentaminen neljännellä laitosyksiköllä", Available at: www.tvo.fi/uploads/File/YVA_ohjelma_FI(1).pdf

139. TVO, 2012, "OL4 Sähköä tulevaisuuden Suomelle", Teollisuuden Voima Oyj – Hyvinvointia ydinsähköllä, Available at: www.tvo.fi/uploads/File/2012/OL4_Sahkoa_tulevaisuuden_Suomelle.pdf

140. United Nations, 1968 , " Treaty on the Non-Proliferation of Nuclear Weapons (NPT)" Available at: http://www.un.org/disarmament/WMD/Nuclear/NPT.shtml

141. U.S. NEWS, 2012, "US licenses first nuclear reactor since 1978" - U.S. NEWS on NBCNEWS.com, 9 February, 2012, Available at: http://usnews.nbcnews.com/_news/2012/02/09/10362722-us-licenses-first-nuclear-reactors-since-1978?lite

142. U.S.NRC United States Nuclear Regulatory Commission, 1978, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants, LWR Edition", Regulatory Guide 1.70, Revision 3, Available at: http://pbadupws.nrc.gov/docs/ML0113/ML011340072.pdf

143. U.S.NRC United States Nuclear Regulatory Commission, 2004, "Regulatory Guide 1.168, Verification, Validation, Reviews, and Audits for Digital Computer Software Used in Safety Systems of Nuclear Power Plants", Available at: http://pbadupws.nrc.gov/docs/ML0404/ML040410189.pdf

144. U.S.NRC United States Nuclear Regulatory Commission, 2009, "Nuclear Power Plant Licensing Process", NUREG/BR-0298, Revision 2, Office of Public Affairs, U.S. Nuclear Regulatory Commission, July 2009

145. U.S.NRC United States Nuclear Regulatory Commission, 2009, Guidance for ITAAC Closure Under 10 CFR PART 52", Revision 0, October 2009, 10 CFR52 NRC Regulator's Guide 1.215,

146. U.S.NRC United States Nuclear Regulatory Commission, 2012, "Advanced Reactor Research", Page Last Reviewed/Updated Thursday, March 29, 2012, Available at: http://www.nrc.gov/reactors/advanced/adv-reactor-research.html

147. U.S.NRC United States Nuclear Regulatory Commission, 2012, "New Reactor Licensing Applications", Available at: www.nrc.gov/reactors/new-reactors/new-licensing-files/new-rx-licensing-app-legend.pdf

148. U.S.NRC United States Nuclear Regulatory Commission, 2012, "Licensing", Page Last Reviewed/Updated Thursday, March 29, 2012, Available at: http://www.nrc.gov/about-nrc/regulatory/licensing.html

149. U.S.NRC United States Nuclear Regulatory Commission, 2012, "Advanced Reactors", Page Last Reviewed/Updated Monday, September 10, 2012, Available at: http://www.nrc.gov/reactors/advanced.html

150. U.S.NRC United States Nuclear Regulatory Commission, 2012, "Reactor Oversight Process (ROP)", Page Last Reviewed/Updated Thursday, March 29, 2012, Available at: www.nrc.gov/NRR/OVERSIGHT/ASSESS/index.html

151. U.S.NRC United States Nuclear Regulatory Commission, 2012, "Design Specific Review Standard for mPOWER TM iPWR, 14.3.5 Instrumentation and Controls - Inspections, Tests, Analyses, and Acceptance Criteria", Available at: http://pbadupws.nrc.gov/docs/ML1220/ML12200A157.pdf

152. U.S.NRC United States Nuclear Regulatory Commission, 2013, "New Reactors", Page Last Reviewed/Updated Wednesday, February 20, 2013, Available at: http://www.nrc.gov/reactors/new-reactors.html

153. U.S.NRC United States Nuclear Regulatory Commission, 2013, " Design Certification Applications for New Reactors", Page Last Reviewed/Updated Tuesday, March 29, 2013, Available at: www.nrc.gov/reactors/new-reactors/design-cert.html

154. U.S.NRC United States Nuclear Regulatory Commission, NRC Regulations (10 CFR) , 2009, "Regulatory Guide 1.206 - Combined License Applications for Nuclear Power Plants", Page Last Reviewed/Updated March 29, 2012, Available at: www.nrc.gov/reading-rm/doc-collections/reg-guides/power-reactors/rg/01-206/

155. U.S.NRC United States Nuclear Regulatory Commission, NRC Regulations (10 CFR) , 2013, "PART 50—Domestic Licensing of Production and Utilization Facilities", Page Last Reviewed/Updated February 19, 2013, Available at: www.nrc.gov/reading-rm/doc-collections/cfr/part050/

156. U.S.NRC United States Nuclear Regulatory Commission, NRC Regulations (10 CFR) , 2013, " PART 51—Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions", Page Last Reviewed/Updated February 19, 2013, Available at: www.nrc.gov/reading-rm/doc-collections/cfr/part051/

157. U.S.NRC United States Nuclear Regulatory Commission, NRC Regulations (10 CFR) , 2013, " PART 52—Licenses, Certifications, and Approvals for Nuclear Power

Plants", Page Last Reviewed/Updated February 19, 2013, Available at: www.nrc.gov/reading-rm/doc-collections/cfr/part052/

158. U.S.NRC United States Nuclear Regulatory Commission, Office of New Reactors, 2007, "NUREG-0800, Standard Review Plan (SRP) for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition", U.S. NRC, NUREG-0800, Rev. 6

159. Uusitalo, E., Raatikainen, M., 2012, "Training Material for Specifying Requirements in Structured Natural Language", SAREMAN project, 15.1.2012, Aalto University

160. Valtonen, K., 2010, "Deterministic safety analyses in the licensing process", Presented at: Workshop on experience from construction and regulatory oversight of Nuclear Power Plants, Helsinki/Olkiluoto, 30 Aug - 3 Sep 2010

161. Valtonen, K., 2010, "Detailed design of plant systems", Presented at: Workshop on experience from construction and regulatory oversight of Nuclear Power Plants, Helsinki/Olkiluoto, 30 Aug - 3 Sep 2010

162. Virolainen, T., 2010, "Activities, preparations and expectations before construction license phase", Presented at: Workshop on experience from construction and regulatory oversight of Nuclear Power Plants, Helsinki/Olkiluoto, 30 Aug - 3 Sep 2010

163. Virolainen, T., 2010, "Resources for licensing and regulatory oversight for new build", Presented at: Workshop on experience from construction and regulatory oversight of Nuclear Power Plants, Helsinki/Olkiluoto, 30 Aug - 3 Sep 2010

164. Von Dobschuetz, P., "Dismantlement of NS Otto Hahn", Federal Ministry of Environment, Germany, Available at: www.iaea.org/OurWork/ST/NE/NEFW/CEG/documents/ws052005_6E.pdf

165. Wahlström, K., 2010, "Ydinvoimaloihin tarjottavien koneiden, laitteiden ja järjestelmien kelpoistus", Sähkö-ja automaatiojärjestelmät toimisto, STUK, 8.9.2010

166. Wang, S., Woo, G., Zhongming, C., 2007, "What Software Do We Expect? An Engineering View vs. IT View", Presented at: SPE Annual Conference and Exhibition in Anaheim, California, USA, 11-14.11.2007

167. West A., 2007, "NASA Study on Flight Software Complexity", Final Report, Commissioned by the NASA Office of Chief Engineer, Technical Excellence Program

168. Western European Nuclear Regulators' Association (WENRA), 2007, "WENRA Reactor Safety Reference levels", WENRA Reactor Harmonization Working Group, December 2007, Available at:

www.wenra.org/media/filer_public/2012/11/05/list_of_reference_levels_january_2007.pdf

169. Western European Nuclear Regulators' Association (WENRA), 2009, "Safety Objectives for New Power Reactors", WENRA Reactor Harmonization Working Group, December 2009, Available at: www.wenra.org/media/filer_public/2012/11/05/rhwg_report_newnpp_dec2009.pdf

170. Western European Nuclear Regulators' Association (WENRA), 2010, "Harmonization of licensing requirements - WENRA experience, and potential application to new nuclear systems", Presented at: INPRO Dialogue Forum on Nuclear Energy Innovations, Vienna, 1-4 February 2010

171. Western European Nuclear Regulators' Association (WENRA), 2012, "WENRA", Available at: www.wenra.org/

172. Western European Nuclear Regulators' Association (WENRA), 2012, "Members", Available at: www.wenra.org/members-and-observers/

173. Western European Nuclear Regulators' Association (WENRA), 2012, "Safety of new NPP designs", Draft 9, October 2012, page 9, Available at: www.wenra.org/media/filer_public/2012/11/15/rhwg_booklet_safety_of_new_npp_designs_2012-10-08.pdf

174. World Nuclear Association (WNA), 2010, "International Standardization of Nuclear Reactor Designs", Available at: www.world-nuclear.org/uploadedFiles/org/reference/pdf/ps-cordel.pdf

175. World Nuclear Association (WNA), 2012, "Design Evaluation and Licensing (CORDEL) Working Group Annual Report 2011-2012", Available at: www.world-nuclear.org/uploadedFiles/org/WNA/Publications/Working_Group_Reports/CORDEL_Annual_Report.pdf

176. World Nuclear Association (WNA), 2013, "Nuclear Power in Canada", Updated 22 March 2013, Available at: www.world-nuclear.org/info/Country-Profiles/Countries-A-F/Canada--Nuclear-Power/

177. World Nuclear Association, 2013, "Small Nuclear Power Reactors", Updated March 2013, Available at www.world-nuclear.org/info/inf33.html

178. The World Nuclear Association’s Working Group on Cooperation in Reactor Design Evaluation and Licensing (CORDEL), 2013, "Aviation Licensing and Lifetime Management – What Can Nuclear Learn?", WNA Report, Report No: 2013/001

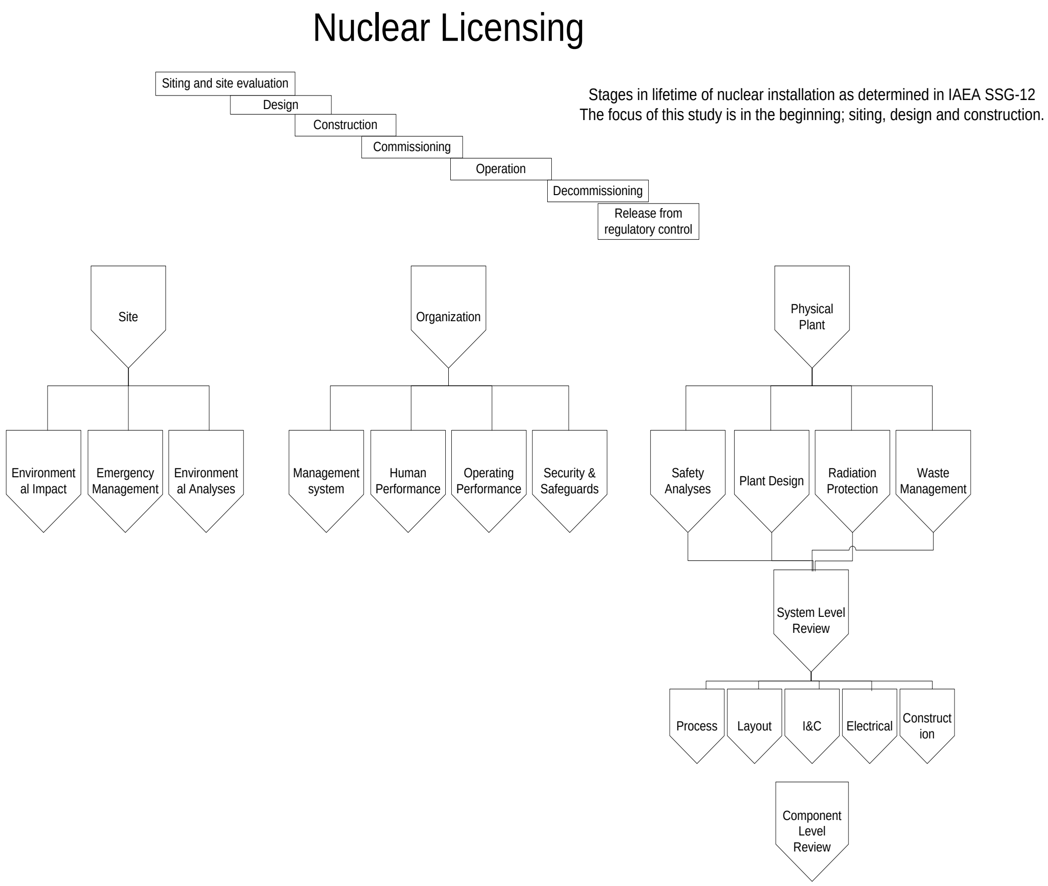
179. World Nuclear News, 2013, "Second round of SMR funding announced", 13 March 2013, Available at: www.world-nuclear-news.org/NN-Second_round_of_SMR_funding_announced-1303134.html

180. Zotov, D., 2007, "Safety Cases: Beyond Safety Management", Available at: http://asasi.org/papers/2007/Moving_From_SMS_to_Safety_Case_Dmitri_Zotov_PPT.pdf

APPENDIX 1

Questions:

These questions are set up to indicate certain features of the licensing process. The questions are chosen to indicate the suitability of the licensing process to the specific features of Small Modular Reactors (SMR). Following figure presents background information of licensing, issued in the questions.



