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Nuclear Regulatory Organisations' Oversight of New Licensee Organisational Capability

Workshop Proceedings
Chester, United Kingdom
March 2017

Appendices

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NEA/CNRA/R(2017)6/ADD1

Nuclear Regulatory Organisations' Oversight of New Licensee Organisational Capability

Workshop Proceedings **(Appendices)**
Chester, United Kingdom
March 2017

Report produced in association with the British

Contents

Introduction

This supplementary document contains the appendices that are referred to in the proceedings report for the NEA Workshop on Regulatory Oversight of New Licensee Organisational Capability.

This document contains 5 sections, these are outlined below:

- Appendix A contains the results from the survey that initiated this workshop,
- Appendix B contains the position papers,
- Appendix C contains the workshop presentations,
- Appendix D contains the slide packs (both session slides and feedback slides) of the breakout sessions, and
- Appendix E contains summaries of the breakout sessions.

Appendix A – Survey Results

An analysis of the results of the survey can be found on the following pages:

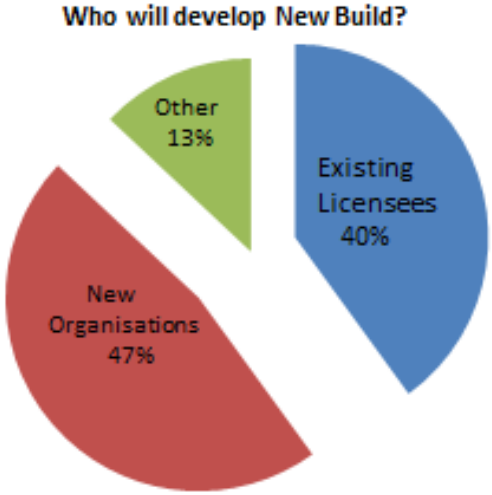
Survey Results

The Survey had 9 respondents and:

- Gathered information on how Organisational Capability is dealt with by regulators at present and the new built landscape experienced in each country.
- Sought feedback on the issues experienced by regulators and the issues each respondent wanted to explore at the workshop.

Survey Results

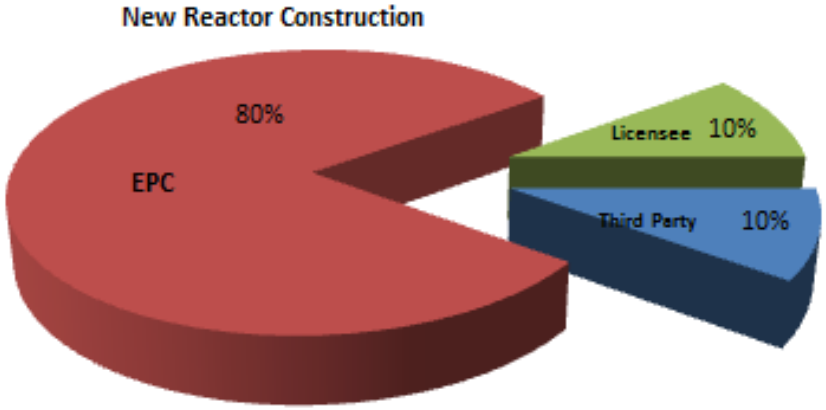
Question 1: In your country, will new nuclear reactor facilities be developed, built and operated by existing licensees and/or new organisations?



Survey Results

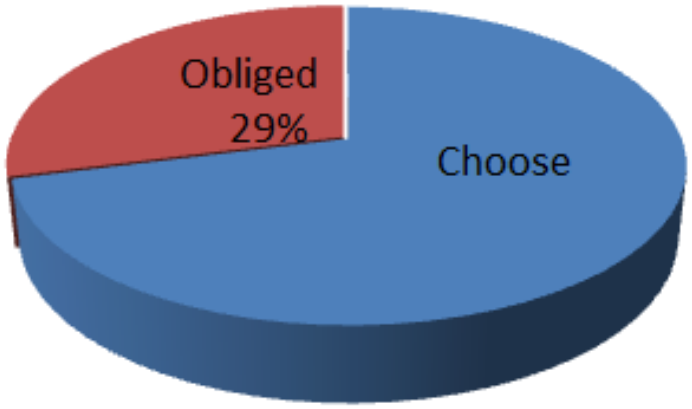
Question 2: In your country, What is the business model that will be used during construction of new nuclear reactor facilities;

a) Who is the construction lead body?



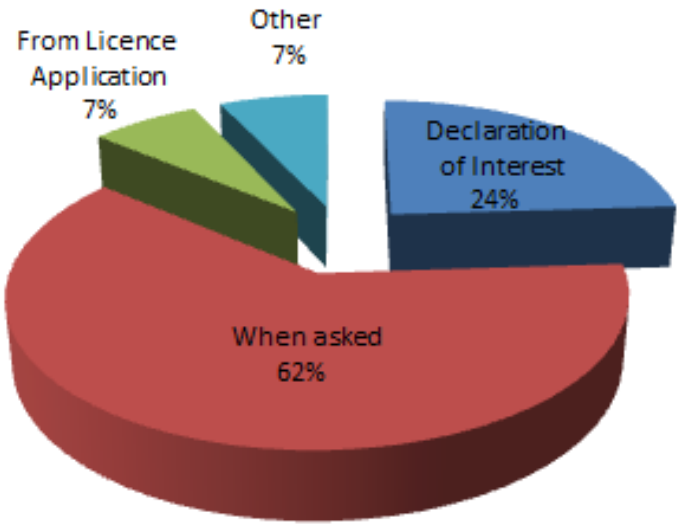
Survey Results

Question 3: Do you have the legal authority to engage with companies intending to construct and operate nuclear facilities before they submit a licence application ('early engagement')? Do you choose to do so or are you obliged to do so?



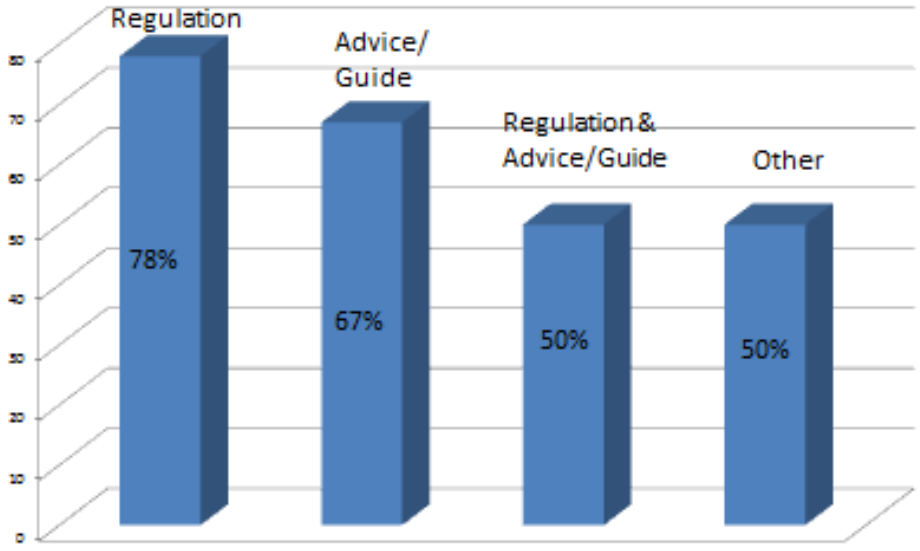
Survey Results

Question 4: When do you start to engage with the new build organisation?



Survey Results

Question 4a: Do you proactively offer advice and guidance?



Survey Results

Question 4b:Do you engage only in response to requests or safety submissions?

Yes: 33%

No: 67%

Survey Results

Question 4c: Are you formally assessing anything prior to licence application?

Yes: 78%

No: 22%

Survey Results

Question 5: Do you have published regulatory expectations regarding the development of organisational capability by companies intending to develop, construct and operate nuclear reactor facilities?

Yes: 67%

No: 33%

Survey Results

Q6: Do you use any other guidance to inform the development of your national regulatory expectations, guidance and approach?

IAEA Standards – 78%

Other - 67%

Examples include ISO standards, WENRA Reference Levels, ANSI, ASME

Survey Results

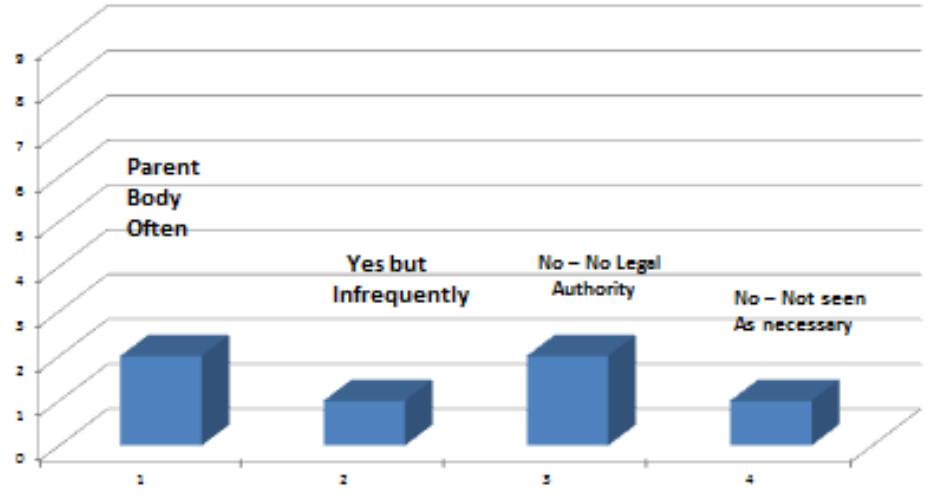
Q7: Do you consider there are any gaps in your guidance, or areas That warrant revision or further development?

Yes – 78%

Examples: IC, Safety Culture, Ownership, Procurement of equipment and services, SMR's, Regulatory interactions with NB Orgs.

Survey Results

Q8: Do you interact with parent bodies of the proposed new build, Development/construction/operation organisations regarding their roles in areas such as funding and the influence they have on the Licensee development?



Survey Results

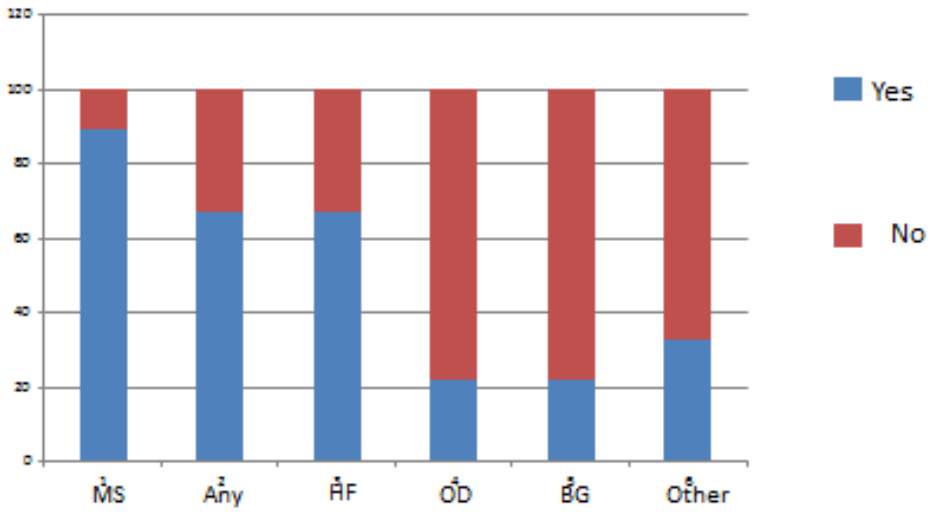
Q9: What level of regulatory resource is dedicated to engaging with New organisations specifically on the development their organisational capability?

- Typically 1 to 2 FTE's prior to Licence application
- Typically 2 to 3 FTE's prior to Licence Grant

One respondent had a larger dedicated resource of around 5 FTE's both pre and post licence application. However, some respondents stated that they also used external technical support to assist them in their assessments in this area.

Survey Results

Q10: Do you specify any experience or competence requirements for your regulatory inspectors who work in this area?



Survey Results

Q11: Who do you engage with in the new build/construction/ operation organisation and what do you do?

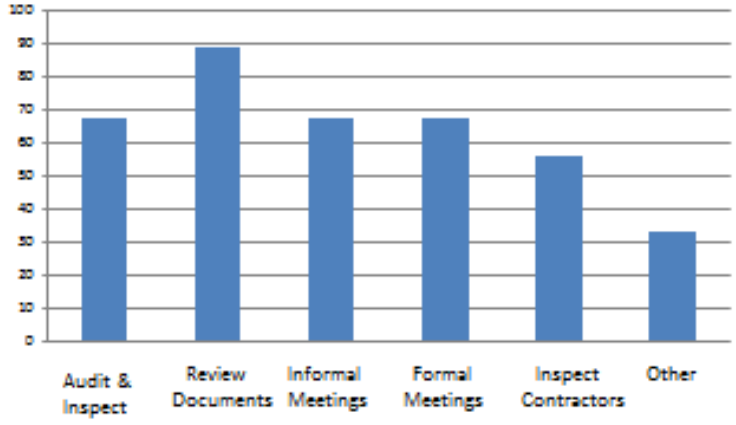
11a: Who do you engage with?

- 8 respondents are engaging at all levels
- 1 respondent is engaging on technical issues only

Survey Results

Q11: Who do you engage with in the new build/construction/ operation organisation and what do you do?

11b: What do you do?



Survey Results

Q12: You were asked to list your top 5 challenges to the development of new build Organisations:

1. Lack of nuclear experience in building OC
2. Shortage of resource in a competitive market
3. Lack of awareness of regulatory expectations
4. Building an OC is not a priority
5. Over reliance on RD, EPC contractor and OE
6. Underestimation of task of building OC
7. Slow pace of delivery
8. Building an adaptable organisation
9. Development and implementation of a Management Systems

Survey Results

Q13: You were asked to list your top 5 challenges you face in relation to your regulatory oversight of OC development:

1. Regulatory resources/conflicting priorities
2. Training and experience of regulators in OC
3. Powers under legal framework
4. Availability of guidance
5. Information on good practise
6. New build company understanding and reaction
7. Relationships with other involved regulators

Survey Results

Q14: You were asked to list your top 5 most effective approaches To share with your colleagues:

1. Early engagement
2. Establishing regulatory expectations and guidance and communicating these to NB Orgs.
3. Establishing internal regulatory expectations and guidance and training regulatory staff
4. Establishing and maintaining a licensing plan by NB Org.
5. Establishing a Regulatory Inspection Plan in some NB Org. self audits
6. Understanding the impact of OC on the development of the SC - integration of technical assessment and OC assessment

Survey Results

Q15: What are the top five topics that you would like the WGRNR Workshop in March 2017 to cover?:

- New ownership and operating models being proposed by NB organisations – impact on IC, safety culture and governance
- Establishing and measuring good nuclear safety culture in licensee applicant organisations.
- Best practise in regulatory oversight of HOF in licensee applicant
- Reliance upon oversight of RD, EPC and OE during design and construction – establishing best practise.
- SMR's and operating/ownership models – OC – potential inexperienced operators
- Procurement of equipment and services – IC capability.
- Access to design information from the RD/Vendor over lifetime of the project.

Survey Results

Q15: What are the top five topics that you would like the WGRNR Workshop in March 2017 to cover?:

- Training and certification of inspectors.
- Many of the new emerging companies in new build have a very significant technical/design focus rather than on building a capable organisation.
- Regulatory culture and risk appetite
- Establishing international and national regulatory guidance for requirements and assessment of OC
- Transition from established nuclear organisations to new build organisations – knowledge management/transfer issues.
- Generic design assessments (UK&Canada) versus site specific SC approach

Survey Results

Thematic analysis is subjective based on interpretation and aggregation of associated themes. Can be interpreted in different ways.

Similar analysis has been conducted by NEA based on survey returns (not including the UK's return) and has yielded similar themes but with a different emphasis and is equally valid. The WGRNR should consider the themes identified in the two analysis approaches and select an agreed set of themes for the workshop.

Based upon:
The analysis in this presentation
The NEA analysis

Appendix B – Position Papers

The Position Papers are provided covering the following topic areas and questions. These are the collated responses from the countries/organisations that replied to the following questions for each topic:

1. Challenges in Developing Organisational Capability

1.1. Building Organisational Capability

1.1.1. How can new licensee awareness of regulatory expectations be improved?
1.1.2. Do new licensees understand the scale of the task?
1.1.3. Are new licensees focused on building a capability that can adapt through the phases of the project?
1.1.4. How can capability be developed in a competitive market short of nuclear skills?

1.2. Developing Leadership and Governance

1.2.1. What should be your expectations for new licensee governance standards?
1.2.2. How should these expectations change as the project develops?
1.2.3. What should be your leadership expectations across new licensees?
1.2.4. Is there sufficient guidance/best practise available on these issues?
1.2.5. How do ownership models influence governance and leadership?

1.3. Developing Strong Safety Culture

1.3.1. What's different about developing strong safety culture in new licensees (compared to long established operators)?
1.3.2. What is best practise for developing strong safety culture?
1.3.3. How should you assess safety culture in new licensees?
1.3.4. What are the risks to maintaining strong safety culture across the project lifecycle?

1.4. Developing Internal Independent Regulation

1.4.1. How important is the concept of IR and is it essential for new licensees?
1.4.2. Do you have sufficient regulatory guidance on your expectations for IR?
1.4.3. How should regulators interact with internal regulators?

2. Regulatory Challenges with New Licensees

2.1. Regulatory Readiness

2.1.1. What are the regulatory skills and experience needed to support the development of OC in new build organisations?
2.1.2. How should regulatory staff be trained for assessment of OC in new build organisations?
2.1.3. How can regulators attract experienced/skilled staff in a competitive market?
2.1.4. What are the challenges of transitioning your regulators from dealing with long established licensees to new build organisations?

2.2. Engagement Strategies

2.2.1. When should you engage with new build organisations?
2.2.2. How should you engage with new build organisations?
2.2.3. Should you engage with parent bodies, if so when and how?
2.2.4. Should you engage with contractors and suppliers, if so when and how?

2.3. Development of Guidance

2.3.1. What are the key areas regulators need to focus across OC for new build organisations?
2.3.2. Do you have sufficient guidance across areas regulators need to focus across OC for new build organisations?
2.3.3. Do you have sufficient guidance across these areas – where are the gaps?

2.4. *Interfacing* with other Regulators

2.4.1. Are you legally required to engage with other regulators?
2.4.2. How and when do you engage?
2.4.3. Do you coordinate regulatory activities with the new licensee?
2.4.4. Which stakeholders do you engage with and how?

3. Oversight of Contractors and Suppliers by New Licensees

3.1. Balance between New Licensee Capability and Reliance on Contractors

3.1.1. Where is the correct balance?
3.1.2. What are your expectations for the role of the IC?
3.1.3. What are your expectations for the use of embedded contractors?
3.1.4. What should be your expectations in the use and reliance upon an Owners Engineer?

3.2. The EPC Model

3.2.1. What should be your expectations for the oversight of the EPC contractor by the new licensee?
3.2.2. What are your expectations for IC in relation to the EPC?

3.3. Supplier Surveillance

3.3.1. Do you have the legal framework to adequately regulate the use of the supply chain?
3.3.2. Do suppliers understand the regulatory requirements?
3.3.3. What should be your expectations of new licensees in overseeing the supply chain – is there sufficient guidance?

3.4. Project Management

3.4.1. What should be your expectations in regard to project management for new build organisations?
3.4.2. Do you have sufficient guidance and cited best practice?
3.4.3. How should you assess new licensee project management capabilities and influence them?

Topic 1 – Challenges in Developing Organisational Capability

1.1. Building Organisational Capability

Answers	Learning
CANADA	
1.1.1 How can new licensee awareness of regulatory expectations be improved? By engaging with potential licensees as far as possible before they intend to construct and operate nuclear facilities. CNSC will provide information regarding requirements and guidance, and the licensing process. Companies are encouraged to have such discussions early to understand the most efficient licensing paths available for them to use and to understand where their approaches may present regulatory challenges (i.e. state of licensee and/or technology readiness). The engagement can be informal or more formal. One particularly useful formal process available to reactor vendors is the CNSC's Pre-Licensing Vendor Design Review Process. A pre-licensing review is an optional service provided by the CNSC. The review can be undertaken by a reactor vendor prior to an applicant's submission of a licence application to the CNSC. This review can provide early identification and resolution of potential regulatory or technical issues in the design process, particularly those that could result in significant changes to the design or safety analysis. A part of this process is a review of the management system for the design process and quality assurance in design and safety analysis, which would feed into the licensee's own management system. . The review however is not part of the licensing process because the licensing process concerns an applicant for a licence to conduct activities regulated under the Nuclear Safety and Control Act. The technology vendor may use the results of the Vendor Design Review Process in discussions with a potential applicant seeking to reference the design in their application for a licence and therefore can be used to improve licensees' awareness of regulatory expectations 1.1.2 Do new licensees understand the scale of the task? In the short time, no new licensees are envisaged as the current potential vendors are in discussion with existing capable licensees. However should new licensees come to the table, it is anticipated that education on the amount of responsibilities and scale of the task would be needed. 1.1.3 Are new licensees focused on building a capability that can adapt through the phases of the project? 1.1.4 How can capability be developed in a competitive market short of nuclear skills?	- **The benefits of formal versus informal engagement with potential future licensees** - **The need for the Regulator to provide funded learning mechanisms (processes and tools) to enable licensees to develop and maintain an understanding of:** · **the role of regulation and regulatory fundamentals** · **The fundamental principles underpinning regulatory expectations** · **The relationship between regulatory requirements and the licensee's (i.e. user) requirements** · **Fundamental attributes of the nuclear sector that are similar or differ from other industry sectors and what that means from an organisational capability perspective** · **The difference between the Canadian regulatory framework and requirements and other nuclear regulatory regimes**

FINLAND	
1.1.1 How can new licensee awareness of regulatory expectations be improved? Hold meetings with licensee, organise trainings concerning regulations, constant discussion with the licensee, it is also possible to review licensees documentation before the construction licence application is sent. 1.1.2 Do new licensees understand the scale of the task? Depends on how much experienced personnel they have, lack of experience in previous projects is not a good thing. Then the scale is probably underestimated. 1.1.3 Are new licensees focused on building a capability that can adapt through the phases of the project? Certainly they are trying, this is very difficult to assess but long term plans are made for resourcing and development of organisations. Generally the main outlook is quite short sighted so this could be improved. 1.1.4 How can capability be developed in a competitive market short of nuclear skills? Challenging issue, it is good to have contacts that can be attempted to be recruited. Good training programs and ability to hold on to employees is important. Good reputation should be focused on (needs good safety culture also).	**Finland has already submitted the survey where such items were identified and the proposal for the program earlier and those issues should be discussed.**
HUNGARY	
1.1.1 How can new licensee awareness of regulatory expectations be improved? There are several possible ways to achieve this: - well structured, and sufficiently detailed legal requirements; - comprehensive set of regulatory guidelines; - appropriate requirement management solutions; - regular interaction with licensee, on both management and expert level; 1.1.2 Do new licensees understand the scale of the task? Overall yes, but we've observed shortfalls in mid- and long term planning of task and resources. 1.1.3 Are new licensees focused on building a capability that can adapt through the phases of the project? Yes. 1.1.4 How can capability be developed in a competitive market short of nuclear skills? The challenge is that usually staff with nuclear experience is not available on the market, so people for non-nuclear	**Challenges** **Capability development in a competitive market**

industries have to be hired. Because of this, stakeholders have to develop a robust human resources development plan, which includes a comprehensive training plan. Due to shortfalls in the available training opportunities on the market, the training plan has to focus mostly on in-house and on-the-job training, or look for international training opportunities.

KOREA

1.1.1 How can new licensee awareness of regulatory expectations be improved?

- In Korea, regulatory information such as Atomic Energy Act, Enforcement Regulation, Regulatory Guides are provided through the web site of Nuclear Safety Information Centre(NSIC, http://nsic.nssc.go.kr/main.do).
- **In addition, most of regulatory expectations could be delineated in the annual workshop for regulatory information.**

1.1.2 Do new licensees understand the scale of the task?

- **The Korea Institute of Nuclear Safety (KINS) thinks that the new licensees can understand the scale of the task including the organization capability.**

1.1.3 Are new licensees focused on building a capability that can adapt through the phases of the project?

- The KINS believes that new licensees have to focus on building their capability prior to start new project. However, we don't have new licensee trying to construct a commercial nuclear power plant in Korea.

1.1.4 How can capability be developed in a competitive market short of nuclear skills?

- The short of nuclear skill and experts are one of the biggest obstacles for development of organization capability, and new licensee will try to recruit experienced engineers from current utilities.

NETHERLANDS

1.1.1 How can new licensee awareness of regulatory expectations be improved?

- Early start with pre-licensing meetings
- Explanation on the way the Regulatory Body will perform the PSAR review (Technical Review Plan)
- Meetings in which the Dutch Safety Requirements are explained and discussed.

1.1.2 Do new licensees understand the scale of the task?

No, see point 4 'Learning'

1 lack of national nuclear experience base in building a reactor company capability

2 building an organisation and infrastructure that can adapt as project progresses

3 management system development and

1.1.3 Are new licensees focused on building a capability that can adapt through the phases of the project?

No, see point 1 'Learning'

1.1.4 How can capability be developed in a competitive market short of nuclear skills?

Question mark, see point 5 'Learning'

implementation

4 underestimation of scale of task to build capable organisation

5 shortage of resource in a competitive market

POLAND

1.1.1 How can new licensee awareness of regulatory expectations be improved?

Publication of non-binding regulatory guides; working level meetings between future licensee and regulatory body.

1.1.2 Do new licensees understand the scale of the task?

Their understanding is increasing during the project.

1.1.3 Are new licensees focused on building a capability that can adapt through the phases of the project?

They have such intentions.

1.1.4 How can capability be developed in a competitive market short of nuclear skills?

It's even harder in embarking countries without ant nuclear power industry.

General topic to be discussed at workshop:

Situation of embarking countries where one has to face not only new licensee but also new regulatory body (or regulatory body without experience in regulation of large scale industrial project like NPP construction and commissioning).

RUSSIA

1.1.1 How can new licensee awareness of regulatory expectations be improved?

Until recently there was only one operating organization (which is also licensee) for NPPs in Russia - JSC "Concern Rosenergoatom". At present, Rostechnadzor considers an application for the construction license of BREST-OD-300 demonstration reactor facility from the new operating organization JSC "Siberian Chemical Combine". This organization, however, has considerable experience in the field of nuclear energy use (it is the operating organization for a number of nuclear fuel cycle facilities), and hence the significant experience of cooperation with Rostechnadzor. Therefore Rostechnadzor has no specific goal to improve the awareness of new licensees about the regulator's expectations, since the new licensee is the organization with the extensive experience in this field.

The expectations of the regulator are stated in rules and regulations of nuclear energy use, safety guidelines and other guidance documents provided by the regulator and available for any stakeholders.

1.1.2 Do new licensees understand the scale of the task?

Yes, they are quite aware of this. (See also the answer to p. 1.1.1)

In accordance with Russian legislation, nuclear installation

siting license applicant must be recognised by the control body in the field of nuclear energy use (State Corporation ROSATOM) as suitable to operate a nuclear reactor, handle radioactive materials and to work on design, construction, operation and decommissioning of nuclear installations, on their own or with the assistance of other organizations. The applicant attaches these data to the application when applying for a license to regulator (Rostechnadzor), along with other documents, including a set of safety case documents. Thus, multi-stage control system is implemented.

1.1.3 Are new licensees focused on building a capability that can adapt through the phases of the project?

Issues of funding and logistical & human resources are in the area of responsibility of the operating organization (p.1.2.2.4 of the federal rules and regulations in the field of nuclear energy use "General regulations on ensuring safety of nuclear power plants" NP-001-15); the current situation in these areas is under the regulatory supervision.

1.1.4 How can capability be developed in a competitive market short of nuclear skills?

The shortage of skills in the nuclear field is not typical for the Russian licensees.

Basically it is advisable to develop a potential in a competitive market by ensuring equal regulation requirements for all licensees and adjusting these requirements according to contemporary science and technology and the best practices.

UNITED ARAB EMIRATES

1.1.1 How can new licensee awareness of regulatory expectations be improved?

Early and regular communication. Communication can be initiated by either licensee or regulator and should begin in advance of license application submittals. Example: FANR initiated communication with ENEC / Nawah 1.5 years in advance of operating license application submittal to discuss topics where differences exist between FANR regulatory requirements and regulatory body country of origin – Republic of Korea (e.g. Integrated Management System, operational readiness process)

1.1.2 Do new licensees understand the scale of the task?

One issue with new comer country is that regulatory framework may be developing at same time the license application is being prepared which can lead to misunderstandings in requirements and expectations. From the regulatory perspective it is apparent that the prospective operating licensee is finding challenges particularly in area of staffing for operations and qualifying staff to perform work. The regulatory expectations however are clear but this has taken time.

1.1.3 Are new licensees focused on building a capability that can adapt through the phases of the project?

This depends on how the organization and contractual arrangements are established and can differ greatly from project to project. In the UAE, the initial approach was for a Korean design, build, and operate arrangement. This approach changed pre-construction which has created several challenges for developing capability and adapting from commissioning to operations.

1.1.4 How can capability be developed in a competitive market short of nuclear skills?

The UAE has benefitted in this regard due to its ability to attract experienced nuclear professionals from around the world (competitive compensation packages, English speaking business culture, stability, and lifestyle). However most new comer countries or expanding nuclear programs would find this very challenging. Capacity building initiatives should be established well in advance of the decision to begin a nuclear program to ensure capability in the pipeline (university programs, research initiatives).

UNITED KINGDOM

1.1.1 How can new licensee awareness of regulatory expectations be improved?

The ONR publishes its guidance on regulatory expectations for licensing of nuclear installations. The document, Licensing Nuclear Installations (LNI), details ONR's general expectations. Specific requirements are published in the ONR's Safety Assessment Principles (SAPs) and in our Technical Assessment Guides (TAGs) for Inspectors and our supporting Technical Inspection Guides (TIGs) for Inspectors. The latter focus upon Licence Condition Compliance. These guidance documents aim to incorporate appropriate international and national guidance.

ONR engages with potential new licensees early in their licensing preparations by providing advice and guidance as they develop their licence application and develop their organisation and arrangements.

ONR sets out its approach to this phase of engagement in a published Pre-Application Intervention Strategy, which is specific to each potential licensee.

Whilst the range of guidance is extensive there are still some gaps, for example, specific guidance from ONR regarding Corporate Governance and structured guidance on justification of site suitability.

1.1.2 Do new licensees understand the scale of the task?

In general, the scale of the task seems to be underestimated by most prospective licensees but the degree varies considerably. Some potential licensees have existing direct links to current Operators and construction organisations to

draw upon. Others lack these direct links but may be linked to designers and vendors. This variability has the potential to lead to a lack of understanding of what the organisation actually needed at each stage of the project. In our experience, the rush to secure nuclear professionals in a very competitive market and can lead to having the wrong skills/knowledge profile early in the development of the organisation, which then leads to subsequent major re-alignment once a greater understanding is acquired.

There is also the potential that the focus of new organisations is on technical design issues rather than the organisational development issue. The UK has separated these issues by introducing the GDA process which assesses the design for suitability in the UK regulatory environment. The UK licensing process does not license the design; it licenses a Corporate Body to undertake specified nuclear activities on a specific site. The site specific design and safety case, subsequent construction, commissioning, operational and decommissioning activities are controlled using a permissioning regime under the nuclear site licence.

1.1.3 Are new licensees focused on building a capability that can adapt through the phases of the project?

As discussed under question 1.1.2 above, the extent to which prospective licensees understand this varies considerably. As stated earlier, in a competitive nuclear skills market there can be a rush to secure scarce resource which can lead to the wrong skills/knowledge profile at the wrong time/phase of the project. This can require major re-adjustments to fledgling organisations. Nuclear Power stations are not built very often and in many Western countries, have not been built for several decades. Hence the knowledge of what is required from an organisational perspective at each of these pre-operational stages of the project is scarce with most nuclear professionals in the UK for example having the majority of their experience in the operational phase for existing reactors.

1.1.4 How can capability be developed in a competitive market short of nuclear skills?

Building a nuclear new build organisation is a significant task and needs to be planned in detail well in advance. A strategic approach to organisational development is necessary to avoid re-adjustments to organisational capability plans. For a country like the UK, the majority of nuclear skills are in operational environments and not in design, build and commissioning – hence the UK has a skills gap in these areas. Government has a role to play in developing educational strategies that develop the skills needed to meet its long term energy policies but this does not develop experience. This experience can only come from building and commissioning; this is a shortfall that needs to be addressed to support major new build programme as the UK or indeed many western

countries has not been engaged in reactor new build for some time.

The licensing of a new build organisation and the design, build and commissioning of a new reactor takes the best part of a decade and many of the operating staff may be in, or entering, the education process at this time. Hence, new build organisations need to engage with the local educational institutions early to ensure that a flow of individuals with the correct skills, aptitudes and knowledge are available locally to join the experienced workforce that may have to be drawn from a wider geographical base (depending on the local nuclear skills profile).

UNITED STATES OF AMERICA

1.1.1 How can new licensee awareness of regulatory expectations be improved?

The NRC improves new licensee awareness of regulatory expectations through (1) providing publically available information on regulatory requirements, guidance, and expectations, (2) meeting with potential new licensees to discuss their plans and NRC requirements and expectations, and (3) outreach through workshops and seminars. In addition, new licensees should (1) make use of information developed by organizations such as the American Nuclear Society, Electric Power Research Institute, and Institute for Nuclear Power Operations, and (2) engage with existing licensees and companies involved in commercial nuclear power plant development and operations to understand how they have historically met regulatory expectations.

Prospective new licensees initiate communications with the NRC at their discretion. It is important for prospective applicants to become familiar with the NRC's regulatory structure, policies, requirements, and processes early in the application planning process. The NRC's public Web site (http://www.nrc.gov/) is a resource for such information. The NRC's Web site for new reactors (http://www.nrc.gov/reactors/new- reactors.html) is a source for current requirements, guidance, and information on new reactors and applications. In addition, this Web site provides extensive information on applications currently undergoing NRC review and the licenses, certifications, and permits recently issued. The NRC's advanced reactors Web site (http://www.nrc.gov/reactors/advanced.html) is a source for current regulatory and technical issues concerning advanced reactors and small modular reactors. In addition, this Web site provides information on the business entities currently engaged in pre-application activities and the respective reactor designs.

1.1.2 Do new licensees understand the scale of the task?

The extent to which prospective new licenses understand the scope and scale of the needed organisational capability and regulatory process and expectations varies considerably. New licensees that have had some exposure to commercial nuclear power plant development and operations are generally more familiar with the needed organisational capability and therefore, more prepared to undertake the task.

Prospective new licensees should become familiar with the identification and resolution of regulatory and technical issues encountered by prior applicants/pre-applicants. The NRC's Web sites provide electronic links to information authored by both applicants/pre-applicants and the NRC throughout the application submittal and review process (e.g., pre-application public meetings, applicant authored topical reports and FSARs, NRC requests for additional information and applicant responses, and NRC safety evaluation reports).

1.1.3 Are new licensees focused on building a capability that can adapt through the phases of the project?

Within the U.S., most new nuclear power plants are being pursued by existing licensees. As such, these organizations are more able to transition new build projects through the various phases such as concept, development, construction, pre-operational testing, and operations. New licensees with no prior experience should consider the need to request assistance from organizations and individuals with experience in building organisational capability associated with commercial nuclear power plants.

1.1.4 How can capability be developed in a competitive market short of nuclear skills?

Significant planning needs to occur in advance to mitigate challenges associated with potential skill shortages. This includes assessing the critical skills needed, determining when they are needed, and designing a strategy to fill the critical skills. Potential actions could include assuring that colleges and technical organizations have programs in place to develop and prepare individuals with the appropriate skills that are forecast to be in shortage, and the programs themselves should be periodically updated to meet projected future demands and evolving technologies. Programs can also be put in place to accelerate the learning of journeyman to transition them into experienced professionals. In the absence of sufficient planning and preparation, organizations typically rely upon contractors and external organizations to bring about the needed expertise.

1.2. Developing Leadership and Governance	
Answers	**Learning**
CANADA	
1.2.1 What should be your expectations for new licensee governance standards? 1.2.2 How should these expectations change as the project develops? 1.2.3 What should be your leadership expectations across new licensees? 1.2.4 Is there sufficient guidance/best practise available on these issues? 1.2.5 How do ownership models influence governance and leadership? Discussion on new ownership and operating models for power reactor facilities (whether NPPs or SMRs) given the increasingly international approach to deployment and customer support. Ownership models are evolving into models that increasingly draw resources from foreign vendor and related services companies. CNSC regulatory document RD/GD-369, Licence Application Guide: Licence to Construct a Nuclear Power Plant, addresses human and organisational factors throughout its guidance. It stresses the necessity for the applicant to demonstrate the knowledge, skills and abilities of its workers and those of the major contractors and their subcontractors. CSA N286 standards on management system spells out requirements for management of contractors /suppliers. For instance, the applicant should : - provide a policy on the use of contractors - provide a process of assessment or qualification of contractors **- ensure there is rights of access for inspection of contractors by licensee and regulatory body** In practice this means that the utility must have direct oversight over EPC company.	-**How to further reinforce the Intelligent Customer model in a regulatory framework** **-Providing clearer guidance on what a minimum level of licensee capabilities should look like to be an Intelligent Customer when dealing with extensive use of outsourced (and international) equipment and services suppliers**
FINLAND	
1.2.1 What should be your expectations for new licensee governance standards? No such requirements from the Finnish regulator possibly there should be… Good leadership, management and prioritising safety is always expected. 1.2.2 How should these expectations change as the project develops?	

1.2.3 What should be your leadership expectations across new licensees? Good understanding of safety culture is a must. it must be understood that safety issues and project progress decisions must be handled together. 1.2.4 Is there sufficient guidance/best practise available on these issues? Practical guidance not so much, a lot of requirements exists. 1.2.5 How do ownership models influence governance and leadership? One should be aware of possible conflicts of interest. In Finland the oversight focus has not been so much in these issues.	
HUNGARY	
1.2.1 What should be your expectations for new licensee governance standards? 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. 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. 1.2.2 How should these expectations change as the project develops? It is expected, that before any nuclear safety related activity (e.g. design) starts, a management system ensuring robust leadership and governance should be developed, put in place and then evaluated for effectiveness. After it has been successfully implemented meeting the highest expectations, and nuclear safety related activities have started, they shouldn't change, taking into account specific circumstances by any given lifecycle stage. 1.2.3 What should be your leadership expectations across new licensees? The top management shall determine individual and institutional values as well as behavioural expectations for the organization to support the implementation of the management system, and shall provide good example of the implementation of these values and expectations in practice. The management at all levels shall communicate to employees	**Regulatory expectation in the different stages of the project**

the need to adopt the individual and institutional values and behavioural expectations as well as to comply with requirements of the management system. Management at all level shall promote involvement of the whole organization in the implementation, continuous improvement and development of the management system. The top management shall ensure that it is clear when, how, and by whom decisions are to be made within the management system. The top management shall regularly require independent assessments: a) to evaluate the effectiveness of processes in achieving policies, strategies, plans, and objectives; b) to determine the adequacy of work performance and leadership; 1.2.4 Is there sufficient guidance/best practise available on these issues? Yes, HAEA issued a specific regulatory guide for IMS development. 1.2.5 How do ownership models influence governance and leadership? **We observed, that if the licensee and the owner are different legal entities, interaction between the two could increase the length of certain decision-making processes.**	
KOREA	
1.2.1 What should be your expectations for new licensee governance standards? - KINS doesn't have specific regulatory requirement for licensee's governance standards, but prospective new licensee has to secure sufficient skill and engineer enough to manage the project such as control of design, management of construction and operation. 1.2.2 How should these expectations change as the project develops? - In the phase of review for construction permit, the capability of design and construction skill would be checked, and the capability of operation and maintenance would be reviewed when operating license is applied. 1.2.3 What should be your leadership expectations across new licensees? 1.2.4 Is there sufficient guidance/best practise available on these issues? - **As for developing leadership and governance of**	

new licenses, the KINS doesn't have specific guidance and best practise. 1.2.5 How do ownership models influence governance and leadership?	
NETHERLANDS	
1.2.1 What should be your expectations for new licensee governance standards? At least in line with ISO and NEA/IAEA requirements. 1.2.2 How should these expectations change as the project develops? By graded approach: the bigger the organization, the larger the number of organisational requirements. 1.2.3 What should be your leadership expectations across new licensees? Leadership should be safety driven in the first place, as a statue for all employees. 1.2.4 Is there sufficient guidance/best practise available on these issues? NEA and IAEA have enough guidance on strategic level. On operational level more guidance is needed. 1.2.5 How do ownership models influence governance and leadership? Responsibility and accountability influence the way of thinking about governance and leadership.	
POLAND	
1.2.1 What should be your expectations for new licensee governance standards? Integrated management systems with strong safety culture awareness programs to allow understating of differences between nuclear sector and other sectors. 1.2.2 How should these expectations change as the project develops? They should commensurate to existing risks. 1.2.3 What should be your leadership expectations across new licensees? Understanding of nuclear industry specifics and fundamentals i.e. safety priority. 1.2.4 Is there sufficient guidance/best practise available on these issues? No, and it will be very hard to prepare soothing applicable to all interested countries taking into account all legal, cultural and economic differences.	

