MULTI-SECTOR WORKSHOP ON INNOVATIVE REGULATION

Challenges and benefits of harmonising the licensing process for emerging technologies

14-18 December 2020
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Challenges and benefits of harmonising the licensing process for emerging technologies

Welcome

Day 1 – Monday 14 December
Opening remarks: objectives of the workshop, frame the challenges

Mr. William D. Magwood, IV
Director-General
OECD Nuclear Energy Agency (NEA)

Ms. Rumina Velshi
President and Chief Executive Officer
Canadian Nuclear Safety Commission (CNSC)
Opening remarks: objectives of the workshop, frame the challenges

Mr. William D. Magwood, IV
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Ms. Rumina Velshi
President and Chief Executive Officer
Canadian Nuclear Safety Commission (CNSC)
Innovative Nuclear Technologies and Harmonization

Innovation is impacting sectors around the world. We must ensure safety and readiness to regulate. Looking to other high-reliability sectors for lessons learned, opportunities and challenges. International collaboration is key – none of us has all the answers. Standards, requirements and frameworks must be commensurate with risks. Trust is essential among regulators and with the public and proponents.

Regulating risk from innovation safely, smartly and effectively.
Challenges for you to consider

I. Setting requirements that are risk-informed and allow for innovation and technical advancement

II. Leveraging lessons learned from other high-reliability sectors with nuclear regulators

III. Balancing harmonization and sovereignty

IV. Embarking on this journey while ensuring public trust

Innovation, harmonization, risk, sovereignty, trust and always safety
Session 2

The nuclear sector innovative regulation process: challenges to serve safety of emerging technologies
Session 2 - The nuclear sector innovative regulation process: challenges to serve safety of emerging technologies

POLL
Mr. William RANVAL
Director of ENISS (European Nuclear Installations Safety Standards)
The concept of European Reactor Design Acceptance (ERDA)

OECD/NEA Zoom Webinar – 14-18 December 2020

MULTI-SECTOR WORKSHOP ON INNOVATIVE REGULATION: CHALLENGES AND BENEFITS OF HARMONIZING THE LICENSING PROCESS FOR EMERGING TECHNOLOGIES

ENISS - William Ranval
OUTLINE

1. Introduction – General Considerations

2. Presentation of the ERDA concept (European Reactor Design Acceptance) European Nuclear Energy Forum (ENEF), 2012

3. Presentation of a Common European Pre-licensing Process “Benchmarking of nuclear technical requirements against WENRA safety reference levels, EU regulatory framework and IAEA standards” from Enco report for the European Commission, 2019

4. Open Questions / Key Enablers
1. Introduction – General Considerations (1/2)

What are the main objectives of a multi-national acceptance process?

✓ Enable project deployment through a reduction in licensing risk and uncertainties, through a stepwise and timely process
✓ Standardization in Design / Manufacturing / Erection
✓ Positive knock-on effects, e.g. encourage innovation for more competitive and safer solutions, facilitate funding

What has been different in the last decades?

✓ Rather small global market
✓ Investment by privately owned companies in highly competitive markets
✓ Competition with subsidized renewable generation in de-regulated markets
✓ Lessons learnt from NPP events, improvements in knowledge and computation capabilities, societal and political positions, have lead to much more stringent requirements / expectations
✓ Emergence of a more innovative period, with new expectations: SMRs and several technologies are making promises
A key invariant: the need for the regulators to build high confidence, independently, in the regulated object to exert their responsibility/accountability towards the people, the society and the environment.

Building this confidence takes time and resources because the judgment capability has to rely on well developed technical competencies and knowledge.

Other general considerations:
- Facilitating aspects: a well known technology, well known design features (e.g. based on a reference plant the regulator has already licensed)
- Welcoming innovations implies higher cost and longer time in prescriptive frameworks

Adaptability is enhanced through the implemention of risk-informed and performance-based culture and processes, and cooperation.
EU centered proposal made in 2012 – from recent lessons learnt from GEN III design assessments and licensing

ERDA initiative by the sub-group “Nuclear Installations Safety” led by the industry (FORATOM, ENISS), in the frame of ENEF

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ERDA Concept: achieve a common design review and acceptance, the results of which are shared among several EU Member States. A reactor design acceptance would be issued or mutually shared by a voluntary group of national regulators

Based on the idea that a nuclear reactor design should be reviewed and approved in a more harmonized, efficient and consistent way rather than being separately reviewed by each national regulator in each EU Member State where a NPP of that design is to be built
In close cooperation with the first regulator and after its own review, the regulator could “validate” the design acceptance, if necessary with some changes or caveats.

