Nuclear Regulation
NEA/CNRA/R(2022)1
May 2025
www.oecd-nea.org

Survey of the Regulatory Approach on the Oversight of New Nuclear Power Plant Construction

OECD
BETTER POLICIES FOR BETTER LIVES

NEA
NUCLEAR ENERGY AGENCY

Nuclear Energy Agency

NEA/CNRA/R(2022)1

Unclassified English text only

23 May 2025

NUCLEAR ENERGY AGENCY
COMMITTEE ON NUCLEAR REGULATORY ACTIVITIES

Survey of the Regulatory Approach on the Oversight of New Nuclear Power Plant Construction

This document is available in PDF format only.

JT03566846

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

The OECD is a unique forum where the governments of 38 democracies work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD member countries are: Australia, Austria, Belgium, Canada, Chile, Colombia, Costa Rica, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Türkiye, the United Kingdom and the United States. The European Commission takes part in the work of the OECD.

OECD Publishing disseminates widely the results of the Organisation's statistics gathering and research on economic, social and environmental issues, as well as the conventions, guidelines and standards agreed by its members.

NUCLEAR ENERGY AGENCY

The OECD Nuclear Energy Agency (NEA) was established on 1 February 1958. Current NEA membership consists of 34 countries: Argentina, Australia, Austria, Belgium, Bulgaria, Canada, Czechia, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Korea, Luxembourg, Mexico, the Netherlands, Norway, Poland, Portugal, Romania, Russia (suspended), the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Türkiye, the United Kingdom and the United States. The European Commission and the International Atomic Energy Agency also take part in the work of the Agency.

The mission of the NEA is:

- to assist its member countries in maintaining and further developing, through international co-operation, the scientific, technological and legal bases required for a safe, environmentally friendly and economical use of nuclear energy for peaceful purposes;
- to provide authoritative assessments and to forge common understandings on key issues, as input to government decisions on nuclear energy policy and to broader OECD policy analyses in areas such as energy and sustainable development.

Specific areas of competence of the NEA include the safety and regulation of nuclear activities, radioactive waste management and decommissioning, radiological protection, nuclear science, economic and technical analyses of the nuclear fuel cycle, nuclear law and liability, and public information. The NEA Data Bank provides nuclear data and computer program services for participating countries.

COMMITTEE ON NUCLEAR REGULATORY ACTIVITIES (CNRA)

The Committee on Nuclear Regulatory Activities (CNRA) addresses NEA programmes and activities concerning the regulation, licensing and inspection of nuclear installations with regard to both technical and human aspects of nuclear safety. The Committee constitutes a forum for the effective exchange of safety-relevant information and experience among regulatory organisations. To the extent appropriate, the Committee reviews developments which could affect regulatory requirements with the objective of providing members with an understanding of the motivation for new regulatory requirements under consideration and an opportunity to offer suggestions that might improve them and assist in the development of a common understanding among member countries. In particular it reviews regulatory aspects of current safety management strategies and safety management practices and operating experiences at nuclear facilities including, as appropriate, consideration of the interface between safety and security with a view to disseminating lessons learnt. In accordance with *The Strategic Plan of the Nuclear Energy Agency: 2017-2022*, the committee promotes co-operation among member countries to use the feedback from experience to develop measures to ensure high standards of safety, to further enhance efficiency and effectiveness in the regulatory process and to maintain adequate infrastructure and competence in the nuclear safety field.

The committee promotes transparency of nuclear safety work and open public communication. In accordance with the NEA Strategic Plan, the committee oversees work to promote the development of effective and efficient regulation.

The committee focuses on safety issues and corresponding regulatory aspects for existing and new power reactors and other nuclear installations, and the regulatory implications of new designs and new technologies of power reactors and other types of nuclear installations consistent with the interests of the members. Furthermore, it examines any other matters referred to it by the NEA Steering Committee for Nuclear Energy. The work of the committee is collaborative with and supportive of, as appropriate, that of other international organisations for co-operation among regulators and consider, upon request, issues raised by these organisations. The Committee organises its own activities. It may sponsor specialist meetings, senior-level task groups and working groups to further its objectives.

In implementing its programme, the committee establishes co-operative mechanisms with the Committee on the Safety of Nuclear Installations (CSNI) in order to work with that committee on matters of common interest, avoiding unnecessary duplications. The committee also co-operates with the Committee on Radiological Protection and Public Health (CRPPH), the Radioactive Waste Management Committee (RWMC), and other NEA committees and activities on matters of common interest.

Foreword

This report was prepared by Kyle Cormier, Dylan Pierce and Chantal Morin of the Canadian Nuclear Safety Commission (CNSC, Canada) and is based on survey results provided by Canada, Finland, France, Hungary, Poland, the Slovak Republic, Slovenia, the United Kingdom and the United States.

It was approved by the CNRA on 30 January 2022.

Table of contents

List of abbreviations and acronyms

AEA	Atomic Energy Act
ASL	Approved suppliers list
ASN	Autorité de sûreté nucléaire (French Nuclear Safety Authority)
CHS	Conventional health and safety
CIP	Construction inspection programme
CLA	Construction licence application
CLG	Construction Licence Grant
CNRA	Committee on Nuclear Regulatory Activities (NEA)
CNSC	Canadian Nuclear Safety Commission
COL	Combined licence
EDF	Électricité de France
EPC	Engineering, procurement and construction
EPCM	Engineering, procurement and construction management
FOAK	First-of-a-kind
HAEA	Hungarian Atomic Energy Authority
HPC	Hinkley Point C
HSWA	Health and Safety at Work etc Act 1974
I&C	Instrumentation and control
IAEA	International Atomic Energy Agency
IRSN	Institut de Radioprotection et de Sûreté Nucléaire (French Institute for Radiological Protection and Nuclear Safety)
ITAAC	Inspections, Tests, Analyses, and Acceptance Criteria
LER	Licensee event reports
LWA	Limited work authorisation
MDEP	Multinational Design Evaluation Programme
MEH	Mechanical, Electrical & HVAC
MOC	Memorandum of co-operation
NEA	Nuclear Energy Agency

NPE	Nuclear pressure equipment
NRC	Nuclear Regulatory Commission (United States)
NSCA	Nuclear Safety Control Act
NSC	Nuclear Safety Code
NOAK	Nth-of-a-Kind
OECD	Organisation for Economic Co-operation and Development
OLC	Operating limits and conditions
ONR	Office of Nuclear Regulation (United Kingdom)
PAA	National Atomic Energy Agency (Poland)
PICS	Process control system
PSAR	Preliminary Safety Analysis Report
PSIR	Preliminary safety information report
PTO	Provisional takeover
PWR	Pressurised water reactor
QA	Quality Assurance
QMS	Quality Management Systems
RB	Regulatory body
ROP	Reactor oversight process
SAP	Safety Assessment Principles
SICS	Safety control system
SMR	Small modular reactor
SNQ	Supplier nuclear qualification
SNSA	Slovenian Nuclear Safety Administration
SSC	Structures, systems and components
STUK	Finnish Radiation and Nuclear Safety Authority
SZC	Sizewell C
TAG	Technical Assessment Guides
TSO	Technical Support Organisation
VICWG	Vendor Inspection Co-operation Working Group (MDEP)
VVER	See WWER
WGRNR	Working Group on the Regulation of New Reactors (NEA)
WWER	Water-cooled water moderator energy reactor (Russian design)

1. Introduction

The construction of nuclear power plants has always been challenging. This seems to have become more significant in recent decades (circa 2000 and later) as nuclear power plant projects in many NEA countries have experienced significant delays in construction caused, in part, by fabrication and construction errors, control of contracted work activities, engineering errors created by translation and unit conversion issues, a globalised supply chain, and access to qualified and skilled craft experienced in nuclear power construction and fabrication processes and procedures. In response, industry is turning to innovations such as factory or modular construction and the use of new construction methods in order to improve performance. As these innovations are introduced into construction, regulatory bodies will be challenged to oversee construction activities.

Many of the organisations that plan to build new nuclear power plants are organisations that already operate existing nuclear power plants. An operational organisation typically has a highly stable workforce that is skilled and knowledgeable in the operation, maintenance, and testing of the facility. Such an operational organisation faces unique challenges as it embarks on construction projects that rely on external construction organisations that are typically contracted to build the plant. Similar challenges will be faced by organisations that are planning to build their first nuclear power plant. Construction organisations often rely on transient workforces that come and go to the site as needed based on the phase of construction. The differences between an operational (or new owner) organisation and a construction organisation can create management and co-ordination issues that affect the execution of construction activities.

Regulatory bodies have a role in overseeing the construction of new nuclear power plants to ensure that the as-built plant meets the as-designed and licensed facility. The oversight of these activities requires that the regulatory body understands not only the approach (and innovations) being used to build the facility, but how the organisational structure affects the ability of the license holder to ensure the plant is built as designed to ensure safe operation. To better understand this issue, the Working Group on the Regulation of New Reactors (WGRNR) initiated a survey to share best practices and experiences from nuclear regulators regarding their oversight of the construction of commercial nuclear power reactors. This survey included experience in the use of various contracting models to support management of the construction and procurement activities such as engineering, procurement and construction (EPC) or engineering, procurement and construction management (EPCM) models.

The survey results and the report are arranged in three broad themes:

1) Delivery/contracting models

    - Experience with delivery models that are either being used or proposed to be used in new build or major refurbishments. Insights from this will support the regulatory body as it plans to oversee the fabrication and construction of the facility. This will allow the regulatory body to identify the skills needed to oversee construction activities and the schedule for when oversight activities should be conducted.

2) Licensee oversight frameworks

- Experience with oversight frameworks used or proposed by licensees under different delivery models. This would include licensees' approaches to intelligent customer capability (intelligent client), oversight capability and time-frame capacity. Insights from understanding this will allow regulatory bodies to have confidence that the results of their oversight activities provide assurance that the licensee has a healthy quality management system (or quality assurance programme) capable of ensuring that design requirements are met throughout the fabrication and construction.

3) Regulatory oversight frameworks

- The approaches used by regulatory bodies will need to be able to adapt to the differences in EPC and EPCM approaches to contracting to construct a nuclear power plant. Sharing the experiences from regulatory bodies that have overseen construction activities under the different construction approaches will provide insights that will support adapting regulatory approaches to effectively oversee construction activities.

2. Survey

The survey was divided into three broad themes and contained a number of questions within each theme. Each question is repeated below along with a high-level overview of the responses. All survey responses are also included in Annex 1.

2.1. Delivery and contracting models

2.1.1. Question 1.1

In your country, which contract delivery models do applicants/licensees use or are proposing? For example, engineering, procurement and construction (EPC), engineering, procurement and construction management (EPCM), bespoke, or partnerships and alliances?

The majority of respondents note that licensees make use of an EPCM or EPC model for a range of construction activities.

Canada, Slovenia, Finland, the United Kingdom and the United States indicated that licensees have formed alliances or partnerships in these arrangements.

The Slovak Republic noted that mid-project, the EPCM contractor left the project and in response, the licensee assumed the role overseeing construction project management.

Canada, Poland and the Slovak Republic indicated that new builds projects are still in early stages and the proposed delivery models are not yet known.

2.1.2. Question 1.2

Given an increasingly global supply chain, what regulatory requirements and expectations do you have regarding applicants/licensees or the delivery organisation's extensive reliance on foreign:

a) material and major component supply, and modular construction.

Overall, most countries do not have specific requirements or expectations for licensees related to foreign material, major component supply and modular construction. In the case of Slovenia, for construction of a new nuclear power plant, it was noted that the national regulation is still being developed and is heavily based on US standards and requirements, and that standards from the country of origin of the technology supplier (United States) were used.

b) site construction labour with different working languages, cultural norms and practices.

Most countries do not have specific requirements; however, the United Kingdom noted that there are requirements to manage potential implications of various cultural and language challenges. Similarly, Canada, France, Hungary and the United States indicated that there are safety culture and/or quality requirements that must be met, such that the safety policy is understood and implemented by contractors and subcontractors respectively. The Slovak Republic and Slovenia identified that site construction labour with different working languages, cultural norms and practices is an issue. Slovenia further stated that in order to meet low construction costs, companies

may employ a transient workforce that may not speak a common language, noting that even where great efforts were put into training among the construction workforce there was poor recognition of the importance of their work. Canada and the United States indicated that having different working languages, cultural norms and practices was usually not an issue due to geographic location and having a stable and experienced nuclear construction workforce.

c) application of home country construction, environmental, and occupational health and safety standards and working practices different from your country.

The majority of respondents indicated that national construction, environmental, and occupational health and safety standards apply and that an applicant must demonstrate that their practices meet national requirements. Poland and Slovenia noted that if standards from the technology supplier are applied, the applicant must provide evidence that national requirements are met.

2.2. Licensee oversight framework

2.2.1. Question 2.1

What regulatory expectations do you have regarding the licensee's evaluation of the contracted entity to ensure adequate capability to construct the facility?

The majority of respondents expect that licensees ensure that the contracted entity has adequate capabilities and qualifications to construct the facility. In general, respondents expect licensees to ensure that contractors have adequate:

- management systems in place;
- procedures, processes, security requirements, and training to ensure contracted personnel have relevant competencies;
- human resources and are well prepared to perform the contracted task; and
- quality assurance and verification techniques to effectively manage the delivery of contracted work.

Canada, the Slovak Republic, Slovenia and the United States indicted that the licensee must confirm through means such as assessment, inspection, verification and evaluation that activities and their products meet the specified requirements and ensure that products perform satisfactorily in service.

2.2.2. Question 2.2

Please describe how the transfer and ownership of the facility from the construction organisation to the operation organisation is done in your country.

France, Hungary and the United States noted that from experience, a single licensee is typically in charge of both the construction and operation phases of the facility. This most often is done by having the licensee made up of two entities, one for construction and the other for operation. Therefore, no transfer of ownership is necessary, instead personnel in the licensee's construction entity transitioned to the operating entity as required. Hungary noted that construction and operation activities are permitted by separate licences The United States indicated that the Nuclear Regulatory Commission (NRC) has specific regulations, requirements, and experience issuing a combined construction and operating licence. The United Kingdom noted that the Office of Nuclear Regulation (ONR) grants a

single licence to a corporate body to conduct a prescribed set of activities on a specific site; this covers the full life cycle, which includes construction, commissioning, operations and decommissioning.

Poland indicated that transfer of ownership of the facility from the construction organisation to the operations organisation happens in two steps with separate licences for construction, operation and commissioning:

- after construction, an entity can apply for a commissioning licence;
- when commissioning is finished successfully, an entity can apply for an operating licence.

2.2.3. Question 2.3

What regulatory expectations exist for the transfer and ownership of the facility from the construction organisation to the operation organisation?

In general, most respondents described expectations regarding the transfer and ownership of the facility. These expectations could be summarised as:

- Licensees are expected to have sufficient knowledge across all phases of the project and effectively manage transitions between phases.
- Licensees must provide necessary documentation to confirm that all tests, limits, and legal and licence conditions have been met.
- Licensees must have processes and procedures to control the turnover of work.

Canada, Finland and the Slovak Republic provided detailed responses of turnover of work requirements in their full responses.

France, Hungary and the United States noted that for new build projects, it was the same entity responsible for construction and operation. In the United Kingdom, the ONR grants a single licence against a corporate body to conduct a prescribed set of activities on a specific site; this covers the full life cycle, which includes construction, commissioning, operations and decommissioning.

2.2.4. Question 2.4

Does your country have any regulatory requirements and expectations on licensees for competencies and activities they must retain in-house and not contract externally?

The Slovak Republic indicated that in the stage of construction, there are no activities that must be retained in-house; however, the licensee remains responsible for all activities throughout the lifetime of the nuclear power plant.

Poland indicated that there is no regulation about any restriction of activities; however, the licensee shall have within its organisation the knowledge, expertise and resources to maintain control and oversight of safety at all times.

Finland also noted that there are no regulatory requirements on what competencies and activities must be retained in-house, apart from the requirement that reactor operators must be directly employed by the licensee.

France has a specific requirement for the licensee to limit, as much as possible, the number of levels of subcontracting. In particular, from commissioning to decommissioning, the activities important to the protection of security, safety, public health and sanitation, nature and the environment cannot be performed by a subcontractor with more than two levels of

subcontracting inside the perimeter of the installation without informing the Nuclear Safety Authority (ASN).

Hungary referenced a specific requirement in order for the licensee to maintain an adequate level of safety. Specifically, the top management determines what knowledge and resources are required to be developed and maintained within the organisation and what knowledge and resources are appropriate to be obtained from outside the organisation. Furthermore, additional requirements were described that included that the licensee shall ensure, in all phases of the construction, the sufficiency of its own, and its supplier's competence, particularly the collective competence of the general designer, the manufacturers, the construction and installation organisations, and the operator. Slovenia described similar requirements.

Canada and the United States indicated that the licensee should have the capability to understand the nuclear safety significance of any purchased expertise or equipment, specify requirements, supervise the work, and technically review the output before, during and after implementation. Contractors at all levels in the supply chain should expect to be audited on a regular basis as part of contractual arrangements.

The UK ONR expects a licensee/aspirant licensee to define a business model, which clearly articulates and justifies the core safety capability for the organisation; further detail is provided in TAG 049 (ONR, 2024). Principle 1 - "The licensees should maintain a core safety capability of staff to ensure effective management for nuclear safety". Principle 3 - "Licensee choices between sourcing work in-house or from contractors should be informed by a company policy that takes into account the nuclear safety implications of those choices".