Basic features of the licensing process and regulatory requirements

1. Are the regulatory requirements organized according to their level of importance and/or according to the object (plant/system/component level)?
2. How deeply do your nation's regulatory requirements address specific plant, system or component requirements?
3. Could LWR SMRs be applied according the current regulatory framework? If no, why not?
4. How is the modularity (particularly the use of reactor modules as they are used in SMRs) taken into account when planning licensing activities?

5. What influences in review times, application processing times and process in general does your licensing process allow for in repetitive licensing of many identical power plants in series?
6. How would your country use information from either plant licensing or certification from another country?
7. Does your country have any guidelines on the application of risk informed thinking (graded approach) to nuclear facilities? In particular, how would grading be permitted for SMRs?
8. Construction and Operating Licenses: In case of an SMR facility with many reactor modules in one plant (for example NuScale or a multi-unit B&W mPower), will the entire facility plant be under one license (for all the reactor modules) or many licenses (one license per reactor module)?

Contents of certain licensing steps

<u>Design</u>

9. Are the systems design approved in more than one licensing stage?
   If yes, in which licensing steps are the systems design reviewed and approved?
10. How does the safety classification approach in your country assist in determining the applicable review organizations (Regulator / Inspection Organization)?
11. Does your country have any regulatory requirements specific to passive safety features? If so, could you describe, at a high level, what these requirements are seeking?
    If not, do existing requirements apply also to passive safety features?
12. In which stage is I&C architecture/functional design of the plant with corresponding systems (including I&C) being reviewed by the regulator?

System Engineering and Requirements Management in the licensing process

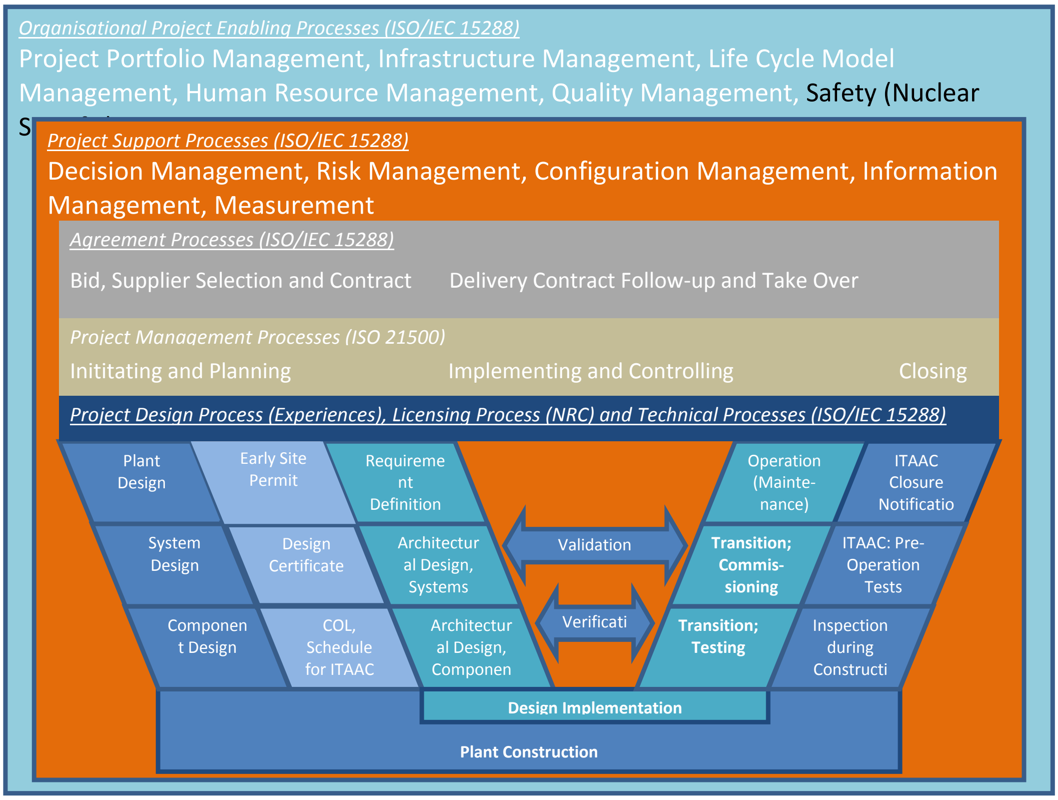
The project control and management processes, such as Decision Management, Risk Management, Configuration Management, Information Management and Requirements Management, are issued in certain standards (ISO/IEC 15288, ISO 21500). Requirements Management is one of the management disciplines getting more and more focus in nuclear industry. Figure representing the overall project control and management processes is presented in the appendix.

Requirements Management process

13. What kind of Requirements Management process and tools are required for the licensee?
14. For each licensing stage, what parts of a licensee's Requirements Management process and tools are reviewed and (if applicable) accepted by the regulator? Are there differences in review depth for each licensing phase?
15. How, and at what stages of licensing is validation and verification planned as a separate process or included in the licensing steps?
16. Does you country have a set of requirements that covers Validation and Verification program activities? (please provide a link if available)
17. Who does the planning of validation and verification?
18. What are the roles of different stakeholders?
    - Who plans the V&V procedures?
    - Who makes the necessary tests/experiments?
    - Who can review the results?
    - How does the regulator accept the results?

Appendix

The project control and management processes, including requirements management process and the US licensing process (in the V-curve), are presented in the following figure. This is an example to give some background information for the questions 13-18.



The USA answers 1

Basic features of the licensing process and regulatory requirements

1. US requirements are embodied in NRC regulations and guidance, which are finely tuned to light water reactor technology. The regulatory system is highly prescriptive, with requirements organized in content and format according to the Standard Review Plan (NUREG-0800) [115] and Regulatory Guides 1.70 [119] and 1.206 [120], with subject matter arranged by plant system or function and focused on safety.
2. Regulatory requirements address specific plant, system and component requirements to the level of detail necessary to ensure adequate protection of public health and safety and the common defense and security.
3. The current regulatory framework can be applied to SMRs, but a few issues are under discussion to provide a more rational framework that takes account of power production with multiple small modules versus more traditional, large power reactors. Several NRC policy issues have addressed security, decommissioning funding, insurance and liability, emergency planning, operator staffing and a move to risk-informed, performance-based regulation. NRC policy documents provide details (see http://www.nrc.gov/reactors/advanced/policy-issues.html.) [121]
4. How modularity is taken into account is an evolving issue, discussed at length in NRC policy documents noted in Question 3, above.
5. US governing statutes and implementing regulations were reformed in the 1980s and 1990s to account for standardization of reactors in series, with the creation of the "one-step" licensing process under 10 CFR 52 [118], where plant designers may obtain a design certification, and operators may obtain an early site permit and a combined construction and operating license that references the certified design. Permits may be issued for up to 20 years, and can be renewed. The intent is that safety issues are resolved before construction begins. To further streamline the licensing process for standard units in series, the first power plant in the series may be designated the reference plant, with subsequent plants simply referring to the license of the first, except for site-specific differences (this is a practice and not a requirement, referred to as the Design-Centered Working Group approach).
6. The technical information generated in country of origin licensing could be used to inform US licensing, but US license applications must meet specific US requirements for format and content, including verification and validation of analytical methods and limits imposed on safety performance. It is expected that other countries would employ a similar approach.
7. All nuclear plant designs must meet NRC Safety Goals and must account for potential severe accidents in a risk-informed approach. All design certification applications must include results of a probabilistic risk assessment (PRA), and must use derived risk insights in the design. License applicants would then develop plant-specific PRAs and document results. The most recent thinking in this area is embodied in NUREG-2150 [114]. Additional considerations for SMRs are discussed in SECY-11-0024 [122] and SECY-11-0156 [123].
8. This is under discussion, but the parameters of Question 5 (above) will still apply. Currently, the NRC accepts applications for multiple units at a single site, but each unit must be licensed and will have individual license and docket numbers to account for staggered inspection and commissioning schedules between units.

Contents of certain licensing steps

Design

9. All systems are licensed at the design certification stage, with site-specific aspects permitted at the combined license stage.
10. In the US, regulatory requirements and inspection activities are organized by system and function, not by safety classification. Safety classification is used to apply licensing acceptance criteria.
11. No, but the US NRC policy on advanced reactors and industry trends would suggest greater use of passive safety features. With design certification applicants employing more passive features in recent submittals, the NRC has issued revisions to regulatory guidance documents that address passive safety features directly.
    If not, do existing requirements apply also to passive safety features? Yes, as applicable to particular functions.
12. The regulator reviews I&C at the design certification stage, but also inspects these and other systems of safety significance during construction and over the operating life of the plant.

System Engineering and Requirements Management in the licensing process

Requirements Management process

13. The licensee must have a requirements data management system that directly connects safety regulations and licensing documents with equipment and system design specifications.
14. Requirements management is generally covered under the aegis of quality assurance (QA) and 10 CFR 50 Appendix B [116]. The regulator regularly audits the QA program at all stages to the level of detail available.
15. Verification and validation (V&V) are part of the required quality assurance program at all stages; however, analytical methods and computer software must undergo V&V and be approved by the regulator before they are applied to design or operation.
16. V&V requirements are generally covered under 10 CFR 50 Appendix B, but a number of regulatory guides cover specific V&V requirements applied to specific areas. Regulatory Guide 1.168 is a good example (see http://pbadupws.nrc.gov/docs/ML0404/ML040410189.pdf). [126]
17. Planning of V&V is normally done by methods developers and system designers, in dialogue with independent third parties and the regulator.
18. What are the roles of different stakeholders?

    Who plans the V&V procedures? Procedures are written by methods developers and system designers, in dialogue with quality assurance professionals.

    Who makes the necessary tests/experiments? Tests and experiments are done by plant and equipment designers and independent testing organizations.

    Who can review the results? The results are reviewed by the designer, independent third parties, customer auditors and the regulator.

    How does the regulator accept the results? A licensing topical report must be submitted to the regulator for review and approval. The regulator publishes a final safety evaluation report that releases the subject of the topical report for application.

The USA answers 2

Basic features of the licensing process and regulatory requirements

1.

The U.S. regulatory requirements for power reactors are found in 10 CFR Part 50 [116] and are generally organized according to the object (plant/system/component level) and potential accident scenarios. Some efforts have been made to organize the requirements in accordance with their level of importance. A good reference on this topic is NUREG-2150, "A Proposed Risk Management Regulatory Framework", dated April 2012.

http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr2150/ [114]

2.

