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NUCLEAR ENERGY AGENCY
COMMITTEE ON NUCLEAR REGULATORY ACTIVITIES

Nuclear Regulatory Organisations' Oversight of New Licensee Organisational Capability

Workshop Proceedings, Chester, United Kingdom, March 2017

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**Workshop Proceedings
Chester, United Kingdom
March 2017**

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The mission of the NEA is:

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

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

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

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

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

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

Foreword

The Committee on Nuclear Regulatory Activities (CNRA) of the OECD Nuclear Energy Agency (NEA) is an international committee composed primarily of senior nuclear regulators. It was set up in 1989 as a forum for the exchange of information and experience among regulatory organisations and for the review of developments, which could affect regulatory requirements. The Committee is responsible for the NEA programme concerning the regulation, licensing and inspection of nuclear installations. In particular, the Committee reviews current practices and operating experience.

The CNRA created the Working Group on the Regulation of New Reactors (WGRNR) at the Bureau meeting of December 2007. Its mandate was to “be responsible for the programme of work in the CNRA dealing with regulatory activities in the primary program areas of siting, licensing and oversight for new commercial nuclear power reactors (Generation III+ and Generation IV)”. Therefore the WGRNR constitutes a forum of experts on the licensing of new and advanced commercial nuclear power reactors seeking to facilitate a co-operative approach to identifying key new regulatory issues, and to promote a common resolution.

The Committee on the Safety of Nuclear Installations (CSNI) created the Working Group on Human and Organisational Factors (WGHOFF) to improve the understanding and treatment of human and organisational 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.

In this context, the WGRNR organised a joint workshop with the WGHOFF on the regulatory oversight of new licensee organisational capability. The workshop was an opportunity to bring together experts from nuclear regulatory organisations on commissioning activities. Its main purpose was to foster broad international co-operation and to share commendable practices and recent experience related to the commissioning of new reactors. The workshop focused on generic aspects of the topics, including regulatory priorities and practices, the oversight and regulation of prospective/new licensees, and organisational issues which are not licensee-specific. Information obtained as a result of this workshop should give understanding of regulatory issues when interacting with prospective/new licensees, and promoting a method to address them.

ACKNOWLEDGEMENTS

This report, prepared by Mr Paul Stenhoff, from the Office for Nuclear Regulation (ONR), United Kingdom, is based on discussions and input provided by the members of the Workshop Organising Committee and Session Chairpersons/Rapporteurs.

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LIST OF ABBREVIATIONS AND ACRONYMS

ANSI	American National Standards Institute
ASME	American Society of Mechanical Engineers
CNRA	Committee on Nuclear Regulatory Activities (NEA)
CNSC	Canadian Nuclear Safety Commission
CSNI	Committee on the Safety of Nuclear Installations (NEA)
EA	Environment Agency (United Kingdom)
EPC	Engineer-procure-construct
FANR	Federal Authority for Nuclear Regulation (United Arab Emirates)
FTE	Full time equivalent
GDA	Generic design assessment
GSR	General safety requirements
HFE	Human factors engineering
HOF	Human and organisational factors
HPC	Hinkley Point C (United Kingdom)
HSE	Health and Safety Executive
IAEA	International Atomic Energy Agency
IC	Intelligent customer
IR	Internal regulator
ISO	International Organisation for Standardization
KINS	Korean Institute for Nuclear Safety
LNI	Licensing nuclear installations
MDEP	Multinational Design Evaluation Programme
MoU	Memorandum of Understanding
NEA	Nuclear Energy Agency
NPP	Nuclear power plant
NRC	Nuclear Regulatory Commission (United States)
NSIC	Nuclear Safety Information Centre (United States)
NSSC	Nuclear Safety and Security Commission (Korea)
OC	Organisational capability
OECD	Organisation for Economic Co-operation and Development
ONR	Office for Nuclear Regulation (United Kingdom)
OSART	IAEA Operational Safety Review Team (Austria)
PSAR	Preliminary Safety Analysis Report
QA	Quality assurance

RHWG	Reactor Harmonisation Working Group of the Western European Nuclear Regulators Association (Belgium)
SAP	Safety assessment principles
SC	Safety culture
SMR	Small modular reactor
SSG	Specific safety guide
SSM	Radiation Safety Authority (Sweden)
STUK	Radiation and Nuclear Safety Authority (Finland)
SuC	Supply chain
TAG	Technical assessment guide
TIG	Technical inspection guide
UAE	United Arab Emirates
UK	United Kingdom
USA	United States
WANO	World Association of Nuclear Operators
WENRA	Western European Nuclear Regulators Association (Belgium)
WGHO	Working Group on Human and Organisational Factors (NEA)
WGRNR	Working Group on the Regulation of New Reactors (NEA)

Executive summary

A prospective nuclear licensee must develop the organisational capability to discharge the obligations associated with holding a nuclear site licence. This can be challenging where it is a new body or where the availability of experienced personnel is scarce. Issues such as organisational design and governance; resourcing strategies; development of a design authority and intelligent customer capability; and development of an integrated management system are just some of the key challenges.

The regulatory body must consider how to develop and deploy its own resources in order to deliver the right level of regulatory oversight against these and other areas of organisational development.

In order to establish relevant good practice and identify key issues for further international investigation the Committee on Nuclear Regulatory Activities (CNRA) Working Group on the Regulation of New Reactors (WGRNR) and the Committee on the Safety of Nuclear Installations (CNSI) Working Group on Human and Organisational Factors (WGHOFF) developed a joint workshop designed to engage the international community in addressing these key areas. A survey was developed which gathered relevant information on the international landscape which was used to design the event and furthermore detailed information was gathered from position papers provided by participant countries to frame the workshop sessions.

The workshop took place in Chester, United Kingdom in March 2017 and was attended by almost 50 international delegates drawn from the WGRNR and WGHOFF. This report contains all the survey outputs and analysis, the individual country position papers, the event format and the outputs and key learning from the event.

Areas of relevant good practice are identified as well as a number of areas where further work is required in order to establish relevant good practice. The areas identified for further work are allocated to either the WGRNR or WGHOFF as a set of recommendations and the CNRA and CSNI are invited to consider these recommendations for inclusion in the forward work programmes for these groups.

1. Introduction

The Nuclear Energy Agency (NEA) Committee on Nuclear Regulatory Activities (CNRA) Working Group on the Regulation of New Reactors (WGRNR) held a joint workshop with the Committee on the Safety of Nuclear Installations (CSNI) Working Group on Human and Organisational Factors (WGHO) on “Regulatory Oversight of New Licensee Organisational Capability”. The workshop was organised, in collaboration with the UK Office for Nuclear Regulation (ONR), on the 20-22 March 2017 at the Queen Hotel, Chester, United Kingdom.

1.1 Background

A prospective nuclear licensee must develop the organisational capability to discharge the obligations associated with holding a nuclear site licence. This can be challenging where it is a new body or where the availability of experienced personnel is scarce. Issues such as organisational design and governance; resourcing strategies; development of a design authority and intelligent customer capability; and development of an integrated management system are just some of the key challenges.

The regulatory body must consider how to develop and deploy its own resources in order to deliver the right level of regulatory oversight against these and other areas of organisational development.

1.2 Objectives

The objective of the Chester workshop was to share approaches and areas of contention or issue when interacting with a prospective licensee. The workshop also sought to establish and share good practices and identify areas warranting further consideration, regarding the organisational capability of the prospective licensee.

2. Survey

A short survey on regulatory approaches to oversight of development of new licensee organisational capability was carried out to inform the workshop in advance and to pick up discussion topics. The focus of this survey was on regulatory oversight of the organisational capability that is put in place by bodies seeking a licence to construct a nuclear reactor facility. This includes interactions from the start of the organisation's development through to licence grant and readiness to construct.

For the purposes of this survey, "organisational capability" was defined as the resources, processes and infrastructure that an organisation seeking a licence to construct and operate a nuclear reactor facility puts in place to conduct its activities safely.

The survey requested information about:

- current regulatory expectations regarding the development of new licensee organisational capability; especially during the period between a body announcing its intention to become a nuclear licensee and the granting of a site licence;
- initial views on gaps or weaknesses in existing regulatory guidance;
- deployment of regulatory effort – resource, competence/experience and timing;
- the type of interaction between the regulator and the prospective licensee;
- challenges – facing prospective licensee in development of organisational capability;
- challenges – facing regulatory body;
- learning from experience; and
- suggestion of workshop topics.

An analysis of the survey can be found in Appendix A in the Appendices Supplement.

2.1 Review of survey responses

Once responses to the survey were received, they were analysed and used to generate 3 main topics areas (with 4 sub-topic areas each, and a set of questions for each sub-topic area) as shown below. These were reviewed at the 17th WGRNR meeting and a working group drawn from both the WGRNR and WGHOFF.

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 practice 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 practice 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 internal regulator (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 organisational capability (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 co-ordinate 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 intelligent customer (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 engineer-procure-construct (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?

In order to obtain some initial information on the regulatory landscape around these topics and questions WGRNR/WGHOF members were asked to prepare position papers in response to these questions in advance of the workshop. In total, 10 countries responded, those were: Canada, Finland, France, Hungary, Korea, the Netherlands, Poland, Russia, the United Arab Emirates and the United Kingdom.

The replies were collated and position papers on each topic area were generated; these can be found in Appendix B in the Appendices Supplement.

The position papers were used by the nominated session chairs, who were drawn from the membership of the WGRNR and WGHOF, to develop a structure for their workshop sessions.

3. Workshop programme

3.1 Workshop organising group

A joint workshop organising group comprised of members from the Working Group on the Regulation of New Reactors (WGRNR) and the Working Group on Human and Organisational Factors (WGHOE) was selected and provided with the survey, respondent data and the position papers. The agreed subject areas for the workshop were prioritised and agreed by the workshop organising group and subsequently developed into the workshop programme.

3.2 Workshop topics and format

The workshop lasted three days and was split into three breakout sessions (see Table 3.1 below). The morning session of the first day was dedicated to introductory presentations and a guest speaker from the Hinkley Point C (HPC) New Build Project in the United Kingdom. All presentations that were given on the day by scheduled speakers can be found in Appendix C.

The breakout sessions took place in sequence and lasted half a day each. The sessions addressed four sub-topic areas in parallel. For each sub-topic, the position papers, provided in Appendix B, were used to structure the session and identify the key points of debate.

The breakout sessions were moderated by a chair with assistance from a rapporteur from WGRNR or WGHOE. Appendix C and D contains the opening presentations and the feedback from the breakout sessions. The key learning outcomes from the discussions held in each breakout session can be found on the following pages.

Table 3.1: Breakout Sessions

Breakout Session 1	Breakout Session 2	Breakout Session 3
Challenges in developing organisational capability	Regulatory challenges with new licensees	Oversight of contractors and suppliers by new licensees
1.1 Building organisational capability	2.1 Regulatory readiness	3.1 Balance between new licensee capability and reliance on contractors
1.2 Developing leadership and governance	2.2 Engagement strategies	3.2 The EPC model
1.3 Developing strong safety culture	2.3 Development of guidance	3.3 Supplier surveillance
1.4 Developing internal independent regulation	2.4 Interfacing with other regulators	3.4 Project management

Breakout Session 1

Breakout Session 1 focused on the challenges in developing organisational capability. The aim of this session was to discuss the challenges associated with ensuring a new/prospective licensee will have an organisation that is capable of achieving, and then enhancing, nuclear safety by ensuring that other demands on the licensee are not considered separately from nuclear safety requirements.

Breakout Session 2

Breakout Session 2 focused on the challenges that regulators face when interacting with new licensees. The aim of this session was to share experiences of regulating new licensees and some of the challenges that regulators have faced.

Breakout Session 3

Breakout Session 3 focused on the oversight of contractors and suppliers by new licensees. The aim of this session was to discuss the challenges that new licensees face when managing a nuclear new build, specifically, ensuring that their choice of contractors and suppliers understand the additional standards placed on them when embarking on a nuclear new build.

3.3 Discussion outcomes

The discussions held during each sub-session were captured by the rapporteur. The complete discussion can be found in Section 4, with a summary table provided in Appendix E.

4. Learning outcomes

4.1 Breakout Session 1 – Challenges in developing organisational capability

Session 1.1 – Building organisational capability

Introduction

This session focused on the topic of building organisational capability based on four questions:

- How can licensee awareness of regulatory expectations be improved?
- Do new licensees understand the scale of the task?
- Are new licensees focused 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?

Table 4.1 below provides a summary of the Breakout Session 1.1. The full session notes follow this summary.