2.2.5. Question 2.5

What are your regulatory requirements and expectations for the operating organisation to be involved in construction oversight?

France and Slovenia described that the licensee must perform oversight activities during the construction phase due to their role as licensee. Furthermore, Finland, Poland and the Slovak Republic did not indicate any specific requirements for the operating organisation's involvement but described that adequate oversight provisions must be in place by the licensee.

The Slovak Republic further described that in practice, licensee staff of existing operating reactors were involved in the construction of new reactor units. It was also noted that certain commissioning activities starting with the integrated cold hydro test that required manipulation of systems, such as the process control system (PICS) and safety control system (SICS), can only be performed by certified staff.

The United States specified the expectation that the operating organisation is engaged in oversight as construction progresses. Similarly, Canada indicated expectations that during construction, the licensee will develop evolving operational phase training and personnel certification approaches for those who will be involved in commissioning, operation, maintenance and technical support activities.

The United Kingdom also acknowledged the benefits of future operators and maintainers being sufficiently involved in the commissioning activities in order to transfer knowledge and understanding of the nuclear power plant prior to commencing operations. ONR also expects the licensee to put in place adequate arrangements for provision of independent advice and guidance and to have a robust independent nuclear oversight capability.

2.2.6. Question 2.6

If any, what experience do applicants/licensees have embedding their own staff into the contracted entity during construction, and the basis for doing so?

The Slovak Republic noted a positive experience with operational staff involvement during the construction phase (e.g. embedding nuclear safety oversight experts). Finland similarly noted experience where a licensee embedded a few of its own staff into a plant supplier's commissioning organisation. The feedback from the licensee was that this is an effective way to perform tasks and collect knowledge for future operations of the nuclear power plant.

Slovenia and the United States did not describe any instances of licensees embedding themselves in contracted entities; however, they reiterated that licensee staff are expected to provide oversight of the contracted entity. The Slovak Republic elaborated that the licensee is primarily involved in the organisation, co-ordination and supervision of activities.

Canada noted experience where a licensee embedded a number of its own staff into an EPC contractor's organisation. This was done following a noted reduction in project management performance. The same licensee stated this will be their business model for future new build nuclear power plants, and has recently formed a partnership with an SMR vendor to licence, construct, operate and decommission an SMR through a company formed to be the licensee for all life cycle phases. The licensee intends to provide the majority of personnel for this project.

The United Kingdom also noted experience with a licensee embedding staff, noting that the ONR make a distinction between the embedding of a contractor's staff into the licensee organisation in contrast to a contractor undertaking a package of work on behalf of a licensee. Where a package of work is carried out on behalf of a licensee, the licensee must specify and oversee that work within the intelligent customer framework. Where contractor staff are embedded into the licensee organisation, they effectively become part of the licensee and undertake activities under the licensees's arrangements and have to meet the licensees' competency requirements; in this case ONR's focus is also on the contractual arrangements in place to ensure the licensee retains a resilient and capable organisation.

Hungary, Poland and the United States have no experience with licensees embedding themselves into contracted entities during construction.

2.3. Regulatory oversight framework

2.3.1. Question 3.1

Do you adapt your oversight framework for regulating a fleet deployment of the same technology (beyond first-of-a-kind - proven technology within the country) and if so, what are the principles/approach of your oversight framework?

The UK ONR indicated that they adopt a targeted and proportionate regulatory model when considering the adequacy of a technology that is second-of-a-kind or beyond. The ONR would focus its assessment on any unique site-specific features of the design and establishing an adequate organisational capability to safely oversee/deliver the work. France also noted that ASN can, after due consideration of past experiences with the same design, reduce its oversight on activities with which they have had a positive experience. This could be applicable for proven technologies or N^{th}-of-a-Kind (NOAK) reactors.

Finland indicated that there is no formal explicit method for adapting oversight beyond first-of-a-kind deployment. However, in principle, should a licensee apply to construct a plant that is similar to an existing plant, only the changes in the design would have to be reviewed. Canada and the United States had similar responses in that the respective nuclear regulatory bodies have not yet determined if the oversight framework will be adapted for regulating a fleet deployment of new technology such as SMRs. The oversight framework is not adjusted for a fleet. However, the oversight framework is adjusted for the risk profile of the design and the safety performance of the plants. In the United States, during a new nuclear power plant construction, the staff identified attributes associated with the reactor oversight process and the AP1000 design that informed revisions to the baseline inspection procedures.

In general, most respondents indicated that through application of the graded approach, regulatory oversight is proportional to the safety designations of structures, systems and components (SSC).

2.3.2. Question 3.2

Where a reference facility exists in your country or another, how do you ensure use-of-experience is disseminated and acted upon; including those from other country's regulatory body experience with construction, commissioning and operation?

Respondents cited various mechanisms to facilitate the dissemination of information and use-of-experience from other countries:

- Inspector exchange programmes.
- Multilateral or bilateral exchanges of information regarding design reviews of advanced reactor/SMR designs.
- Leveraging results of testing and commissioning of reference designs to minimise duplication of efforts where testing has previously been performed.
- Reviews of applicable international incident reports to consider lessons learnt.
- Expectations for applicants to describe reference plants including design differences and descriptions of the lessons learnt from previous projects.

France additionally noted that, for nuclear pressure equipment, the regulatory framework requires that the licensee make operational lessons learnt available for the nuclear plant equipment manufacturer.

2.3.3. Question 3.3

Do you have a policy or practice for conducting audits and inspections directly on the supply chain organisations and on-site construction activities independent of the licensee? What criteria do you apply to prioritise certain aspects of the facility during construction (i.e. risk-informed inspection)?

The majority of respondents have policies or practices for conducting audits or inspections on the supply chain organisations, either directly or indirectly; however, in practice, the methods vary. Typically, respondents implemented one or more of the categories described below, where they:

1. Have regulations, policies, or practices that allow for the regulator to directly inspect supply chain organisations (designers and manufacturers), with the regulator taking advantage of this for safety-significant items and services or where

a supplier's activities justify review (France, Hungary, Poland, the United Kingdom [for the UK-based supply chain], the United States*),

2. Have a policy or practice that allows for the regulator to directly inspect supply chain organisations, though the regulator is performing the audit or inspection as an observer or in tandem with an audit or inspection being performed by the licensee (Finland, the United Kingdom [for non-UK based supply chain]), or,
3. Indirectly audit or inspect supply chain organisations via regulatory oversight of the licensee's oversight measures (Canada, the Slovak Republic, Slovenia, the United Kingdom [for both the UK and non-UK supply chains]).

Regardless of the method for auditing or inspecting supply chain organisations, the criteria for performing audits or inspections are based on graded or risk-informed approaches, which take into account the amount of experience of a supply chain organisation or the level of risk involved in an activity being performed by the supply chain organisation.

* See annex for more detailed response with criteria

2.3.4. Question 3.4

What arrangements exist if you identify conditions adverse to quality/safety-product or activity, such as when conducting audits and inspections, or made aware by a whistle blower, directly on material, major component suppliers and site construction activities independent of the licensee?

All respondents make use of a graded approach for enforcement in the event that conditions adverse to quality/safety are noted. Regulatory staff assess the significance of the non-compliance and determine the appropriate enforcement action from a list of available actions. The list of available actions is similar among all respondents, always starting with discussion or notifications to licensees and progressing to legal actions depending on the severity of the highlighted condition(s).

Typically, the arrangements highlighted by respondents are as follows:

1. Independent assessment by regulatory staff.
2. Written notices/discussion to informing licensee.
3. Increased regulatory scrutiny.
4. Licensing actions.
5. Monetary or financial penalties.
6. Revocation of a licence.
7. Legal prosecution.

Several respondents have set up applications that allow for anonymous whistle-blowers to identify conditions or concerns adverse to quality/safety to the regulator.

2.3.5. Question 3.5

What arrangements exist to ensure that the regulatory body will have the right of access to suppliers and sub-suppliers (including off-site activities)?

Respondents highlight that regulators have a legal right to enter and perform inspections of suppliers and sub-suppliers, either announced or unannounced. In practice, most regulators expect licensees to provide the regulator with access to suppliers and sub-suppliers.

It was noted that, in the Slovak Republic and the United Kingdom, the regulatory bodies do not have a legal right to enter suppliers' premises (either announced or unannounced) as they do for licensed sites. They have the right to inspect the quality of items which will be used on a licensed site and ultimately can stop items being brought onto a licensed site.

2.3.6. Question 3.6

What authority/experience do you have to audit and inspect foreign material and major component suppliers?

Many respondents noted they acted as observers of vendor audits and inspections (for example, observing factory acceptance tests), rather than conducting direct inspections. Here, Hungary (HAEA) noted that the main issues identified so far include:

- project-specific managements system documentation not being available or not sufficiently developed by the supplier;
- suppliers' knowledge of Hungarian regulatory requirements being insufficient or non-existent;
- document management procedures not being fully established (e.g. how, in what format, and through what channels the sub-subcontractor should hand over the documents);
- information transfer from the higher tiers to the lower tiers being inadequate;
- the "chain of command" not always being clear.

Countries with more direct involvement varied in approach. Finland (STUK) specified that direct inspections of the main designers are common, though supplier inspections are less common. France (ASN) indicated that the ASN inspects the activities of the manufacturer that are related to design and manufacturing at their own premises or in their subcontractors' premises, in France and abroad. In the case of an inspection conducted at a subcontractor's premises abroad, the nuclear plant equipment manufacturer makes prior arrangements with the subcontractor so that the inspection can be carried out. The United States (NRC) indicated that the imposition of legal requirements (10 CFR Part 21 [US NRC, 2024]) in the procurement documents and the existence of an office in the United States by the foreign supplier allows the NRC access to perform vendor inspections outside the United States. The United Kingdom (ONR) indicated that vendor inspections are performed and, where the supplier is outside of the United Kingdom, ONR can conduct inspections facilitated by/with the licensee (using their contractual access) or could collaborate with other VICWG members through witnessed, joint or multinational (collaborative) inspections using existing MDEP VICWG collaboration protocols. However, it should be noted that ONR does not have the authority to inspect suppliers outside of the United Kingdom directly, unlike some other regulators associated with product certification arrangements.

2.3.7. Question 3.7

Do you have the capability (authority/experience) to assess construction organisation's management systems, or do you rely on either domestic or foreign expertise?

Most regulators have the capability to assess construction organisations' management systems. Some note that if specific expertise is required, there are options to engage with domestic or international counterparts. It was noted that for the regulatory oversight of the construction of nuclear power plants, the inspection scope has included an assessment of

key management infrastructure elements, including quality assurance, supply chain, construction deviations and resolution, and risk management/control.

2.3.8. Question 3.8

What regulatory expectations do you have around the licensee's reconciliation considerations for long lead items ordered prior to the finalisation of design requirements?

Responses are split: either there are regulatory expectations around a licensee's reconciliation considerations for long lead items ordered prior to finalisation of design requirements or there are none.

For those regulators that do have regulatory expectations related to long lead items, the approaches are similar. In general, licensees must evaluate, reconcile and report to the regulator on any differences between original purchasing requirements, licence-to-construct design basis and as-built items associated with long lead items.

In Canada, specific to pressure-boundary materials and components, CSA N285.0-12 (CSA Group, 2012), the general requirements for pressure-retaining systems and components in CANDU nuclear power plants/material standards for reactor components for CANDU nuclear power plants, sets out information regarding specific items that have long lead times that require them to be ordered before the issuance of the construction licence. The licensee must obtain acceptance from the regulatory authority for the use of an earlier code (ASME) effective date. The licensee must submit a comparison of the differences in the applicable parts under the standards of the two dates to the regulatory authority within six months of the issuance of the construction licence.

2.3.9. Question 3.9

What capability and competencies do you have for oversight of construction activities, including first-of-a-kind construction methods, and use of innovative and emerging technologies?

All regulators have the capability and competency for oversight of construction activities, including first-of-a-kind construction methods and use of innovative and emerging technologies. If a particular project requires capabilities or competencies not present, regulators:

- ensure staff competency by providing access to training for first-of-a-kind (FOAK) methods;
- interface with international counterparts to gain knowledge associated with FOAK designs; or
- supplement knowledge via specialist contractors under a technical support framework, as required.

2.3.10. *Question 3.10*

What is your practice for including regulatory hold and witness points throughout the manufacturing and construction processes?

Responses are spread across three categories:

1) Regulatory hold/witness points used during both manufacturing and construction,

2) Regulatory hold/witness points used during either manufacturing or construction, or,

3) Regulatory hold/witness points not used during manufacturing and construction.

Where regulatory hold/witness points are not used during manufacturing and construction, regulators rely on communication with a licensee, or participating in an inspection of the licensee, to verify critical attributes of safety-related SSCs in construction, installation and testing are being met.

3. Conclusions

This report focused on the results of a survey on the regulatory approach to the oversight of new nuclear power plant construction. Based on a comparison of the information provided in response to the survey, the observations listed below were made.

- The majority of respondents note that licensees make use of an EPCM or EPC model for a range of construction activities. Specific to contract delivery models, many respondents noted experience with the licensee embedding a number its own staff into an EPC contractor's organisation. Where this is the case, this does not relieve the licensee of the need to specify and oversee that work.
- Most respondents indicated that there are no specific requirements or expectations for licensees related to non-domestic material, major component supply and modular construction. That being said, most countries noted that there are safety culture and/or quality requirements that must be met by suppliers and sub-suppliers and that national construction, environmental, and occupational health and safety standards are applicable to site construction labour.
- For construction activities undertaken by contractors, most countries have requirements for the licensee to oversee and ensure (through means such as assessment, inspection, verification and evaluation activities) that contractors have adequate:
  - management systems in place;
  - procedures, processes, security requirements and training to ensure contracted personnel have relevant competencies;
  - human resources and are well prepared to perform the contracted task;
  - quality assurance and verification techniques to effectively manage the delivery of contracted work.
- Regulatory requirements regarding what competencies and activities must be retained in-house and what can be contracted externally differed greatly between respondents.
- Regardless of the differences between licensing regimes or ownership for construction and operation, respondents described requirements regarding the turnover of work from construction and operation organisations. In addition, some countries require that the future operator's organisation be directly involved in the oversight of construction activities; others recognise this as a good practice.
- Most countries identified that the regulatory oversight framework does not fundamentally change for fleet deployment beyond the first of kind; however, most respondents indicated that through application of the graded approach, regulatory oversight is proportional to SSC technology readiness and safety designation.
- Respondents identified various means to leverage international experience with respect to reactor design reviews, inspection activities at nuclear power plants and vendor inspections of supplier and sub-suppliers. Some of the means mentioned were the MDEP programme and the NEA VICWG work.

References

CSA Group (2012), CSA N285.0-12 - General requirements for pressure-retaining systems and components in CANDU nuclear power plants/Material Standards for reactor components for CANDU nuclear power plants, www.csagroup.org/fr/store/product/2422019/?srsltid=AfmBOoqNkVo2XrVgZ0RNTmS_gkJffER39_YUjjL0xHMmQqZZwtNzrEch.

ONR (2024), TAG 049 - *Technical Assessment Guides 49 - Licensee Core Safety and Intelligent Customer Capabilities*, Office for Nuclear Regulation, United Kingdom, https://onr.org.uk/publications/regulatory-guidance/regulatory-assessment-and-permissioning/technical-assessment-guides-tags/nuclear-safety-tags/technical-assessment-guides-tags-nuclear-safety-full-list/.

US NRC (2024), 10 CFR Part 21 - *Reporting of Defects and Noncompliance*, United States Nuclear Regulatory Commission, www.nrc.gov/reading-rm/doc-collections/cfr/part021/index.html.

Annex I. Country responses to survey

Delivery and contracting models

Question 1.1

In your country, which contract delivery models do applicants/licensees use or proposing? For example, engineering, procurement and construction (EPC), engineering, procurement and construction management (EPCM), bespoke, or partnerships and alliances?

Canada

Regarding the delivery models of existing licensees, current projects have different delivery models on almost identical project scopes. Of the current refurbishment and major component replacement projects, one licensee opted for a variant EPC approach to a two-company joint-venture entity with one contractor taking the lead role, and the licensee building a major worker training facility.

The other licensee chose a split-package contract model splitting the scope of work over several contracts to several entities thus taking on more risk overseeing the contracts to ensure the work is co-ordinated between contractors. With this model, one contractor provided the same type of training facility.

For new builds, projects are still in early stages with the proposed delivery models not yet known.

Finland

The current Finnish new build nuclear power plant projects Olkiluoto-3 and Fennovoima use an EPC contracting model.

The spent nuclear fuel repository project by Posiva uses a modified alliance model with nuclear specific licensee responsibility.

France

Introduction:

The French regulatory framework defines the protected interests as security, safety, public health and sanitation, nature and environment (Article L.593-1 of the Environment Code). In the answers below, the mention of "interests" always refer to these protected interests listed in Article L.593-1 of the Environment Code.

Also, in France, there is a specific regulatory framework for design, manufacturing and operation of nuclear pressure equipment, which is complementary to the regulatory framework regarding other equipment and activities important to the protection of the interests.