**OPTION 1**

Validation process

- Regulator A
  - design review
  - design approval by regulator A
  - NPP licence by regulator A

- Regulator B
  - design approval by regulator B
  - NPP licence by regulator B

**OPTION 2**

Joint Design Evaluation and Acceptance

- Team of regulators: A, B, C
  - Joint design review
  - Joint design acceptance
  - NPP licence by regulator A
  - NPP licence by regulator B
  - NPP licence by regulator C

**Case A:** joint evaluation results voluntarily transferred into the national licensing process by each participating regulator.

**Case B:** EU Member States in a multinational agreement to implement the joint acceptance in their national framework.

- ERDA is not suggesting reactor licensing by a new dedicated EU authority
- Formal delivery of a license by the national regulator still necessary for any NPP project to proceed
Joint Assessment by TSOs

- Support from the collaboration of European TSOs (e.g. via ETSON) to perform joint design reviews under the auspices of a regulator or a group of regulators, enabling options 1 and 2
- The EC could also establish a European Nuclear Safety Assessment Team (ENSAT) based on technical resources of ETSON and other technical review institutions

Prerequisites

- Introduce a “stand-alone design acceptance” process as a first step in all licensing regimes, resulting in a “design acceptance certificate” – Call to the EC to promote implementation of such a process
- Progress in harmonization of safety requirements to support common reactor design acceptance. Well underway through WENRA and IAEA standards. Further should be done to promote the recognition and adoption of nuclear industry common standards
- Changes in some regulatory frameworks and practices, and a new coordination between Regulators, TSOs and SDOs
2. Presentation of ERDA 2012 (4/4)

Safety Benefits

- Fleets of standardized reactors (OPEX basis ++, sharing good practices ++, …)
- Regulators: Common and consistent positions on generic issues, Sharing resources, methods and data

Licensing Benefits: reduce uncertainties / duration, less delays and re-design work

Economic Benefits: Series effect / Lower costs / Off-the-shelf standardized items / Long term planning / Reduce bottleneck effects (e.g. manufacturing / inspections)

Overall: Facilitate education/training and transfer/maintenance of know-how

Potential weaknesses / difficulties - Examples from analysis in the report:

- Complexity of collaboration / Consensus slow to reach
- Piling up inconsistent requirements
- Access to new vendors
  - ERDA makes sense only if realistic for the design to be chosen by operators
  - No discrimination in access to ERDA
3. Presentation of a common European pre-licensing (1/4)

EU sponsored study, published in 2019

Aim: “provide a description of the technical content that a EU common pre-licensing process should include, considering different types of reactors, applicable safety standards and (as far as possible) the diversity of MS national framework”

Analysis of existing approaches for pre-licensing reactor design evaluation on the basis of publicly available information

A concept for a Joint Overall Design Assessment (JODA) to be performed by the regulators of several MS, leading to a Common Opinion on Design Acceptability (CODA)
## Comparison of some national processes

<table>
<thead>
<tr>
<th>Purpose</th>
<th>UK GDA</th>
<th>US Design Certification</th>
<th>French Review of Safety Options</th>
<th>Canadian VDR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic Design Acceptance</td>
<td>Licensing decisions finalized before construction</td>
<td>Opinion on design safety options, in advance of an appl. for construction project</td>
<td>Verification, at a high level, of design acceptability</td>
<td></td>
</tr>
<tr>
<td>Binding effect</td>
<td>Not legally binding but relevant in practice</td>
<td>Legally binding</td>
<td>Not legally binding</td>
<td>Not legally binding but relevant in practice</td>
</tr>
<tr>
<td>Definition of design</td>
<td>PCSR, PCER, Reference Design Configuration</td>
<td>Design Control Document</td>
<td>Safety options dossier</td>
<td>Submitted documents; no mandatory template</td>
</tr>
<tr>
<td>Scope</td>
<td>Full scope for a meaningful assessment, plus some operator-specific aspects</td>
<td>&quot;Full scope&quot; excluding site and operational aspects</td>
<td>Flexible – applicant can submit &quot;all or some&quot; of the safety options</td>
<td>Virtually &quot;full scope&quot;, 19+ &quot;focus areas&quot;</td>
</tr>
<tr>
<td>Level of detail</td>
<td>Grade 3</td>
<td>Grade 4</td>
<td>Grade 1 or 2</td>
<td>Grade 2 plus Grade 3 for chosen topics</td>
</tr>
<tr>
<td>Safety Requirements</td>
<td>goal-oriented approach (ALARP)</td>
<td>US NRC rules – prescriptive</td>
<td>French regulations</td>
<td>Canadian regulations</td>
</tr>
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</table>
3. Presentation of a common European pre-licensing (3/4)

