NEA
NUCLEAR ENERGY AGENCY

CNSC CCSN

OECD
BETTER POLICIES FOR BETTER LIVES

MULTI-SECTOR WORKSHOP ON INNOVATIVE REGULATION

Challenges and benefits of harmonising the licensing process for emerging technologies

14-18 December 2020

NEA
NUCLEAR ENERGY AGENCY

CNSC CCSN

OECD
BETTER POLICIES FOR BETTER LIVES

MULTI-SECTOR WORKSHOP ON INNOVATIVE REGULATION

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)

NEA
NUCLEAR ENERGY AGENCY

CNSC CCSN

OECD
BETTER POLICIES FOR BETTER LIVES

Opening remarks: objectives of the workshop, frame the challenges

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

NEA
NUCLEAR ENERGY AGENCY

OECD
BETTER POLICIES FOR BETTER LIVES

Opening remarks: objectives of the workshop, frame the challenges

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

NEA
NUCLEAR ENERGY AGENCY

OECD
BETTER POLICIES FOR BETTER LIVES

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

1. Introduction – General Considerations *(2/2)*

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

2. Presentation of ERDA 2012 *(1/4)*

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

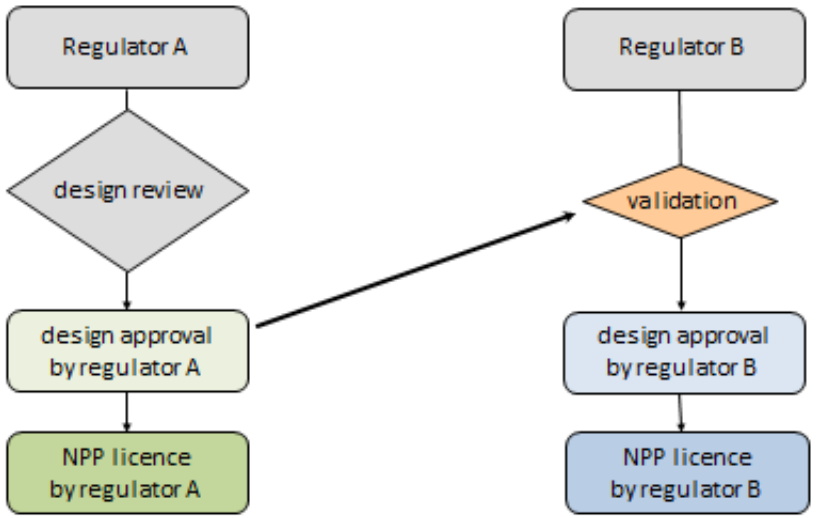
ERDA Concept: achieve a common design review and acceptance, the results of which are shared among several EU Member States. A reactor design acceptance would be issued or mutually shared by a voluntary group of national regulators

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

2. Presentation of ERDA 2012 *(2/4)*

OPTION 1

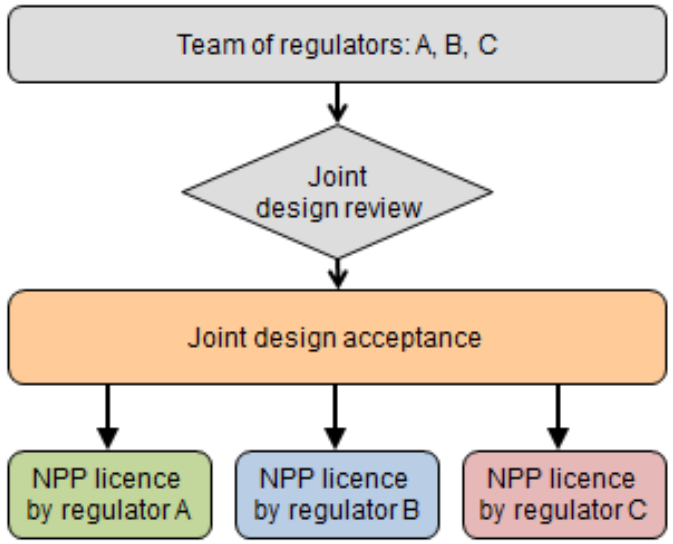
Validation process



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

Joint Design Evaluation and Acceptance



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*

2. Presentation of ERDA 2012 *(3/4)*

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)