A significant amount of guidance has been written for reviews of reactor designs. NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," provides significant detail about requirements including references to codes and standards.

http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/ [118]

3.

Yes, LWR SMRs will be reviewed according to the current regulatory framework. Introduction - Part 2: Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: Integral Pressurized Water Reactor Edition provides additional guidance on how this will be done.

http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/cover/ [118]

4.

The NRC staff provided an information paper to the Commission on this subject on June 12, 2011 (SECY-11-0079.) In this paper, the staff stated that it believes that continuing the practice of issuing a license for each reactor module is the best approach.

http://www.nrc.gov/reactors/advanced/policy-issues.html [14]

5.

In general, significant savings in review times and resources can be realized if applicants reference a standard design. 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" [118] contains requirements for Standard Design Certifications, Combined Licenses, and Standard Design Approvals. As standard designs are certified, they are added to the appendices to 10 CFR Part 52. Once a design has been certified, the only information that an applicant must provide is site-specific information. Under the 10 CFR Part 50 [116] licensing process, history shows that subsequent applicants were able to incorporate much design information from previous submittals of similar designs. Delays in licensing were due to site-specific issues and quality assurance problems.

It is up to the reactor designer to decide how many modules to include in a standard design. B&W is proposing two modules for its mPower design, while NuScale Power is proposing 12.

6.

The NRC is an active participant in the NEA Multinational Design Evaluation Program (MDEP) and expects that SMR designs would be included in this program as they mature and enough countries show interest.

7.

We are attempting to use a risk-informed approach to the review of SMRs, as requested by our Commissioners. In SECY-11-0024, "Use of Risk Insights to Enhance the Safety Focus of Small Modular Reactor Reviews," [122] dated February 18, 2011, we outlined the approach. We recently published "Introduction - Part 2: Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: Integral Pressurized Water Reactor Edition" for public comment. This document provides more information about our approach and can be found at

http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/cover/ [115]

8.

Each module will have its own license. See answer to question 4.

Contents of certain licensing steps

Design

9.

The applicant has a choice of licensing processes. If they choose the 10 CFR Part 50 process [116], the design is reviewed in two stages. If they choose the 10 CFR Part 52 process [118], all of the design, except for site-specific information is reviewed during the design certification review. The following brochure provides more information on our licensing processes.
http://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0298/index.html

10.

The regulator (NRC) includes licensing, inspection (oversight), research, and enforcement organizations. In general, we try to focus on risk-significant SSCs during licensing reviews and inspections. A good description of our oversight process can be found at
http://www.nrc.gov/NRR/OVERSIGHT/ASSESS/index.html [124]

11.

Yes, we have established requirements that we call "Regulatory Treatment of Non-Safety Systems." These requirements were developed during the review of the first design that featured passive safety features (AP600) and have recently been consolidated into a new section of our review guidance – SRP 19.3.
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/ch19/ [115]

12.

As discussed in question 9, the applicant decides on the review process. We have recently published a proposed review standard for the I&C review of the mPower design. This can be found in our document management system (ADAMS) at ML113630435 [125].

Canada answers (incorporated the 1 and 2)

Basic features of the licensing process and regulatory requirements

1.

Regulatory requirements in Canada are in the process of being organized, by facility type, according to the CNSC's Safety and Control Area (SCA) Framework (see Appendix B for the current list). SCAs are the technical topics CNSC staff use across all regulated facilities and activities to assess, evaluate, review, verify and report on regulatory requirements and performance. This framework is used throughout our core processes.

The SCAs are presented in a comprehensive framework consisting of 14 safety and control areas which are grouped into three primary "functional" areas (Management, Facility and Equipment, and Core Control Processes).

Specific areas define the individual SCAs, and serve as a list of options that can be selected, as deemed appropriate, by line management for each of the regulated facilities or activities. These specific areas will enable improved communication amongst ourselves as well as externally, with licensees, the Commission, and the public.

The SCA Framework provides us with a common set of safety and control terms that are applicable across the entire CNSC. By consistently using the same terms when referring to the same SCA, we will improve communication amongst ourselves as well as externally, with licensees, the Commission, and the public.

Regulatory and guidance documents are established by a process that ranks issues by regulatory importance. These documents, when developed, expand on the regulations by establishing requirements and guidance at a topical level such as Deterministic Safety Analysis, or Design. They typically reference applicable Canadian codes and standards where possible. Where an applicant seeks to apply foreign codes and standards, they are required to demonstrate broad equivalency between their standards and Canadian standards and to propose how gaps between the two will be addressed.

2.

CNSC requirements tend to be established at a broad level (non-prescriptive) but referenced codes and standards in regulatory documents then address technical issues down to specific processes (for example welding methodologies). In Canada, the applicant for a licence proposes their own specific requirements to be applied to the regulated activities and may also reference CNSC regulatory documents as well as accompanying codes and standards in the proposed licensing basis. The CNSC then reviews and 'accepts' them (through the Commission) as part of the licensing basis which is then contained in the licence and accompanying Licence Condition Handbook.

In Canada, the applicant for a licence is required by law to meet the requirements of the Nuclear Safety and Control Act (NSCA) and its associated and applicable Regulations. The NSCA and its Regulations contain, with some exceptions, non-prescriptive high-level requirements. The onus is on the applicant to demonstrate meeting these requirements and this is normally achieved by establishing own specific and more detailed requirements. Such specific requirements are in most instances drawn from CNSC's regulatory documents as well as from detailed industry codes and standards (e.g., Canadian Standards Association – CSA, ASME, IEEE, etc.) and other guides. Thus, such requirements become detailed up to the system and component level. The CNSC then reviews and 'accepts' them (through the Commission) as part of the licensing basis which is then contained in the licence and accompanying Licence Condition Handbook.

3.

Yes, however, CNSC recognizes that some additional clarity is needed around application of the graded approach when an applicant is applying specific requirements. Additional work on this issue is being planned.

4.

Regarding "conventional" nuclear power plants built in a modular fashion: No major changes to the licensing process are expected, however, CNSC will examine the licensee's overall processes for control / oversight of the supply chain. Where construction methodologies are considered 'novel' to the nuclear sector, CNSC will seek additional information from the licensee that demonstrates the proven nature of those construction methods. CNSC also recognizes that some of these modules may be treated as 'long-lead' items that are ordered prior to the construction licence being issued. There is already a well understood process for engaging with the utility to set code classes for long-lead items, however the utility will be 'at-own-risk' when ordering fabrication and delivery of long lead items before the construction licence is granted.

Regarding multiple module reactors in one facility: (for example a NuScale design) When a utility is deciding to site a reactor facility, they are generally advised to consider the maximum number of units they would consider placing on that site regardless of near-term versus long-term plans. This allows the environmental assessment to 'bound' the maximum effects from the site from the maximum number of units that would ever exist there. This reduces the possibility of another environmental assessment being triggered should the utility wish to add more "units" over and above the near term new build plans (up to the maximum bounding number of units). Expansion beyond that bounding number of units would trigger another environmental assessment and associated licensing activities.

Whether under a Licence to Prepare Site, Licence to Construct, or Licence to Operate etc, the CNSC uses a single licence to encompass the entire facility. Once construction is well advanced and a number of modules are ready to begin operation, the facility licence is then superseded by an Operating Licence which retains a construction component in the licence to allow additional modules (up to the maximum) to be installed, commissioned and placed in service. The construction portion remains in the licence until all modules for the project are in service. The licensee is expected to operate and maintain the individual modules per their technical specifications (which may be different because of vintage). The licence is able to accommodate technical differences between modules.

5.

We cannot supply time specifics, but as long as there are no major changes to the succeeding units, significant technical review efficiencies will be gained based on the review of the previous ones. With that said, the technical review is only a small part of the licensing process.

If the <u>same</u> licensee is constructing multiple copies of units on <u>one</u> site, then a single licensing process can be used for all of the units on that site and succeeding units will only need to be reviewed for design differences from the previous units.

If the same design is being built for <u>different licensees and different sites</u>, the efficiencies are only gained in the technical review. The rest of the licensing review process focuses on the licensee, their management systems and their capabilities. In Canada, each licensee generally proposes their own programs to be encompassed by their unique license (every company is different). In those cases review efficiencies from previous licensing reviews are only present if a licensee adopts (in whole) the accepted program of another licensee. Another factor to consider is that each site is influenced by its own public participation process which is a mandatory part of licensing. These participation timelines are generally fixed.

6.

As is the case for any country, Canada has the sovereign right to perform an independent safety review and the mandate of the CSNC actually obliges it to do so on behalf of the people of Canada. Each country has its own laws, cultural attributes, government structures and politics and all of these influence certification and licensing activities. CNSC recognizes that these factors need to be taken into account when considering regulatory findings and conclusions from the other country. With that said, CNSC, as part of it normal licensing activities regularly reviews licensing and certification information available from other countries to inform its own specific review activities. This is done both during pre-licensing and actual licensing activities. Under regulatory groups such as MDEP, the regulators have the ability to share their review results and insights openly. Information may be used as follows:

- CNSC may review, assess and accept some findings (but this requires a solid trusting relationship between the regulators and some independent assessment is still necessary) "Trust but Verify"
- CNSC may use some findings to target other areas for review or inspection. Most regulators use some form of sampling approach. We may choose to sample other areas other regulators may not have covered in depth.
- CNSC participates in common vendor inspection initiatives through MDEP and bilateral agreements with other regulators such as USNRC. In these inspections, CNSC might be either an observer or an active participant and has the ability to accept the results of such inspections.

7.

CNSC policy document P-299 Regulatory Fundamentals, particularly sections 4.2 *Basing Regulatory Action on Levels of Risk* and 4.3 *Making Independent, Objective and Informed Decisions*, direct CNSC staff to consider risk in all decision-making.

The Canadian regulatory approach to regulation permits a proponent to put forth safety cases that employ graded or risk-informed approaches so long as requirements are being met. Where a requirement may not be met, the proponent is expected to explain either why there is no need to address that requirement (may use risk arguments) or how an alternative approach will result in a high level of safety and still address the *intent* of the requirement.

CNSC has been working for the past few years to clarify, in some cases, where some additional flexibility may be applied in a safety case for a small reactor (example RD-367 Design of Small Reactor Facilities.). (generally less than 200 MWth, however grading is not limited to reactor size. It is true, however, that the larger the reactors (i.e. core inventory and source terms) the less likely a graded approach argument would be accepted in many areas. (for example confinement is likely possible for a small reactor, but large reactors generally require containment.

CNSC has recognized that, between P-299 and more precise documents such as RD-367, there is a need to clarify the concept of the Graded Approach further and is embarking on an initiative to document this in 2013.

8.

See response to question 4. One licence per facility with conditions, as necessary for technical differences between units.

Contents of certain licensing steps

Design

9.

Yes, however the "approvals" have different purposes:

a. There is generally a code-class approval in the early design stage
b. A detailed review and design acceptance of systems as part of the Construction licence application. A specific design would be approved for construction and that design is then captured in the Preliminary Safety Analysis Report, PSAR and is referenced in the Construction Licence) As part of the construction licence review, CNSC reviews and approves the licensee's overall process for reviewing and accepting plant SSCs from the construction and commissioning organizations (for in-service declaration). This process becomes part of the licensing basis.
c. For the Operating stage - As required, CNSC review and acceptance that the as-built design matches the approved design in the PSAR (which becomes the FSAR). Here, CNSC will perform risk-informed sampling inspections of SSCs and related records to confirm the licensee's acceptance process (discussed in previous bullet) is being followed.

10.

CNSC takes the lead role in reviewing and approving the licensee's proposed Safety Classification and related methodologies. Part of this review involves examining how safety classification and code classification interrelate. (they are expected to show a strong link) Those applicable codes determine which additional review organizations may be needed during review of the design, construction inspections and commissioning & in-service declaration work. CNSC disciplines from all related fields are involved in both the safety classification and codes and standards discussions. Although CNSC takes the lead role in field inspections, it may draw upon external expertise from those codes and standards agencies to assist in its review and compliance activities. Where foreign codes and standards are used, CNSC staff will initially seek assistance from the vendor country's regulator.