For the EPR of Flamanville, which is the only commercial reactor under construction in France, the licensee, EDF, leads the construction activities. This project is organised into an EPC model, granting EDF the full financial and regulatory responsibilities for the construction activities. This model fits with the French legal framework that considers the licensee as responsible for the management of the risks and inconveniences of its installation, as of the submission of an authorisation of creation file.

For the nuclear pressure equipment (NPE), the French regulation considers the NPE manufacturer as responsible for design and manufacturing activities, the licensee being responsible for providing relevant information for these activities.

EDF has decided to separate the project management, engineering activities, construction activities and licensing activities into different entities.

Hungary

The Hungarian new nuclear power plant construction project (Paks II) has a turn-key EPC model, where on the Hungarian side the licensee (Paks II Project Company) is the owner and future operator of the plant, and the main supplier/plant vendor is JSC Atomstrojexport Engineering Company. Official handover to the owner is expected at the end of the commissioning phase.

Poland

The project of construction of nuclear power plant in Poland is still in an early stage, with the proposed delivery models not yet known.

The Slovak Republic

In the Slovak Republic there is only one existing licensee. The company Slovenské Elektrárne, is a joint-stock company, where the Slovak Republic owns 34% shares and the rest is divided into ENEL and EPH. This entity is currently the licence holder for construction of Unit 3 and 4 Mochovce Nuclear Power Plant. The suspended project was restarted in 2008. It was decided to use a multi-contract model. The nuclear island was apportioned among five main contractors. For the conventional island and BOP the EPCM model was used. In 2015, the EPCM contractor left the project and the whole project was integrated into Mohovce 34 project team, which has taken a role of general contractor with the responsibility to oversee a construction project management.

New build project JESS is still in early stage and delivery model is not yet known.

Slovenia

Regarding implementation of safety upgrades, design modifications or implementation of other major services (i.e. in-service inspections, SG chemical cleaning…) the supplier is chosen based on detailed technical specification, prepared by engineering department, and public international tender. Supplier is chosen from the approved suppliers list (ASL). Supplier usually uses different subcontractors.

In recent upgrades (new bunker buildings with alternative equipment and also construction of forthcoming Spent Fuel Dry Storage, SFDS) the Krško Nuclear Power Plant uses the EPCM model with intensive involvement of nuclear power plant staff. Sometimes only nuclear power plant representatives are involved in management (classic EPCM) but sometimes staff from both companies work together as a project team. But still in almost all projects the contractor is more or less responsible for the management of the project.

The United Kingdom

All the questions below are answered from a major new build perspective:

There are two active (post nuclear site licence application) new build projects – Hinkley Point C (HPC) and Sizewell C (SZC), currently in the United Kingdom.

HPC commence J0 pour (nuclear island concrete) in late 2018. The project has established a Mechanical, Electrical & HVAC (MEH) Alliance to deliver the installation of equipment on site (excluded NSSS), with some bulk procurement of supplies. This alliance has been

in the early stages of development for the last two years, but will significantly increase from the end of 2021, when bulk installation commences.

The MEH Alliance is anticipated to be around 5 000 front line delivery staff from four major partners (trades and semi-skilled). The HPC Project has established trade testing centres for key skills to ensure competency (weld/electrical/mechanical). The need for these centres was identified earlier in the project when contract staff started to conduct work on site.

SZC project is currently scheduling J0 in 2026. The project is exploring various partnering/alliance models for the delivery of the project, including the Australian Government - Project Alliancing Model. It is too early to confirm their approach.

It is worth noting that the now cancelled Horizon Nuclear Power Project that was proposing to build two advanced boiling water reactors at Wylfa on Anglesey in Wales had originally proposed an EPC delivery model having set up an organisation called Mentor Newydd as the delivery contractor. As the project progressed the significant risks faced by Mentor Newydd in delivering the project led to high costs and the model was abandoned in favour of a project management partner approach where a joint delivery office was to be set up comprising of both the PMC and Horizon staff working in direct collaboration to deliver the project. In this model the licensee and the PMC would work in partnership to deliver the project with all other contractors (including the responsible designer) under their control and oversight. Separately, the licensee would also have a further level of independent oversight focused specifically on nuclear safety and compliance.

A further example in the United Kingdom is in relation to delivery of large projects at Sellafield where a collaborative partnership model is employed. In this model four lot partners (contractors) operate under a specific contract under an aligned incentive agreement that covers all partners. Sellafield as the licensee has two roles in this model; firstly, as an intelligent client and secondly as a fifth partner with licensee staff embedded into the aligned delivery teams working alongside the supply chain resources to deliver major projects. This arrangement provides for the licensee to maintain both an intelligent client and a project delivery capability.

The United States

The NRC is not involved in the licensee's contract delivery models.

The NRC notes that for the AP1000 construction projects, the licensee and the designer (Westinghouse) entered into an EPC contract. During construction, the contract was renegotiated so the licensee had access to the Westinghouse's supply chain. Additionally, for these projects, construction management is being conducted by a third organisation.

Question 1.2

Given an increasingly global supply chain, what regulatory requirements and expectations do you have regarding applicants/licensees or the delivery organisation's extensive reliance on foreign:

a) material and major component supply, and modular construction;

b) site construction labour with different working languages, cultural norms and practices;

c) application of home country construction, environmental, and occupational health and safety standards and working practices different from your country.

Canada

The CNSC does not have such regulatory requirements and expectations; the decision rests with the applicant/licensee:

a) For material and major component supply, and modular construction, this is usually determined through contractual local supply requirements where possible.

b) For site construction labour with different working languages, cultural norms and practices, this not usually an issue with Canada being geographically located in North America and having a stable and experienced nuclear construction workforce.

c) For application of home country construction, environmental, and occupational health and safety standards and working practices different from Canada, again this not usually an issue as Canada does not have a history of importing foreign labour for nuclear construction projects. Should the situation change regulatory document REGDOC-2.8.1, conventional health and safety, sets out information regarding conventional health and safety (CHS) and the implementation and maintenance of a CHS programme.

Legislative authority over CHS is divided among federal, provincial and territorial governments. It is the responsibility of applicants and licensees to be able to identify and comply with all applicable legislation. The following are some of the more significant Canadian regulatory framework and related standards for CHS and OHS:

- Federal acts and regulations
- Canada Labour Code, Part II
- Canada Occupational Health and Safety Regulations
- Provincial and territorial acts and regulations (who have or are considering deploying nuclear power stations)
- Alberta: Occupational Health and Safety Act/Occupational Health and Safety Regulation
- Saskatchewan: The Occupational Health and Safety Regulations, 1996 / The Mines Regulations, 2003, Saskatchewan Uranium Mines and Mills Exclusion Regulations
- Manitoba: Manitoba Workplace Safety and Health Act and Regulation, 2014

- Ontario: Occupational Health and Safety Act, R.S.O. 1990, c. O.1 / Workplace Safety and Insurance Act, 1997, S.O. 1997, c. 16, Sched. A
- New Brunswick: Occupational Health and Safety Act, S.N.B. 1983, c. O-0.2

Finland

No requirements exist specifically regarding foreign vendors or suppliers.

However, the licensee is responsible for safety and that responsibility includes any effect the above mentioned could have on safety. The licensee is required to do risk management during the construction and the mentioned issue should be identified as potential risks if applicable. The licensee should also perform other adequate risk management actions as necessary.

France

a) Licensee can rely on foreign companies for material and major components supply and modular construction, except for some particular activities (see 2.4). However, in order to be able to control the realisation of activities important to the interests' protection, Article R.593-10 of the Environment Code requires from the licensee to limit, as much as possible, the number of levels of subcontracting. Also, the regulatory requirements regarding oversight are applicable (see 2.5).

b) There is no requirement about different working languages, cultural norms and practices. However, Article 2.3.2 of the Order of the 7 February 2012 requires from the licensee to make sure that its policy regarding the protection of the interests is, not only shared with its subcontractors, but also known, understood and implemented by them.

c) In the labour regulation, there are several requirements regarding the translation of key documents regarding the security of workers.

d) Regardless of where they have been realised, activities important to the interests' protection must meet the requirements detailed in the Order of the 7 February 2012. In particular, these activities must be realised by staffs with adequate skills, and undergo technical controls and traceability.

Hungary

According to the Hungarian regulatory requirements, in Annex 2 to Govt. Decree No. 118/2011 (VII. 11.) are the generic management system requirements, and in Annex 9 are the specific management system requirements for the design, and construction phases. The generic and specific requirements are presented for supply chain management, both in terms of what is expected from the licensee, as well as entities of the supply chain.

a) Annex 9 to Govt. Decree No. 118/2011 (VII. 11.) 9.3.7.0100.-0500 describe the using of standards the hierarchical system of standards in the design, manufacturing, construction, assembly, testing, and inspection of systems and system components. It is prioritising the using of national standards. The list of standards recommended by the nuclear safety authority for use in various fields of expertise shall be included in a guideline.

b) This is not regulated in detail. But requirements for safety culture aspect are in Section 2.2.2. of Annex 2 to Govt. Decree No. 118/2011.

c) In Hungary it is necessary to fulfil and apply the Hungarian regulatory framework and related standards on construction, environmental, and occupational health and

safety standards. It is the responsibility of applicants and licensees to be able to identify and comply with all applicable legislation.

The following are some of the more significant Hungarian regulatory framework and related standards:

1. 205 of the Act I of 2012 on the Labour Code

2. Govt. decree on 487/2015. (XII. 30.) on the protection against ionising radiation and the corresponding licensing, notification and inspection system (hereinafter referred to as Radiation Protection decree).

Poland

The PAA does not have such regulatory requirements and expectations. Existing regulations are based on IAEA requirements. Nevertheless, GSR Part-2 requirements are not introduced yet.

a) The decision rests with the applicant/licensee.

b) Poland has experience with construction labour from different working languages, cultural norms and practices. The applicant/licensee is responsible for ensuring that the delivery organisations maintain adequate human resources to fulfil the legal rights.

c) The applicant can use nuclear technology standards derived from the country of origin of nuclear technology supplier when domestic standards are not against them. Regarding environmental and occupational health and safety standards and working practices, domestic law must be fulfilled.

The Slovak Republic

ÚJD SR has no regulatory requirements and expectations in the current legislative framework.

a) There are no requirements or expectations regarding material and major component supply.

b) Site construction labour with different working languages, cultural norms and practices was recognised as an issue in the Mochovce 34 project. Currently any regulatory requirements do not exist.

c) For application of home country construction, environmental, and occupational health and safety standards and working practices different from the Slovak Republic is in competence other authorities as National Labour Inspectorate, Public health authority and Ministry of Environment.

Slovenia

During the construction of our nuclear power plant it was decided to use the standards of the origin of nuclear power plant project supplier. The supplier was Westinghouse, so consequently the US standards and also NRC requirements were used. During the time we have established our own regulation that is still dependent on the NRC regulation. For the recent upgrades the nuclear power plant uses US standards for material and major components, as well. The modular construction has not been used so far.

Slovenia has very strict regulations regarding working conditions and all construction companies should be in line with this regulation. The working language should be English since the nuclear power plant personnel speak English fluently and using multiple languages can create problems. But in many cases the people from the construction

company do not speak English proficiently and do not speak any Slovenian. Sometimes the pressure for low construction costs leads to a very transient workforce with little or no knowledge of the importance of nuclear safety. That is why cultural norms and practices are important. Nuclear power plants put a lot of effort into training and also indoctrination of the suppliers' workers, but many times they have very low achievements, because their linguistic aptitude is not at the same level of the fluent workforce already in place. Workers need to be able to understand the importance of their jobs.

For the above-mentioned standards there are very strict rules in Slovenia and only Slovenian regulation (laws, rules and standards) could be used. The construction company should provide the evidence that all their "standards" are in line with Slovenian requirements.

The United Kingdom

ONR places the onus on the licensee/aspirant licensee to specify their requirements (including safety case considerations) for material and major components on the supply chain within their contracts. Then oversee and manage the contracts through their intelligent customer capability (see TAG 049 & 077).

ONR expect the licensee to establish adequate arrangements for any activities that could impact on safety. ONR does not prescribe specific arrangements; rather, it operates an outcome focused objective setting regime with expectations set out in its Safety Assessment Principles (SAPs) and its supporting Technical Assessment Guides (TAGs).

With regard to cultural norms and languages, all licensees/aspirant licensees are required to implement adequate arrangements on site to manage potential implication of various cultural and language challenges. This is achieved through site inductions (HPCs induction programme is available in multiple languages), English speaking supervisors and employee support programmes. Future detail on ONR expectations in TIG 070, CDM regs and IAEA guidance.

ONR is accountable for regulating the nuclear and conventional safety on new build sites, covering the activities on the nuclear licenced site and conventional safety on the broader construction site. ONR are not accountable for environmental regulation. Prior to the granting of a nuclear site licence conventional safety for a construction site where site preparation and pre-construction activities are undertaken then these activities are regulated by the Health and Safety Executive which then transfer to ONR at NSL Grant.

All currently identified sites for new nuclear power plants in the United Kingdom are listed in the UK Nuclear Policy Statement and all are adjacent to existing nuclear facilities. For this reason, prior to NSL Grant a Construction Site Security Plan is required which is regulated by ONR Security. At NSL Grant a Nuclear Site Security Plan is then required.

The United States

The NRC does not regulate as to where a licensee can purchase safety-related structures, systems and components (SSCs). The NRC regulations require licensees to impose Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants" and 10 CFR Part 21 "Reporting of Defects and Noncompliances" in all safety-related procurements whether those procurements are domestic or international. As specified in Criterion VII of Appendix B to 10 CFR Part 50, licensees are required to ensure that measures are established to assure that purchased material, equipment and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or

subcontractor source, and examination of products upon delivery. Documentary evidence that material and equipment conform to the procurement requirements shall be available at the nuclear power plant or fuel reprocessing plant site prior to installation or use of such material and equipment. This documentary evidence shall be retained at the nuclear power plant or fuel reprocessing plant site and shall be sufficient to identify the specific requirements, such as codes, standards or specifications, met by the purchased material and equipment. The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services.

Licensee oversight framework

Question 2.1

What regulatory expectations do you have regarding the licensee's evaluation of the contracted entity to ensure adequate capability to construct the facility?

Canada:

Regulatory document REGDOC-2.3.1, Construction and commissioning programmes, sets out information regarding licensee activities to be accomplished through a construction readiness review, where in preparation for construction, the applicant/licensee shall ensure the contractors are ready to proceed with construction by verifying:

- management systems are in place;
- adequate planning has been conducted;
- procedures and training are complete;
- construction hazards are adequately evaluated and control measures identified.

Additionally, Section 4.1.3 of REGDOC-1.1.2, *Licence to Construct a Reactor Facility version 2* includes organisational arrangements that the applicant should evaluate and confirm of the EPC, EPCM, or PMC+C contractors to ensure that they possess the adequate capability and capacity to carry out activities with nuclear safety significance to specification.

* Management system: Focus is on aspects of the management system, organisation and staffing for the execution of the construction project. It is expected key construction positions are established, related organisational roles and responsibilities are clear, and p+K5roject staff are sufficiently staffed to oversee construction activities. Additionally, management systems should be in place to monitor performance against the project baseline.

Finland

There are no specific requirements for the evaluation of contracted entity. However, requirements regarding supply chain oversight apply here, too. The requirements are described in Regulatory Guide YVL A.3 "Leadership and management for safety".

For example, there shall be appropriate procedures for supplier assessment and selection. Furthermore, the licensee shall have procedures and competent personnel to assess, approve, control and guide suppliers of safety-significant products and services. The actions to oversee suppliers shall be planned.

France

According to Article L.593-6-1 of the Environment Code, the licensee must oversight activities important to the interests' protection. In particular, the licensee has to make sure that the subcontractors have got the technical abilities to realise these activities. Article R.593-13 of the Environment Code details this idea, stipulating that the licensee shall, prior to the choice of the subcontractors, make sure that the subcontractors possess the adequate technical capacities to realise the activities and to deal with the associated risks.

In the case of NPE, this approach is reinforced with similar regulatory expectations applied directly to the NPE manufacturer (through the assessment of their quality management system) and to their subcontractors.

Moreover, Article 2.5.5 of the Order of the 7 February requires from the licensee to make sure that its subcontractors take adequate provisions regarding training and skills management.

Hungary

Detailed regulatory requirements are described in the so-called Nuclear Safety Code (NSC), in which Vol. 2. has generic management system requirements, and Vol. 9. has specific (additional) management system requirements for the design, and construction phases. In these NSC Volumes generic and specific requirements are presented for supply chain management, both in terms of what is expected from the licensee, as well as entities of the supply chain. The overarching fundamental principle for supply chain management is that the licensee has to have sufficient in-house capabilities to oversee and control the supply chain (also known as principle of "intelligent customer capability").

Concerning the supply chain management, the primary and ultimate responsibility for safety is on the licensee, so it is their responsibility to make sure members of the supply chain are adequate and well-prepared for their task, and they also have to constantly monitor their activities from start to finish. In line with this, the regulatory body (with one or two specific exemptions) is in an observer role, but it has the necessary credential to do supplier inspections and also has the right to intervene (e.g. stop certain activities) if needed. It is also expected that specific procedures have to be established and documented within the licensees' management system for supply chain management.