Table 4.1: Summary of the Breakout Session 1.1

Session 1: Challenges in developing organisational capability: 1.1 Building organisational capability	
Lessons learnt/commendable practices	Identified challenges
<ul style="list-style-type: none"> • Recommendation of early engagement prior to formal submittal of application: <ul style="list-style-type: none"> - documentation of a formalised 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). 	<ul style="list-style-type: none"> • “Just-in-time” approach towards organisational capability by prospective licensees demonstrates lack of appreciation for scale of task. • Organisational instability of prospective licensees can present challenges in understanding and coping with scale of the task. • Poor culture, reputation within organisations can present challenges for recruitment and retention of resources.

<ul style="list-style-type: none"> • Existing licensees seeking new authorisations should be treated similarly to new licensees if long gaps exist in new build projects. • IMS may be useful tools for organisational capability. • “Baseline” approach to demonstration and justification of organisational staffing should incorporate long term planning with a 3-5 year perspective. 	
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Position paper response summary

Position papers answers were given for each question to be discussed in this sub-session. A summary of the responses is given and points of special interest are highlighted.

How can new licensee awareness of regulatory expectations be improved?

Generally answered with “by early engagement with potential licensees and with information about requirements, guidance and licensing process”.

Canadian Nuclear Safety Commission (CNSC) engages 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 encounter regulatory challenges (i.e. state of licensee and/or technology readiness). The engagement may be informal or more formal.

Besides regular interaction with licensees, on both the management and expert level Radiation and Nuclear Safety Authority (STUK) Finland sees several possible ways to achieve new licensees awareness of regulatory expectations, e.g. by:

- well structured, and sufficiently detailed legal requirements;
- a comprehensive set of regulatory guidelines;
- appropriate requirement management solutions.

Hungary holds meetings with licensees, organises trainings concerning regulations, has constant discussions with licensees, and mentions the possibility to review licensee documentation before the construction license application is submitted.

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

In the Netherlands, the process starts early with pre-licensing meetings about the way the regulatory body will perform the Preliminary Safety Analysis Report (PSAR) review and in which the Dutch Safety Requirements are explained and discussed.

Poland publishes non-binding regulatory guides and has working level meetings between prospective licensees and the regulatory body.

In Russia, 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. Until recently there was only one operating organisation, which is also a licensee, for nuclear power plants (NPPs) (JSC “Rosenergoatom”). At present, the Regulatory Body Rostekhnadzor considers an application for the construction licence of a demonstration reactor facility from the new operating organisation JSC “Siberian Chemical Combine”. This organisation, however, has considerable experience in the field of nuclear energy use (it is the operating organisation for a number of nuclear fuel cycle facilities), and hence significant experience of co-operation with Rostekhnadzor. Therefore, Rostekhnadzor has no specific goal to improve the awareness of new licensees about the regulator's expectations, since the new licensee is an organisation with extensive experience in this field.

In the United Arab Emirates, the regulatory authority, Federal Authority for Nuclear Regulation (FANR), initiated communication with the license applicant Nawah 1.5 years in advance of the operating license application submittal to discuss topics where differences exist between FANR regulatory requirements and regulatory body country of origin – Korea (e.g. Integrated Management System, operational readiness process).

In the United Kingdom, the Office of Nuclear Regulation (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.

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 technical assessment guides (TAGs) and supporting technical inspection guides (TIGs) for inspectors. The latter focuses upon licence condition compliance. These guidance documents aim to incorporate appropriate international and national guidance.

While 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.

In the United States, prospective new licensees initiate communications with the Nuclear Regulatory Commission (NRC) at their discretion. The NRC emphasises the importance for applicants to become familiar with the regulatory structure, policies, requirements, and processes early in the application planning process. The NRC improves new licensee awareness of regulatory expectations through:

- providing publically available information on regulatory requirements, guidance, and expectations;
- by meeting with potential new licensees to discuss their plans and NRC requirements and expectations;
- through workshops and seminars.

The NRC encourages prospective and new licensees to make use of information developed by organisations such as the American Nuclear Society, Electric Power Research Institute, and Institute for Nuclear Power Operations, and engage with existing licensees and companies involved in commercial nuclear power plant development and operations to understand how they have historically met regulatory expectations.

Points of special interest in the countries responses were:

CNSC (Canada) has a *Pre-Licensing Vendor Design Review Process*, which is a formal process available to reactor vendors. This 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.

As part of early communication with applicants the regulator should encourage a *discussion on* topics where *differences* exist between the regulatory requirements of the reactor design country of origin and the regulatory requirements of the country where a license is being sought (e.g. integrated management system, operational readiness process) (United Arab Emirates).

ONR (United Kingdom) sets out its approach to the phase of early engagement in a published *Pre-Application Intervention Strategy*, which is specific to each potential licensee.

The NRC (United States) has multiple *web sites* in place. The NRC's public web site (www.nrc.gov/) is a resource for such information. The NRC's web site for new reactors (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 (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.

Do new licensees understand the scale of the task?

Although CNSC (Canada) foresees that the current list of potential vendors would engage with existing, capable licensees, new licensees would require education on the scale of the task and level of responsibility that is needed to undertake a nuclear power project.

STUK (Finland) reports that the understanding of the scale of the task relies heavily on the experience level in the new licensee's personnel. A lack of experience has led to an underestimation of the scale of the task. This has also been experienced in Hungary where, although the perception is that new licensees have the understanding, there have been shortfalls in the mid and long term planning of tasks and resources.

Korea and Poland both report that the regulatory perception is that new licensees are aware of the scale and would be able to cope with it, especially as understanding improves once the project commences. This is also reported by Russia as Russian legislation is clear in its requirement for license applicants for siting of nuclear installations be recognised by the control body in the field of nuclear energy use as suitable to conduct all activities associated with design, construction, operation, and decommissioning of a nuclear installation.

The ongoing new build experience in the United Arab Emirates has shown that new licensee understanding is influenced by, in many cases, the concurrent development of the regulatory framework, which can lead to misunderstanding of requirements.

The ONR (United Kingdom) and the NRC (United States) reported similarly that there is a general underestimation of the scale of the task by new licensees but that this varies considerably based on the linkages that new licensees have with current operators, experienced vendors, and construction organisations. A rush to secure nuclear professionals in a very competitive market can lead to new licensees having the wrong skill/knowledge profile early in their development. This can lead to major organisational re-alignment once a better understanding is acquired. Competitive market demands for nuclear professionals are also cited by the Netherlands as a risk to new licensee understanding. One means to foster understanding, offered by the NRC, is the provision of electronic links to information on the application submittal and review process authored by both applicants and pre-applicants and the NRC on the NRC website.

Points of special interest in the countries responses were:

In the United Kingdom context, there is the potential that the focus of new organisations is on the technical design issues rather than on development of the organisational capability. The United Kingdom has separated these issues by introducing the generic design assessment (GDA) process, which assessed a reactor design for suitability in the United Kingdom regulatory environment. The United Kingdom licensing process does not license the design; it licenses a Corporate Body to undertake specified nuclear activities on a specified nuclear site. The site-specific design and safety case, subsequent construction, commissioning, operational, and decommissioning activities are controlled using a permission regime under the nuclear site licence.

The Polish and United Arab Emirates experiences have shown that for countries that embark on new nuclear programmes, the understanding of the scale of the task is imperative not only for new licensees but for new regulatory bodies as well.

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

A general comment raised by several of the respondent countries was that the outlook of prospective licensees is short sighted and there is a potential lack of understanding of what the organisational requirements are at each stage of the project. From the regulator perspective, this is not necessarily from a lack of trying, as there is a mutual understanding that this is a significant undertaking and very difficult to accurately assess organisational needs upfront.

In the Netherlands, the lack of a national nuclear experience base from which to draw from creates difficulties for prospective licensees both in planning and executing organisational development activities. In Hungary and Poland, the regulator recognises that new licensees do understand the importance of this task and are taking adequate steps to build the requisite capability.

It is clear in the Russian framework that funding, logistical, and human resources issues are the responsibility of the prospective licensee, in accordance with federal rules and regulations. The development of organisational capability is also not hindered by a lack of nuclear expertise in Russia as it is in other countries.

The focus on building organisational capability for all phases can be affected by the contractual arrangements established between the owner, the constructor, and the eventual operator. In the United Arab Emirates the initial approach for the nuclear power plant was a design, build, operate arrangement

by an experienced external contractor. The change to this approach has created some challenges in the development of capability, most notably for the operating phase.

In the United States, it is predominantly existing licensees who are pursuing new nuclear projects. As such, these organisations are more able to transition new build projects through the various phases such as concept, development, construction, pre-operational testing, and operations. New licensees could consider requesting assistance from these organisations prior to beginning the application process.

Considering that new build projects have not occurred in the United Kingdom for several years, the knowledge that is required from an organisational perspective at each of the pre-operational phases of the project is scarce since the majority of nuclear professionals have mainly operating experience.

There were no points of special interest in the country responses for this topic.

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

STUK (Finland) considers this a challenging issue, for which it is good to have contacts that can be attempted to be recruited, and for which good training programmes are important. Finland also highlights the importance of the ability to hold on to employees, in which regard good reputation should be focused on and which also needs good safety culture.

Hungary mentions the challenge that usually staff with nuclear experience is not available on the market, so people from non-nuclear industries have to be hired. Because of this, stakeholders have to develop a robust human resource 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 considers the shortage of nuclear skills and experts to be one of the biggest obstacles for development of organisational capability, and new licensees will try to recruit experienced engineers from current utilities.

Poland draws attention to the fact that developing capability in a competitive market short of nuclear skills is even harder in embarking countries without a nuclear power industry.

Russia notes that the shortage of skills in the nuclear field is not typical for Russian licensees and calls it basically 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.

The United Arab Emirates has benefitted in this regard due to its ability to attract experienced nuclear professionals from around the world (offering competitive compensation packages, English speaking business culture, stability, and lifestyle). However, most new comer countries or expanding nuclear programmes would find this very challenging.

ONR (United Kingdom) considers this a significant task for a nuclear new build organisation that 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 United Kingdom, the majority of nuclear skills are in operational environments and not in design, build and commissioning – hence the United Kingdom 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 United Kingdom 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, building 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).

According to the NRC (United States), 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 organisations have programmes in place to develop and prepare individuals with the appropriate skills that are forecast to be in shortage, and the programmes themselves should be periodically updated to meet projected future demands and evolving technologies. Programmes 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, organisations typically rely upon contractors and external organisations to bring about the needed expertise.

Points of special interest in the countries responses were:

The importance of 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 organisations have programmes in place to develop and prepare individuals with the appropriate skills and the programmes themselves should be periodically updated to meet projected future demands and evolving technologies (United States).

Capacity building initiatives should be established well in advance of the decision to begin a nuclear programme to ensure capability in the pipeline (university programmes, research initiatives) (United Arab Emirates).

Discussion summary

How can new licensee awareness of regulatory expectations be improved?

The need for early engagement is felt in general, with different strategies being used in the participating countries. There is a need for clear guidance for early engagement as well as how to manage this and how to cover the costs. Examples of early engagement given were discussion on regulatory requirements and expectations (siting, organisations, and technology) as well as giving advice of licensing, review and assessment processes.

From the discussion in this sub-session, the following points emerged:

- early engagement with prospective licensees is important if not necessary (should happen in advance of formal submittal of application);
- development by regulator of a formalised documented framework that describes a “roadmap” of the steps required to obtain a license;

- establishment of “rules of engagement” so as to set clear intentions and expectations for early discussions (the regulator needs to maintain its independence in the process);
- regulators should not assume that maturity or historical prominence of applicants reduces the need for early engagement;
- in many cases the standard set of nuclear requirements are well understood by experienced applicants so it is important to focus on areas that are less understood or where there is a lack of guidance;
- the 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 (United States).

Do new licensees understand the scale of the task?

There was a consensus by the group that regulators can and should encourage prospective licensees to interact and learn from the experience of existing licensees before pursuing licences.

From the discussion on this sub-session, the following points emerged:

- 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 organisational 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 licensee 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 authorisations should be treated similarly to new licensees considering long gaps in new build projects (Europe, United States);
- culture of safety is different in nuclear (e.g. compared to 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;
- organisational instability of prospective licensees can present challenges in understanding and coping with scale of the task.

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

It was agreed that building organisational capability is very situation dependent and the focus placed on it by a prospective licensee may be influenced by the existing regulatory environment, the availability of human resources, and the technology being considered.

From the discussion on this sub-session, the following points emerged:

- 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 United Kingdom for operating NPPs);
- United Kingdom “baseline” approach to demonstration and justification of organisational staffing is potential commendable practice. Baseline approach should incorporate long term planning, 3-5 years prospective;
- different approaches to regulation/oversight of organisational capability aspects may be effective (the United States 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 organisational capability and, at least, these should be linked.

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

While discussing this issue 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 and/or policy makers).

Additional points that were highlighted in the discussion:

- poor culture and/or reputation within organisations can present challenges for recruitment and retention of resources;
- it is 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 the most desirable candidates.