11.

Not specifically, but CNSC has recognized that passive features are becoming the design norm for new reactor designs. Currently passive safety features are considered to be one of many valid safety approaches to be considered in a reactor facility and current requirements apply to them. Some examples for specific requirements being considered for passive features can be found in Draft RD-337 version 2 Design for new Nuclear Power Plants (e.g. 7.6.2 *Single failure criterion)*

Requirements and guidance specific to this area will focus on the need for strong evidence that the passive feature is well understood and proven. This includes looking at the R&D behind the passive feature, hardware, software and analysis tools used to model and understand passive phenomena and how such tools are validated. These requirements will also feed into the commissioning program for the plant, in particular for the first-of-a-kind-unit to demonstrate that the passive phenomena behave as predicted.

12.

The approach in Canada is as described in the response to Question 9. Some of the high level architecture is reviewed in a limited manner during the pre-licensing Vendor Design Review process; however, the detailed review and acceptance for construction occurs in the construction licence application and continues into construction if the design is not complete at time of application for the licence. The licensee retains the full responsibility for accepting systems for in-service use. CNSC will perform independent inspections of the licensee's processes for accepting systems with a sampling focus on I&C. CNSC may also choose to witness certain I&C integration tests during various stages of commissioning.

System Engineering and Requirements Management in the licensing process

Requirements Management process

> **Note:**
>
> **CNSC Answers below are given under the following context:**
>
> CNSC has its own requirements management process. The responses are given in the context of the licensee's program.
>
> Requirements management is the licensee's process of documenting, analyzing, tracing, prioritizing and agreeing on requirements and then controlling change and communicating to relevant stakeholders. It is a continuous process throughout a project. A requirement is a capability to which a project outcome (product or service) should conform.
>
> The purpose of requirements management is to ensure a licensee's documents, verify and meet the needs and expectations of its customers and internal or external stakeholders. Requirements management begins with the analysis and elicitation of the objectives and constraints of the organization. Requirements management further includes supporting planning for requirements, integrating requirements and the organization for working with them (attributes for requirements), as well as relationships with other information delivering against requirements, and changes for these.
>
> The traceability thus established is used in managing requirements to report back fulfillment of company and stakeholder interests, in terms of compliance, completeness, coverage and consistency. Traceabilities also support change management as part of requirements management in understanding the impacts of changes through requirements or other related elements (e.g., functional impacts through relations to functional architecture), and facilitating introducing these changes.
>
> Requirements management involves communication between the project team members and stakeholders, and adjustment to requirements changes throughout the course of the project. To prevent one class of requirements from overriding another, constant communication among members of the development team is critical. For example, in software development for internal applications, the business has such strong needs that it may ignore user requirements, or believe that in creating use cases, the user requirements are being taken care of.

13.

CNSC does not prescribe specific processes or tools for the licensee to use. In Canada, the licensee (or applicant) is expected to propose those necessary tools as part of its overall management system for conducting and overseeing all licensed activities. Generally, high level requirements under the Canadian Standards Association (such as CSA N286-2012 *Management System Requirements for Nuclear Facilities*) are used as a basis for comparison against the licensee's proposal. It should be noted that licensees may propose to follow another standard as long as they address all of the areas in Canadian standards. The licensee's proposed program is reviewed as part of the application for each licence because processes change / evolve with each licensing phase (as licensed activities change / become more complex). The proposed program is expected to demonstrate processes are in place to manage and track their requirements (including change control). CNSC does risk-informed and targeted compliance inspections of the licensee's programs which includes how they manage requirements in the targeted area.

14.

Review: Because each licensee's requirements management program is proposed by the licensee and is 'customized' to their company's management systems, the CNSC uses a risk-informed sampling approach to determine scope and depth of the review. Generally, the method used is to take a broad look at the licensee's program and then to select a few specific areas (vertical slices) for a deeper examination. If issues are found, CNSC staff have the option to either perform more vertical slice reviews of processes and tools or probe, at a deeper level, along a horizontal area that cross-cuts many requirements areas. (for example, look at how change control is performed for requirements that affect contacting, materials purchasing, supply chain management etc.) The same approach is used for each licensing phase because each phase should have a requirements management program, but that program evolves from a more simplistic one at site preparation to a complex one through construction and into operation.

Acceptance: Following review by the CNSC, the licensee's program as well as licensee's resolution paths for issues discovered (commitments), is incorporated into the licensing basis which is then captured in the licence and the accompanying Licence Condition Handbook (LCH). If the Commission grants a licence, then CNSC compliance activities will be conducted against the specific licensing basis using the referenced codes and standards.

15.

Validation and verification is a licensee process that a licensee is expected to be examining well before the onset of licensing discussions. Various V&V techniques are expected to be applied by the design vendors and suppliers in each of their product development (e.g., conceptual design, basic engineering design, final and site-specific design) and implementation phases. The V&V techniques can differ in scope (e.g., V&V for systems and components design, V&V for computer codes used in safety and design analyses), in depth (depending on the product development stage) and in choice (e.g., analytical vs. testing or a combination of them, benchmarking vs. validation, etc.). Although there are no requirements to regulate V&V prior to entering the licensing process, the CNSC expects the licensee to demonstrate "smart buyer" (intelligent customer) thinking once licensing discussions begin. As a result, CNSC has articulated requirements around V&V in topic specific regulatory documents and guides. The V&V program and associated processes are subject to CNSC review and compliance activities in each licensing stage. As discussed in question 14 the CNSC uses a risk-informed sampling approach to determine scope and depth of the review or any compliance activities. As well, the licensee's V&V program becomes part of the licensing basis as captured in the licence and accompanying LCH.

16.

Programmatic Requirements: As discussed in the response to question 13, generally, high level requirements under the Canadian Standards Association (such as CSA N286-2012 *Management System Requirements for Nuclear Facilities*) are used as a basis for comparison against the licensee's V&V program proposal.

Technical Area Specific V&V Requirements: CNSC does not prescribe detailed requirements per se, but rather sets broad requirements in topic-specific regulatory documents and regulatory guides. Where necessary CNSC may directly reference Canadian standards as required for use or may reference them as a basis for comparison, such as CSA standard N286.7-99, *Quality Assurance of Analytical, Scientific, and Design Computer Programs for Nuclear Power Plants*, which "shall be applied in safety analysis code development and use" as stated in RD-310 Safety Analysis for Nuclear Power Plants.

An example of a broad requirement can be found in RD-367 Design of Small Reactor Facilities, §7.11.2 *Use of computer-based systems or equipment* as follows:

> Appropriate codes and standards for the development, testing and maintenance of computer hardware and software shall be applied to the design of systems or equipment important to safety that are controlled by computer. These codes and standards shall be implemented throughout the life cycle of the system or equipment. In this respect, special attention shall be given to the software development cycle.
>
> A top-down software development process shall be used to facilitate verification and validation activities. Software provided by a third-party vendor that is used in systems or equipment important to safety shall be developed, inspected and tested in accordance with standards of a category commensurate with the safety function provided by the given system or equipment.
>
> The software development process, including control, testing and commissioning of design changes, as well as the results of independent assessment of that process, shall be reviewable and shall be systematically

documented in the design documentation.

Another example can be found in RD-308 Deterministic Safety for Small Reactor Facilities, §4.7 *Quality of deterministic safety analysis* as follows:

> Deterministic safety analysis shall be subjected to a comprehensive QA program that is applied to all activities affecting the quality of the results. The QA program shall identify the quality assurance standards to be applied and shall include documented procedures and instructions for the complete deterministic safety analysis process, including, but not limited to:
>
> a. collection and verification of reactor facility data
> b. verification of the computer input data
> c. validation of codes used in deterministic safety analysis
> d. assessment of results of simulations
> e. documentation of deterministic safety analysis results

These types of requirements are explained in more depth in regulatory guides such as GD-310 Guidance on Safety Analysis for Nuclear Power Plants. Some examples can be found in the following sections however examples are available throughout the document:

- §5.4.5.1 *Computer code applicability*
- §5.4.5.2 *Code validation and quantification of accuracy*
- §5.4.4.5 – which looks at validation of human actions

17.
Generally, the vendor does it for their own product development activities. As part of the licensing process though, the licensee is expected to confirm and demonstrate that V&V is being conducted to appropriate quality standards whether conducted by themselves or by contractors.

France answers 1

Basic features of the licensing process and regulatory requirements

1.
Not in my knowledge.
2.
As you probably know, there are no detailed regulatory requirements in France. The philosophy is that it is the burden of the applicant to demonstrate, on a case by case basis, that the general safety objectives are correctly met by mean of the selected safety options. Of course, the required performances of several systems are impacted by regulatory framework dealing with radiation protection, environmental and health protection, etc.
3.
In France, there would be no impediment for an applicant to seek authorization to build an SMR plant, especially if it is derived from an LWR. In fact the authorization is to be granted on the basis of the technical demonstration and the environmental impact study as required in the law of June 2006 (security and transparency in nuclear activities). In this law it is also written that the Safety Authority (ASN) can take some complementary" decisions in the technical domain, but it is a case by case approach. In the fundamental Safety Rules issued by the ASN, more detailed recommendations can be found. These are recommendations to nuclear operators, defining security objectives and practices which the ASN considers to be a satisfactory approach to meet these objectives. The FSR are clearly applicable to PWRs of a commercial size (like those built in France), but we use to use them for experimental reactors (ex. Jules Horowitz Reactor). Nevertheless, the FSR are not mandatory.
4.
So far, no modular installation has been built in France. By "modular plant", I mean plants with several reactors using systems in common like common power conversion system, or auxiliary systems. Nevertheless, the IRSN has initiated the discussion with EDF concerning the way to cope with the supporting functions which may be pooled in a same site. In case several units are built on the same site (which is often the case) safety demonstration of one unit takes into account potential hazards induced by neighboring units (external hazards).
5.
As far as I know, each plant is considered a "separate" case, as, for each one, the applicant must issue a safety report. As you know, another EPR was planned in France, but this project has been canceled or postponed at the stage of the preliminary safety report. But, many items were to be examined in addition to those already reviewed for Flamanville, so it is not an example of "licensing" of a standard design.
6.
In France (and I guess in European countries as well), a license issued by a foreign national Safety Authority has no legal value. The approach is rather a top-down one. As an example, the MDEP (OECD) initiative is dedicated to exchanges between TSOs and Safety Authorities on several reactor designs including the EPR. From these discussions, requirements can be integrated in the French approach. In fact, there are many possibilities to organize an "international" feedback on safety assessment: stress tests conducted after Fukushima are a good example. Up to now, the idea is first to issue widely shared safety principles (as WENRA objectives, for example) and then to adapt them within national regulatory frames.
7.
Personally, I don't see any difference in principles between SMRs and present commercial reactors on this point (in France). Each risk management approach has to be "graded", but the main principle is to apply an ALARA approach, when dealing with the radiological risk. The risk informed approach, outside the frame of the designer work, is not yet integrated in the safety assessment.
8.
According to the decree of November 2007, it is possible for an operator to apply for a joint authorization procedure if he wants to build several units on the same site. Nevertheless, besides the "creation decree", each unit (reactor) will probably have to obtain an operating permit (note that in France there is no "site permit", site assessment in included in the Safety Report presented to apply to the "creation decree"). Construction permit is delivered by the local Administrative Authority on the basis of a public inquiry and environmental impact study. But the fact that some safety functions or systems might be shared between the units should be evaluated.

Contents of certain licensing steps

Design

9.

The design of the safety systems is reviewed during the assessment of the Preliminary Safety Report. There is no "approval" of the design, because the analysis is done on a case by case basis. After the authorization of creation of the plant ("creation decree"), some design aspects may be reviewed in further version of the Safety Report, before the plant is put into operation. The associated requirements address:

- provisions to cope with accidents and their consequences on the public,
- conditions for water withdrawals,
- provisions to limit the noise charge,
- waste management,
- management of radioactive sources,
- monitoring of environmental impact,
- Public and Safety authority information.