1.2.5 How do ownership models influence governance and leadership? Level of reliance on in-house versus external expertise and work force.	
RUSSIA	
1.2.1 What should be your expectations for new licensee governance standards? Russian NPPs licensees are not newcomers in the field of nuclear energy use (See also the answer to p. 1.1.1). Therefore management standards are implemented and were assessed by Rostechnadzor while licensing and in the course of inspections. 1.2.2 How should these expectations change as the project develops? In accordance with federal rules and regulations in the field of nuclear energy use (p. 4.1.1 of "General regulations on ensuring safety of nuclear power plants" NP-001-15), the operator must ensure the continuous monitoring of the entire activities affecting the safety of the NPP, including by the self-assessment method, which promotes timely adaptation and adjustment of existing practices in the area of governance and leadership. 1.2.3 What should be your leadership expectations across new licensees? Russian NPPs licensees are not newcomers in the field of nuclear energy use (See also the answer to p. 1.1.1). Generally the leading role of new licensees seems to be doubtful. 1.2.4 Is there sufficient guidance/best practise available on these issues? Presently Rostechnadzor develops the safety guide "Guidelines for the formation and maintenance of the safety culture at NPPs and operating organizations of NPPs," which is to consider issues of governance and leadership. 1.2.5 How do ownership models influence governance and leadership? There is a single ownership model in the Russian Federation – licensees of NPPs are joint stock companies and 100% of shares belong to the state.	**What should be the requirements of the regulator to the qualifications and knowledge of managers and persons performing activities affecting safety?**
UNITED ARAB EMIRATES	
1.2.1 What should be your expectations for new licensee governance standards? FANR REG-01 establishes requirements for management systems throughout all phases of the nuclear program, which includes requirements for management responsibility, resource management, process management, and self-assessment among others. The expectation is that governance and leadership can be built and implemented through the management system. IAEA	

safety guides are acceptable methods of conformance – e.g. GS-G-3.1, GS-G-3.5, NS-G-2.4 FANR also has regulations for content of license applications, which require information on the organisational structure, financial resources, etc. 1.2.2 How should these expectations change as the project develops? Different phases may require different leadership and governance structures and people. The organisational arrangements may also change with each phase. The higher level expectations should not change appreciably and should be well established within the regulatory framework. 1.2.3 What should be your leadership expectations across new licensees? Leadership should be focused on establishing the organisational culture that values safety and security using a graded approach commensurate with the risks at each phase of the project. An effectively established management system can help in this regard. 1.2.4 Is there sufficient guidance/best practise available on these issues? Not familiar with the entire set that exists but the IAEA and NEA have sufficient guidance documents for our purposes. 1.2.5 How do ownership models influence governance and leadership? The perception is that there is strong influence but we are unaware of empirical evidence to fully support this and establish the type, direction of influence. Different models can achieve similar results.	
UNITED KINGDOM	
1.2.1 What should be your expectations for new licensee governance standards? In the UK, there are no explicit expectations for standards of Corporate Governance for nuclear licensees. Indeed, the relevant good practice as contained in the UK Corporate Governance Code (formerly known as the Combined Code) only specifically applies to listed companies on a 'comply or explain basis'. However, ONR has used this good practice as a tool to compare proposed governance arrangements in new build organisations. The UK government has recently launched a major review of corporate governance standards for UK companies, which is still in progress and will also consider extending these good practice guide requirements to large private companies. The review group is expected to report later this year. ONR has not yet developed its own guidance in this area. ONR awaits the outcome of the government's review and will then evaluation the requirement for,	

and content of such, guidance. This is clearly a potentially significant issue for new build licensee organisations, where a wide range of ownership models are emerging. The international nature of these models present different cultural approaches to corporate governance and challenges the widely accepted Western model of a balanced Board with sufficient truly independent (of shareholders and the organisation) Non –Executive Directors (NEDs). The desire of parent companies, who are investing the very large sums of money necessary for nuclear new build, to retain control of the new build licensee organisation is very strong and may threaten the independence of these new licensees. 1.2.2 How should these expectations change as the project develops? In the pre-application phase of engagement ONR has no power to insist on any particular model of corporate governance. The aspirant licensee will be a developing company at this stage and ONR will offer advice and guidance of expectations for a balanced Board which places due priority on nuclear safety. When the new build organisation applies for a nuclear site license, it will be required to put in place an acceptable corporate governance structure in advance of licence grant, with sufficient time to allow ONR to assess the adequacy of the governance arrangements and their implementation. As the project progresses from these early phases where adoption of the reactor design, pre-construction management and construction planning are the key activities being undertaken, the expectation is that the Board Executive Directors and the Independent Non –Executive Directors should have relevant experience in these areas. Other nuclear safety governance committees such as the Nuclear Safety Committee (required by LC13 of the nuclear site licence – or a shadow Nuclear Safety Committee in advance of licence grant) should similarly be composed of senior advisors with relevant nuclear safety experience pertinent to the activities currently being undertaken. ONR assesses these arrangements against relevant good practice as discussed above and also against specific ONR guidance in the case of Nuclear Safety Committees and Leadership expectations as laid down in ONR's Safety Assessment Principles, Technical Assessment Guides and Technical Inspection Guides. 1.2.3 What should be your leadership expectations across new licensees? ONR's expectations for leadership are laid out in the Safety Assessment Principles, Technical Assessment Guides and Technical Inspection Guides. These guidance documents take due account of relevant international guidance. The nuclear site licence does not licence the reactor design – it licences the	

corporate body to undertake specific nuclear activities on a specific nuclear site. As such, the organisational capability of the licensee is crucial to the safe undertaking of these activities. This is a key area of interest for ONR and significant effort is made during the pre-application phase to advise the aspirant licensee on our organisation capability expectations and in particular our expectations in safety leadership. 1.2.4 Is there sufficient guidance/best practise available on these issues? The ONR believes the key gap in ONR's guidance is in the area of Corporate Governance. As discussed above, the UK expectations for standards of Corporate Governance are not explicit for nuclear licensees. Indeed the relevant good practice as contained in the UK Corporate Governance Code (formerly known as the Combined Code) only specifically applies to listed companies and applies on a comply or explain basis. However, ONR has used this good practice as a tool to compare proposed governance arrangements in new build organisations. The UK has recently launched a major review of corporate governance standards for UK companies which is still in progress and is considering extending these good practise guide requirements to large private companies and the review group is expected to report later this year. ONR has not developed its own guidance in this area and is currently considering this and the timing of publishing such guidance after the government publishes the outcome of its review. 1.2.5 How do ownership models influence governance and leadership? This is clearly a significant issue for new build licensee organisations where a wide range of ownership models are emerging. The international nature of these models present different cultural approaches to corporate governance and challenges the widely accepted Western model of a balanced Board with sufficient truly independent (of shareholders and the organisation) Non –Executive Directors. The desire of parent companies who are investing the very large sums of money necessary for nuclear new build, to retain control of the new build licensee organisation is very strong and threatens the true independence of these new licensees.	
UNITED STATES OF AMERICA	
1.2.1 What should be your expectations for new licensee governance standards? For applicants proposing to engage in the design, construction, fabrication or operation of a nuclear facility, the NRC has established requirements and guidance for corporate level management and technical support organizations, including the quality assurance program. These requirements and guidance include the following:	

10 CFR 50.40(b) requires that applicants for construction permits (CPs), operating licenses (OLs), and combined licenses (COL), or manufacturing licenses are technically and financially qualified to engage in the proposed activities in accordance with the regulations. NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Chapter 13, Section 13.1.1, "Management and Technical Support Organization, " Revision 5, addresses review of the corporate level management and technical organization of the applicant for a CP, OL, COL, or license transfer. The review will include the applicant's major contractors, including the nuclear steam supply system vendor, and architect-engineer for the project. The technical resources to support the nuclear power plant design, construction, testing, and operation are reviewed. The review for a CP or COL will include the responsibilities, technical staff, interface arrangements, and management controls used to ensure that the design and construction of the facility will be performed in an acceptable manner. The review will also examine the applicant's corporate organization and the technical staff that will support safe plant operation. 10 CFR 50, Appendix A, Criterion I, requires, in part, that structures, systems, and components important to safety be designed, fabricated, erected, and tested to quality standards commensurate with their importance to safety and requires the establishment of a quality assurance program. 10 CFR 50.34(a)(7) and 10 CFR 52.79(a)(25) require (as part of the contents of license applications) a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems and components of the facility. Regulatory Guide 1.28, Quality Assurance Program Criteria (Design and Construction) provides guidance that the NRC finds acceptable for licensees and applicants to meet the requirements of 10 CFR 50 and 52 which refer to 10 CFR 50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," for establishing and implementing a quality assurance (QA) program for the design and construction of nuclear power plants and fuel reprocessing plants. The regulatory guide endorses, subject to specified additions and modifications, the guidance of ASME NQA-1, 2008 and the NQA-1a-2009 Addenda, "Quality Assurance Requirements for Nuclear Facility Applications." ASME NQA-1, 2008, provides, in part, guidance pertaining to organisational structures (including interfaces with other organizations) and responsibilities for quality assurance; the quality assurance program; training and qualifications of quality assurance program personnel; design control; procurement document control; document control; control of purchased items	

and services; handling, storage and shipping; and quality assurance records. NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Chapter 17, Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," provides guidance for the quality assurance staff reviews and evaluates quality assurance program descriptions (QAPDs) submitted by applicants. The QAPDs submitted are reviewed and evaluated in accordance with the applicable sections of this Standard Review Plan. 1.2.2 How should these expectations change as the project develops? NRC's expectations are set forth as requirements in the Code of Federal Regulations (CFR), or occasionally as orders, and in guidelines (e.g., Regulatory Guides) that describe acceptable means for meeting these requirements. The applicability of these documents are typically limited to specific classes of NRC license which may correspond to phases of a project (e.g., construction permit, combined license holder). See the response to 1.2.1 for a description of specific requirements and guidance. The focus of NRC reviews may also change as the project develops to direct NRC resources to review licensee activities and documentation the NRC deems most important to providing reasonable assurance of safety and security. For example, NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Chapters 13 and 17 provide the NRC guidance for review of matters related to licensee governance standards. Chapter 13, Section 13.1.1, "Management and Technical Support Organization," includes guidance applicable to Design Certification, Construction Permit, and Combined License applications as well as Operating License and Combined License holders. These reviews are "focused on the applicant's past experience in the design and construction of nuclear power plants." Guidance is provided pertaining to the content of the applications with regard to specific phases of the project including, for example, "design and construction responsibilities" and "preoperational responsibilities." Similarly, Chapter 17, Sections 17.1 and 17.2 are focused on quality assurance during the design and construction phase and quality assurance during the operations phase, respectively. 1.2.3 What should be your leadership expectations across new licensees? As described in the documents cited in response to question 1.2.1 and 1.2.2, NRC sets forth requirements and guidance pertaining to licensee organizations, including matters such as areas or responsibility, authority, inter-relationships and independence, but does not establish requirements for how individuals in these positions lead their organizations (i.e., leadership as we	

understand the term in this context). However, the NRC has set forth expectations for licensee leadership, in the form of guidance, through the Commission's Safety Culture Policy Statement. The first of nine traits listed in the policy statement is "Leadership Safety Values and Actions—Leaders demonstrate a commitment to safety in their decisions and behaviours." As described in the response to 1.3.2, the NRC provides educational materials to support implementation of the policy statement, including each of the nine traits. Although the policy statement is not specific to new licensees it is nevertheless applicable to new licensees. 1.2.4 Is there sufficient guidance/best practise available on these issues? The NRC strives to be a continuously learning organization and seeks to improve its guidance to remain current with the state of the art. At this time, the NRC does not have a specific initiative in progress to update its guidance on matters concerning licensee governance or leadership. 1.2.5 How do ownership models influence governance and leadership? Although the technical literature would likely provide insights regarding the influence of ownership models, the NRC has not undertaken the research that would be necessary to characterize such literature and provide an answer with an associated technical basis.	

1.3. Developing Strong Safety Culture	
Answers	**Learning**
CANADA	

1.3.1 What's different about developing strong safety culture in new licensees (compared to long established operators)?
 	
1.3.2 What is best practise for developing strong safety culture?
 	
1.3.3 How should you assess safety culture in new licensees?
 	
1.3.4 What are the risks to maintaining strong safety culture across the project lifecycle?
 	
Licensee organisations need to establish clear lines of authority and communication so that individuals throughout the organization are aware of their responsibilities toward nuclear safety. Senior management is ultimately responsible for the safety of the NPP and is, therefore, expected to develop processes to encourage and track the effectiveness of safety programs and to demonstrate through action that safety is of overriding concern. Supervisors' behaviour must also show that they expect their workers to follow safety processes while, at the same time, encouraging a questioning attitude.
 	
The CNSC defines safety culture as:
 	
The characteristics of the work environment, such as the values, rules and common understandings that influence employees' perceptions and attitudes about the importance that the organization places on safety.
 	
When reviewing NPP management systems, the CNSC pays particular attention to the way nuclear, radiological and conventional safety; environmental protection; and the security of the facility are all managed and integrated within the general management system. Canadian management system requirements introduce the promotion of safety culture (as discussed in subsection 10(a)) and include several measures related to organisational changes.
	- **How to promote more effectively the key organisational attributes that signify a top down healthy culture of 'safety first' in an economically challenging environment**
	
	- **How is safety culture promoted to all contracting parties?**
	  - How are licensees implementing the necessary management system processes to integrate with technological features presented by the new design concept?
	  - Workers, including contractors, are knowledgeable of the safety significance of the work

FINLAND	
1.3.1 What's different about developing strong safety culture in new licensees (compared to long established operators)? New licensees may have very limited understanding of how safety culture should be developed in general and the management might have very limited understanding of why good safety culture is expected. 1.3.2 What is best practise for developing strong safety culture? The right attitude and systematic and planned development. Safety	

culture specialists should be available. 1.3.3 How should you assess safety culture in new licensees? Licensee should assess themselves, but questionnaires/interviews by regulator can be used. 1.3.4 What are the risks to maintaining strong safety culture across the project lifecycle? Project delays can cause pressure, lack of understanding about safety requirements, lack of management commitment, lack of understanding about nuclear safety risks caused by non-systematic ways of working, weak safety culture oversight (or general oversight) by the regulator can also partially effect the situation in practise.	
HUNGARY	
1.3.1 What's different about developing strong safety culture in new licensees (compared to long established operators)? **Based in our observations, the main difference about the new licensee is, that most of its staff has no previous working experience in the nuclear field, so expectation on nuclear safety culture are necessarily known by them. Also, due to the lack of previous experience, even after appropriate training, it takes time to fully implement a working attitude necessary for a strong safety culture.** 1.3.2 What is best practise for developing strong safety culture? **The managements of the licensee organisation and the supplier organisations shall consistently and definitely expect and support the attitude required for a strong safety culture at all levels, and shall ensure that the employees recognise and understand the key considerations of safety culture. Among other things, they shall implement this in such a way that they do not support excessive self-confidence and encourage an open reporting culture and a questioning attitude, which prevent activities and conditions unfavourable from a safety point of view.** **The management system shall provide the means required for the systematic development and support of attitudes resulting in a strong safety culture. The suitability and efficiency of the means developing and supporting the safety culture shall be verified at regular intervals, in self-assessments and a review of the management system.** **The licensee shall ensure that suppliers and subcontractors also meet the requirements.** **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.** 1.3.3 How should you assess safety culture in new licensees? Requirements are in Nuclear Safety Codes. We assess via inspections. **Based on the legislative framework HAEA performs inspections in connection with the level of licensee's safety culture including its**	**Methods, guidance, best practices for developing strong safety culture**

self-assessment. HAEA is collecting the relevant data from the inspections and events. 1.3.4 What are the risks to maintaining strong safety culture across the project lifecycle? Main risks identified so far: - Insufficient training (focusing on safety culture development); - Lack of systematic procedures to regularly measure and evaluate the "level" of safety culture; - Lack of a systematic safety culture development plan (short- , mid- and long term); - Key positions in the organisation are filled by different individuals during the different lifecycle stages, thus making information transfer difficult; - Time pressure on the licensee resulting from a tight schedule could also result in difficulties for other involved parties;	
KOREA	
1.3.1 What's different about developing strong safety culture in new licensees (compared to long established operators)? - In case of the long established operators, a level of awareness of the importance of the safety culture is very high. However, it takes long time to improve their safety culture because a custom of long standing or practice is deeply embedded in their culture. - On the other hand, we believe that the new licensee can easily build the frame (i.e. organization, education program) for safety culture, but lack of knowledge and experience could be one of big obstacles in settlement of safety culture. 1.3.2 What is best practise for developing strong safety culture? - **The KINS believes sharing of information and experience regarding to safety culture could be a great help to develop and enhance safety culture.** 1.3.3 How should you assess safety culture in new licensees? - **In general, the KINS reviews the organization and educational program related to the safety culture when the CP or OL is applied.** 1.3.4 What are the risks to maintaining strong safety culture across the project lifecycle? - **A peace-at-any-price principle or habitual behaviour is one of the most risks to maintaining strong safety culture.**	
NETHERLANDS	
1.3.1 What's different about developing strong safety culture in new licensees (compared to long established operators)? At the start of a new licensee organization, there exists no culture.	

Establishing a culture needs some years. Working on an intended culture could start from day one. 1.3.2 What is best practise for developing strong safety culture? First step should be to gain enough knowledge and insights about safety culture and its consequences and to share this knowledge. Working on safety culture should be explicitly programmed and should be priority of top-management. 1.3.3 How should you assess safety culture in new licensees? Regular monitoring by the licensee itself, by the regulator and by third parties . Monitoring by combination of observation, (in) formal discussion and by checking procedures and so on. 1.3.4 What are the risks to maintaining strong safety culture across the project lifecycle? Unwanted and/or unseen shifts of paradigm, and complacency, by the sitting staff or newcomers.	
POLAND	
1.3.1 What's different about developing strong safety culture in new licensees (compared to long established operators)? Starting from the scratch might have negative (quite obvious) and positive impact (sometime it's hard to change existing culture/approaches) 1.3.2 What is best practise for developing strong safety culture? Involvement of the top management and real (instead of phoney/formal) implementation of safety culture programmes. 1.3.3 How should you assess safety culture in new licensees? By use of safety culture indicators adjusted to given program stage. 1.3.4 What are the risks to maintaining strong safety culture across the project lifecycle? Scale of the project, subcontractors (with own culture), tight schedule, dynamic environment.	
RUSSIA	
1.3.1 What's different about developing strong safety culture in new licensees (compared to long established operators)? There are no examples in relation to the Russian Federation, because NPPs licensees are not newcomers in the field of nuclear energy use (See also the answer to p. 1.1.1). In our opinion, it is expected that to create a safety culture new licensee requires a significant time to gain experience, establish trust on all management levels, develop partnership between managers and workers in matters of safety and form a positive attitude towards safety, to evolve team-work and self-management skills. 1.3.2 What is best practise for developing strong safety culture? Presently Rostechnadzor develops the safety guide "Guidelines for the	

formation and maintenance of the safety culture at NPPs and operating organizations of NPPs," which summarizes the regulator's understanding of the best practices in the field of safety culture. Managers at all levels have particular influence on developing and sustaining safety culture. Leading by example, they must demonstrate commitment to safety creating atmosphere of trust, openness and accountability. A necessary condition for the development of strong safety culture is a constant evaluation and self-checking, performed by workers and managers of a new licensee and the regulator. The regulator can stimulate safety culture development by identifying, promoting and publicizing the experience of operators (licensees) with strong safety cultures. The international experience, in particular, IAEA recommendations might be of great help in creating a safety culture. 1.3.3 How should you assess safety culture in new licensees? In our view, the order of a safety culture assessment of new licensees generally must comply with such an order for the other licensees. The particular attention should be given to issues of professional competence at all levels, as well as openness in discussing issues related to safety and security. 1.3.4 What are the risks to maintaining strong safety culture across the project lifecycle? One of the risks is the safety culture degradation due to excess self-assuredness, arising as a result of good performance in the past and self-complacency that leads to negligence, weakening of self-control, denial regarding negative inspection results, to delay or cancellation of improvement programs.	
UNITED ARAB EMIRATES	
1.3.1 What's different about developing strong safety culture in new licensees (compared to long established operators)? Lack of "lived" experience that is effective in cultivating attitudes, values, beliefs. Opportunity for new organizations to cultivate strong cultural values since they are new – starting with blank slate. 1.3.2 What is best practise for developing strong safety culture? This is very situation dependent. The UAE program has brought together people from all over the world, with different cultural backgrounds, levels of experience, native language differences, etc. Generally though developing a strong safety culture takes time, stability, and effective leadership. 1.3.3 How should you assess safety culture in new licensees? IAEA TecDoc 1707 provides good recommendations for effective oversight by regulators. Licensees should take the lead to self-assess and regularly communicate with regulator on results. Regulator should inspect to confirm these self-assessments are taking place, corrective actions are being addressed, and are in line with accepted practices. 1.3.4 What are the risks to maintaining strong safety culture across the	

project lifecycle? Organisational changes create transience and lack of stability which can hamper the development of a strong safety culture. Once operational, these risks should reduce.	
UNITED KINGDOM	
1.3.1 What's different about developing strong safety culture in new licensees (compared to long established operators)? **The main difference from ONR's perspective is that the term 'nuclear safety culture' (as understood by long established nuclear operators) needs to be interpreted in a meaningful way for a construction / project environment, in which individuals and organisations may have little or no nuclear background. New licensees need to articulate how behaviours in the construction phase influence future nuclear safety, and set suitable expectations for the conduct of activities. These need to be continually reinforced because of the transient nature of the construction / project workforce.** 1.3.2 What is best practise for developing strong safety culture? ONR has set relevant good practice for the development (and maintenance) of a strong safety culture in the form of Safety Assessment Principles (SAPs) (http://www.onr.org.uk/saps/saps2014.pdf). These are set at a high level and apply throughout the project lifecycle. They include principles relating to leadership, organisational capability, decision making and learning. The SAPs are supported by Technical Assessment Guides and Technical Inspection Guides (TAGs / TIGs), e.g. NS-TAST-GD-078 (Safety Management Prospectus) and NS-TAST-GD-080 (Nuclear Safety Challenge) (http://www.onr.org.uk/operational/tech_asst_guides/index.htm), as well as ONR's publication 'Licensing Nuclear Installations' (http://www.onr.org.uk/licensing-nuclear-installations.pdf). **The SAPs and TAGs / TIGs are reviewed and updated periodically to reflect relevant international standards. ONR also contributes to the development of good practice guides by the UK Safety Director's Forum (http://www.nuclearinst.com/Publications).** 1.3.3 How should you assess safety culture in new licensees? **ONR's approach is as follows:** 1. ONR encourages self-assessment of safety culture by licensees. This should use suitable methodologies with leadership commitment to address the findings of the assessments and make necessary improvements. 2. ONR carries out interventions at Board and Executive level to evaluate and reinforce the expectations of leaders set out in its Safety Assessment Principles (SAPs). **3. ONR carries out periodic assessments against the four leadership and management for safety principles contained in the SAPs (MS.1 to MS.4). This includes assessments to support decisions on licence applications and consents during construction (e.g. http://www.onr.org.uk/hinkley-point-c/assessment-reports.htm)**	**What are the factors in successfully establishing a strong nuclear safety culture on a new construction site ?**

1.3.4 What are the risks to maintaining strong safety culture across the project lifecycle? **In ONR's opinion, factors which can contribute to the erosion of a positive safety culture include:** • Continual change, downsizing and contractorisation • A pattern of acceptance leading to diminished standards • Ineffective checks and balances • Conflicting messages on programme and costs versus safety • Managers not hearing or listening to engineer's concerns • **Undue questioning or suppression of dissenters**	
UNITED STATES OF AMERICA	
1.3.1 What's different about developing strong safety culture in new licensees (compared to long established operators)? The NRC sets forth the same safety culture expectations for all licensees (see response to 1.2.3). Nevertheless, the NRC recognizes that the conditions and challenges faced by new licensees may differ from those of existing licensees. The following are potential differences: · Existence of a pre-existing/well-established culture – If the new licensee is a wholly new organization, then the lack of a pre-existing safety culture can be an opportunity to establish a strong safety culture from "day 1." If the new licensee is an established organization, but new to nuclear, the new licensee could face significant challenges modifying organisational values and behaviours that were accepted/successful for the organizations former mission/scope of work but are not conducive to a strong nuclear safety culture. · Rate of organisational change – Whether a new licensee is a new organization built from the ground up or is a restructuring/outgrowth of an existing organization, the new licensee will be experiencing a rapid rate of change in personnel, processes, and organisational structures as it evolves to address the new mission. The rate of change can stress resources as well as challenge the ability to maintain consistent communications and practices reinforcing safety culture · Maturity of organisational processes – The organisational processes that support a strong safety culture (e.g., quality assurance and employee concerns programs) of new licensees will be in their infancy and therefore may still require further development to resolve unforeseen limitations and attain widespread visibility and familiarity/staff competence. · Level of operating experience – New licensees may comprise a higher percentage of staff with little to no experience in the nuclear domain. A lack of familiarity with the hazards and experience in observing the many ways in which minor errors or deficiencies can propagate into significant safety matters can be a challenge to staff recognizing and embracing the importance of safety as a first priority.	

· Temporal proximity to the hazards – For new licensees that are constructing a new nuclear facility, the immediate, everyday hazards are those pertaining to worker safety. Without a radioactive source on site, matters of nuclear safety and security can seem distant and less tangible, even though they may recognize that activities during construction directly affect nuclear safety and security. The temporal distance to these hazards can induce a sense that safety concerns can be deferred/addressed in the intervening time. · Sense of ownership for operating facility safety and security – New licensees constructing a new nuclear facility will likely employ many contract personnel whose services will only be used during construction, and perhaps only for small period or portion of construction. Ensuring that these individuals embrace a strong safety culture can be a challenge if they do not see themselves as having ownership of the safe and secure operation of the facility or understand how their work contributes to safety and security. 1.3.2 What is best practise for developing strong safety culture? The NRC's Safety Culture Policy Statement https://www.gpo.gov/fdsys/pkg/FR-2011-06-14/pdf/2011-14656.pdf identifies nine traits of a positive safety culture. These traits are: · Leadership Safety Values and Actions—Leaders demonstrate a commitment to safety in their decisions and behaviours · Problem Identification and Resolution—Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance · Personal Accountability—All individuals take personal responsibility for safety · Work Processes—The process of planning and controlling work activities is implemented so that safety is maintained · Continuous Learning—Opportunities to learn about ways to ensure safety are sought out and implemented · Environment for Raising Concerns—A safety conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination · Effective Safety Communication—Communications maintain a focus on safety · Respectful Work Environment—Trust and respect permeate the organization · Questioning Attitude—Individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action The policy statement sets forth the NRC's expectation that all individuals and organizations, performing or overseeing regulated activities involving nuclear materials will promote a positive safety culture by fostering these traits as they apply to their organizations. The NRC provides educational materials to further describe these traits,	

including why they are important and what they look like in the field. These educational materials can be viewed at: https://www.nrc.gov/docs/ML1624/ML16244A152.pdf 1.3.3 How should you assess safety culture in new licensees? The NRC provides oversight of licensee performance, including oversight of licensee safety culture through the Reactor Oversight Process (ROP) and construction Reactor Oversight Process (cROP). Although the cROP does not make a distinction between new or existing licensees, the guidance is specific to an activity common to new licensees, i.e., construction of a nuclear facility. Inspection Manual Chapter (IMC) 0613, "Documenting 10 CFR Part 52 Construction Inspections," and IMC 2505, "Periodic Assessment of Construction Inspection Program Results," provide guidance to assess the safety culture of a construction site. IMC 2505 also includes references to the supplemental inspection procedures, which are used when there is a decline in safety performance at a construction site. These procedures provide NRC with guidance on how to assess the safety culture at a construction site with escalating levels of efforts commensurate with the significance of a site's performance decline. The supplemental inspection procedures also provide NRC with the tools to communicate safety culture issues to stakeholders. 1.3.4 What are the risks to maintaining strong safety culture across the project lifecycle? The NRC understands this question to be seeking insights regarding the challenges to maintaining a strong safety culture from the design phase through decommissioning. We note that the Swedish Radiation Safety Authority (SSM) has issued a report addressing this topic, “2015:10, SafePhase: Safety culture challenges in design, construction, installation and commissioning phases of large nuclear power projects.” The report is available at: www.stralsakerhetsmyndigheten.se. This report is insightful in addressing this topic. Following are examples of the insights/concerns captured in the SSM report: Design Phase: · Economic pressure to make a good deal with a design firm may be a disincentive to a licensee to disclose all safety requirements and challenges · Lack of regulatory authority over contract organizations · Organizations may not share same safety philosophy · Distributing roles and responsibilities between different stakeholders in design is challenging · The slowness of nuclear design process challenges the systemic view on safety, knowledge transfer and continuity · Conceptions on the scope of designers’ responsibility Construction Phase: · The challenge of dynamic project network with temporary workforce · The challenge of understanding in practice what is safe and what is unsafe	

· Start of construction before design completion Commissioning Phase: · Compromising testing as a result of delays in construction Decommissioning Phase: · Preservation of staff competence and moral · Preservation of knowledge and corporate memory	

1.4 Developing Internal Independent Regulation	
Answers	**Learning**
CANADA	
1.4.1 How important is the concept of IR and is it essential for new licensees? 1.4.2 Do you have sufficient regulatory guidance on your expectations for IR? 1.4.3 How should regulators interact with internal regulators? For the most part, Canada has a relatively non-prescriptive nuclear regulatory regime for NPPs that sets general requirements and performance standards, thereby allowing applicant and licensees some flexibility to meet them in a manner that best meets their needs. The licensees are responsible for addressing the requirements in their systems, programs, processes and designs. Descriptions of these provisions are submitted to the CNSC at the time of licence application. If accepted by the CNSC, these provisions become part of the licensing basis for the NPP. Licensees must demonstrate that NPP operations during the life cycle of the project satisfy performance standards. Licensees fulfil their responsibilities through the following activities: - complying with the regulatory requirements set out in applicable laws and regulations - operating in accordance with the licensing basis - developing safety policies and an organisational culture committed to ensuring safe NPP operation - monitoring both employee and facility performance to ensure expectations are met - ensuring adequate financial resources are available to support the safety of each NPP throughout its life - ensuring adequate qualified resources are always available to respond to planned activities and contingencies	**Definition of licensing basis**

- implementing managed systems to control risks associated with NPP operations to govern the above activities	
FINLAND	
1.4.1 How important is the concept of IR and is it essential for new licensees? It is important to have independent safety assessment because the competence in new licensee organisations can be lacking. 1.4.2 Do you have sufficient regulatory guidance on your expectations for IR? Only top level requirement. 1.4.3 How should regulators interact with internal regulators?	
HUNGARY	
1.4.1 How important is the concept of IR and is it essential for new licensees? **The Licensee has to 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 should be subordinated to the top management of Licensee.** 1.4.2 Do you have sufficient regulatory guidance on your expectations for IR? **Yes, there are specific regulatory requirements on this subject.** 1.4.3 How should regulators interact with internal regulators? Our practice is that the IR – with specific exceptions – is considered as the licensee's official contact point on safety relevant subjects. For instance SSCs related inquiries are reviewed and submitted by the IR to the regulator, and a representative or the IR is always present at regulatory inspections. Also, we hold regular meetings with the IR to discuss open issues.	**Role of IR** **Independency of IR**
KOREA	
1.4.1 How important is the concept of IR and is it essential for new licensees? - **Independent Regulation by the utilities themselves is specified in the Quality Assurance Program (QAP), and the QAP shall be developed prior to any works related to safety of plant.** 1.4.2 Do you have sufficient regulatory guidance on your expectations for IR? - **There are KINS regulatory standards and guides including the QA program, and the detail guidance for**	

organization, qualification of workers, procedure and maintenance of QA are specified. 1.4.3 How should regulators interact with internal regulators? - **The KINS doesn't have specific rule for interaction with internal regulators of utilities, however the KINS's QA team confirm the suitability of utilities' QA program in the phase of the review of CP, OL, and pre-operational inspection.**	
NETHERLANDS	
1.4.1 How important is the concept of IR and is it essential for new licensees? New licensees needs to work on establishing a strong safety culture. Part of that work is developing an internal system of rules, independent of the economic conditions . 1.4.2 Do you have sufficient regulatory guidance on your expectations for IR? No, not at all. 1.4.3 How should regulators interact with internal regulators? On a regular base, cooperative as well as judicial.	
POLAND	
1.4.1 How important is the concept of IR and is it essential for new licensees? It's important for increasing understanding of the project, and during contacts with vendors and subcontractors. 1.4.2 Do you have sufficient regulatory guidance on your expectations for IR? No. We have some requirements for internal technical regulations but not for managerial aspects. 1.4.3 How should regulators interact with internal regulators? Joint trainings/workshops, but formal cooperation regarding project.	
RUSSIA	
1.4.1 How important is the concept of IR and is it essential for new licensees? It is important. There are internal (departmental) inspections at Russian NPPs. In accordance with the Russian Federation Governmental Decree of 3 March 1997 № 240 such internal inspectors must have the permission of Rostechnadzor to carry out work in the field of nuclear energy use. In accordance with Russian regulations, the licensee must ensure constant monitoring of all activities that affect the NPP safety, including on the self- assessment basis. It is the licensee's responsibility to prepare periodical NPP safety reports, which are sent to the regulatory body (Rostechnadzor) and the control body	**What are the best practices establish a system of rewards and penalties on performance results that fosters openness of actions of the employee and is not conducive to the concealment of errors in their work?**

(Rosatom). In particular, the licensee must continuously monitor compliance with licensing terms and prepare quarterly reports on licensed activity, in order to compile information on the work carried out, identify shortcomings and to put good practices into use. It is recommended that the licensee's work documentation requires of any employee or department to conduct self-assessment of understanding tasks and objectives and their influence on the NPP safety. It is important to promote and encourage in employees a negative attitude towards unsafe practises. Quality assurance programs are an important element of internal self-regulation. 1.4.2 Do you have sufficient regulatory guidance on your expectations for IR? Federal rules and regulations contain limited information about the regulation of the activities of internal inspections. Basically, this issue is in the scope of the activities of the operating organization. 1.4.3 How should regulators interact with internal regulators? Regulator does not directly interact with internal regulator. Issues of the effectiveness of departmental inspections are included in the inspection program carried out by the regulatory body.	
UNITED ARAB EMIRATES	
1.4.1 How important is the concept of IR and is it essential for new licensees? FANR REG-01 requires licensees to implement measurement, assessment, and continuous improvement instruments in addition to regular self-assessments and independent assessments to ensure some level of IR. IR is very important and should be used as a tool by new licensees to assess performance and continuously improve. FANR has requested several independent peer reviews over the years (IRRS, EPREV, etc.) and is advised by the international advisory group on nuclear safety. 1.4.2 Do you have sufficient regulatory guidance on your expectations for IR? FANR REG-01 clearly establishes requirements, and is supported by several IAEA safety guides through FANR RG-002 1.4.3 How should regulators interact with internal regulators? Through the licensee.	
UNITED KINGDOM	
1.4.1 How important is the concept of IR and is it essential for new licensees? ONR defines Internal Regulation as ‘a specific function staffed by suitably qualified and experienced staff that provides key elements of an internal challenge capability’.	

ONR considers that a licensee's capability to manage its activities safely is strengthened by the presence of a robust and effective independent challenge (internal regulation) capability as an additional barrier to flawed decision-making and inappropriate behaviours. Increased regulatory confidence in a licensee's internal regulation capability can also enable ONR to more effectively target and leverage its own resources. The size of an internal regulation function and the range of activities it undertakes will be influenced by the nature of the hazards, the size of the licensee's organisation and how it intends to deliver its internal challenge role. 1.4.2 Do you have sufficient regulatory guidance on your expectations for IR? ONR's Safety Assessment Principles (SAPs) provide its inspectors with a framework for making consistent regulatory judgements on the safety of activities. The Leadership and Management for Safety SAPs recognise the value to the leadership of a licensee organisation of receiving feedback from independent challenge/regulation. The SAPs are supported by Technical Assessment Guides (TAGs) to further assist decision making within the nuclear safety regulatory process and ONR has developed a specific TAG covering internal regulation – 'Challenge Culture, Independent Challenge Capability (including an Internal Regulation function), and the provision of Nuclear Safety Advice' NS-TAST-GD-080. ONR's SAPs and TAGs have been published on the ONR website. 1.4.3 How should regulators interact with internal regulators? Regulators should acknowledge and respect the role fulfilled by licensee Independent Regulator (IR) functions. They should also be overtly supportive of the role that the IR function fulfils in the licensee organisation and, where appropriate, provide appropriate support and encouragement particularly at a senior level in the licensee organisation. Regulators should develop a relationship with the IR function based on trust, openness and mutual respect which should encourage both parties to share good practice and matters of potential concern. Regulators and IR functions should ideally develop complementary inspection/intervention programmes which avoids both parties looking at the same areas of interest and minimises duplication. This should allow Regulators to deploy their resources in a targeted and proportionate manner.	**There is the potential for regulators to overlook or ignore the contribution of internal regulators. It would be beneficial to explore how we can develop a productive working relationship with IRs.**
UNITED STATES OF AMERICA	
1.4.1 How important is the concept of IR and is it essential for new licensees?	

The NRC's regulations stress the importance of the quality assurance (QA) manager providing adequate oversight of activities affecting safety from initial implementation of the program and continuing throughout all phases of plant life. This includes the period from design, construction, and through operation. 1.4.2 Do you have sufficient regulatory guidance on your expectations for IR? The NRC quality standards implementing the regulations require that the organisational structure and responsibility assignments shall be such that: (a) senior management establishes overall expectations for effective implementation of the QA program and is responsible for obtaining the desired end result; (b) quality is achieved and maintained by those assigned responsibility for performing work; (c) quality achievement is verified by those not directly responsible for performing the work; (d) those responsible for assuring that an appropriate QA program has been established and those verifying activities affecting quality have sufficient authority, direct access to responsible levels of management, organisational freedom, and access to work to perform this function, including sufficient independence from cost and schedule when opposed to safety function considerations. These verification functions include: (1) identifying quality problems; (2) initiating, recommending, or providing solutions to quality problems through designated channels; (3) verifying implementation of solutions; (4) assuring that further processing, delivery, installation, or use is controlled until proper disposition of a non-conformance, deficiency, or unsatisfactory condition has occurred. 1.4.3 How should regulators interact with internal regulators? There are NRC inspection procedures that provide amplifying guidance on how to ensure the adequacy of the licensee's QA program. Further, there are inspection procedures providing guidance on verifying the implementation of the QA program. This would include verifying the adequacy of the internal regulator's oversight of activities affecting quality in accordance with licensee's QA program. The NRC's review of the QA program and its implementation is conducted once an entity submits an application for construction of a nuclear facility.	

Topic 2 – Regulatory Challenges with New Licensees

2.1. Regulatory Readiness	
Answers	**Learning**
CANADA	
2.1.1 What are the regulatory skills and experience needed to support the development of OC in new build organisations? 2.1.2 How should regulatory staff be trained for assessment of OC in new build organisations? 2.1.3 How can regulators attract experienced/skilled staff in a competitive market? 2.1.4 What are the challenges of transitioning your regulators from dealing with long established licensees to new build organisations? The CNSC has a flexible, risk-informed, technology-neutral regulatory framework. Feedback on the CNSC's Discussion paper *Small Modular Reactors: Regulatory Strategy, Approaches and Challenges* (DIS-16-04) indicated · There is no need for significant changes to the CNSC's Regulatory Framework. **However the comments received on the discussion paper will inform further improvements into our regulatory framework to address challenges arising from regulations of new advanced reactors and SMR.** **CNSC is also in the process to review its nuclear technical capability and ensuring that gaps in knowledge and expertise to evaluate new reactor designs are appropriately addressed.** The pre-licensing vendor design review process also helps in identifying areas where additional knowledge and expertise need to be developed and acquired.	- **Should international forums be strengthened to build up technical capabilities and capacity with respect to new reactors designs to support regulators world-wide? For example:** o **Increased sharing or safety data and technical information?** o **Mentoring and training of regulatory staff on fundamental nuclear safety principles underpinning expectations**
FINLAND	
2.1.1 What are the regulatory skills and experience needed to support the development of OC in new build organisations? Knowledge in project management in the nuclear sector, general knowledge about quality management, ability to explain expectations concerning licencing, safety culture expertise. 2.1.2 How should regulatory staff be trained for assessment of OC in new build organisations? There should be previous experience in nuclear projects and experiences should be shared within the regulator, above mentioned skills should be available and developed. 2.1.3 How can regulators attract experienced/skilled staff in a competitive market? Provide competitive pay and working conditions and give	

employees the possibility to affect their own work. 2.1.4 What are the challenges of transitioning your regulators from dealing with long established licensees to new build organisations? Understanding that the new licensees can have very low competence when they are starting and also their understanding of licencing and other regulatory expectations can be weak. New organisations can also have different ways of working than established organisations so an open mind is needed in assessment of new organisations.	
HUNGARY	
2.1.1 What are the regulatory skills and experience needed to support the development of OC in new build organisations? - Management system development and assessment; - Safety culture development and assessment; - Development and assessment of design authority capabilities; - High level nuclear legislation knowledge (e.g. legal interpretation of licensee ”prime responsibility”); - Project management; - Supply chain supervision, including supplier qualification and readiness assessment; - **HR development;** 2.1.2 How should regulatory staff be trained for assessment of OC in new build organisations? **On one side, the training should be the same as for the OC assessment for exiting licensee, because principles and methods are generally the same. On the other side emphasis should be put on how to review and assess the initial development of the OC, taking into account new build specific requirement and lifecycle specific circumstances.** 2.1.3 How can regulators attract experienced/skilled staff in a competitive market? **A competitive income, stable workplace and clear carrier opportunities are essential, but the challenge is that usually staff with nuclear experience is not available on the market, so people for non-nuclear industries have to be hired, and extensively trained.** 2.1.4 What are the challenges of transitioning your regulators from dealing with long established licensees to new build organisations? - professional contacts have to be newly established; - no or little prior knowledge on nuclear industry practices at the new licensee - a significant part if the licensee’s staff has no prior nuclear experience; - shortcomings in the quality and quantity of human resources;	**Training methods of regulatory staff for assessment of OC in new build organisations** **Hiring process in a competitive market** **Transition inspectors**

- management of regulatory requirements; - interpretation of goal based regulatory requirements and their practical implications; - EPC contract vs. licensee's prime responsibility; - **"Intelligent Customer" capabilities;**	
KOREA	
2.1.1 What are the regulatory skills and experience needed to support the development of OC in new build organisations? - **In general, a wide knowledge on the organization, safety culture and QAP is helpful for support the development of OC.** 2.1.2 How should regulatory staff be trained for assessment of OC in new build organisations? - **Regulatory staff have to understand the standards and guidance related to the organization capability.** 2.1.3 How can regulators attract experienced/skilled staff in a competitive market? - **Job stability and working condition are top priority consideration for appointment of experienced staff.** 2.1.4 What are the challenges of transitioning your regulators from dealing with long established licensees to new build organisations? - New organisation's comprehensive understanding of regulatory standards and communication between our regulator and new licensee are the most challenges.	
NETHERLANDS	
2.1.1 What are the regulatory skills and experience needed to support the development of OC in new build organisations? In general, organisational insights and knowhow. 2.1.2 How should regulatory staff be trained for assessment of OC in new build organisations? By conducting regular reviews as exercises (work in progress) 2.1.3 How can regulators attract experienced/skilled staff in a competitive market? For example by offering a sound and challenging working environment 2.1.4 What are the challenges of transitioning your regulators from dealing with long established licensees to new build organisations? One challenge is dealing with old habits and old ideas.	
POLAND	
2.1.1 What are the regulatory skills and experience needed to support the development of OC in new build organisations? Same skills like in conventional industry + nuclear specific safety	

and security culture. 2.1.2 How should regulatory staff be trained for assessment of OC in new build organisations? See above. 2.1.3 How can regulators attract experienced/skilled staff in a competitive market? Higher job stability in case of civil service. 2.1.4 What are the challenges of transitioning your regulators from dealing with long established licensees to new build organisations? Need to create new approach.	
RUSSIA	
2.1.1 What are the regulatory skills and experience needed to support the development of OC in new build organisations? Regulator (Rostechnadzor) is to supervise this process and needs: - Experience in conducting inspections and analysing the causes of discovered failures and establishing their connection to licensee's OC; - To develop guidelines on assessment and self-assessment of organisational culture taking into account the best practices and international experience. 2.1.2 How should regulatory staff be trained for assessment of OC in new build organisations? The training process is the same for new and established organizations. It includes both study of theoretical basis and practical skills, including the implementation of them in licensing and supervision. 2.1.3 How can regulators attract experienced/skilled staff in a competitive market? Attractiveness of state safety regulator as an employer is determined by: - Competitive wages; - The organisation's prestige and privileges established by the legislation for state employees; - Challenging work, ability to utilise valuable professional experience. To participate in inspections and in examination of safety justification documents qualified experts can be engaged on a contractual basis from other organizations without interrupting their main work. 2.1.4 What are the challenges of transitioning your regulators from dealing with long established licensees to new build organisations? If the licensee intends to use innovative technologies regulator may need to obtain new technical knowledge.	
UNITED ARAB EMIRATES	

2.1.1 What are the regulatory skills and experience needed to support the development of OC in new build organisations? 2.1.2 How should regulatory staff be trained for assessment of OC in new build organisations? 2.1.3 How can regulators attract experienced/skilled staff in a competitive market? 2.1.4 What are the challenges of transitioning your regulators from dealing with long established licensees to new build organisations? -Transition plan developed to ensure regulatory attributes are in place to support oversight of operating licensee. - Staff should be trained on reviewing the organization capability, integrated management system and operators training. -Regulators should offer competitive packages and set up ideal working environment.	
UNITED KINGDOM	
2.1.1 What are the regulatory skills and experience needed to support the development of OC in new build organisations? A range of skills and experience are required covering: · Applicable legislation and regulatory approach to compliance · Organisational design and development · Corporate governance · Intelligent customer · Design Authority · Engineering and design processes · Management systems · Quality assurance and quality control · Supply chain management · EPC and other project delivery approaches · Safety case development and assessment · Construction site management (under a regulatory regime) Nuclear Inspectors need to be sufficiently knowledgeable and experienced in the above areas to advise and influence the development of new build organisations and to regulate an organisation's activities once a nuclear site licence is granted. 2.1.2 How should regulatory staff be trained for assessment of OC in new build organisations? The regulatory skills and experience (attributes) required should be clearly defined in a role profile and the desired level of competence for each attribute and for the role in totality clearly established. Individuals should be assessed against the attributes and any gaps	

identified. Training should be a mixture of generic, focussing on the specific nature of the new build environment, and specific where there is an identified gap. Regulatory organisations may choose to deliver the training either in-house where there is specific in-house competence to do so, or using specialist training organisations where the subject matter is not part of the regulatory body's core competence e.g. corporate governance. 2.1.3 How can regulators attract experienced/skilled staff in a competitive market? By offering competitive salaries and attractive employment packages, together with good career prospects. Vacancies should be advertised using a variety of media and directed towards the target market. Regulators should develop relationships with licensees which open up opportunities for secondments from those organisations for initially finite periods of time but with the opportunity for the secondments to be converted into permanent appointments if both parties are in agreement. 2.1.4 What are the challenges of transitioning your regulators from dealing with long established licensees to new build organisations? The new build environment is a fast –paced, commercially orientated project environment. New build organisations in the UK are owned by international shareholders. Regulators in this environment need to have a flexible and constructive approach, recognise the high dependence on the supply chain, to be aware of cultural differences and be prepared for schedule and cost to be the developer's number one priority.	**There is need to apply judgement in the application of organisational capability principles to recognise the differences between a developing new build organisation and a mature, established licensee. It would be beneficial to explore approaches adopted by other regulators to applying regulatory requirements to immature, project-orientated organisations.**
UNITED STATES OF AMERICA	
2.1.1 What are the regulatory skills and experience needed to support the development of OC in new build organisations? Licensees are responsible for meeting applicable NRC requirements. As an independent regulatory authority, the NRC provides guidance on acceptable means for meeting these requirements but does not engage in activities that are the responsibility of the licensee. Accordingly, NRC engagement relative to organisational capability would be in the form of staff review or inspection of relevant licensee documentation and activities as addressed under 2.1.2. 2.1.2 How should regulatory staff be trained for assessment of OC in new build organisations? Regulatory staff should be knowledgeable of the authority's applicable requirements and guidelines as well as their underlying technical bases. The staff should also possess, as applicable, the technical review and inspection skills necessary to assess conformance with these requirements and guidelines. The NRC has established qualification requirements for performing inspections in areas pertaining to organisational capability. For	

example, NRC Inspection Manual Chapter (IMC) 1245, Appendix C-12, Safety Culture Assessor Training and Qualification Journal (https://www.nrc.gov/docs/ML1602/ML16020A397.pdf) sets forth the competencies required for qualification as a safety culture assessor and specifies the training and equivalency requirements. Similarly, IMC 1245, Appendix C-8, Vendor Inspector Technical Proficiency Training and Qualification Journal, sets forth training and qualification requirements for vendor inspectors, including training applicable to the assessment of vendor quality assurance programs. NRC also specifies qualification requirements for technical reviewers in NRC's Office of Nuclear Reactor Regulation and Office of New Reactors. These qualification programs focus on knowledge of and skills in NRC's requirements, policy, and processes. To ensure the staff possess the relevant technical expertise, the organizations consider a job candidate's education and experience relative to the review responsibilities of the position. As an example, the organization with primary review responsibility for review of management and technical support organizations (i.e., conducting reviews in accordance with Section 13.1.1, of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition") are the organizations responsible for the review of human performance. These organizations typically comprise individuals with education and experience in industrial/organisational psychology, human factors engineering, training, and industrial engineering. 2.1.3 How can regulators attract experienced/skilled staff in a competitive market? To assure sufficient staffing, several aspects need to be considered including (1) an understanding of the type of work (e.g., operating reactor, new reactor, advanced reactor) to be undertaken, (2) the critical skills (e.g., thermal hydraulics, operator licensing) needed to complete the work, (3) a strategy to acquire the resources, and (4) a strategy to retain the resources. NRC has been successful in attracting staff as a result of many factors such as emphasizing the unique safety mission of the agency, providing interesting and challenging job assignments, providing training opportunities and qualification programs, providing a competitive salary and benefits, offering hiring and retention incentives, and providing flexible work schedules to accommodate personal needs. 2.1.4 What are the challenges of transitioning your regulators from dealing with long established licensees to new build organisations? Some of the challenges include (1) making sure that regulatory staff is sufficiently trained in any new technologies that the new organisations may propose, (2) gaining a complete understanding of the new organization's plans and schedule, (3) gaining confidence that the new organisations understand the regulatory requirements and expectations, and (4) assuring clear communications between the regulator, new build organizations, and external stakeholders to avoid misunderstandings.	