3. Presentation of a common European pre-licensing *(2/4)*

Comparison of some national processes

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

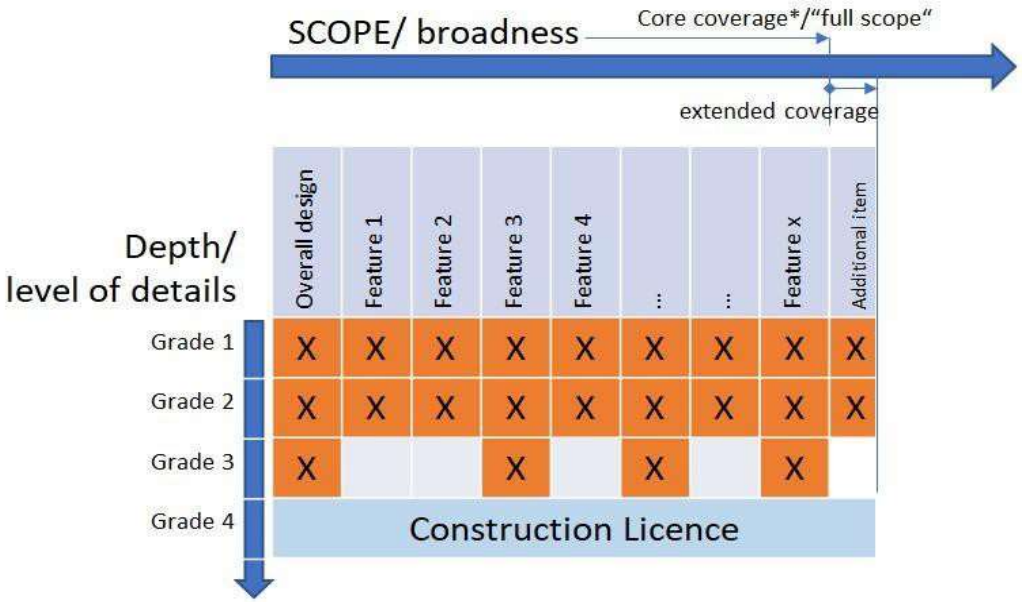
3. Presentation of a common European pre-licensing *(3/4)*

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.

3. Presentation of a common European pre-licensing *(4/4)*

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?

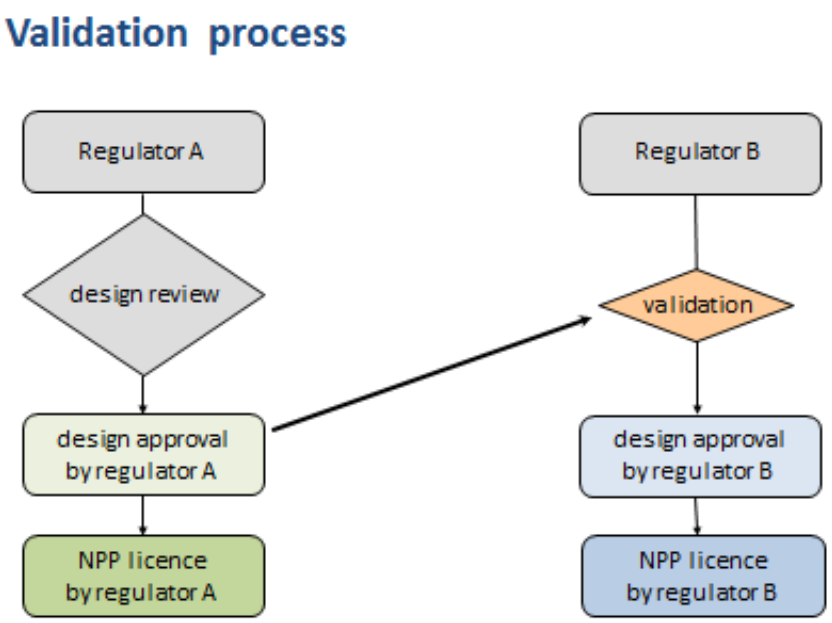
- National governments' steer and commitment, with long term views
- Stable energy policies / Market of sufficient size
- Willingness to establish international cooperation
- Regulatory regimes based on risk-informed and performance based principles
- Make best use of international initiatives and their 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**