The specific implementation in the Paks II project is that before a supplier starts its activities, the licensee has to perform a so-called supplier nuclear qualification (SNQ) procedure. Although this procedure is performed by the licensee, the regulatory body is informed beforehand, and it participates as an observer in the procedure. The SNQ procedure is contract specific, meaning that if the same supplier is used for another activity for a different contract, the SNQ procedure has to be executed for that other contract as well. After a successful SNQ procedure the supplier receives a certificate, which has a time limited validity (usually 2-3 years). Follow-up procedures have to be performed regularly within the validity period of the supplier certification.

In line with principle of "intelligent customer capability", it is also expected, that the licensee should have procedures in place to handle problems concerning the supply chain; for instance, they are expected to do a risk assessment, and also action plans for losing a major supplier.

Poland

The Regulator expects the licensee to submit during the licensing process (licence for construction of nuclear facility):

- a declaration that the applicant and other participants of the facility's construction are performing the works that are essential for ensuring nuclear safety and radiological protection, and employ an appropriate number of employees with qualifications required for the construction phase of a nuclear facility;
- a schedule for training and recruiting crucial staff;
- emergency procedures;
- an integrated management system.

The Slovak Republic

General binding regulations 430/2011 on requirements for nuclear safety and 431/2011 on Quality Management Systems (QMS) define requirements regarding licensee obligation in all stages of nuclear facility. The construction of nuclear installations shall be guided by the relevant stage programmes for quality assurance and safety rules approved by the regulator. The licensee shall evaluate the contractors:

In accordance with the requirements EN ISO 9001:2008 and the directive SE/SM-600 the licensee performs, at regular intervals, the assessment of contractors. The assessment concerns main contractors with complex contracts and important service contractors that are selected for the assessment according to conditions given in the *Methodical Guide Vendor Rating Process.*

Slovenia

In accordance to the *Rules on Radiation and Nuclear Safety Factors* the investor or facility operator of a radiation or nuclear facility shall:

- Within its management system, identify the control of processes, or work performed within a process, contracted to external organisations. The investor or facility operator shall retain the overall responsibility for any works executed by contractors.
- Request that its contractors establish, document and implement an appropriate management system.
- Select contractors and suppliers according to criteria set in advance.
- Evaluate the performance of contractors and suppliers.
- Develop and specify purchasing requirements and document them. A supplier shall furnish the investor or facility operator with documentary evidence of compliance with the requirements before the product is used.
- When ordering safety-related SSCs, request that manufacturers or suppliers provide the means for supervision by its personnel or inspection by the SNSA, including access to the manufacturer’s or supplier’s premises for inspection.
- Through inspection, verification and evaluation, confirm that activities and their products meet the specified requirements and ensure that products perform satisfactorily in service.

The United Kingdom

ONR expect a licensee/aspirant licensee to have adequate human resources (LC 36), with the appropriate competency (LC 10 & 12) to ensure safety on the licensed site or through the supply chain (Health and Safety at Work etc Act 1974 [HSAW] Section 6).

As discussed earlier the licensee has an intelligent customer role for the work conducted on its behalf. An example is TAG 049 principle 5 – "The licensee should ensure that it only provides contracts for work with nuclear safety significance to contractors with suitable competence, safety standards, management systems, culture and resources."

ONR would also expect the licensee to have developed and implemented adequate quality management arrangements/system to effectively manage the safe delivery of the work (LC 17). ONR expectations in regard to supply chain oversight and assurance arrangements are laid out in TAG 77.

The United States

Regulatory expectations are established in 10 CFR 50, Annex B, Criterion VII, "control of purchased material, equipment, and services", which requires that "measures shall be established to assure that purchased material, equipment and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. Documentary evidence that material and equipment conform to the procurement requirements shall be available at the nuclear power plant or fuel reprocessing plant site prior to installation or use of such material and equipment. This documentary evidence shall be retained at the nuclear power plant or fuel reprocessing plant site and shall be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased material and equipment. The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services."

Question 2.2

Please describe how the transfer and ownership of the facility from the construction organisation to the operation organisation is done in your country.

Canada:

Regulatory document REGDOC-2.3.1, construction and commissioning programmes, sets out information regarding turnover of work to operations/commissioning:

Process and procedures established to control and co-ordinate the turnover of work should include the following activities:

- review of the facility configuration information relating to SSCs, and areas by the party;
- turning over the work and the party receiving it for completeness and accuracy;
- performance of tests to ensure the SSCs have been manufactured, constructed and installed according to design specifications;
- identification and assessment of any remaining non-conformities or incomplete components, to ensure there is no safety implication during commissioning activities;
- development of inaugural or baseline inspection data for systems or components for comparative purposes for in-service inspection agreement upon, planning and scheduling of any outstanding work identification of termination points of the boundaries of turned over SSCs (or parts thereof) in turnover documentation with associated required configuration;

- inspection of turned over components and associated records and documents;
- assessment of compatibility of information and communication technology systems when turning over electronic documents and records;
- documentation of the turnover of responsibilities;
- establishment and turnover of approved as-built plans together with adequate and precise plant configuration details;
- marking and tagging of all SSCs turned over.

Finland

Regulatory documents YVL A.1, A.5, set out the licensee responsibility. From the fuel loading, the plant is an operating unit, when the licensee is responsible for the operation of nuclear power plants. For example, in OL3, before the fuel loading, systems are transferred from the commissioning organisation to the operation organisation.

Transfer process includes the system readiness, which is verified by commissioning inspection for the safety-significant systems or components. In the commissioning inspection, the test run of the system is conducted in compliance with the test run plan. It is verified from the test run records and by witnessing the test run that:

- the licensee has acceptably completed the licensee's commissioning inspection of electrical and I&C equipment;
- the test run has been completed in a scope complying with the test run plan and the results are acceptable;
- there are no non-conformities preventing the commencement of operation.

Operation and commissioning organisation are integrated with licensee and plant supplier. During the nuclear commissioning phase, the plant supplier is responsible for commission, but the licensee is responsible for the operation of nuclear power plants. After the commissioning phase comes the provisional take over (PTO), when the licensee takes over the plant.

France

For the EPR of Flamanville, EDF is in charge of both construction/commissioning and operation activities. In this case, from a regulatory point of view, the transfer and ownership of the facility does not raise any particular concern. EDF's entity in charge of construction/commissioning activities transfers the installation to the entity in charge of its operation by parts. EDF defines in its internal procedures how these transfers are conducted.

However, since commissioning and operating activities are realised by different teams inside EDF, ASN is attentive to the preparedness and the installation's appropriation of the personnel that will be in charge of operating activities. The state of the installation and the documentary database must be consistent. In particular, ASN is attentive to the traceability of the management of deviations, modifications, and events that have occurred during construction and commissioning phases.

Hungary

The licensee (Paks II Project Company) is the owner, the construction organisation and the future operator of the new build plant.

The Act CXVI of 1996 on Atomic Energy Section 7 (1) Preliminary consent in principle of the government shall be required for the acquisition of ownership of a nuclear facility and radioactive waste repository or transferring the right of its use by any right.

Annex 1 to Govt. Decree No. 118/2011 (VII. 11.) 1.2.10.0100. The announcement of the intention to replace the licence holder shall be considered a new licence application, and a new licensing procedure shall be conducted. In the cases regulated in Section 7(1) of the Atomic Act, the original copy of the government's preliminary consent in principle shall be attached to the application. In the case of documents named as part of the application in the regulation but not concerned by the change in the person of the licensee, it is enough to refer – ensuring retrieval – to the previous procedure within the frame of which the documentation was submitted to the nuclear safety authority. The declaration of the current licensee stating that the current licensee agrees with the person of the new licensee and that after issuing the new licence, the current licensee does not wish to remain licence holder shall be attached to the application.

1.2.10.0200. In the procedure, the nuclear safety authority shall examine the existence of technical, technological, material and human resources necessary for the safe performance of at least the activity specified in the licence.

The transfer from the construction phase to the operating phase is divided into two licensing processes, the commissioning and operating licence. The requirements of these two processes are described in Annex 1 to Govt. Decree No. 118/2011 (VII. 11.).

Poland

Transfer and ownership of the facility from the construction organisation to the operation organisation according to Atomic Law art 39a. happen within two steps (in Poland there are separate licences for construction, operation and commissioning), phases:

- after construction time, entity can apply for commissioning licence;
- when commissioning is finished successfully, entity can apply for operation licence.

The Slovak Republic

The Atomic Act sets in Section 10 Obligation of the licensee duty of the licensee to perform a post assembly conformity inspection before the systems are turned over to non-active commissioning tests. After successful tests by the construction organisation the technological systems and civil structures are handed over to the operational organisation. In our case the construction organisation is the only other entity in the licence holder enterprise.

Process and procedures established in the turnover process include the following activities:

- turnover package scope definition (TPSD);
- system turnover package (STP);
- list of boundary points;
- planned incomplete items and temporaries.

The handover of the construction site is set by the Building Act 50/1976 and agreed contractual terms with the contractor.

Slovenia

This will be valid only for the new power plant. Therefore, we have no experience with this.

The United Kingdom

ONR grant a single licence against a corporate body to conduct a prescribed set of activities on a specific site, this covers the full life cycle, which includes construction, commissioning, operations and decommissioning. (NIA 65). Once an NSL is granted, ONR regulates the licensee via a permissioning regime. ONR can specify regulatory hold points and undertake proportionate assessments and inspections as part of permissioning to allow the licensee to proceed to the next project stage.

ONR would expect the licensee to have sufficient knowledge across all the phases of the project life cycle and effectively manage the transition between these phases.

ONR would routinely monitor the effectiveness of the licensee's management arrangements in maintaining an adequate level of control.

The United States

For the AP1 000 new construction project at Vogtle 3 and 4, the construction and operation organisations are part of the same parent company (southern nuclear). The NRC expects that as both units' complete construction, start-up and power ascension testing, the construction organisation will be phased out and merged with the operations organisation.

Question 2.3

What regulatory expectations exist for the transfer and ownership of the facility from the construction organisation to the operation organisation?

Canada

Refer to the response for 2.2.

Finland

YVL Guide A.5 requirement 328 states that the licensee organisation shall have adequate human resources and competence for the facility's commissioning and operation well in advance of the start of commissioning so that the persons can familiarise themselves with and become experienced in the nuclear facility's operation during the project.

Ownership of the main control room activities are expected to be taken by the licensee prior to fuel loading. For example, all operations of plant systems and components should be done under the command of the licensee's shift supervisor and operators.

France

From a regulatory point of view, the organisation that carries the responsibility is the licensee. If the construction activities are realised by a subcontractor, the licensee must oversight this subcontractor as detailed in response 2.5.

Hungary

See the answer to question 2.2.

Poland

The regulator expects that the licensees, who are responsible for construction, will apply for commissioning and operation licences together with necessary documentation confirming that all tests, limits and others legal and licence conditions are met. Specific regulations exist that determine what documentation must be submitted for each stage of plant life.

The Slovak Republic

Refer to the response for 2.2.

Slovenia

This will be valid only for the new power plant. Therefore, we have no experience with this.

The United Kingdom

Refer to the response for 2.2.

The United States

The NRC issued a combined licence (COL) under 10 CFR Part 52 for the AP1 000 new construction project at Vogtle 3 and 4. The COL enables the licensee to construct and operate a nuclear power plant once construction is complete. The COL Annex C includes Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC). The completion and verification of ITAAC provides the NRC reasonable assurance that the constructed facility conforms to the AP1 000 certified design. Upon successful completion of the ITAAC:

- 10 CFR 52.99(c)(4) requires the licensee to inform the NRC that all the ITAAC have been completed.
- When the NRC verifies that all ITAAC acceptance criteria are met, it will make a finding under 10 CFR 52.103(g) that all the acceptance criteria are met.
- Following the NRC's 52.103(g) finding, the licensee is authorised to load fuel and start plant operations in accordance with the conditions of their COL, including Annex A (Technical Specifications).

(See Item 2.2)

Question 2.4

Does your country have any regulatory requirements and expectations on licensees for competencies and activities they must retain in-house and not contract externally?

Canada

Regulatory document REGDOC-2.3.1, Conduct of Licensed Activities: Construction and Commissioning Programmes, sets out information regarding the licensee having the primary responsibility for safety and security of all construction activities, including work carried out on its behalf by contractors. The licensee shall also have within its organisation the knowledge, expertise and resources to maintain control and oversight of safety at all times.

Regulatory document REGDOC-2.3.1, further sets out information regarding how the licensee should have the capability to understand the nuclear safety significance of any purchased expertise or equipment, specify requirements, supervise the work, and technically review the output before, during and after implementation. This is known as the intelligent customer capability.

Contractors at all levels in the supply chain should expect to be audited on a regular basis as part of contractual arrangements. Contractors could also be visited by the CNSC as part of regulatory oversight, particularly if the equipment they are manufacturing has high nuclear safety significance.

Finland

There are no regulatory requirements on what competencies and activities must be retained in-house, apart from the requirement that reactor operators must be directly employed by the licensee.

YVL Guide "Leadership and management for safety" A.3 requirement 505. states the general requirement that: "The management shall define which competences and resources shall be found inside the organisation and which ones can be outsourced. The organisation shall have adequate expertise and clear procedures for the definition and management of outsourced services as well as for the assessment of activities and outcomes."

Additionally, A.3 requirement 507 states that "The organisation's structure of the nuclear facility, tasks, the number of necessary personnel, qualification requirements, and recruitment shall be planned already during the facility's design stage".

Requirement 508 defines that "the management system shall include procedures to ensure that the personnel have the adequate individual competence and qualifications necessary in the tasks specified for them and that the personnel understand the safety implications of their work."

France

In compliance with Article L.593-6-1 of the Environment Code, the reliance on subcontractors for the realisation of some activities that are particularly important to the interests' protection can be limited or regulated by public powers. Article R.593-9 of the Environment Code specify that the licensee must keep internally the capacity to operate its installation and to master the activities that present particular risks or inconveniences for these interests.

Also, as explained in, Article R.593-10 of the Environment Code requires from the licensee to limit, as much as possible, the number of levels of subcontracting. In particular, from commissioning to decommissioning, the activities important to the protection of the interests cannot be realised by a subcontractor of more than two levels of subcontracting inside the perimeter of the installation without advising ASN before (see R.593-10 and R.593-12 of the Environment Code).

ASN provides guidance regarding these articles in its guide n° 30 about policy regarding risk and inconveniences' management and integrated management system.

Hungary

The requirements are in the Govt. Decree 118/2011 (VII. 11.) on the nuclear safety requirements of nuclear facilities and on related regulatory activities:

1. The organisation of the licensee shall be transparent, and shall have clearly determined and described assignment of tasks, resources, collaborative relationships and scopes of responsibility.
2. The top management of the licensee shall have full liability for the availability of the necessary technical support in each area associated with nuclear safety by either its own employees or suppliers throughout the lifetime of the nuclear facility.
3. The operational personnel of the nuclear facility shall meet, at all times, the requirements with regard to the number of employees, academic qualifications, professional skills, state of health, physical and psychological conditions, as set out in writing for the given task.

4. An organisational unit being independent of operation shall be established within the nuclear power plant organisation of the licensee, which is in possession of the relevant expertise, resources, information and decision-making competencies for the supervision of nuclear safety.

Annex 2 to Govt. Decree No. 118/2011 (VII. 11.) 2.4.2.0150. To maintain an adequate level of safety the top management determines what knowledge and resources are required to be developed and maintained within the organisation and which knowledge and resources are appropriate to obtain from outside.

More detailed requirements on the organisation of the licensee are listed in Section 4.4. of the Annex 4 to Govt. Decree No. 118/2011 (VII. 11.). and in Annex 9:

> *9.2.1.0400. The availability of all required competencies shall be provided by the licensee in all phases of the construction. The licensee shall ensure, in all phases of the construction, the sufficiency of its own, and its supplier's competence, particularly, the collective competence of the general designer, the manufacturers, the construction and installation organisations, and the operator.*
>
> *9.2.1.0410. The licensee shall provide human resources in appropriate number and with appropriate qualifications as well as technical resources in appropriate quantity and quality for the construction and maintenance of the management system.*
>
> *9.2.1.0420. The licensee shall regularly review the effectiveness of the management system and the existence of the required resources; it shall forecast to the extent reasonably achievable what changes are expected in the future and shall show how it prepares for their management.*
>
> *9.2.1.0500. Licensee shall have, at all times, a knowledge, experience, resource and responsibility minimum, which shall be determined with appropriate margin.*
>
> *9.2.1.0600. The functions, responsibilities, organisational structure, the staff number and qualification requirements of the organisation performing the design and construction work shall be specified and documented prior to the commencement of the given work. If the design and construction are not carried out entirely or partially by the licensee, then the relationship of the organisation doing so with the licensee shall also be determined.*

Poland

There is no regulation about any restriction of activities. The licensee has the primary responsibility for safety and security of all construction activities, including work carried out on its behalf by contractors. The licensee shall also have within its organisation the knowledge, expertise and resources to maintain control and oversight of safety at all times.

Contractors at all levels in the supply chain can be inspected by the regulatory body as part of regulatory oversight. It is a part of contractual arrangements which is obligatory for all contractors.