2.2. Engagement Strategies	
Answers	**Learning**
CANADA	
2.2.1 When should you engage with new build organisations? 2.2.2 How should you engage with new build organisations? 2.2.3 Should you engage with parent bodies, if so when and how? 2.2.4 Should you engage with contractors and suppliers, if so when and how? **CNSC is proactively engaging with many different stakeholders, such as potential vendors, licensees and the public including indigenous communities.** The CNSC's outreach activities, meetings with vendors and potential applicants, and its vendor design review process facilitate regulatory reviews of new technologies, and preparation for submission of applications. In addition, CNSC staff and management have made numerous presentations and workshops and workshops, and have posted their presentations on the CNSC's external website. **CNSC also workshops on the key areas in our regulatory framework needing further clarification.** CNSC also has a pre-licensing vendor design review process to engage formally in pre licensing discussion with potential vendors.	
FINLAND	
2.2.1 When should you engage with new build organisations? Quite early, in Finland the requirements are quite detailed and there are many requirements concerning licencing, quality and safety. In practice these requirements need to be clarified with the licensee. 2.2.2 How should you engage with new build organisations? Meetings, review documentation if they request 2.2.3 Should you engage with parent bodies, if so when and how? Not done in oversight in Finland 2.2.4 Should you engage with contractors and suppliers, if so when and how? Yes, Three party meetings between regulator, licensee and suppliers can be useful, STUK also inspects suppliers directly during the construction licence phase.	
HUNGARY	
2.2.1 When should you engage with new build organisations? **As early as reasonably possible.** 2.2.2 How should you engage with new build organisations?	

On all levels, commensurate with their role in the organisation (top management, mid-level management, expert level, etc.) 2.2.3 Should you engage with parent bodies, if so when and how? **It depends on the regulatory structure, but for instance, if another body regulates environmental protection issues, there should be an engagement.** 2.2.4 Should you engage with contractors and suppliers, if so when and how? Direct engagement should be avoided as far as practicable, due to the prime responsibility of the licensee. Should an interaction need arise, it should happen thru the licensee. Nevertheless, the regulatory body should be always open for discussion on topics related to safety requirement interpretation.	
KOREA	
2.2.1 When should you engage with new build organisations? - **Basically AEAP (as early as possible) is desirable, but the feasibility of new organisation's project should be realized prior to an engagement with regulatory body.** 2.2.2 How should you engage with new build organisations? - **It is possible to engage with new build organisations when they apply pre-application review for their prospective project. In general, the KINS widely check the completion and sufficiency of the application documents focused on the possibility of issuing construction permit in the pre-application review.** 2.2.3 Should you engage with parent bodies, if so when and how? - **It depend on the relationship of parent bodies and new organisations. If they are separate in a QA point of view, it is not easy to find the legal basis to engage with parent bodies.** 2.2.4 Should you engage with contractors and suppliers, if so when and how? - **In general, the KINS engage with contractors and suppliers by means of QA or supplier/vendor inspection program. However it is possible after the new licensee apply the construction permit.**	
NETHERLANDS	
2.2.1 When should you engage with new build organisations? preferably early, before a license application is submitted 2.2.2 How should you engage with new build organisations? - (pre-)licensing meetings - Discussion on expectations of both parties - See answer to 1.1.1 2.2.3 Should you engage with parent bodies, if so when and how?	

Question mark (we only interact with the (future) license-holder. That could be the owner of the plant) 2.2.4 Should you engage with contractors and suppliers, if so when and how? See answer 2.2.7, early interaction with contractors and suppliers (in the Netherlands) normally is limited. In the case of oversight at long lead items or when the requirements needs to be explained, there could be contact.	
POLAND	
2.2.1 When should you engage with new build organisations? As soon as possible. Working-level non-binding contacts are possible on request; formal contacts are impossible without official submissions. 2.2.2 How should you engage with new build organisations? Meetings, workshops, joint-trainings. 2.2.3 Should you engage with parent bodies, if so when and how? No. 2.2.4 Should you engage with contractors and suppliers, if so when and how? Inspections of suppliers and contractors are possible but other communications should go through licensee.	
RUSSIA	
2.2.1 When should you engage with new build organisations? The regulator should engage with new organisations once they apply for a license. 2.2.2 How should you engage with new build organisations? New organizations (operating organizations and subcontractors) must get the corresponding licenses from the regulatory body. The licensing process is to verify the applicant's ability to provide safety and security; subsequently the regulatory body performs the supervision of a licensee. 2.2.3 Should you engage with parent bodies, if so when and how? In our opinion basically the regulator should interact directly with the licensee in order to assess his ability to perform its activities in the field of nuclear energy use in accordance with the safety requirements. 2.2.4 Should you engage with contractors and suppliers, if so when and how? The primary responsibility for the selection of contractors and suppliers is on the licensee. However, in Russia the activities of contractors and suppliers are the subject of licensing. The regulatory body assesses their ability to ensure the safety of nuclear power plants in the implementation of the stated activities.	

UNITED ARAB EMIRATES	
2.2.1 When should you engage with new build organisations? 2.2.2 How should you engage with new build organisations? 2.2.3 Should you engage with parent bodies, if so when and how? 2.2.4 Should you engage with contractors and suppliers, if so when and how? Early stage from the start, it is the best time of engagement -Inspection of main operator, vendors and contractors -Regulator should be engaged with parent bodies to set a resolution when dealing with its branched organizations. - Regulator should carry inspection activities with contractors and suppliers at early stage	
UNITED KINGDOM	
2.2.1 When should you engage with new build organisations? ONR engages with new build organisations very early and at their request. This approach is advised as it is likely to ensure that these new organisations fully understand ONR's expectations for each facet of their development for each phase of the project. Once the new licensee and the ONR have agreed to engage on the licensing process a Pre-Application Engagement Strategy is developed agreed. This strategy is published by ONR and clearly sets out the governance framework employed to structure the engagement and ONR's high level expectations during this phase up to the application for a nuclear site licence. Once an application is made, the process enters the Nuclear Site Licence (NSL) application assessment phase. During this phase the arrangements developed in the pre-application phase are assessed for both the adequacy of the arrangements against our published expectations and the adequacy of their implementation through structured interventions. In parallel, the applicant will continue to mature and grow its arrangements and capabilities during the assessment phase and ONR continue to provide advice and guidance during this phase. If ONR judges that the aspirant licensee has met the requirements for issue of a nuclear site licence, then one will be issued and the corporate body becomes a Nuclear Licensee and from that point is regulated against the conditions attached to the licence. 2.2.2 How should you engage with new build organisations? ONR engage with the aspirant licensee as an enabling regulator. ONR seeks to provide clarity of our expectations engaging in a positive atmosphere. Nuclear site licensing is a very complex activity and needs to take place within a structured framework as described in the section above. ONR's published pre-application strategy aims to provide that structure. Once an application is made, ONR publishes a further engagement strategy for the application assessment phase. These documents are applicant specific and are	

published on ONR's website. 2.2.3 Should you engage with parent bodies, if so when and how? The relationship between an aspirant licensee and their parent body is unique to those organisations. As discussed above, some parent bodies are reactor designers and have no experience in operations – indeed they may also have limited experience of construction. Other parent bodies may have significant experience across several phases of the project. The ownership of new build organisations is likely to change several times during the project. Financing of such a huge investment for a highly complex project brings significant risks and challenges and these factors drive ownership decisions and evolution of the relationship between parent bodies and the new build organisation. Whilst the new build organisation is the duty holder for the nuclear site licence and is held responsible in law for all its activities, the parent bodies clearly have the potential to significantly influence the new build (licensee) organisation. For these reasons ONR focuses on the corporate governance arrangements in assessing if the parent bodies can exert undue influence on the licensee organisation in relation to nuclear safety. ONR therefore does engage with parent bodies when required to explain our expectations in these areas. However, most of the necessary engagements are through the aspirant licensee organisation. Where the parent body is also the designer, engagement takes place directly on design assessment activities but this is done through the Generic Design Assessment (GDA) process which is separate from the licensing process. The GDA takes place between the Requesting Party (the designer) and the ONR. The licensing process takes place between the aspirant Nuclear Site Licence Company (licensee organisation) and the ONR. 2.2.4 Should you engage with contractors and suppliers, if so when and how? Contractors and suppliers clearly have the potential to influence nuclear safety through the design and quality of the goods and services they supply to the licensee. ONR has specific powers under the nuclear site licence to engage directly with contractors and suppliers for their activities on the site itself. Additionally, ONR has the power under the Health and Safety at Work Act to inspect the quality of materials and equipment supplied to the nuclear site in locations away from the nuclear site (for example at suppliers works) where that material or equipment is important for nuclear safety. During the pre-application and assessment phases ONR engages with suppliers and contractors in the presence of the aspirant licensee organisation as they develop their contractual and oversight arrangements for the construction phase of the project.	
UNITED STATES OF AMERICA	
2.2.1 When should you engage with new build organisations?	

The NRC encourages the earliest possible interaction with applicants, vendors, and other Government agencies to provide for early identification of regulatory requirements and to provide all interested parties, including the public, with a timely, independent assessment of the safety and security characteristics of new reactor designs. The NRC foresees that such interaction early in the design process will contribute to stability and predictability in the licensing and regulation of new reactors. This is especially important for advanced reactor where there is an absence of a significant history of operating experience. The NRC encourages the sharing of plans for the innovative use of proven technology and/or new technology development programs as early as possible, so that the NRC can assess how the proposed program might influence regulatory requirements. The NRC interacts with prospective applicants in varying type, scope, formality, and frequency as a prospective applicant progresses toward tendering an application. Pre-application activities support NRC readiness to conduct licensing reviews in a predictable timeframe, and major policy, technical, and licensing issues should be identified and progress should be made in understanding how such issues can be resolved before the NRC receives the applications. 2.2.2 How should you engage with new build organisations? Prior to the receipt of an application, the NRC engage with new build organizations through pre-application activities. NRC Regulatory Guide 1.206, “Combined License Applications for Nuclear Power Plants (LWR Edition),” discusses pre-application activities and how it encompasses all the communications, correspondence, meetings, document submittals/reviews, and other interactions that occur between the NRC and a prospective applicant before the tendering of an application. The NRC considers pre-application activities to be mutually beneficial to both the NRC and prospective applicants and encourages prospective applicants to initiate interactions early in the application planning process. Pre-application activities, although encouraged and recommended by the NRC, are not required and are voluntary by prospective applicants. 2.2.3 Should you engage with parent bodies, if so when and how? Yes, to the extent that parent bodies have influence over prospective applicants. The NRC interacts with parent bodies through pre-application activities as discussed in the response to 2.2.2. 2.2.4 Should you engage with contractors and suppliers, if so when and how? Yes, to the extent that prospective applicants have agreements with contractors and suppliers to provide safety-related services, testing,	

equipment, materials, or activities, the NRC engages with them typically through inspections.	

2.3. Development of Guidance	
Answers	**Learning**
CANADA	
2.3.1 What are the key areas regulators need to focus across OC for new build organisations? 2.3.2 Do you have sufficient guidance across areas regulators need to focus across OC for new build organisations? 2.3.3 Do you have sufficient guidance across these areas – where are the gaps? **The regulatory documents in the Canadian regulatory framework do provide guidance on how to apply specific regulatory requirements. In addition, CNSC has prepared internal work processes to address the construction license application reviews, of which one topic is the organisational management and human factors.**	**-Providing clearer guidance on what a minimum level of licensee capabilities should look like to be an Intelligent Customer when dealing with extensive use of outsourced (and international) equipment and services suppliers**
FINLAND	
2.3.1 What are the key areas regulators need to focus across OC for new build organisations? Safety Culture, competence, resource planning, management system development. 2.3.2 Do you have sufficient guidance across areas regulators need to focus across OC for new build organisations? Practical oversight guidance could be improved, we have enough requirements for the licensee. 2.3.3 Do you have sufficient guidance across these areas – where are the gaps? There is a sufficient amount of regulatory requirements, internal guidance concerning oversight could be improved.	
HUNGARY	
2.3.1 What are the key areas regulators need to focus across OC for new build organisations? - Establishment and continuous development of a management system; - "Intelligent Customer" capabilities; - **Configuration and requirements management;** 2.3.2 Do you have sufficient guidance across areas regulators need to focus across OC for new build organisations? **No, we have not developed guidance for this area.** 2.3.3 Do you have sufficient guidance across these areas – where are the gaps?	

No, we have not developed guidance for this area.	
KOREA	
2.3.1 What are the key areas regulators need to focus across OC for new build organisations? - **Financial capacity, design and construction capability, and QA program are the key areas we have to mainly check.** 2.3.2 Do you have sufficient guidance across areas regulators need to focus across OC for new build organisations? - **In the KINS regulatory standards and guidance, general requirements related to the OC are described, but they are not limited to the new build organisations.** 2.3.3 Do you have sufficient guidance across these areas – where are the gaps?	
NETHERLANDS	
2.3.1 What are the key areas regulators need to focus across OC for new build organisations? The resources, nuclear knowledge, safety culture, quality of the working-processes 2.3.2 Do you have sufficient guidance across areas regulators need to focus across OC for new build organisations? No, input from organisational, human factor and economic studies/areas is needed. 2.3.3 Do you have sufficient guidance across these areas – where are the gaps? - How to deal with a possible shift in responsibilities from an organization taking care of the application to an organization running an installation? - Which criteria to use in reviewing the organisational capabilities in the pre-licensing phase? - Which level of detail to use in reviewing the organisational capabilities in the pre-licensing phase?	- **How to deal with a possible shift in responsibilities from an organization taking care of the application to an organization running an installation?** - **Which criteria to use in reviewing the organisational capabilities in the pre-licensing phase?** - **Which level of detail to use in reviewing the organisational capabilities in the pre-licensing phase?**
POLAND	
2.3.1 What are the key areas regulators need to focus across OC for new build organisations? Training programs, safety culture, needed skills and competences 2.3.2 Do you have sufficient guidance across areas regulators need to focus across OC for new build organisations? No. 2.3.3 Do you have sufficient guidance across these areas – where are the gaps?	

No.	
RUSSIA	
2.3.1 What are the key areas regulators need to focus across OC for new build organisations? Russian NPPs licensees are not newcomers in the field of nuclear energy use (See also the answer to p. 1.1.1). However, we believe that the main attention should be paid to ensure professional capability, a clear distribution of responsibility, as well as the efficiency of communication between employees (including managers) on security issues. 2.3.2 Do you have sufficient guidance across areas regulators need to focus across OC for new build organisations? Russian NPPs licensees are not newcomers in the field of nuclear energy use (See also the answer to p. 1.1.1) and specific guidance were not developed for new organizations. 2.3.3 Do you have sufficient guidance across these areas – where are the gaps? Russian NPPs licensees are not newcomers in the field of nuclear energy use (See also the answer to p. 1.1.1) and specific guidance were not developed for new organizations.	
UNITED ARAB EMIRATES	
2.3.1 What are the key areas regulators need to focus across OC for new build organisations? 2.3.2 Do you have sufficient guidance across areas regulators need to focus across OC for new build organisations? 2.3.3 Do you have sufficient guidance across these areas – where are the gaps? -Development and effective implementation of a comprehensive Integrated Management System. Implementation meaning that all procedures required to support and execute the IMS functions are approved and ready for use and the people needed to support IMS functions are in place and appropriately trained and qualified. -Training programs that are SAT based – for licensee staff and contractors performing work that affects Safety -Contractual arrangements that introduce requirements that may impact Safety (e.g. contracts that are heavily based on financial incentives / motives rather than Safety incentives / motives) Guidance in this area is not strong nor detailed enough. FANR has developed its own approach towards determining organisational operational readiness. WANO performance objectives and criteria are being used by the applicant but are not accessible to non WANO members. See above. Reliance on strictly qualitative criteria can create difficulties to reach “reasonable assurance” finding for licensing. Nawah (applicant for Barakah OL) has developed an approach to holistically determining readiness for operations,	

including OC, that is based on several inputs across functional areas: alignment with Korean Model, readiness of procedures, staff levels and qualifications, WANO SOERs appropriately addressed.	
UNITED KINGDOM	
2.3.1 What are the key areas regulators need to focus across OC for new build organisations? The ONR approach is to licence the aspirant organisation rather than the technology and on this basis the guidance of Licensing Nuclear Installations (LNI) has been developed. LNI sets out how and why we regulate licence sites that carry out prescribed activities. An aspirant Licensee would submit a Nuclear Site Licence (NSL) application to the ONR for assessment. The ONR's key areas of focus for organisational capability during the formal NSL application assessment phase prior to NSL granting are; the development of capability, company structures, governance and procedures, including: · Safety management prospectus · Company manual · Core capability · Employment model · Nuclear baseline · Intelligent customer · Design authority · Internal challenge · Procurement 2.3.2 Do you have sufficient guidance across areas regulators need to focus across OC for new build organisations? The ONR publishes its guidance on regulatory expectations for licensing of nuclear installations. The document Licensing Nuclear Installations (LNI) details ONR's expectations. Specific requirements are published in the ONR's Safety Assessment Principles (SAPs) and in our Technical Assessment Guides for Inspectors (TAGs) and our Technical Inspection Guides for Inspectors (TIGs). These guidance documents aim to incorporate appropriate international and national guidance. The ONR believes there is sufficient guidance in place to support the regulation of core organisational capability of the Licensee. However, further guidance on Corporate Governance, particularly for companies seeking to develop major nuclear projects in another country would be beneficial. 2.3.3 Do you have sufficient guidance across these areas – where are the gaps? The core organisational capability of licensee is covered in the	**Guidance for regulating oversees companies seeking to develop major nuclear infrastructure projects in another country, with a particular focus on Corporate Governance and Independence.**

ONR's published guidance, with the exception of the issue raised in question.	
UNITED STATES OF AMERICA	
2.3.1 What are the key areas regulators need to focus across OC for new build organisations? As noted in responses to previous questions, NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Chapters 13 and 17 provide guidance pertaining to organisational capabilities. Areas for emphasis will likely depend upon the experience level and structure of the licensee as well as project phase. Potential challenge areas that may warrant specific regulatory attention include licensee dependence on contractors, level of experience in the workforce, and level of familiarity with regulatory expectations. 2.3.2 Do you have sufficient guidance across areas regulators need to focus across OC for new build organisations? Additional guidance to address the challenge areas identified under 2.3.1 would be beneficial assuming best practices are available. 2.3.3 Do you have sufficient guidance across these areas – where are the gaps? Additional guidance to address challenge areas identified under 2.3.1 would appear to address some of the gaps.	

2.4. Interfacing with other Regulators	
Answers	**Learning**
CANADA	
2.4.1 Are you legally required to engage with other regulators? 2.4.2 How and when do you engage? 2.4.3 Do you coordinate regulatory activities with the new licensee? 2.4.4 Which stakeholders do you engage with and how? CNSC interfaces with other regulators with respect to new advanced reactors in a number of different forums, such as NEA, WGRNR and MDEP, IAEA SMR forums and by participating in many international workshops and seminars. Also from time to time CNSC interfaces with specific foreign nuclear agencies in bilateral meetings.	- **Regimes by which to share specific technical and regulatory information of design concepts for the purposes of informing each regulator's decision-making processes (secured information space). For example:** o **Expanding vendor inspections cooperation between regulators** o **Sharing information of construction and commissioning of new technologies**
FINLAND	
2.4.1 Are you legally required to engage with other regulators? 2.4.2 How and when do you engage? There are meetings between safety regulators (e.g. fire safety, security and STUK) sometimes or they meet in public discussions concerning the project. 2.4.3 Do you coordinate regulatory activities with the new licensee? We inform them of our oversight plans and have regular meetings, licensee informs us about future audits. 2.4.4 Which stakeholders do you engage with and how? Ministries and the public in general, different organisations and regulators by meetings, interviews, official documentation etc.	
HUNGARY	
2.4.1 Are you legally required to engage with other regulators? Yes, but only during licensing procedures. Besides that, we can request interactions as needed (e.g. common on-site inspection). Also, based on bilateral agreements, we engage with foreign regulatory bodies. 2.4.2 How and when do you engage?	

On licensing issues, we have to use an electronic governmental channel. On other subjects, we can use regular channels (e-mail, phone, etc.). In case of licensing issues, engagement rules (when, how, what) are stipulated in legally binding administrative regulations. To further enhance cooperation we have an annual meeting with all co-regulators. 2.4.3 Do you coordinate regulatory activities with the new licensee? **Yes, but only as far as necessary, and without causing a conflict of interest.** 2.4.4 Which stakeholders do you engage with and how? Actively: - Licensee of the new build; - Other licensee as needed (e.g. neighbouring nuclear installations); - Other regulatory bodies; - Suppliers (thru or in the presence of the licensee); - Government organisations; - **Press;** As needed: - The public; - NGOs; - Third parties;	
KOREA	
2.4.1 Are you legally required to engage with other regulators? - **In the area of nuclear power plant, the KINS doesn't have many chance to engage with other regulators. However, there is another regulatory agency dealing with the security of nuclear while the KINS mainly focus on the safety.** 2.4.2 How and when do you engage? - **When there are interfaced issue between safety and security, the KINS engage with the other regulatory agency through meeting or workshop organized by Nuclear Safety and Security Commission(NSSC)** 2.4.3 Do you coordinate regulatory activities with the new licensee? - **In general, we don't coordinate regulatory activities with the new licensee. But we are willing to provide information if it is needed.** 2.4.4 Which stakeholders do you engage with and how?	

- **Regional committee meeting (composed of regulators and local residents) is held periodically, and the safety issues or public concerns are discussed in the meeting.**	
NETHERLANDS	
2.4.1 Are you legally required to engage with other regulators? Yes, based on article 3 of the Nuclear Energy Act, the Dutch regulator has to cooperate with other European regulators as well as maintaining relationships with other national and international organisations. The Dutch regulator gives all the information needed by other ministries (for Social Affairs and for Public Health) for the performance of their s 2.4.2 How and when do you engage? With other regulators (for example the Belgian regulator) there is regular contact at working and top-management level 2.4.3 Do you coordinate regulatory activities with the new licensee? In the preliminary phase coordination is an important issue. 2.4.4 Which stakeholders do you engage with and how? There is engagement with all stakeholders. Not only with government, industry and others in and out the nuclear field (as IAEA and NEA), but also with the public and with NGO's. Engagement is partly formal and partly informal oriented.	
POLAND	
2.4.1 Are you legally required to engage with other regulators? Not required but allowed. 2.4.2 How and when do you engage? International organizations and bilateral agreements. 2.4.3 Do you coordinate regulatory activities with the new licensee? Yes 2.4.4 Which stakeholders do you engage with and how? Future licensee, other governmental bodies, universities	
RUSSIA	
2.4.1 Are you legally required to engage with other regulators?	

Yes, in accordance with their competencies within the framework of inter-agency Agreements. 2.4.2 How and when do you engage? On the basis of inter-agency Agreements Rostechnadzor engages experts from these regulatory bodies to participate in: - Development of federal rules and regulations on the use of nuclear energy and other documents establishing requirements to NPP safety; - Conducting inspections (audits) and other measures of control of operation, modernization, extending the life and decommissioning of NPP and making mutually agreed decisions; - Training and professional development of the employees, overseeing NPP safety. With the license application, among other documents, applicant presents the conclusion of ecological examination (by the Ministry of Natural Resources and Environment) and sanitary-epidemiological conclusion for handling nuclear materials and radioactive substances (by Ministry of Health), and also a report on fire safety (coordinated with the Ministry of Emergency situations). 2.4.3 Do you coordinate regulatory activities with the new licensee? No, regulatory activities are carried out by the same rules with new and existing licensees. We may coordinate with new licensees to clarify the certain requirements of these rules. 2.4.4 Which stakeholders do you engage with and how? In addition to licensees, operating organizations and other authorities regulator (Rostechnadzor) cooperates with the State Corporation Rosatom (nuclear control body) and, if necessary, with local authorities. In preparing new and revising existing regulations, regulator “Rostechnadzor” closely cooperates (involvement in discussion and revision) with organisations of the principle reactor designer, general NPP designer and scientific organisations. In discussing safety issues regulator “Rostechnadzor” also cooperates with non-governmental organisations such as, for instance, ''The Nuclear Society'', local environmental organisations. “Rostechnadzor” experts participate in international cooperation within IAEA, NEA OECD and others, support bilateral cooperation with foreign regulators.	
UNITED ARAB EMIRATES	
2.4.1 Are you legally required to engage with other regulators?	

2.4.2 How and when do you engage? 2.4.3 Do you coordinate regulatory activities with the new licensee? 2.4.4 Which stakeholders do you engage with and how? There is no legal requirement to engage with other regulators but the law promotes adopting other regulators and international experiences. - All time regulators should maintain a close engagement with other regulators. - Frequent communication with the new licensee should be established to coordinate the regulatory activities with the new licensee **- Regulators should engage with other governmental authorities and even private sectors which are considered stakeholders in many activities i.e. emergency preparedness and development of regulations.**	
UNITED KINGDOM	
2.4.1 Are you legally required to engage with other regulators? Yes, under the Energy Act 2013 (which vested ONR as a Public Corporation); ONR has a specific duty to cooperate with the Health and Safety Executive (HSE) where the HSE is the primary Competent Authority, for example, for CDM and COMAH. ONR has also entered into various Agency Agreements and Memoranda of Understanding with other government departments and regulators (for example, the Environment Agency) to clarify respective responsibilities. These are published on ONR's website (http://www.onr.org.uk/agency-agreements-mou.htm). 2.4.2 How and when do you engage? ONR engages with other regulators on a continual basis in a variety of ways, including: · Joint inspections · Staff secondments · Information exchange (with other national regulators) · Publication of joint guidance · Cooperation in investigations 2.4.3 Do you coordinate regulatory activities with the new licensee? In relation to new licensees in particular, coordination of regulation activities is via: · Joint operation of the process for generic design	**Given the international nature of supply chains is there an opportunity for better sharing of intelligence between regulators on supply chain performance?**

assessment of new reactors (with Environment Agency). This is described in further detail on ONR's website (http://www.onr.org.uk/civil-nuclear-reactors/generic-design-assessment.htm).

- Joint programme working for new reactor licensing and construction (with Environment Agency). This includes:
  - Structured interactions with licensees (Level 1 - 4 meetings) with escalation mechanisms where necessary
  - Monthly programme boards in which both regulators participate to:
    - § define the strategy and tactics for new build regulation;
    - § set regulatory focus to ensure a targeted and proportionate approach;
    - § ensure alignment to corporate strategic themes;
    - § commission work and setting priorities;
    - § assess the effectiveness of interventions;
    - § provide a review panel and consenting body.
  - Interaction with licensees through defined workstreams / leads within the respective regulators and the licensee. The status of each workstream is reported monthly.
  - Joint administrative arrangements.

2.4.4 Which stakeholders do you engage with and how?

ONR engages with a variety of stakeholders in relation to new licensees, including:

- Site stakeholder groups
- Government, including the Department for Business, Energy & Industrial Strategy
- Other national regulators (via information exchange arrangements)
- WENRA Reactor Harmonisation Working Group (RHWG)
- NEA Multinational Design Evaluation Programme (MDEP)
- The media and general public (via ONR's

corporate communications team)	
UNITED STATES OF AMERICA	
2.4.1 Are you legally required to engage with other regulators? **The NRC engages with other federal regulators, state and local governments, and American Indian Tribes in preparing to review new applications and throughout the review of new applications. Whereas NRC has sole responsibility for determining the adequacy of matters relating to radiological safety, the NRC interacts with other regulators and government organizations in assessing the proposed impact of a nuclear facility on the environment.** 2.4.2 How and when do you engage? **The NRC engages with other organizations prior to recent of an application and during the review of the application.** 2.4.3 Do you coordinate regulatory activities with the new licensee? **The NRC keeps prospective new licensees aware of our efforts to interface with other federal regulators, state and local governments, and American Indian Tribes; however, we do not necessarily coordinate with them. The NRC has the responsibility to conduct these activities regardless of any coordination with prospective new licensees.** 2.4.4 Which stakeholders do you engage with and how? As mentioned in response 2.4.1, the NRC interfaces with other federal regulators, state and local governments, and American Indian Tribes. In addition, the NRC reaches out to local stakeholders (e.g., general public, advocacy organizations) in the vicinity of where a new nuclear power plant would be located.	

Topic 3 - Oversight of Contractors and Suppliers by New Licensees

3.1. Balance between New Licensee Capability and Reliance on Contractors	
Answers	**Learning**
CANADA	
3.1.1 Where is the correct balance? 3.1.2 What are your expectations for the role of the IC? 3.1.3 What are your expectations for the use of embedded contractors? 3.1.4 What should be your expectations in the use and reliance upon an Owners Engineer? CNSC regulatory document RD/GD-369, Licence Application Guide: Licence to Construct a Nuclear Power Plant, addresses human and organisational factors throughout its guidance. It stresses the necessity for the applicant to demonstrate the knowledge, skills and abilities of its workers and those of the major contractors and their subcontractors.	- **What specific key performance measures can address the licensee's knowledge of contractor's work?** - **Intelligent Customer**
FINLAND	
3.1.1 Where is the correct balance? New licensee should be self-sufficient in all safety related core competences. 3.1.2 What are your expectations for the role of the IC? Requirements are the same for all suppliers, graded approach should be used. 3.1.3 What are your expectations for the use of embedded contractors? Requirements are the same for all suppliers, graded approach should be used, there are no specific requirements for certain types of suppliers, and external consultants working for a long time within the licensee's organisation should have similar introduction and training than licensees' employees. 3.1.4 What should be your expectations in the use and reliance upon an Owners Engineer? They can support, but all competence should not be within their organisations.	
FRANCE	
3.1.1 Where is the correct balance? **According to the French regulation, the licensee may resort to contractors for activities important for safety but shall retain the capability to ensure the mastery of these activities. Operational responsibility and control, including the management of accidents, incidents and events, emergency preparedness and emergency management, shall not be entrusted to contractors.**	

3.1.2 What are your expectations for the role of the IC? **When selecting contractors, the licensee shall give priority to safety and to the protection of people and the environment. The contractors have to meet the regulatory and contractual requirements specified by the licensee. They are expected to have the technical capabilities to perform the operations for which they have been hired and to control the risks and consequences associated with these operations. They openly report any deviations to the licensee.** 3.1.3 What are your expectations for the use of embedded contractors? **To ensure the mastery of the activities important for safety, the licensee is required by the French regulation to keep the number of subcontracting levels as low as possible, with a maximum of three tiers including the contract holder. The licensee may nevertheless resort to a greater number of subcontractors in specific cases (*e.g.* for operations requiring particular skills) with the prior authorization of the regulatory body.** 3.1.4 What should be your expectations in the use and reliance upon an Owners Engineer? **It is preferable that the licensee should take on the role of owner's engineer to have the full knowledge and understanding of the design of its installation and to better exercise its responsibility for the control of operations in its installation.**	**Should the regulatory body control the selection process of contractors?**
HUNGARY	
3.1.1 Where is the correct balance? The New Licensee shall have, at all times, knowledge, experience, resource and responsibility minimum, which shall be determined with appropriate margin. 3.1.2 What are your expectations for the role of the IC? An intelligent customer shall have enough competencies to order a product (to prepare an adequate specification). An IC shall be able to identify all relevant safety requirements for the products and shall be able to require it. An IC shall be able to assess whether the products meet these specifications before the product is used. **The IC shall be able to select the suppliers of products and services based on specified criteria and evaluate their performance.** 3.1.3 What are your expectations for the use of embedded contractors? **The decision on the involvement of suppliers shall be based on well-established strategy. Pre-defined criteria shall be used for the selection of suppliers.** 3.1.4 What should be your expectations in the use and reliance upon an Owners Engineer? The New Licensee shall build up its own capabilities for engineering activities or use of an Owners Engineer. In case of use of Owners	**knowledge, experience, resource and responsibility minimum** **evaluate the IC capabilities** **Selection of supplier and evaluate their capabilities**

Engineer, the Licensee shall have the core competencies (see 3.1.1 and 3.1.2)	
KOREA	
3.1.1 Where is the correct balance? - **In Korea, the balance between licensee and contractors are specified in the Fair Transactions in Subcontracting Act and Dispatched Work Act.** 3.1.2 What are your expectations for the role of the IC? 3.1.3 What are your expectations for the use of embedded contractors? - **The use of embedded contractors would be preferable and desirable in the way that they are usually familiar with regulatory requirements.** 3.1.4 What should be your expectations in the use and reliance upon an Owners Engineer? - **In general, the Owners Engineer have wide experiences on their works and a good understanding on the regulatory requirements. Therefore, the use of Owners Engineers has many advantages in a viewpoint of safety compare with external engineer.**	
NETHERLANDS	
3.1.1 Where is the correct balance? New licensees are primarily responsible for nuclear safety and security of their installation. They shall act upon to their contractors. Reliance is by far not enough. 3.1.2 What are your expectations for the role of the IC? ?? 3.1.3 What are your expectations for the use of embedded contractors? See answer 3.1.1. 3.1.4 What should be your expectations in the use and reliance upon an Owners Engineer? See answer 3.1.1.	
POLAND	
3.1.1 Where is the correct balance? 3.1.2 What are your expectations for the role of the IC? 3.1.3 What are your expectations for the use of embedded contractors? 3.1.4 What should be your expectations in the use and reliance upon an Owners Engineer? *No answers*	

RUSSIA	
3.1.1 Where is the correct balance? The right balance should be determined by taking into account different factors such as the available resources (for the licensee and the regulator), as well as the degree of influence at the safety of nuclear power plants of an activity carried out by the contractor. 3.1.2 What are your expectations for the role of the IC? No certain specific expectations. 3.1.3 What are your expectations for the use of embedded contractors? The involvement of contractors should not reduce the responsibility of the operating organization for ensuring safety. The operator must exercise effective control over the activities of the contractors, including the control of performance of quality assurance programs. 3.1.4 What should be your expectations in the use and reliance upon an Owners Engineer? No certain specific expectations.	
UNITED ARAB EMIRATES	
3.1.1 Where is the correct balance? This is very situation dependent. Different arrangements can achieve similar results. Ideally the reliance on contractors would be reduced over time as new licensees / new comer countries build capacity and capability. Regardless of organisational arrangements the licensee has prime responsibility for safety. 3.1.2 What are your expectations for the role of the IC? Not sure what IC is. 3.1.3 What are your expectations for the use of embedded contractors? From the regulatory perspective, embedded contractors are expected to conduct work in accordance with the regulatory requirements and the licensing basis. Embedded contractors should be trained and qualified in accordance with the licensee's program. 3.1.4 What should be your expectations in the use and reliance upon an Owners Engineer? Not sure what Owners Engineer is.	
UNITED KINGDOM	
3.1.1 Where is the correct balance? ONR's expectations on the balance between licensee capability and reliance on contractors is set down in NS-TAST-GD-049 - Licensee Core and Intelligent Customer Capabilities (http://www.onr.org.uk/operational/tech_asst_guides/ns-tast-gd-049.pdf).	**How should regulators define the minimum capability requirements for new licensees ?**

ONR's position is that the licensee must be able to demonstrate sufficient knowledge of the plant design and safety case for all plant and operations on the licensed site. The licensee must be in control of activities on its site, understand the hazards associated with its activities and how to control them, and have sufficient competent resource within its organisation to be an 'intelligent customer' for any work it commissions externally. This core capability includes, but is not necessarily be limited to, technical, operational and managerial resources. NS-TAST-GD-079 sets specific expectations in relation to licensee's Design Authority capability. 3.1.2 What are your expectations for the role of the IC? ONR's expectations for the role of the intelligent customer (as per NS-TAST-GD-049) are: 1. The licensee should 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; 2. 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; 3. The licensee should maintain an 'intelligent customer' capability for all work carried out on its behalf by contractors that may impact upon nuclear safety; 4. The licensee should ensure that it only lets contracts for work with nuclear safety significance to contractors with suitable competence, safety standards, management systems, culture and resources; 5. The licensee should ensure that all contractor staff are familiar with the nuclear safety implications of their work and interact in a well-coordinated manner with its own staff; 6. The licensee should ensure that contractors' work is carried out to the required level of safety and quality in practice. 3.1.3 What are your expectations for the use of embedded contractors? ONR's expectations are set down inNS-TAST-049 and NS-TAST-GD-065. Embedded contractors may form part of the licensee's core capability (above), however the licensee should be able to demonstrate that these individuals are subject to the licensee's processes for competence assurance, line management, discipline, succession planning etc. ONR considers that such contractors need not be subject to control and oversight different from a normal employee. The licensee's nuclear baseline* should identify where roles are held by embedded contractors to show that it understands where it is vulnerable to loss of contract resource, and to	

demonstrate that the balance of staff-contractors is suitable. *The nuclear baseline is the means by which the licensee demonstrates that its organisational structure, staffing and competencies are, and remain, suitable and sufficient to manage nuclear safety throughout the full range of the licensee's business. 3.1.4 What should be your expectations in the use and reliance upon an Owners Engineer? ONR does not have specific expectations in relation to use and reliance upon an Owners Engineer. However the generic expectations above on licensee capability and intelligent customer oversight of contractors apply.	
UNITED STATES OF AMERICA	
3.1.1 Where is the correct balance? As noted in response to 2.3.3, the balance of capability between licensee and contractor may not be sufficiently addressed in guidance and a technical basis that reflects the many considerations is likely needed. 3.1.2 What are your expectations for the role of the IC? Criterion I of Appendix B to 10 CFR Part 50 states that because of the number of variables involved, such as the number of personnel, the type of activity being performed, and the locations where activities are performed, the organisational structure for executing the QA program may take various forms. The IC may delegate to others the work of establishing and executing the QA program. However, the IC retains responsibility for the QA program. Further, the authorities and duties of persons and organizations performing activities affecting safety must be clearly established and delineated in writing. 3.1.3 What are your expectations for the use of embedded contractors? Embedded contractors are normally trained and qualified to work under the cognizant Appendix B to 10 CFR Part 50 quality assurance program requirements. The training and qualification would address the applicable quality procedures and processes that the embedded contractors would be expected to adhere to in the performance of their specific duties. 3.1.4 What should be your expectations in the use and reliance upon an Owners Engineer? The expectations for use of an Owners Engineer are be the same. It should be pointed out that for work conducted by engineering personnel that the applicable requirements of Appendix B would apply to activities affecting quality. The verification or checking on the adequacy of design, such as by the performance of design reviews by the use of alternate or simplified calculations or by the performance of testing must be conducted. Additionally, the verifying or checking process must be performed by individuals or groups	

other than those who performed the original design.	
3.2. The EPC Model	
Answers	**Learning**
CANADA	
3.2.1 What should be your expectations for the oversight of the EPC contractor by the new licensee? 3.2.2 What are your expectations for IC in relation to the EPC? Discussion on new ownership and operating models for power reactor facilities (whether NPPs or SMRs) given the increasingly international approach to deployment and customer support. Ownership models are evolving into models that increasingly draw resources from foreign vendor and related services companies.	- **How much involvement would the regulator have into ensuring that the licensee verifies the major contractors' quality of work and supply chain?** - **Providing clearer guidance on what a minimum level of licensee capabilities should look like to be an Intelligent Customer when dealing with extensive use of outsourced (and international) equipment and services suppliers** - **Reliance on ISO Certification**
FINLAND	
3.2.1 What should be your expectations for the oversight of the EPC contractor by the new licensee? Licensee should have very active oversight and do regular audits constantly. EPC contractor should have strong understanding of the requirements and should communicate requirements very well. EPC contractor scopes can be different. EPC contractor should have strong oversight and review processes and licensee should expect that. 3.2.2 What are your expectations for IC in relation to the EPC?	
FRANCE	
3.2.1 What should be your expectations for the oversight of the EPC contractor by the new licensee? According to the French regulation: - The licensee shall have sufficient technical capabilities to ensure the mastery of the activities carried out in its installation. This requirement may be achieved through agreements with third parties. - It shall retain competencies to understand and assimilate the basis of the installation activities on the long term. These	

competencies must be available in-house, in subsidiaries or in companies under its control. - **As part of its responsibility for the control of the risks and consequences resulting from the activities carried out in its installation, it shall have sufficient technical capabilities to take any decisions and implement any protective measures with full knowledge of the facts and in a timely manner. These technical capabilities must be retained in-house.** **The French regulation does not encourage EPC-type contracts and does not differentiate major contractors from other contractors. The licensee shall supervise that its safety policy is implemented by all contractors and that all the processes, products and services they provide meet the specified requirements. The licensee shall not delegate the oversight of the contractors to a third party but may be assisted in this activity by an outside organization, provided it retains the competencies required to master this activity.** 3.2.2 What are your expectations for IC in relation to the EPC? The EPC contractor is expected to liaise between the ICs. It relies on contracts that clearly define the responsibilities of each party, their commitments in terms of quality and results and the applicable requirements. The statutory oversight of all contractors by the licensee does not release the EPC contractor from its responsibilities in the management of the ICs.	
HUNGARY	
3.2.1 What should be your expectations for the oversight of the EPC contractor by the new licensee? Pre-defined criteria shall be used for the selection of the EPC contractor. The Licensee shall evaluate the EPC contractor's capabilities for the implementation an EPC project before starting the implementation. The Licensee shall evaluate the EPC contractor's capabilities before each implementation stage. The Licensee shall be able to evaluate the EPC contractor's capability for controlling the all supply chain. **The Licensee shall be able to control the implementation activities.** 3.2.2 What are your expectations for IC in relation to the EPC? **Every entity in the supply chain shall have the IC capability.**	**evaluation the EPC contractor's capabilities for the implementation an EPC project** **evaluation the Licensee's and the EPC contractor's capabilities for controlling the all supply chain**
KOREA	
3.2.1 What should be your expectations for the oversight of the EPC contractor by the new licensee? - **If the new licensee well understand the QA program and regulatory requirements, there are no significant difference between the new and existing licensee.** 3.2.2 What are your expectations for IC in relation to the EPC?	
NETHERLANDS	

3.2.1 What should be your expectations for the oversight of the EPC contractor by the new licensee? See answer 2.2.7 , we only interact with the (future) license-holder. That could be the owner of the plant. The contractor shall operate as if being the owner of the plant, so in the same framework of nuclear safety (culture) and security. 3.2.2 What are your expectations for IC in relation to the EPC? ??	
POLAND	
3.2.1 What should be your expectations for the oversight of the EPC contractor by the new licensee? Responsibility for safety rests with licence holder. 3.2.2 What are your expectations for IC in relation to the EPC?	
RUSSIA	
3.2.1 What should be your expectations for the oversight of the EPC contractor by the new licensee? No certain specific expectations. 3.2.2 What are your expectations for IC in relation to the EPC? No certain specific expectations.	
UNITED ARAB EMIRATES	
3.2.1 What should be your expectations for the oversight of the EPC contractor by the new licensee? EPC contractor should meet requirements of licensee's IMS including quality program. Licensee should be conducting regular oversight activities to ensure conformance with contract. Regulator communicates with licensee but should conduct its own program of inspections and oversight of EPC and EPC sub-contractors. 3.2.2 What are your expectations for IC in relation to the EPC? Not sure what IC is.	
UNITED KINGDOM	
3.2.1 What should be your expectations for the oversight of the EPC contractor by the new licensee? The primary responsibility for the safety of a nuclear installation rests with the Licensee. The Licensee is expected to establish effective Supply Chain Management arrangements and carry out adequate oversight, assurance and acceptance of items or services being supplied or undertaken on its behalf where their sub-standard delivery has the potential to impact on nuclear safety. 3.2.2 What are your expectations for IC in relation to the EPC? The primary responsibility for the safety of a nuclear installation rests with the Licensee. The Licensee must be able to demonstrate sufficient knowledge of the plant design and safety case for all plant	

and operations on the licensed site. The Licensee must be in control of activities on its site, understand the hazards associated with its activities and how to control them, and have sufficient competent resource within the licensee organisation to be an 'Intelligent Customer' for any work it commissions externally. In the context of effective Supply Chain Management, the Licensee should maintain an 'Intelligent Customer' capability to know what is required, to fully understand the need for a contractor's services, at any level of the SC, should specify requirements, should supervise the work and should technically review the output before, during and after implementation.	
UNITED STATES OF AMERICA	
3.2.1 What should be your expectations for the oversight of the EPC contractor by the new licensee? The NRC's requirements would require the new licensee to provide adequate oversight of the EPC (Engineering and Procurement Contractor). The quality standard implementing the regulations require that the new licensee ensure that the EPC's QA program meets regulatory requirements and is adequately implemented. The standard states that a new licensee may delegate any or all of the work to others, such as an EPC, but shall retain overall responsibility. The quality standard requires that where more than one organization is involved in the execution of activities, the responsibilities, interfaces, and authority of each organization shall be clearly defined and documented. The quality standard also requires that external interfaces between organizations and the internal interfaces between organisational units, and any changes be documented in the EPC's and new licensee's QA manual. The NRC has identified instances where new licensees for on-going nuclear power plant construction were not providing adequate oversight of their EPCs. Appropriate enforcement actions were taken to require the new licensees to meet their regulatory responsibilities. 3.2.2 What are your expectations for IC in relation to the EPC? The regulations and quality standard applicable to the entities involved require that prior to award of a contract to the EPC, the new licensee must evaluate the EPC's capability to design, procure necessary items or services and construct the new facility in accordance with the requirements of the procurement documents. The new licensee's evaluation and selection of the EPC is required to be documented and must include: (a) the EPC's history of adequately providing an identical or similar service; (b) that the EPC's history shall reflect its current capability the new licensee objectively evaluating past performance; and (c) the new licensee determine the EPC's technical and quality capability by direct evaluation of the facilities, personnel, and the implementation of the EPC's QA program.	