Lessons learnt

The lessons learnt gathered during this sub-session are:

- 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 it is important to focus on areas that are less understood or where there is a lack of guidance;

- different regulatory practices can be effective in setting requirements and conducting oversight of prospective licensee organisational arrangements.

Commendable practices

The following points are to be considered as commendable practices:

- early engagement with prospective licensees is important if not necessary (should happen in advance of the formal submittal of an application);
- development by regulator of a formalised documented framework that describes a “roadmap” of the steps required to obtain a license;
- establishment of “rules of engagement” so as to set clear intentions and expectations for early discussions (regulator needs to maintain independence);
- the United Kingdom “baseline” approach requiring the demonstration and justification of organisational arrangements by prospective licensees.

Identified challenges

- 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 (United States).

Areas warranting further work

How much technical details are discussed in this phase? (WGRNR)

Others

How about engaging with parent companies?

Session 1.2 – Developing leadership and governance

Questions

This session focused on the topic of developing leadership and governance by exploring the following questions:

- What should be your expectations for new licensee governance standards?
- How should these expectations change as the project develops?
- What should be your leadership expectations across new licensees?
- Is there sufficient guidance/best practice available on these issues?

- How do ownership models influence governance and leadership?

Table 4.2 below provides a summary of the Breakout Session 1.2. The full session notes follow this summary.

Table 4.2: Summary of the Breakout Session 1.2

Session 1: Challenges in developing organisational capability: 1.2 Developing leadership and governance	
Lessons learnt/ commendable practices	<ul style="list-style-type: none"> • 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 organisation. • Importance of internal provision for supervising its contractors and subcontractors including periodical assessment. • Necessity of generic requirement on leadership and organisational capability for the baseline of capability in the management line. • Assessment of leadership in the senior management appointment process (e.g. 360 degree evaluation, organisational 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. • Balanced number between internal and external board directors. • Guidance on intelligent customer capability. • Comprehensive inspection system with a multidisciplinary 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.
Identified challenges	<ul style="list-style-type: none"> • 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.
Recommendations	<ul style="list-style-type: none"> • Development of general guidance on organisational capability building.

Key lessons learnt

Agreed understanding of the meaning of governance and leadership

Before starting discussion of the topics on the development of governance and leadership, an agreed definition of concepts was necessary as there were no shared understanding of the concepts. The concept of governance was defined as; establishment of an integrated management system which entails policies, procedures and continuous monitoring of their proper implementation, by the members of the governing body of an organisation. It includes the mechanisms required to balance the powers of the members (with the associated accountability), and their primary duty of enhancing the safety, prosperity and viability of the organisation.

The leadership role was also discussed and defined as someone that influences someone to perform a certain task in a committed and safety way. Leadership is related to the interaction between persons and therefor related to the relationship between employee and the leader.

The management role is related to the formal function that an individual has over a person or a group of employees to co-ordinate, plan and direct the work in an efficient way. A leader does not need to have a management role for being influential. However, it is important that a manager is a good leader.

Guidance on licensee's governance

Almost all participating countries in the workshop do not have specific guidance regarding licensee's governance. Nevertheless, participants in Sub-session 1.2 discussed how governance should look like, what elements should be included in the governance, etc. from a broad point of view, and participants came up with elements which should be included, as a minimum requirement, in the governance of a company as follows: structure, roles and responsibilities, authorities, inter-relationships between different divisions, expertise, safety culture and values as a high-level arrangement, behaviour expectation specific to project phases. Additionally following governance aspects were identified in need of attention:

- assurance of oversight for the internal regulator to see how the governance is implemented in its integrated management system;
- periodic assessment of the governance and leadership;
- independence from external pressure which can jeopardise safety;
- dynamic adaptation capability in complex business situation of a new build project;
- composition of executive board and safety committee with a right balanced control power;
- competence of the members of the executive board and safety committee;
- human and organisational factor/safety culture representatives in the executive board and safety committee; and
- method to support systemic oversight depending on phases.

Adaptation to business fluctuation

Another lesson learnt is that under fluctuating business situation, it is recommended for the licensee to make a short term specific plan with a long term generic plan rather than making full scope specific plan, which will help prospective licensee be adapted to and quickly manage the new situation.

Role of internal regulator

Some of business models have the internal oversight function or “internal regulator function” within the licensee organisation, which is responsible for the independent review of activities of licensee or contractors and would interact with the regulatory authorities. When such establishment is put in place, it might make regulatory authority role easier.

Supervision of contractor by licensee

The regulator should establish a requirement for the licensee to make internal provision for supervising its contractors and subcontractors including periodic assessment. (This was also discussed in another break-out session in a more elaborated fashion.)

Establishment of requirement for organisational capability

One of the shared experiences in the discussion is that if the owner has insufficient knowledge about the project, lack of knowledge will influence overall quality of a project or even delay the progress of the project. The owner has influence of the project, even in the cases when the owner is not the licensee and therefore it is of vital importance that knowledge alignments exist. It is recommended to establish generic requirement rather than specific requirement on leadership and organisational capability, which allows regulator to assess overall capability of licensee’s management levels. Additionally the minimum level (baseline) of knowledge or capability in different management levels should be clearly stated in the requirement. With this kind of holistic requirement, regulator may assess whether licensee satisfies the minimum level of qualification through regulatory inspection, e.g. interviews with managers in management system. When it comes to leadership at management levels, it could be assessed to identify whether appropriate level of leadership is put in place at management levels. For example, appointed senior management could utilise the approach of a 360 degree evaluation, and this performance assessment would be based on the output against organisational values. The outcome of such evaluations and its related action plans could then be basis for the regulatory oversight of the licensees’ leadership capacity building.

Early engagement of regulation

When a new prospective licensee shows an intention to construct nuclear facility, it is unlikely that they are well acquainted with regulatory requirement on organisational capability. Therefore, it is necessary for the regulatory body to take a proactive approach to early engagement with the prospective licensee 2 or 3 year earlier than official licensing application or to issue a general guideline instructing what the prospective licensee needs at the early stage of project to prepare for strong organisational capability including leadership and specific governance from the regulatory point of view. Some participating countries engage with the prospective licensee with educational purposes. It is suggested that through early engagement of the regulation with the prospective licensee, regulators provide advice on how to build governance and leadership capabilities, e.g. providing provision of guidance documents, arranging “informal or secret meetings”, conducting education on the licensing process and the requirements. However, it has been acknowledged that most regulatory bodies do not have guidance on early engagement. In addition to that, holistic regulatory approach has been discussed in which the regulatory body should review governance with broader regulatory perspective to firstly confirm whether all elements are involved in the licensee’s governance and give a right direction to the licensee at the early stage of a project, and then as the project evolves, detailed contents of the governance will be developed in a more detailed way.

Intelligent regulator

The concept of intelligent customer capability might be needed for a new regulator or regulators in general with regard to what special competence they need for oversight of new licensee organisational capability.

Regulators should have capabilities to oversee a prospective licensee regarding what they should do at early stage, how they develop their capability, and how regulators confirm whether a prospective licensee follows regulatory guidance, etc. It may be accomplished through establishing guidance. ONR has guidance for inspecting licensee's leadership and secures designated inspector in the area of licensee governance.

Commendable practices

Balanced number of board directors

The United Kingdom emphasised the importance of independent executive board of directors as well as the balanced number of board directors between internal and external members. External board directors should have the equal qualification and authority to the internal board directors. Depending on the project phases, board members should oversee the progress of project compared to a scheduled plan.

Intelligent customer

The United Kingdom has developed guidance on intelligent customer capability. An intelligent customer is an organisation with a capability which can know what is required, understand the need for a contractor's services, specify requirement, supervise the work and review the output before, during and after implementation. This concept was developed by ONR and has gained international acceptance.

Multidisciplinary team inspection

Hungary established a multidisciplinary (7~15 technical fields) team inspection in which individual inspectors with specialty in specific area perform inspection and they share their inspection results after inspection to draw inspection conclusion in a holistic or comprehensive manner. Finland has a similar multidisciplinary approach. In Finland, all organisational aspects including safety culture are evaluated by regulatory body. Inspection is conducted in a simultaneous manner, both hierarchically and functionally. Inspectors gather all information during first week and they also inspect leadership and soft aspect of organisation. After conducting inspection, inspection results are analysed by the team and conclusions are drawn in a holistic and comprehensive manner. This system has a merit to assess the inspection results from the holistic regulatory point of view with inputs from different discipline inspection areas.

Continuous improvement of integrated management system

Integrated management systems may provide good basis for implementation of governance and leadership, and monitoring of appropriate implementation of governance and leadership is important. Self-reflection approach can help licensee quickly adapt to changes making licensee be able to manage whatever challenges come up. Russia has a requirement for operator to ensure the continuous monitoring of the entire activities affecting the safety of nuclear power plant including self-assessment method within integrated management system, which promotes timely adaptation and adjustment of existing practices in the area of governance and leadership.

Selection of hold-point

Finland and the United Kingdom set so-called "hold points" where the licensee needs to demonstrate that sufficient level of governance implementation has been achieved.

Communication within licensees

The licensees organise “Safety Director Forum” with senior managers from different entities to share good practices and experience, and the regulator is invited to the forum to give regulatory advice.

Identified challenges

Owner’s intervention

From an owner point of view in business model, financial and project progress aspects may be emphasised. When an 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. This situation is applied when owner and licensee are different entities. In this case, the licensee will possibly get schedule pressure by the owner and this situation may affect the safety culture, ultimately nuclear safety.

Gap in guidance

It has been identified that almost all participating countries do not have specific guidance on licensee’s governance and leadership because these areas have not yet gotten sufficient attention even though it was recognised that these aspects are of pivotal importance for a successful projects. The cause might be due to lack of specification and not being part of the conventional regulatory framework or. However, some countries are carrying out regulatory engagement in the governance or leadership area as part of existing inspection but not dedicated inspection to those areas, and other countries identify these areas as gaps in development of guidance. As an example, the United Kingdom has identified governance guidance to be one of the biggest gaps in their regulatory system.

Practical oversight of leadership capability

Even though inspection regarding licensee’s leadership capabilities is performed in rare case, main activity is to check documented qualification files at licensee’s management levels. Therefore, it is questioned on how to evaluate the proven leadership capabilities of management levels rather reviewing the paper works.

Suggestion

Participants suggested that NEA develop general guidance or high-level document (type of green booklet) on organisational capability building. The publication should include organisational capability assessment methodologies as well as methods on how to establish organisational capability.

Session 1.3 – Developing strong safety culture

Introduction

This session focused on the topic of safety culture. The challenges and best practices of developing a healthy safety culture were discussed from the viewpoint of a new licensee organisation as well as from the viewpoint of the construction project with a large subcontractor network. The questions used as a basis for this section were:

- What is different about developing strong safety culture in new licensees (compared to long established operators)?
- What is the best practice for developing a strong safety culture?
- How should you assess safety culture in new licensees?

- What are the risks to maintaining strong safety culture across the project lifecycle?

Table 4.3 below provides a summary of the Breakout Session 1.3. The full session notes follow this summary.

Table 4.3: Summary of the Breakout Session 1.3

Session 1: Challenges in developing organisational capability: 1.3 Developing strong/healthy safety culture	
Commendable practices	<ul style="list-style-type: none"> • 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 (SC). • Having trained specialists assessing SC in organisation. • Safety Culture Working Group with licensee, vendor, and tier 1 and 2 contractors.
Identified challenges	<ul style="list-style-type: none"> • 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).
Recommendations	<ul style="list-style-type: none"> • Development of guidance and toolbox on the SC applicable to the lifecycle of the project.

Position paper response summary

In the position paper the members answered to the following questions.

What is different about developing strong safety culture in new licensees (compared to long established operators)?

The answers pointed out that building up a safety culture in a new company/new licensee takes time. Lack of pre-existing organisational culture to build on sets special challenges for safety culture work since a new licensee does not have shared practices, values and understanding of important matters. Furthermore, the management and staff of a new licensee company may have limited or no experience in the nuclear industry and therefore they may experience difficulty to genuinely internalise the expectations set for a nuclear industry organisation.

The answers also highlighted that the concept of safety culture needs to be interpreted for construction/project environment in a meaningful way. Some new build projects have seen a tendency of the projects to focus on occupational safety rather than on nuclear safety due to the temporal proximity to the hazards.

The project environment brings along many inherent features which challenge the development of a shared safety culture. These include transient, contracted and multinational workforce.

What is the best practice for developing a strong safety culture?

The answers suggested that new licensee organisations need knowledge, experience and insight of safety culture and its importance. Management commitment to safety, followed by clear expectations for a strong safety culture was emphasised.