These requirements may be applicable to several units on the same site.

10.

The Safety Authority reviews and monitor the fabrication and construction important SSCs with the help of the IRSN. The safety assessment is performed by the IRSN alone. All safety classified equipment is taken into account, whatever the classification level.

11.

There is no specific regulatory requirement concerning passive safety systems in France.

If not, do existing requirements apply also to passive safety features?

A priori, existing requirements apply to any safety systems whether they may be passive or active. Note that, there are very few passive safety systems in the EPR because we consider that systems which need a DC supply to actuate valves or sensors are not completely passive.

12.

All these aspects are reviewed during the Preliminary Safety Report assessment. As said before, the Safety Authorities may issue specific technical requirements before the start-up authorization.

PS: Note that I speak about Safety Authorities and not "regulator". As you know, the IRSN is a TSO and the main part of our work is not directly link to regulation. Moreover, the Authorities need an expert to assess a safety case especially when it is not possible for the designer to fulfill a well-known standard requirement…

System Engineering and Requirements Management in the licensing process

Requirements Management process

13.

The licensee has to comply with a quality management rule. He has to present its technical capabilities (technical resources, staff management, etc.) at the stage of the Preliminary Safety Report. Apart from these elements, there are no specific requirements regarding the way he will manage its application (regarding management tools in particular).

14.

See above.

15.

As far as I know V&V approach is applied:

- in the field of numerical modeling,
- in the field of systems and functional analysis.

Essentially, numerical models are assessed during the Preliminary Safety Report phase. But numerical models are not subject to any kind of licensing in France. During the review , the IRSN analyses the validation and qualification procedures associated with the numerical tools which are mentioned in the accidental studies.

For the plant systems, V&V is not in assessed after the "creation decree" issuance.

16.

Not in my knowledge.
17.
The applicant set up the test program.
18. What are the roles of different stakeholders?

Who plans the V&V procedures?

The applicant.

Who makes the necessary tests/experiments?

The applicant (usually a subcontractor of the applicant)

Who can review the results?

The applicant, an independent expert is also required (paid by the applicant - so called "third verification level") and the TSO.

How does the regulator accept the results?

By issuing the authorization of operation of the plant (sometimes it is a step by step authorization : 25% of NP, full power)

France answers 2

Basic features of the licensing process and regulatory requirements

1.

There are regulatory documents which are dealing with different levels. For example the new decree issued in February 2012 is dealing globally to the full installation (in French: “Installation Nucléaire de base” (INB) (Basic nuclear installation). It can be a single unit (NPP) or several units located on the same site.

Another example of a decree which is applicable at the component level is for nuclear pressurized equipment (so called “ESPN” order.

2.

The regulatory requirements in France do not detail to an equivalent and systematic extent as in the YVL guides the design requirements for the SSCs. There is the intent to develop this kind of document in France. But this target has been postponed. My interpretation is maybe to establish some links and/or incorporate in some way the work done by WENRA on the safety objectives for new reactors.

3.

If there were a SMR project launched in France, it was have to follow exactly the same steps than a NPP project.

4.

The modularity aspect could be beneficial in the sense that once the technical design of one module is assessed and approved, the assessment do not need to be repeated. But the licensing of the nuclear installation should deal with the final installation with all modules foreseen to be erected. This is of course relevant when considering the potential impact on the environment.

5.

There is no built-in explicit provision in the regulation but it can be anticipated that the construction in series of exactly the same design would save time and effort for the licensing and construction of the subsequent modules.

This is more or less on this kind of process that the first wave of NPP constructions proved to be very efficient in the seventies and eighties.

6.

There is no direct decision process which is the consequence of a decision taken in an other country but there is a lot of exchanges and cooperation between regulators (WENRA, ENSREG, MDEP, CNRA and CSNI from the NEA) that it is clear that any finding in one country is quickly shared among the regulator community.

7.

There is no such guideline in France.

8.

I assume there will be a single license for all the installation.

Contents of certain licensing steps

<u>Design</u>

9.

The systems are approved step by step. In France three steps are considered:

- Safety option review
- Construction licence
- Operating license

The system design will be reviewed at each step going to more and more details according to the flow of the engineering work.

10.

It is per the decision of the regulator which can decide in all circumstances to subcontract the review work to a third party organization.

11.

No there is no such requirement.

If not, do existing requirements apply also to passive safety features?

The general safety principles apply also to passive safety features.

12. As for system design, I&C architecture is assessed step by step. The first step can be done very early with the safety option review.

The UK answers 1

Basic features of the licensing process and regulatory requirements

1.
The are a set of safety assessment principles supported by more detailed assessment guides. These are discipline based. See attached [129] and http://www.hse.gov.uk/nuclear/operational/tech_asst_guides/ [127]

2.
not at all

3.
yes no specific plant issues are fundamental

4.
It needs to be taken into account by the designer. It is routine in UK. Most AGR are multi reactor.

5.
We regulate by sampling. We do not approve safety cases, we permission actions. This sometimes includes premissioning modifications to safety cases or justification for operations. This does not imply that we agree with everything in a safety case.

Our intervention strategy is required to be proportionate and target on risk. We would generally not sample something twice.

See the following for detail on how we work http://www.hse.gov.uk/nuclear/operational/index.htm [128]

6.
The origin is immaterial to us, but we would require the licensee to approve the documents. Responsibility can not be delegated.

7.
See attached document. [129]

8.
It would be for discussion on application for the site licence, but prescient suggests one license.

Contents of certain licensing steps

Design

9.
We do not approve designs, we permit activities. There needs to be sufficient information to warrant construction or operation when the relevant permission is sought.

10.
See above.

11.
See attached [129]

12.
ONR will need a minimum level of information prior to granting a construction license. More will be needed to permission specific activities.

System Engineering and Requirements Management in the licensing process

Requirements Management process

13.
The license has a set of requirements see link http://www.hse.gov.uk/nuclear/regulation-and-licensing.htm [130]

14.
Interventions will be planned and targeted based on risk, novelty etc.

15.
As above

16. -

17.
The licensee needs to meet the quality requirements in the licence.

18.
Responsibility remains with the licensee.

The UK answers 2

Basic features of the licensing process and regulatory requirements

General Comments

The depiction of the stages of the Nuclear Licensing process is rather oversimplified and is potentially misleading particularly as it relates to design. In the UK, designs are not licensed, as such, and in practice design work is started by vendors prior to the involvement of the licensee. In fact in an ideal world an operator might like to buy an "off the shelf" complete design. However, as the licensee, the operator must satisfy themselves that the design is suitable for the intended site and can be operated safely. Thus it is the design acceptance process, including any adaption to local conditions and requirements which will be the concern of the regulator.

The actual NPP design is often a result of combining the inputs from a number of vendors (NSSS, turbine, civil structures etc.). This may be carried out by Architect Engineers or by the Operating company. In the UK the early reactor designs were produced by consortia formed from a number of UK companies. Initial basic design work was carried out by the UKAEA with the more detailed design work being undertaken by the consortia and funded by the CEGB (the intended operator). The plants were initially built as turnkey contracts. Over time the consortia merged so that the AGR (Advanced Gas-cooled Reactor) plants were built by 3 consortia. One of these failed during the construction of the first plant and so the CEGB had to step in and take it over. The others were subject to delays and cost overruns so that when the second phase AGRs were built they were not let as turnkey contracts. CEGB acted as its own Architect Engineer and more comprehensive detailed design information was required before the project started.

This was the process used for the last UK NPP to be built, Sizewell B, though by that time the remaining two consortia had merged to produce NNC. This plant was to be built on an existing site and the operator (CEGB) was an existing licensee so did not have the challenges posed by a new site and new operator but does illustrate the process followed. The Regulator required that, before licensing a new PWR power station they needed the following information:

(a) the safety principles and criteria to be used in the design;
(b) a statement of the design in outline (the reference design), to be supplemented later by more detailed information;
(c) a preliminary safety report (PSR) outlining the principles and the basis on which the safety case is to be made, together with information showing how the reference design meets the safety criteria. It provides a preliminary safety analysis of the critical fault conditions and preliminary assessment of the proposed protection equipment;
(d) statements of the proposed research and development work in support of the safety case;
(e) proposals for quality assurance;
(f) details of the contract design, i.e. the design intended for construction; and
(g) a pre-construction safety report (PCSR) containing a more comprehensive statement than the PSR of the safety case and design description including more detailed safety analysis and assessment of the performance and standard of the proposed protection equipment.

It was expected that the information would be provided chronologically in approximately the order shown above and that the process of review and assessment by the Inspectorate would cover a period of about two years, taking into account the work already carried out in an earlier generic review. The acceptance of the design as meeting the required standards of safety was dependent on the regulator being satisfied that there was a small chance of significant modifications subsequently being required for safety reasons. At this stage the licence variation is issued and construction can begin.

The review and design finalisation stage took longer than originally anticipated (about 5 years rather than 2) but the processes to obtain the other planning permissions necessary to start construction took even longer (6 ½ years) so licensing was not the critical path. The work that went into resolving design issues prior to the start of construction paid dividends and there was only one major design change during construction which severely threatened the programme, but this was due to the failure of the original control and instrumentation supplier to deliver the product on time (i.e. not a safety issue). Despite this the plant was completed to time and to budget.

First of a kind designs pose particular challenges, particularly in a deregulated commercial environment. Operators are not prepared to subsidise the development of a detailed design that they may not use and vendors are not prepared to commit too much resource without a prospective customer. In some cases Governments step in to fund new design developments undertaken by their own national vendors (e.g. USDoE funding of the development up to FDA status a number of ALWRs). The alternative is to proceed on the basis of less detail and develop the detail in parallel with other activities. This does not pose a fundamental problem for regulators since there is no nuclear risk until you put fuel in the plant so that is the key hold point. It does however mean that the operator has to accept that he is proceeding at commercial risk. It can also result in the regulator being put under political pressure to compromise when a lot of money has already been invested in construction. However there are cases where plants have never been able to load fuel because the regulator was not satisfied with the safety of the plant.

It is useful to review some of the main features of the UK regulatory system and how it has developed. The UK licensing system is a goal setting one in which it is not prescriptive about how the goals are met. The Nuclear Installations Act requires the licensing of sites which are to be used for the installation or operation of nuclear fission reactors (except reactors forming part of a means of transport) and certain other classes of nuclear installations which may be prescribed. Currently the latter are prescribed via the Nuclear Installations Regulations 1971 (SI 1971/381). Prior to 1971 (when BNFL was created as a separate entity) licensing just covered commercial NPP. The remit of the regulator has expanded to cover not only fuel manufacture and processing, and waste processing but all the activities of the former UKAEA and some of the defence establishments, which used to be subject to internal regulation.

Nuclear Regulation in the UK is based on the same principles as is used for other UK industries:

- the owner and operator bears ultimate responsibility for safety
- they must do whatever is reasonably practicable to reduce risk to both the public and the workforce

Most legislation is based on the ALARP principle, which is a legal requirement. As was noted above the first thing the regulator expects to see is a statement of the safety principles and criteria to be used in the design. The CEGB established a set of design safety criteria (DSC) and guidelines (DSG) for its plant. The regulator set down a set of Safety Assessment Principles (SAPs) to be used by its assessors in assessing safety cases. Although these were generally consistent they were not the same. Prior to the Sizewell B Public Inquiry there were separate sets of SAPs for Nuclear Power Stations and for Nuclear Chemical Plants.

The DSC and SAPs made use of a common starting point, the fundamental principles for radiation protection set down by ICRP:

- No person shall receive doses in excess of the statutory dose limits as a result of normal operation.
- The exposure of any persons shall be kept as low as is reasonably practicable.
- The collective dose equivalent to operators and-to the general public as a result of operation of the nuclear installation shall be kept as low as is reasonably practicable.
- All reasonably practicable steps shall be taken to prevent accidents.
- All reasonably practicable steps shall be taken to minimise the radiological consequences of any accident.