3.3. Supplier Surveillance	
Answers	**Learning**
CANADA	
3.3.1 Do you have the legal framework to adequately regulate the use of the supply chain? 3.3.2 Do suppliers understand the regulatory requirements? 3.3.3 What should be your expectations of new licensees in overseeing the supply chain – is there sufficient guidance? Canadian NPP licensees have smart buyer functions to assure that the services rendered to them serve the purpose and meet the relevant requirements. In short, a smart buyer is an organization that knows what it will likely receive, its implications, the methodology used by outside contractors to arrive at certain positions, and how the results received will be managed. For example, a smart buyer function establishes a number of key attributes to enable recognition of the quality of outputs provided by outside organizations that might affect safety: - sufficient staff to maintain specialized expertise in the required discipline (e.g., thermal hydraulics) - in-depth knowledge of past and present regulatory issues - rapport with regulatory staff specialists - in-depth knowledge of NPP design and operation - ability to provide leadership on technical issues within the Canadian nuclear industry	**-Providing clearer guidance on what a minimum level of licensee capabilities should look like to be an Intelligent Customer when dealing with extensive use of outsourced (and international) equipment and services suppliers**
FINLAND	
3.3.1 Do you have the legal framework to adequately regulate the use of the supply chain? Yes, we have the required legislation and very detailed requirements concerning supply chain management. 3.3.2 Do suppliers understand the regulatory requirements? This can be very challenging and it is dependent on the culture. Sometimes they do not understand and it takes time to develop understanding. 3.3.3 What should be your expectations of new licensees in overseeing the supply chain – is there sufficient guidance? There is a sufficient amount of requirements, internal guidance and oversight strategies for the regulator should be developed. It is expected that the licensee has some control over the entire supply chain by using the graded approach.	
FRANCE	
3.3.1 Do you have the legal framework to adequately regulate the	

use of the supply chain?	
Except for assessing the conformity of nuclear pressure equipment, ASN does not directly control suppliers. The licensee is responsible for the control of the risks and consequences resulting from the activities carried out in its installation. As such, it defines technical and quality requirements to be met by the suppliers. The technical requirements are based on design and construction rules issued by the nuclear industry. The requirements for the processes important for safety are specified by the licensee. The licensee supervises that the suppliers comply with all regulatory and contractual requirements. The oversight of the suppliers by the licensee is imposed by the French regulation (see item 3.3.3 below).	**Should the regulatory body directly control the suppliers?** **If so, should the regulatory body control both compliance with the technical requirements and quality assurance process?**
3.3.2 Do suppliers understand the regulatory requirements?	
It is the responsibility of the licensee to inform the suppliers of the regulatory requirements they have to comply with and to explain to them how to meet these requirements. Suppliers' potential weaknesses include the reporting of deviations (*e.g.* defective components are discarded without notice to the licensee) and the identification and mastery of the manufacturing processes important for safety. **As a matter of interest, an ISO standard specific for the suppliers of the nuclear industry will shortly be issued (ISO 19443 *"Quality management systems specific requirements for the application of ISO 9001 and IAEA GSR part 2 by organizations in the supply chain of the nuclear energy sector"*).**	
3.3.3 What should be your expectations of new licensees in overseeing the supply chain – is there sufficient guidance?	
The regulatory requirements on the oversight of the contractors (see item 3.2.1) also apply to the suppliers. The licensee is expected to control the various stages of product manufacturing and conformity assessment through both on-site inspections and document review. **In the special case of nuclear pressure vessels, the French regulation states that conformity is under the responsibility of the manufacturer (which may be taken by the licensee) and must be assessed by an authorized organization. For vessels belonging to the highest risk categories, this assessment is monitored by the regulatory body.**	**How could the regulatory body control that the licensee appropriately oversees its suppliers?**
Guidelines relating to the supply chain management in the nuclear industry have been published by the IAEA (Nuclear Energy Series NP-T-3.21 *"Procurement engineering and supply chain guidelines in support of operation and maintenance of nuclear facilities"*; TECDOC-1169 *"Managing suspect and counterfeit items in the nuclear industry"*, which is currently under revision). **Following the deviations and incorrect documents discovered in the Creusot Forge manufacturing, ASN considers its oversight practices should be strengthened to deal with NCFSIs. It is deemed necessary to push the licensees to increase their control as well.**	

HUNGARY	
3.3.1 Do you have the legal framework to adequately regulate the use of the supply chain? **The existing legal framework adequately regulates the use of supply chain for the existing nuclear installations. This regulation was amended because of the new reactors project. The adequacy of the regulation for the new reactors will be evaluated based on its use.** 3.3.2 Do suppliers understand the regulatory requirements? **Suppliers of the existing nuclear installations understand the regulatory requirements.** 3.3.3 What should be your expectations of new licensees in overseeing the supply chain – is there sufficient guidance? **The regulatory expectations are well defined in the Nuclear Safety Codes. Additional regulatory guidance was not requested by the Licensee on this subject.**	**Level of elaboration of regulatory requirements and guides**
KOREA	
3.3.1 Do you have the legal framework to adequately regulate the use of the supply chain? - **The KINS recognized the importance of regulation through the entire supply chain, and prepared the legal framework for supplier/vendor inspection.** 3.3.2 Do suppliers understand the regulatory requirements? - **It depend on the suppliers' size and experience on the NPP works, and a small-scale supplier suffering from establishing and executing the QA program in accordance with the regulatory requirements.** 3.3.3 What should be your expectations of new licensees in overseeing the supply chain – is there sufficient guidance? - **The KINS provides the regulatory guidance for supplier/vendor inspection, and it would be helpful to oversee the supply chain by new licensee.**	
NETHERLANDS	
3.3.1 Do you have the legal framework to adequately regulate the use of the supply chain? No, although we are working on it by incorporating GSR-Part 2.(as guidance) in our legal system 3.3.2 Do suppliers understand the regulatory requirements? At least they should. The new licensee is responsible for that. 3.3.3 What should be your expectations of new licensees in overseeing the supply chain – is there sufficient guidance? New licensees are primarily responsible for nuclear safety of their installation. So the licensee shall foster all what is needed to maintain this responsibility. The headlines of this responsibility are	

sufficiently written down in IAEA-guidance, see GSR-Part 2.	
POLAND	
3.3.1 Do you have the legal framework to adequately regulate the use of the supply chain? Inspections of suppliers are required 3.3.2 Do suppliers understand the regulatory requirements? 3.3.3 What should be your expectations of new licensees in overseeing the supply chain – is there sufficient guidance? There are general requirements on licensee managements system, but no detailed guidance.	
RUSSIA	
3.3.1 Do you have the legal framework to adequately regulate the use of the supply chain? Yes there is. Suppliers must obtain the appropriate license from the regulator to perform their activities. 3.3.2 Do suppliers understand the regulatory requirements? Yes they understand. Suppliers must obtain the appropriate license from the regulator to perform their activities. 3.3.3 What should be your expectations of new licensees in overseeing the supply chain – is there sufficient guidance? Russian NPPs licensees are not newcomers in the field of nuclear energy use (See also the answer to p. 1.1.1)	
UNITED ARAB EMIRATES	
3.3.1 Do you have the legal framework to adequately regulate the use of the supply chain? 3.3.2 Do suppliers understand the regulatory requirements? 3.3.3 What should be your expectations of new licensees in overseeing the supply chain – is there sufficient guidance? Main operator and its suppliers are committed to implement, codes and standards, i.e. ASME, NQA1-1994 to verify their compliance with the standards. - In general the operator cascade down the requirements to the prime contractor and its sub-suppliers. **- Standards which are widely used in the nuclear industry are adequately sufficient.**	
UNITED KINGDOM	
3.3.1 Do you have the legal framework to adequately regulate the use of the supply chain? Licence Condition 17: Management systems, identifies that: 1 Without prejudice to any other requirements of the conditions attached to this licence, the licensee shall establish and implement	

management systems which give due priority to safety.

2 The licensee shall, within its management systems, make and implement adequate quality management arrangements in respect of all matters which may affect safety.

As such, ONR expects Licensees to make and implement adequate supply chain management system arrangements.

Specific to the Supply Chain:

The Energy Act (2013) and the Health and Safety (Enforcing Authority) Regulations 1998:

- Identifies the ONR as the enforcing authority for subsections 1, 2, 4 and 5 of section 6 of the HSWA74, but only in so far as those requirements relate to:
  - Articles for use at work which are designed, manufactured, imported or supplied; or
  - Substances which are manufactured, imported or supplied

Where the articles or substances are to be used exclusively or primarily in the installation, operation or decommissioning of a GB nuclear site or authorised defence site.

The Health and Safety at Work etc. Act (1974) – (HSWA74)

- Section 6 requires that any person who designs, manufactures imports or supplies any article for use at work:
  - Must ensure, so far as is reasonably practicable, that the article is designed and constructed as to be safe and without risk to health when properly used;
  - Must carry out or arrange for the carrying out of such testing and examination as may be necessary to comply with the above duty;
  - Must provide adequate information about the use for which it is designed and has been tested to ensure that, when put to use it will be safe and without risk to health.

3.3.2 Do suppliers understand the regulatory requirements?

UK suppliers have a good understanding of their responsibilities as duty holders under the Health & Safety at Work Act.

Licensees support the promulgation of regulatory requirements through their contracts and Supply Chain Management arrangements. As a result, the understanding of ONRs vires as Enforcing Authority for section 6 of the Health & Safety at Work Act (under certain conditions), within UK suppliers, has been enhanced.

3.3.3 What should be your expectations of new licensees in overseeing the supply chain – is there sufficient guidance?

ONR have published Technical Assessment Guides that define regulatory expectations for Supply Chain Management &

Intelligent Customer Capability. TAGs contain guidance to advise and inform ONR staff in the exercise of their regulatory judgment. TAGs are not written for duty holders, and although they may be used as a source of guidance or good practice, they are not a prescriptive set of legal requirements. **The two key TAGs related to Supply Chain Management are:** o NS-TAST-GD-049 – Licensee Core and Intelligent Customer Capabilities o **NS-TAST-GD-077 – Supply Chain Management Arrangements for the Procurement of Nuclear Safety Related Items or Services** **TAG 77 states that the purchaser should conduct effective oversight and assurance of the SC, including the acceptance of items or services for work with nuclear safety significance.** **The purchaser should establish effective arrangements for the oversight of supplier performance throughout the contract period and assurance to ensure that items or services meet the specified intent. The purchaser should ensure that it has sufficient capability to oversee and assure performance throughout the tiers of the SC.**	
UNITED STATES OF AMERICA	
3.3.1 Do you have the legal framework to adequately regulate the use of the supply chain? The NRC's requirements related to the regulator's oversight of the supply chain are described in 10 CFR Part 21 (Part 21), "Reporting of Defects and Noncompliance." Part 21 requires that an entity subject to these regulations permit the NRC to inspect records, facilities, activities and basic (e.g., safety-related) components as necessary. Part 21 also requires that the procurement documents associated with a safety-related item or service identify the applicability of this requirement to the affected Supplier. 3.3.2 Do suppliers understand the regulatory requirements? As stated in 3.3.1, the requirements of Part 21 must be documented in the associated procurement documents which are considered to be a legally binding contractual obligation. When the NRC conducts an inspection of a Supplier, inspection procedures direct the staff to ensure that the Supplier is adequately implementing the regulatory requirements. Additionally, the NRC conducts semi-annual workshops and participate in industry meetings where the NRC's expectations for meeting the regulatory requirements are stressed. 3.3.3 What should be your expectations of new licensees in overseeing the supply chain – is there sufficient guidance? The regulations and quality standard applicable to suppliers are identical to the answer given to Question 3.2.2. The Purchaser is required to ensure that prior to award of a contract to the supplier, to evaluate the Supplier's capability to provide the items or services in accordance with the procurement documents. The Purchaser's evaluation and selection of the Supplier is required to be	

documented and must include: (a) the Supplier's history of adequately providing an identical or similar service; (b) that the Supplier's history reflects its current capability by the Purchaser's objective evaluation of past performance; and (c) the Purchaser determines the Supplier's technical and quality capability by direct evaluation of the facilities, personnel, and the implementation of the Supplier's QA program. There are also additional regulatory positions imposed upon the Purchaser that must be in the QA program that are identified in Regulatory Guide (RG) 1.28, "Quality Assurance Program Requirements (Design and Construction). The regulatory guide requires a Purchaser to periodically evaluate the performance of a Supplier providing a safety-related item or service. The regulatory guide also requires that on a triennial basis, the actions initially taken to assess a Supplier be duplicated to ensure adequate oversight. These same requirements would also be imposed upon an EPC as outline in Question 3.2.2.	

3.4. Project Management	
Answers	**Learning**
CANADA	
3.4.1 What should be your expectations in regard to project management for new build organisations? 3.4.2 Do you have sufficient guidance and cited best practice? 3.4.3 How should you assess new licensee project management capabilities and influence them? The NPP licensees utilize a design authority function to ensure that the integrity of approved designs and the design process is maintained. The design authority is executed by the chief engineer, who has overall responsibility for the smart buyer function. The design authority encompasses overall responsibility for the design process, approval of design changes, and assurance that the requisite knowledge of the reference design is maintained as defined and implemented in the management system. The scope of accountability ensures that: - a knowledge base of relevant aspects of the facility and products is established and kept up to date, while experience and research findings are taken into account - all design information required for a safe facility is available - the requisite security measures are in place - design configuration is maintained for approved designs - appropriate design verification is applied - all necessary interfaces are in place - all engineering and scientific skills are maintained - appropriate design rules and procedures, including codes and standards, are used - engineering work is executed by qualified staff using appropriate methods in compliance with procedures	**Licensee of projects using internationally developed technologies are becoming increasingly reliant on information controlled by business interests outside of their sphere of control. (i.e. offshore technology owners of intellectual property) What are the impacts on the licensee as:** - **an intelligent customer** - **a credible design authority**
FINLAND	
3.4.1 What should be your expectations in regard to project management for new build organisations? Same as for existing licensees (in principle). Modern project management methods should be used and project management should be based on a standard (or similar acknowledged guidance like PMBOK) 3.4.2 Do you have sufficient guidance and cited best practice? We rely on the fact that proper standards are used. 3.4.3 How should you assess new licensee project management	

capabilities and influence them? We do assess them, but the licensee should fulfil requirements. There is no intentional influence but we expect that safety issues are always taken into account when decision concerning the project management are taken. We asses by assessing documents and we perform inspections.	
FRANCE	
3.4.1 What should be your expectations in regard to project management for new build organisations? **Project management must guarantee that priority is given to safety and to the protection of people and the environment in all decisions. The licensee must demonstrate that it has made appropriate arrangements in terms of organization and resources to comply with the regulatory requirements and to implement its safety policy. Special provision must be made for skills management, for the identification and mastery of the activities important for safety, for the investigation of deviations and events, for the use of experience feedback and for continuous improvement.** 3.4.2 Do you have sufficient guidance and cited best practice? **An integrated management system must be developed from the early stages of the project (*i.e.* sitting, design and construction). Requirements and guidelines for developing an integrated management system in the nuclear industry are found in international (*e.g.* IAEA) standards and in most national regulations. A guidance document on integrated management system is under development in France.** 3.4.3 How should you assess new licensee project management capabilities and influence them? **The new licensee must demonstrate that it has the financial and in-house technical capabilities to complete its project in accordance with the regulatory requirements and that it has made appropriate arrangements for carrying out its future activities, including decommissioning, in a safe and compliant manner.** When assessing the capabilities of the licensee, the following questions should be addressed. This list is not exhaustive. *Financial capabilities* - Does the licensee have a realistic budget? - How is the licensee financed? What are the conditions of the loans it took out? What is the relationship with the parent company (if applicable)? - What is the credit rating of the licensee? - What is the financial resilience of the licensee? What is its ability to cope with unplanned heavy maintenance without compromising provision for future activities? With market risk? - Has adequate provision been made for future activities, including for the management of spent fuel, radioactive and	**How to interact with the new licensee and influence it so that it increases its technical and financial capabilities?**

non-radioactive waste? *Technical capabilities* - Does the licensee have sufficient technical capabilities, including equipment, staff and skills, to ensure the mastery of all activities? - Does the licensee have sufficient staff and skills to monitor the contractors and the supply chain? - Does the licensee have sufficient technical capabilities to assess the risks resulting from its activities, to prevent incidents and accidents and limit their consequences in a timely manner? - What are the methods used for recruitment, skills assessment, training and retraining? - Are the key positions filled by experienced people? - What are the measures taken to keep the knowledge and understanding of the installation design on the long term?	
HUNGARY	
3.4.1 What should be your expectations in regard to project management for new build organisations? We have no specific requirement for project management. 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. Project management processes shall be covered by the integrated management system. 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. 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. **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.** 3.4.2 Do you have sufficient guidance and cited best practice? The regulatory expectations are well defined in the Nuclear Safety Codes. Additional regulatory guidance was not requested by the Licensee on this subject. 3.4.3 How should you assess new licensee project management capabilities and influence them? **The HAEA regularly assess the Licensee's Management System by comprehensive inspections and by inspection of the activities.**	**Methodologies for assessments**
KOREA	
3.4.1 What should be your expectations in regard to project management for new build organisations?	

- The KINS doesn't have a specific guideline with respect to the project management for licensee, but project management usually focus on the process control and completion of project. - **Through the periodic meeting or workshop with licensee, therefore, we recommend focusing on the achievement of the safety goal.** 3.4.2 Do you have sufficient guidance and cited best practice? - **In the area of NPP, it is not easy to find a good guidance or best practice related to the project management.** 3.4.3 How should you assess new licensee project management capabilities and influence them? - **In the phase of review for construction permit, the capability of design and construction skill would be checked, and the capability of operation and maintenance would be reviewed when operating license is applied.**	
NETHERLANDS	
3.4.1 What should be your expectations in regard to project management for new build organisations? The bottom line is that project-management is a reflection and an expression of the basic principle of nuclear safety and security. 3.4.2 Do you have sufficient guidance and cited best practice? Certainly not. 3.4.3 How should you assess new licensee project management capabilities and influence them? Basically assessing/reviewing if project management is the reflection and expression of the basic principle of nuclear safety and security.	**How should we assess new licensee project management capabilities and influence them?**
POLAND	
3.4.1 What should be your expectations in regard to project management for new build organisations? 3.4.2 Do you have sufficient guidance and cited best practice? No 3.4.3 How should you assess new licensee project management capabilities and influence them? Description of licensee IMS is part of licence application.	
RUSSIA	
3.4.1 What should be your expectations in regard to project management for new build organisations? Russian NPPs licensees are not newcomers in the field of nuclear energy use (See also the answer to p. 1.1.1) and there are no specific expectations in regard to project management for new build	

organizations. 3.4.2 Do you have sufficient guidance and cited best practice? Basically, the operating organization implements the guidance in this area. 3.4.3 How should you assess new licensee project management capabilities and influence them? Russian NPPs licensees are not newcomers in the field of nuclear energy use (See also the answer to p. 1.1.1) and there are no specific expectations in regard to project management for new build organizations.	
UNITED ARAB EMIRATES	
3.4.1 What should be your expectations in regard to project management for new build organisations? 3.4.2 Do you have sufficient guidance and cited best practice? 3.4.3 How should you assess new licensee project management capabilities and influence them? -Ensure to have process in place, integrated management system, have certified project management official with nuclear industry background. -The ability to deliver the project based on timeframe and plan. **-Meeting the regulatory requirements**	
UNITED KINGDOM	
3.4.1 What should be your expectations in regard to project management for new build organisations? The ONR would expect the Licensee to produce and maintain Safety Reports for the phases of construction and commissioning, while: · Maintaining control and oversight of all safety significant matters · Sustain adequate organisational capability to manage for safety · Implement arrangements for licence condition compliance and ensure continued adequacy · Manage construction activities and modifications to design and organisation The ONR would seek assurance that Project Management personnel are suitably qualified and experienced to manage the safe delivery of work, working within the framework of the Licensee's arrangements. The Project Managers must understand the safety significance of the work they are managing, consider key interdependences with other work packages and any potential for latent or secondary safety related impact and raise concerns with the appropriate authority in a timely manner to enable informed decision making. Project Management should promote the appropriate safety culture	

through the project profession/discipline and into their supply chain, encouraging individual and management commitment to safety, supported by the appropriate management systems. The ONR is aware that Institutions/Associations for project management fail to differentiate the increased demands associated with managing nuclear projects over conventional projects, which has the potential to impact delivery. 3.4.2 Do you have sufficient guidance and cited best practice? The ONR publishes its guidance on regulatory expectations for licensing of nuclear installations. The document Licensing Nuclear Installations details ONR's expectations. Specific requirements are published in the ONR's Safety Assessment Principles and in our Technical Assessment Guides for Inspectors and our Technical Inspection Guides for Inspectors. These guidance documents aim to incorporate appropriate international and national guidance. The ONR believe it has a range of existing guidance that addresses the core capability of a Licensee organisation. However, there is an opportunity to enhance the guidance more explicitly for Project Management expectations, building on the existing framework and the associated safety culture traits. 3.4.3 How should you assess new licensee project management capabilities and influence them? The ONR would seek to gain confidence in the Project Management capabilities through a licensee's competency framework, which should capture the qualifications and experience of the individual's undertaking the work. Ideally this framework should also cover the associated behavioural requirements for the roles and posts, within the core capability of the licensee's organisation. The comprehensiveness of this framework and the equivalent processes within the supply chain organisations are essential in providing this assurance. The ONR would also consider the adequacy of the training/development plans in respect to nuclear safety and culture. And where beneficial, conduct interventions to assess the working practices/ways of working during project execution.	**Guidance for evaluating an organisation's Project Management capability for delivering a safety Project, including their supply chain engagement and management, and promoting and maintaining the appropriate safety culture.**
UNITED STATES OF AMERICA	
3.4.1 What should be your expectations in regard to project management for new build organisations? The NRC does not regulate the project management of new build organisations. Rather, the NRC focuses on whether new build organisations meet and maintain compliance with NRC safety requirements. NRC oversight is focused on the performance of the organisations in meeting NRC requirements, including the quality assurance program, rather than on the management of the project. 3.4.2 Do you have sufficient guidance and cited best practice? The NRC does not issue guidance or best practices on project management for new build organisations. Within the U.S., this type of guidance is generally developed and issued by organizations such as the Institute of Nuclear Power Operations, Electric Power	

Research Institute, and American Nuclear Society. 3.4.3 How should you assess new licensee project management capabilities and influence them? **The NRC does not assess new licensee project management capabilities. Nevertheless, the NRC does indirectly influence project management through the assessment of an organisations ability to meet NRC requirements.**	

Appendix C – Workshop Presentations

The presentations from the workshop are provided on the next pages.

Welcome Presentation

Office for Nuclear Regulation

Welcome

Elaine Vinton: Professional Lead - Human and Organisational Factors
Office for Nuclear Regulation

Why do Organisational Factors Matter?

- Organisational / cultural weaknesses are invariably underlying factors in major accidents and events
- This holds true world-wide for a wide range of sectors including nuclear
- It also holds true regardless of the specific technical aspects of the accidents and events

Office for Nuclear Regulation

Nimrod, 2006

- **A failure to establish an Intelligent Customer capability** – The MOD contracted-out the Nimrod Safety Case and simply accepted that they completed this task, with little review or challenge. This is a good example of a failure to act as an 'intelligent customer', MOD 'outsourced its thinking'.

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Counterfeit, Fraudulent and Substandard Items - supply chain

- Areva – Le Creusot 2015- irregularities in 400 documents concerned with parts meeting quality standards
- Korea Hydro and Nuclear Power Company- 60 falsified certificates

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Counterfeit, Fraudulent and Substandard Items - supply chain

- Areva – Le Creusot 2015- irregularities in 400 documents concerned with parts meeting quality standards
- Korea Hydro and Nuclear Power Company- 60 falsified certificates

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ONRs Safety Assessment Principles

MS.1 - Leadership
Directors, managers and leaders at all levels should focus the organisation on achieving and sustaining high standards of safety and on delivering the characteristics of a high reliability organisation.

MS.2 - Capable Organisation
The organisation should have the capability to secure and maintain the safety of its undertakings.

MS.3 - Decision Making
Decisions made at all levels in the organisation affecting safety should be informed, rational, objective, transparent and prudent.

MS.4 - Learning from Experience
Lessons should be learned from internal and external sources to continually improve leadership, organisational capability, the management system, safety decision making and safety performance.

Office for Nuclear Regulation

Useful ONR Guides

NS-TAST-GD-048 – Organisational Capability
NS-TAST-GD-049 – Licensee Use of Contractors and Intelligent Customer Capability
NS-TAST-GD-065 – Function & Content of the Nuclear Baseline
NS-TAST-GD-072 – Function & Content of a Safety Management Prospectus
NS-TAST-GD-077 Procurement of Nuclear Related Items or Services
NS-TAST-GD-079 – Licensee Design Authority Capability
T/AST/080 – Nuclear Safety Advice and Challenge

Office for Nuclear Regulation

ONR's approach in New Build

- Proportionate application of expectations held in Licensing of Nuclear Installations; one of three themes; to evaluate if applicant has adequate organisational capability and arrangements in place to manage nuclear safety and comply with Licence conditions when licence is granted.

Office for Nuclear Regulation

- Continues through site-specific assessment commensurate with the permissioning phase, building confidence in maturation and effectiveness of arrangements

Office for Nuclear Regulation

Regulatory Oversight of New Licensee Organisation Capability

Office for Nuclear Regulation

Regulatory Oversight of New Licensee Organisational Capability

Richard Savage
Chief Nuclear Inspector
Office for Nuclear Regulation

Good Morning.

It gives me great pleasure to present at this workshop today and have the opportunity to address such a number of highly respected regulators from around the world.

The organisational capability of new licensees is vital for the safe and secure operation of nuclear facilities. There are many challenges facing organisations around the world as they strive to meet the obligations associated with holding a nuclear site licence. This can be particularly challenging when it is a new organisation or where the availability of experienced personnel is scarce. I certainly recognise this to be the case in the UK, where the nuclear renaissance is really beginning to gain momentum, with the expectation that two new organisations will be submitting their nuclear site licence applications this year.

There is also a significant challenge for the regulatory body itself to ensure that it gives the right level of regulatory oversight to organsational capability, whilst balancing this against its other priorities. Within ONR, this is particularly challenging as we strive to deliver effective, prioritised, targeted and proportionate regulation across all of our regulatory programmes.

This workshop therefore represents an ideal opportunity for regulators to share approaches and good practices that I believe will be of great benefit to us all.

UK Nuclear New Build

- Construction underway at Hinkley C

New Licence Application

Great importance on 'Organisational Capability'

Typical areas for assessment include:
- Organisation Design and Governance
- Resourcing Strategies
- Development of Design Authority
- Intelligent Customer Capability
- Development of an Integrated Management System

Within th gain
moment ıg in
earnest ı of the
first nucl r GDAs) in
train – w onth and
that for t the
Chinese HPR 1000 design. However, whilst the GDA process is recognised internationally, as it allows early identification of key issues long before construction begins, it is not legally binding. For ONR, a vitally important element of the new-build regulation comes as part of the licensing process.

The safety of nuclear installations in Great Britain is secured primarily through the nuclear site licence and the conditions attached to it. Operators of nuclear sites have an obligation to protect their workforce and the public from risk so far as is reasonably practicable. The licensing process is an important stage in confirming that they are ready and able to meet these obligations, and in so doing provides assurance to employees, local communities and the wider public. It also, importantly, provides stringent tools and powers which enable ONR to ensure that future operations are supported by adequate safety cases and are subject to appropriate regulatory permission and oversight.

Any organisation wanting to install or operate a prescribed nuclear installation will need a nuclear site licence, which is granted for an indefinite period and, providing there are no material changes to the basis on which the licence was granted, it can cover the entire lifecycle of a site from installation and commissioning through operation and decommissioning to site clearance and remediation.

We are expecting this year two nuclear site licence applications from Horizon (for the ABWR) and NuGen (for the AP1000) and we have held extensive discussions with both prospective licensees to ensure they fully understand the necessary requirements associated with a holding a nuclear site licence.

The Nuclear Installations Act provides for a nuclear site licence to be granted to a named corporate body to install or operate specified nuclear installations in a defined location.

ONR needs to be satisfied that the applicant's choice of site is suitable, that it understands the hazards and risks of the activities that it proposes to carry out, and that it has a suitable schedule of safety submissions leading through to the pre-construction safety case.

But, and most relevant to this workshop, we require confidence that the applicant has the organisational capability to lead and manage for safety effectively. This means that we must be satisfied with the applicant's governance arrangements, resources, competencies and management processes before we will consider granting a licence.

We will be looking in depth for demonstration of this when we assess the two nuclear site licence applications that we are expecting to receive this year.

Given the significant challenges facing regulators with the developing new nuclear build around the world, I think it's worth sharing with you some specific challenges (and opportunities) from the UK perspective.

As a sovereign regulator, we are legally empowered to hold industry to account on behalf of the public and we will continue to do this. However, we recognise that some issues cannot be tackled in isolation and we believe that a constructive, joint working approach with licensees and other stakeholders that focuses on outcomes can be highly beneficial. We have taken this 'Enabling Approach' to long-standing problems, such as the remediation of legacy facilities at Sellafield, with some considerable success. At ONR we are looking to implement this approach across all of our regulatory activities, where it is appropriate to do so. I believe there are particular benefits to be gained in engaging constructively with prospective new licensees to ensure they are clear about the requirements needed in terms of organisational capability and then working with them on their journey to ensure they meet the necessary requirements to become a nuclear licensee.

There is growing interest world-wide around Small Modular Reactors and this is also the case within the UK. However, there are many challenges associated with this technology, not least from the licensing/ organisational capability point of view. Within the UK, a prospective nuclear power plant licensee usually holds a licence from "cradle to grave" – i.e., it is the licensee throughout all stages of the plant life cycle from installation to decommissioning. However, new investment models for SMRs may lead to proposals for a company to be licensed to construct a facility and a different company with different types of expertise to become the licensee/operator.

There is no legal impediment to corporate vehicles being established which enable licensing of one company for construction and another for operations. However, ONR would need to be satisfied that any proposal to change licensee is properly managed, including matters

such as transfer of knowledge and capability, and that the licensee has the right organisational capability so that at all times it is in control of decisions that affect safety.

I believe there is scope for ONR to work with the international community to share ideas and to think differently about how we might licence organisations at various stages of SMR projects – this may be an area for further discussion in this workshop or at a future workshop.

Supply chain. Often this is thought about in terms of physical hardware – many of you I'm sure are aware of the issues surrounding Areva and the supply of components to the new Hinkley C reactor. ONR is taking this issue extremely seriously and expects the licensee NNB GenCo to provide clear assurances around the quality of nuclear safety critical components to be used in the reactor. However, supply chain has a much wider remit and can also apply to resources and organisational capability – in this context, regulators need to have assurances that organisations have the right arrangements in place to ensure that their staff, particularly those that have responsibility for nuclear safety and security, have the right competence, expertise and experience. Again, this may be a topic for discussion at this workshop.

In summary, I have highlighted the new build nuclear landscape in the UK and the challenges faced by both prospective licensees and regulators. Organisational capability features high on this list of challenges and so this workshop is incredibly important as it provides an ideal opportunity for regulators to share experiences and good practices as well as identify issues and work together to develop potential solutions.

Thank you.

Role and Work of the WGRNR

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Working Group on the Regulation of New Reactors (WGRNR)

Janne Nevalainen

Chair-WGRNR

Presentation to the WGRNR/WGHOF Workshop on Regulatory Oversight of New Licensee Organizational Capability
20 – 22 March 2017, Chester, England

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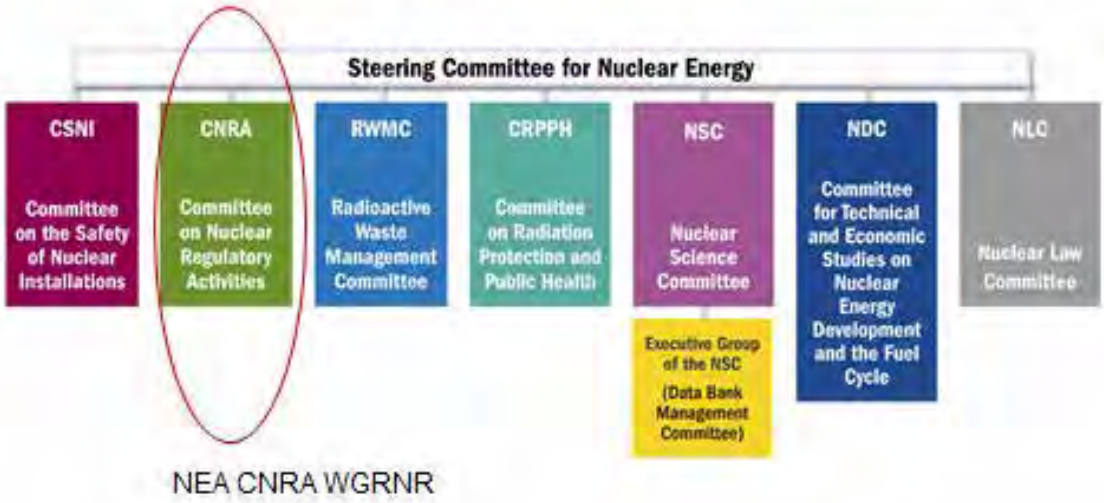
NEA Committees



NEA CNRA WGRNR

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CNRA WGRNR Mandate

- The Working Group on the Regulation of New Reactors (WGRNR) shall be responsible for the programme of work in the CNRA dealing with regulatory activities in the primary programme areas of siting, licensing and oversight for new commercial nuclear power reactors (Generation III+ and Generation IV reactors).
- The working group shall constitute an international forum for exchanging information and experience and with the agreement of CNRA will plan its work to ensure improvements in nuclear safety through more effective and efficient regulation.

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WGRNR Objectives

- The group shall constitute a forum of experts for the licensing of new commercial nuclear power reactors and should facilitate a cooperative approach to identify key new regulatory issues and promote a common resolution.
- The group should co-ordinate its work with the work performed by the Multinational Design Evaluation Programme (MDEP)
- The group should ensure that construction inspection issues and construction experience is shared through existing CNRA working groups or new working groups as appropriate.
- The group should plan for the transition of new reactors into the operational phase and established CNRA programs.
- The group should identify support needed from CSNI.

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Current WGRNR activities

- Meetings
- ConEx database
- Status of current tasks
  - Licensing survey – phase 2 vol. 5 (Classification of Structures, Systems, and Components)
  - Passive Safety Systems Used in New NPP Designs
  - Commissioning Workshop
  - Regulatory Oversight of New Licensee Organisational Capability

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Meetings

- **17th WGRNR meeting**
  - 18-19 October 2016 in Paris, France
    - ✓ **9 participating countries** (Canada, Finland, Germany, Hungary, Korea, Poland, Russia, UK and USA) **and WENRA & MDEP**
- **Next (18th) meeting:**
  - 23-24 March 2017 in Chester, UK
- **Workshop**
  - WGRNR/WGHOF joint workshop on regulatory oversight of new licensee organisational capability
  - 20-22 March 2017 in Chester, UK

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ConEx Database

ConEx Database

- Contains a collection of construction experiences deemed to provide lessons learned useful for the regulation of new build design, construction and testing activities.
- Allows regulators to share experience during the construction phase which can be incorporated into their regulatory oversight and improving their inspection programmes.

Current Status

- 102 events
  - ✓ 5 events were added to ConEx database in 2016. (France:3, Slovak Republic:2)
- Revision of guideline and user's manual

To be added soon

- Finland (1), Hungary (2), Korea (2), USA

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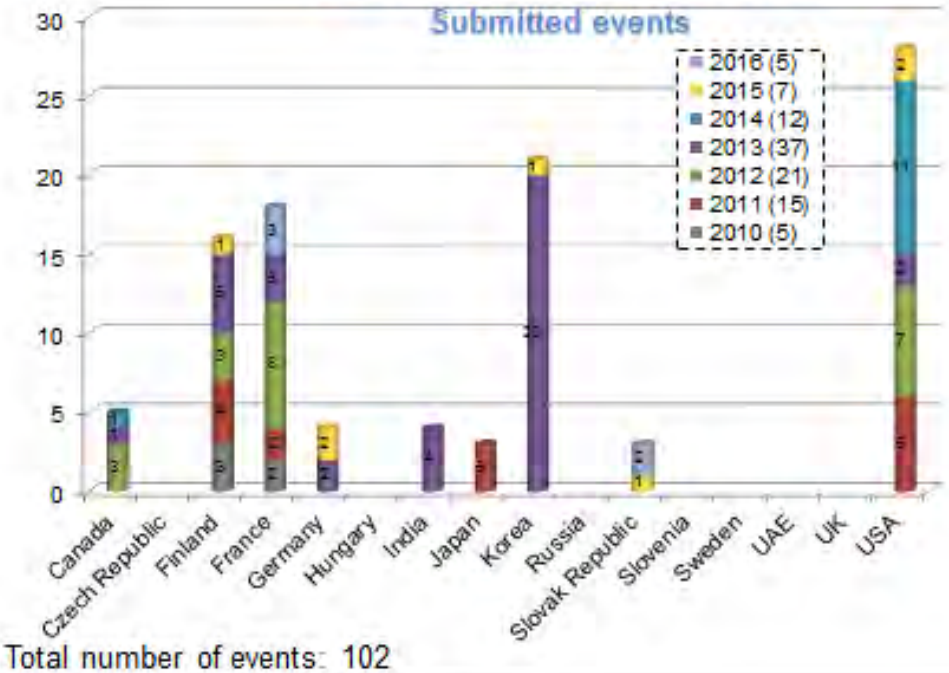
ConEx database entries



Total number of events: 102

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ConEx second synthesis report (1/4)

1st report: *First Construction Experience Synthesis Report*
NEA/CNRA/R(2012)2 issued in May 2012
Covered 7 ConEx events 2008-2011 + others

- Objective: communicate lessons gained from Construction Experience with the goal of improving the quality of the various technical disciplines within design, fabrication, construction and testing of new nuclear reactor builds
- Team: **Finland** (lead), France, Korea, Poland, UAE, USA, UK, EU

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ConEx second synthesis report (2/4)

- 63 events from the ConEx database divided into 7 technical disciplines:

1. Design
2. Civil construction
3. Mechanical
4. Electrical
5. Instrumentation and control
6. Site construction, erection and installation
7. Commissioning, pressure testing

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ConEx second synthesis report (3/4)

- Conclusions:
  - Management system processes:
    - Need for the licensee to define and maintain a robust management system during all the construction
    - Improve the configuration and change management to ensure that all modifications are assessed taking into account their potential interdependencies with other systems
    - Need to ensure interdependencies among the various design disciplines
  - Safety culture:
    - Need to have decision making process prioritising nuclear safety
    - Need for a questioning attitude and a prudent approach
    - Need for an open an effective communication and for efficient feedbacks of operating experience
    - Need for an effective verification of the applicants, licensees and their contractors

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ConEx second synthesis report (4/4)

- Conclusions:
  - Human and organisational issues:
    - Need for a good housekeeping
    - Need for high levels of organisational management including efficient inspection programmes by the licensee and the regulatory body
    - Need to ensure comprehensive and timely communication between all parties involved in the construction of the NPP
    - Need to have robust process for the production of testing and operation procedures
  - Supply chain management:
    - Need for a rigorous design control process
    - Need to have competent staff well-acquainted with In-Service-Inspection (ISI) requirements

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Licensing Survey

Team: **USA** (lead), Germany, Slovenia, UAE and UK

- **A comprehensive report on each member's:**
  - Regulatory structure & licensing processes
  - Skill sets needed to perform reviews, assessments and construction oversight
  - Number of regulatory personnel
  - Types of training needed for regulatory activities
- **Based on a survey (3 phases)**
  - Reports are produced through survey and the workload is divided into three phases; General, Design and Construction.
  - Phase 1 and 3 (General and Construction) have been completed and phase 2 (Design) is underway.
- **Purpose**
  - Serve as a guide for developing regulatory bodies
  - Benchmarking for more developed regulators

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Overview of Phase 2: Design Survey

- **Development status**
  - A report on responses to the survey is presented as a multi-volume text.
  - Each volume focuses on one of the eleven technical categories covered in the survey.
- **11 General Technical Categories (based on IAEA GS-G-4.1)**
  - Instrumentation & Control (Vol. 1)
  - Civil Engineering Works and Structures (Vol. 2)
  - Reactor (Vol. 3)
  - Reactor Coolant and Associated Systems (Vol. 4)
  - Classification of SSCs (Vol. 5) – Drafted report
  - Engineered Safety Features (Vol. 6) – Receiving survey responses
  - Electric Systems
  - Auxiliary System
  - Power Conversion Systems
  - Assessment and Verification of Safety
  - Technical Specifications
- **69 Technical sub-topics to be addressed**

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Overview of Phase 2: Design survey questions

❑ Questions

➢ For each topic, members are asked to answer seven survey questions

1. What information is provided by the applicant?
2. Describe the analysis, reviews and/or research performed by the reviewer and the scope of the review.
3. What type of confirmatory analysis (if any) is performed?
4. What is the technical basis for regulatory authorization?
5. What skill sets are required to perform the review?
6. What specialized training, experience and/or education is needed to perform the review?
7. What is the level of effort needed to perform the review?

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Phase 2 reports development status

❑ Technical topics to be addressed in the survey:

➢ **Vol. 5: Classification of SSCs:** Drafted report
- ✓ Classification of SSCs (e.g., Functions, includes supports, piping systems)
- ✓ Plant design for protection against postulated piping rupture
- ✓ Seismic and dynamic qualification of safety related mechanical and electrical equipment
- ✓ Environmental qualification of mechanical & electrical equipment

➢ **Vol. 6: Engineered Safety Features (ESF):** Receiving responses
- ✓ Emergency core cooling system (ECCS)
- ✓ Containment systems
- ✓ Habitability systems
- ✓ Containment heat removal
- ✓ Fission product cleanup systems

❑ Participants: 9 countries

➢ Finland, France, India, Japan, Korea, Slovakia, Slovenia, UK, USA

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Phase 2 reports development status

- **Technical topics to be addressed in the survey:**
  - **Vol. 5: Classification of SSCs:** Drafted report
    - ✓ Classification of SSCs (e.g., Functions, includes supports, piping systems)
    - ✓ Plant design for protection against postulated piping rupture
    - ✓ Seismic and dynamic qualification of safety related mechanical and electrical equipment
    - ✓ Environmental qualification of mechanical & electrical equipment
  - **Vol. 6: Engineered Safety Features (ESF):** Receiving responses
    - ✓ Emergency core cooling system (ECCS)
    - ✓ Containment systems
    - ✓ Habitability systems
    - ✓ Containment heat removal
    - ✓ Fission product cleanup systems

- **Participants: 9 countries**
  - Finland, France, India, Japan, Korea, Slovakia, Slovenia, UK, USA

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Passive Safety Systems Used in New NPP Designs (2/3)

- **Approach**
  - Phased approach in development of survey
    - ✓ Stage1: General aspects of passive systems (DBA+DEC)
    - ✓ Stage 2: Severe accident
  - After completing Phase 1, Phase 2 will be tasked.
- **Questionnaire (Stage 1)**
  - I. Requirements for passive safety systems
  - II. Testing and analyses of passive safety systems
  - III. Regulatory review of passive safety systems
  - IV. Commissioning and Periodic Verification Testing
  - V. Experience with Passive Safety Systems

❖ Developed by taking into account WENRA work and MDEP input.