The Slovak Republic

Act No. 541/2004 Coll. on the Peaceful use of nuclear energy (Atomic Act) and on the amendments and supplements to some acts as amended sets obligation within the scope of the permission or of the authorisation. In the stage of construction there are no activities that should be retained in-house. However, there are the responsibilities which the licensee is responsible for during the whole lifetime of the nuclear power plant and it cannot be delegated to someone else. They are the nuclear safety and security and emergency

preparedness, including their verification. It means the licensees have the primary responsibility for safety and security of all construction activities, including work carried out by the contractors.

Section 23 sets the requirement to maintain financial resources and human resources for ensuring nuclear safety, including appropriate working conditions and the necessary engineering and technical support in all areas relating to nuclear safety.

In Section 25 the licensee is required to develop, document, introduce, maintain and review a quality management system, comply with the quality management system documentation, as well as to improve its effectiveness, and that is also when such activities are being performed by a third party for the licensee.

According to the quality assurance programme all contractors at all levels in the supply chain should expect to be audited on a regular basis as part of contractual arrangements.

ÚJD SR could take a part in these quality audits. ÚJD SR has the right to supervise performing factory acceptance tests and check suppliers and activities performed by suppliers, including facilitation of control audits of suppliers and participation of the Authority's inspectors in these audits.

Slovenia

The operator is primarily responsible for safety; therefore it has to develop and maintain adequate resources to maintain and continuously improve nuclear safety, including oversight of vendors and contractors.

The Rules on Radiation and Nuclear Safety Factors include the following requirement:

- The operator of a radiation or nuclear facility shall always have in-house sufficient personnel with suitable competences to understand the licensing basis of the radiation or nuclear facility as well as to understand the actual design and the operation of the facility in all its states, to develop project tasks and acceptance criteria to outsource works relevant to radiation or nuclear safety to contractors, to supervise the execution of such works and to evaluate them upon acceptance.

The United Kingdom

ONR expect a licensee/aspirant licensee to define a business model, which clearly articulates and justifies the core safety capability for the organisation; further details are available in TAG 049. Principle 1 - “The licensees should maintain a core safety capability of staff to ensure effective management for nuclear safety”. Principle 3 - “Licensee choices between sourcing work in-house or from contractors should be informed by a company policy that takes into account the nuclear safety implications of those choices”.

The expectations are underpinned by the requirements of LC36 – Organisational Capability and LC 10 & 12, and the associated SAPs MS 1 to 4.

The challenge for new build is these organisations are often in a state of transformation through the different stages prior to commencing operations, resulting in changes in key staff and skills, which need to be strategically led and controlled through a suitable management of change process.

The United States

Qualifications to submit a licence application to the US NRC

10 CFR 50.30 and 10 CFR 50.33. Specifically, 10 CFR 50.33 requires details of the applicant and the licence for which the application is being submitted, foreign ownership,

control or domination, financial assurance, decommissioning funding, legal and financial relationships, and other requirements.

Foreign ownership, control, or domination of commercial nuclear power plants

Section 103d of the Atomic Energy Act of 1954, as amended (AEA) provides, in relevant part, that:

No licence may be issued to an alien or any corporation or other entity if the Commission knows or has reason to believe it is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government. In any event, no licence may be issued to any person within the United States if, in the opinion of the Commission, the issue of a licence to such person would be inimical to the common defence and security or to the health and safety of the public.

Section 104d of the AEA contains a nearly identical prohibition. Section 50.38 of Title 10 of the Code of Federal Regulations (10 CFR) implements this statutory prohibition, providing that:

Any person who is a citizen, national, or agent of a foreign country, or any corporation, or other entity which the Commission knows or has reason to believe is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government, shall be ineligible to apply for and obtain a licence.

Financial assurance

The NRC's regulations governing financial qualification reviews of applications for licences to construct or operate nuclear power plants are in Section 50.33(f) of Title 10 of the Code of Federal Regulations. Guidance from the US NRC on meeting that requirement is contained in NUREG-1577, Revision 1, "Standard Review Plan on Power Reactor Licensee Financial Qualifications and Decommissioning Funding Assurance."

10 CFR 52.79, "Content of Applications"

This regulation specifies that an application to the US NRC for a licence must contain, among many other topics, in its Final Safety Analysis Report, "The applicant's organisational structure, allocations or responsibilities and authorities, and personnel qualifications requirements for operation."

Other applicable regulatory guidance

See NUREG-0800, *Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition*, describes information that should be in an application for a licence, including that information needed by NRC to complete its evaluation of the fitness of an applicant to receive a licence.

Question 2.5

What are your regulatory requirements and expectations for the operating organisation to be involved in construction oversight?

Canada

Regulatory document REGDOC-2.3.1, Construction and commissioning programmes, sets out information regarding the licensee having operational phase training and personnel certification approaches, such as for those who will be involved in commissioning, operation, maintenance and technical support activities should be considered. Training programme provisions evolve as construction progresses.

It is also to be considered that oversight of the construction activities supports the operations safety case and to note that when applying for a licence to operate, an applicant will have to describe the performance under the previous licence period.

Finland

There are no general requirements regarding this. However, YVL Guide A.5 "Construction and commissioning of a nuclear facility" states requirements that apply during commissioning, for example:

- *The licensee organisation shall have adequate human resources and competence for the facility's commissioning and operation well in advance of the start of commissioning so that the persons can familiarise themselves with and become experienced in the nuclear facility's operation during the project.*
- *The licensee shall assess the nuclear facility's construction and plant modification project during the project, after the completion of its various phases and after the project has finished. The information and experiences gathered in the review shall be utilised in project development and in improving the organisation's operation.*
- *The licensee's personnel shall participate in the commissioning testing to familiarise themselves with the facility and its systems.*

France

Regarding oversight, Article R.593-11 of the Environment Code stipulates that the licensee must oversight activities that could have a meaningful impact on the risks and inconveniences of the installation for the interests. At this effect, the licensee should implement an information transmission system in order to collect the return of experience.

Also, Article 2.2.2 of the Order of 7 February 2012 requires from the licensee to oversight the subcontractors in order to make sure that they respect its policy regarding the protection of the interests. According to the same article, the licensee's oversight over subcontractors aims also at making sure that the provided activities, goods or services respect the requirements and that the subcontractor respects the dispositions of this Order. This oversight depends on what is at stake regarding the interests.

Finally, Article 2.2.3 of the Order of 7 February 2012 stipulates that the oversight of activities important to the interests' protection cannot be assigned to a subcontractor, except under specific conditions. Indeed, the licensee can get assistance from a subcontractor to oversight these activities only if he keeps in-house the skills to realise these oversight activities. Also, the licensee must make sure that the subcontractor that provides assistance has the skills, the independence and the impartiality necessary. ASN can ask the list of companies that assist the licensee for oversight activities.

Hence, in France, the licensee, in charge of operating activities, is expected to be fully involved in construction oversight.

ASN expects from the licensee to build its oversight programme by taking into account the issues at stake, the return of experience and the assessment of the subcontractors. During its inspections, ASN assesses the licensee's oversight and the consistency of its programme.

Hungary

See the answer in 2.4 for general requirements and special requirements are in Section 9.2. of Annex 9 to Govt. Decree No. 118/2011 (VII. 11.).

9.2.1.0100. A management system shall be established by the licensee for the complete management of the design and construction process, including work planning and time scheduling, procurement, and the control of suppliers. In the framework of the management system, a management manual and a documentation system shall be established for the subordinated management functions specified in the manual.

9.2.1.0200. The organisations and roles involved in design, construction and future operation, the rights and obligations assigned to these roles, as well as the way of obtaining information shall be clearly and fully identified in the management manual.

9.2.1.0300. The management system shall ensure the continued accountability of all parties involved in the design and construction project, with regard to their responsibility for the safety.

9.2.1.0700. The licensee shall establish a safety organisation for the independent evaluation of activities having significant effect on safety, which are carried out during the design and construction work, and for the conduction of the supervisory actions within its scope of authority. The direction and the supervision of the safety organisation shall be subordinated to the top management of licensee.

9.2.1.0710. In agreement with Section 2.2.2 of Annex 2, the organisations involved in the design, construction and commissioning, including suppliers and concerned authorities, shall establish a work environment that facilitates a high-standard safety culture and encourages the employees to clarify their questions relating to their work in accordance with documented rules.

9.2.1.0900. The licensee shall elaborate a system for the management of non-compliances, which shall be suitable for the management of all safety important non-compliances identified during the construction process in the activity of all the participants of the construction.

9.2.1.1000. In addition to the non-compliances specified in Annex 2, the following deviations shall be considered non-compliance during the construction process:

- *a) physical characteristics deviating from the specified limit values, particularly the dimensions and material parameters, assembly errors, product or system malfunctions;*
- *b) deviation from the approved processes and procedures;*
- *c) error of the personnel responsible for performing the activity, inspection or test instruction or the failure to comply with the regulations;*
- *d) deficient documentation or incorrect content thereof;*
- *e) insufficient qualification of the personnel for safety-related activities to be carried out within their respective scope of responsibility;*
- *f) failures, deviations, and other events;*
- *g) deficiency of a regulation; and*
- *h) unpermitted operational state or process.*

9.2.1.1100. The licensee, to manage the deviations from the licences issued by the nuclear safety authority (modification) shall develop a documented approach graded according to safety significance of the deviations.

9.2.1.1200. The licensee, after entering into force of the construction, building, commissioning, fabrication, purchase or assembly licence, may deviate from the provisions of the licence or from the documentation supporting the licence in a regulated manner.

9.2.1.1300. Knowing the character of the deviations recognised per Section 9.2.1.1600. and planned according to Section 9.2.1.1200. and the requirements on the deviations, the licensee, after assessing the safety consequences of the deviation, shall prepare a preliminary safety assessment, and then based on that it shall carry out the categorisation per Section 9.2.1.1400. During the assessment the deviation shall be addressed in a complex manner, from the aspect of its effect on the safety of the whole nuclear facility.

9.2.1.1400. The deviations from the issued licences shall be categorised according to the following based on their safety significance:

a) The deviation affects the capability of the safety system, structure or component to fulfil its safety function, or the change considerably influences the operation of the organisation implementing the licenced activity;

9.2.2.0300. The organisation performing the design and construction work shall identify the rules of co-operation with the suppliers.

9.2.2.0400. The authorities and responsibilities, the information necessary for taking these authorities and responsibilities, and the decision competencies of the suppliers shall always be in harmony with each other.

Poland

The licensee has the primary responsibility for safety and security and must have implemented integrated management system which consist inter alia of:

- quality assurance system;
- description of responsibilities, duties, powers and interactions in the fields of management, implementation and evaluation;
- quality policy;
- description of the processes taking place in the entity along with supporting information explaining how the preparation, review, implementation, documentation, evaluation and improvement of activities is performed.

The Slovak Republic

We do not have legislative requirements for the operating organisation's involvement in construction oversight. In the Slovak Republic only one company is a licensee. This company is the licence holder for operation of Units 1 and 2 and for the same company the construction licence was granted for construction Unit 3 and for 4. Staff from operated units was involved in construction from the beginning. A special team called "future operation" was established. Its tasks were to comment detail design from operational point of view, participate in turn over process and support non-active commissioning activity. Following this, the technology was handed over to operational staff. As regards MCR staff there is a rule that only qualified personnel can do manipulation on PICS (process control system) and SICS (safety control system). Therefore, starting with the integrated cold hydrostatic testing all manipulation have been done by personnel qualified to manipulate the PICS and SICS. Within the application for commissioning and operation the applicant

has to document fulfilment of the qualification programme for selected job positions important for nuclear safety.

Slovenia

In Slovenia, the operator has to have competent personnel to perform oversight activities. In practice the operator maintains high qualified, certified and experienced experts who regularly renew their knowledge what through an initial and continuing training programme.

The United Kingdom

Licensee arrangements for construction and installation should maintain the integrity of the justified design during construction and installation (LC 19).

ONR acknowledge the benefits of future operators and maintainers being sufficiently involved in the commissioning activities in order to transfer knowledge and understanding of the nuclear power plant prior to commencing operations.

Once again the expectations laid out in TAG's 49 and 77 apply.

In addition to the specific arrangements for oversight of all activities on the nuclear site, ONR also expects that the licensee to put in place adequate arrangements for provision of independent advice and guidance and to have a robust independent nuclear oversight capability. Expectations in this area are laid out in LC13 – the requirement that the licensee has in place a nuclear safety committee with an appropriate number of independent members to advice the licensee on matters of nuclear safety. ONR expectations regarding the provision of independent advice and on independent nuclear assurance are described in TAG 80.

The United States

For new nuclear plants licensed under 10 CFR Part 52, the licensee is governed by the provisions and conditions of a combined licence (COL). An EPC contractor for a new facility is expected to adhere to COL requirements and the licensee's quality assurance programme. The operating organisation will become increasingly engaged in oversight as construction progresses, specifically through:

- system turnover (construction-to-operations);
- pre-operational testing;
- integrated testing;
- plant start-up activities;

Question 2.6

If any, what experience do applicants/licensees have embedding their own staff into the contracted entity during construction, and the basis for doing so?

Canada

In Canada, this has been experienced once where a licensee embedded a number of its own staff into an EPC contractor's organisation following a noted reduction in project management performance.

The same licensee stated this will be their business model for future new build nuclear power plants, and has recently formed a partnership with an SMR vendor to license, construct, operate and decommission an SMR in Ontario through a company formed to be

the licensee for all life cycle phases. The licensee intends to provide the majority of personnel for this project.

Finland

In OL3 there is some experience where a licensee embedded a few of its own staff into the plant supplier's commissioning organisation. The feedback from the licensee was that this is an effective way to perform the tasks and collect knowledge on the operation of nuclear power plants.

France

No response provided.

Hungary

In Hungary the new build project is in the regulatory assessment of construction application phase so until now we have no special experience on this field.

Poland

So far we do not have such experience.

The Slovak Republic

In the Slovak Republic, we have positive experiences with operational staff involvement during the construction phase. For example, experts from nuclear safety oversight were regularly part of the team of the extraordinary event committee and their role was very positive.

Slovenia

The licensee's own staff is primarily involved in organisation, co-ordination and supervision of activities. Basis is the operator's primary responsibility for safety.

The United Kingdom

As part of the MEH Alliance on the HPC site, the licensee will have embedded staff working within the alliance, providing expert knowledge of the design and quality requirements. The detail of these arrangements has yet to be implemented and tested by ONR.

A more integrated approach is also being considered by the SZC project, but it is too early to assess.

The overarching principle from ONR is the "Licensee shall retain overall responsibility for, and control and oversight of, the nuclear and radiological safety and security of all of its business, including work carried out on its behalf by contractors."

The embedding of contracted staff into the licensee is a recognised practice within the United Kingdom. All these staff are subject to the same competency assessment as an equivalent member of the licensee's staff.

ONR make a distinction between the embedding of a contractors' staff into the licensee organisation in contrast to a contractor undertaking a package of work on behalf of a licensee. Where a package of work is carried out on behalf of a licensee then the licensee must specify and oversee that work within the intelligent customer framework discussed earlier. Where a contractors' staff are embedded into the licensee organisation then they effectively become part of the licensee and undertake activities under the licensees' arrangements and have to meet the licensees' competency requirements – in this case

ONR's focus is also on the contractual arrangements in place to ensure the licensee retains a resilient capable organisation.

The United States

For new nuclear plants licensed under 10 CFR Part 52, the NRC is not aware of applicants or licensees embedding their own staff into the contracted entity during construction. However, the licensee is expected to provide oversight of the contracted entity during construction.

Regulatory oversight framework

Question 3.1

Do you adapt your oversight framework for regulating a fleet deployment of the same technology (beyond first-of-a-kind, proven technology within the country) and if so, what are the principles/approach of your oversight framework?

Canada

For the proposed new build SMR programme with the possibility of regulating a fleet deployment of the same technology, the CNSC has yet to determine whether its oversight framework requires adapting.

For the current fleet of nuclear power plants, all CANDU technology, the CNSC has a robust and flexible oversight programme built on several decades of experience and continual improvement.

Regulatory document REGDOC-3.5.3, *Regulatory Fundamentals*, outlines the CNSC's regulatory philosophy and approach to applying the Nuclear Safety and Control Act. It provides information for licensees, applicants and the public, more specifically it sets out information addressing the major elements that comprise the CNSC's regulatory approach including applying a graded approach as a systematic method or process by which elements such as the level of analysis, the depth of documentation and the scope of actions necessary to comply with requirements.

CNSC policy document *Policy on the Use of a Risk-Informed Approach for Regulatory Oversight of Nuclear Activities and Facilities*, further sets out information to establish governance for the application of a risk-informed approach when making regulatory recommendations and decisions across all regulatory programme activities.

Finland

There is no formal, explicit method for adapting oversight beyond first-of-a-kind deployment. However, in principle, should a licensee apply to construct another plant similar to an existing plant, only the changes in the design would have to be reviewed.

France

ASN, with the technical assistance from the IRSN, oversees the deployment of a nuclear reactor through:

- examination of the detailed design documents;
- an inspection programme that addresses the activities of the licensee's engineering services, the worksite and the manufacturers;
- examination of the management of deviations that can arise during engineering, construction and commissioning activities.

ASN identifies and regularly reassesses oversight priorities following a graded approach, utilising its competences, its field experience, and the return of experience.