The guidance documents were discussed at the Sizewell B Public Inquiry and following this the Inspector recommended that the NII's SAPs and the CEGB's DSC and DSG should be re-examined to eliminate avoidable inconsistencies. This was done and NII and Nuclear Electric (the operator of the former CEGB nuclear power stations) issued revisions. In 1992 NII revised the SAPs for nuclear power reactors and those for nuclear chemical plants and merged them to produce the Safety Assessment Principles for Nuclear Power Plants. This revision took account of lessons from both the Sizewell B and Hinkley Point C public inquiries as well as the HSE Tolerability of Risks from Nuclear Power Stations, which had also been published as a result of a recommendation from the Sizewell B inquiry (initially issued as a Consultation Document in 1988).

In 1993 Nuclear Electric declared that for future plants it would use Chapter 2.1 of the European Utilities Requirements document as its safety assessment principles in place of the DSCs. This has been carried forward and EDF Energy is using a version (amended to align with UK radiological targets) of this for its new build projects.

In 2006 the current version of the SAPs was issued. This both benchmarked the SAPs against IAEA requirements and extended their application to all the nuclear facilities which are now regulated, including defence sites. The technical requirements for nuclear power reactors remained broadly as they were in the 1992 SAPs. Copies of the various versions of the SAPs can be found on the ONR Website http://www.hse.gov.uk/nuclear/saps/index.htm; this also includes a useful guide to the licensing of nuclear installations which has recently been issued.

The regulatory targets used in the UK are all expressed in terms of doses to workers or members of the public. As such they would be applicable to SMRs and indeed they are already applied to research reactors and isotope production facilities. The use of dose targets means that the application should be proportionate since the dose will be directly affected by the size of the source of activity. The SAPs also explicitly set down expectations for multi-unit sites. Given that the UK licence is a "site" rather than a "facility" licence, the system should have no difficulties with SMRs

The principle means of control is the Nuclear Site Licence (copy of the standard licence is available on ONR Website). A single licence is issued to control construction, commissioning, operation and decommissioning. This has 36 standard conditions:

1 Interpretation
2 Marking of the site boundary
3 Restriction on dealing with the site
4 Restrictions on nuclear matter on the site
5 Consignment of nuclear matter
6 Documents, records, authorities and certificates
7 Incidents on the site
8 Warning notices
9 Instructions to persons on the site
10 Training
11 Emergency arrangements
12 Duly authorised and other suitably qualified and experienced persons
13 Nuclear Safety Committee
14 Safety documentation
15 Periodic review
16 Site plans, designs and specifications
17 Management Systems
18 Radiological protection
19 Construction or installation of new plant
20 Modification to design of plant under construction
21 Commissioning
22 Modification or experiment on existing plant
23 Operating rules
24 Operating instructions
25 Operational records
26 Control and supervision of operations
27 Safety mechanisms, devices and circuits
28 Examination, inspection, maintenance and testing
29 Duty to carry out tests, inspections and examinations
30 Periodic shutdown
31 Shutdown of specified operations
32 Accumulation of radioactive waste
33 Disposal of radioactive waste
34 Leakage and escape of radioactive material and radioactive waste
35 Decommissioning
36 Organisational Capability

The licence conditions generally require the licensee to put in place "suitable arrangements" to control the activity. The regulator may formally approve these arrangements, if they want to, but normally very few are formally approved. Their agreement is sought but approval is not necessary as the licensee can be prosecuted for breaching licence condition arrangements, whether they have been approved or not.

It is normal for some of the licence conditions to require the involvement of the regulator. Construction and Commissioning can be divided into stages and the regulators consent could be required to move from one stage to the next. Thus, although there is no operating licence, as such, the loading of fuel is normally the last of the construction (Licence Condition (LC) 19) consent points and requires the regulators consent as well as a comprehensive preoperational safety report (FSAR). Modifications to the plant are categorised according to their safety significance and the most significant ones require the regulators approval.

1.

The structure is hierarchical; the 2006 SAPs structure is appended

2.

The requirements focus on principles and the ability of the systems to reliably fulfil their safety duties.

3.

Yes the requirements are technology neutral

4.

This would be treated in the same way as any component manufactured off-site and suitable control and inspection processes would need to be put in place by the licensee with provisions for regulatory inspection if required. If the reactor modules are to come into service in a phased fashion then this would need to be taken into account in the safety case. This would need to show adequate protection of operating units from construction/installation activities. In terms of overall risk this would normally be bounded by assuming all modules are operational (i.e. the highest on site core inventory), but interactions during construction will have to be carefully examined. As noted above, specific expectations are required for multi-unit sites. If a set of safety cases is written for the different unit, a cross-site safety case is also required (TAG/051).

5.

The assessment of the site dependencies would be required in each case but the design assessment will be straightforward provided that not too much time has elapsed. ONR now make use of a facilitative process to assess proposed design (Generic Design Assessment). Once a Design Acceptance Certificate is issued this will remain valid for a period of time (~10years – the same interval as for PSR). The assessment is carried out based on a generic site so the suitability of the actual site needs to be confirmed and the design adopted by the licensee (GDA is vendor rather than licensee led). Even in the case of a standard direct site licence application repetitive licensing of a standard design is faster for the second and subsequent designs, since it is not necessary to repeat the basic design assessment. Thus when a replica of Sizewell B was to be built at Hinkley Point in the 1990s the initial safety case was simply that for Sizewell B with revised radiological assessments for the Hinkley site together with revised grid and cooling water reliabilities, where necessary.

6.

In the past the regulator has used licensing information from the country of origin to inform their preliminary assessment. They also enter into cooperation agreements with the regulator of the country of origin. They will make their own assessment but would use previous assessments where possible. One of the difficulties in the past has occurred because with the single licence, the UK has required a lot more information before the start of construction than has been required in the past for a normal construction licence. However the regulator will use whatever is available as part of their assessment. An important consideration is that the UK regulator has responsibility for ensuring that the operator has met the law. This means the licensee must submit the safety case. Using another regulator's findings would be of only limited assistance, unless the submitted information was exactly the same and the process of review and assessment based on the same safety goals.

7.

Risk informed decision making has been inherent in the UK approach since the early 1970s. The requirement to reduce risk (defined as "the possibility of danger") so far as is reasonably practicable has meant that the use of probabilistic assessment tools has been normal practice. Although it is recognised that the basic design process is, by its nature, deterministic, safety assessment should not be purely deterministic. Since the late 1970s the UK operator has required the use of numerical probability analysis in safety assessments, wherever appropriate,

- to ensure a systematic approach is followed
- to achieve a balanced design

Proportionality is required by the regulators guidance on enforcement so that the requirements of safety should be applied in a manner which is commensurate with the magnitude of the hazard. The setting of non-mandatory targets within the SAPs reflects this with the acceptable dose limits being reduced as the magnitude increases. Since these are expressed in terms of dose to the public, the size of the reactor would have an impact.

8.

The reactors are not licensed individually; the licence is for a site operated by a single licensee.

Contents of certain licensing steps

Design

9.

Designs are not formally approved, sites are licensed for activities to be carried out. If that activity is generating electricity using a nuclear reactor then the design is material to the decision, but the design itself is not approved. The most important review stage is prior to the issue of the licence and the start of construction. However although the aim is to resolve the major design issues at this stage (this is largely driven by the licensee wanting to reduce commercial risk) it is recognised that further design development may be required and that the design will not be fully underwritten until after the equipment has been commissioned. LC 20 requires the licensee to have in place arrangement to control the design during construction. This requires the reference design and its safety case to be defined and brought under configuration control so any changes can be categorised in terms of their potential safety significance and assessed and approved by a process appropriate to their safety significance. For the highest level this normally requires the regulators approval, but in a well controlled project, which was adequately assessed before the reference design was finalised, these should be few in number. For instance there were only 4 category 1 changes made to Sizewell B during construction (there were many lower category changes all of which were available to the regulator for review but did not require their approval). The production of the POSR (pre operational safety report) was the key focus for review following the issue of the site licence. This brought together all the work to consolidate the design and the final safety justification. This was required to be available for review by the regulator 1 year before fuel was loaded. It was not formally approved but formed part of the basis for the granting of consent to load fuel and start active commissioning. The POSR then provides the basis for the operational safety case (=POSR + any changes due to commissioning results)

10.

The responsibility for review rests with the operating organisation and appropriate independent third part review are procured in line with the safety classification. These are made available to the regulator for their assessment. For components where an "incredibility of failure" argument is made (e.g. the RPV) additional diverse and redundant inspections are required. The regulator may choose to carryout their own inspections but may also rely on the third party inspections procured by the operator. Regulators may also become part of the inspection teams to satisfy themselves that it is suitably independent. The inspection regimes will be agreed as part of the arrangements put in place by the licensee.

11.

In general the requirements in the SAPs "*apply to both active and passive safety systems. However, in the case of passive safety systems, not all of the principles may apply or their application may be more restricted because of the inherent features of such systems*"(SAPs para 334). Paragraph 38 of the SAPs addresses "Alternative approaches" and states

"The principles are written bearing in mind the content of safety cases likely to be submitted to the NII. However, dutyholders may wish to put forward a safety case that differs from this expectation and, as in the past, the inspector will consider such an approach. In these cases the dutyholder is advised to discuss the method of demonstration with NII beforehand. Such cases will need to demonstrate equivalence to the outcomes associated with the use of the principles here, and such a demonstration may need to be examined

in greater depth to gain such an assurance. An example of such a situation is the greater use of passive safe concepts."

12.

The I&C architecture and functional design are reviewed prior to the granting of the site licence since they are vital to establishing the adequacy of the safety provisions. The detailed design and the justification of the reliability will take place later in the design process but this must always be shown to support the claims and arguments made in the safety case. At the time the licence is granted the basic architecture including redundancy and diversity provisions should be agreed.

System Engineering and Requirements Management in the licensing process

I am not quite sure what you mean by "requirements management". I also have to admit to being a rather old fashioned cynic when it comes to project management and the associated tools, when pursued as an end in itself. Too may projects come to grief because they are pursued by "experts" in project management who don't understand the technology that they manage. However I do very firmly believe in QA and V&V!

I assume that by "requirements management" you are referring to commitments made during the licensing process. In addressing top level requirements it is often not possible to simply satisfy the requirement at an early stage and commitments have to be made to undertake confirmatory work or additional analysis at a suitable time. This is generally managed using an overall hold point procedure which allows activities to be tied to particular decision points. The decision points are defined as part of the project scheduling and are classified according to their importance from both a project management and licensing view point. A project process is put in place to manage the release of these hold points. A comprehensive set are established for the purposes of overall project management. A small number of these may be selected and agreed with the regulator as licensing hold points. The choice will be agreed with the regulator and then be tagged as requiring formal consent before they can be cleared. For Sizewell B there were 12 consent points which were initially chosen as significant evolutions occurring at roughly 6 month intervals. Other hold points will be managed using internal processes which may be subject to audit by the regulator. A log of licensing commitments was also kept whose clearance was tied to various consent points.

Requirements Management process

13.

In our standard site licence LC 17 requires that "*the licensee shall make and implement adequate quality assurance arrangements in respect of all matters which may affect safety*." Further guidance is given in the inspection guide http://www.hse.gov.uk/nuclear/operational/tech_insp_guides/tins017.pdf.
The licensee must have an adequate management system, but under the goal-setting approach the choice of process and tools is for the licensee to make and is not restricted by the regulator. However, the regulator will check adequacy of the arrangements.

14.

All that are relevant, including the vendors during GDA. The regulatory oversight is proportionate and will concentrate on those aspects particularly relevant to the licensing stage.

15.

They are included at each step, as needed.

16. -

17. -

18.