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Passive Safety Systems Used in New NPP Designs (3/3)

- Team: **Russia** (lead), Canada, Finland, Germany, USA
- Schedule (Stage 1):
  - May. 2016: Distribution of new version of questionnaire to WGRNR and MDEP STC members for comments
  - June 2016: Approval from CNRA for the revised CAPS
  - July 2016: Distribution of Stage 1 questionnaire to WGRNR members for responses
  - Oct. 2016: Responses to Stage 1 questionnaire by members
  - January 2017: Planned teleconference on draft report
  - March 2017: Stage 1 first draft report
  - Oct. 2017: Discussion on Stage 1 final draft report
- Current Status: Report on survey result has been drafted.

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Commissioning Workshop (1/2)

- **Objective**
  - Share commendable practices and experience from member countries' regulatory approaches
- **Team**: **Korea** (lead), Finland, France, US, and UK
- **Schedule**
  - Sept. 2015: Workshop advertisement
  - 12 Feb. 2016: Short country position papers to be sent to NEA
  - March 2016: WGRNR-MDEP Workshop
  - Oct. 2016: Discussion on draft report by WGRNR members
  - June 2017: Report on workshop results for CNRA approval

Role and Work of WGHOF

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CSNI Working Group on Human and Organizational Factors WGHOF

Sean Peters
WGHOF

Regulatory Oversight of New Licensee Organizational Capability
March 20-22, 2016

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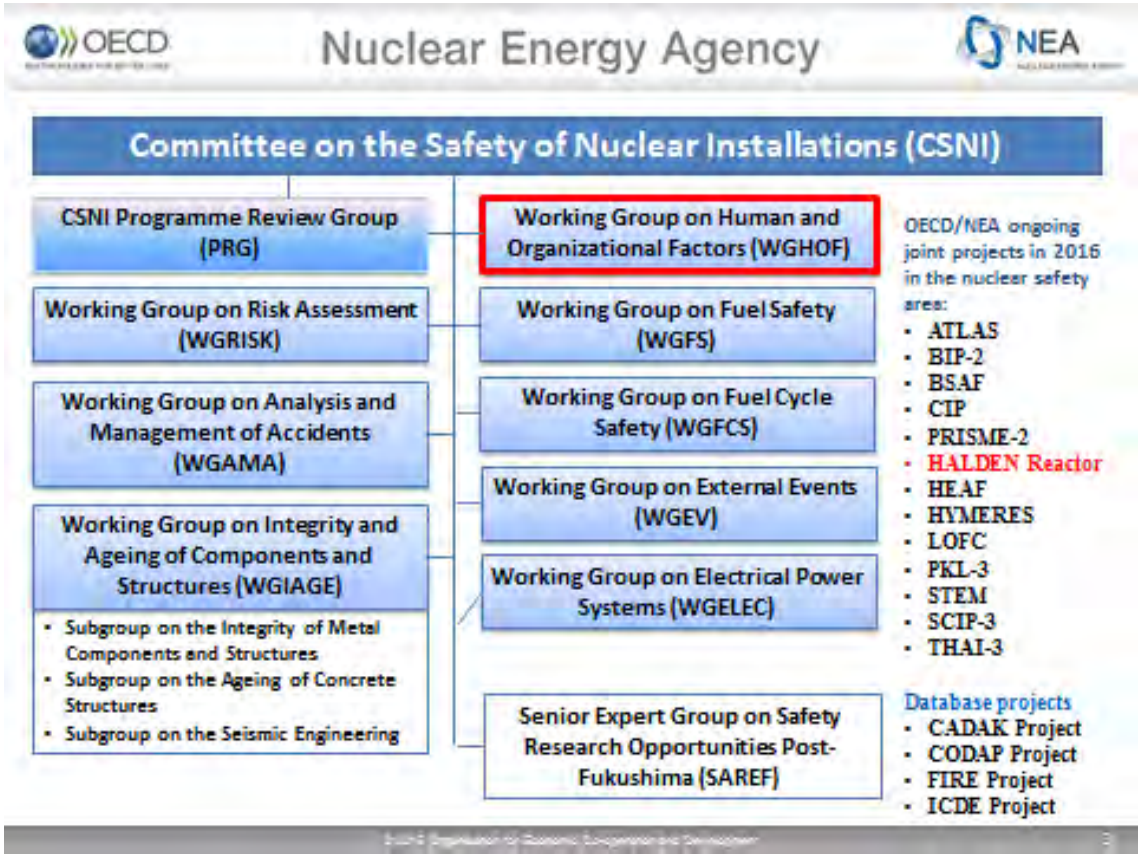
NEA Committees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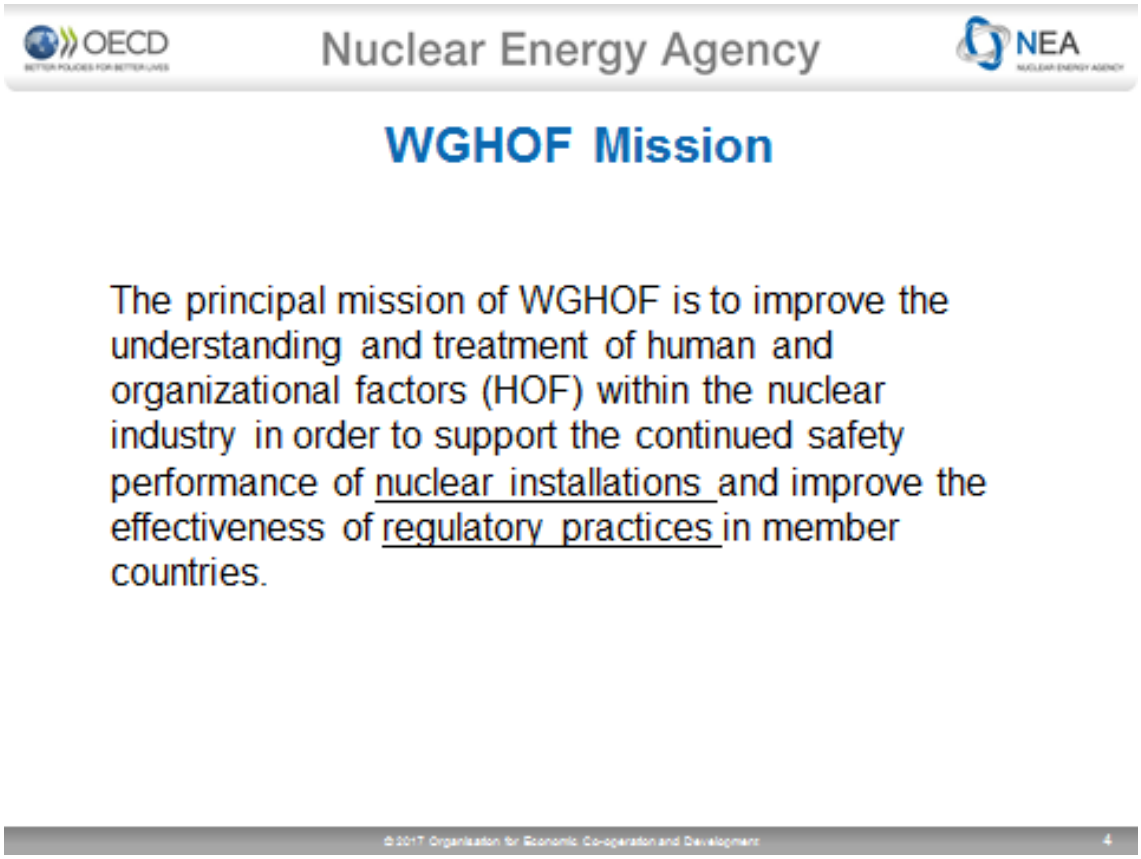
NEA
Committee on the Safety of Nuclear Installations (CSNI)
CSNI Programme Review Group (PRG)
Working Group on Risk Assessment (WGRISK)
Working Group on Analysis and Management of Accidents (WGAMA)
Working Group on Integrity and Ageing of Components and Structures (WGIAGE)
• Subgroup on the Integrity of Metal Components and Structures
• Subgroup on the Ageing of Concrete Structures
• Subgroup on the Seismic Engineering
Working Group on Human and Organizational Factors (WGHOF)
Working Group on Fuel Safety (WGFS)
Working Group on Fuel Cycle Safety (WGFCS)
Working Group on External Events (WGEV)
Working Group on Electrical Power Systems (WGELEC)
Senior Expert Group on Safety Research Opportunities Post-Fukushima (SAREF)
OECD/NEA ongoing joint projects in 2016 in the nuclear safety area:
• ATLAS
• BIP-2
• BSAF
• CIP
• PRISME-2
• HALDEN Reactor
• HEAF
• HYMERES
• LOFC
• PKL-3
• STEM
• SCIP-3
• THAI-3
Database projects
• CADAK Project
• CODAP Project
• FIRE Project
• ICDE Project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Nuclear Energy Agency
NEA
WGHOF Mission
The principal mission of WGHOF is to improve the understanding and treatment of human and organizational factors (HOF) within the nuclear industry in order to support the continued safety performance of nuclear installations and improve the effectiveness of regulatory practices in member countries.
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Human and Organisational Factors

- Draft changes to the WGHOF mandate:

"Human and organizational factors include all those elements of a socio-technical system which interact to influence individuals at every level of an organization in carrying out work safety and effectively. This includes factors such as human capabilities and limitations, work organization and job design, procedures, design of technology, leadership, safety culture and the broader environment etc. which all have the potential to influence nuclear safety."

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WGHOF

- Human and organizational factors experts from regulatory bodies, technical support organizations, research institutions, industry, and international organizations (EC, IAEA, WANO)
- A forum for exchange of information and operating experience, and for identifying HOF issues, methodologies and practices
- Surveys, workshops and proceedings, technical opinion papers and state-of-the-art reports have been produced in the past by WGHOF on various topics.

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Scope of WGHOF Activities

- Human Factors Engineering and New Technologies
  - Human Factors Considerations in NPP Modifications, Workshop October 2003, Technical Opinion Paper, 2008
  - Advanced Reactor Research Needs - Workshop on Future Control Station Designs and Human Performance Issues in Nuclear Power Plants, Workshop May 2006.
  - Technical Opinion Paper – Research Program Topics on Human Performance in New Nuclear Plant Technology, 2008
  - Human Performance and the Operation of New Nuclear Plant Technology – Identification of Research Activities and Priorities, workshop – March 2010
  - Integrated System Validation – Workshop 2015
  - Multi-Stage Validation – Workshop 2017
- HOF in Human Reliability
  - Establishing Desirable Attributes of Current Human Reliability Assessment (HRA) Techniques in Risk Assessment, Final Report, 2014, WGRisk collaboration
  - Human Reliability Assessment in External Events – Survey and Methods of Practice, October 2016 WGRisk collaboration
- HOF in Operational Experience
  - Human and Organizational Factors in Event Analysis, September 2009
  - HOF Lessons Learned from Implementation of Post-Fukushima Actions

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Scope of WGHOF Activities continued

- Human Performance
  - Better Nuclear Plant Maintenance: Improving Human and Organizational Performance. Workshop October 2005, Technical Opinion Paper, 2008
  - Human Performance and Intervention under Extreme Conditions, February 2014
  - WGFCS workshop, Developments in Fuel Cycle Facilities after the Fukushima Daiichi Nuclear Power Station Accident, November 2016. Results of the WGHOF task Human Performance under Extreme Conditions to be presented.
- Organizational Capability
  - Justifying the Suitability of Nuclear Licensee Organizational Structures, Resources and Competencies, September 2008, Technical Opinion Paper 2011
  - Regulatory Oversight of New Licensee Organizational Capability, March 2017, WGRNR collaboration
- Safety Culture, Leadership and Managing for Safety
  - State-of-the-Art Report on Systematic Approaches to Safety Management, February 2006
  - Maintaining Oversight of Licensee Safety Culture – Methods and Approaches, May 2007
  - An Analytical Review of Approaches to Maintaining Oversight of Leadership, Managing for Safety and Safety Culture, a Regulatory Perspective, September 2011

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Fukushima Related Work

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Collaboration with CNRA

- WGHOF contributed to an effort led by the NEA's Committee on Nuclear Regulatory Activities (CNRA) to develop a Green Booklet, "The Safety Culture of an Effective Regulatory Body."
- HOF issues identified in the CNRA Green Booklet, "The Implementation of Defence in Depth at Nuclear Power Plants."

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National and Organisational Influences on Safety Culture

WGHOF examined the influence of national characteristics on safety (DIET Report).

White Paper - Draft Conclusions:

- The accepted safety culture framework should be used as a basis for safety in nuclear organizations.
- National cultural traits should not be judged as either positive or negative but how its influence may support or detract from nuclear safety.
- Safety culture should be assessed and enhanced in a holistic manner taking into consideration all of the possible factors influencing nuclear safety.
- Organizations should share good practices in developing a healthy safety culture in the context of their national cultural traits.

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Human Performance under Extreme Conditions

Workshop Objectives:

- Share experience and develop knowledge about human and organizational performance under extreme conditions
- Identify specific currently applied HOF principles in the nuclear industry and compare them with available knowledge (e.g. from academic knowledge and experience in non-nuclear field)
- Provide a basis for improvements and necessary research for taking into account HOF issues in the design and use of measures

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Current areas of interest

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Lessons learned from exercises conducted in response to Fukushima

- Licensees beginning to conduct validations of manual mitigation actions, training, drills and exercises to test and demonstrate the effectiveness of their capabilities to mitigate severe accidents.
- This task involves identifying and developing a means (e.g., surveys) to gather and share lessons learned from the implementation of these exercises throughout the international nuclear community
- The objective of this task:
  - to facilitate/accelerate industry learning of best practices and identify areas requiring additional research and development.

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Multi-Stage Human Factors Validation of NPP MCR Designs and Modifications

- Integrated System Validation report – June 2016
- Topics identified for further work – Multi-Stage Validation
- Benefits:
  - Approaches and terminology vary
  - Guidance for application is limited
  - Methods for enhancing confidence in validation conclusions have not been formally explored
- Task group – international representation from regulators, TSO, research institutes, vendors
- White paper, workshop in June 2017, consensus approach developed

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Human and Organizatinal Performance

- Human and organizational performance plays a key role in 60 – 80% of events in high reliability industries.
- Research and experience show the use of event free tools to prevent human errors does not produce the lasting changes.
  - a more holistic view of human performance strengthens the factors which promote desirable human performance
- The objective of this task:
  - To identify the individual, technological and organizational factors which may affect human and organizaitonal performance
  - describe current approaches to the implementation of human performance programs
  - identify best practices in regulatory oversight

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Resilient Organisations

- Organisational resilience is required to ensure safety in normal conditions (design basis) and when facing the unexpected (beyond design basis).
- The objective of this task:
  - to explore the link to safety culture, safety management systems and other concepts already in use,
  - identify the gaps to resilience (set of skills, practices required), and
  - then to evolve these concepts as a basis for a true systemic approach to safety for coping with the unexpected

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New Topic

- HOF considerations for licensees approaching or undergoing nuclear phase out, safe storage, and decommissioning of nuclear facilities:
  - Staffing levels
  - Training and competence
  - Organizational structure, roles and responsibilities
  - Safety Culture, motivation
  - Impact of financial pressures

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All NEA publications and institutional documentation available at
www.oecd-nea.org

HPC Project – Update and Reflections

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Agenda

- Introduction to the Hinkley Point C Project
- Current progress and challenges
- Organisational Capability – some reflections in hindsight

HPC

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EDF Energy's focus for nuclear new build

HPC

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What we will build at Hinkley Point

- Pressurised water reactor (like Sizewell B)
- 2 x 1630 MW (electrical)
- Each can supply around 2.5 million homes
- Uses 17% less uranium & produces less waste
- Under construction in France, Finland & China
- c. 900 operating staff
- 60 year operating life
- 6 year construction programme from start of Nuclear Island

Cross section of single UK EPR (illustrative layout)

HPC

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The EPR: a proven and evolutionary technology

The EPR reactor evolutionary design builds on significant operating experience history at existing stations in Britain, France and Germany

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The Journey

2007	GDA started
2011	NSL Application
2012	NSL Granted GDA Completed
2013	DCO Granted CFD Agreed with HMG
2014	EU State Aid review completed
2015	CGN join the project
2016	EDF SA give FID HMG approves Project
2017	First permanent nuclear structures

HPC

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HPC Project Values & Disciplines – developed with lessons learned in mind

Our Nuclear New Build

Values

- HUMILITY
- RESPECT
- SOLIDARITY
- POSITIVITY
- CLARITY

Knowing how far we've come, how far we've got to go and how we're going to get there

Our

CORE DISCIPLINES

for a successful project

HPC

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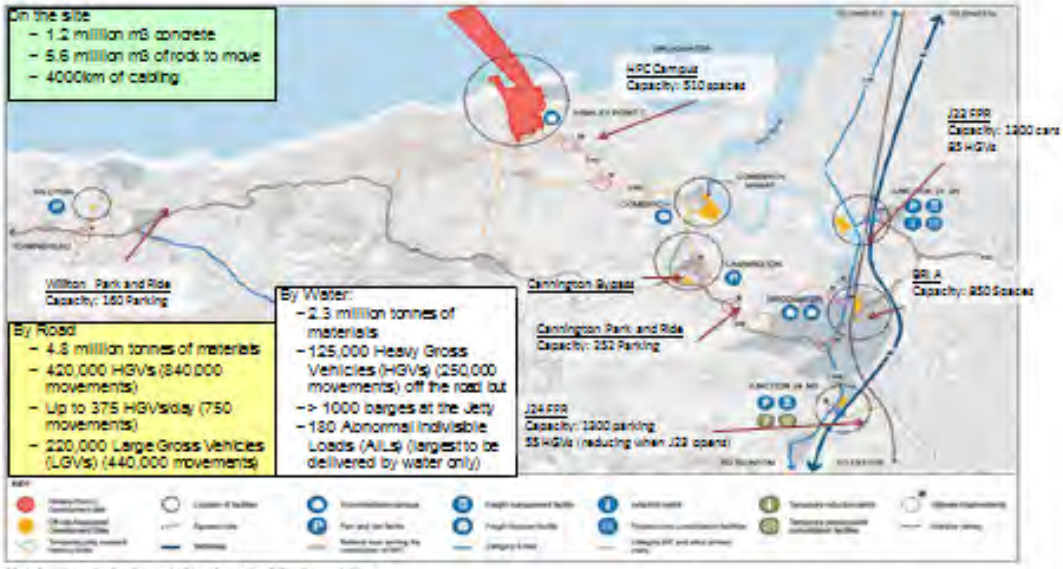
Scale of Operations

On the site
- 1.2 million m3 concrete
- 5.6 million m3 of rock to move
- 4000km of cabling

By Road
- 4.8 million tonnes of materials
- 420,000 HGVs (840,000 movements)
- Up to 375 HGVs/day (750 movements)
- 220,000 Large Gross Vehicles (LGVs) (440,000 movements)

By Water:
- 2.3 million tonnes of materials
- 125,000 Heavy Gross Vehicles (HGVs) (250,000 movements) off the road but
- -> 1000 barges at the Jetty
- 180 Abnormal Indivisible Loads (AILs) (largest to be delivered by water only)



Bringing equipment, material and people to HPC site efficiently

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Pathway from Education, through Training, to Employment

Education → **Skills** → **Employment**

Inspire Programme

Over 60,000 student engagements across Somerset

Expanding Opportunity throughout the County

WORK READY

- Apprentices
- FE/NVQ Short Courses
- £15 million funding for schools and colleges in the South West
- The Hinkley Strategic Delivery Forum

JOB READY

Sustainable Employment Opportunities

5,600 workers on site at peak

Over 2000 now registered with the Hinkley Jobs Service

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Business Engagement – Somerset *(Local Engagement Strategy)*

Offices & Welfare Location / Logistics

Somerset Larder

host

Somerset Multi-gang Partnership Board

SKANSKA

forest

On site / off site People Logistics:
5,600 at peak
22,000 people movements

Chamber

Safety & Traffic Management

Waste Logistics & Recycling

Campus Accommodation
1,500 beds

Catering
1.2million cups of tea a year

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Development to Delivery

- FID was declared on 29th September 2016
- Progress at site is focussed on creating the infrastructure to manage the construction
- Preparations are well advanced for starting construction of the Technical Galleries

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Delivery Operating Model

- The Command Centres are supported by integrated teams for buildings and systems
- The supply chain is being integrated into the project: construction, equipment and site services

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Involvement of the Supply Chain

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Development to Delivery

- The detailed design of the plant is underway
- It is being integrated with the safety case established during GDA, subsequently amended to cover the site specific requirements and UK context
- Early Contractor Involvement contracts in place to ensure availability of design information
- As with all mega projects, HPC is not without its challenges

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Organisational Capability – reflections

- Role of NNB
- Development of NNB as a prospective Licensee
- Our relationships with our parent organisations
- Our employment model and our culture
- Forecasting, reporting and managing change
- Regulatory engagement

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HPC

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THANK YOU

HPC

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Appendix D – Breakout Session Slides

Session 1.1 Building Organisational Capability

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Agenda -2-

- Four sheets per question:
  - Response summary
  - Points of special interest
  - Learning points from cpp's
  - Points to be discussed

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Agenda -2-

- Four sheets per question:
  - Response summary
  - Points of special interest
  - Learning points from cpp's
  - Points to be discussed

OECD Nuclear Energy Agency NEA

Agenda -2-

- Four sheets per question:
  - Response summary
  - Points of special interest
  - Learning points from cpp's
  - Points to be discussed

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Learning points -1-

The following learning points where collected:

- Canada:
  - The benefits of formal versus informal engagement with potential future licensees (also see sub session 2.2 *Engagament strategies*)
- Finland:
  - Lack of awareness of regulatory expectations

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Points to be discussed -1-

- ❑ Discussion
- ❑ Commendable practices
- ❑ Challenges
- ❑ Further work

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Response Summary -2-

- ❑ Do new licensees understand the scale of the task?
  - ➢ Answers vary from yes to no
  - ➢ Depends on availability of experienced personnel
  - ➢ Education could be needed
  - ➢ Shortfalls in mid- and long term planning of task and resources
  - ➢ Understanding is increasing during the project
  - ➢ Potential focus on technical design issues rather than the organisational development issue
  - ➢ In new comer country regulatory framework may be developing at same time the license application is being prepared which can lead to misunderstandings in requirements and expectations
  - ➢ Prospective new licensees should become familiar with the identification and resolution of regulatory and technical issues encountered by prior applicants

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Points of Special Interest in Countries' Responses -2-

- Do new licensees understand the scale of the task?
  - Siting license applicant must be recognised by the control body (ROSATOM) on their own or with the assistance of other organizations before applying for a license to regulator (Rostechnadzor). Thus, multi-stage control system is implemented (Russia)
  - The rush to secure nuclear professionals in a very competitive market can lead to having the wrong skills/knowledge profile early in the development of the organisation, which then leads to major re-alignment once a greater understanding is acquired (UK)
  - Separated technical design and organizational issues by a process to assess the design for suitability in the UK regulatory environment. Licensing of a Corporate Body to undertake specified nuclear activities on a specific site. Site specific activities are controlled using a permissioning regime under the nuclear site license (UK)

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Learning points -2-

- Canada:
  - The need for the Regulator to provide funded learning mechanisms (processes and tools) to enable licensees to develop and maintain an understanding of (also see sub session 2.3 *Development of guidance*):
    - role of regulation and regulatory fundamentals
    - fundamental principles underpinning regulatory expectations
    - relationship between regulatory requirements and the licensee's (i.e. user) requirements
    - fundamental attributes of the nuclear sector similar or different from other industry sectors and what that means for organizational capability
    - difference between Canadian regulatory framework and requirements and other nuclear regulatory regimes
- Netherlands:
  - Underestimation of scale of task to build capable organisation

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Points to be discussed -2-

- ❑ Discussion
- ❑ Commendable practices
- ❑ Challenges
- ❑ Further work

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Response Summary -3-

- ❑ Are new licensees focused on building a capability that can adapt through the phases of the project?
  - ➢ Also here answer vary from yes to no and between
  - ➢ Generally the main outlook is quite short sighted and potential lack of understanding of what the organisation needs at each stage of the project
  - ➢ Major re- adjustments needed once a greater understanding is acquired
  - ➢ Issues of funding and logistical & human resources are in the area of responsibility of the operating organization and under regulatory supervision
  - ➢ Depends on the organization and contractual arrangements and can differ greatly from project to project
  - ➢ Lack of experience in many Western countries
  - ➢ Most NPP's are pursued by existing licensees

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Points of Special Interest in Countries' Responses -3-

- Are new licensees focused on building a capability that can adapt through the phases of the project?
  - Long term plans are made for resourcing and development of organisations (Finland)
  - New licensees with no prior experience should consider the need to request assistance from organizations and individuals with experience in building organisational capability associated with commercial nuclear power plants (USA)

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Learning points -3-

- Finland:
  - Lack of priority focus on building a capable organisation
- Netherlands:
  - Building an organisation and infrastructure that can adapt as project progresses
- Poland
  - Situation of embarking countries where one has to face not only new licensee but also new regulatory body (or regulatory body without experience in regulation of large scale industrial project like NPP construction and commissioning) (also see sub session 2.1 *Regulatory readiness*)

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Points to be discussed -3-

- ❑ Discussion
- ❑ Commendable practices
- ❑ Challenges
- ❑ Further work

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Response Summary -4-

- ❑ How can capability be developed in a competitive market short of nuclear skills?
  - ➢ With experienced nuclear professionals from current utilities and around the world, as well as non-nuclears
  - ➢ Majority of nuclear skills often in operation, not in design, build and commissioning
  - ➢ Capacity building initiatives well in advance of the decision to begin a nuclear program (e.g. university programs, research initiatives)
  - ➢ Government role in educational strategies, but experience comes by doing
  - ➢ New builds engaging with the local educational institutions
  - ➢ Shortfalls in training opportunities give focus on in-house and on-the-job training - look for international training opportunities
  - ➢ In the absence of planning and preparation, organizations rely upon contractors and external organizations to bring about the needed expertise

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Points of Special Interest in Countries' Responses -4-

- How can capability be developed in a competitive market short of nuclear skills?
  - Ability to hold on to employees - good reputation (also needs good safety culture) (Finland)
  - Develop a potential by ensuring equal regulation requirements for all licensees and adjusting these requirements according to contemporary science and technology and the best practices (Russia)
  - Planning in advance, including assessing the critical skills needed, determining when they are needed, and designing a strategy to fill the critical skills. Potential actions could include assuring that colleges and technical organizations have programs in place to develop and prepare individuals with the appropriate skills and the programs themselves should be periodically updated to meet projected future demands and evolving technologies(USA)

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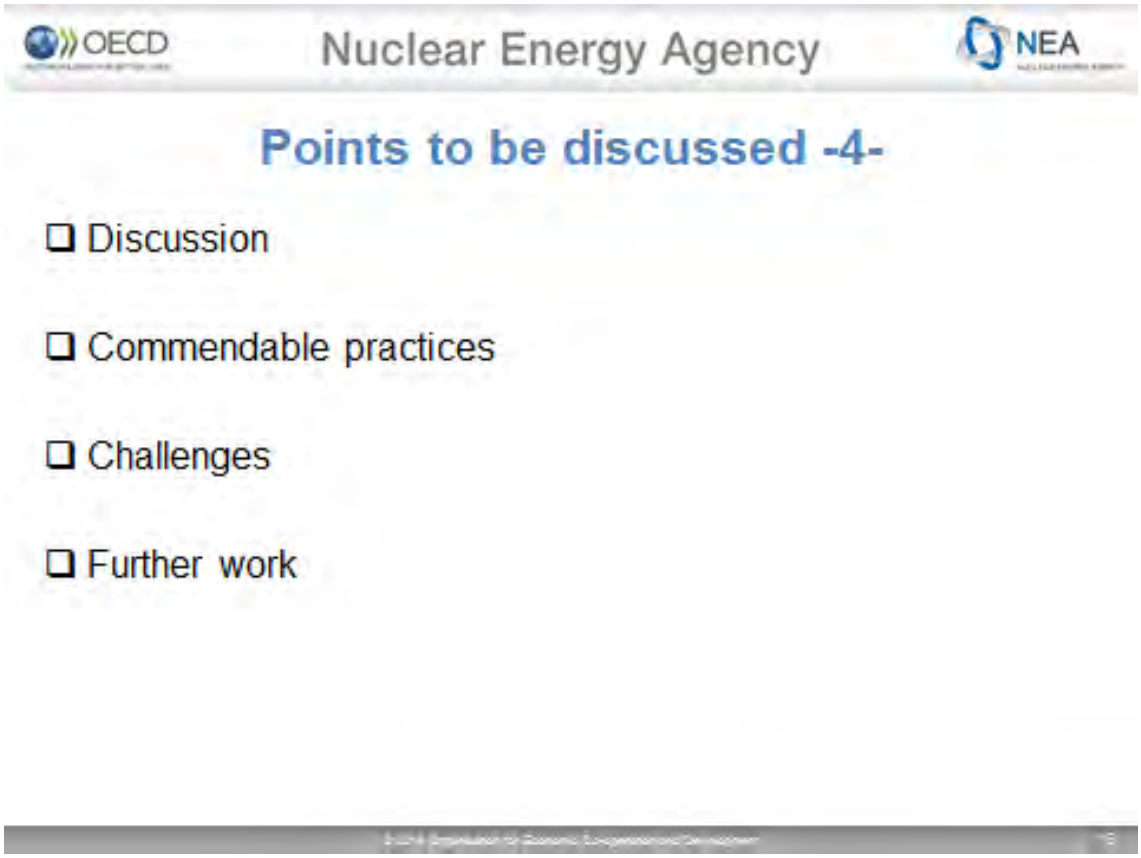
Learning points -4-

- Finland:
  - Shortage of resource in a competitive market

Hungary:

- Capability development in a competitive market
- Netherlands:
  - Shortage of resource in a competitive market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NEA
Points to be discussed -4-
Discussion
Commendable practices
Challenges
Further work

Session 1.1 Building Organisational Capability – Feedback

OECD Nuclear Energy Agency NEA

NEA/CNRA/CSNI
WGRNR/WGHOF Workshop

Regulatory Oversight of New Licensee Organizational Capability

Session 1: Challenges in Developing Organizational Capability

1.1 Building Organizational Capability

Rapporteur: Spencer Brown
Chair: Margreet Steenhuisen

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Feedback on 1.1.1: How can new licensee awareness of regulatory expectations be improved?

- early engagement with prospective licensee is important if not necessary (should happen in advance of formal submittal of application)
- development by regulator of a formalized documented framework that describes "roadmap" of steps required to obtain license
- establishment of "rules of engagement" so as to set clear intentions and expectations for early discussions (regulator needs to maintain independence)
- regulators should not assume that maturity or historical prominence of applicants reduces the need for early engagement
- standard set of nuclear requirements are well understood by experienced applicants so important to focus on areas that are less understood or where there is a lack of guidance
- regulator and prospective licensee approach can be significantly influenced by past experience with other country's regulatory approach which challenges the achievement of acceptance and alignment to expectations
- cost implications for prospective licensees may reduce their motivation to engage with regulators at an early stage (USA)

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Feedback on 1.1.2: Do new licensees understand the scale of the task?

- regulators should encourage new licensees to interact with existing licensees who have navigated the licensing process (licensees from other countries may also be consulted if licensing processes, regulatory approach are similar)
- "just in time" approach towards organizational capability by prospective licensees demonstrates lack of appreciation for scale of task
- manpower strategies should be structured around project phases rather than strictly functional requirements
- leadership approach of prospective licensees can impact its ability to appreciate the scale of the task (cultural background, regulatory approach by country of origin, familiarity with differing regulatory framework)
- existing licensees seeking new authorizations should be treated similarly to new licensees considering long gaps in new build projects (Europe, USA)
- culture of safety is different in nuclear compared to e.g. conventional coal plants- much has to do with the regulatory requirements and industry focus. Similarly, requirements pertaining to "institutional defence in depth" present unique challenges for new and prospective licensees
- organizational instability of prospective licensees can present challenges in understanding and coping with scale of the task

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Feedback on 1.1.3: Are new licensees focused on building a capability that can adapt through the phases of the project?

- new licensees should be encouraged to learn from experience of existing licensees
- determination of and building the requisite capability to adapt to all phases is situation dependent (e.g. Korean utility licensee staffing is approximately half of that of UK for operating NPPs)
- UK "baseline" approach to demonstration and justification of organizational staffing is potential commendable practice. Baseline approach should incorporate long term planning, 3-5 years prospective
- different approaches to regulation / oversight of organizational capability aspects may be effective (USA is more "hands off" in this area, whereas several European regulators are more "hands on")
- IMS and project plans may be useful tools towards ensuring sustainability for organizational capability and, at least, these should be linked.

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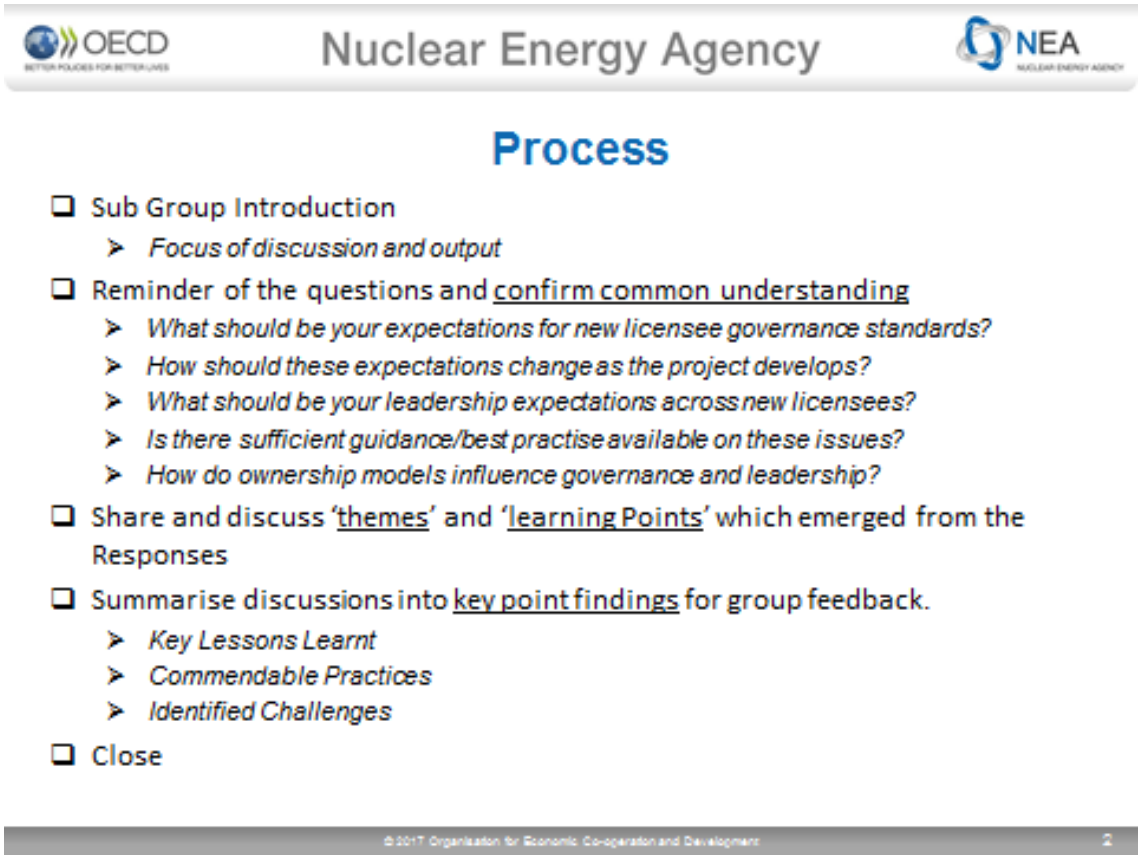
Feedback on 1.1.4: How can capability be developed in a competitive market short of nuclear skills?

- the group found that this question may not fully fit the scope of the workshop since it is not really in the purview of regulators to resolve or focus attention on this issue (more the responsibility of industry)
- poor culture, reputation within organizations can present challenges for recruitment and retention of resources
- important for regulators to maintain objective independence rather than be visible advocates of nuclear power
- new licensees with unreasonable schedules may be pushed to recruit and hire people who are available in the market rather than most desirable candidates

Session 1.2 Developing Leadership and Governance



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Response Summary

- **What should be your expectations for new licensee governance standards?**
  - Canada
    - ✓ Applicant should demonstrate the knowledge, skills and abilities of its workers and those of the major contractors and their subcontractors (RD/GD-369)
    - ✓ Applicant's management system should spell out requirements for management of contractors/suppliers (CSAN286).
    - ✓ In practice this means that the utility mush have direct oversight over EPC company
  - Finland: No specific requirement
    - ✓ Good leadership, management and prioritizing of safety is an overall requirement
  - Hungary: No specific requirement
    - ✓ A management system shall be established and regularly reviewed by the licensee for the complete management of the design and construction process

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Response Summary

- Korea: No requirement
  - ✓ Should be demonstrated through its performance
- Netherlands: No specific requirement
  - ✓ At least aligned with ISO, IAEA and NEA requirements/guidance
- Poland: No requirement
  - ✓ Integrated management systems with strong safety culture awareness
  - ✓ Russia: No specific requirement
  - ✓ No new licensees in Russia
- UAE: FANR REG-01, IAEA safety guides
  - ✓ Established requirements for management systems throughout all phases of the nuclear program (management responsibility, resource management, process management, and self-assessment among others)

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Response Summary

- UK: No explicit expectation
  - ✓ Good practice as contained in the UK Corporate Governance Code is only specifically applied on a comply or explain basis.

    → Used as a tool to compare proposed governance arrangements in new build organizations.
- USA
  - ✓ Established requirements and guidance for corporate level management and quality assurance program.
  - ✓ Organizational aspect: NUREG-0800 (13.1.1)
    - Addresses review of the corporate level management
    - Includes major contractors, NSSS vendor, AE for the project
    - Review technical resources (responsibilities, technical staff, interface arrangement, and management control)
  - ✓ Quality assurance program: 10CFR50 App. B, RG 1.28, ASME NQA-1, etc.
    - Review organizational structure (interface between org.), quality assurance program, training & qualifications of QAP personnel, design control, procurement document control, etc.

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Response Summary

- ❑ **How should these expectations change as the project develops?**
- Russia
  - ✓ Operator (applicant) must ensure the continuous monitoring of the entire activities affecting the safety including the self assessment method, which promotes timely adaptation and adjustment of existing practices in the area of governance and leadership.
- Korea & UAE
  - ✓ Depending on the licensing stage, different phases may require different leadership and governance structures and people.
  - ✓ Organizational arrangements may also change with each phase.
- UK
  - ✓ In the pre-application phase, ONR has no power to insist on any particular model of corporate governance. ONR will offer advice and guidance of expectations for a balanced Board.

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Response Summary

- ✓ As the project progresses from these early phases where adoption of the reactor design, pre-construction management and construction planning are the key activities being undertaken, the expectation is that the Board Executive Directors and the Independent Non –Executive Directors should have relevant experience in these areas.
- ✓ ONR assesses these arrangements against relevant good practice and also against specific ONR guidance in the case of Nuclear Safety Committees and Leadership expectations as laid down in ONR's Safety Assessment Principles, Technical Assessment Guides and Technical Inspection Guides.

➢ USA

- ✓ Focus of NRC reviews may also change as the project develops to direct NRC resources to review licensee activities and documentation
  - NUREG-0800, Chapters 13 and 17 provide the NRC guidance for review of matters related to licensee governance standards.

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Response Summary

❑ **What should be your leadership expectations across new licensees?**

➢ Finland

- ✓ Good understanding of safety culture is a must.

➢ Hungary

- ✓ Top management shall determine individual and institutional values as well as behavioural expectations for the organization to support the implementation of the management system.

➢ UAE

- ✓ Leadership should be focused on establishing the organizational culture that values safety and security using a graded approach commensurate with the risks at each phase of the project.

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Response Summary

- UK
  - ✓ Organisational capability of the licensee is crucial to the safe undertaking of activities.
    - This is a key area of interest for ONR and significant effort is made during the pre-application phase to advise the aspirant licensee.
- USA
  - ✓ NRC sets forth requirements and guidance pertaining to licensee organizations, including matters such as areas or responsibility, authority, inter-relationships and independence.
    - but does not establish requirements for how individuals in these positions lead their organizations
  - ✓ NRC has set forth expectations for licensee leadership, in the form of guidance, through the Commission's Safety Culture Policy Statement.

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Response Summary

- ❑ **Is there sufficient guidance/best practise available on these issues?**
- Overall
  - ✓ Sufficient practical guidance is not available
  - ✓ IAEA issued a specific regulatory guide for IMS development.
  - ✓ ONR believes the key gap in ONR's guidance is in the area of Corporate Governance.
    - ONR uses the relevant good practices as contained in the UK Corporate Governance Code
  - ✓ NRC does not have a specific initiative in progress to update its guidance on matters concerning licensee governance or leadership.
- ❑ **How do ownership models influence governance and leadership?**
- Overall
  - ✓ Ownership models are evolving into models that increasingly draw resources from foreign vendor and related services companies.
  - ✓ If the licensee and the owner are different legal entities, interaction between the two could increase the length of certain decision-making processes.

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Points of Special Interest in Countries' Responses

- How to further reinforce the Intelligent Customer model in a regulatory framework (Canada)
  - Providing clearer guidance on what a minimum level of licensee capabilities should look like to be an Intelligent Customer when dealing with extensive use of outsourced (and international) equipment and services suppliers (Canada)
- Regulatory expectation in the different stages of the project (Hungary)
- What should be the requirements of the regulator to the qualifications and knowledge of managers and persons performing activities affecting safety? (Russia)

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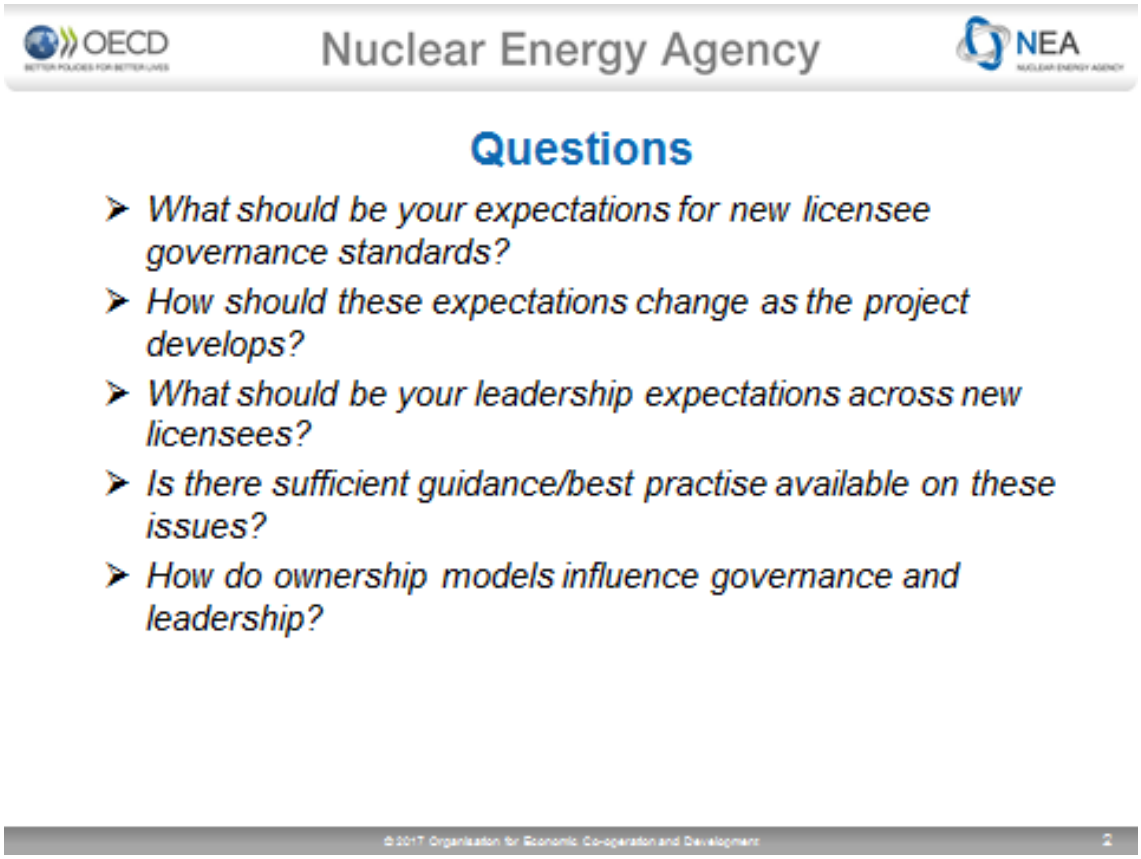
Points to be discussed

1. Is it enough to establish well designed management system?
2. Over the different phases, what specific approaches are needed to ensure strong leadership and accurate governance?
3. How should sub-contractors governance be insured?
4. In practice how can the applicants level of qualification related to leadership and organizational capability be assessed?
5. Under the circumstance of international business model, how much should owner retain control of the new build licensee organization?
6. How can leadership of a new licensee be promoted?
7. How can different ownership models influence the governance and leadership?
8. What best practices has been identified to be effective?
9. What type of additional guidance in this area would be helpful?