APPENDIX

Presentation of ERDA 2012

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

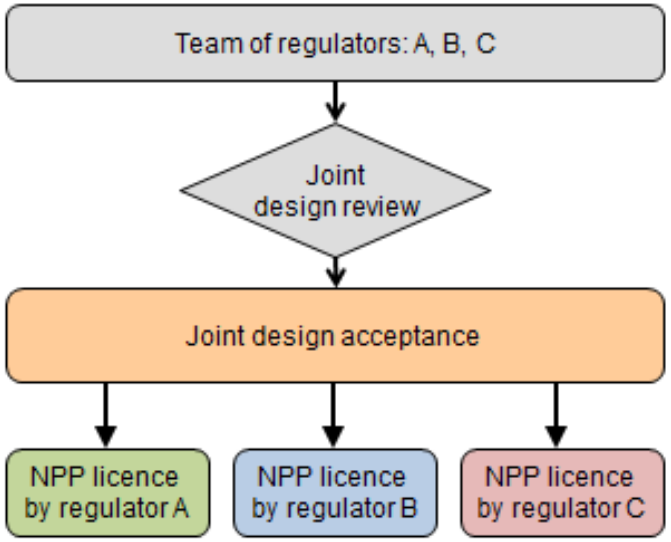


Presentation of ERDA 2012

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

Joint Design Evaluation and Acceptance



ENISS www.eniss.eu

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

NEA
NUCLEAR ENERGY AGENCY

OECD
BETTER POLICIES FOR BETTER LIVES

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

OECD-NEA Multi-Sector Workshop: Session 2

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

Office for Nuclear Regulation

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**

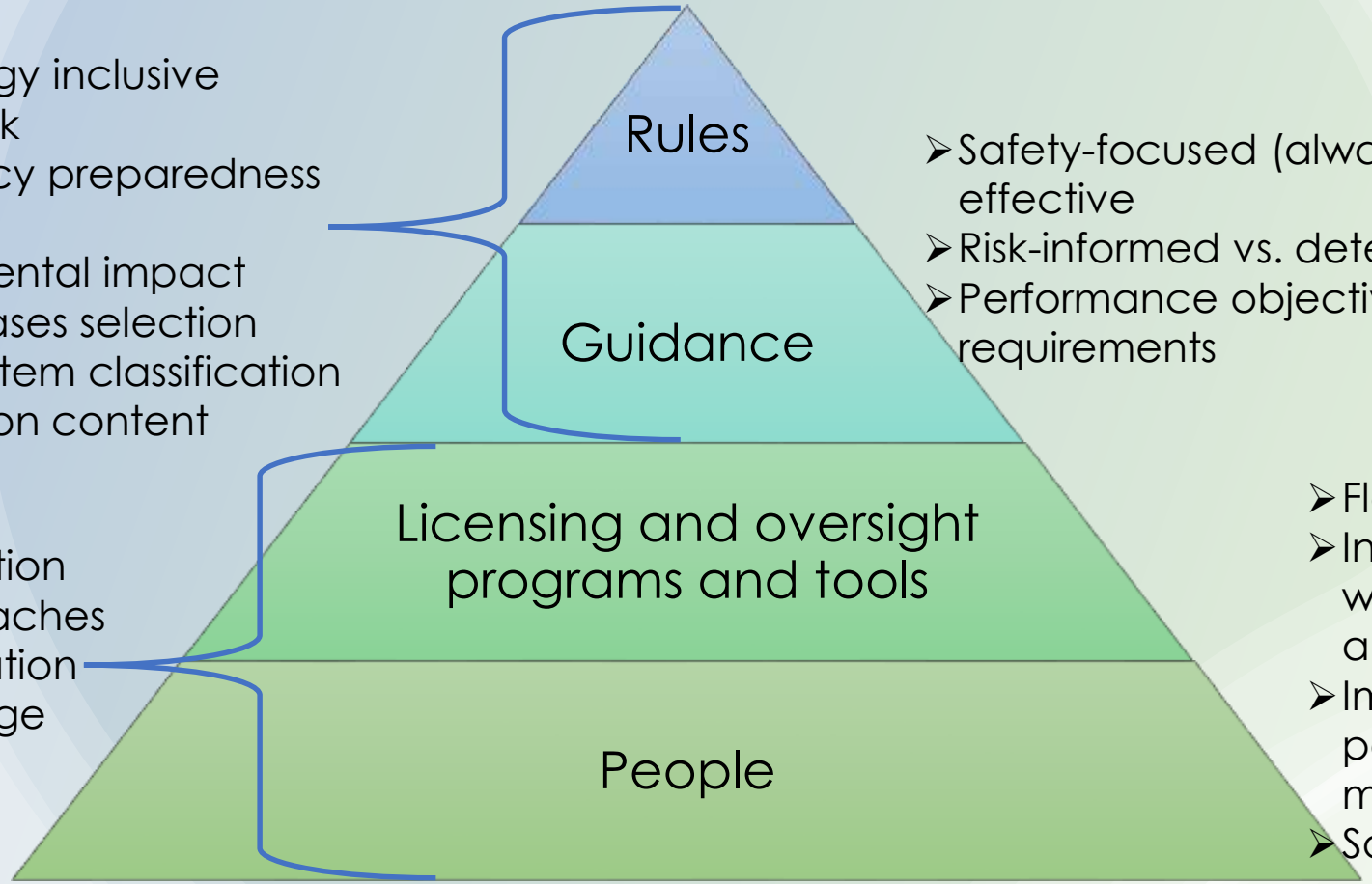
Mr. Ho NIEH

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) <u>and</u> 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

FLOATING NPP | **50 MWe** | **LAND-BASED 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

- 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

Ms. Maria G. KORSNICK

President and Chief Executive Officer, Nuclear Energy Institute, US

Mr. Mark FOY

Chief Nuclear Inspector for the Office for Nuclear Regulation in the UK

Mr. Ho NIEH

Director, Office of Nuclear Reactor Regulation, US Nuclear Regulatory Commission

Mr. Simon IRISH

Chief Executive Officer, Terrestrial Energy

Mr. Anton MOSKVIN

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

Mr. William RANVAL

Director of ENISS (European Nuclear Installations Safety Standards)

NEA NUCLEAR ENERGY AGENCY

CNSC CCSN

OECD BETTER POLICIES FOR BETTER LIVES

QUESTIONS FROM PARTICIPANTS

- Question 1
- Question 2
- Question 3

NEA
NUCLEAR ENERGY AGENCY

CNSC CCSN

OECD
BETTER POLICIES FOR BETTER LIVES

MULTI-SECTOR WORKSHOP ON INNOVATIVE REGULATION

Challenges and benefits of harmonising the licensing process for emerging technologies

Thank you for your participation today and see you all tomorrow!