The responsibility for implementing QA and V&V rests with the licensee who would normally require that their contractors have in place suitable systems as part of contractual arrangements. These would be subject to QA inspection by the licensee. The regulator may also wish to carryout inspections as part of their assessment of the adequacy of the licensees arrangements. There is no specific guidance on V&V programmes.

2006 SAPs structure

INTRODUCTION

FUNDAMENTAL PRINCIPLES

LEADERSHIP AND MANAGEMENT FOR SAFETY

THE REGULATORY ASSESSMENT OF SAFETY CASES

THE REGULATORY ASSESSMENT OF SITING

ENGINEERING PRINCIPLES

EKP – Key principles
ECS – Safety classification and standards
EQU – Equipment qualification
EDR – Design for reliability
ERL – Reliability claims
ECM – Commissioning
EMT – Maintenance, inspection and testing
EAD – Ageing and degradation
ELO – Layout
EHA – External and internal hazards
EPS – Pressure systems
EMC – Integrity of metal components and structures
ECE – Civil engineering
EGR – Graphite components and structures
ESS – Safety systems
ESR – Control and instrumentation of safety-related systems
EES – Essential services
EHF – Human factors
ENM – Control of nuclear matter
ECV – Containment and ventilation
ERC – Reactor core
EHT – Heat transport systems
ECR – Criticality safety

RADIATION PROTECTION

FAULT ANALYSIS

NUMERICAL TARGETS AND LEGAL LIMITS

ACCIDENT MANAGEMENT AND EMERGENCY PREPAREDNESS

RADIOACTIVE WASTE MANAGEMENT

DECOMMISSIONING

CONTROL AND REMEDIATION OF RADIOACTIVELY CONTAMINATED LAND

Finland answers 1

Basic features of the licensing process and regulatory requirements

1.

Principly yes.

Plant level and system level guides are mainly in VNA 733/2008, YVL:s B.1 and B.7, Site issues are issued in YVL A.2 and Components are issued in YVL E-series.

Focus of CL is in plant and system level review, and LLI review.

Large and important, binding legal requirements are already presented in VNA.

New YVL-guides are divided into groups according to the level of the requirements.

The importancy of different requirements in YVL guides is issued also by the dividision of the requirements (different series), but in deeper level the importancy of the requirements is not issued. Inside one YVL guides, all requirements are in same level. The licensee can interpret the requirements and divide them into different cothegories.

2.

Requirements are in detailed level (very specific), including requirements all the way until the component level. It shall be taken into account that the same level of safety can be applied with different approach (deviation from YVL guides), with detailed background information and justification.

3.

Yes, in principle.

4.

Modularity is seen as a positive feature, because it demands the design majurity level high. Detailed design is important in modular design approach.

Audits can be issued more effective way, and the review and audit process shall be well organized and optimized.

5.

Series production is seen as a benefit for the review, since the regulatory body expertise considering the design increases, the review can be made in shorter time.

Only small changes are probably needed, all the design changes need to be reviewed. Configuration management and change management becomes even more important factor of licensing.

6.

The information can be used, both bilateral and multiratelar contracts are issued between different regulators.

Own independent safety review is handled from the beginning to the end.

Safety requirements are harmonization work in ongoing in Europe through WENRA.

7.

Graded approach is seen as safety classification (fundamental issue).

Risk informed approach is seen as PRA analyses requirements.

Deterministic safety approach is required, PRA is used as holistical analsis tool to guide the design and review.

Deterministic approach can not be taken out of the licensing process. Risk informed approach can be used to help the determining the deterministic analyses and focus the review.

8.

This is not decided or defined in Finland.

IRRS missio: STUK independence in licensing to be increased - from TEM

IAEA IRRS mission: "The Government should strengthen the legislative framework by embedding, in law, STUK as a body separated from other entities having responsibilities or interests that could unduly influence its decision-making"

Contents of certain licensing steps

Design

9.

DiP - preliminary reviewed, CL approved, OL changes of the design approved

Continuous review process through regulatory approvals.

Licensing plan is an important document to understand the design process and licensing process during the project.
Frozed configuration versus design changes - when do changes need approval through licensing process, needs to be defined how the changes affect the design.
In modular design the level of design is such, that the regulatory approvals are probably not needed between CL and OL.

10.
Yes, it does. New YVL guides are planned to discuss this in more detailed. YVL (E-series discusses this issue and determines: SC1,2 will be reviewed by STUK, SC 3, EYT will be review in system level by STUK and inspections will be carried out by acredited independent inspection organization. The inspection organization will need acreditation by national accreditation body FINAS , STUK will participate to the accreditation process. . Inspection activities will not be allowed in the future by the licensee (license holder), as is the practice nowadays.

11.
Yes. YVL B.1 includes DiD approach. YVL-guides are to be discussed if applying a design with purely passive safety features. As mentioned earlier, the safety level shall be fulfilled, YVL guides deviations are possible with justification.

12.
Reviewed in DiP (general level), in more detailed level in CL, which is the main review of the I&C Architecture (OL3 lessons learned). Minor changes may occur and they are in that case reviewed later (OL phase).

Requirements Management process

13.
YVL Guide A.5 requires RM as part of configuration management process. Developed RM tool required (not tool specific)

14.
STUK will not review the RM process or tools. The process will be reviewed in construction inspection program. Proces need to be defined and instructed, project instructions shall be sent to STUK for information.

15.
V&V overall process is not included in th YVL requirements.
V&V elements are included in YVL guides. This differs widely between different technical disciplines.

16.
There is no set of requirements for this, discipline specific.

17.
Experts in licensee organization - discipline specific approach.

18. What are the roles of different stakeholders?

Who plans the V&V procedures?
Included in principle in YVL guides. Not clearly indicated though.

Who makes the necessary tests/experiments?
Defined according to the SC.

Who can review the results?
Defined according to the SC.

How does the regulator accept the results?
Defined according to the SC.

Finland answers 2

Basic features of the licensing process and regulatory requirements

1.

Regulatory framework in Finland is actually based on the risks to population and the environment and their limitation. This limitation is presented in nuclear legislation. In the level of VNA the risk limitation is clear. However, the next level of regulations (YVL guides) mix the goal with the methods to deliver it. In YVL guides the focus is in the detailed requirements handling mainly the methods to receive the safety level required in the VNA. This level the prescriptive approach is even too much emphasized.

2.

See answer to question 1.

3.

Modularity is not specified in current regulatory framework. Both construction modules and even more reactor modules licensing need more discussion and it is not clearly indicated how this would suit in Finnish regulatory framework.

4.

See answer to question 3.

5.

The review times would probably be shorter if many identical units were licensed in series. However, it shall be discussed if many new units should be included in one single construction license. It is not feasible to go through licensing process for every single identical unit built on the same site in a sequence.

6.

Within the current practise each single project or initiative is evaluated separately. The evaluation is based on the demonstration specific to the intitiative, however, the reference design is requested to be presented and somewhat credited. The current practise using the reference design should not be limited as it is, but it could be extended. The use of certified or licensed designs (in Western countries with known and corresponding requirements) in Finnish licensing should be discussed. How the licenses or certifications could be utilized, focusing only on an additional review needs?

7.

Graded approach should be applied from high level of organizations, viewing the whole big picture, partly this is the case currently as well. This would handle the overall grading bringing up the actually important issues. Currently the graded approach is issued in lower levels as well, which is miss leading. This approach brings up only the important factors in the corresponding field, even if it is unrelevant in the big picture. This kind of grading increases licensing burden and should be avoided when streamlining the licensing process.

8.

It shall be discussed if many reactors and also many units could be issued under one license. The practise has not been settled at this point of time.

Contents of certain licensing steps

<u>Design</u>

9.

The main focus is to keep the responsibility and liability within the licensee. Currently the design in Finland is reviewed and approved in two phases.

It shall be discussed how detailed review is needed within the PSAR/CL phase. The background of PSAR has been in conceptual/basic design issuing only the overall systems design and demonstrating its safety level. The limitations within the detailed design shall be avoided in early phase of the project.

As each design shall be redesigned for Finland (within the current practise), the systems' detailed design shall not be required in too early phase, since the design work is very expensive. To enable the new NPP projects in economical point of view, too detailed design requirements shall not be issued in early phases of the projects. The situation would be different if the design certification was issued in Finland. The inspection and control could be sampling approach and the main review could be situated in later phases of

the project. The possibility to stop the project would be available to and used by STUK, if it is seen as necessary.
STUK could give preliminary decisions in certain issues, if required by the licensee. However, the overall detailed design should not be completely reviewed by STUK. This kind of approach would put the responsibility even stronger in the sholders of the licensee. Sanctions of the findings that are issued afterwards, could be heavy, which is the practise in the US. This kind of approach would emphasize the licesee (proponent) responsibility in terms of lincensing.

10. -
11. -
12. -

APPENDIX 2

Questions about licensing in aviation and railway industry fields.

The main focus is on licensing and sertification processes and requirements in aviation and railway industries. As the background information, the nuclear licensing process is presented here.
In Finland nuclear licensing has 3 main steps as presented in the figure below with green licensing steps. This example is the Olkiluoto 3 case with it's licensing steps.

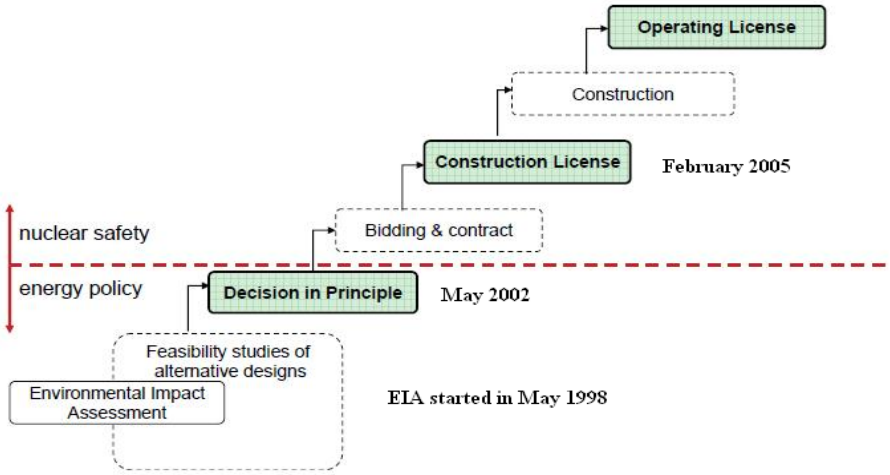


Figure 1. Finnish nuclear licensing process

The licensing requirements can be presented with the Finnish Regulatory Pyramide, including diferent level of requirements in Finnish nuclear regulatory framework.
In addition to these requirement, there are international standards, that are followed, such as IAEA Safety Standards and WENRA Reference Levels and RHWG ”booklet” on safety of new reactors.

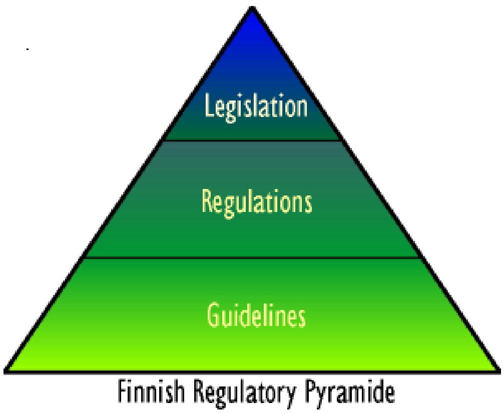


Figure 2. Finnish regulatory requirements

The focus of my study is to find new licensing approaches to develop the nuclear licensing to suit the Small Modulare Reactors (SMR) better.
SMRs have many similar features with aviation and railway industry since we are discussing about reactor modules, that could be compared with e.g. an aircraft. Similarities between these industry fields stakeholders in Finnish environment, since Finnish industry players are mainly buyers and regulators (not developers or designers). The case is similar in different industry fields, since they all buy items from other countries and are responsible to license or certificate the tems in Finland.