Safety culture development needs to be systematic. However, it was emphasised that the development programmes and tools are situation dependent. Tailoring the safety culture development programme and tools for the situation/context calls for expertise on the topic.

Involvement of the suppliers and subcontractors in to the safety culture development was seen as important.

How should you assess safety culture in new licensees?

First of all, the respondents emphasised that the licensees need to conduct self-assessments of their safety culture.

Most regulators seem to monitor new licensee safety culture through “normal” oversight tools: inspections, reviewing the management system and other documents, observations, event analysis, (in)formal discussions and third party assessments.

The answers touched upon interesting topic whether or not there should be a lifecycle specific focus when assessing safety culture. The answers varied in this respect but mostly the safety culture of the new licensee is assessed against the criteria used for all other licensees as well. Literature that can help in designing the oversight of safety culture was identified. For example the IAEA TecDoc 1707 provides good recommendations for effective oversight by regulators, and the Swedish Radiation Safety Authority (SSM) research report *2015:10, SafePhase: Safety culture challenges in design, construction, installation and commissioning phases of large nuclear power projects* (www.stralsakerhetsmyndigheten.se) identifies safety culture challenges in different lifecycle stages.

What are the risks to maintaining strong safety culture across the project lifecycle?

Inherent features of project activities may cause risks to maintaining strong safety culture. These include e.g. time pressure (delays in project case even more pressure), economic pressures, scale of a nuclear new build project (multiple actors) and lack of continuity (change of workforce, organisational changes, shifts of paradigm).

The respondents also noted many other issues that could lead to inability to pay attention to safety issues. These included complacency, lack of understanding of the safety requirements, peace-at-any-price principle (a pattern of acceptance leading to diminished standards).

Managers not listening to the engineers and ineffective checks and supervision.

Lack of training and a systematic safety culture programme were identified as risks as well.

Discussion summary

There was a fairly shared understanding that a healthy safety culture means organisational performance where safety is prioritised. However, the group discussed the difficulty to define the scope of the safety culture concept: should it cover all aspects of safety (security, environmental safety, occupational health, etc.). The same underlying organisational values and attitudes influence the behaviours towards all the

aspects of safety. However, in most cases the participant regulatory organisations focus mainly on nuclear safety-related aspects on organisational culture when they talk about safety culture, although e.g. occupational safety performance can give indications on the level of safety culture in the organisation.

When safety culture is seen as a subset of organisational culture it is a deep and broad phenomenon. The group discussed how far into the supply chain one should go when addressing safety culture. The group concluded that a graded approach should be used, where safety critical contractors have higher requirements/expectations. This does not mean that other contractors can act against the principles of a healthy safety culture but that more effort is put into the oversight of the safety critical actors. They also need to have more systematic means of demonstrating that their organisational performance fulfils the expectations set towards strong safety culture. The group's viewpoint was that safety culture expertise is needed in the core organisations of the new build project. One of the challenges identified was that the motivation of the contractor companies to develop a strong nuclear safety culture may vary, e.g. companies that are at site for a short term may not have same incentive for a strong safety culture.

The group also discussed how the idea of a strong safety culture fits to the different lifecycle stages, e.g. is it reasonable to expect a strong safety culture from a new licensee from the beginning of the project. Many of the decision done early on in the project will have an impact on the safety of the power plant. Therefore the new build project organisations should have a healthy safety culture from the beginning. The group noted, however, that in practice it is difficult for a new licensee to establish as strong a safety culture as a mature nuclear industry organisation. It takes time and competence. Therefore early involvement is a recommended.

One of the topics was how to promote more effectively the key organisational attributes that signify a safety first thinking (or strong safety culture) to a new licensee organisation. The members shared their practices. The role of selecting good leaders was emphasised. In many countries the regulator expects that any senior management position should have proper education and experience. If the managers come outside the nuclear industry their training programme should be paid attention to. In addition, the leadership skills and sufficient understanding of safety culture is required from the managers in the key positions. They need to lead by example. Another theme discussed was safety culture development programmes. Although the group saw the systematic safety culture development programmes as important it also felt that there is a risk to superficial compliance to safety culture tools without a real change in the way the new build project is managed and executed.

Lessons learnt

One of the main lessons learnt was the necessity for the early involvement, even before the applicant applies. This is important because building a culture takes time and there will be challenges. Future licensee also needs to understand the regulatory requirements and expectations.

Another key lesson was the importance of the selection and assessment of leaders. Especially in a new company and in a turbulent project setting the role of the senior leadership is crucial for the development of the culture.

Third lesson was that supply chain safety culture assessment and development needs more practical guidance.

Commendable practices

The discussion allowed us to identify some good practices applied in the member countries:

- The licensee is asked to lay out their strategic approach on how they are going to develop and promote safety culture. The regulator and the licensee meets regularly (early involvement) to provide guidance on the approach until the licensee's approach reaches the expected level.
- The licensee is expected to utilise lessons learnt from previous nuclear new build projects construction experience and to build on it.
- Any senior management position should have proper education and experience (which cover SC) otherwise a proper education programme is set up. The education programme can include taking part in peer review missions such as IAEA Operational Safety Review Team (OSART) or World Association of Nuclear Operators (WANO) missions.
- Regulatory body approves/certifies certain key positions in the organisation. An assessment of the competence and leadership style is part of the approval process.
- Having trained specialists assessing safety culture in organisation.
- Co-creation of safety culture, integrated work practices (like HPC project).
- Safety Culture Working Group in the new build project: one person from licensee, vendor, and tier 1 and 2 contractors.

Identified challenges

The group identified many generic as well as practical challenges of establishing a strong safety culture in new build project. One of the generic challenges is that the project pressures may challenge the safety culture of both licensee and the regulators. Effective balancing of competing goals as well as external pressures is needed. In addition, the different aspects of safety (nuclear, occupational, environmental, security, safeguards...) require balancing.

Another challenge relates to the dynamic nature of projects. Safety culture is often perceived as somewhat static phenomenon, but it needs to evolve with the dynamics of the project, e.g. when the licensee organisation grows or the project moves from design to construction stage.

One of the clear challenges relates to the supply chain. There is still need for practical approaches that help the licensees to take safety culture into account in supplier/subcontractor selection. Furthermore, sharing the means to promote nuclear safety culture in various contractor companies is needed.

The group also recognised that safety culture assessments can take a lot of time and energy and therefore can be difficult to properly address. There is a danger of performing superficial safety culture assessments, which may lead to false sense of safety. All and all a question was raised that how to ensure that safety culture activities are not superficial but fresh and effective. This also relates to the last identified challenge which is the expertise on safety culture. The key organisations should have competent experts who understand organisational culture and its relationship to safety. In some countries there is a lack of such experts.

Areas warranting further work

- How to ensure that the supply chain meets full expectation in safety culture?

- How to support the development of organisational culture in the various lifecycle stages of the project in such a way that it fulfils the expectations of a strong safety culture. How to evolve the safety culture with the dynamics of the project?
- Guidance and toolbox development on both above-mentioned topics.

Session 1.4 – Developing internal independent regulation

Introduction

This session focused on the topic of developing internal independent regulation. It considers the factors that are important in establishing the level of regulatory oversight necessary during the development and building of a new nuclear power station. The aim of the session was to identify “commendable practices”, “challenges” and “areas warranting further work”. The questions used as a basis for this section were:

- How important is the concept of 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?

Table 4.4 below provides a summary of the Breakout Session 1.4. The full session notes follow this summary.

Table 4.4: Summary of the Breakout Session 1.4

Session 1: Challenges in developing organisational capability: 1.4 Developing internal independent regulation	
Lessons learnt/ commendable practices	<ul style="list-style-type: none"> • 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. • 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	<ul style="list-style-type: none"> • 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.

Position paper response summary

This section contains the consolidated responses to the three questions on developing internal independent regulation. Key responses were as follows.

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

- The general consensus was that regulators are not resourced to and can't check everything in a licensee organisation. A strong and effective IR function can give external regulators confidence that a licensee's arrangements are being subject to an appropriate level of independent scrutiny.
- An IR function is well placed to understand how a licensee organisation works, gain an inside view of the positive and negative aspects of how its arrangements are working in practice, and to recommend solutions.
- Given that external regulators generally have finite resources they may choose to give a licensee less attention if they have confidence in the effectiveness of its IR function, and potentially divert their attention to other priorities to the mutual benefit to both parties.
- It is extremely important that senior management understand and support the role of the IR function. They should act as an "intelligent customer" for IR and ensure that it is appropriately resourced. It is important that senior management have oversight of the findings from internal inspections and ensure that appropriate action is taken to address the findings.
- The IR role is not mandatory but it is desirable and beneficial. It should be used to evaluate, challenge and continuously improve the licensee organisation.
- It is important that a licensee organisation has the right culture if the IR role is to be effective. This culture must include a willingness to be open, honest and to be challenged. The licensee has to be prepared to receive the findings from IR inspections and to act on them as appropriate.
- Senior leadership is an essential element of the culture because leaders must embrace the philosophy, encourage and support the IR function, ensure that it has sufficient, competent resources, and act on inspection findings.
- The introduction of an IR function into a new licensee organisation can be very beneficial because these organisations can lack competence in individual functional area and in totality. An IR function staffed by experienced individuals has the potential to take a "holistic" view of the new licensee's activities and identify areas of strength, weakness, overlap and duplication.
- The timing of the introduction of an IR function into a new licensee organisation is important because:
 - if it is introduced too soon, the organisation may not be ready for it and it may identify deficiencies that the organisation is not mature enough to address;
 - if it is introduced at the right time it can help to "fast track" development of the organisation by having a holistic view of how activities fit together.

Do you have sufficient guidance on your expectations for IR?

- There was a mixed response to this question ranging from “yes” to “yes but not sufficient” to “none at all”.
- In some countries the requirement for IR is specified in the licence but this tends to occur in a prescriptive regulatory regime and results in the IR function having a very technically orientated role.
- Reference to IAEA guidance is considered to be the default position for most member states in the absence of national guidance but in reality there is very little specific IAEA guidance on this topic.
- One of the difficulties was perceived in preparing guidance was the differences in regulatory regimes and whether guidance could be prepared which takes into account both prescriptive and goal-setting regimes.
- The group questioned whether countries should write their own guidance but did not come up with a consensus on this.
- Overall a lack of adequate guidance was considered to be an area of weakness. There is very little international guidance and most member states have very little national guidance.

How should regulators interact with internal regulators?

- All parties agreed that a good, high-level relationship is important. External regulators have an important role to play in reinforcing the role of the IR function within the licensee organisation and providing support. The credibility of the IR function can be greatly enhanced if external regulators actively seek advice and views from the IR function.
- External regulators should try to work collaboratively and constructively with IR functions sharing areas of mutual concern, seeking views before and feeding back after regulatory inspections. Both parties should consider undertaking joint inspections if their relationship is mature enough.
- Regulators may need to be intelligent when engaging with IR functions. Although independent within a licensee organisation, IR staffs are employed by licensees and they have to be careful how much information they share with external regulators. Often messages may be ‘coded’ by the IR function and external regulators have to be capable of interpreting them.
- IR functions should preserve their independence from a licensee organisation and should answer for or defend it.
- There was a consensus that joint training is a good way of understanding the respective roles of internal and external regulators and provides a good opportunity for relationship building.
- External regulators need to understand how mature the IR function is and to avoid having unrealistic expectations. They need to understand the challenges that IR staffs face and the career risk that they face if the messages that they convey in the licensee organisation are not received well.

- External regulators need to recognise that IR functions can never be as strong as they are because of the internal constraints that they face.
- External regulators are uniquely positioned to check what licensee senior management think about their IR function and to provide positive feedback and support to them.

Key lessons learnt

The group concluded that an effective IR function can add real value to a licensee organisation when working well but there needs to be the right organisational culture to make it work i.e. a “challenge culture” an appropriate balance between “blame”, “no blame” and “fair blame” when matters of concern are uncovered. Licensee leadership have a key role to play in acting as the client for the IR functions activities and providing overt support to the IR function and individual staffs.

The licensing regime often dictates a licensee’s approach to IR. A “prescriptive” regime may result in a very technically focused approach whereas a “goal-setting” regime may result in a wider ranging approach. The focus of an IR function should be on assurance rather than compliance and it should not operate in “audit” mode. Its focus should be on the effectiveness of a licensee’s management arrangements rather than compliance with them. A mature IR function should be regarded as part of a licensee’s approach to continuous improvement.

The timing of establishing an IR function in a new organisation is important. If it is introduced too soon it may find itself trying to comment on immature arrangements and, in the worst case, trying to look at arrangements that have not been fully developed and implemented. Conversely, a competent IR function can add great value to a new licensee organisation due to its ability to look holistically at the arrangements.