The oversight priorities are consistent with the stakes as they take into account the risks presented by the activities and the means implemented to manage them. They also take into account the return of experience, which explains that, for equivalent stakes regarding the interests listed in Article L.593-1 of the Environment Code, an activity that has shown deficiencies will undergo a sustained oversight, in comparison with an activity with solid experience. ASN is particularly attentive to first-of-a-kind technology or innovative techniques that present a risk for the interests.

However, after due consideration on the stakes, ASN can reduce its oversight on activities that have a positive return of experience. This could be applicable for proven technologies or N^{th}-of-a-Kind reactors.

Hungary

The Government Decree 118/2011 Section 7 states, in part,

> *The most important components of the defence-in-depth of the nuclear facility: a) design solutions applying the appropriate safety margins (including the selection of an appropriate site, diversity and redundancy as well as the application of tested, highly reliable technologies and materials), implementation and operation to a high standard*.

Annex 3 to Govt. Decree No. 118/2011 (VII. 11.).3.2.1.2200. states:

> *Systems, structures and components providing safety functions shall be designed by using such construction methods that have been previously tried and tested. For other instances such technologies and products shall be used, the applicability of which is evaluated and verified. In case of new design solutions, which differ from the accepted solutions of the engineering practice, the applicability shall be substantiated from safety aspect with adequate research, tests and analyses of experience from other applications. New solutions shall be tested before implementation. The operation of the system and components shall be monitored during operations for final validation of suitability.*

More detailed requirements are in the N1.7 regulatory guide on "New nuclear power plant mechanical system components manufacturing and procurement licensing documentation".

Poland

PAA has oversight framework based of international standards (IAEA, UE). All regulations are primarily based on IAEA safety requirements and guides including SSR 2/1 and SSR 2/2 for nuclear power plants and the scope of that regulation is similar to IAEA documents.

The Slovak Republic

For the proposed potential new build and possible new construction model, adoption of an oversight framework would be required.

For the current fleet of nuclear power plants, all WWER 440 technology, the ÚJD SR introduced a complex oversight programme which was continually adaptive and improved in compliance with IAEA requirements and recommendations.

The Atomic Act on peaceful use of nuclear energy and the general biding regulations provide information for applicants, licensee holders and the public. The oversight framework is based on a graded approach. Selected components must be identified and

subsequently categorised based on their function and importance for nuclear safety into safety classes one to four. Classification of selected components is performed in a graduated manner, so that Class I includes selected facilities with the highest demands on reliability, qualification, quality assurance, number and scope of inspections, and related documentation. Selected facilities must be designed, engineered, manufactured, operated and maintained so that their quality and reliability correspond to their classification.

The high-level deterministic principles relate to the provision of defence-in-depth and large safety margins and the lower-level principles relate to single failure requirement, preventing common cause failure supported by PSA, and associated analyses (for example, sensitivity studies, uncertainty analyses and importance measures) are considered as parts of an integrated decision-making process.

Slovenia

The SNSA's oversight methodology is developed for the PWR technology used at the Slovenian only Krško Nuclear Power Plant. Currently there is no need for adopting oversight to deployment of other technology.

The United Kingdom

ONR adopt a targeted and proportionate regulatory model when considering the adequacy of a second-of-a-kind and beyond. ONR would focus its assessment on any unique site-specific features of the design and establishing an adequate organisational capability to safely oversee/deliver the work. This is demonstrated through our approach to SZC.

ONR is responsible for firm but fair enforcement of relevant nuclear, health and safety, security, and radioactive materials transport legislation, using principles set out in the Legislative and Regulatory Reform Act 2006. These principles are:

- Targeting
- Proportionality
- Consistency
- Transparency
- Accountability

ONR used a graded, risk-informed approach to regulation, throughout the new build projects.

The United States

The NRC has not yet determined if the oversight framework will be adapted for regulating a fleet deployment of new technology such as SMRs.

Currently, the NRC uses the reactor oversight process (ROP) to inspect, measure, and assess the safety and security performance of operating commercial nuclear power plants, and respond to any decline in performance. The oversight framework is not adjusted for a fleet. However, the oversight framework is adjusted for the risk profile of the design and the safety performance of the plants. Additional information on the ROP can be found at: https://www.nrc.gov/reactors/operating/oversight.html.

During Vogtle construction, the staff identified attributes associated with the ROP and the AP1 000 design which informed revisions to the baseline inspection procedures. Additional information about this effort can be found in SECY-20-0050, *Planned Revisions to the Baseline Inspection Programme for the AP1 000 Reactor Design* (ADAMS Accession No. ML20058F491). In addition, the NRC developed a plan to transition Vogtle

Units 3 and 4 from the construction ROP to the ROP for operating reactors. Information on the staff's transition plan can be found at ADAMS Accession No. ML20191A383 and ML20191A398).

Question 3.2

Where a reference facility exists in your country or another, how do you ensure use-of-experience is disseminated and acted upon; including those from other country's regulatory body experience with construction, commissioning and operation?

Canada

Regulatory document REGDOC-1.1.2, *Licence Application Guide: Licence to Construct a Reactor Facility, version 2*, sets out information regarding how the applicant should provide a list of any similar facilities owned or operated by the applicant that have been assessed and licensed by either the CNSC or any foreign national regulatory body, and a description of the main differences or design improvements made since that earlier licence was granted. The list should include the following information:

- facility name
- location

With this information, the CNSC can apply a graded approach to how they could leverage scientific and technological information from other regulatory bodies to inform regulatory activities. It is always the applicant's responsibility to demonstrate how meeting foreign requirements also addresses Canadian requirements.

This sharing of information could be facilitated by multilateral and bilateral co-operation activities.

Recently, the CNSC signed a memorandum of co-operation (MOC) on advanced reactor and small modular reactor technologies with the United States Nuclear Regulatory Commission (US NRC) and UK ONR. The MOC enables detailed and specific co-operation on the regulation of activities involving SMRs and advanced reactor designs. More specifically, the MOC allows the CNSC to take US NRC review results into account should an applicant propose to construct and operate a reactor design currently under review or previously reviewed by the US NRC. In turn, the US NRC may consider insights from pre-licensing vendor design reviews and licensing review processes.

Finland

Accordance with Nuclear Energy Act (990/1987) 7 a § guiding principles states that, "The safety of nuclear energy use shall be maintained at as high a level as practically possible. For the further development of safety, measures shall be implemented that can be considered justified considering operating experience and safety research and advances in science and technology." STUK considers the construction experience as a part of operating experience.

More in detail in Regulatory Guide YVL A.5 "Construction and commissioning of a nuclear facility" set the following requirement in chapter 3.7 "Lessons learned from construction":

> *372. In construction projects of nuclear facilities, experiences gained on the construction and operation of other equivalent safety-critical facilities, systems, structures or components and also best practices from other fields of industry shall be utilised, taking into account, however, the potential effects on radiation and nuclear safety of the procedures.*

Please note that there are not specific requirements specifying a need to have a reference facility.

In addition to overseeing that the licensee fulfils the requirement mentioned above, STUK takes part in international co-operation where applicable. For example, STUK is a member in the VVER and EPR working groups.

France

Article 2.4.1 of the Order of 7 February 2012 requires that the licensee's integrated management system contains provisions in order to collect and capitalise the return of experience.

Regarding the EPR of Flamanville, ASN enacted a decision (Decision no 2013-DC-0347 of the 7 May 2013) that requires from the licensee to forward to ASN, on a yearly basis, a synthesis of the return of experience collected from:

- pre-operational testing realised on other reactors operated by EDF in France;
- pre-operational testing realised on other EPR reactors abroad.

As for NPE, Article 8 of the Order of 31 December 2015 requires the licensee to make operational lessons learnt available for the NPE manufacturer.

In addition, through its participation in international working groups and bilateral meetings with other regulatory bodies, ASN collects information and return of experience. This information and return of experience can influence ASN's oversight programme.

Hungary

According to the Hungarian regulatory requirements, the licensee has the option to submit a so-called preliminary safety information report (PSIR), which is an information package on the reference plant, using the format and structure of the preliminary safety analysis report (PSAR) to present it. In case of the Paks II project the licensee decided to submit a PSIR, which presented information on the Leningrad II Nuclear Power Plant. This document was assessed by the regulatory body, and feedback was given to the licensee on the findings (the PSIR assessment is not an official licensing procedure). This feedback is expected to be taken into account during the development of the PSAR.

In terms of the PSAR, according to the regulatory requirements, the licensee is expected to present the following information on the reference plant:

- description of the reference plant;
- description of design differences compared to the reference plant;
- description of lessons learnt from earlier projects (generic international experience, plus information from the vendors' previous projects).

Also the Hungarian Regulatory Body has bilateral connection to other regulatory bodies, who have construction projects with the same plant family (Belorussia, Finland, Russia, Türkiye, ,). Regular consultations and mutual site visits are arranged.

The Hungarian Regulatory Body and licensee collect the experience from the EU stress test on the nuclear power plant from the same plant family.

Poland

PAA has bilateral agreements with many authorities. Closer co-operation with reference authority will be established after selection of the technology.

The Slovak Republic

Regulation 431/2011 sets out requirements regarding how the project of nuclear facility should take into account proper technical practice and operating experience. The design of a nuclear facility must take into account operating experience from similar nuclear facilities and available results of research programmes.

ÚJD SR is a member of the forum of the regulatory bodies of the countries operating WWERs. The objective of the forum is to promote higher safety and radiological protection in the countries concerned by way of utilising the collective experience, information sharing and joint efforts of the national regulatory bodies to address safety issues and improve the policy and practices of regulatory activities.

The regulatory bodies experience is also an exchange based on bilateral and multilateral agreement. The bilateral and multilateral meetings are organised annually.

Slovenia

In preparation to licensing of important modification or facility the SNSA tries to identify good practices and experiences from other regulators and apply them in its own regulations, licensing process and supervision methodology. When possible, special scientific visits at the other RB are organised to exchange information and experiences.

The United Kingdom

Learning is a fundamental component of an organisations safety management system and ONR's Safety Assessment Principles (SAPs) set out ONR's expectations under organisational learning – Lessons should be learnt from internal and external sources to continually improve leadership, organisational capability, the management system, safety decision-making and safety performance.

Additionally, licensees are required to have effective organisational learning processes that demonstrate transferable learning from site events and other relevant projects (LC7).

ONR utilises a number of sources of information to inform our regulatory approach/strategy for new build, which includes regulatory intelligence from other EPR projects, major projects across the United Kingdom and interactions with other regulatory bodies, within the United Kingdom or international community.

ONR itself participates in relevant regulatory forums such as MDEP, CNRA, CSNI as well as having specific bilateral international agreements. Licensees also participate in international forums such as WANO, INPO etc.

The United States

AP1 000 construction and commissioning projects have been on going at Sanmen and Haiyang, China over the last several years. The NRC and the National Nuclear Safety Administration (Chinese regulator) collaborated on an inspector exchange programme to share perspectives and insights regarding plant construction and testing. This allowed NRC inspectors first hand field experience and observations of construction and testing activities. Some first-of-a-kind testing completed in China was leveraged to satisfy testing requirements for the domestic AP1 000 projects. NRC inspectors were able to compile lessons learnt regarding AP1 000 construction and start-up testing.

Additionally, the NRC continues to receive operational experience reports through the international incident reporting system and screens each for applicability to NRC licensees, and sustains engagement with the international community through semi-annual working group meetings to share operating experience and significant items/issues.

The NRC reviewed and approved several licence amendment requests where the licensee requested to credit first-of-a-kind testing performed at Sanmen and Haiyang. Once the licence amendments were approved, the licensee did not have to perform the specific first-of-kind testing for their facilities.

Question 3.3

Do you have a policy or practice for conducting audits and inspections directly on the supply chain organisations, and on-site construction activities independent of the licensee? What criteria do you apply to prioritise certain aspects of the facility during construction (i.e. risk-informed inspection)?

Canada

The CNSC's approach to compliance verification is through regular inspections and evaluations verify that licensees are complying with laws and regulations, as well as the conditions of their licence. In this way, the CNSC can ensure licensees are operating safely and adhering to their licence conditions.

The CNSC verifies compliance through site[1] inspections and the review of operational activities and licensee documentation. We require licensees to report routine performance data and unusual occurrences.

The CNSC does not have a policy or practice for conducting audits and inspections directly on the supply chain organisations, and on-site construction activities independent of the licensee. The current practice is to oversee the licence's oversight measures.

Regulatory document REGDOC-2.3.1, Section 3.2.3 Oversight of contractors, sets out information regarding the licensee to develop measures to ensure contractors and subcontractors meet their respective contractual obligations in accordance with an appropriate safety management system. The licensee shall also maintain records of its oversight activities and report to the CNSC relevant contractor performance that has affected, or has the potential to affect, the quality of construction and future operational safety.

CNSC staff routinely observe licensees performing their oversight on supply chain organisations and on-site construction activities.

Finland

According to Guide YVL A.5 "Construction and commissioning of a nuclear facility" requirement 505 gives a mandate for STUK to conduct inspections directly on the supply chain main design organisations: "STUK can focus its own inspections directly on organisations responsible for the nuclear facility's design. In such cases, the inspection item is significant for safety, e.g. the design functions of the company supplying the nuclear island. The inspections assess the functionality of the organisation's management system and the adequacy of the procedures. STUK's regulatory control is described in more detail in the field-specific and technology-specific YVL Guides."

Criteria for STUK to conduct the inspections is the safety significance of the scope of delegated design assignments.

STUK does not conduct audits but can take part in licensee audits.

[1] Site in the context of this response includes supply chain organisation locations.

France

The French regulatory framework, and in particular Article L. 593-6 of the Environment Code, considers the licensee as responsible for the management of the risks and inconveniences of the stakeholders affected by its installation.

The Environment Code provides the possibility for ASN to conduct inspections on activities important to the protection of the interests, even if they are realised outside the installation's perimeter, or by subcontractors. Hence, ASN can lead inspections involving supply chain organisations.

These inspections enable ASN to assess:

- The quality of the goods and services provided by the subcontractors. In particular, ASN has recently adopted an action plan against the risk of fraud.
- If the subcontractors' organisation is compliant with the requirements detailed in the Order of 7 February 2012.
- The licensee's oversight.

The criteria presented in the French response to question 3.1 are applicable to this kind of inspection.

As for NPE, ASN can conduct inspections on activities related to design and manufacturing, involving the manufacturer, their subcontractors, and third-party bodies authorised for conformity assessment.

Hungary

The Hungarian Regulatory Body (HAEA) has elaborated a procedure (ME-5-2-3-Regulatory supervision of facility suppliers and their activities) for conducting regulatory review, that aims to identify non-compliances with the findings of previous inspections of suppliers of nuclear installations carried out by a third party or organisation on behalf of the authority, and to monitor corrective action.

Suppliers are directly inspected by the HAEA in the following cases:

a) if information has become available in connection with the supplier's activities which justifies an official review;

b) if it does not agree with the decision made after the nuclear safety qualification of the supplier, which is related to the conformity of the quality system of the supplier and / or the permitted activities in the documents issued to the supplier (also sent to the HAEA for information);

c) if its annual inspection plan includes an inspection of one of the licensees' suppliers.

The HAEA will inform in writing the relevant organisation (supplier) – and in above-mentioned cases b-c the licensee as well – about the planned review and other circumstances of the inspection prior to the review.

As the new nuclear power plant is not yet in the construction phase in Hungary, HAEA is still preparing to develop criteria applying during construction. The prioritised aspect is graded approach.

Poland

According to existing atomic law it is possible to conduct inspection on the supply chain organisation. The criteria that will be used to prioritise inspection activities have not yet

been decided. Inspection programme for existing nuclear facilities in Poland rely mainly on safety classes of SCCs.

Inspectors conducted inspections of suppliers of the research reactor in Poland and other nuclear facilities.

The Slovak Republic

The ÚJD SR does not conduct audits or inspections directly on the supply chain organisations. ÚJD SR just takes part in the quality audits of selected contractors carried out by the licensee as an observant. ÚJD SR does conduct inspections of on-site construction activities following the current project schedule, applying risk-informed approaches to the inspections. The ÚJD has developed a complex and sophisticated construction inspection programme to carry out its inspection duties, applying a holistic approach. The goals and objectives of the inspection programme are: the licensee has control over the project (site, engineering, manufacturing, vendor, subcontractors, EPCM contractor…), the licensee has systematic processes and procedures in place for processing safety and quality issues, the licensee's quality assurance (QA) programmes and plans ensure performance and product conformity, the safety and technical requirements are met, installation has been done according to technological procedure.

Slovenia

SNSA do not perform independent audits or inspections on the supply chain organisations. We perform inspections of operator's system for vendors' supervision. We can perform inspection of important on-site construction activities. The operator is responsible for correcting the deficiencies found.

The United Kingdom

ONR have an established vendor inspection programme, which is reviewed on an annual basis. The programme targets key suppliers for the nuclear industry and ONR conducts these inspections using TAG 077 as the main source of relevant good practice.

ONR do have powers under the Health and Safety at Work Act (1974) under Section 6 of the Act, to inspect the supply chain in the United Kingdom where equipment is manufactured for the nuclear industry. However, in most cases ONR influences the supply chain through the licensee's control and oversight arrangements. ONR conduct regular licence interventions to gain confidence in the quality of components and their functionality within the supply chain. These interventions are conducted in conjunction with the licensee.