Guestions for the basis of interviews:

Curent status of the industry
Have you been purchasing new items in past years?
Is there experiences, that you could share?
Do you have experience in the licensing/certification process?
Has the licensing/certification process been developed lately?

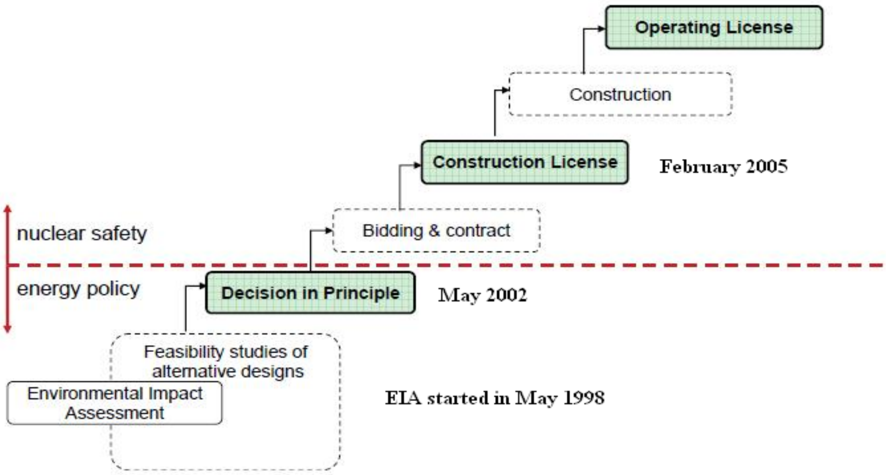
Licensing/certification stakeholders and process
Could you describe the regulatory framework in your industry field?
What are the main stakeholders in licensing/certification process?
Is the licensing/certification process international or national or partly both?
If both, could you describe the responsibilities of international and national stakeholders?
Can international licences/certificates be used in Finland?
If yes, are the technical issues reviewed by Finnish regulator or simply approved?

Licensing/certification regulatory requirements
What are the main licensing requirements in your industry field?
What is the structure of the licensing/certification requirements?
Are there different licensing/certification requirements in different countries or are they internationally harmonized?
Could you present some advantages and challenges you have faced with the requirements?

Other issues
Is the public acceptance an important issue in your industry field?
Is the organizational issues discussed as part of the licensing/certification?
How are the environmental issues discussed as part of the licensing/certification?
What have found to be the main challenges in the licensing/certification?

Questions concerning nuclear legislation in Finland
Haastattelukysymykset lakimuutoksen tarpeista.

Taustaa
Tutkimuksen tavoitteena on löytää ratkaisevia tekijöitä SMRien lisensioinin tehostamiseksi. Nämä löydetyt tekijät pyritään ottamaan huomioon Suomalaisessa lisensiointikäytännössä niin, että nykyinen järjestelmä säilyisi mahdollisimman pitkälle nykyisenä.
Muutosta lisensiointikäytäntöön voidaan esittää muutokseksi ainoastaan SMRien osalta, jolloin suuret yksiköt voisivat edelleen toimia nykyisen prosessin mukaisesti.
Lähtökohdaksi on otettu tämä esimerkki OL3:n lisensiointikäytännöstä.

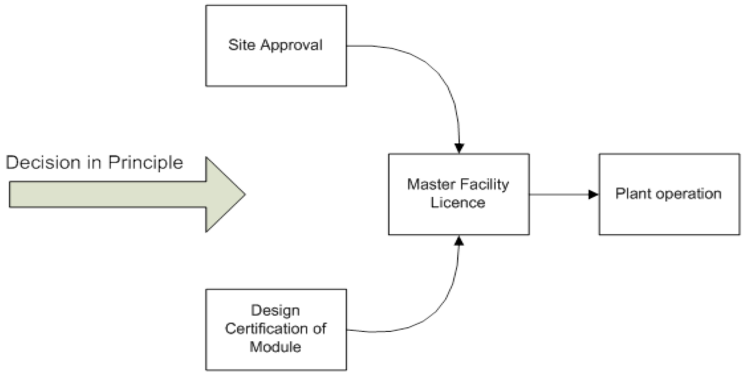


Kuva 1. Suomalainen Lisensiointiprosessi

SMRien lisensioinnissa tulee huomioida näiden laitosyksiköiden erityispiirteet, joita on määritetty seuraavasti:

- Standardisointi
- Modulaarisuus
  - useita reaktorimoduuleja yhdessä laitoksessa
  - modulaarinen rakentaminen - tehdasvalmisteiden suuri aste
- Useita laitoksia samalla sitella
  - Rakentaminen sarjassa & esivalmistetut rakenteet
- Laitossuunnittelun yksinkertaistaminen (passiiviset turvallisuusominaisuudet)
- Lyhyet rakentamisajat
- Pienemmät kertainvestoinnit
  - Joustavuus ja tarpeen huomioiminen investoinneissa

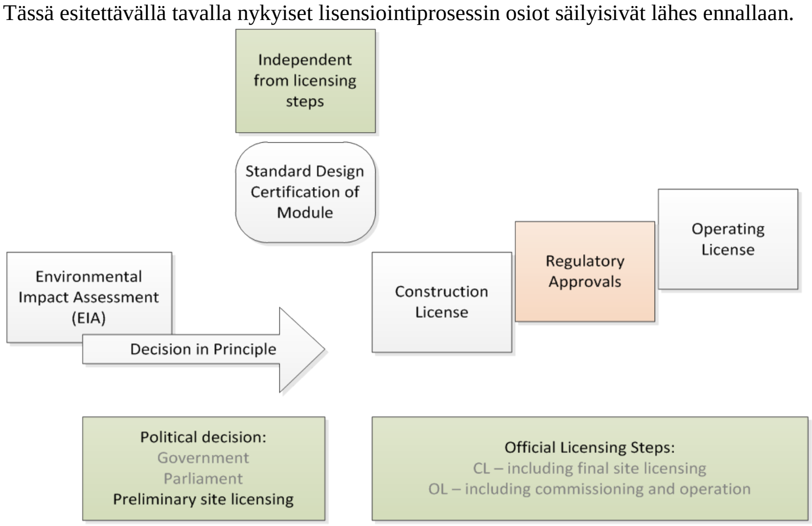
Yksinkertaistettu ja SMRille optimoitu lisensiointiprosessi, voisi näyttää seuraavalta.



Kuva 2. SMRille optimoitu lisensiointiprosessi

Huomaa poliittinen päätös prosessin alussa (lisensiointiriskin pienentäminen). Design sertifikaatti moduulille (standardi reaktorimoduuli ja turvallisuusjärjestelmät).
Näillä ominaisuuksilla saadaan aikaan poliittisesti turvattu lisensiointiprosessi ja standardoidun reaktorimoduulin sertifikaatin avulla voidaan monen moduulin laitoksella lisensioida moduuli vain kerran (kopioida tarpeen mukaan moduuleja rakennettaessa). Tämän lähestylistavan kautta Master Facility License voi sisältää ainoastaan koko laitoksen yhteisiä uhkia, kuten ulkoiset uhat, yhteisviat, tms.
Siten lisensiointi, sekä moduulin sertifiointi voidaan tehdä itsenäisesti projektin tilanteesta välittämättä, joka lyhentää projektia merkittävästi lisäten kustannustehokkuutta.

Suomeen pyritään ylläesitetyt asiat huomioimaan niin, että nykyistä lisensiointikäytäntöä tarvitsis muokata mahdollisimman vähän.
Tässä esitettävällä tavalla nykyiset lisensiointiprosessin osiot säilyisivät lähes ennallaan.



Kuva 3. Ehdotettava uusi lisensiointiprosessi SMRille Suomeen

<u>Kysymykset haastatteluun:</u>
Ydinenergialaki

1. Onko tarvetta muuttaa ydinenergialakia jos lisensiointiprosessia muokataan esitetyllä tavalla? Otetaan mukaan uusi lisensiointisteppi - standardi moduulin sertifiointi?

2. Miten kohta: "5 a) ydinvoimalaitoksella sähkön tai lämmön tuotantoon tarkoitettua ydinreaktorilla varustettua ydinlaitosta tai samalle laitospaikalle sijoitettujen ydinvoimalaitosyksiköiden ja niiden yhteydessä toimivien muiden ydinlaitosten muodostamaa laitoskokonaisuutta; (23.5.2008/342) " tulee tulkita?

Tarkoittaako tämä käytännössä, että laitos jossa on useita reaktorimoduuleja, on lain mukaan yksi ydinvoimalaitos?

Periaatepäätös

3. Tarvitseeko lakia muuttaa jos periaatepäätöksessä ei mainita lainkaan reaktorien määrää, vaan ainoastaan tehotaso, jota suunnitellaan?
4. Onko laissa rajoitusta periaatepäätöksen voimassaolon pituudesta, periaatepäätöshän on myönnetty viimeaikaisille hankkeille 5 vuodeksi? 24 § "Lupa, rakentamislupaa lukuunottamatta, myönnetään määräaikaisena. Määräajan pituutta harkittaessa on otettava huomioon erityisesti turvallisuuden varmistaminen ja toiminnan arvioitu kesto. Luvassa voidaan määrätä, että se lakkaa olemasta voimassa, jollei toimintaa aloiteta määräajassa luvan myöntämisestä."
5. Jos reaktorimoduuleita halutaan rakentaa myöhemmin lisää, tarpeen kasvaessa, miten periaatepäätöstä tulisi käsitellä? Miten voidaan välttää periaatepäätöksen uudelleen hakeminen?

Rakentamislupa/käyttölupa

6. Tarvitseeko lakia muuttaa jos rakentamisluvan sisältöä ja vaatimuksia muutetaan?

Riskiperusteinen lisensiointikäytäntö

7. Onko jonkinasteinen riskitasoon perustuva kevyempi lisensiointi mahdollista toteuttaa nykyisen lain puitteissa?
8. SMRien riskit ovat pienen koon ja suunnitteluperusteiden vaikutuksesta huomattavasti pienempiä suuriin laitosyksiköihin verrattuna. Onko tällaisella perusteella mahdollista karsia lisensiointivaatimuksia, rajoittaako laki asiaa jollain tavalla?

Muut asiat

9. Onko mahdollisesti laissa muita rajoitteita, jotka tulisi ottaa huomioon?

Ydinenergia-asetus

1. Onko tarvetta muuttaa Ydinenergia-asetusta jos lisensiointiprosessia muokataan esitetyllä tavalla? Otetaan mukaan uusi lisensiointisteppi - standardi moduulin sertifiointi?

Periaatepäätös

2. Tarvitseeko Ydinenergia-asetusta muuttaa jos periaatepäätöksessä ei mainita lainkaan reaktorien määrää, vaan ainoastaan tehotaso, jota suunnitellaan?
3. Miten asetusta tulee tulkita, kun siinä sanotaan: "kunkin ydinlaitoshankkeen osalta"?
4. Onko Ydinenergia-asetuksessa rajoitusta periaatepäätöksen voimassaolon pituudesta?

Rakentamislupa/käyttölupa

5. Tarvitseeko asetusta muuttaa jos rakentamisluvan sisältöä ja vaatimuksia muutetaan?

Riskiperusteinen lisensiointikäytäntö

10. Onko jonkinasteinen riskitasoon perustuva kevyempi lisensiointi mahdollista toteuttaa nykyisen Ydinenergia-asetuksen puitteissa?
11. SMRien riskit ovat pienen koon ja suunnitteluperusteiden vaikutuksesta huomattavasti pienempiä suuriin laitosyksiköihin verrattuna. Onko tällaisella perusteella mahdollista karsia lisensiointivaatimuksia, rajoittaako Ydinenergia-asetus asiaa jollain tavalla?

Muut asiat

12. Onko mahdollisesti Ydinenergia-asetuksessa muita rajoitteita, jotka tulisi ottaa huomioon?

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527. JÄPPINEN, EERO. The effects of location, feedstock availability, and supply-chain logistics on the greenhouse gas emissions of forest-biomass energy utilization in Finland. 2013. Diss.