Session 1.2 Developing Leadership and Governance Feedback



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Sub Group Output

Key Lessons Learnt

- Different understanding of the terminology (IC, EPC, Governance, Leadership)
- Almost all participating countries do not have specific guidance regarding governance
- However guidance documents were presented which represents different aspects of governance (structure, roles and responsibilities, authorities, inter-relationships, independence, expertise etc)
- Additionally following governance aspects were identified in need of attention:
  - Assurance of oversight and monotoring
  - Assessment
  - Independence (from external pressure which can jeopardize safety)
  - Dynamic adaptation capability
  - Composition of executive board and safety committee
  - Members competence of the executive board and safety committee
  - HOF/safety culture experts the executive board and safety committee
  - Method to support systemic oversight depending on phase

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Sub Group Output

Key Lessons Learnt

- Under fluctuating business situation, it is recommended for licensee to make a short term plan for easy update to quickly manage the new situation
- The role of "internal regulator" within licensee organization is important, who is responsible for the independent review and interacts with the regulator
- Regulator should establish a requirement for licensee to make internal provision for supervising its contractors and subcontractors including periodical assessment
- It is recommended to establish generic requirement on leadership and organizational capability. Additionally state the minimum level (baseline) of knowledge or capability in the management line
- If the owner has insufficient knowledge about the project it is plausible it will delay the project
- The senior management appointment process (360 degree evaluation, organizational value assessment) can be used for assessing the leadership

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Sub Group Output

Key Lessons Learnt

- When new prospective licensee shows an intention to construct nuclear facility, it is unlikely that they are well acquainted with regulatory requirement on organizational capability
- Integrated management systems provides good basis, but is not enough to ensure accurate governance and leadership. Self-reflections and continuous improvements are also needed.
- It was suggested that early involvement of the regulatory in the project to provide advice on how to build governance and leadership capabilities (provision of guidance docs, "secret meetings", educate on the process and the requirements)
- However, most regulatory bodies do not have guidance on early engagement
- The concept of Intelligent Customer should be applied also on the regulator

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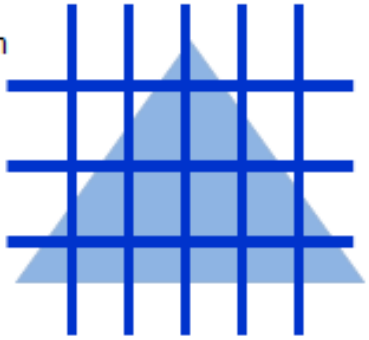
Sub Group Output

Commendable Practices

- UK emphasized the importance of independent executive board of directors as well as the balanced number of board directors between internal and external
- UK has developed guidance on Intelligent Customer Capability
- Hungary has establishment a comprehensive inspection system. A multi-disciplinary team (7~15 persons) perform a five day inspection. The inspection is conducted in a simultaneous manner, both hierarchically and functionally. The inspection results are analyzed by the team and conclusions are drawn in a holistic and comprehensive manner.
- Finland has a similar multi-disciplinary approach



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Sub Group Output

Commendable Practices

- Russia has a requirement for the licensee to ensure the continuous monitoring of the all activities affecting the safety which includes a self-assessment method. This method promotes timely adaptation and adjustment of existing practices in the area of governance and leadership
- UK and Finland sets so called "hold-points" where the licensee needs to demonstrate that sufficient level of governance has been achieved
- The licensees organize Safety Director Forum to issue good practice guidance and the regulator is invited to participate

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Sub Group Output

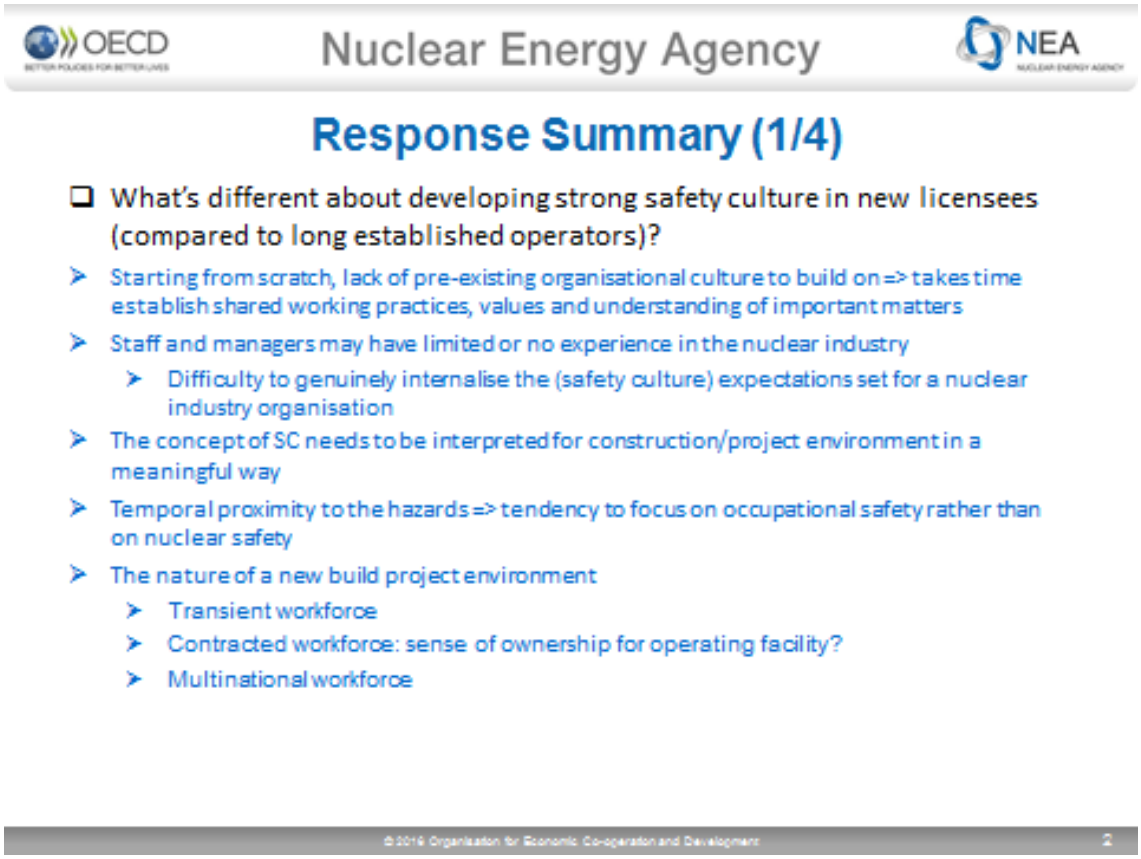
Identified Challenges

- The owner invests a large portion of construction cost in project, it is likely that owner wants to retain large control power for licensee corresponding to the investment
- ONR has identified governance guidance to be one of the biggest gaps
- Oversight of the proven leadership capabilities (rather than documented qualifications)

Suggestion

- In addition, participants suggested that NEA develop general guidance or high level document (green booklet) on organizational capability building. The publication should include organizational capability assessment methodologies as well as methods on how to establish organizational capability

Session 1.3 Developing Strong Safety Culture



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Response Summary (2/4)

- What is best practise for developing strong safety culture?
  - Gaining knowledge, experience and insight of safety culture and its importance
  - Management needs to demonstrate commitment to safety and set clear expectations for a good safety culture
  - SC development programme/tools are situation dependent => needs expertise to tailor a well functioning SC development programme
  - SC development needs to be programmed and systematic
  - Involvement of the suppliers and subcontractors

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Response Summary (3/4)

- How should you assess safety culture in new licensees?
  - The licensees need to conduct self-assessments
  - Most respondent regulators monitor new licensee SC through "normal" oversight tools:
    - Inspections, reviewing the management system and other documents, observations, event analysis, (in)formal discussions, third party assessments
  - The need have lifecycle specific focus when assessing the SC? Yes and no... Mostly the SC of the new licensees is assessed against the criteria used for all other licensees as well.
  - IAEA TecDoc 1707 provides good recommendations.

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Response Summary (4/4)

- What are the risks to maintaining strong safety culture across the project lifecycle?
  - Project delays cause time pressure
  - Scale of the project
  - Lack of continuity
    - changing workforce
    - organisational changes
    - unforeseen shift of paradigm
  - Complacency
  - Lack of understanding of the safety requirements
  - Peace-at-any-price principle, a pattern of acceptance leading to diminished standards (concerns both the licensee and the regulator?)
  - Managers not listening to the engineers
  - Ineffective checks and supervision
  - Lack of training and systematic SC programme

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Points of Special Interest in Countries' Responses

- How to promote **more effectively** the key organizational attributes that signify a top down healthy culture of 'safety first' **in an economically challenging environment**
- **Methods, guidance, best practices** for developing strong safety culture
  - All contracting parties
  - Especially on a construction site
- How to ensure that **workers, including contractors, are knowledgeable of the safety significance of the work?**
- How are licensees implementing the necessary **management system processes to integrate with** technological features presented by the **new design concept?**

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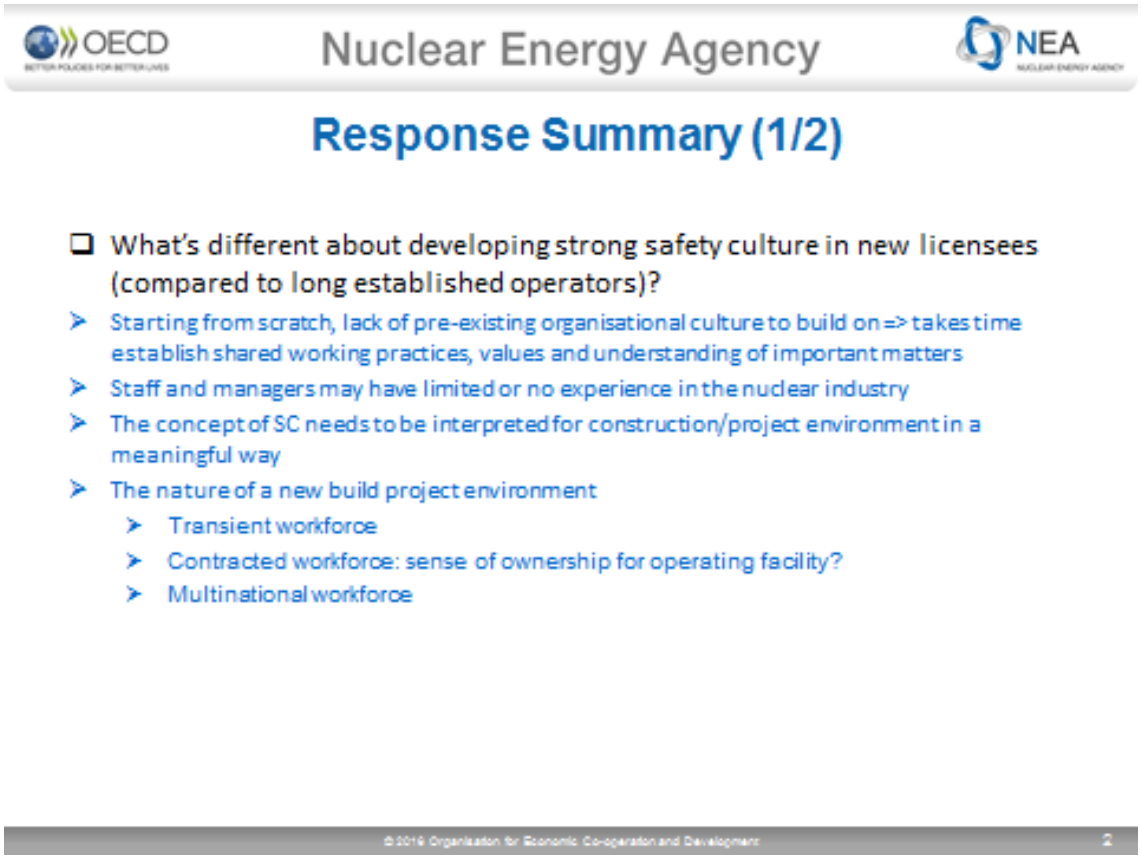
Points to be discussed

- How to promote **more effectively** the key organizational attributes that signify a culture of 'safety first' **at a new licensee organisation** (that faces all the challenges previously mentioned)
  - **Practical methods and guidance** – what concrete measures and activities should the regulators expect from the new licensees
- How is safety culture promoted **to all contracting parties**?
  - **Practical methods and guidance** – what concrete measures and activities should the regulators expect from supply chain

Session 1.3 Developing Strong Safety Culture Feedback



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Response Summary

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  - Managers not listening to the engineers
  - Ineffective checks and supervision
  - Lack of training and systematic SC programme

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Points of Discussion

What is the extent of safety culture?

- What safety are we talking about? environmental, nuclear, health and safety, security and safeguards
  - Primary mandate of safety culture is nuclear safety, although all types of safety can be indicators
- What is culture? is safety a subset of organizational culture
  - Underlying traits/values that drives a community

- What is strong/healthy SC:

-Organisational performance prioritizes safety.
-Need consistent/strong leadership to maintain Safety

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Points of Discussion

- **How far in the supply chain do you need to go?**
  - Need expertise in SC/human performance in the supply chain.
  - Main proponents: vendor, main licensee and regulator should have expertise.

A graded approach should be used, where safety critical contractors have higher requirements/expectations.

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Points of Discussion

How is SC affected by the phase of the life cycle

- The concept of safety culture stays the same
  - however in practice it might be difficult to have as strong a SC for a new organisation as for a mature company.
    - the transient workforce puts pressure on the SC
    - company that may be on a site for short term may not have same incentive for strong SC.

The tool box:

-guidance to apply the top principles of SC depending on lifecycle/organization phase

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Points of Discussion

How to promote more effectively the key organizational attributes that signify a SC first to a new licensee organization?

- Any senior management position coming from outside the nuclear industry should have proper education and experience
  - Leadership is very important to SC
  - Selection of leaders is key
  - Need proper expertise on SC.
  - Management need to be aware of challenges of their own SC.

- Development of SC has to be goal oriented and systematic. How to avoid the risk of complacency or superficial compliance to SC tools?
  - Real life examples can be communicated such as shared learning examples, videos,
  - First line of command needs to lead by example

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Commendable practices (1/1)

- Early involvement, even before the applicant applies
  - Building culture takes time and there will be challenges
  - Future licensee understands the regulatory requirements and expectations. In some countries there is some requirements for Safety Culture.
  - Early capacity to evaluate the construction experience and to build on it.
    -For example the HPC example of using nuclear grade concrete everywhere to build expertise
- Ask the licensee to lay out their strategic approach on how they are going to develop and promote Safety Culture.
  - Some countries require this to be documented.
  - Some countries meets regularly to provide guidance on the approach until it reach an agreement.

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Commendable Practices (2/2)

- Any senior management position coming from outside the nuclear industry should have proper education and experience (which cover SC)
  - otherwise a proper education program is set up which include taking part in peer review missions such as IAEA OSART or WANO missions.
  - Approve/certify certain key positions in the organization
- Having trained specialists assessing SC in organisation
- Co-creation of SC
  - Integrated work practices (like HPC project)
  - Safety Culture Working Group: one person from licensee, vendor, and tier 1 and 2 contractors.
    - Can be a better approach than setting requirements.

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Identified Challenges

- How to ensure supply chain meets full expectation in SC?
- Different aspects of safety can be a challenge in implementing SC.
- Having the SC develop with the lifecycle of the project. How to evolve the SC with the dynamics of the project.
- The project pressures can put pressure on the SC of both licensee and the regulators. Balancing the external pressures can be a challenge.

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Identified Challenges (2/2)

- SC assessments can take a lot of time and energy and therefore can be difficult to properly addressed. Danger of performing superficial safety culture assessments.
- How to ensure that SC is not superficial but (kept fresh)
- How to ensure licensee have enough/ sufficient capability in terms of understanding organisational culture

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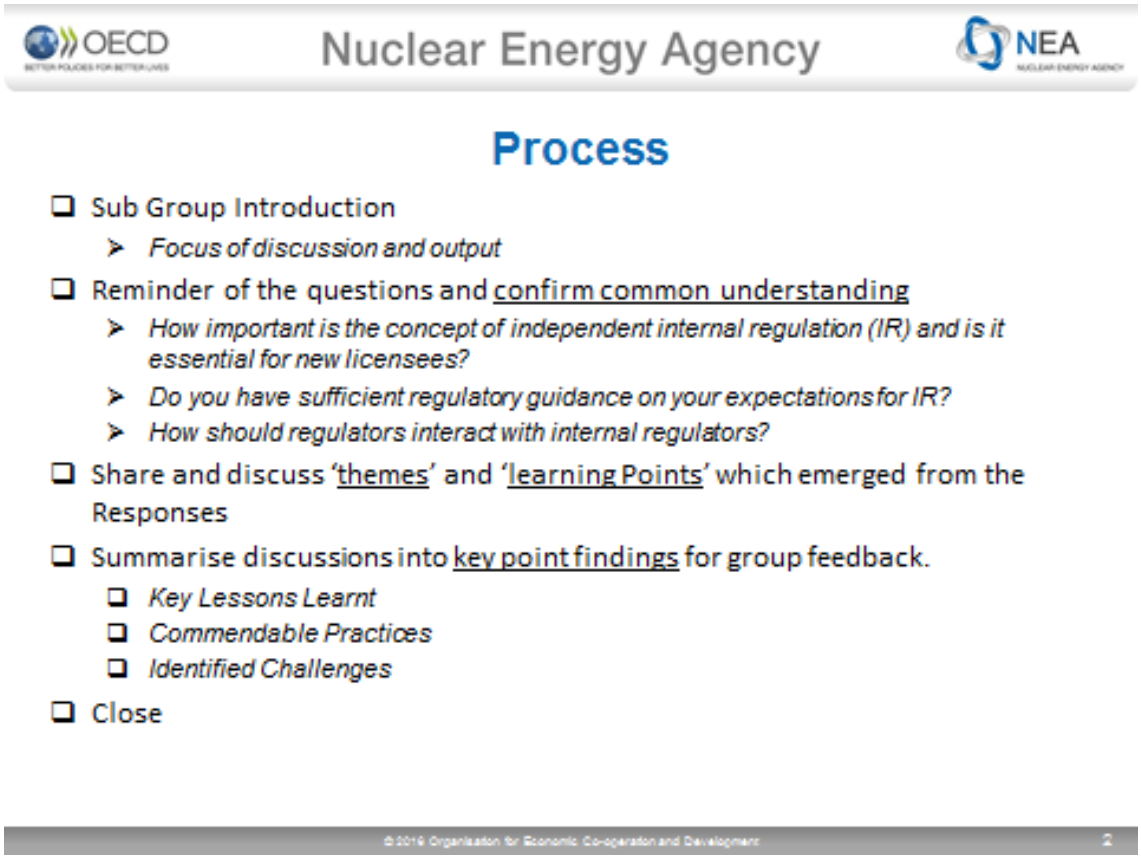
Areas for future work

Areas Warranting Further Work:

- How to ensure supply chain meets full expectation in SC?
- Having the SC develop with the lifecycle of the project. How to evolve the SC with the dynamics of the project. Guidance and toolbox development.

Session 1.4 Developing Internal Regulation



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'Themes' for discussion emerging from Responses

How important is the concept of IR and is it essential for new licensees?

- Licensees must demonstrate that NPP operations during the lifecycle of the project satisfy performance standards **(Canada)**
- It is important to have independent safety assessment because competence in new licensee organisations can be lacking **(Finland)**
- The licensee has to establish a safety organisation for the independent evaluation of activities having a significant effect on safety **(Hungary)**
- Independent regulation by the utilities is specified in the Quality Assurance Program **(Korea)**
- New licensees need to work on establishing a strong safety culture – part of that work is developing an internal system of rules **(Netherlands)**
- It's is important for increasing understanding of the project, and during contacts with vendors and subcontractors **(Poland)**
- The licensee must continuously monitor compliance with licensing terms in order to compile information on the work carried out, identify shortcomings and put good practices into use **(Russia)**
- IR is very important and should be used as a tool by new licensees to assess performance and continuously improve **(UAE)**
- A licensee's capability is strengthened by the presence of a robust and effective internal regulation capability **(UK)**
- The QA manager should provide adequate oversight of activities affecting safety throughout all phases of plant life **(USA)**

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'Themes' for discussion emerging from Responses

Do you have sufficient guidance on your expectations for IR?

- Provisions are submitted at the time of licence application and, if accepted, become part of the licensing basis for NPP **(Canada)**
- Only top level requirements **(Finland)**
- Yes, there are specific regulatory requirements on this subject **(Hungary)**
- There are regulatory standards and guides including the QA program **(Korea)**
- No, not at all **(Netherlands)**
- No. We have some requirements for internal technical regulations but not for managerial aspects **(Poland)**
- Federal rules and regulations contain limited information about the regulation of the activities of internal inspections **(Russia)**
- We have established requirements which are supported by several IAEA safety guides **(UAE)**
- There is a specific Technical Assessment Guide covering Internal Regulation **(UK)**
- Quality standards implementing the regulations require that quality achievement is verified by those not directly responsible for performing work **(USA)**

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'Themes' for discussion emerging from Responses

How should regulators interact with internal regulators?

- Our practice is that the IR, with specific exceptions, is considered as the licensee's official contact point on safety relevant subjects **(Hungary)**
- We don't have a specific rule for interaction with internal regulators of utilities **(Korea)**
- On a regular basis, cooperative as well as judicial **(Netherlands)**
- Joint training/workshops, but formal cooperation regarding the project **(Poland)**
- Regulator does not directly interact with the internal regulator. Issues of the effectiveness of departmental inspections are included in the inspection program carried out by the regulatory body **(Russia)**
- Through the licensee **(UAE)**
- Regulators should develop a relationship with the IR function based on trust, openness and mutual respect which should encourage both parties to share good practice and matters of potential concern **(UK)**
- There are inspection procedures that provide amplifying guidance on how to ensure the adequacy of the licensee's QA program **(USA)**

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Summary of Responses

Question: How important is the concept of IR and is it essential for new licensees?

- Key points - IR is important because it:
  - Provides independent oversight of compliance with regulations
  - Provides independent evaluation of activities having a significant effect on safety
  - Increases understanding of the project – in particular of the supply chain
  - Strengthens the licensee's organisational capability and is an important element of a licensee's safety culture

Question: Do you have sufficient regulatory guidance on your expectations for IR?

- Key points - guidance is available:
  - As part of licence application
  - Only at a high level
  - As regulatory standards and guides
  - As part of quality assurance arrangements
  - Not at all

Question: How should regulators interact with internal regulators?

- Key points - interactions with IR functions are:
  - As an official licensee point of contact
  - On a regular basis
  - Not directly
  - Not at all
  - Through a relationship based on trust, openness and mutual respect

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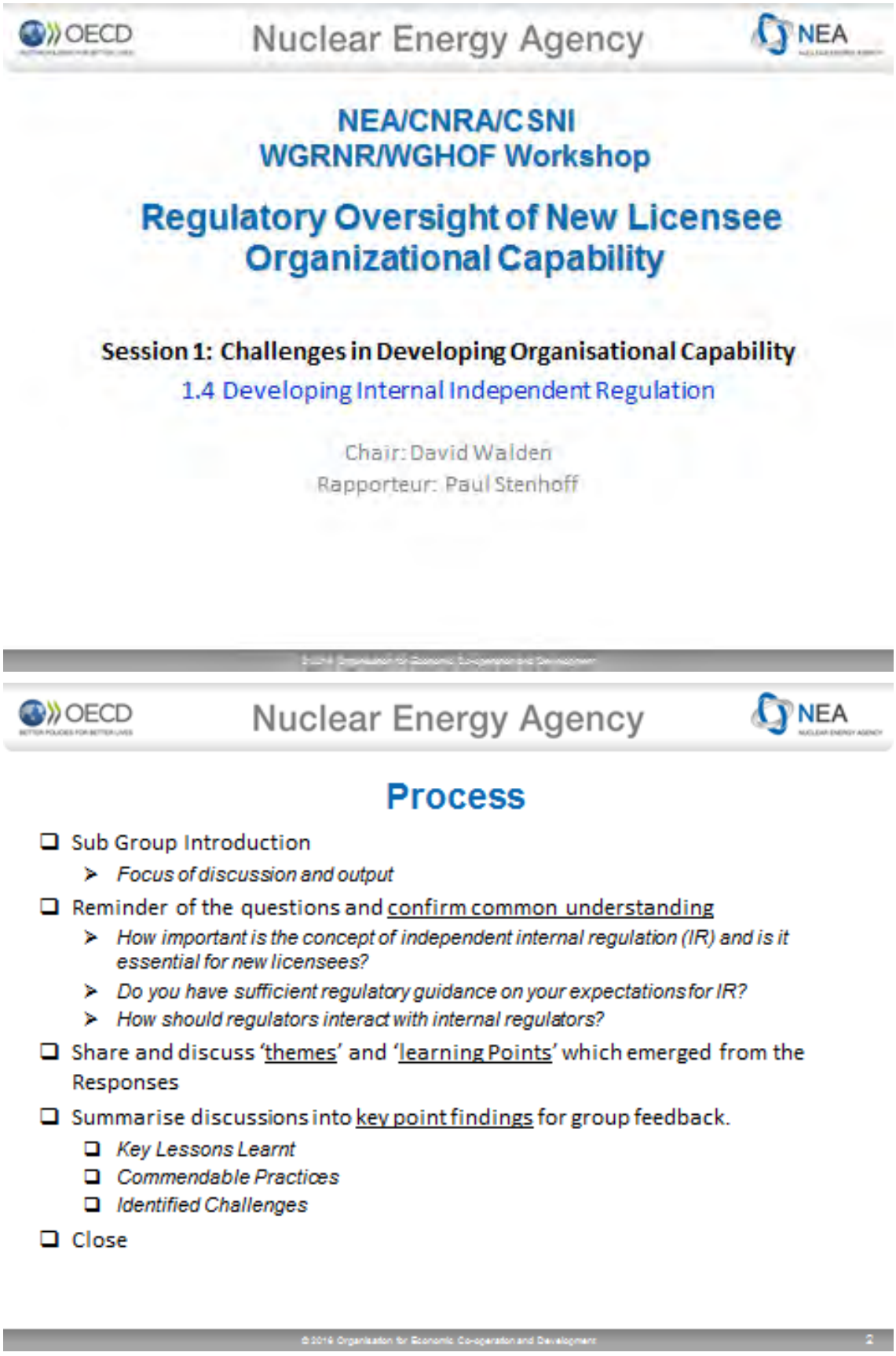
Learning Points for discussion from Responses

- Definition of licensing basis **(Canada)**
- Role of IR **(Hungary)**
- Independence of IR **(Hungary)**
- What are the best practices in establishing a system of rewards and penalties on performance results that fosters openness of actions of the employee and is not conducive to the concealment of errors in their work? **(Russia)**
- There is potential for regulators to overlook or ignore the contribution of internal regulators. It would be beneficial to explore how we can develop a productive relationship with IRs **(UK)**

Session 1.4 Developing Internal Regulation Feedback



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NEA/CNRA/CSNI
WGRNR/WGHOF Workshop

Regulatory Oversight of New Licensee Organizational Capability

Session 1: Challenges in Developing Organisational Capability

1.4 Developing Internal Independent Regulation

Chair: David Walden
Rapporteur: Paul Stenhoff

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Process

- Sub Group Introduction
  - *Focus of discussion and output*
- Reminder of the questions and confirm common understanding
  - *How important is the concept of independent internal regulation (IR) and is it essential for new licensees?*
  - *Do you have sufficient regulatory guidance on your expectations for IR?*
  - *How should regulators interact with internal regulators?*
- Share and discuss 'themes' and 'learning Points' which emerged from the Responses
- Summarise discussions into key point findings for group feedback.
  - *Key Lessons Learnt*
  - *Commendable Practices*
  - *Identified Challenges*
- Close

 2

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'Themes' for discussion emerging from Responses

How important is the concept of IR and is it essential for new licensees?

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- There are inspection procedures that provide amplifying guidance on how to ensure the adequacy of the licensee's QA program **(USA)**

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Summary of Answers to Questions

Question: How important is the concept of IR and is it essential for new licensees?

- Considered to be important
  - Regulators can't check everything in a licensee organisation
  - IR have an inside view of positives and negatives and are able to recommend fixes
  - There will be less external regulatory attention if IR is effective
  - Senior management must support the role
  - The role is not mandatory but it is desirable and beneficial
  - Role should be used to evaluate, challenge and continuously improve
  - Needs the right organisational culture to be effective
  - It is important to have IR because competence in new licensee organisations can be lacking
  - Timing of introduction of IR in new licensees is important
    - Can be introduced too early i.e. the organisation isn't ready for it
    - Can help to 'fast track' development of an organisation by having a holistic view of how activities fit together

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Summary of Answers to Questions

Question: Do you have sufficient regulatory guidance on your expectations for IR?

- Mixed responses ranging from yes to yes but not sufficient to none at all
- In some countries the requirement for IR is specified in the licence
  - Generally in a prescriptive regime but very technically orientated
- IAEA guidance is the default in the absence of adequate country guidance
- Prescriptive v goal setting
- Should countries write their own guidance?

Question: How should regulators interact with internal regulators?

- Good, high level relationship is important
- Collaboratively with a constructive approach
- Regulators need to be intelligent when engaging with IR functions
  - May need to interpret the messages being given
- IR shouldn't answer for the organisation
- Joint training can help
- Need to understand how mature the IR function is
- Need to understand the challenges IR functions face
  - Career risk to individuals
- IR functions can never be as strong as external regulators
- Check what licensee senior management think about their IR function

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Sub Group Output

Key Lessons Learnt

- Need to be clear about the role - compliance v assurance
- Licensing basis often determines approach to IR - prescriptive v goal setting
- Need the right organisational culture to make it work.
  - 'Challenge' culture
  - Blame v no blame v fair blame
- Can add real value when working well
- Timing/organisational maturity of establishing an IR function is important
- Leadership support is essential

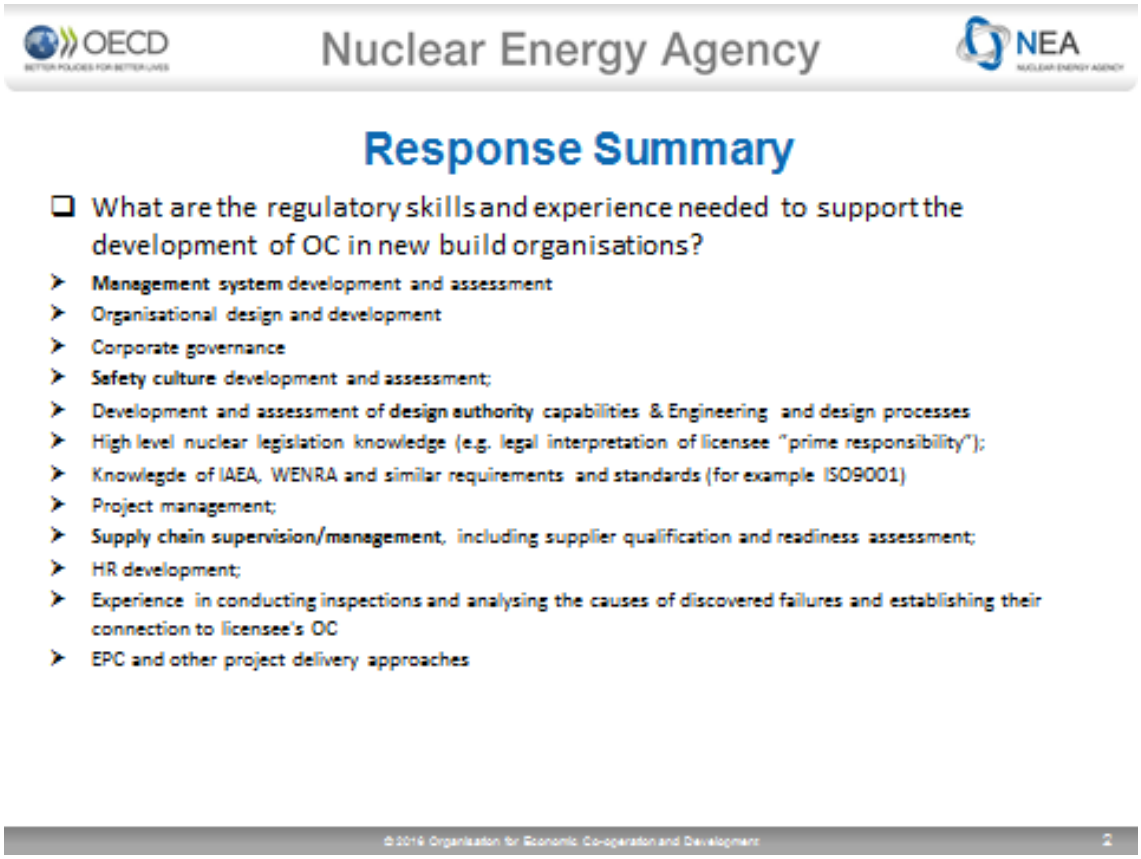
Commendable Practices

- Close working relationship between external regulators and IR functions
- Use of IR as the first point of contact in licensees
- Joint training
- Joint inspections
- Sharing of findings and areas of concern

Identified Challenges

- Creating the right organisational culture
- Engaging licensee leadership
- Developing a relationship based on trust, openness and mutual respect
- Developing IR from compliance assessment to continuous improvement

Session 2.1 Regulatory Readiness



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Response Summary

- How should regulatory staff be trained for assessment of OC in new build organisations?

- **Previous experience in nuclear projects**, Experiences should be shared within the regulator, above mentioned skills should be available and developed.
- On one side, the training should be the same as for the OC assessment for exiting licensee, because principles and methods are generally the same. On the other side emphasis should be put on how to review and assess the initial development of the OC, taking into account new build specific requirement and lifecycle specific circumstances.
- By conducting regular reviews as exercises
- **Theoretical basis and practical skills**, including the implementation of them in licensing and supervision
- A mixture of generic, focussing on the specific nature of the new build environment, and specific where there is an **identified gap**
- **Capability to assess vendor & supplier quality and project plans etc**
- Educational background also important

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Response Summary

- How can regulators attract experienced/skilled staff in a competitive market?

- Provide competitive pay and working conditions and give employees the possibility to affect their own work.
- challenge can be that usually staff with nuclear experience is not available on the market, so people for non-nuclear industries have to be hired, and extensively trained.
- Job stability, sound and challenging working environment
- Challenging work, **ability to utilise valuable professional experience.**
- To participate in inspections and in examination of safety justification documents qualified experts can be engaged on a contractual basis from other organizations without interrupting their main work.
- Vacancies should be advertised using a variety of media and directed towards the target market. Regulators should develop relationships with licensees which open up opportunities for secondments from those organisations .
- **Strategic approach**
- **emphasizing the unique safety mission**

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Response Summary

- What are the challenges of transitioning your regulators from dealing with long established licensees to new build organisations?

- Make sure that **understanding of emerging technologies** is up to date
- Understanding that the **new licensees can have very low competence** when they are starting
- Their (new build organisations) understanding of licencing and other regulatory expectations can be weak
- professional contacts have to be newly established;
- shortcomings in the quality and quantity of human resources
- interpretation of goal based regulatory requirements and their practical implications
- **EPC contract vs. licensee's prime responsibility**;
- "Intelligent Customer" capabilities
- communication between our regulator and new licensee
- Transition plan developed to ensure regulatory attributes are in place to support oversight of operating licensee
- Regulators in this environment need to have a flexible and constructive approach, recognise the **high dependence on the supply chain**, to be aware of cultural differences and be prepared for schedule and cost to be the developer's number one priority.
- gaining a complete understanding of the new organization's plans and schedule

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Points to be discussed

- Training methods of regulatory staff for assessment of OC in new build organisations
- Hiring process in a competitive market
- Transition inspectors
- There is need to apply judgement in the application of organisational capability principles to recognise the differences between a developing new build organisation and a mature, established licensee. It would be beneficial to explore approaches adopted by other regulators to applying regulatory requirements to immature, project-orientated organisations.
- Should international forums be strengthened to build up technical capabilities and capacity with respect to new reactors designs to support regulators world-wide?

Session 2.1 Regulatory Readiness Feedback

OECD Nuclear Energy Agency NEA

NEA/CNRA/CSNI
WGRNR/WGHOF Workshop

Regulatory Oversight of New Licensee Organizational Capability

- Summary of responses and discussions

Session 2: Regulatory Challenges with New Licensees

2.1 Regulatory Readiness

Chair: Juha Väisäsvaara
Rapporteur: Mari Nykänen

OECD Nuclear Energy Agency NEA

Regulatory skills to support the development of OC in new build organisations

- **Regulator needs to manage its own knowledge too!**
- **Management system** development and assessment
  - **especially** in a case when new licencee organisations are building from the ground up
- Project management capabilities, regulator needs to ask the right questions;
  - It must be clear to everyone how the project will progress (work breakdown structures etc)
- Organisational design and development, HR development
  - Organisational changes can have safety impacts
  - Organisational development needs to be planned based on construction project needs (which need to be identified)
- **Safety culture** development and assessment;
  - New licensees can have challenges for example if top/mid management background is non-nuclear
- Human factors (incl. Human Factors Engineering) competence
  - HFE in design stage
- Financial "competence"
  - Regulator needs to understand to an extent the financial realism and motivators in projects
    - NRC preforms a financial review (realistic planning, waste taken into account etc)
    - Avoid potential safety culture risks also with sound financial planning

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Regulatory skills to support the development of OC in new build organisations

- Regulators own competence of licencing: need to instruct licensee and set clear expectations
- **Supply chain supervision/management**, including supplier qualification and readiness assessment;
  - Capability to assess vendor & supplier quality and project plans
- Development and assessment of **design authority** capabilities & Engineering and design processes
- Corporate governance
- High level nuclear legislation knowledge (e.g. legal interpretation of licensee "prime responsibility");
- Knowlegde of IAEA, WENRA and similar requirements and standards (for example ISO9001)
- Experience in conducting inspections and analysing the causes of discovered failures and establishing their connection to licensee's OC
- EPC and other project delivery approaches

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Regulatory staff training for assessment of OC in new build organisations

- Regulator needs to manage its own knowledge too!
  - Sometimes regulators need to challenge and question in order to move conversations with the licensee to more challenging aspects where the real deficiencies may lay – competence needs to be at a high level
  - Identify gaps and plan →
- Training should be planned and executed systematically and thoroughly
  - Theoretical and practical skills, understanding the role of the regulator
  - Some countries have specific qualification steps for inspectors → sometimes years of training needed before more responsible roles are possible
  - On the job training/assisting other inspectors in addition to theoretical knowledge
  - Short (e.g. 3-6 months) work "visits" at another country's regulatory body
- **Previous experience in nuclear projects (which have a specific nature)**. Experiences should be shared within the regulator.
- Observational skills and interview skills are also important, detection of weak signals?
- Developing language skills can be a big plus
  - Supplier documents can be written in any language

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How can regulators attract experienced/skilled staff in a competitive market?

- **Strategic approach:** Again, planning is important. What is the outlook in the near and far future? What resources are needed?
- Provide competitive pay and stable working conditions and give employees the possibility to affect their own work.
  - Probably differences between countries, some might offer more incentives
- It is possible to use headhunting & sometimes possible to use outside organisations in supporting roles in oversight
- Challenging work, **ability to utilize valuable professional experience**.
- Vacancies should be advertised using a variety of media and directed towards the target market. Regulators should develop relationships with licensees which open up opportunities for secondments (transfers) from those organisations.
- Should there be an internationally recognized master's degree for regulators?
- emphasizing the **unique safety mission**

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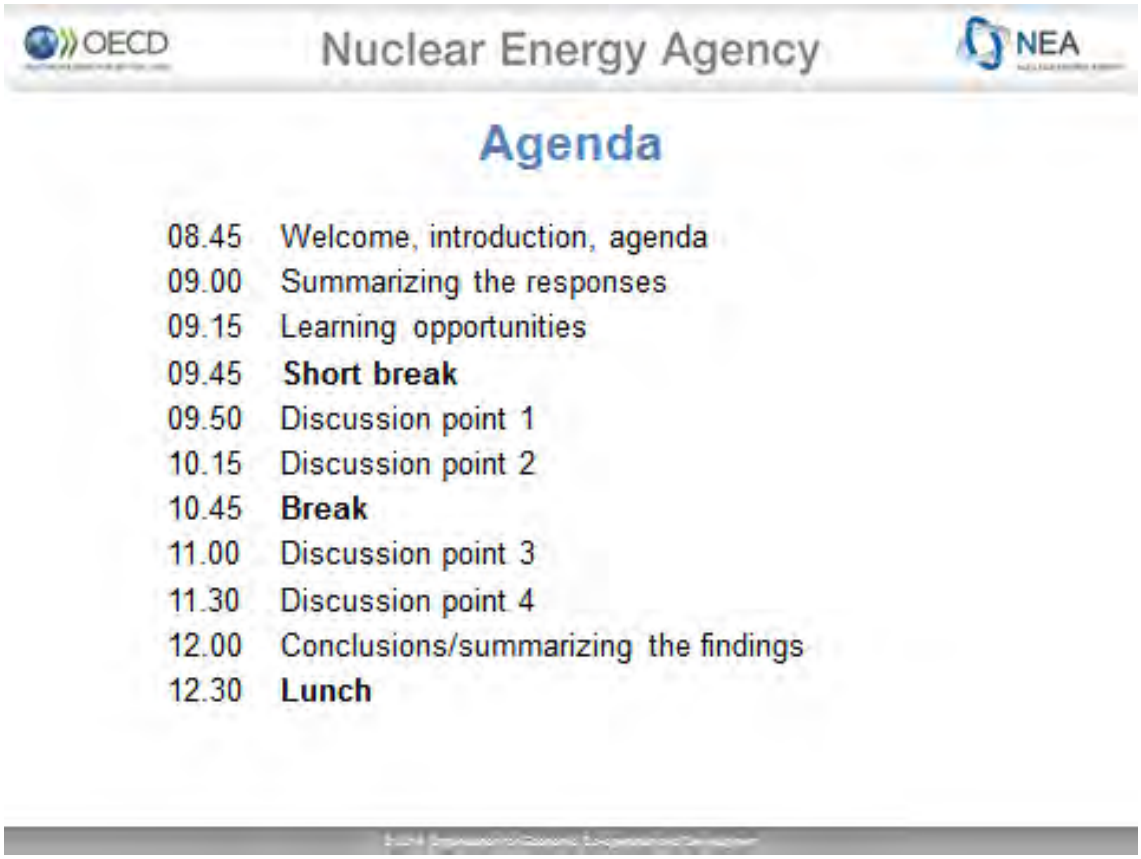
Challenges of transitioning your regulators from dealing with long established licensees to new build organisations?

- Make sure that **understanding of emerging technologies (e.g. small modular reactors)** is up to date
- Understanding that the **new licensees can have very low competence** when they are starting
  * Their (new build organisations) understanding of licencing and other regulatory expectations can be weak
- professional contacts have to be newly established; communication methods have to established
- Transitions need to be planned so that oversight of operating plants is not compromised
- Regulators in this environment need to have a flexible and constructive approach, recognise the **high dependence on the supply chain**, to be aware of cultural differences and be prepared for schedule and cost to be the developer's number one priority.
  - Understanding the potential weaknesses of different contracting models (e.g. turn-key can be dangerous and impossible in practice)

Session 2.2 Engagement Strategies



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When should you engage?

- **Engagement:**
  - AEAP/AEARP/ASAP
- **Engagement is:**
  - encouraged
  - voluntarily
  - not required
  - necessarily
  - on their request
- **Engagement is:**
  - before application
  - in pre licensing process
  - once application is submitted

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How should you engage?

How	Who	What about
meeting	all levels	expectations
website	top management	safety and security
presentations	middle management	
workshop	experts	
joint training	....	
review of documentation		

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Should you engage with parent bodies?

- **No, because:**
  - the regulator should interact directly with the applicant in order to assess his ability to perform its activities in accordance with the safety requirements
- **Yes, depending on:**
  - relationship of parent bodies and new organisations
  - regulatory structure, but for instance, if another body regulates environmental protection issues, there should be an engagement.
  - influence over prospective applicants

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Should you engage with contractors/suppliers?

- **Direct engagement with contractor/supplier:**
  - pre-licensing vendor design review process
  - three party meetings (regulator, applicant and suppliers)
  - by assessing their ability to ensure the safety of power plants
  - by inspecting the quality of materials and equipment on locations away from the nuclear site (for example at suppliers works)
- **Indirect engagement, only through applicant:**
  - by inspection programs, but all communications through applicant
  - by means of QA or supplier/vendor inspection program
- 'The regulatory body should be always open for discussion on topics related to safety requirement interpretation'

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Response Summary

When should you engage with new build organisations?