Commendable practices

The close working relationship between external regulators and the IR function which was evident in some member states was considered to be a good practice with potential benefits to be gained by both parties. Particular examples were the use of the IR function as the first point of contact in a licensee organisation, joint training, joint inspections and sharing of findings and areas of concern.

Identified challenges

The challenges identified were largely cultural, based around creating a “challenge culture”, engaging licensee leadership and developing a relationship based on trust, openness and mutual respect. The relationship issues were considered to be just as important within a licensee organisation as they are with external regulators.

Developing the IR function from an initial compliance based approach to one where it is regarded as part of a licensee’s approach to continuous improvement was also seen as a key challenge.

Areas warranting further work

No specific areas were identified by the group at the workshop but it is the Chair’s contention that there is a shortfall in international guidance relating to independent internal regulation and that consideration should be given to developing some to give some clear guidelines to member states and individual licensees.

4.2 Breakout Session 2 – Regulatory challenges with new licensees

Session 2.1 – Regulatory readiness

Introduction

This session focused on the topic of regulatory readiness concerning the oversight of new licensees. The questions used as a basis for this section were:

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

Table 4.5 below provides a summary of the Breakout Session 2.1. The full session notes follow this summary.

Table 4.5: Summary of the Breakout Session 2.1

Session 2: Regulatory challenges with new licensees: 2.1 Regulatory readiness	
Lessons learnt/ commendable practices	<ul style="list-style-type: none"> • 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 licensing. • 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.

	<ul style="list-style-type: none"> • Strategic planning approach, e.g. what resources are needed? • Competitive pay and stable working conditions. • Headhunting & using outside organisations in supporting roles in oversight. • Development of relationship with licensees, which open up opportunities for secondments (transfers) from those organisations. • Understanding of emerging technologies (e.g. small modular reactors). • Transition plan not to compromise the oversight of operating plants. • Flexible and constructive approach recognising high dependence on the supply chain, cultural differences, potential weaknesses of different contracting models.
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Position paper response summary

Regulatory readiness

What are the regulatory skills and experience needed to support the development of OC in new build organisations?

- management system development and assessment;
- organisational design and development;
- corporate governance;
- safety culture development and assessment;
- development and assessment of design authority capabilities and engineering and design processes;
- high-level nuclear legislation knowledge (e.g. legal interpretation of licensee “prime responsibility”);
- knowledge of IAEA, WENRA and similar requirements and standards (for example ISO9001);
- project management;
- supply chain supervision/management, including supplier qualification and readiness assessment;
- HR development;
- 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.

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, focusing 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.

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 organisations 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.
- Emphasising the unique safety mission.

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 licensing 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 organisation's plans and schedule.

Discussion summary

The session revealed that there are several important aspects and challenges concerning the readiness of the regulator. Careful planning is needed and the specific demands of the project in question have to be considered.

Lessons learnt

- Perhaps the clearest lesson to emerge from the session is the need for the regulator to manage their own knowledge and capabilities.
- The requirements for knowledge are demanding.
- Training should utilise several different approaches.

Commendable practices

Knowledge

Regulator should make sure that there is sufficient knowledge and understanding of management systems and management system requirements in the regulator's own organisation. This is especially important when a new licensee organisation is being built from the ground up.

The regulator also has to be able to ask the right questions concerning project management. Therefore, expertise in this area is also required. The regulator has to understand what is the logical order of performing activities in a vast new build project.

The regulator should also have understanding about organisational design and development of organisations and HR practices.

Regulator shall also have safety culture expertise. Developing good safety culture can be challenging in a new build organisation especially if people in key positions have a background from outside the nuclear industry.

Human Factors Engineering (HFE) capabilities and understanding what HFE means in the design phase are important factors.

Financial “competence” of the regulator

- It was discussed that the regulator needs to understand to an extent the financial realism and motivators in projects.
- It was stated that NRC performs a financial review (realistic planning, waste taken into account etc.).
- Does sound financial planning reduce the risk of potential safety culture issues?
- Regulators own competence of licensing is important because the regulator needs to instruct licensee and set clear expectations.
- Supply chain supervision/management, including supplier qualification and readiness assessment.
- Regulator should have the capability to assess vendor & supplier quality and project plans.
- Regulator should have understanding of development and assessment of design authority capabilities & engineering and design processes.

In general, previous experience in nuclear projects (which have a specific nature) is important and experiences should be shared within the regulator.

Observational skills and interview skills are also important for example in detection of so-called weak signals. Developing language skills can also be a big plus because supplier documents can be written in any language.

Other fields where the regulator should ascertain competence are:

- corporate governance;
- high-level nuclear legislation knowledge (e.g. legal interpretation of licensee “prime responsibility”);
- knowledge 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.

Training

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 – regulator competence needs to be at a high level in order to succeed in this.

Knowledge gaps should be identified and training planned based upon this analysis.

Training should be planned and executed systematically and thoroughly. Theoretical and practical skills, understanding the role of the regulator are important focus points. 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 was seen as important in addition to theoretical knowledge. Short (e.g. 3-6 months) work “visits” at another country’s regulatory body can also be beneficial.

Attracting experienced/skilled staff

Strategic approach should be utilised in attracting people. Planning is important and it should be understood what the outlook in the near and far future is. Needed resources should be identified based on this approach.

The regulator should also provide competitive pay and stable working conditions and give employees the possibility to affect their own work. There are probably differences between countries; some might offer more incentives, which might be beneficial in attracting new employees.

It is possible to use headhunting and sometimes possible to use outside organisations in supporting roles in oversight. Regulator work is challenging work and it should be emphasised that there exist many possibilities to utilise 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.

It was discussed whether there should there be an internationally recognised master’s degree for regulators (or some sort of an extended course).

Emphasising the unique safety mission can also be a possible way to attract some individuals.

Transitioning regulators from dealing with long established licensees to new build organisations:

The regulator should make sure that understanding of emerging technologies (e.g. small modular reactors) is up to date. It is also important to understand that the new licensees can have very low competence when they are starting: New build organisations understanding of licensing and other regulatory expectations can be lacking.

Professional contacts have to be newly established and communication methods between the regulator and licensee have to establish.

Transitions within the regulator need to be planned so that oversight of operating plants is not compromised.

Regulators in new build environments need to have a flexible and constructive approach, recognise the high dependence on the supply chain, 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. turnkey can be “dangerous” and sometimes impossible in practice) is important.

Session 2.2 – Engagement strategies

Introduction

Session 2 was about regulatory challenges with new licensees. One of the challenges for the regulator is their engagement with new build organisations or new licensees. The regulator needs to develop a strategy to cope with that. In sub-session 2.2 the following four questions were discussed:

- When should you engage with new build organisations?
- How should you engage with new build organisations?
- Should you engage with parent bodies, if so when and how?
- Should you engage with contractors/suppliers, if so when and how?

Table 4.6 below provides a summary of the Breakout Session 2.2. The full session notes follow this summary.

Table 4.6: Summary of the Breakout Session 2.2

Session 2: Regulatory challenges with new licensees: 2.2 Engagement strategies	
Lessons learnt/ commendable practices	<ul style="list-style-type: none"> • Proportional early engagement: <ul style="list-style-type: none"> - level of engagement depends on structure; - state run licensee versus co-operate licensee. • “New and novel” requires more involvement: licensee, parent bodies, contractors, supplier. • Be transparent, publish/communicate: <ul style="list-style-type: none"> - requirements & guidelines; - important outcomes of decisions; - process & engagement strategy. • Use different ways to communicate with management and experts: <ul style="list-style-type: none"> - 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.
Identified challenges	<ul style="list-style-type: none"> • Complex models of ownership: <ul style="list-style-type: none"> - influence of safety-related decisions by parent organisation, they have the money; - risk management during different phases. • Foreign contractors/suppliers/designers: <ul style="list-style-type: none"> - interpretation of regulation/guidance; - control of supply chain of safety-relevant items.

Position paper response summary

The session members contributed the next views, beliefs or ideas about the four questions:

When should you engage with new build organisations?

Most participants agreed that engagement should be organised as early as possible aiming to get informed, to clarify requirements and processes, for mutual understanding. In practice the procedures differ per country, depending on the national legal system. Engagement is often a voluntarily process.

How should you engage with new build organisations?

Engagement can be organised by meetings, workshops, document review and joint training. In some countries engagement is based on regulator pre-licensing process arrangements.

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

The participants expressed different opinions on engagement with parent bodies. Some regulators do engage because parent bodies influence their applicants. Other regulators do not want to engage with the parent body because the applicant is primarily responsible.

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

Again, different opinions arose from the participants on engagement with contractors/suppliers. Some regulators do not (or limited) engage with contractors/suppliers because the applicants are primarily responsible. Other regulators do engage with contractors/suppliers by inspections because contractors/suppliers provide safety-related work/goods/services.

Discussion summary

When should you engage with new build organisations?

The regulators have different approaches to engaging with new build organisations due to the various national conditions and systems.

The extent to which engagement is encouraged differs from necessarily, voluntarily or on request. In most countries every organisation can apply and it is also perceived as an informal process to give guidance and support to the licensee.

In case of a state run licensee engagement is not required. Also is the case that a pre-condition is that the new build organisation is suitable for its task, engagement is deemed not necessary.

How should you engage with new build organisations?

Engagement process should be structured and used to discuss different topics like organisation development, preparation of the safety case, license compliance issues, legal issues and security issue. In addition, the timing of deliverables should be discussed.

It is preferable to have communication on all levels in the engagement process.

For the engagement process communication via different media was suggested. These media includes: meetings, websites, presentations, workshops, workshop, joint training, review of documentation, assessment and (multidisciplinary) inspections.

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

Generally the participants agreed that there should be engagement with the licensee and not with parent organisation, “unless we have a good reason”.

It should be kept in mind that the appearance of parent bodies can differ a lot.

A parent body can:

- inform regulator in case of new built (state run licensees);
- have technical capabilities, more than a licensee;
- be relatively new (corporate licensee);

- support/delay the process.

In some countries an assessment is required on the minimum financial qualification of the parent bodies and the amount of influence on decision making/communication. Some countries foreign parent bodies are not allowed.

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

Direct engagement with contractor/supplier can be organised by:

- pre-licensing vendor design review process;
- assessing their ability to ensure the safety of power plants;
- inspecting the quality of materials and equipment on locations away from the nuclear site.

The participants agreed that indirect engagement can only be organised through the applicant:

- by inspection programmes, but all communications through applicant;
- by means of quality assurance (QA) or supplier/vendor inspection programme.

Some regulators used a combination approach of direct and indirect engagement.

Lessons learnt

The next items were indicated as learning points:

- proportional early engagement:
 - level of engagement depends on structure;
 - state run licensee versus co-operate licensee.
- “new and novel” requires more involvement;
- licensee, parent bodies, contractors, suppliers:
 - be transparent, publish/communicate.
- requirements and guidelines;
- important outcomes of decisions;
- process and engagement strategy:
 - use different ways to communicate with management and experts.
- workshops, website, training workshops, meetings:
 - always be open for discussion on interpretation of safety requirements;
 - 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.

Commendable practices

Engagement process should be structured and used to discuss different topics like organisation development, preparation of the safety case, license compliance issues, legal issues and security issue. In addition, the timing of deliverables should be discussed.

It is preferable to have communication on all levels in the engagement process.

Identified challenges

- Complex models of ownership:
 - influence of safety-related decisions by parent organisation (they may decide on budgets).
- Foreign contractors/suppliers/designers:
 - interpretation of regulation/guidance;
 - control of supply chain of safety-relevant items.

Areas warranting further work

See identified challenges.

Others

None.

Session 2.3 – Development of guidance*Introduction*

This session focused on the guidance that is required to effectively regulate the development of new licensee organisational capability. The questions used as a basis for discussion were:

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

Table 4.7 below provides a summary of the Breakout Session 2.3. The full session notes follow this summary.

Table 4.7: Summary of the Breakout Session 2.3

Session 2: Regulatory challenges with new licensees: 2.3 Development of guidance	
Commendable practices	<ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - design authority – definition and implementation; - guidance for organisational configuration control: <ul style="list-style-type: none"> • including organisation change management; • to enable design configuration management. - guidance on safety culture and leadership. • Including contractors: <ul style="list-style-type: none"> - regulatory expectation of licensee organisation structure and resource: <ul style="list-style-type: none"> • resource plan, resource model, justification e.g. baseline (core capability); • organisation design principles (new guidance identified); • life cycle management (new guidance identified). - procurement and supply chain: <ul style="list-style-type: none"> • including major EPC contract; • specification management of supply chain. - intelligent customer capability and use of contractors.
Identified challenges	<ul style="list-style-type: none"> • 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.

