



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

14 - 18 December 2020

WORKSHOP SYNOPSIS AND FINDINGS



Workshop background

Note: the objective of this document is to provide a high-level overview of the workshop by concisely summarising each session. Readers seeking additional detail on a particular topic are encouraged to review the presentations of each session available here: [Nuclear Energy Agency \(NEA\) - Multi-sector workshop on innovative regulation: Challenges and benefits of harmonising the licensing process for emerging technologies \(oecd-nea.org\)](https://www.oecd-nea.org/2020/12/14-18-dec-2020-workshop).

The OECD Nuclear Energy Agency (NEA) in collaboration with the Canadian Nuclear Safety Commission (CNSC) hosted an international, multi-sector workshop on 14-18 December 2020 to focus on safely regulating innovative and disruptive technologies.

Regulatory frameworks vary across each sector and from country to country. Each has its own set of stakeholders, safety standards, history, and legal framework. Despite these differences, regulatory frameworks share a common goal: to allow society to reap the benefits of a particular activity or technology (e.g. commercial flights, medical devices) while ensuring that the risks to individuals and society are maintained at an acceptable level. Sharing this strategic goal means that regulators from different sectors and countries can learn from one another by exchanging best practices.

Regulators in non-nuclear sectors have undergone recent changes that can help shape the collective intelligence of the regulatory community. The goal of this workshop was to provide a forum for them to share their experiences in standardisation, design review, licensing and reporting systems, and international co-ordination.

Objectives of the workshop

The objective of this workshop was to discuss best practices that the nuclear sector can adopt when licensing innovative technologies including, but not limited to, small modular reactors (SMRs). While many SMR concepts are under development, most involve the concept of modules where the majority of fabrication and construction takes place in a factory. Following assembly, the modules can be shipped anywhere in the world and installed where power is needed. This approach makes standardisation essential and requires a uniform approach to codes and standards. SMR deployment would likely be rendered impractical if each module were to be custom designed and fabricated according to country-specific requirements. Some limited-scope efforts at international co-operation are already underway and this workshop included a discussion on early observations from those projects.

The workshop brought together over 500 regulators and stakeholders, including industry representatives, and international organisations to share information between nuclear and other highly regulated sectors towards harmonised, efficient, and effective regulatory processes in the context of innovation.

The workshop focused on practical examples of how regulators can address two key challenges:

- **Challenge #1** – How should regulators approach licensing of innovative and disruptive technologies? Licensing decisions on paradigm-breaking technologies can be difficult for regulators. These technologies often rely on principles that do not fit neatly into the existing regulatory structure. For example, the regulations for the current fleet of nuclear reactors focus on preventing fuel melt during accident conditions; however, some advanced designs under consideration rely on fuel that is in a liquid state during normal operations. Do transformational changes in technology require transformational solutions by the regulator or are there viable incremental approaches?
- **Challenge #2** – How can regulators leverage international co-operation? In theory, international co-operation should assist regulators by allowing countries that are interested in a common technology to pool their resources. For example, if the safety case for a new technology is based on test results, multiple countries could collaborate on reviewing and verifying those results. In a practical sense, this type of collaboration has proven to be challenging for the nuclear sector partly due to differences in regulatory approaches and legal frameworks.

From a policy perspective, countries often have different legal and regulatory requirements that they apply to prospective designs and to licensing decisions. This may present challenges when a proposed design, while otherwise acceptable, lacks a safety feature that some countries consider mandatory but that others consider optional.

From an engineering perspective, countries often rely on different codes and standards to assess quality-assurance-activities such as design and fabrication. For example, the acceptability of concrete is typically assessed in the United States using American Concrete Institute (ACI) codes, while European countries often rely on codes developed by the European Committee for Standardisation. While each country must ultimately take its own final decisions about the acceptability of a given regulated technology, the workshop explored how countries can leverage bi-lateral or multi-lateral technical work in making their final safety decision.

For both challenges, the workshop emphasised pragmatic, real-world examples rather than hypotheticals. Panellists from all sectors were encouraged to provide success stories and cautionary tales, according to their experiences.

Session 1

Opening remarks

Following a brief introduction from the NEA staff covering logistics and technical issues, NEA Director-General, Mr William D. Magwood IV provided opening remarks for this workshop. First, he noted the significant amount of preparation that went into the workshop from the NEA, CNSC, and also the speakers and panellists. He thanked all those involved for their time. Next, he introduced the participants to the two key topics of the workshop (as described in the previous section). Finally, he made the following key points:

- Not since the 1950s has the nuclear industry seen the burst of innovation that is taking place today.
- We have established industry and a regulatory framework that is geared toward Generation II and III reactors. Are nuclear regulators ready for SMRs? Gen IV? Are regulators ready to assess truly disruptive technologies? Our existing structures must not stifle innovation.
- At times, regulators have struggled with paradigm-changing technologies. For example, in 1865 Britain passed the “Red Flag Act”. This law was intended for locomotives but applied to all “self-propelled vehicles” meaning that it affected a new technology (cars) as well. The law required all self-propelled vehicles to be manned by a crew of at least three people, with a max speed of 4mph, and upon entering a town, one crew member was required to get out and wave a red flag to warn pedestrians of the incoming vehicle. Although repealed in 1896, the Red Flag Act severely stifled development of road transportation in British Isles.
- This shows that regulations can be an impediment to progress; however, this need not be the case. Regulations can ensure public safety while also enabling, rather than stifling, new technologies.
- Nuclear regulators today are facing something similar with SMRs and advanced reactors. There are many parallels in other sectors as they grapple with how to assess drones, satellite-based air traffic control, AI, machine learning, personalised medicine, and other disruptive technologies. These technologies are evolving rapidly to solve major challenges in our societies and regulators need to keep up.
- Despite the different technologies, lexicon, legal and regulatory frameworks, regulators in different sectors are facing a similar set of core issues. This is why we have assembled this workshop; so that regulators can exchange best practices. Regulatory frameworks are based on national sovereignty. New technologies (e.g. SMRs) will be most successful if they have access to global markets.
- The workshop’s second key topic is quite challenging: how can regulators work collectively to make new technologies available across borders? The NEA has been at the centre of several efforts in this area (e.g. MDEP) but we are not even close to where we could be. The goal of this workshop is to gain insights that will help the nuclear sector move forward.

Ms Rumina Velshi, President and Chief Executive Officer of the Canadian Nuclear Safety Commission (CNSC) also gave opening remarks, offering the following key highlights:

- Readiness for innovation: the nuclear sector around the world is adapting well during the COVID-19 pandemic and should be preparing for future advancements in innovative technologies.
- Collaboration on SMRs: it is a collaborative effort to regulate innovative technologies, such as SMRs. With many innovative technologies, there are limited resources. There is a need to share knowledge, best practices and lessons learnt for more efficiency and effectiveness in assessing and regulating SMRs. The CNSC is engaging bilaterally with the United States and the United Kingdom as well as playing an active role at SMR-related engagements at the International Atomic Energy Agency (IAEA) and the NEA, working towards a greater degree of harmonisation.
- Global harmonisation: an early step towards global harmonisation, in particular the licensing process, could be the sharing of regulatory reviews to establish technical baselines. In addition to current efforts at the IAEA's Commission on Safety Standards (CSS) which prioritise safety standards for SMRs and ensure IAEA standards can be applied in a technology neutral manner commensurate with risk, regulators are encouraged to work toward harmonised requirements that are acceptable for all countries.
- Building trust: building and maintaining trust with other regulators, proponents, and the public is key while working towards harmonisation.

Ms Rumina Velshi encouraged participants from other sectors to share their experiences and lessons learnt on innovation, particularly related to the opportunities or challenges that have arisen from harmonisation. She posed the following four questions as a challenge to workshop participants at the end of her remarks:

1. How will we set clear regulatory requirements for safety that are both risk-informed, so as to reflect an understanding of the actual risks posed by the technologies, and which also allow room for, and encourage, innovation and technical advancement?
2. How do we leverage lessons learnt and operational experience on harmonisation from other high-reliability sectors such as aviation, transportation, pharmaceutical, and finance?
3. What is the correct balance between harmonisation and national regulator sovereignty – are we limited to reviews, standards, and requirements, or will it be ultimately possible to harmonise licensing processes and approvals?
4. How do regulators embark on this journey while ensuring public trust in us as regulators and in our processes and decisions?

Session 2

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

DESCRIPTION OF SESSION

Since its inception, the commercial nuclear power sector has adopted a strong focus on safety. Often this focus on safety has resulted in conservative decision-making and a risk-adverse culture. While this culture offers benefits, it has at times caused a resistance to change and a reluctance to adopt new technologies such as digital instrumentation and controls. While they may present challenges when first adopted, these new technologies may offer improved economic and safety performance if adopted properly and with effective regulatory oversight.

Another key aspect of the nuclear sector is that nuclear laws and regulations tend to vary widely among different countries. This has led to substantial variations in reactor design and construction even for reactors that are nominally the same make and model. While this country-specific approach has worked reasonably well for the current fleet of large light-water reactors, the next generation of reactors is likely to consist of small modular reactors. These reactors could be fabricated in factories and shipped to their final place of deployment. The economics of these designs are such that a standardised approach where a single reactor design could be manufactured and shipped to multiple countries for installation would be highly advantageous.

This session set the scene for the workshop by outlining the challenges that the nuclear sector is facing in adopting emerging nuclear technologies, and discussed considerations for improving harmonisation of regulatory requirements and standards for licensing of nuclear and innovative technologies going forward, in particular for SMRs. During the discussions, panellists shared their experiences and views based on their organisation's involvement in the nuclear sector and in this topic.