On the construction site, regular licence compliance inspections are conducted to ensure the licensees arrangements provide adequate oversight of construction / installation activities.

ONR inspection activity is influenced by a risk and performance approach through sub-programme reviews and inspection planning processes.

The United States

Yes, the NRC's construction reactor oversight process (cROP) is described in detail in IMC 2506, "Construction reactor oversight process general guidance and basis document." The cROP is implemented when an applicant announces its intent to submit an application pursuant to 10 CFR Part 52 for an early site permit (ESP), a limited work authorisation (LWA), and/or a combined construction permit and operating licence (COL). The cROP will remain in effect until regulatory oversight for the plant is transitioned to the reactor oversight process (ROP). The cROP consists of the following key aspects to provide

independent oversight for applicant/licensee activities during the development of the application for and the subsequent construction of a new reactor facility:

a) Construction inspection programme (CIP).

b) Construction assessment programme.

c) Construction enforcement programme.

d) Inspections, tests, analyses, and acceptance criteria (ITAAC) closure verification process.

e) Vendor inspection programme.

f) NRC allegation programme.

g) Construction experience programme (ConE).

h) NRC open government plan (Communications).

The NRC's vendor inspection programme is described in IMC 2507, "Vendor Inspections". The vendor inspection programme is implemented for both operating reactors and nuclear power plants under construction. Vendor inspections can occur once a licensee or applicant places a safety-related procurement. As stated in IMC 2507, the selection of vendors for inspection is based on several factors that include:

a) the significance to safety of the equipment or service provided;

b) vendors manufacturing major plant modifications, (i.e. replacement of steam generators and reactor vessel heads, new fuel design, etc.);

c) verification of ITAAC in support of on-site construction activities;

d) input from the technical staff necessary to support completion of design certification and COL reviews;

e) the frequency and significance to safety of problems identified with vendor-supplied materials, equipment, or services, including third party auditing organisations;

f) the number of licensees affected by the problem identified, the performance history of a vendor; and

g) other information received from allegations, 10 CFR Part 21 reports, 10 CFR Part 50.55(e) reports, licensee event reports (LERs), and other NRC organisations.

The NRC uses the results of past inspections, event evaluations, and inspector and management reviews to inform the focus of inspections at each vendor facility.

Question 3.4

What arrangements exist if you identify conditions adverse to quality/safety-product or activity, such as when conducting audits and inspections, or made aware by a whistle blower, directly on material, major component suppliers, and site construction activities independent of the licensee?

Canada

Under the Nuclear Safety Control Act (NSCA) and its associated regulations, various levels of regulatory action can be taken by the CNSC to correct non-compliance by a licensee and protect the health, safety and security of Canadians and the environment.

The CNSC uses a graduated approach to enforcement to encourage, to compel compliance and to deter future non-compliances. When a non-compliance (or a continued non-compliance) has been identified, CNSC staff assess the significance of the non-compliance, and determine the appropriate enforcement action, based on the CNSC's graduated approach to enforcement. Each enforcement action is a discrete and independent response to non-compliance.

Measures used to encourage and compel compliance and deter further non-compliances include in escalating order:

1) Informing licensee/discussion.
2) Written notices.
3) Requests under General Nuclear Safety Regulations Section 12(2).
4) Orders.
5) Increased regulatory scrutiny.
6) Licensing actions.
7) Administrative monetary penalties.
8) Decertification.
9) Prosecution.

The CNSC's approach to compliance includes activities to encourage compliance, verification activities to assess the actual level of compliance, and graduated enforcement actions in cases of non-compliance (up to and including licensing actions [including revocation of licences] and/or prosecution for an offence).

Enforcement actions can be applied independently or in combination with other actions. Regulatory judgement must be applied, and multiple factors taken into account, to determine the most appropriate enforcement strategy for any given situation. If the initial enforcement action does not result in timely compliance, other actions will be used.

Finland

Depending on the severity of the finding, an appropriate reaction is chosen. For more severe findings and issues, a more severe regulatory action is warranted.

These regulatory actions include (in increasing severity):

- Discussion with the licensee/supplier.
- Withholding approval if a regulatory hold point is related to the issue.
- Instructing the licensee to fix the issue by issuing a decision with a requirement.
- Withholding approval or safety evaluation required for a licence.
- Imposing a conditional fine unless the issue is fixed.
- Suspending or limiting the operation related to the issue.
- Suspending or limiting the operation with assistance from the police authority or other authorities.
- Propose to revoke a licence (STUK cannot revoke a licence, only propose).

France

In 2018, ASN opened a portal to the public so that anyone wishing to do so can inform it of any irregularities. Also, ASN has set up an in-house process for dealing with these reports and has reinforced interviews during its inspections. This, in addition to the previous practices, enable ASN to be aware of dysfunctions in subcontractors' work or organisations.

After a technical assessment of the issues, a quick response, such as corrective and preventive actions can be decided in proportion with the stakes. Also, if appropriate, ASN can share the information with the other administrations and licensees concerned, or even with ASN's foreign counterparts.

The protection of the interests relies on the implementation, in appropriate timelines, of corrective actions to manage non-compliances. ASN's means of sanction and coercion should be used following a graded approach, considering the stakes and the attitude of the licensee, combining dialogue, incitement, coercion and sanction.

There are different ways to encourage or to push the licensee (who is responsible) to meet the requirements:

- Discussions;
- Written positions;
- Coercive measures;
- Sanctioning measures (administrative or penal).

In case of fraud, the subcontractor can be prosecuted.

Hungary

Basically, HAEA does not carry out direct inspections and audits of suppliers independent of the licensee except in the cases listed in the previous answer. The review will be the subject of a report and the report will address what activities are proposed to allow the supplier to perform, which activities are not explicitly recommended and which are justified by the comments received during the review.

A decision must be made on the issues for which the review procedure was initiated by the HAEA, item by item:

- the quality management system of the inspected supplier is adequate for the activities he carries out for the licensee;
- has the necessary facilities, organisation, personal and material conditions, technology, references and other official permits (certificates) necessary for the work performed;
- what activities may be authorised for the nuclear installation or whether the certification previously issued may remain valid;
- its existing licence must be revoked and transfers to a nuclear installation must be permanently or temporarily prohibited or its transport activities restricted;
- list the discrepancies detected, set a deadline for corrective action.

Poland

The PAA uses a graded approach to enforce compliance, to compel compliance, and to deter future non-compliances. When a non-compliance has been identified, PAA staff

assess the significance of the non-compliance, and determine the appropriate enforcement action, based on the atomic law.

Measures used to encourage and compel compliance and deter further non-compliances include in escalating order:

1) Written recommendation;
2) In case of detection of irregularities or non-compliances, issuing injunctions or interdictions by President of PAA;
3) If any direct threat to nuclear safety or radiological protection has been identified during the inspection, the inspector shall issue orders containing injunctions or interdictions;
4) Financial penalties;
5) Revocation of the licence.

If an order to remedy the irregularity or non-compliances is issued, the licensee must complete this task within the prescribed period.

In reference to inspection of producers and suppliers of nuclear facility systems, construction elements and installations, as well as contractors for systems, components and works important for the nuclear safety, radiological protection and safe operation of installations, according to Article 37 sections 5 and 6 to the Atomic Law:

If in the course of overseeing any nuclear facility system, construction element or installation an item is found to negatively affect nuclear safety and radiological protection, the President of PAA shall order the organisational entity conducting activities involving exposure and consisting in construction, commissioning, operation or decommissioning of nuclear facilities to stop using the system or element.

If in the course of overseeing any works performed at a nuclear facility items are found to have a negative impact on nuclear safety and radiological protection, the President of PAA shall order the organisational entity conducting activities involving exposure and consisting in construction, commissioning, operation or decommissioning of nuclear facilities to suspend the works in question.

The Slovak Republic

Under the Atomic Act and its associated regulations, various levels of regulatory action can be taken by the ÚJD SR to correct non-compliance by a licensee and protect nuclear or technical safety, the environment and public health.

The ÚJD SR uses a graduated approach to enforcement. The ÚJD SR is authorised to take the necessary steps including:

- Warning letter.
- Prescribe the corrective action to eliminate findings.
- Cessation of construction or breaking of assembly.
- Dismantling and reinstallation.
- Imposing penalties.
- The proposal for imposing penalties is performed by the relevant division.
- According to administrative order ÚJD SR starts the administrative procedure against the licensee.

- The decision prepared is approved by the chief inspector and legal department.
- The licensee has the right to lodge protest against this decision.
- Considering the proposal of the commission for appeal, the protest is judged by the chairman.

Enforcement actions can be applied independently or in combination with other actions. Regulatory judgement must be applied, and multiple factors taken into account, to determine the most appropriate enforcement strategy for any given situation. If the initial enforcement action does not result in timely compliance, other actions will be used.

Slovenia

The operator is obliged to request corrective actions from the supplier. All deviations at the site should be fixed and all potential suspicious equipment should be replaced.

The United Kingdom

ONR has an established regulatory framework that ensures safety or quality issues are subject to appropriate regulatory oversight to ensure any adverse conditions are addressed, which include – regulatory advice/formal enforcement/criminal prosecution/potential financial penalties through the UK judicial system.

ONR also has processes in place for whistle-blowers concerns to be duly investigated, which includes senior level oversight from within ONR. The ONR whistle-blower process includes measures to protect the anonymity of the whistle-blower whether they are internal or external to ONR.

The United States

Licensees are subject to 10 CFR 50 Appendix B (Quality Assurance) requirements, including Appendix B Criterion XVI "Corrective Action." Conditions adverse to quality are expected to be addressed and resolved through the corrective action process; significant conditions adverse to quality require identification of root cause(s) and actions to prevent recurrence. The NRC inspection programme relies on the licensee's continuing and sustained diligence in implementing an effective corrective action programme.

Additionally, NRC Management Directives include guidance for implementation of the Allegation Programme which allows for intake processing, disposition, inspection follow up, and closeout of instances/reports of potential wrongdoing related to NRC-regulated activities. The allegation programme and related policies remain a significant element of the NRC's focus on the nuclear industry safety conscious work environment philosophy.

Question 3.5

What arrangements exist to ensure that the regulatory body will have the right of access to suppliers and sub-suppliers (including off-site activities)?

Canada

Although not directly referenced in the NSCA or applicable regulations, regulatory document REGDOC-1.1.2, *Licence Application Guide: Licence to Construct a Reactor Facility, version 2*, sets out information regarding how the applicant shall ensure, as a contractual obligation:

- that the applicant and the CNSC will have right of access to the premises of any supplier to the construction programme (including off-site testing);
- that all sub-suppliers will provide right of access to their premises by those clients who are suppliers to the construction programme (including off-site testing).

For context on how this requirement for right of access would become compliance verification criteria, applicants who wish to carry out licensed activities are expected to use licence application guides for regulatory expectations on the information to submit for a licence.

Here the applicant would be bound to fulfil this requirement as the safety and control measures described in the licence application and the documents needed to support the licence application become part of the licensing basis that sets the boundary conditions for a regulatory activity, and establishes the basis for the CNSC's compliance programme.

Additionally, regulatory document REGDOC-2.3.1, Section 5.3 Manufacture and assembly, sets out information regarding how the licensee shall ensure right of access to facilities and records for witness points or audit by the CNSC.

Finland

In case of domestic suppliers and sub-suppliers, STUK has the right of access by law. The Nuclear Energy Act Section 63 paragraph 3 entitles STUK with right to "require that nuclear fuel or the structures and components intended as parts of the nuclear facility be manufactured in a manner approved of by the Radiation and Nuclear Safety Authority, and oblige the licence holder or licence applicant to arrange for STUK sufficient opportunity to control manufacture of the fuel or such structures and components". Section 63 paragraph 4 entitles STUK with the right to "receive necessary information and be provided with the plans" concerning the nuclear facility and its structures.

Furthermore, the Nuclear Energy Decree requires the licensee applicant to describe the arrangements in place to ensure these supervisory rights domestically and internationally. These can include contracts, or other legal agreements..

A construction licence can be granted only if these arrangements are deemed sufficient by STUK.

France

As mentioned in response 3.3, the law enables ASN to conduct inspections where the activities important to the interests' protection are realised, even if they are realised by suppliers and sub-suppliers outside the installation's perimeter.

Hungary

Arrangements are defined in the Governmental Decree 118/2011. pursuant to Section 22 (4): "The nuclear safety authority is entitled to carry out announced inspections at the licensee and suppliers and, if necessary to achieve the purpose of the inspection, unannounced inspections."

On the basis of Section 22 (5) of the Government Decree 118/2011.: "The licensee is obliged to create the conditions for the inspection of the nuclear safety authority by a foreign supplier."

Poland

According to Article 37 of Atomic Law, nuclear safety inspectors as well as other bodies as far to the extent they are authorised to do so, shall inspect producers and suppliers of nuclear facility SSC, as well as contractors for systems, components and works important for the nuclear safety, radiological protection and safe operation of installations referred to in the regulations issued under Article 5, Section 4 of the Technical Inspection Act of 21 December 2000, carried out or provided during construction, commissioning, operation and decommissioning of a nuclear facility.

Arrangements in law mentioned above guarantee the regulatory body the possibility to perform inspection of contractors and suppliers.

During inspections the inspectors shall be authorised to request an assessment to be drawn up by specific public administration bodies, and in particular, by the office of technical inspection, and, as far as and to the extent that any specialist knowledge related to nuclear safety is required in drawing such assessments, also by:

1) expert laboratories and organisations authorised by the President of PAA – to control producers and suppliers of nuclear power plant SSC, as well as contractors for works during construction, fitting and decommissioning of a nuclear power plant;
2) independent experts and laboratories – to control producers and suppliers of SSC of other nuclear facilities, as well as contractors for works during construction, fitting and decommissioning of such nuclear facilities.

The Slovak Republic

There is directly reference in the Atomic Act or applicable regulations regarding the inspector's rights. Our inspectors have the right to enter at any time and without restrictions only in the premises of the licensee and the premises of nuclear installations and the premises, where nuclear materials, special materials and equipment are held or where radioactive waste or spent nuclear fuel are managed, to carry out inspection activity.

Slovenia

This is not in Slovenian regulations. Access to suppliers and sub-suppliers can be done together with the operator in accordance with advance agreement.

The United Kingdom

On the licensed nuclear site – ONR inspectors have the legal powers to require entry to the nuclear site at all times.

In regard to off-site activities, ONR is the enforcing authority, in certain circumstances, for the nuclear industry supply chain and could investigate the supplier directly regardless of the contract tier – however, Section 6 of HSWA does not provide direct power of entry to a suppliers site. However, ONR generally arrange to inspect the supply chain through the

licensee and undertake joint inspections with the licensee. Ultimately, if ONR have concerns then control can be applied once the component is received at the nuclear site.

The United States

10 CFR Part 50, Appendix B, Criterion IV, "Procurement Document Control", requires that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors. Specially, this means that Appendix B to 10 CFR Part 50 and 10 CFR Part 21 shall be imposed on all safety-related procurements. Part 21 (Section 21.41) requires that each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall permit the Commission to inspect records, premises, activities, and basic components as necessary to accomplish the purposes of this part.

Question 3.6

What authority/experience do you have to audit and inspect foreign material and major component suppliers?

Canada

In addition to the response in 3.5, CNSC staff have participated, as observers, to several members state MDEP VICWG vendor audits and inspections, namely in Japan and the United States. A CNSC staff member also participated in the joint ASN and ONR investigation inspection at the Creusot Forge foundry unit of French nuclear group Areva, following the discovery of irregularities in reporting metallurgical results.

The CNSC does not currently conduct inspections directly on foreign material and major component suppliers. However, with foreign SMR designers looking to deploy their reactor in Canada, which may include foreign material and major component supply, the CNSC is assessing the feasibility to conduct such inspections.

The CNSC has a number of suitability qualified and experienced personnel to conduct such inspections having industry experience. More recently, CNSC staff have accompanied nuclear power plant licensee auditors and inspectors on their visits to Canadian major component suppliers on the current major refurbishment, and major component replacement projects.

Finland

The licensee is obliged to assess suppliers and decide oversight actions. Audits is a part of the assessment process. The licensee invites STUK to participate in the audits as an observer. STUK decides whether to participate or not. This process covers all suppliers and almost all supplier assessments are conducted in this way. STUK´s role is preferably that of an active observer who takes part in discussions related to its requirements and field inspection practices.

STUK inspects main designers regularly, but supplier inspections are conducted quite rarely, based on safety significance and graded approach. Examples for inspection reasons include supplier´s special importance, newcomers in nuclear industry or a major mishap during manufacturing.

France

As for NPE intended for a French installation, the regulatory framework mentioned above (see response 3.5) is applied.

In practice, ASN inspects activities of the manufacturer, related to design and manufacturing, in their own premises or in their subcontractors' premises, in France and abroad.

In the particular case of an inspection conducted in a subcontractor's premises abroad, the NPE manufacturer makes prior arrangements with the subcontractor so that the inspection can be carried out.

Hungary

HAEA regularly inspects the licensee as it conducts nuclear qualification audits of foreign suppliers. Main issues identified so far are:

- project specific managements system documentation is not or not sufficiently developed by the supplier;
- suppliers' knowledge of Hungarian regulatory requirements is insufficient or non-existent;
- documents management procedures are not fully established (e.g. how, in what format, and through what channels should the sub-subcontractor hand over the documents);
- information transfer from the higher tiers to the lower tiers is inadequate;
- "chain of command" is not always clear.