Recommendations	<ul style="list-style-type: none"> • Workshops or other fora to share international good practice and develop guidance: <ul style="list-style-type: none"> - 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.
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Position paper response summary

Most countries identified a core set of areas that regulators need to focus on when reviewing new build organisations. These included the development of competence and resource, safety culture, integrated management systems and design & construction capability. However, gaps in guidance were also identified and these formed the substantive basis for the group discussion.

Discussion summary

The discussion commenced by identifying guidance needed to enable regulatory oversight of the development of new licensee organisational capability. The group identified candidate areas for guidance. Subsequently the group identified where existing guidance directed towards oversight of operating facilities was generally adequate, in need of revision to better meet the needs for oversight of new licensees, or absent. Suggestions to address gaps in guidance were proposed by the group and are captured in the recommendations section below.

Lessons learnt

The group identified that:

- There is some existing guidance that can be used for new licensees in its current form:
 - training and competence;
 - integrated management system (esp. well defined structure and integrated links between teams to communicate issues/decisions/request help).
- There is a need for new guidance for new licensees:
 - 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).

There is a need to tailor existing guidance for existing licensee for a new build licensee:

- 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) (United Kingdom – core capability);
 - organisation design principles (new guidance identified);
 - life cycle management (new guidance identified).
- procurement and supply chain:
 - including major EPC contract;
 - specification management of supply chain.
- intelligent customer capability and use of contractors.

Identified challenges

The group then went on to identify challenges to developing international guidance:

- 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.
- Countries can have different legal frameworks and different national cultures where development/implementation of international guidance can be challenging.
- 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.

Areas warranting further work

Several areas of further work were identified in order to propose a way to develop, gather and share international guidance.

- NEA/IAEA could facilitate lifecycle/thematic (see Lessons learnt for potential thematic topics) 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 Specific Safety Guide (SSG) 38 to consider learning from recent construction experience.
- Encouraging wider use of WGRNR ConEX database to capturing relevant regulatory experience including the identification of gaps in guidance.

Session 2.4 – Interfacing with other regulators

Introduction

This session focused on the topic of interfacing with other regulators based on four questions:

- Are you legally required to engage with other regulators?
- How and when do you engage?
- Do you co-ordinate regulatory activities with the new licensee?
- Which stakeholders do you engage with and how?

Table 4.8 below provides a summary of the Breakout Session 2.4. The full session notes follow this summary.

Table 4.8: Summary of the Breakout Session 2.4

Session 2: Regulatory challenges with new licensees: 2.4 Interfacing with other regulators	
Lessons learnt/ commendable practices	<ul style="list-style-type: none"> • 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 (Multinational Design Evaluation Programme) to facilitate joint vendor inspections.
Identified challenges	<ul style="list-style-type: none"> • Co-operation 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.

Position paper response summary

In ten countries, position paper answers were given on each question to be discussed in this sub-session. A summary of the responses is given and points of special interest are highlighted.

Are you legally required to engage with other regulators?

Generally, the reporting countries indicated that there is no legal requirement to engage with other regulators, domestic or international. The exceptions to this are in Hungary, Russia and the United Kingdom.

In Hungary, the requirement to engage applies only during licensing procedures. In Russia, the requirements are based on the competencies within the framework of inter-agency agreements. The ONR (United Kingdom) is obligated under the Energy Act 2013 to co-operate with the Health and Safety Executive (HSE) where HSE is the primary Competent Authority. ONR has also entered into various Agency Agreements and Memoranda of Understanding with other government departments and regulators to clarify respective responsibilities. These agreements, however binding, are not legal requirements.

How and when do you engage?

The means by which engagement occurs can differ depending on the nature of the interaction and on the stage of the programme. In Hungary, the use of an electronic government channel is required for inter-regulatory communications that regard licensing issues. There also exist strict rules of engagement, which are stipulated in legally binding administrative regulations. On other subjects, the use of traditional communication methods is acceptable (e.g. email, phone, etc.). Hungary also enhances inter-regulatory co-operation through annual meetings.

STUK (Finland) reports the frequency of meetings with other safety regulators is occasional and these meetings typically take place in public discussion fora. Korea Institute for Nuclear Safety (KINS) engages with other regulatory agencies through meetings or workshops organised by the Nuclear Safety and Security Commission (NSSC), while the NRC (United States) reports that engagement with other regulators occurs most often during the lead up to and review of licence applications.

On the basis of inter-agency agreements, Rostechndzor (Russia) engages experts from other regulatory bodies to participate in:

- development of federal rules and regulations on the use of nuclear energy and other documents establish requirements for NPP safety;
- conducting inspections and audits and other measures of control of operations, modernisation, life extension, and decommissioning of NPPs in order to make mutually agreed decisions;
- training and professional development of employees that oversee aspects of NPP safety.

The ONR (United Kingdom) engages with other regulators on a continual basis in a variety of ways, including:

- conduct of joint inspections;
- staff secondments;
- information exchange (between national regulators);
- publication of joint guidance;
- co-operation in investigations.

Do you co-ordinate regulatory activities with the new licensee?

There was limited information provided by the country respondents in response to this question. From the responses received, there is consensus that co-ordination is important especially in the early stages of new projects. The ONR (United Kingdom) has specified a process to manage the co-ordination with prospective licensees. This involves a joint process for generic design assessments and a joint programme for new reactor licensing and construction. These activities focus on co-ordination primarily with the Environment Agency and include structured interactions with prospective licensees and monthly programme meetings between the ONR, Environment Agency (EA), and the prospective licensees.

The NRC (United States) keeps prospective licensees aware of their efforts interface with other federal regulators, state and local governments, and the American Indian Tribes. However, the NRC (United States) does not necessarily co-ordinate these interfaces with new licensees.

In the cases of KINS (Korea) and Rostechnadzor (Russia), there is no co-ordination of regulatory activities with prospective licensees.

Which stakeholders do you engage with and how?

The term “stakeholders” was understood by most respondents to represent a broader population than just other regulators and involves all parties who may have an interest in the development of the project.

The CNSC (Canada) interfaces with several stakeholders including other regulators. These interfaces take place mainly to address items related to advanced reactor designs through working groups, technical meetings, and international seminars and workshops (e.g. NEA, IAEA, small modular reactors (SMR) fora).

The ONR (United Kingdom) engages with a variety of stakeholders in relation to new licensing, including:

- site stakeholder groups;
- government, including the Department of Business, Energy and Industrial Strategy;
- other national regulators;
- WENRA Reactor Harmonisation Working Group (RHWG);
- NEA Multinational Design Evaluation Programme (MDEP);
- the media and general public.

Similarly, Hungary actively engages with the following stakeholders:

- new build licensee;
- other licensees as needed (e.g. neighbouring nuclear installations);
- other regulatory bodies;
- suppliers (through or in the presence of the licensee);
- government organisations;
- the media.

The public, non-governmental organisations and various third parties are engaged with as needed.

KINS (Korea) participate in periodic regional committee meetings to discuss safety issues and matters of public concern. FANR (United Arab Emirates) also hosts periodic public fora to educate the public and other stakeholders about nuclear power and the UAE nuclear power programme generally.

In the preparation/revision of regulations, Rostechndzor (Russia) closely co-operates with organisations of the principle reactor designer, general NPP designer, and scientific organisations. Rostechndzor also co-operates with the State Corporation Rosatom and, as needed, with local authorities.

In addition to engaging with several of the same types of stakeholders as mentioned above by Hungary and the United Kingdom, the NRC (United States) reaches out to local stakeholders (e.g. advocacy organisations) in the vicinity of where new NPPs are proposed to provide information on regulatory requirements and address other issues of concern.

Discussion summary

Are you legally required to engage with other regulators? How and when do you engage?

The above questions are grouped here as the discussion of these questions overlapped significantly. Regarding 2.4.1, the group agreed that the interpretation of “other regulators” includes both domestic and international regulators.

With regards to engagement with domestic regulators, the ONR (United Kingdom) uses the law proactively to engage with other agencies and meets its obligations for engagement through:

- memoranda of understanding (MOU) with other government departments and regulators;
- strategy consultant teams, which provide advice to government;
- conduct of joint inspections with defence nuclear safety regulator and EA is also well established.

Russia discussed challenges with adopting international documents and approaches, having difficulties to find compatibility with Russian national culture.

Canada has no legal engagement requirement. Their regulatory documents are heavily influenced with IAEA documents. The UAE uses a “working group” approach to engage with other domestic regulators, in an effort to harmonise their approaches.

The group agreed that problems in supply chain for new build often can be attributed to differences in approach between the country of the supplier and the country building the new NPP. These problems can arise due to differences in legal and regulatory frameworks. This emphasises the need and usefulness of co-operation between the country regulators.

Regulatory bodies from several states also voiced that they face challenges in co-ordinating joint inspection activities within their own agencies (e.g. joint inspections for safety and security).

Poland has some requirement for engagement with other domestic agencies. They have in past conducted joint inspections on research reactor safety and are developing further approaches.

Do you co-ordinate regulatory activities with the new licensee?

There was little discussion on this topic other than general consensus that co-ordination is part of the normal engagement activities discussed above.

Which stakeholders do you engage with and how?

There was no further discussion on this topic other than that reported above.

Lessons learnt

The lessons learnt gathered during this sub-session are:

- There are differences in approach between countries. Some countries have requirements regarding engagement, some not. Some engage through informal means, others through more formal means (manifestos, agreements, etc.)
- Regardless the approach, regulatory bodies usually find a way to co-ordinate according their national specifics and context.
- 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 (NEA MDEP presents a suitable forum).

Commendable practices

The following points are to be considered as commendable practices:

- To share the regulatory progress openly and publicly. This helps other agencies to step into processes. It shows consistency, shows the whole plan to the future; especially what the inspection plan is and what stakeholders can expect.
- Share training capacity with other regulators. Several regulators have common activities that can be jointly trained on (e.g. conduct of inspections).
- It is beneficial to have government activity, which annually gets all government departments and agencies to communicate and share information.
- MDEP (NEA) facilitates 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.

Identified challenges

- International engagement may be challenging due to differences in national cultures.
- Given the nature of nuclear industry stakeholders the range to engage is very wide.
- There is also new group of stakeholders from financial area (investors), which are interested in the regulatory process. Regulatory body has to adapt to cope and communicate accordingly.
- In co-operation with foreign regulatory bodies, the differing levels of openness to public may bring new problems.

Areas warranting further work

The area of SMRs is advancing with the need for new regulations and sharing of information, which can be enhanced through effective and structured engagement between both domestic and international regulators.

4.3 Breakout Session 3 – Oversight of contractors and suppliers by new licensees

Session 3.1 – Balance between new licensee capability and reliance on contractors

Introduction

This session examined the balance between new licensee capability and reliance on contractors. It considered the factors influencing the correct balance and regulatory expectations on the role of the licensee as an “intelligent” or “informed” customer, use of “embedded” contractors and use of, and reliance upon, an owner’s engineer by the licensee. The following questions were used as a basis for discussion:

- Where is the correct balance?
- What are your expectations for the role of the IC?
- What are your expectations for the use of embedded contractors?
- What should be your expectations in the use and reliance upon an owners engineer?

Table 4.9 below provides a summary of the Breakout Session 3.1. The full session notes follow this summary.

Table 4.9: Summary of the Breakout Session 3.1

Session 3: Oversight of contractors and suppliers by new licensees: 3.1 Balance between new licensee capability and reliance on Contractors	
Lessons learnt/ commendable practices	<ul style="list-style-type: none"> • 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.
Identified challenges	<ul style="list-style-type: none"> • 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

	<p>expectations.</p> <ul style="list-style-type: none"> • 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”, “seconded”, etc. and hence their legal status (sometimes considered as employees, sometimes as contractors).
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Position paper response summary

Ten member states provided a response to the position paper prior the workshop.

Where is the correct balance between new licensee capability and reliance on contractors?

The majority of responses emphasised that it is the licensee who has prime responsibility for safety, i.e. it is the licensee who should be in control and should possess certain core competences and resources such as a design authority (IAEA INSAG-19 refers) and emergency response capability.

Some responses indicated that the suitability of the balance between licensee capability and reliance on contractors depends on the circumstances. For example, early in the lifecycle of a project, the licensee may not have all the detailed, specialised knowledge required of the plant’s systems and components and it would be expected to demonstrate how it will acquire a suitable and sufficient design authority capability over time.

What are your expectations for the role of the ‘intelligent customer’?

Some countries have set expectations for the licensee’s role as “intelligent customer”, others have not.

Where expectations have been set they focus on:

- the selection of contractors and preparation of an adequate specification (with due priority to safety);
- the supervision of the contractors work; and
- the assessment of whether the product or service meets the specification.

What are your expectations for the use of embedded contractors?

Specific expectations for the use of embedded contractors have been set by some countries, e.g. that such contractors are subject to the licensee’s processes for competence assurance, line management, discipline and succession planning (*Function and Content of the Nuclear Baseline*, NS-TAST-GD-065, United Kingdom).