- early (to get informed, to clarify req's and processes, for mutual understanding)
- procedures differ, depending on the national legal system (often voluntarily)

How should you engage with new build organisations?

- by meetings an(on all levels), workshops, document review, joint training .....
- based on regulator pre-licensing process arrangements

Should you engage with parent bodies, if so when and how?

- yes, because parent bodies influence there applicants
- no, the applicant is primarily responsible (legal base?)

Should you engage with contractors/suppliers, if so when and how?

- no (or limited) because the applicant is primarily responsible
- yes, by inspections because c/s provide safety-related work/goods/services

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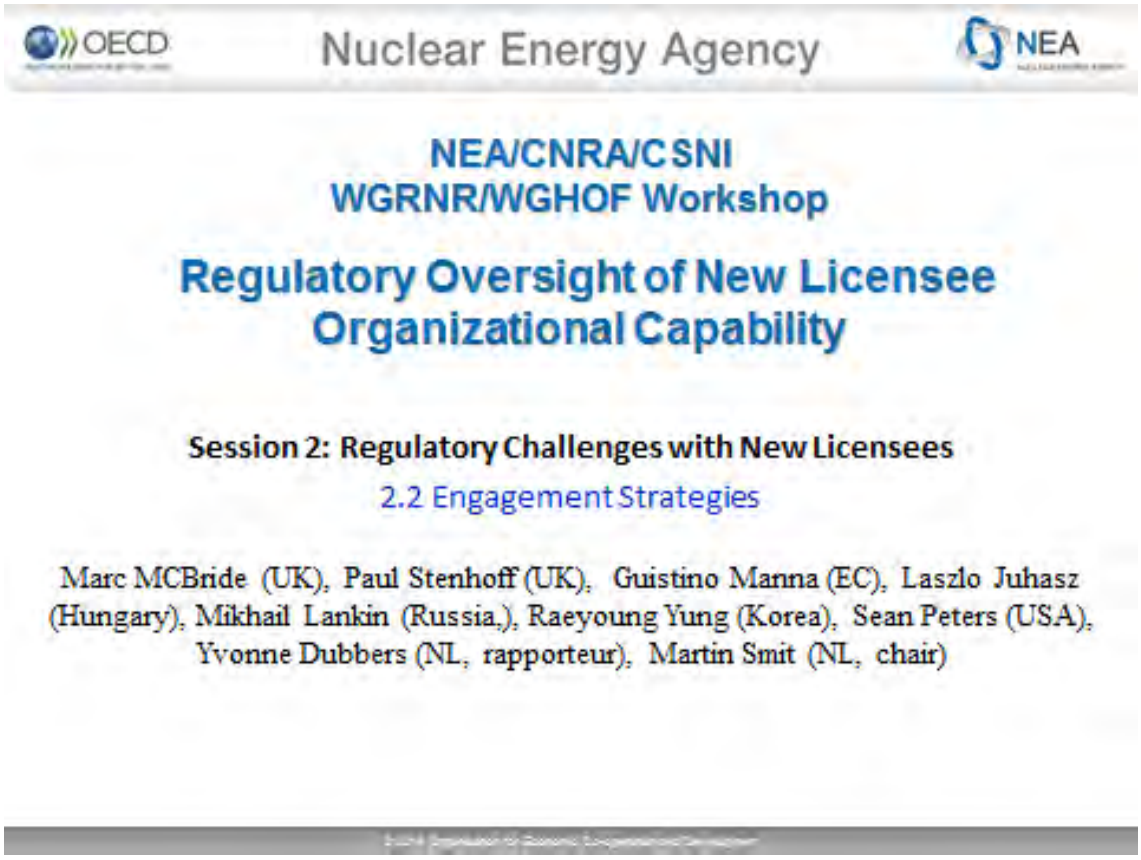
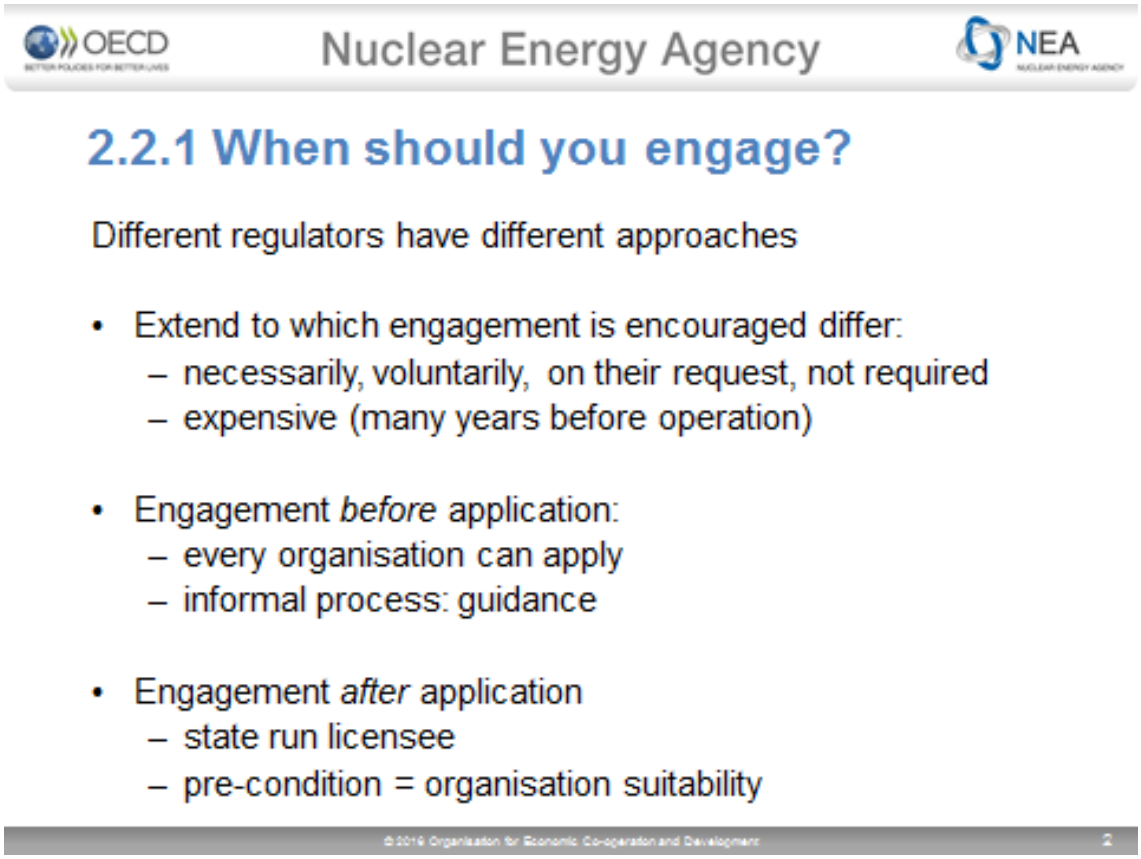
Optional points to be discussed

1. What are the risks of early engagement, and how to manage those risks?
2. When is a new build organization sufficient mature for engagement?
3. Which stakeholders should be involved?
4. Which organisational levels of the applicant should be involved in engagement and in which way?
5. How to balance involvement & responsibility (RB) in case of assessing documents in early stage?
6. Engaging with parent organizations: which problems to overcome?
7. What are the risks/benefits of direct engagement with vendors/suppliers?

Session 2.2 Engagement Strategies Feedback





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2.2.2 How should you engage?

- Engagement process should be structured
  - engage on organisation development, preparation of the safety case, license compliance issues, legal issues, security issues…
  - timing of deliverables
- Communication on all levels
  - management & experts
- Use of different methods
  - meetings, websites, presentations, conferences, workshop, joint training, review of documentation, assessment, (multidisciplinaire) inspections

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2.2.3 Should you engage with parent bodies?

- Engagement with licensee, not with parent organisation,
  ….. *'unless we have a good reason'*
- Appearance of parent bodies:
  - can informs regulator in case of new built (state run licensees)
  - have technical capabilities, more than a licensee
  - relatively new (coorperate licensee)
  - support / delay the process
- In some countries an assessment is required on:
  - minimum financial qualification parent bodies
  - Influence on decision making/communication
- Some countries foreign parent bodies are not allowed

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2.2.4. Should you engage with contractors/suppliers

- Direct engagement with contractor/supplier
  - pre-licensing vendor design review process
  - by assessing their ability to ensure the safety of power plants
  - by inspecting the quality of materials and equipment on locations away from the nuclear site
- Indirect engagement, only through applicant
  - by inspection programs, but all communications through applicant
  - by means of QA or supplier/vendor inspection program
- Combination direct & indirect engagement
  - example of a regulator upgraded amount of subcontractors inspections
  - example of a regulator reduced amount of inspections in factories

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Lessons learned

- Proportional early engagement
  - level of engagement depends on structure
  - state run licensee versus cooperate licensee
- 'New and novel' requires more involvement
  - licensee, parent bodies, contractors, supplier, ..
- Be transparent, publisch/communicate:
  - requirements & guidelines
  - important outcomes of decisions
  - process & engagement strategy
- Use different ways to communicate with management & experts
  - conferences, website, training workshops, meetings
- Be (always) open for discussion on safety requirement interpretation

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Lessons learned

- Relation between regulator and parent body is not absolute required but if issues arise then contact can give a solution
- Make sure supply chain of safety relevant items is controlled

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Identified challenges/Gaps

- Complex models of ownership
  - influence of safety related decisions by parent organisation, they have the money
  - risk management during different phases
- Foreign contractors/ suppliers /designers
  - interpretation of regulation/guidance
  - control of supply chain of safety relevant items

Session 2.3 Development of Guidance

OECD Nuclear Energy Agency NEA

NEA/CNRA/CSNI
WGRNR/WGHOF Workshop

Regulatory Oversight of New Licensee Organizational Capability

Session 2: Regulatory Challenges with New Licensees

2.3 Development of Guidance

Chair: Craig Reiersen
Rapporteur: Neil Correia

OECD Nuclear Energy Agency NEA

Response Summary

- ❑ What are the key areas regulators need to focus on when reviewing OC for new build organisations?
  - ➢ Several focus on development of competence & resource; safety culture; IMS; design and construction capability
- ❑ Where are the main challenge areas, or gaps, in regulatory guidance on new build organisations' OC?
  - ➢ Unsurprisingly, these tend to be in areas that are less subject to regulatory review for established licensees. eg:-
    - ➢ financial capability;
    - ➢ corporate governance;
    - ➢ early dependence on contractors and what minimum "intelligent customer" capability looks like;
    - ➢ operational readiness assessment;
    - ➢ defining firm criteria against which to judge licensee progress/readiness;
    - ➢ (& implementing new and less familiar guidance consistently)

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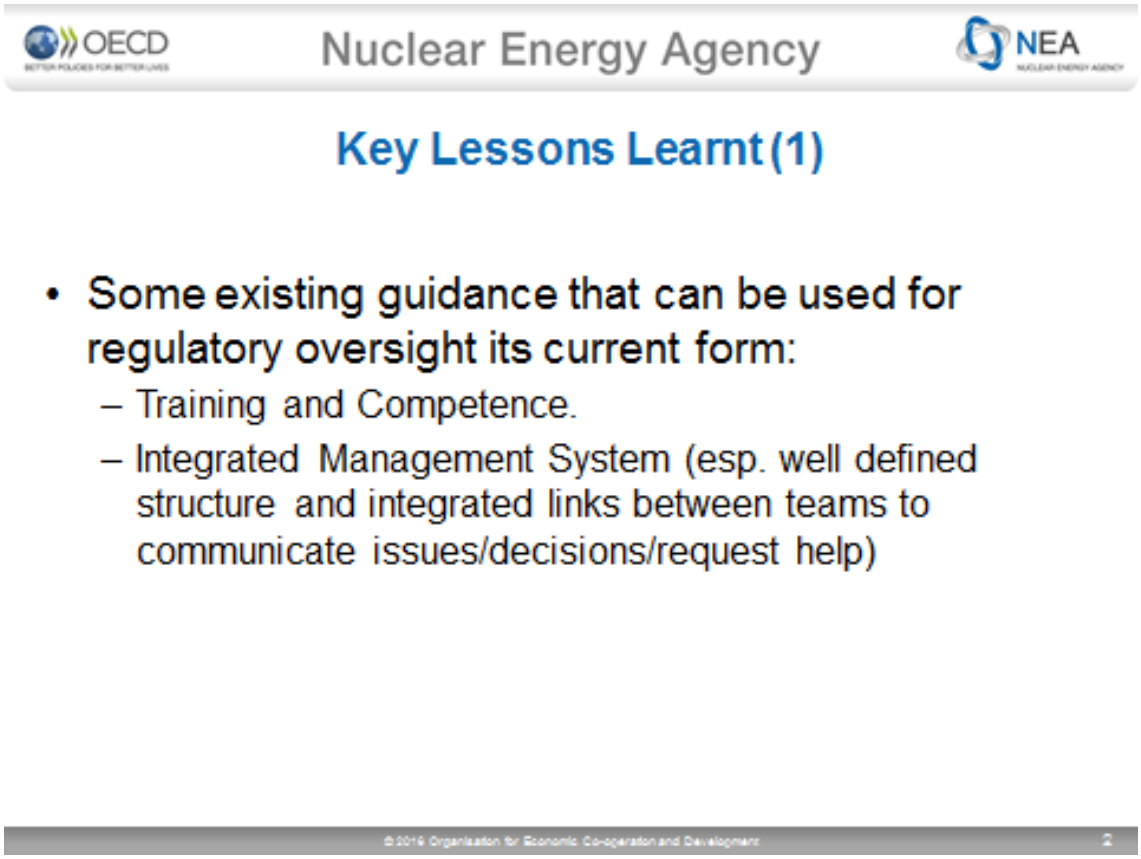
Points to be discussed

- Can we get consensus on the OC areas where we believe it would, and would not, be helpful to establish guidance for/expectations of a ***new*** licensee ?
- Where do we feel there are major gaps in current guidance ?
- What are the main challenges we face in developing ***international*** standards & guidance ?
  - Can we really get international Principles & Guidance in areas where there may be differing national legislative and cultural factors
- What experience do we have in implementing guidance - have new licensees – and Inspectors - understood and been responsive ?
- What guidance should we have on regulatory expectations for the new licensee's development of OC through the different stages of development (ie, from birth through to power operations) ?
- How should we recommend NEA and IAEA to go forward in terms of guidance development ?

Session 2.3 Development of Guidance Feedback



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Key Lessons Learnt (2)

- There is a need for new guidance for regulatory oversight :
  - Corporate Governance – e.g. Board structure, advisory committees, leadership, etc.
  - Development of Internal Advice and Challenge Capability
  - Use of Third Party Inspection Bodies
  - Financial guidance / Demonstration of financial adequacy to secure safety
  - Project Management (Client and Delivery Organisation including Stage Gate definition and guidance)

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Key Lessons Learnt (3)

- There is a need to tailor existing guidance for regulatory oversight :
  - Design Authority – definition and implementation
  - Guidance for Organisational Configuration Control
    - Including Organisation Change Management
    - To enable Design Configuration management
  - Guidance on Safety Culture and Leadership
    - Including contractors
  - Regulatory Expectation of Licensee Organisation Structure and Resource
    - (resource plan, resource model, justification e.g. baseline) (uk - core capability)
    - Organisation Design Principles (new guidance identified)
    - Life cycle management (new guidance identified)
  - Procurement & Supply Chain
    - Including major EPC contract
    - Specification management of supply chain
  - Intelligent Customer Capability and Use of Contractors

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Identified Challenges (1)

- Countries can have different legal frameworks and different national cultures where development/implementation of international guidance can be challenging
- Establishing an international vehicle for sharing regulatory and industry experience.
- When creating country specific guidance, the reference to international guidance takes time to implement when the specific country's experience/guidance is evolving at a faster pace than international guidance

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Identified Challenges

- Establishing consensual international guidance can be challenging in view of differing national legal frameworks
- Gathering relevant experience from countries with significant new reactor build programmes
- IAEA construction guide, SSG-38, should be revisited as OPEX from FA3 and Korea can be used to review and reassess the document.

Recommendations for Moving Forward

- NEA/IAEA could facilitate lifecycle/thematic (see themes identified in slide 1) workshops (including Developers) to gather and share international good practice
- NEA/IAEA could develop guidance documents based on the gathered experience from lifecycle/thematic workshops
- NEA/IAEA to consider gaps in guidance especially lifecycle management and regulatory expectations for pre-construction phase
- IAEA to consider revising SSG-38 to consider learning from recent construction experience
- Encouraging use of ConEX and capturing relevant regulatory experience including identification of gaps in guidance

Session 2.4 Interfacing with other Regulators

OECD Nuclear Energy Agency NEA

NEA/CNRA/CSNI
WGRNR/WGHOF Workshop

Regulatory Oversight of New Licensee Organizational Capability

Session 2: Regulatory Challenges with New Licensees

2.4 Interfacing with Other Regulators

Chair:
Rapporteur: Radim Dolezal

OECD Nuclear Energy Agency NEA

Points of Special Interest in Countries' Responses

Other Regulators – interpreted two ways

- International bodies (e.g. IAEA, WENRA, etc)
  - Adopt best practices, guidance, commitments to follow guidelines and report on activities
  - Bi-lateral agreements with foreign regulators for information sharing
- Domestic regulators – labour, environment, pressure boundary, fire, emergency measures
  - Work collaboratively to ensure requirements are met and results shared e.g.
    - Pressure boundary work is inspected by a separate agency on behalf of the regulator
    - Implementation of environmental act carried out by the nuclear or other regulator

 2

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Response Summary

- Are you legally required to engage with other regulators?
  - Domestic: Only legally required to engage if there is a contractual agreement in place or where multiple regulatory bodies have jurisdiction over different aspects of safety e.g. emergency management, environment etc.
  - International: Convention on Nuclear Safety – members become signatories to the CNS and report on activities. Member countries are held accountable. Others, WENRA, IAEA, NEA,
  - All respondents indicated that engagement with other regulators was a good idea and promoted even if it wasn't legally required.
- How and when do you engage?
  - Regular bilateral meetings, public hearings regarding licensing decisions, request for assistance with the review and development of rules and regulatory documents, training of regulatory staff, coordinated decision making, joint inspections, staff secondments, information exchange, cooperation in investigations, publication of joint guidance or consensus guidance, annual meeting with all co-regulators etc.

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Response Summary

- Do you coordinate regulatory activities with the new licensee?
  - Coordination is an important issue at the beginning of the project but only the UK has specified a process to manage this coordination of regulatory activities and exchange of information.
  - There may be clarification of requirements with new licensees
  - Limited information provided by respondents– it is possible this question was misinterpreted.
- Which stakeholders do you engage with and how?
  - Stakeholders applies to a broader population than just regulators. This involves all parties who may have an interest in the project development.
    - Licensee of the new build, other neighbouring licensees, other domestic regulatory bodies, suppliers, NGOs, the public, press, aboriginal consultation, design organizations, WENRA Reactor Harmonization Working Group, MDEP, advocacy groups etc.

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Points to be discussed

- Hungary – annual meeting of all co-regulators. Please describe in greater detail, participants, format, agenda, style etc. What are the benefits of this practice? Is this a good practice that might be adopted by others?

- UK – fairly extensive and formal process for coordination of regulatory activities with new licensees. Please describe in greater detail. Is this process useful? What are the perceived benefits? Drawbacks?

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Points to be discussed

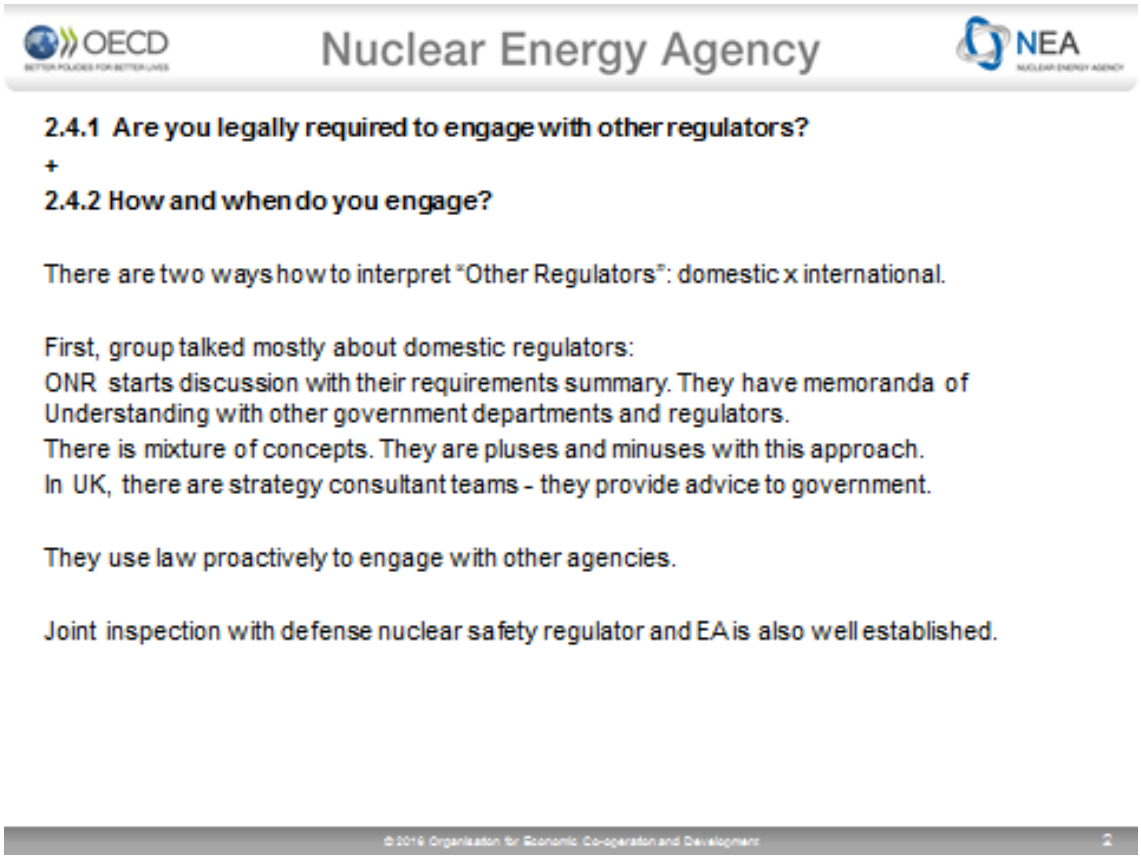
- Processes by which to share specific technical and regulatory information regarding design concepts for the purposes of informing each regulator's decision-making processes

For example:

  - Given the international nature of supply chains, is there an opportunity for better sharing of intelligence between regulators on supply chain performance?
  - Sharing information regarding construction and commissioning of new technologies

- Are there common regulatory expectations across countries which could facilitate the sharing of information for regulatory and technical perspectives?

Session 2.4 Interfacing with other Regulators Feedback



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2.4.1 Are you legally required to engage with other regulators?

+

2.4.2 How and when do you engage?

- Russia talked about challenges with adopting international documents and approaches, with have problem to find compatible way with Russian national culture.
- Canada has no legal engagement requirement. Their regulatory documents are heavily influenced with IAEA documents.
- UAE member talked about working groups, where they harmonize their approach.
- Problems in supply chain for new build often can lead to another country and need to be resolving according their law. There is kind of necessity to cooperate.
- Regulatory bodies from several states (UAE, UK) still facing also challenges with joint complex inspection inside agencies - safety with security etc.
- Poland has some requirement for engagement with other domestic agencies. They have in past joint inspection on research reactor safety and developing further approach.

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2.4.3 Do you coordinate regulatory activities with the new licensee?

Coordination is part of engagement activities.

2.4.4 Which stakeholders do you engage with and how?

Stakeholders applies to a broader population than just regulators. This involves all parties who may have an interest in the project development.

Licensee of the new build, other neighbouring licensees, other domestic regulatory bodies, suppliers, NGOs, the public, press, aboriginal consultation, design organizations, WENRA Reactor Harmonization Working Group, MDEP, advocacy groups etc.

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Best practices

1. Interfacing with domestic regulators

There are differences in approach. Some countries have requirements, some not. Same use informal way how to engage. There are manifestos, agreements etc.

In any way, regulatory bodies usually find its way how to coordinate according their national specifics and context.

Regardless if it is requirement, there is good practice to proactively engage with other regulators.

Here are list of good practices from ONR:

To share openly and publicly regulatory progress. It helps other agencies to step into processes. It show consistency, show whole plan to the future, especially what is inspection plan and what stakeholders can expect.

Share training capacity with other regulators.

Is beneficial to have government activity, which annually gets all government departments and agencies to communicate and share information, risk in some areas etc.

Canada also has this kind of annual coordinate meetings of environmental departments and agencies.

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Best practices

2. Adopting of international practices, guides and rules

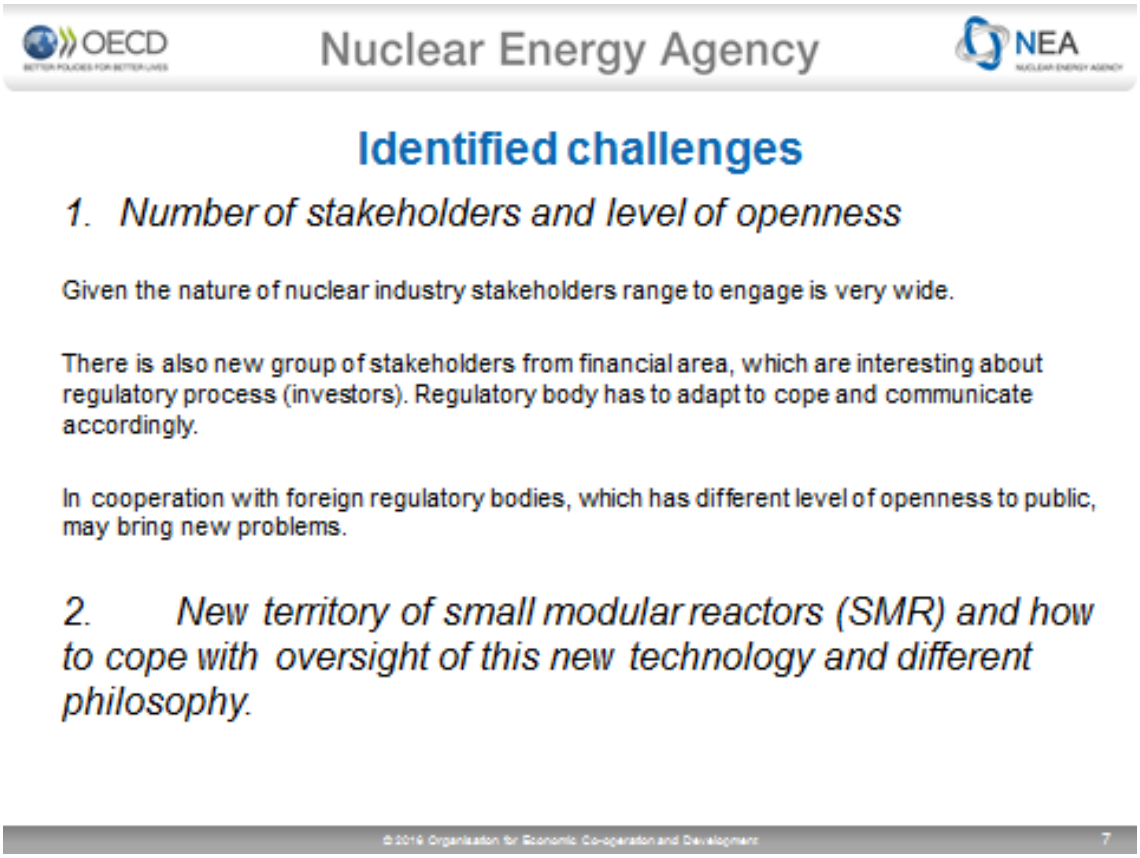
It may be challenging due different national cultures. But it is mostly cultural thing, less engagement issue.

3. Coping with international supply chain

Given the international nature of supply chains, there is an opportunity for better sharing of intelligence between regulators on supply chain performance.

Sharing information regarding construction and commissioning of new technologies is important.

Good practice from MDEP (NEA Multinational Design Evaluation Programme) to facilitate joint vendor inspections. It is based on agreement between the countries. The nuclear regulatory authorities of 15 countries participate in MDEP, which includes 5 design-specific working groups and 3 issue-specific working groups.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Identified challenges
1. Number of stakeholders and level of openness
Given the nature of nuclear industry stakeholders range to engage is very wide.
There is also new group of stakeholders from financial area, which are interesting about regulatory process (investors). Regulatory body has to adapt to cope and communicate accordingly.
In cooperation with foreign regulatory bodies, which has different level of openness to public, may bring new problems.
2. New territory of small modular reactors (SMR) and how to cope with oversight of this new technology and different philosophy.
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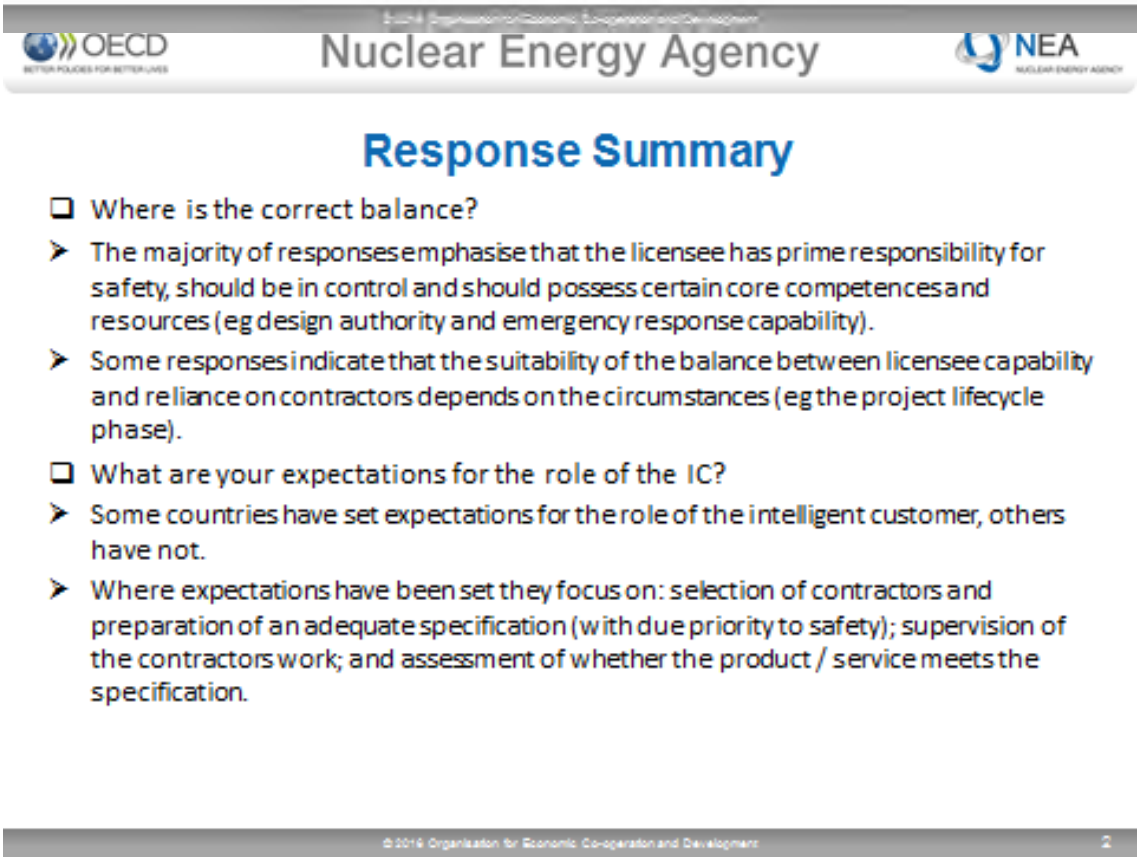
Session 3.1 Balance between New Licensee Capability and Reliance on Contractors



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Response Summary

- ❑ What are your expectations for the use of embedded contractors?
  - ➢ Specific expectations have been set by come countries, eg that such contractors should be part of the same training and competence assurance process as the licensee's employees.
- ❑ What should be your expectations in the use and reliance upon an Owners Engineer?
  - ➢ No countries appear to have specific expectations in relation to use of an Owner's Engineer. However the general expectations above in relation to the licensee's core capability apply. Two countries expressed the benefits of the Owner's Engineer being an in-house function.

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Points of Special Interest in Countries' Responses

- Some countries' responses point to more detail contained in references which are openly available, eg:
  - NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Chapters 13 and 17 (United States)
  - Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants" (United States)
  - RD/GD-369, Licence Application Guide: Licence to Construct a Nuclear Power Plant (Canada)
  - NS-TAST,GD-049, Licensee Use of Contracts and Intelligent Customer Capability (United Kingdom)

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Points to be discussed

- What expectations should regulators set for the core capability of a licensee ?
- What does it mean to be an 'intelligent customer' for contracted work ? How can 'intelligent customer' capability be evaluated ?
- What specific key performance measures can address the licensee's knowledge of the contractors' work ?
- What criteria should be used for the selection of suppliers and evaluation of their capability ?
- What (if any) expectations should regulators set for the use of embedded contractors ?

Session 3.1 Balance between New Licensee Capability and Reliance on Contractors Feedback

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NEA/CNRA/CSNI
WGRNR/WGHOF Workshop

Regulatory Oversight of New Licensee Organizational Capability

Session 3: Oversight of Contractors and Suppliers by New Licensees

3.1 Balance between New Licensee Capability and Reliance on Contractors

Chair: Marc McBride
Rapporteur: Karel Matejka

OECD Nuclear Energy Agency NEA

Response Summary

❑ 3.1.1 Where is the correct balance?

- The majority of responses emphasise that the licensee has prime responsibility for safety, should be in control and should possess certain core competences and resources (eg design authority and emergency response capability).
- The suitability of the balance between licensee capability and reliance on contractors depends on the circumstances (eg the project lifecycle phase).
- Additional notes:
  - The licensee should establish an integrated management system and systematic approach to training within its own organisation and promulgate similar requirements in the supply chain using a graded approach (UAE)
  - Primary focus of the regulator should remain with licensee
  - Licensee should establish a system for learning learning from experience within its own organisation and its contractors (France)
  - There should be an appropriate balance between new starters and experienced personnel to ensure that the key steps during the commissioning are achieved safely (Korea)
  - Knowledge should be actively managed throughout the project lifecycle

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Response Summary

❑ 3.1.2 What are your expectations for the role of the Intelligent Customer?

- The term 'intelligent customer' is not widely used
- Some countries have set expectations for the role of the intelligent customer (based on international OPEX)
- Where expectations have been set they focus on: selection of contractors and preparation of an adequate specification (with due priority to safety); supervision of the contractors work; and assessment of whether the product / service meets the specification.
- See GSR Part 2 for a definition of "informed customer"
- Additional notes:
  - Licensee (nor regulator) should rely solely on experience or good name of a contractor
  - There have been examples of where a licensee was not aware of the lack of competence of a contractor (Sweden)

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Response Summary

❑ 3.1.4 What should be your expectations in the use and reliance upon an Owners Engineer?

- Not all countries use the term 'Owner's Engineer' (not in IAEA glossary)
- No countries appear to have specific expectations in relation to use of an Owner's Engineer. However the general expectations above in relation to the licensee's core capability apply. Two countries expressed the benefits of the Owner's Engineer being an in-house function.

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Points of Special Interest in Countries' Responses

- Some countries' responses point to more detail contained in references which are openly available, eg:
  - NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Chapters 13 and 17 (United States)
  - Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants" (United States)
  - RD/GD-369, Licence Application Guide: Licence to Construct a Nuclear Power Plant (Canada)
  - GP: NS-TAST-GD-049, Licensee Use of Contracts and Intelligent Customer Capability (United Kingdom)

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Best Practices and Identified Challenges

❑ 3.1.1 Where is the correct balance?

- Challenge: There should be careful consideration of the roles within the licensee filled by embedded contractors (eg supervisory roles) and clear expectations on behaviours as well as technical competences
- Challenge: Expectations on safety culture should be set by the licensee and there should be oversight by the licensee of how contractors implement these expectations
- Challenge: Regulators should examine the standards set by licensee for the performance of the supply chain, test the licensee's assurance that these standards are being met, and independently sample implementation
- Good practice: The requirement that there should be no more than three layers of subcontracting in the commissioning and operations phase (France / Sweden) (commissioning and operation phases)
- Good practice: The requirements that certain functions cannot be contracted out, e.g. reactor control room operation, event management, oversight of contractors, establishment of the management system and emergency preparedness / response (France)

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Best Practices and Identified Challenges

- 3.1.2 What are your expectations for the role of the Intelligent Customer?

- Challenge: Reliance on overseas contractors when the country's own capability is not yet established (e.g. nuclear security)
- Challenge: Oversight of the implementation of the procurement process (i.e. selection of contractors) (France)
- Good practice: NS-TAST-GD-049, 'Licensee Use of Contracts and Intelligent Customer Capability' (United Kingdom)

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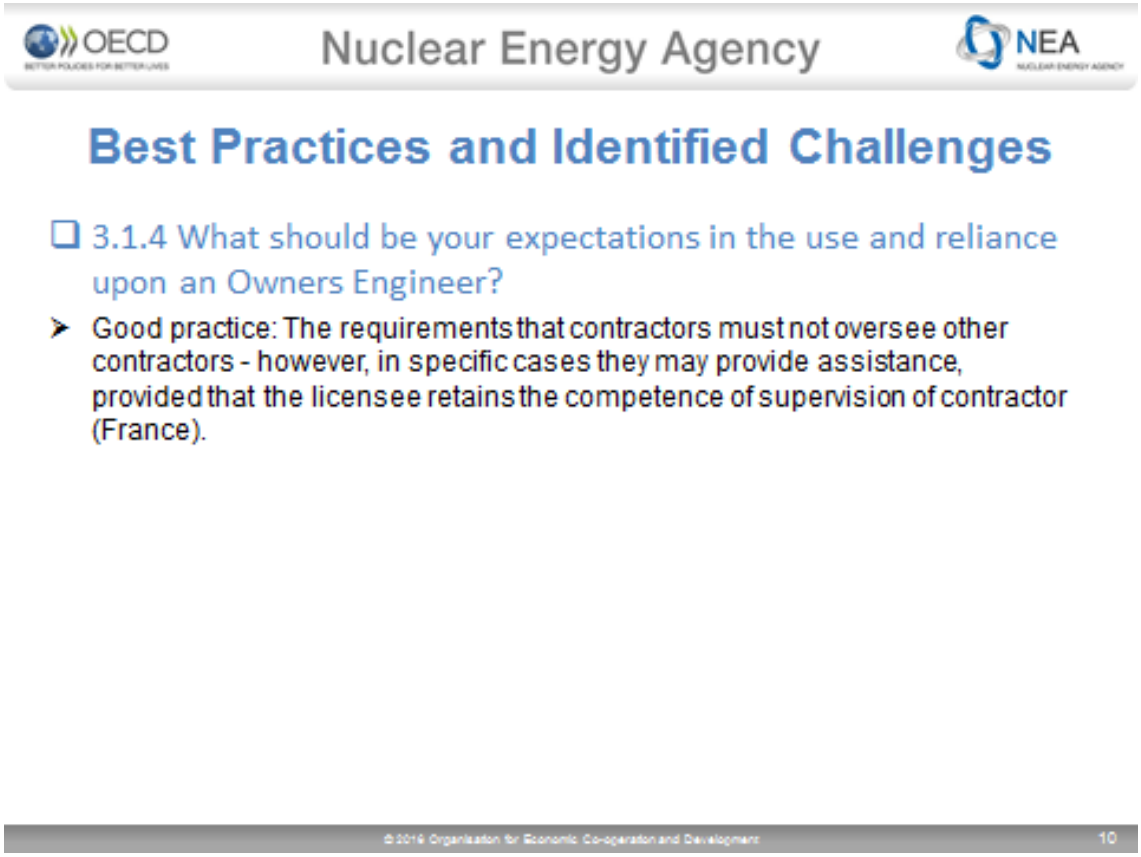
Best Practices and Identified Challenges

- 3.1.3 What are your expectations for the use of embedded contractors?

- Challenge: There is varied understanding of the terms 'embedded contractor', 'secondee' etc and hence their legal status (sometimes considered as employees, sometimes as contractors)
- Potential good practice: The requirements that the licensee and contractor should formalise its system of communication (France)
- Good practice: Clarity on the application of intelligent customer oversight (not required for embedded contarctors)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NEA
Best Practices and Identified Challenges
3.1.4 What should be your expectations in the use and reliance upon an Owners Engineer?
Good practice: The requirements that contractors must not oversee other contractors - however, in specific cases they may provide assistance, provided that the licensee retains the competence of supervision of contractor (France).
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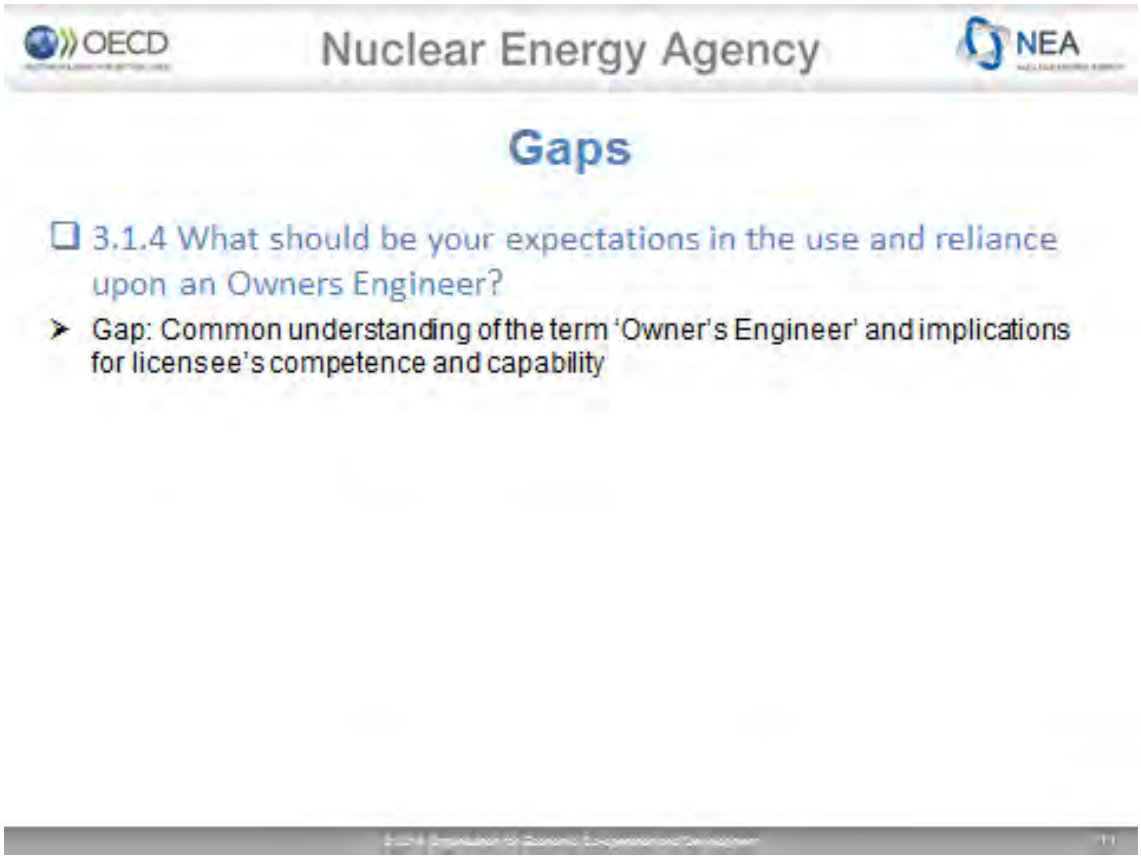
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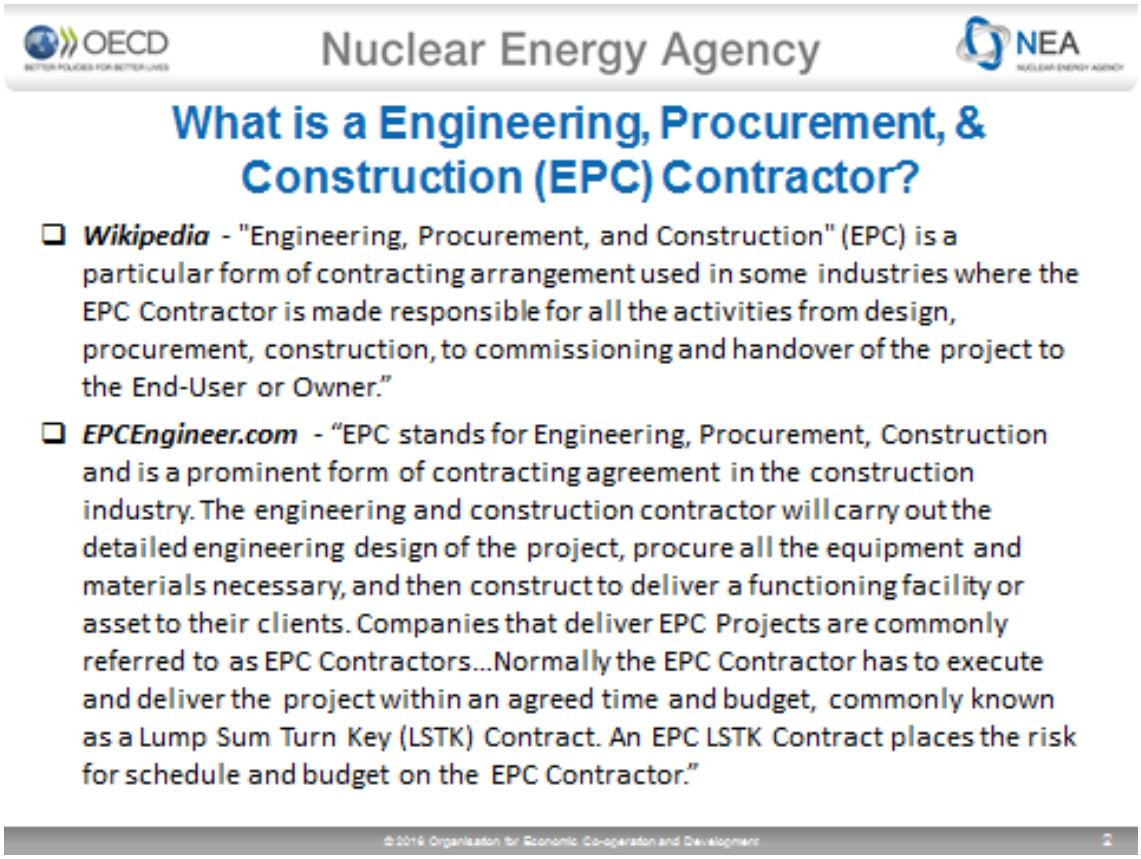
NEA
Gaps
3.1.4 What should be your expectations in the use and reliance upon an Owners Engineer?
Gap: Common understanding of the term 'Owner's Engineer' and implications for licensee's competence and capability

Session 3.2 The EPC Model



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Response Summary – Q 3.2.1

- What should be your expectations for the oversight of the EPC contractor by the new licensee?
  - Licensee should have very active oversight and conduct regular audits
    - Confirm EPC contractor has strong understanding of the requirements and ability to communicate them
    - Confirm EPC contractor demonstatres strong oversight and review processes
  - Licensees shall have sufficient technical capabilities to ensure the mastery of the activities carried out in its installation
  - Licensees shall retain competencies to understand and assimilate the basis of the installation activities on the long term. These competencies must be available in-house, in subsidiaries or in companies under its control.