Poland

PAA does not currently conduct inspections of foreign material and major component suppliers.

The Slovak Republic

ÚJD SR inspectors have participated, as observers, to several vendor audits and inspections (FAT-factory acceptance tests), namely at AREVA, SIEMENS in Germany, ASE in Russia, Rolls-Royce in France and Syscom Instruments in Swiss.

ÚJD SR did not conduct inspections directly on foreign material and major component suppliers, because all these components were delivered on site as an original delivery in the 1990s.

Slovenia

See 3.5.

The United Kingdom

ONR conducts vendor inspections as the enforcing authority for Section 6 of HSWA. ONR shares the outcomes of our vendor inspections with MDEP VICWG.

If the supplier is outside Great Britian (GB) then ONR can facilitate inspections with the licensee (using their contractual access) or could collaborate with other VICWG members through witnessed, joint or multinational (collaborative) inspections using existing MDEP VICWG collaboration protocols. However, it should be noted that ONR does not have the authority to inspect suppliers outside of GB directly unlike some other regulators associated with product certification arrangements.

ONR has developed and is implementing a comprehensive intervention plan, targeting key suppliers of safety-related activities within the supply chain, this includes GB and overseas suppliers. With the exception of the vendor inspection programme, these interventions are

conducted jointly or in the presence of the licensee. ONR would hold the licensee accountable for any deficiencies in quality of components.

ONR participates in multinational inspections with residing countries regulatory bodies. These inspections provide useful intelligence to ONR.

The United States

The NRC has conducted vendor inspections in other countries, such as Canada, France, Italy, Japan, Korea, Spain, and Sweden, where components were manufactured for the US facilities. The imposition of Part 21 in the procurement documents and the existence of an office in the United States by the foreign supplier, allows the NRC access to perform vendor inspections outside the United States.

Question 3.7

Do you have the capability (authority/experience) to assess construction organisations' management systems, or do you rely on domestic or foreign expertise?

Canada

As stated in 3.6, the CNSC has a number of suitably qualified and experienced personnel to conduct such inspections having industry experience.

The CNSC also has considerable experience in assessing construction organisation's management systems; again, staff have industry experience with both Canadian refurbishment and major component replacement, and foreign nuclear power plant construction project experience.

Finland

STUK has the possibility to perform inspections in construction organisations and in the supply chain, but mainly relies on licensee performed audits, which are also required to ensure management systems in safety-related organisations meet the requirements.

According to YVL A.3, requirement 104, organisations participating in the design, construction, operation and decommissioning of a nuclear facility shall employ a management system for ensuring safety and the management of quality.

STUK has performed inspections for construction organisations. STUK has also observed management system audits of the licensee on the construction organisation.

France

ASN has the authority to assess the construction organisation's management systems, especially in order to control its compliance with the Order of 7 February 2012. Moreover, ASN's recent guide about policy regarding risk and inconveniences' management and integrated management system provides recommendations and guidance for licensees. ASN considers this guide as a target for the licensees.

Regarding experience to assess the construction organisation's management systems, ASN is used to include the integrated management systems assessment in its inspections. ASN can also get technical assistance from IRSN to deal with specific topics during inspections.

Hungary

The regulatory body has remote access to the licensee management system documentation, and also to certain parts of their document management system, so the regulatory body has the technical means necessary to continuously monitor these, and to do ad hoc or comprehensive inspections if deemed necessary.

Poland

PAA has a limited number of suitably qualified and experienced personnel to conduct such inspections having industry experience. PAA also has considerable experience in assessing the construction organisation's management systems: staff having industry experience.

The Slovak Republic

ÚJD SR has a number of suitably qualified and experienced personnel, with industry and operational experience, to conduct such inspections.

In some specific cases, we use an external technical support organisation, mainly domestic organisations can be used. However, for commissioning activities, contracts are signed with a consortium of expert organisations that can include companies from abroad.

Slovenia

See 3.5.

The United Kingdom

ONR has established capability within the Human and Organisational Capability specialism to effectively assess the management systems of the licensee and as required key suppliers and to perform its own inspection programmes.

ONR also works with accreditation bodies to ensure learning is fed back into these organisations to address any known shortcomings in their arrangements.

The United States

NRC inspection staff pedigree includes experience in a variety of roles within domestic public utilities and architectural/engineering firms, including familiarity with management infrastructure, and in the development and implementation of operational and engineering programmes. As part of construction oversight, inspection plans include an assessment of management programmes and their propagation to lower tier directives, procedures and guidance for the construction organisation. Examples include NRC Inspection Procedures (IPs) 35007 "Quality Assurance", and 70367 "Inspection of Preoperational Testing Programme." In virtually every inspection conducted for new nuclear plant construction, including those for the current AP1 000 construction projects, inspection scope has included an assessment of key management infrastructure elements, including quality assurance, supply chain, construction deviations and resolution, and risk management/control.

NRC construction oversight staff has utilised, and continues to utilise where practical, foreign assignees to provide exposure and insights into management practices employed by foreign nuclear plant projects, including those in China and Finland, and nuclear plant suppliers in France and Japan.

Question 3.8

What regulatory expectations do you have around the licensee's reconciliation considerations for long lead items ordered prior to finalisation of design requirements?

Canada

The CNSC provides two layers of regulatory requirements for reconciliation considerations for long lead items ordered prior to finalisation of design requirements.

For overall requirements, regulatory document REGDOC-2.3.1, *Conduct of licensed Activities: Construction and Commissioning Programmes*, sets out information regarding any differences between the original purchasing requirements, the license-to-construct design basis and the as-built items shall be evaluated, reconciled and reported to authorised inspection agencies and the CNSC.

Specific to pressure-boundary materials and components, CSA N285.0-12, "General requirements for pressure-retaining systems and components in CANDU nuclear power plants/Material Standards for reactor components for CANDU nuclear power plants", sets out information regarding specific items that have long lead times that require them to be ordered before the issuance of the construction licence, the licensee shall obtain acceptance from the regulatory authority for the use of an earlier code (ASME) effective date. The licensee shall submit a comparison of the differences in the applicable parts under the standards of the two dates to the regulatory authority within six months of the issuance of the construction licence.

Finland

The Nuclear Energy Act Section 55 gives STUK the possibility to review manufacturing documentation and inspect structures and components already before construction licence grant (CLG). Structures and components approved in this way may, however, only be used for the construction of a nuclear facility if they comply with the construction licence.

Regulatory guide YVL A.5. Chapter 3.5. requests for preliminary design basis to be presented before submittal of construction plans. The design basis is commented if deficiencies are found. After CLG the manufactured components and structures shall be demonstrated to fulfil the construction licence.

Risk for LLI component to be rejected is presented and the licensee´s increased own risk in LLI components is highlighted by the regulator.

France

ASN considers that the licensee is responsible of its choice to order long lead items prior to finalisation of design requirements.

ASN controls the compliance of items important to the protection of the interests with the requirements presented in the licensee's file.

In particular, ASN is attentive to the fact that the licensee put the priority on the interests' protection, over planning considerations, for the definition of design requirements.

As for NPE, Article 6 of the Order of 31 December 2015 requires that manufacturing activities are allowed to begin once design activities are sufficiently advanced.

Hungary

According to the Hungarian regulatory requirements, the vast majority of safety-related construction activities have to be licensed or permitted by the regulatory body. This is also true for the manufacturing or purchasing of safety-related items.

The general rule is that a manufacturing permit cannot be submitted before submitting the construction licence application (CLA). During the review of the CLA, the licensee is allowed to submit manufacturing permits, which can be approved by the regulatory body before approving the CLA. After that the licensee has the possibility to execute activities based on the manufacturing permit, but only at their own commercial risk.

The content expectation for a manufacturing permit application is described in specific regulatory requirements, which are supplemented by regulatory guides. According to those,

all the detailed design and manufacturing information should be presented in the application, including their justification.

Poland

There are no specific guidelines around the licensee's reconciliation considerations for long lead items ordered prior to finalisation of design requirements.

The Slovak Republic

The ÚJD SR does not have any special regulatory requirements for reconciliation considerations for long lead items, that require them to be ordered before the construction licence is obtained.

Regulation 431/2011 determines that quality assurance requirements for selected facilities shall be specified in two phases:

a) prior to the selection of a supplier of the selected facility;

b) prior to the start of manufacturing of the selected facility.

Slovenia

The installed parts must meet the design requirements, so the comparison of used and required standards must be done to prove the adequacy of built-in items.

The United Kingdom

ONR have established expectations for an aspirant licensee who may wish to commence procurement of long lead items ahead of completing the assessment process associated with their nuclear site licence application.

These expectations include the signing of a deed between the aspirant licensee and ONR, which provides a commitment by the aspirant licensee to conduct related activities as if they were working under the constraints of a nuclear site licence.

ONR has further guidance on expectations on LLIs within TAG 077

The United States

The NRC requires the use of ASME Section III for the construction of nuclear components in 10 CFR 50.55a, "Codes and standards". Section III of the ASME Code requires that the owner (or US licensee) reconcile the code of record for the long lead items to the licensing basis code of record.

Question 3.9

What capability and competencies do you have for oversight of construction activities, including first-of-a-kind construction methods and use of innovative and emerging technologies?

Canada

The current major nuclear power plant refurbishment and major component replacement projects have provided CNSC the opportunity to enhance its construction activity capability and competencies. Note that the combined cost of these projects is equal to the cost of two large new nuclear power plants.

These projects have introduced the use of innovative and emerging technologies to install new and replacement components for which CNSC staff have updated and maintained their competencies accordingly.

For new build SMRs, vendors are proposing first-of-kind construction methods, such as off-site manufacture of concrete modular shapes for field assembly, and additive manufacturing (3D printing) for non-safety related structures and components.

Finland

STUK inspects all safety class one components and most important safety class two components and structures. FOAKs are highlighted to the licensee and their qualifications are followed closely. Inspectors usually carry relevant university degrees and experience, TSOs of relevant competence may be used to help risk assessment. When necessary and relevant, mock-ups for FOAKs (e.g. civil engineering and construction) have been required by STUK.

France

ASN relies on its internal staff, but also on its technical support, IRSN, to assess and oversight construction activities, including FOAK construction methods, and use of innovative and emerging technologies.

As detailed in answer 3.1, the oversight is proportionate to the stakes, and it is the licensee's responsibility to provide sufficiently detailed information to demonstrate the safety of its construction methods and technologies. If considered necessary, ASN can ask the licensee to proceed to model testing, or to additional testing in order to achieve a high level of confidence.

As for NPE, authorised third party bodies may intervene for oversight of design and manufacturing activities.

Hungary

The Hungarian Regulatory Body has its own competencies for oversight of construction activities, based on the 30 years of experience in the oversight of nuclear facilities. Most importantly, the major nuclear power plant refurbishment and LTO projects have provided HAEA the opportunity to enhance its construction activity capability and competencies. The HAEA also placed great emphasis on the development of the training programme of the staff. The HAEA staff participated in many international activities to bring the knowledge from the new innovative technologies and trends in nuclear safety.

In the case of identified weaknesses the HAEA has the right and resources to involve internal or external TSO's or experts.

Poland

PAA has a number of suitably qualified and experienced personnel for oversight of construction activities and assessment of documentation. We are focusing on existing and proven technologies as opposed to first-of-a-kind and emerging technologies.

The Slovak Republic

Before the construction of Unit 3 and 4 restarted ÚJD SR had enhanced its construction oversight capability and competencies.

Despite the fact that the original design comes from the Soviet time period, this project has brought a lot of innovative and emerging technologies, especially in the I and C area. This fact forced ÚJD SR staff to update and maintain their competencies accordingly. For instance, ÚJD SR has hired experts who are knowledgable about using new platforms for safety systems.

For potential new build, details are not yet known.

Slovenia

The Slovenian regulations give the SNSA an opportunity to use Technical Supporting Organisations each covering their own area of expertise.

The United Kingdom

ONR has the internal skills for overseeing the construction activities of a first-of-a-kind major new build. These skills and experience are supplemented by specialist contractors under a technical support framework, as required.

SMRs/ANTs present a raft of potential additional challenges in relation to modularisation, extensive factory-based manufacture and assembly of significant scale modules and their testing, extensive national and international supply chains, transportation issues and many others. ONR in common with a number of other national regulators are taking part in the IAEA hosted SMR Forum and its subgroups exploring these issues and their likely impacts on our regulatory frameworks. ONR is currently investing in upskilling ONR resources in both technical and licensing fields in order to prepare for future assessment activities for SMRs and ANTs.

The United States

NRC inspectors engaged in construction oversight include discipline-specific specialists (civil/structural, mechanical, electrical), as well as specialists to assess processes (e.g. welding, quality control) and automation (e.g. digital systems design and development) for new generation nuclear plant control. Additionally, NRC inspectors have access to training as needed to refine and/or expand core competencies and expertise in other specialised areas. Construction inspectors are qualified in accordance with the NRC's qualification programme for reactor inspectors, described in Inspection Manual Chapter (IMC) 1245, Appendix C15 (ADAMS Accession No. ML17072A344).

The NRC was able to take direct advantage of previous new nuclear (AP1 000 design) construction in China, allowing inspectors to observe first-of-a-kind (FOAK) construction practices and initial testing for the new design. Inspectors continue to gather operating experience as the China facilities progress (see Item 3.2). Strategically, lessons learnt from this approach would be applied to next generation nuclear plant construction oversight.

Question 3.10

What is your practice for including regulatory hold and witness points throughout the manufacturing and construction processes?

Canada

The CNSC does not customarily apply regulatory hold and witness points throughout the manufacturing and construction processes. Regulatory document REGDOC-2.3.1, *Conduct of licensed Activities: Construction and Commissioning Programmes*, sets out information regarding how contractors could also be visited by the CNSC as part of regulatory oversight, particularly if the equipment they are manufacturing, or their construction/installation has high nuclear safety significance.

Finland

YVL guides define many hold and witness points for manufacturing and are thereby written in design documents.

During construction STUK inspectors may also add inspection points in installation plans according to the extent they deem them necessary.

France

In accordance with the main principle related to the primary responsibility of the licensee, no hold and witness point is imposed by the French regulatory framework before the beginning of construction activities, except for the regulatory hold point mentioned above (3.8) regarding the assessment of design progress before starting the NPE manufacturing activities.

However, if considered appropriate, ASN can enact regulatory decisions to enforce hold points, for critical activities or milestones, or after the finding of a significant non-compliance. For example, ASN's decision no 2013-DC-0347 of 7 May 2013 sets the inner containment pressure test of the EPR of Flamanville 3 as a hold and witness point. Also, ASN enacted a decision (Decision no 2018-DC-0642 of 26 July 2018) to submit the first pressurisation of certain pipes to its approval following the finding of welding issues in the secondary circuit of Flamanville 3.

Hungary

The HAEA determines the regulatory hold and witness points in the licensing process and it is a part of the issued licences. It is based on the information provided by licensees, and the main aspect are the nuclear safety significance using a graded approach.

Annexes 1 and 9 to Govt. Decree No. 118/2011 (VII. 11.). states the following:

> *1.2.3.0500. The schedule and accomplishment of construction activities shall be demonstrated in the licence application in such detail that based on the aforementioned the nuclear safety authority is able to determine retention points applicable for monitoring purposes, and to plan its monitoring.*
>
> *9.5.3.0300. A multilevel schedule shall be prepared, which is suitable for management overview and for the identification of the sequence of successive items of work. The schedule shall include the authority arrest points. The time requirement of the authority inspections shall be considered in the preparation of the schedule.*

Poland

The PAA can establish hold and witness points in licence conditions during the process of granting a licence or consent to modification. So far we can use this only during the modification process.

The Slovak Republic

Although the ÚJD SR has the right to apply regulatory hold and witness points throughout the manufacturing and construction processes this tool is not often used. Nowadays practically no internal provision exists in documentation of ÚJD SR defining some rules or criteria. ÚJD SR more often uses the point of FAT to check manufacturing process.

Slovenia

As it is mentioned in 3.5 direct supervision of the vendor's manufacturing process could be done only together with the operator. In such cases hold and witness points are defined together with the operator.

The United Kingdom

Once an NSL has been granted, ONR controls activities on the nuclear site through a permissioning regime. ONR has the legal framework to specify regulatory hold points, for construction activities on site or for permissioning the receipt of components delivered to the site. This is usually done through derived powers under LC 19 specifically 19(1). The

construction process is divided into stages and the licensee will define hold points through which it will not progress without regulatory approval (derived powers); alternatively, if required, ONR can define a regulatory hold point through which a licensee cannot progress without regulatory approval (primary powers).

The United States

In oversight of construction processes, the NRC has no provisions for imposing hold or witness points in inspection activities. Inspectors rely on pre-inspection co-ordination with licensees to ensure that inspectors are contacted and given the opportunity to witness and/or verify critical attributes of safety-related structure, system, and component construction, installation, and testing. This approach is driven by NRC's goal to have no impact on construction progress and schedule.

In addition, the NRC will conduct vendor inspections to sample the licenses' oversight during the manufacturing process of safety-related components. The NRC does not have hold or witnessing points as part of the manufacturing process.