What should be your expectations in the use and reliance upon an Owner’s Engineer?

No countries appear to have specific expectations in relation to use of an Owner's Engineer by the licensee. However, the general expectations (Section 3.1.1 above) in relation to the licensee's core capability apply. Some countries expressed the benefits of the Owner's Engineer being an in-house function.

Discussion summary

The following sections summarise the key points of the discussion on the balance between new licensee capability and reliance on contractors, taking into account the position paper summary (above).

Where is the correct balance between new licensee capability and reliance on contractors?

The discussion reaffirmed that the primary responsibility for safety rests with the licensee. Additional points of good practice were noted as follows:

- 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.
- The primary focus of the regulator should remain with licensee.
- The licensee should establish a system for learning from experience within its own organisation and its contractors.
- There should be an appropriate balance between new starters and experienced personnel to ensure that the key steps during the commissioning are achieved safely.
- Knowledge should be actively managed throughout the project lifecycle.

What are your expectations for the role of the 'intelligent customer'?

From the discussion, it was noted that the term 'intelligent customer' is not widely used. However, the basic concept is well understood and derives from significant international operating experience, such as the Paks nuclear power plant event (2003) and Buncefield oil storage depot fire (2005).

IAEA General Safety Requirements (GSR) Part 2 (Leadership and Management for Safety) states that an organisation "shall have a clear understanding and knowledge of the product or service being supplied". It terms this capability "informed customer".

It was noted that neither the licensee (nor regulator) should rely solely on experience or the good name of a contractor. Furthermore, there have been examples where a licensee was not aware of the lack of competence of a contractor.

What are your expectations for the use of embedded contractors?

It was apparent from the discussion that not all countries use the term "embedded contractor". In addition, there are related terms such as "seconded", "expatriate" and "temporary worker". The legal status of such workers varies from country to country; they are sometimes considered as employees, sometimes as contractors. In the case of the former, intelligent customer oversight may not be required whereas in the case of the latter it would be required.

It was noted that licensees need to be careful about the potential conflicts in the loyalty of embedded contractors. In their oversight activity, regulators may need to seek assurance of the longer-term security of seconded employees with regard to their potential redeployment to other licensees or projects. It was

agreed that within each country there should be clarity on the definition of embedded contractors, which will then give clarity of the scope of application of the licensee's intelligent customer oversight.

Some regulators considered it acceptable for embedded contractors to fulfil part of the intelligent customer role of a licensee see provided that:

- such contractors are fully embedded in the licensee's organisation, i.e. subject to the same processes of competence assurance, knowledge management etc. as employees; and
- the licensee understands its vulnerability to the use of embedded contractors and this is being effectively managed.

What should be your expectations in the use and reliance upon an owner's engineer?

It was apparent that not all countries use the term "owner's engineer", which also does not appear in the IAEA's glossary. The role of the owner's engineer has however been discussed in IAEA technical meetings and has been defined as "an independent party representative of the owner of a construction or engineering project" or "the provider of comprehensive support (a technical support organisation) or engineering, procurement and construction management". The consensus of the discussion was that licensee should retain a core capability as summarised in the position paper response summary (Section 3.1.1) above.

Lessons learnt and commendable practices

Lessons learnt and commendable practices in the area of new licensee capability and reliance on use of contractors were identified, as summarised below.

Where is the correct balance between new licensee capability and reliance on contractors?

Commendable practices identified were:

- The requirement that there should be no more than three layers of subcontracting in the commissioning and operations phase of a project (Sweden).
- The requirement that the number of subcontracting levels should be kept as low as possible (France).
- The 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 (France).
- The 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 (France).

What are your expectations for the role of the "intelligent customer"?

Commendable practices identified were:

- The United Kingdom's technical assessment guide NS-TAST-GD-049, *Licensee Use of Contractors and Intelligent Customer Capability*.

- The development and implementation of a design assurance model by a United Kingdom new build licensee providing:
 - a definitive reference for design assurance on the project and means of communication to project teams, designers and external stakeholders; and
 - increased visibility and confidence in the designer’s internal assurance processes,
- The requirement that the licensee should implement a system to collect information from the contractors (France).
- Other useful sources of good practice identified were:
 - 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).

What are your expectations for the use of embedded contractors?

A commendable practice identified was clarity on the application of intelligent customer oversight, i.e. that oversight is not required for embedded contractors (United Kingdom).

What should be your expectations in the use and reliance upon an owner’s engineer?

A commendable practice identified in France was clarity on the degree to which licensees can be assisted in oversight of the supply chain. Contracting out oversight of the supply chain is not permitted, however in specific circumstances an external company may be used to provide assistance, provided that the licensee retains the competence to control oversight of the supply chain and that the organisations providing assistance have the necessary skills, independence and impartiality.

Identified challenges

The workshop identified several challenges in the area of new licensee capability and reliance on the use of contractors, as detailed below.

Where is the correct balance?

- 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.

What are your expectations for the role of the “intelligent customer”?

- There may be a need for a country to rely on overseas contractors until its own capability in specialist areas, e.g. nuclear security, is established.

- Regulators should test the implementation of the licensee’s procurement process, e.g. the selection of contractors.

What are your expectations for the use of embedded 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.

Areas warranting further work

Workshop participants observed a gap in the common understanding of the term “owner’s engineer” and the implications for licensee’s competence and capability.

Session 3.2 – The EPC model

Introduction

This session was focused on the expectations and challenges of management and oversight of the engineering, procurement and construction (EPC) management model of new reactor construction. It also explored the concept and expectations of an intelligent customer (IC). The following questions were used as a basis for discussion:

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

Table 4.10 below provides a summary of the Breakout Session 3.2. The full session notes follow this summary.

Table 4.10: Summary of the Breakout Session 3.2

Session 3: Oversight of contractors and suppliers by new licensees: 3.2 The EPC Model	
Lessons learnt/ commendable practices	<ul style="list-style-type: none"> • 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, pre-defined 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

	<p>do foreign audits.</p> <ul style="list-style-type: none"> • To ensure that the licensee verifies the EPC contractor’s work quality and supply chain : <ul style="list-style-type: none"> - 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 on-site resident inspectors during construction. • EPC organisational model – constantly inspect the arrangements against good practices and for effectiveness.
<p>Identified challenges</p>	<ul style="list-style-type: none"> • 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 organisations • 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.

Summary

Because of the downsizing of nuclear power plant licensee organisations within the past couple of decades, licensees began contracting out responsibilities for certain activities previously performed by the licensee’s staff. As such, the regulator for the United Kingdom – The Office of Nuclear Regulation, determined that licensees need to have a level of knowledge of plant activities that make them an “intelligent customer”. The questionnaire and discussion session revealed a general unfamiliarity with the EPC model and the concept of an IC outside of the United Kingdom.

Nevertheless, the session also revealed that even though these concepts were developed in the United Kingdom, the challenges that have been and are being faced in the United Kingdom are not unique. The loss of domestic manufacturing industries, increased globalisation, and economic pressures to reduce licensee staff have created similar EPC management models in other countries.

The countries facing these changes have adapted their regulatory oversight and licensing structures to account for the EPC model of new reactor licensing and have developed concepts and criteria to assess licensee’s capabilities at being effective IC. Some best practices and challenges from the regulatory experience is captured below.

Responses

In answering the postulated questions, several “best practices” and expectations were gathered during the information collection:

What should be your expectations for the oversight of the EPC contractor by the new licensee?

- Licensees shall have very active oversight and conduct regular audits.
- Licensees shall confirm that the EPC contractors have a strong understanding of the requirements and the ability to communicate them.
- Licensees shall confirm that the EPC contractor demonstrates 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 in the long term. These competencies must be available in-house, in subsidiaries or in companies under its control.
- Licensees 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 contractors.
- 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 quality assurance (QA) programme 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.

What are your expectations for IC in relation to the EPC?

- The IC shall oversee every entity in the supply chain.
- The ultimate responsibility for safety rests with the licensee. The licensee must demonstrate sufficient knowledge of the plant design and safety case for all plant 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 resources within the licensee organisation to oversee the activities.

Discussion session

- During the discussion session, the group identified several best practices and challenges/gaps.

Best practices

- Licensees must have the primary responsibility for safety at the plant.
- The licensee must be an intelligent customer and must be active and responsible in the supply chain.
- The licensee must audit, assess, and approve suppliers. The approach can be graded.
- The regulator must get involved with the licensees as they develop the contract. Ensure the proper clauses are included that allow for oversight and inspection of activities.
- Project hold points requiring approval by the regulator to proceed to next phases are positives for the project.
- Licensees should have a formal, transparent, pre-defined 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 – licensees and regulators should develop mechanisms for the regulator and licensee to evaluate foreign contractors (legal or contractual).
- Regulators should 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;
 - the focus should be on high safety significant items;
 - manufacturing schedules should be shared, thereby enabling sampling inspections, staged construction inspections, and ad hoc sampling inspections;
 - information should be shared from other construction projects;
 - on-site resident inspectors should be there during all phases of construction.
- To evaluate the EPC organisational model, the regulators should constantly inspect the arrangements against good practices and for effectiveness.

Challenges/gaps

- Foreign ownership – shareholders expect subsidiary companies to get a share of EPC contracts. This ownership relationship affects the transparency of EPC contract awards.
- The stability of foreign companies may be a question. It is good to have backup plans for suppliers.

- Some companies work in the war industry. Significant advance notice for the inspections of manufacturing may be required.
- There is no regular mechanism to capture lessons learnt from other constructing organisations.
- Turnkey contracts create an uninformed licensee and would be detrimental to safety.
- Foreign contactors may not understand the regulatory requirements/framework of foreign regulator.
- There are no indicators or measurements of the minimum level of capabilities of an IC, though ONR of the United Kingdom has developed criteria.

Session 3.3 – Supply chain

Introduction

This session focused on the arrangements for effectively regulate the Licensee’s supply chain and if the supply chain understand regulatory requirements. The following questions were used as a basis for discussion:

- 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?

Table 4.11 below provides a summary of the Breakout Session 3.3. The full session notes follow this summary.

Table 4.11: Summary of the Breakout Session 3.3

Session 3: Oversight of contractors and suppliers by new licensees: 3.3 Supplier surveillance	
Lessons learnt/ commendable practices	<ul style="list-style-type: none"> • 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).

Position paper response summary

Several countries identified that when regulating the licensee's supply chain (SuC) they had direct authority defined in legislation to inspect the supply chain. Other regulatory bodies had the ability to inspect the supply chain as a result of the licensee's contractual requirements or certificate that is granted to the licensee. Other regulatory bodies relied on the licensee's arrangements and the supply chain's alignment to defined best practice standards.

The majority of regulatory bodies stated that it was the licensee's responsibility to establish adequate supply chain management arrangements and to manage their requirements through dedicated contracts.

With regard to licensee oversight of their suppliers, the regulatory bodies all provided similar answer that was based on the "smart buyer" or IC function and that the licensee should understand how the supplier will meet the licensee's request and to help the supplier understand the safety and cultural requirements of the nuclear industry.

Discussion summary

The discussion focused on three aspects of SC regulation outlined below:

Legal framework for supply chain regulation

The discussion commenced by asking the regulatory bodies present if they had the legal framework to adequately regulate the use of the supply chain. The regulatory bodies present felt that overall, they did have an adequate legal framework to regulate the use of the supply chain. It was considered that inspection activity needs to effectively balance specific technical aspects, quality management system arrangements and leadership and management for safety issues.

Supply chain understanding of regulatory requirements

The discussion then focused on nuclear industry SuC understanding of the regulatory requirements. The group concluded that 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 group believe that licensee and regulator focus in the SuC should consider a risk and performance based approach. It was considered that relying on a performance based approach alone would not identify unrevealed failures, i.e. potential for counterfeit or fraudulent certification records. Therefore, some degree of vendor inspection was considered appropriate to directly assess performance and product/service record.

Regulatory guidance

The final part of the discussion was based on the regulator's expectation of how new licensee's would oversee their supply chain and if there was sufficient guidance for the regulator and the licensee.

It was concluded that new licensees should develop appropriate supply chain oversight arrangements that examine cultural/leadership aspects based on risks.

It was recognised that guidance exists, but understanding was 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 industrial guidance (i.e. NP-T-3.32 and ISO 19443).

Lessons learnt

The group identified that:

- Experienced suppliers to the nuclear industry have developed principles to comply with regulatory requirements. There was uncertainty on how new suppliers would interpret and understand the regulatory requirements of working in the nuclear sector.
- Many SC companies understand the nuclear safety requirements, however, they face challenges in managing the associated infrastructure needed to meet the requirements. New companies may need the support of the licensee to ensure their staff understand the safety significance of the service they are supplying.
- The licensee cannot leave the supply chain to interpret the regulatory requirements by themselves. By communicating, the licensee helps the supply chain to understand what is needed which helps reduce the risk of non-right first time delivery.
- Requirements should apply proportionately. Greater risk issues should require a higher amount of oversight.
- Licensees should establish adequate oversight and assurance arrangements for supplier organisations (e.g. safety culture, management systems, collaboration meetings, etc.) and conduct acceptance testing of products and services.