Proposed scope and depth of JODA

- Full scope and flexible approach within a firm corridor of assessment depth; possibly with phased successive submissions from Grade 1 to Grade 3
- Allowing assessment of designs having completed the Basic Design stage or having been progressing into the Detailed Design
- The approach takes into account the diversity of Member States' national framework:
  
  Grade 1 and 2 assessment performed against high-level safety requirements largely consistent in the EU and comply with Safety Objective in Art. 8a of NSD
  
  Grade 3 assessment involves regulatory guidance as well as industry codes & standards. Implement Grade 3 as an option for specific issues

* Core coverage and features as defined in Table 3 (practically full scope). The coverage can be extended by separate items.
The CODA should mainly comprise:

• Statement of the regulators' common opinion on acceptability of the design
• Statement of the limits of the assessment, of envelope criteria used in the assessment
• Issues to be further analysed in subsequent licensing ("JODA findings")
• Optionally, an appendix with individual statements by regulators (as far as possible to be restricted to a very limited number of issues)
• Interim statements for each phase of the evaluation

Recommended option for JODA implementation

• Not legally binding (not a mandatory step)
• A flexible ad-hoc process facilitated by the EC, or an entity designated by the Commission such as a central office
• Some key issues: agreement on process and common requirements, financing, allocation of assessors, consensus based (escalation process in case of conflict)
• The process should be flexible as well; contractual agreements should “freeze” requirements and process issues for each JODA
4. Open Questions – Key Issues (1/2)

Some open questions:

- Role of the Regulator in the Vendor’s country?

- Proven technology / Proven engineering are rightly important factors in safety assessments. Impact on pace of deployment of advanced reactors?

- What Regulators’ involvement according to the level of design maturity?

- Is the level reached today in harmonization of the safety requirements sufficient?
  - Case of mature technologies, e.g. LWRs
  - Case of Advanced technologies

- How to ensure effective Standardization? *(acceptance of codes & standards, recognized methodologies / practices / processes, share knowledge of best practices)*
4. Open Questions – Key Issues (2/2)

Key enablers?

- National governments’ steer and commitment, with long term views
- Stable energy policies / Market of sufficient size
- Willingness to establish international cooperation
- Regulatory regimes based on risk-informed and performance based principles
- Make best use of international initiatives and their experience feedbacks / Enhance cooperation:
  - Regulators through MDEP, NEA/CNRA, WENRA, SMR Regulators’ Forum
  - Multi-national organizations: EU, IAEA
  - Industry: WNA/CORDEL, EUR, ENISS, SDOs (e.g. CEN/WS64 initiative) Recently created FORATOM/SMRTF
OPTION 1

- A “validation” process to be implemented for dealing with a NPP license application based on a reactor design previously assessed in another Member State. The national regulatory body receiving this application should maximize the benefit of the technical work already done rather than repeating it. In close cooperation with the first regulator and after its own review, the regulator could “validate” the design acceptance, if necessary with some changes or caveats.
OPTION 2

- When a reactor design is submitted to a licensing process in several countries at roughly the same time, the regulators should create a joint team with the adequate competencies and perform a joint design evaluation and acceptance
  - Case A: joint evaluation results voluntarily transferred into the national licensing process by each participating regulator
  - Case B: multinational agreement between the Member States to implement the joint acceptance in their own national processes. Formal delivery of a license by the national regulator would still be necessary for any NPP project to proceed
Focus on Nuclear Safety, Radiation Protection, Security for the whole lifecycle including Long Term Operation, New Build, Waste and Decommissioning

- Develop common views and positions on the evolutions of international standards
- Interact appropriately with the regulators and key stakeholders to ensure that the licensees’ positions are effectively given due consideration
- Maintain an efficient information exchange platform between ENISS members with respect to Nuclear Safety

ENISS has a wide range of interactions, including with WENRA, IAEA, European Commission, ENSREG, ICRP, EUR, WNA/CORDEL, …

ENISS provides technical inputs based on the experience feedback from its members, basis of its legitimacy
Workshop Moderator

Mr. Ramzi Jammal
Executive Vice-President and Chief Regulatory Operations Officer Regulatory Operations Branch
Canadian Nuclear Safety Commission (CNSC)
Ms. Maria G. KORSNICK
President and Chief Executive Officer, Nuclear Energy Institute, US
The nuclear sector innovative regulation process: challenges to serve safety of emerging technologies

How should regulators approach licensing of innovative and disruptive technologies?
- Regulatory framework should be technology-inclusive, risk-informed and performance-based
- Recognize and reward innovation that enhances safety
- Regulators should pursue approaches that are efficient and timely