OECD Nuclear Energy Agency NEA

Response Summary – Q 3.2.1

- What should be your expectations for the oversight of the EPC contractor by the new licensee?
  - Licensee shall supervise that its safety policy is implemented by all contractors and that all the processes, products and services they provide meet the specified requirements.
  - Pre-defined criteria shall be used for the selection of the EPC contractor
  - The licensee shall be able to evaluate the EPC contractor's capability for controlling the supply chain
  - The licensee shall be able to control the implementation activities
  - The licensee shall ensure that the EPC contractor understands the QA program and regulatory requirements
  - The EPC contractor shall operate as if being the owner of the plant, operating in the same framework of nuclear safety (culture) and security

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What is an Intelligent Customer?

- ***Wikipedia*** – "Intelligent Customer Function or 'Intelligent Client' (IC) is an inhouse capability within a host organisation which has responsibility for the ownership, management and delivery of a defined service or range of services on behalf of part or all of the organization, to that organisation…The services for which the IC has responsibility can be delivered by resources employed by the host organization (members of staff) or can be sourced from the market (an outsourced service)."
- ***UK ONR*** – "The trend in the nuclear industry is towards a higher reliance on external - usually contractor - expertise and staff. How then does the regulator decide whether the internal staffing retained within a Licensee is sufficient to meet the requirements of the Licensee's duties, in particular to understand and own work undertaken by others? Different terminology has been used to describe this particular requirement - intelligent customer, informed customer, informed client - but the principle remains the same. NII has chosen to use the term 'intelligent customer'."

OECD Nuclear Energy Agency NEA

Response Summary – Q 3.2.2

- What are your expectations for IC in relation to the EPC?
  - Potential unfamiliarity with the "Intelligent Customer" term
  - The EPC contractor is expected to liaise between the ICs. It relies on contracts that clearly define the responsibilities of each party, their commitments in terms of quality and results and the applicable requirements. The statutory oversight of all contractors by the licensee does not release the EPC contractor from its responsibilities in the management of the ICs.
  - The IC shall oversee every entity in the supply chain

OECD Nuclear Energy Agency NEA

Response Summary – Q 3.2.2

- What are your expectations for IC in relation to the EPC?
  - Ultimate responsibility for safety rests with the licensee. The Licensee must demonstrate sufficient knowledge of the plant design and safety case for all plant and operations.
  - The Licensee must be in control of activities on its site, understand the hazards associated with its activities and how to control them, and have sufficient competent resource within the licensee organization.

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Points to be discussed

- What attributes should a licensee use to evaluate the EPC contractor's capabilities?
- What attributes should a licensee use to evaluate a EPC contractor's capabilities to control the supply chain?
- What are the implications of new ownership and operating models (using resources and services from foreign vendors) for power reactor facilities given the increasingly international approach to deployment and customer support?
- How should the regulator ensure that the licensee verifies the EPC contractor's work quality and supply chain?

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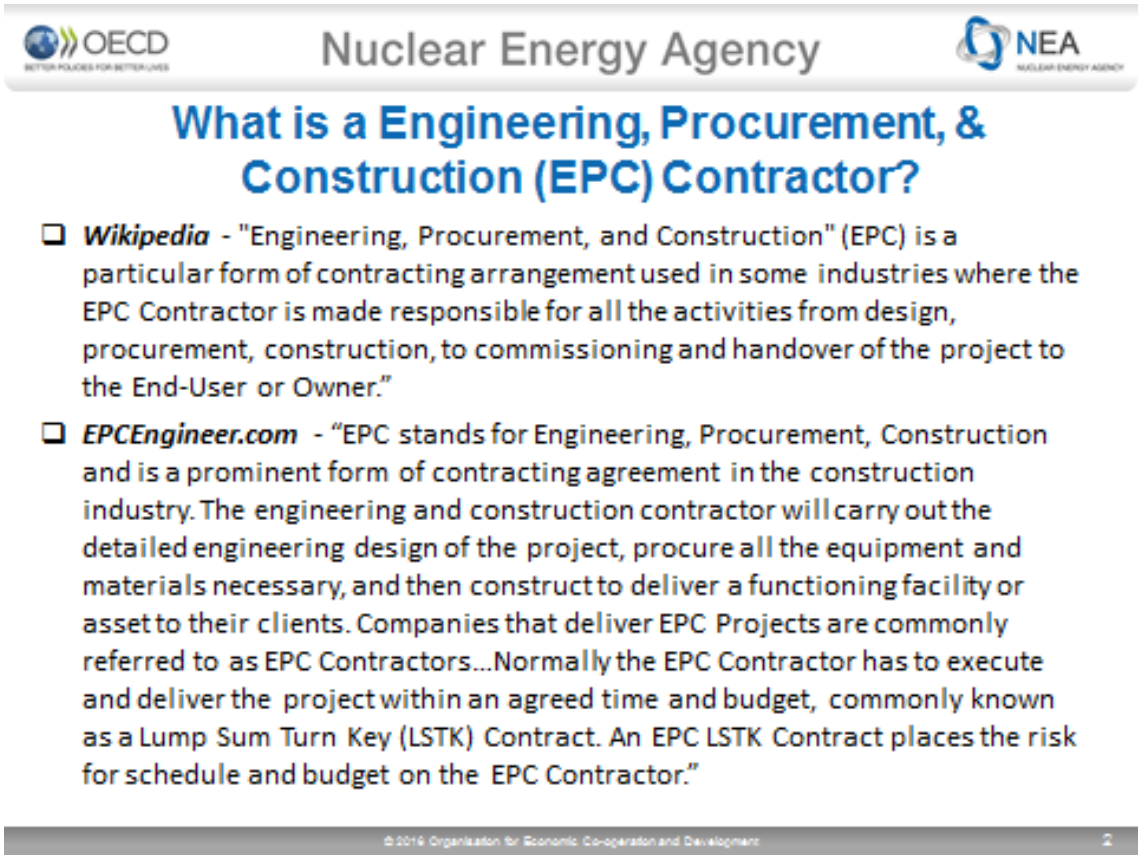
Points to be discussed

- Is the "Intelligent Customer" terminology well known? Are there similar concepts?
- What guidance exists on the minimum level of capabilities an Intelligent Customer should have in overseeing outsourced equipment and services by the licensee?
- How does the regulator evaluate the capabilities and sufficiency of the IC?
- Should credit be given for ISO Certification by an EPC contractor?

Session 3.2 The EPC Model Feedback



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Discussion Identified Best Practices

- Licensee has primary responsibility for safety at plant.
- Must be an intelligent customer.
- Must be active and responsible in the supply chain
- Must audit, assess, and approve suppliers. Approach can be graded.
- Regulator - must get involved with the licensees as they develop the contract. Ensure the proper clauses are included
- Project hold points – approved by the regulator to proceed to next phases
- Licensees should have a formal, transparent, predefined process and a set of criteria to judge the adequacy of the EPC consortium.
- The roles and responsibilities of the EPC contractors should be clear
- Accessibility - Arrange mechanisms for the regulator and licensee to evaluate foreign contractors (law or contractual).
- Develop formal relationships and work through international regulators to do foreign audits.

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Best Practices (Cont.)

- To ensure that the licensee verifies the EPC contractor's work quality and supply chain
  - a graded approach would be useful
  - focus on high safety significant items
  - share manufacturing schedules - enables sampling inspections
  - stage construction – enables ad hoc sampling inspections
  - share information from other construction
  - have onsite resident inspectors during construction
- EPC organizational model - constantly inspect the arrangements against good practices and for effectiveness.

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Identified Challenges and Gaps

- Foreign ownership - shareholders expect subsidiary companies to get a share of EPC contracts – affects transparency of EPC contract award.
- Stability of foreign companies may be a question. Good to have backup plans for suppliers
- Some companies work in the war industry. May need significant advance notice for the inspections.
- No regular mechanism to learn from other constructing organizations
- Turnkey operations can be dangerous.
- Foreign contactors may not understand regulatory requirements/framework.
- No indicators, or measurements of minimum level of capabilities of an Intelligent Customer, though there are criteria.

Session 3.3 Supplier Surveillance

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NEA/CNRA/CSNI
WGRNR/WGHOF Workshop

Regulatory Oversight of New Licensee Organizational Capability

Session 3: Oversight of Contractors and Suppliers by New Licensees

3.3 Supplier Surveillance

Chair: Stuart Allen
Rapporteur: Debbie Fisher

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Process

- Sub group introduction
  - Focus of discussion and output
- Reminder of the questions and confirm common understanding:
  - Do you have the legal framework to adequately regulate the use of the supply chain?
  - Do suppliers understand the regulatory requirements?
  - What should be your expectations of new licensees in overseeing the supply chain – is there sufficient guidance?
- Share response summary, discuss key themes and points of special interest
- Summarise discussions into key point findings for group feedback.
  - Key lessons learnt
  - Commendable practices
  - Identified challenges
- Close

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Response Summary

- Do you have the legal framework to adequately regulate the use of the supply chain?
  - Some countries have direct authority defined in legislation or required by certification or licence, others rely on alignment to defined standards
  - Not clear how the arrangements operate beyond national borders
- Do suppliers understand the regulatory requirements?
  - Inconsistent responses. Some highlight clear understanding with others less confident
  - Appears to be influenced by the supplier experience and exposure to the regulator
- What should be your expectations of new licensees in overseeing the supply chain – is there sufficient guidance?
  - Expectation that licensees establish appropriate arrangements to oversee the supply chain, terms like 'smart buyer' and 'Intelligent Customer' used.
  - Country specific, IAEA and ISO documentation referenced. Notably some recently revised (GSR Part 2), produced (NP-T-3.21) or under development (ISO 19443)

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Points of Special Interest in Countries' Responses

- **Canada** – Providing clearer guidance on what a minimum level of licensee capabilities should look like to be an Intelligent Customer when dealing with extensive use of outsourced (and international) equipment and services suppliers
- **France** - Should the regulatory body directly control the suppliers?
- If so, should the regulatory body control both compliance with the technical requirements and quality assurance process?
- How could the regulatory body control that the licensee appropriately oversees its suppliers?
- **Hungary** - Level of elaboration of regulatory requirements and guides

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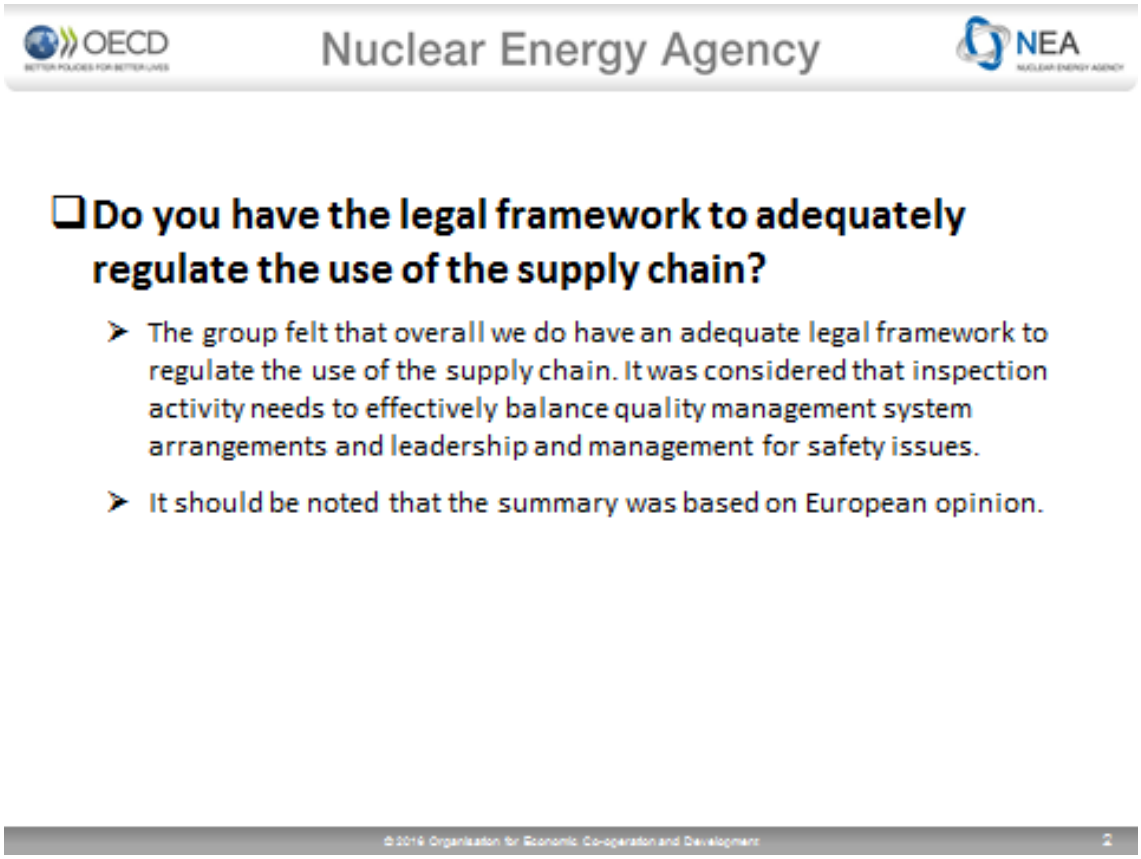
Points to be discussed

- Not clear how regulators operate beyond national borders.
  - Is there a reliance on Licensee contracts, regulatory certification, regulatory cooperation
- Should the Licensee qualify suppliers and establish adequate supply chain oversight and assurance arrangements or should the regulator certify or approve suppliers to their prescribed standards?
- Does current nuclear industry supply chain performance justify a change in approach, for example:
  - France's reference to issues identified within the Creusot Forge Manufacturing Facility
- Does the global nuclear industry supply chain have the required capacity, capability, culture and effective oversight and assurance arrangements?

Session 3.3 Supplier Surveillance Feedback



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❑ Do suppliers understand the regulatory requirements?

- Existing suppliers to the nuclear industry are considered to have broadly adequate arrangements. However, new to nuclear suppliers are considered to be higher risk.
- The regulatory requirements should consider a risk and performance based approach, however relying on a performance based approach alone would not identify unrevealed failures. Therefore, some degree of vendor inspection is considered appropriate.

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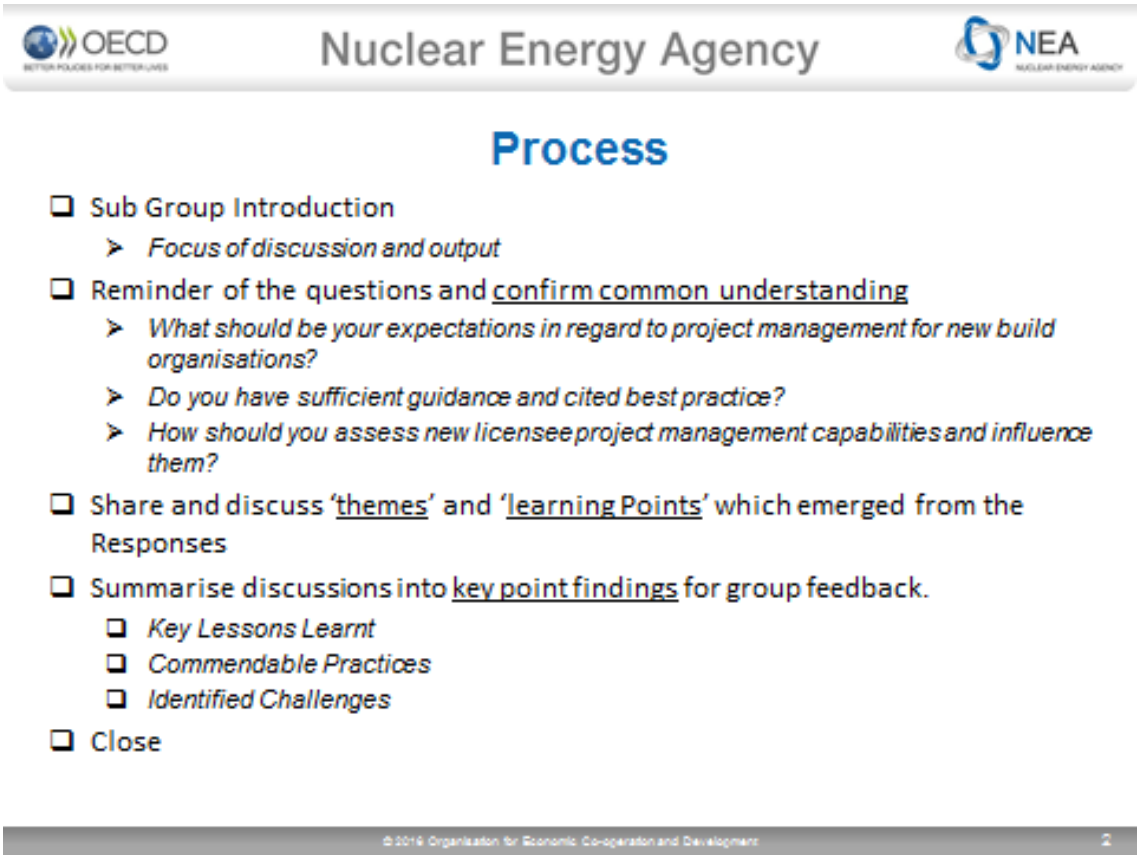
❑ What should be your expectations of new licensees in overseeing the supply chain – is there sufficient guidance?

- New licensees should develop appropriate supply chain oversight arrangements that examine cultural/leadership aspects based on risks.
- Guidance exists, but understanding is inconsistent especially down the supply chain tiers or suppliers new to the nuclear sector
- The group noted that regulatory expectations and requirements supplemented international guidance, albeit consistent in principles. The group considered it would be interesting to see how supply chain standards and performance develop on effective promulgation of new guidance (i.e. NP-T-3.32 and ISO 19443).

Session 3.4 Oversight of Contractors and Suppliers by New Licensees



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'Themes' for discussion emerging from Responses

What should be your expectations in regard to project management for new build organisations?

- The role of Design Authority
- Modern project management methodology – delivering the right outcome safely
- Guaranteeing priority is given to safety *(people & environment)*
- Skills and Experience *(both individuals & organisations)* – understanding the safety significance of the work
- Are nuclear projects different to conventional projects?
- Is learning from experience utilised and knowledge managed
- Approach to design verification and configuration control
- Establishing and maintaining an appropriate safety culture *(inc. supply chain)*
- Is it necessary to have specific expectations in regard to project management?

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'Themes' for discussion emerging from Responses

Do you have sufficient guidance and cited best practice?

- Should be part of a licensee's Integrated Management System and implemented by the licensee.
- Expectations are well defined in the Nuclear Safety Codes
- Not easy to find a good guidance or best practice related to the project management.
- Should it be the role of the regulators to define guidance in this area?

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'Themes' for discussion emerging from Responses

How should you assess new licensee project management capabilities and influence them?

- Design verification and configuration control
- Appropriate Safety considerations in decision making (e.g. gate reviews)
- Technical skills, qualifications and experience of the individual's & organisation
- Use of competency frameworks – Assessing technical and behavioural skills
- Review financial capabilities:
  - realistic budget
  - relationship with the parent company
  - financial resilience
  - adequate provision for future activities
- Staffing level of licensee and their supply chain
- Effectiveness of the Integrated Management System

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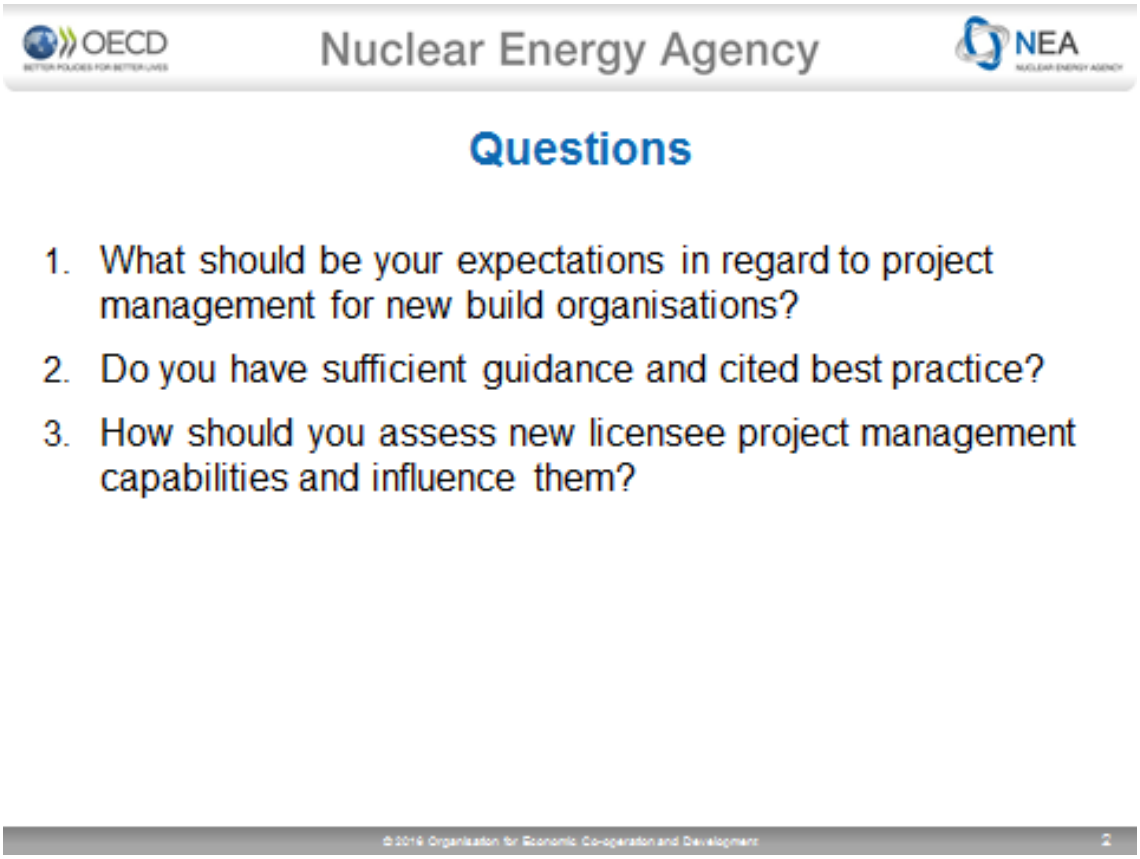
Learning Points for discussion raised in Responses

1. Licensee of projects using internationally developed technologies are becoming increasingly reliant on information controlled by business interests outside of their sphere of control. *(i.e. offshore technology owners of intellectual property)* What are the impacts on the licensee as:
   - an intelligent customer
   - a credible design authority **(Canada)**
2. How to interact with the new licensee and influence it so that it increases its technical and financial capabilities? **(France)**
3. Methodologies for assessments **(Hungary)**
4. How should we assess new licensee project management capabilities and influence them? **(Netherlands)**
5. Guidance for evaluating an organisation's Project Management capability for delivering a safety Project, including their supply chain engagement and management, and promoting and maintaining the appropriate safety culture. **(UK)**

Session 3.4 Oversight of Contractors and Suppliers by New Licensees Feedback



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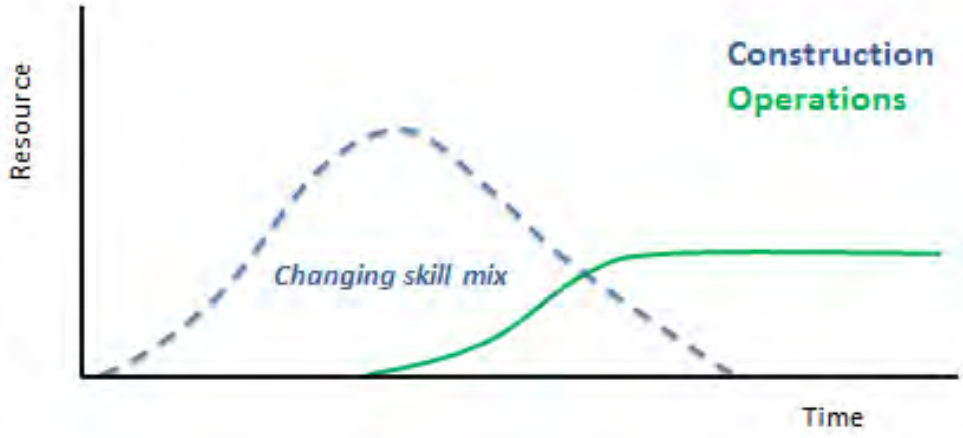
Project Management Deployment



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What should be your expectations in regard to project management for new build organisations?

- Expectations for project management are required. This should *depend* on the stage in the lifecycle.
- Functional vs Project based structure. Also Programme Management?
- Project management should give appropriate consideration to nuclear safety and security aspects. (e.g. Stage gate reviews)
- Nuclear safety culture should integrated with Project Management
- Intelligent customer capability should be built into the early stages of project management
- Non-nuclear project managers need to understand the significance of the work they are responsible for: potential Hazard & Risk

 4

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Do you have sufficient guidance and cited best practice?

- No: We don't have enough guidance.
- We have robust guidance for operating facilities and some guidance for new organisations but this hasn't been fully "stress tested"
- We should look to other industries and regulatory bodies to see what they do for large projects management - best practise.

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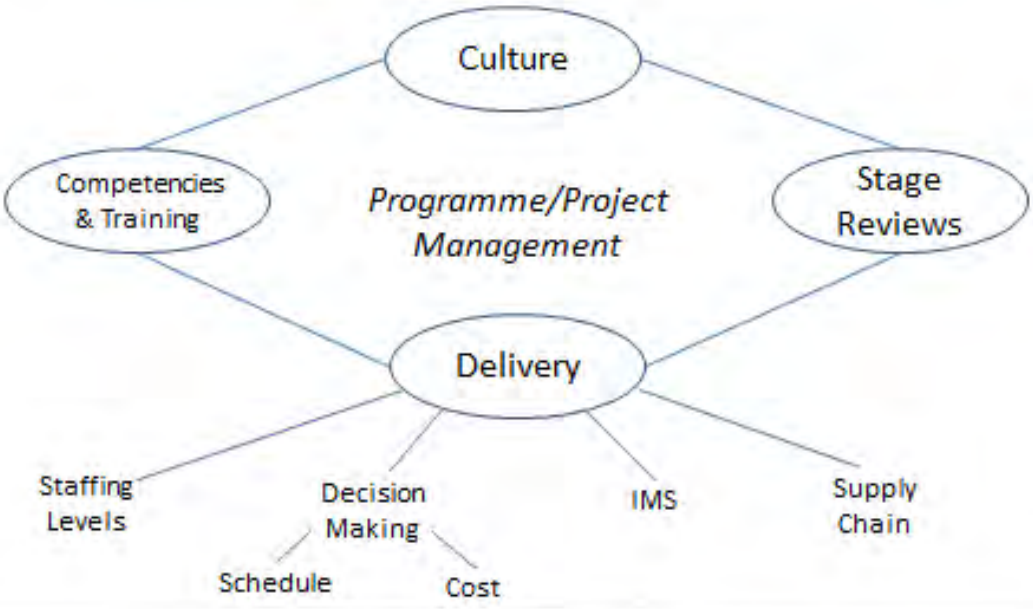
How should you assess new licensee project management capabilities and influence them?



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Sub Group Output (1)

Best practices:

- Early engagement with licensee
- Some Nuclear training for PMs with non-nuclear background

Challenges

- Project management capability is not a core discipline within the regulator - challenge is to understand it well enough to know where we can engage, advise and challenge licensees on safety matters.
- Lack of experience and skills in licensees and regulator with managing large nuclear projects.
- Lack of guidance in this area.

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Sub Group Output (2)

Further Work

- Produce specific guidance, referencing:
  - Safety culture
  - Decision making
  - Competencies/skills
  - Supply chain
- Potentially having a workshop led by IAEA/NEA etc. to share learning between licensees and regulators.
- Review current IAEA guidance on project management (SSG-38)

Appendix E – Session Notes

The following tables contain pertinent information that can be used to understand, on a broad basis, the world wide regulatory landscape for interacting with new licensees and when attempting to influence an organisation so that they are capable of delivering, and operating, a safe nuclear installation.

Each table contains three sections; Lessons Learned/Commendable Practices, Identified Challenges and Recommendations. The section on Lessons Learned/Commendable Practices identifies good practice that can be used by all regulators. Identified Challenges generalises challenges that regulators have faced so that the learning can be captured so that a way forward can be developed. The Recommendations provide regulatory recommendations for the specific session they were captured in.

The complete discussions held during the breakout sessions can be found in Section 4.

Breakout Session 1 – Challenges in Developing Organisational Capability

Session 1.1 – Building Organisational Capability

This breakout session discussed building organisation capability and was structured around 4 questions: How can licensee awareness of regulatory expectations be improved?; Do new licensees understand the scale of the task?; Are new licensees focussed on building a capability that can adapt through the phases of the project?; How can capability be developed in a competitive market short of nuclear skills?

Session 1: Challenges in Developing Organizational Capability: 1.1 Building Organizational Capability		
Lessons Learned/Commendable Practices	**Identified Challenges**	**Recommendations**
• Recommendation of early engagement prior to formal submittal of application - Documentation of a formalized regulatory framework to obtain license - Establishment of "rules of engagement" for early discussions - Development of requirements focusing on areas where a lack of guidances • Regulators should encourage new licensees to interact with existing licensees • Manpower strategies for project phases should be structured • Leadership approach of prospective licensees can impact its ability to appreciate the scale of the task (cultural background, regulatory approach by country of origin, familiarity with differing regulatory framework) • Existing licensees seeking new authorizations should be treated similarly to new licensees if long gaps exist in new build projects • IMS may be useful tools for organizational capability	• "Just in time" approach towards organizational capability by prospective licensees demonstrates lack of appreciation for scale of task • Organizational instability of prospective licensees can present challenges in understanding and coping with scale of the task • Poor culture, reputation within organizations can present challenges for recruitment and retention of resources	
• "Baseline" approach to demonstration and justification of organizational staffing should incorporate long term planning with 3-5 perspective.		

Session 1.2 – Developing Leadership and Governance

Session 1: Challenges in Developing Organizational Capability: 1.2 Developing Leadership and Governance		
Lessons Learned/Commendable Practices	**Identified Challenges**	**Recommendations**
• No specific guidance regarding governance • Making a short term plan for easy update to quickly manage the new situation • Importance of the role of "internal regulator" within licensee organization • Importance of internal provision for supervising its contractors and subcontractors including periodical assessment • Necessity of generic requirement on leadership and organizational capability for the baseline of capability in the management line • Assessment of leadership in the senior management appointment process (e.g. 360 degree evaluation, organizational value assessment) • Importance of self-reflections and continuous improvement of IMS • Early regulatory advice on how to build governance and leadership capabilities • Application of the concept of Intelligent Customer to regulator	• Owner with a large portion of investment tends to retain large control power • Gap on governance guidance • Oversight of the proven leadership capabilities rather than documented qualifications	• Development of general guidance on organizational capability building
• Balanced number between internal and external board directors • Guidance on Intelligent Customer Capability • Comprehensive inspection system with a multi-disciplinary team • Requirement of continuous monitoring of all activities • "Hold-points" where the licensee demonstrates sufficient level of governance has been achieved • Licensees' Safety Director Forum to issue a good practice guidance		

Session 1.3 – Developing Strong/Healthy Safety Culture

Session 1: Challenges in Developing Organizational Capability: 1.3 Developing Strong/Healthy Safety Culture		
Commendable Practices	**Identified Challenges**	**Recommendations**
• Early regulatory involvement for building safety culture due to taking time • Requirement/guidance for licensee to lay out their strategic approach on how they are going to develop and promote Safety Culture. • Having trained specialists assessing SC in organization • Safety Culture Working Group with licensee, vendor, and tier 1 and 2 contractors.	• How to ensure supply chain meets full expectation in SC? • How to evolve the SC with the dynamics of the project. • Project pressures can put pressure on the SC • Difficulty of SC assessments • How to ensure SC is not superficial but (kept fresh)	• Development of guidance and toolbox on the SC applicable to the lifecycle of the project

Session 1.4 – Developing Internal Independent Regulation

Session 1: Challenges in Developing Organisational Capability: 1.4 Developing Internal Independent Regulation		
Lessons Learned/Commendable Practices	**Identified Challenges**	**Recommendations**
• Need to be clear about the role of IR • Need the right organisational culture to make it work. - 'Challenge' culture, Blame vs no blame vs fair blame • Can add real value when working well • Timing/organisational maturity of establishing an IR function is important • Leadership support is essential	• Creating the right organisational culture for IR to be effective • Getting licensee leadership support • Developing a relationship based on trust, openness and mutual respect • Developing IR from compliance assessment to continuous improvement	
• Close working relationship between external regulators and IR functions • Use of IR as the first point of contact in licensees • Joint training, Joint inspections • Sharing of findings and areas of concern		

Breakout Session 2 – Regulatory Challenges with New Licensees

Session 2.1 – Regulatory Readiness

Session 2: Regulatory Challenges with New Licensees: 2.1 Regulatory Readiness		
Lessons Learned	**Identified Challenges**	**Recommendations**
• Organisational design and development, HR development • Management system development and assessment • Management of its own knowledge • Project management capabilities, regulator needs to ask the right questions • Requirement for safety culture development and assessment • Requirement for human factors (incl. Human Factors Engineering) competence • Financial "competence" understanding financial realism to perform a financial review on realistic planning, etc. and to avoid potential safety culture risks with sound financial planning • Regulator competence of licencing • Supply chain supervision including supplier qualification and readiness assessment; capability to assess vendor & supplier quality and project plans • Assessment of design authority capabilities • Understanding of corporate governance • Knowledge of IAEA, WENRA and similar requirements and standards • Understanding of business model (EPC and other project delivery approaches) • Training should be planned and executed systematically and thoroughly • Strategic planning approach, e.g. what resources are needed? • Competitive pay and stable working conditions • Headhunting & using outside organizations in supporting roles in oversight • Development of relationship with licensees which open up opportunities for secondments (transfers) from those organizations. • Understanding of emerging technologies (e.g. small modular reactors) • Transition plan not to compromise the oversight of operating plants • Flexible and constructive approach recognizing high dependence on the supply chain, cultural differences, potential weaknesses of different contracting models		

Session 2.2 – Engagement Strategies

Session 2: Regulatory Challenges with New Licensees: 2.2 Engagement Strategies		
Lessons Learned	**Identified Challenges**	**Recommendations**
• Proportional early engagement - level of engagement depends on structure - state run licensee versus cooperate licensee • 'New and novel' requires more involvement: licensee, parent bodies, contractors, supplier • Be transparent, publish/communicate: - requirements & guidelines, - important outcomes of decisions, - process & engagement strategy • Use different ways to communicate with management & experts - conferences, website, training workshops, meetings • Be (always) open for discussion on safety requirement interpretation • Relation between regulator and parent body is not absolutely required but if issues arise then contact can give a solution • Make sure supply chain of safety relevant items is controlled	• Complex models of ownership - influence of safety related decisions by parent organisation, they have the money - risk management during different phases • Foreign contractors/ suppliers /designers - interpretation of regulation/guidance - control of supply chain of safety relevant items	

Session 2.3 – Development of Guidance

Session 2: Regulatory Challenges with New Licensees: 2.3 Development of Guidance		
Lessons Learned	**Identified Challenges**	**Recommendations**
• Some existing guidance for regulatory oversight: training and competence, integrated management system (especially, well defined structure and integrated links between teams to communicate issues/decisions/request help) • Need for new guidance for regulatory oversight: - Corporate Governance – e.g. Board structure, advisory committees, leadership, etc. - Development of Internal Advice and Challenge Capability - Use of Third Party Inspection Bodies - Financial guidance / Demonstration of financial adequacy to secure safety - Project Management (Client and Delivery Organisation including Stage Gate definition and guidance) • Need to tailor existing guidance for regulatory oversight: - Design Authority – definition and implementation - Guidance for Organisational Configuration Control o Including Organisation Change Management o To enable Design Configuration management - Guidance on Safety Culture and Leadership o Including contractors - Regulatory Expectation of Licensee Organisation Structure and Resource o Resource plan, resource model, justification e.g. baseline (core capability) o Organisation Design Principles (new guidance identified) o Life cycle management (new guidance identified) - Procurement & Supply Chain o Including major EPC contract o Specification management of supply chain - Intelligent Customer Capability and Use of Contractors	• Countries can have different legal frameworks and different national cultures where development/implementation of international guidance can be challenging • Establishing an international vehicle for sharing regulatory and industry experience. • When creating country specific guidance, the reference to international guidance takes time to implement when the specific country's experience/guidance is evolving at a faster pace than international guidance • Establishing consensual international guidance can be challenging in view of differing national legal frameworks • Gathering relevant experience from countries with significant new reactor build programmes • IAEA construction guide, SSG-38, should be revisited as OPEX from FA3 and Korea can be used to review and reassess the document.	• Workshops or other forums to share international good practice & develop guidance - Candidate areas for new guidance identified - Revision of existing guidance to address challenges for regulatory oversight of developing licensee organisations • IAEA encouraged to revise SSG-38 to consider learning from recent construction experience

Session 2.4 – Interfacing with Other Regulators

Session 2: Regulatory Challenges with New Licensees: 2.4 Interfacing with Other Regulators		
Commendable Practices	**Identified Challenges**	**Recommendations**
• Proactively engagement with other regulators to share openly and publicly regulatory progress. • Sharing training capacity with other regulators • Annual meeting of all government departments and agencies to communicate and share information and risk in some areas etc. • MDEP (NEA Multinational Design Evaluation Programme) to facilitate joint vendor inspections.	• Cooperation with foreign regulatory bodies, which has different level of openness to public, may bring new problems • New territory of small modular reactors (SMR) and how to cope with oversight of this new technology and different philosophy.	

Breakout Session 3 – Oversight of Contractors and Suppliers by New Licensees

Session 3.1 – Balance between New Licensee Capability and Reliance on Contractors

Session 3: Oversight of Contractors and Suppliers by New Licensees: 3.1 Balance between New Licensee Capability and Reliance on Contractors		
Commendable Practices	**Identified Challenges**	**Recommendations**
• Requirement that the number of subcontracting levels should be kept as low as possible • Requirement that there should be no more than two layers of subcontracting (i.e. one layer of contractors and two layers of subcontractors) for the activities carried out in the installation area during operation and decommissioning • Requirement that certain functions cannot be contracted out, e.g. operational responsibility and control of operation (including with regard to event management and to emergency preparedness and response), oversight of the activities carried out by contractors • Guidance on 'Licensee Use of Contracts and Intelligent Customer Capability' • Requirement that the licensee should implement a system to collect information from the contractors • Clarity on the application of intelligent customer oversight not required for embedded contractors • Requirements that contractors must not oversee other contractors	• There should be careful consideration of the roles within the licensee filled by embedded contractors (e.g, supervisory roles) and clear expectations on behaviours as well as technical competences • Expectations on safety culture should be set by the licensee and there should be oversight by the licensee of how contractors implement these expectations • Regulators should examine the standards set by licensee for the performance of the supply chain, test the licensee's assurance that these standards are being met, and independently sample implementation • Reliance on overseas contractors when the country's own capability is not yet established (e.g. nuclear security) • Oversight of the implementation of the procurement process (i.e. selection of contractors) • There is varied understanding of the terms 'embedded contractor', 'secondee', etc. and hence their legal status (sometimes considered as employees, sometimes as contractors)	

Session 3.2 –The EPC Model

Session 3: Oversight of Contractors and Suppliers by New Licensees: 3.2 The EPC Model		
Lessons Learned	**Identified Challenges**	**Recommendations**
• Licensee must be an intelligent customer. • Licensee must be active and responsible in the supply chain • Licensee must audit, assess, and approve suppliers. Approach can be graded. • Regulator must get involved with the licensees as they develop the contract. Ensure the proper clauses are included • Project hold points – approved by the regulator to proceed to next phases • Licensees should have a formal, transparent, predefined process and a set of criteria to judge the adequacy of the EPC consortium. • Roles and responsibilities of the EPC contractors should be clear • Accessibility - Arrange mechanisms for the regulator and licensee to evaluate foreign contractors (law or contractual). • Develop formal relationships and work through international regulators to do foreign audits. • To ensure that the licensee verifies the EPC contractor's work quality and supply chain - A graded approach would be useful - Focus on high safety significant items - Share manufacturing schedules - enables sampling inspections - Stage construction – enables ad hoc sampling inspections - Share information from other construction - Have onsite resident inspectors during construction • EPC organizational model - constantly inspect the arrangements against good practices and for effectiveness.	• Foreign ownership - shareholders expect subsidiary companies to get a share of EPC contracts – affects transparency of EPC contract award. • Stability of foreign companies may be a question. Good to have backup plans for suppliers • Some companies work in the war industry. May need significant advance notice for the inspections. • No regular mechanism to learn from other constructing organizations • Turnkey operations can be dangerous. • Foreign contactors may not understand regulatory requirements/framework. • No indicators, or measurements of minimum level of capabilities of an Intelligent Customer, though there are criteria.	

Session 3.3 – Supplier Surveillance

Session 3: Oversight of Contractors and Suppliers by New Licensees: 3.3 Supplier Surveillance		
Lessons Learned	**Identified Challenges**	**Recommendations**
• Needs balanced inspection activity between quality management system arrangements and leadership and management for safety issues. • Existing suppliers with broadly adequate arrangements (understanding of regulatory requirements). However, new suppliers to be higher risk. • Requirements should consider a risk and performance based approach, however relying on a performance based approach alone would not identify unrevealed failures. Therefore, some degree of vendor inspection is considered appropriate. • New licensees should develop appropriate supply chain oversight arrangements • Guidance exists, but understanding is inconsistent especially down the supply chain tiers or suppliers new to the nuclear sector • Regulatory expectations and requirements supplemented international guidance, albeit consistent in principles. It would be interesting to see how supply chain standards and performance develop on effective promulgation of new guidance (i.e. NP-T-3.32 and ISO 19443).		

Session 3.4 – Project Management

Session 3: Oversight of Contractors and Suppliers by New Licensees: 3.4 Project Management		
Commendable Practices	**Identified Challenges**	**Recommendations**
• Early engagement with licensee • Some Nuclear training for PMs with non-nuclear background	• Project management capability is not a core discipline within the regulator - challenge is to understand it well enough to know where we can engage, advise and challenge licensees on safety matters. • Lack of experience and skills in licensees and regulator with managing large nuclear projects. • Lack of guidance in this area.	• Produce specific guidance, referencing: safety culture, decision making, competencies/skills, supply chain • Potentially having a workshop led by IAEA/NEA etc. to share learning between licensees and regulators. • Review current IAEA guidance on project management (SSG-38)

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