Identified challenges

The group identified two challenges with regard to regulation and provision of information to the supply chain:

- As regulatory requirements are different in each country, a supplier that understands the requirement in one country may not understand the requirements in another.
- Issues with “cascadability” of highest risk procurement requirements that should apply consistently to suppliers further down tiers of the supply chain (i.e. Tier 2, Tier 3) without any deterioration to specified requirements.

Areas warranting further work

Through the discussion, two areas were identified where further work could be conducted to enhance the communication between the licensee and the supply chain

- An examination of methods to help the licensee/supplier to cascade high risk requirements through the organisation and its subcontractors
- Guidance should clarify the difference between assessing the capability of the supplier organisation vs. assessing the quality of the product

Session 3.4 – Project management*Introduction*

This session focused on the topic of project management and discusses the level of regulatory oversight necessary during the development and building of a new reactor. The aim of the session was to identify “commendable practices”, “challenges” and ‘areas warranting further work’. The following questions were used as a basis for the session:

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

Table 4.12 below provides a summary of the Breakout Session 3.4. The full session notes follow this summary.

Table 4.12: Summary of the Breakout Session 3.4

Session 3: Oversight of contractors and suppliers by new licensees: 3.4 Project management	
Lessons learnt/ commendable practices	<ul style="list-style-type: none"> • Early engagement with licensee. • Some Nuclear training for PMs with non-nuclear background.
Identified challenges	<ul style="list-style-type: none"> • 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.
Recommendations	<ul style="list-style-type: none"> • 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).

Position paper response summary

This section contains the consolidated responses to the 3 questions on regulating project management. The information was used to prompt the discussion during the dedicated session.

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

- A consideration to the role of design authority was mentioned, suggesting that the design authority should hold overall responsibility for the control of project design.
- It was suggested that modern project management methodologies should be used to ensure that the right outcome is delivered safely.

- Most countries did not have specific expectations related to project management and only consider this along with expectations on management systems.
- A common theme with most countries was that a focus should be given to safety throughout delivery of a nuclear project, which is where a nuclear project may differ from a conventional one. Having appropriate safety culture throughout the project was also stated as essential.
- A number of countries pointed out that due consideration should be given to the skills and experience of project managers and some suggested nuclear industry experience should be required.

Do you have sufficient guidance and cited best practice?

- The consensus was the project management requirements should be captured as part of a licensee's integrated management system. In addition, the licensee would oversee implementation within their organisation and the supply chain.
- There was a stated view that project management expectations are well defined in the Nuclear Safety Codes. This was debated during the session.
- The general view was that it is not easy to find good guidance or best practice related to the project management within a major nuclear project environment and there are a significant number of examples where nuclear projects have overrun on time, cost and potentially quality.
- Do regulators have the expertise to define guidance in this area?

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

- The general feedback was that regulators need to ensure appropriate safety considerations are given during key decision making (e.g. stage gate reviews).
- Consider the technical skills, qualifications and experience of the individual's and the organisations involved in delivering the project management. This should include culture.
- The use of competency frameworks to consistently assess technical and behavioural skills.
- Review financial capabilities of an organisation, noting this can drive behaviours and outcomes:
 - realistic budget;
 - relationship with the parent company;
 - financial resilience;
 - adequate provision for future activities.
- Consider the adequacy of the staffing levels of licensee and equally important is their supply chain.
- Effectiveness of the integrated management system in enabling safety-related decision making, within both the licensee and their supply chain.

Discussion summary

The section below provides a summary of the key points from the discussion, based around the 3 standard questions.

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

There was wide agreement that project management for a nuclear project is a fundamental part of building new reactors and should be given an appropriate level of consideration to ensure safety standards are maintained throughout the life cycle.

As part of this nuclear safety culture must be integrated with the project management requirements throughout, both within the licensee and their supply chain. There must be open debate, challenging and conservative decision making with an appropriate balance between the nuclear safety and project delivery. Furthermore stage gate reviews were suggested as a way to ensure that safety requirements are met before moving on to the next stage of the project lifecycle.

Project managers from non-nuclear backgrounds should be required to understand various aspects of a nuclear project including the hazards, risks, safety requirements and graded decision making.

Active engagement between the supply chain project managers and the licensee/future operators is essential. The role of intelligent customer should be integral to the management system and the organisational culture (*the way we do things*). The importance of effective transition management between the various stages of the project lifecycle was noted.

It was concluded that expectations and guidance for nuclear project management are required and should be developed to reflect the unique challenges faced by licensee in delivering a major nuclear project, while maintaining safety as an overriding priority.

Do you have sufficient guidance and cited best practice?

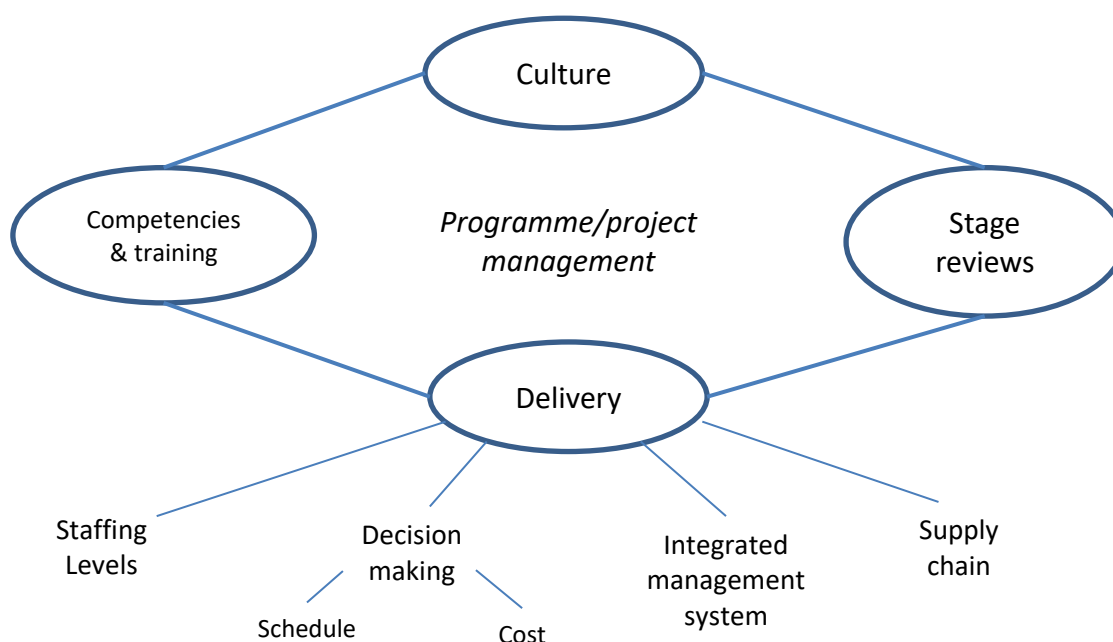
The discussion centred on the lack of specific guidance relating to managing major projects in a nuclear environment. It was noted that the intention would not be to produce guidance on how to manage a large-scale project, as there are already several professional bodies established who do this. But the aim would be to provide specific guidance relating to the nuclear context of delivery.

There was a general consensus that guidance on project management with regards to nuclear projects is scarce. The session concluded that there is not enough specific guidance in the area of project management for large nuclear projects.

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

Figure 4.1 was produced during the discussion and captures the key elements where project management should be assessed and influenced from the discussion.

Figure 4.1: Key elements



The session noted that a number of large-scale nuclear projects commence with a functional based organisational structure derived from their experience of operational facilities. These organisations tend to evolve into a programme/project based structure as the delivery demands of the project grow.

Regulators should seek to engage at the earliest opportunity while the new build organisation is still forming to share advice, guidance and make clear their expectations.

As regulators we need to establish where the project management capability has the potential to impact on nuclear safety. One area that was identified was the “stage gate” process, where a graded approach would need to be adopted based on safety significance. Due to the fact that projects of this nature represent significant financial investment, the balance between ‘cost, schedule and quality’ (ultimately safety) needs to be assured.

It was acknowledged that the new build organisations will be maturing throughout the different build stages; with the organisation capability progressively growing, procedures being developed and implemented, and resources/skill mix changing during each phase. As regulators we need to be mindful of these phases and gain assurance that knowledge is being effectively transferred and managed between the various project teams, particularly where safety could be directly impacted.

The session recognised the importance of nurturing a strong sustainable safety culture throughout the new build lifecycle (*design, construction, commission and into operations*), and the very notable impact the project management discipline can have on positively maintaining the appropriate culture through their leadership style and actions.

We discussed the requirement for competency frameworks to assess and understand any shortfalls within the skill base of the project management staff and ensuring there is a suitable training and development plan in place, adopting a similar approach used for other technical staff.

Holland shared how they have recruited people specifically to look at financial issues. This approach could be beneficial, with financial experts ensuring the credibility of a licensee. The session was mindful that an organisation's financial position can change due to a range of factors.

The session concluded that project management is a controlling factor during a new build project and there are attributes of the project management capability that a regulator could genuinely assess and influence, subject to developing the appropriate guidance framework.

Commendable practices

- Early engagement with the licensee was recognised as very beneficial in shaping an organisation's capability and establishing clear expectations, with regard to project management, culture, training and competence.

Identified challenges

- Project management capability is not a core discipline within the regulators and therefore the challenge is to understand it well enough to know where we can engage, provide advice and challenge the licensees.
- The lack of experience and skills in licensees and regulators with overseeing/managing large nuclear projects is a significant challenge.
- The identified lack of specific guidance for project management in a nuclear environment.

Areas warranting further work

- A review of current guidance on project management for nuclear projects (e.g. IAEA SSG-38).
- The session recommended specific project management guidance be produced, drawing upon and referencing other related topics to ensure adequate focus is given to:
 - safety culture;
 - decision making;
 - competencies/skills/training;
 - supply chain.

It was recommended that a workshop led by an international nuclear organisation e.g. IAEA, NEA, should be arranged to share learning between licensees and regulators in the area of project management. This learning would form the basis for developing project management specific guidance.

5. FUTURE WORK

Participants identified several topics for future work. The outputs are contained in the session summaries above and are provided (with amendments) below for clarity. The future work topics have been allocated to either the Working Group on the Regulation of New Reactors and the Working Group of Human and Organisational Factors.

5.1 Working Group on the Regulation of New Reactors (WGRNR)

The following future work topics are identified for the WGRNR:

- It was recommended that a workshop, led by an international nuclear organisation i.e. IAEA or NEA, should be arranged to share best practices between licensees and regulators in Organisational Capability through a nuclear reactor project lifecycle.
- It was identified that there is a shortfall in international guidance relating to independent internal regulation and that consideration should be given to developing guidance to give some clear guidelines to member states and individual licensees.
- The area of SMRs is advancing with the need for new regulations and sharing of information, this can be enhanced through effective and structured engagement between both domestic and international regulators.
- NEA/IAEA could develop guidance documents based on the gathered experience from lifecycle/thematic workshops, especially the pre-construction phase.
- IAEA to consider revising SSG-38 to consider learning from recent construction experience
- Encouraging wider use of WGRNR ConEX database to capturing relevant regulatory experience including the identification of gaps in guidance

5.2 Working Group on Human and Organisational Factors (WGHOFF)

The following future work topics are identified for the WGHOFF:

- A review of current guidance on project management for nuclear projects (e.g. IAEA SSG-38).
- Specific project management guidance could be produced, drawing upon and referencing other related topics to ensure adequate focus is given to:
 - safety culture;
 - decision making;
 - competencies/skills/training;
 - supply chain.

- General guidance, or a high-level document (type of green booklet), could be developed on organisational capability building. The publication should include organisational capability assessment methodologies as well as methods on how to establish organisational capability.
- Development of guidance on how to ensure that the supply chain meets the licensee's and the regulators expectation on safety culture.
- Development of guidance on how to support the development of organisational culture in the various lifecycle stages of the project in such a way that it fulfils the expectations of a strong safety culture.
- Development of guidance on how the licensee and suppliers should cascade high risk requirements through the organisation and its subcontractors.
- Development of guidance to clarify the difference between assessing the capability of the supplier organisation vs. assessing the quality of the product.

APPENDICES

The appendices are contained within the document NEA/CNRA/R(2017)6/ADD1. The 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 contain the slide packs (both session slides and feedback slides) of the breakout sessions;
- Appendix E contains summaries of the Breakout Sessions.

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