How can regulators leverage international cooperation?
- International regulatory alignment should not be the sum of the most conservative requirements
- NRC-CNSC collaboration is a good model for achieving cross-border regulatory efficiencies
- NRC is an international leader in rethinking the regulatory framework for advanced technologies
Mr. Mark FOY
Chief Nuclear Inspector for the Office for Nuclear Regulation in the UK
Innovative technologies – Licensing and regulation

- Regulator is often, incorrectly seen as a barrier to innovation – Ask for the regulator’s view!
- Regulator must remain independent – Primary role to ensure protection of people and society
- UKs goal-setting regulation and ONRs enabling philosophy encourages innovation and flexible solutions; unbiased views, open to new ideas and novel solutions
- Principles: collaboration; constructive, early engagement; focus on outcomes; fit for purpose solutions; willingness to overcome barriers – Build trust!
- Application of innovation is broad e.g. design/technology, construction/workflow, role of nuclear (hydrogen, heat, isotopes), safety cases
- Publication of ONR’s ‘Approach to Regulating Innovation’ (Sept 2020) - Open and responsive to facilitating the deployment of novel solutions and disruptive technologies
- Four key themes:  
  - Being accessible and enabling
  - Working in a collaborative manner
  - Being adaptable, flexible and agile
  - Effective horizon scanning

- Innovation should enhance nuclear safety and security and we all need to work together to ensure it is achieved successfully
Mr. Ho Nieh
Director, Office of Nuclear Reactor Regulation, US Nuclear Regulatory Commission
USNRC is creating new paradigms to make **SAFE** use of nuclear technology **POSSIBLE**

- Technology inclusive framework
- Emergency preparedness
- Security
- Environmental impact
- Design bases selection
- Safety system classification
- Application content

- Multiple licensing approaches
- Modelling and simulation
- New oversight approaches
- International cooperation
- Training and knowledge management
- Hiring critical skills
- Extensive stakeholder engagement

- Safety-focused (always first) and cost-effective
- Risk-informed vs. deterministic
- Performance objectives vs. prescriptive requirements

- Flexibility
- Integrated safety review with “core team” approach
- Improved resource performance and monitoring
- Safety-focused and enabling mindset
Mr. Simon IRISH
Chief Executive Officer, Terrestrial Energy
Leading the Way to a Bright Energy Future

OEDE-NEA multi-sector workshop on innovative regulation: Challenges and benefits of harmonizing the licensing process for emerging technologies

Private and Confidential
Terrestrial Energy

• Terrestrial Energy is developing a Small Modular Reactor (SMR) power plant
  – *Using Generation IV molten salt nuclear technology*

• Power plant is called the Integral Molten Salt Reactor (IMSR®)

• Pragmatic technology and design choices for affordable nuclear power

• Regulatory process and engineering of IMSR® power plant are well underway

• IMSR® is one of three SMR technologies selected by Ontario Power Generation for potential
  Darlington deployment

• First commercial plant to be operational by 2028
Code standardization and the innovation cycle

**Innovation phase**

- Innovators develop proprietary code with private R&D
  - Code is “IP” and of high commercial value
  - Private code referenced in regulatory applications

**Adoption phase**

- Industrial adoption creates growing incentives to standardize code
  - Industrial adoption generates data used by industry organizations to define standard code

**Maturation phase**

- As product innovation cycle matures strong incentives to find production and operational economies
  - Industry standard codes used widely in regulatory applications
Mr. Anton MOSKVIN
Vice President, Marketing & Business Development, Rusatom Overseas, ROSATOM
ROSATOM experience and vision of SMR licensing

2020: WORLD’S ONLY FNPP
Akademik Lomonosov with KLT-40s reactors commissioned

2027/2028: optimized FNPP commissioning

2027: FOAK land-based NPP commissioning in Russia

FLOATING NPP

• Successful experience of licensing and operation FNPP Akademik Lomonosov will be considered
• Important role of International Maritime Organization in licensing process
• Global efforts to be pooled together to make TNPPs compatible with the international legal framework

50 MWe

LAND-BASED NPP

• Russia has a long history in licensing NPPs
• FOAK: Same approach to licensing SMRs as for large-scale NPPs with amendment of existing C&S
• ROSATOM is actively involved in discussions on global SMR regulatory harmonization
• Russia is moving to a technologically neutral licensing approach
• Potential application of graded approach in regulating SMRs
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Session 2 - The nuclear sector innovative regulation process: challenges to serve safety of emerging technologies

Ms. Maria G. KORSNICK
President and Chief Executive Officer, Nuclear Energy Institute, US

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Vice President, Marketing & Business Development, Rusatom Overseas, ROSATOM

Mr. William RANVAL
Director of ENISS (European Nuclear Installations Safety Standards)
QUESTIONS FROM PARTICIPANTS

• Question 1
• Question 2
• Question 3
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Thank you for your participation today and see you all tomorrow!