Moderator:

Mr Ramzi JAMMAL, Executive Vice-President and Chief Regulatory Operations Officer, Canadian Nuclear Safety Commission (CNSC)

Presenters and panellists:

- Mr William RANVAL, Director of ENISS (European Nuclear Installations Safety Standards)
- Ms Maria KORSNICK, President and Chief Executive Officer, Nuclear Energy Institute, US

- Mr Mark FOY, Chief Nuclear Inspector, UK Office for Nuclear Regulation
- 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, Rosatom Overseas, ROSATOM

KEY CHALLENGES ENCOUNTERED BY THE PANELLISTS INVOLVING REGULATORY APPROVAL OF INNOVATIVE TECHNOLOGIES

The key challenges discussed during the panel session were harmonisation of the licensing process and building public trust.

It was noted that there is a lack of universally recognised standards for advanced nuclear technologies. Given the cost and time associated with the development of new codes and standards, organisations may seek to maximise the use of existing ones as the best way to proceed, instead of creating new codes and standards.

There is a need to take a step forward in the demonstration of a harmonised approach by engaging early in the process and starting with a small number of countries on a specific topic (such as codes and standards for materials, and ways to achieve quality). Using a “functional equivalency approach” may be the best way to proceed. Bilateral work currently underway between the US and Canada is a good example. Cooperation of a small group of countries can then expand to a larger number of countries to achieve harmonisation.

Panellists agreed that everyone has a role to play in building trust and that the public will be looking to the regulator to confirm the safety of new technologies. In order to further build public trust, one of the panellists suggested engaging non-governmental organisations (NGOs) to promote openness around nuclear. It was also suggested that the international standards associations should assist in disseminating the message across the entire sector. Creating trust and transparency in the safety review process and making the safety basis publicly available could help generate public confidence.

KEY CHALLENGES ENCOUNTERED BY THE PANELLISTS WHILE ATTEMPTING TO FACILITATE INTERNATIONAL COOPERATION AND/OR HARMONISATION OF REQUIREMENTS

The key challenges to facilitate international cooperation for harmonisation of requirements were mainly centred on the support of Governments and greater coordination by industry.

Panellists identified a lack of policy direction and support from individual governments, which would help direct regulators to work towards establishing and implementing processes for harmonisation.

A suggestion made was to have the industry coordinate an approach to harmonisation of codes and standards in order to facilitate international adoption. The presenters stated it is important to be forward-looking for harmonisation, and not retrofit existing codes and standards. It was suggested that members start with a smaller group who are licensing the same or similar design and expand the approach from there.

Public trust was also mentioned as a challenge. Unless there are high levels of trust, this initiative would not advance internationally. It was suggested that we need to find common grounds from an acceptable safety perspective, the common equivalent of the safety case. Panellists agreed that there is a role for international organisations like NEA and IAEA to play in enhancing public trust.

KEY EXAMPLES OF HOW THOSE CHALLENGES WERE (OR WERE NOT) OVERCOME

There were various examples provided from the EU-sponsored study, European Reactor Design Acceptance (ERDA) analysis report published in 2019 which includes the following:

- Complexity of collaboration / Slow to reach Consensus
- 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

It was discussed that many challenges to regulating innovation could be overcome by:

- being accessible and having an enabling mindset;
- working in a collaborative manner;
- being adaptable, flexible and agile;
- effective horizon scanning;
- early engagement of vendors with regulators;
- allowing regulatory experts to provide feedback;
- using a graded approach to regulate SMRs;
- having a flexible regulatory framework that incorporates a risk-informed decision making process.

ACTION ITEMS THAT WERE IDENTIFIED DURING THIS SESSION

Governments have a significant role in advancing trust in harmonised nuclear technology. Engagement with the governments at the policy level will help regulators establish risk-informed harmonisation processes in support of their national licensing processes.

International organisations, NEA and IAEA, also have a role to play in harmonisation by conducting early engagement activities with industries and governments to initiate conversations highlighting the benefits of harmonisation. Regulators should not take the lead in these conversations.

Although specific follow up actions were not discussed, it was acknowledged by all participants that everyone has a role to play in building trust.

Session 3

Moving safely from aircrafts to drones: licensing disruptive technologies

DESCRIPTION OF SESSION

Experience from the aircraft sector is relevant since it offers many parallels with the nuclear sector with SMRs licensing in particular. First, in terms of innovation, the aircraft sector has adapted to many technologies that are also used in nuclear power (e.g. digital instrumentation and controls). Second, the aircraft sector has managed to establish a framework of international cooperation that allows planes to take off and land in airports all over the world and that allows countries to leverage technical certification activities that take place in other countries.

Speakers in this session highlighted that a new technology should not be addressed only from a technical point of view but all the implications on its environment should also be considered. As an example, major technical modifications on aircraft might require to review pilot certification, maintenance process or air traffic control procedures. Moreover, the pace of innovation is a challenge. Considering manufacturer and industrial stakeholders are introducing new technologies very rapidly, the regulators should align their processes on a similar pace.

Finally, it was stressed that the acceptance not only from the customers but also from all the stakeholders (the public, regulators, etc.) is a key parameter before introducing a new technology.

Moderator:

Mr Ramzi JAMMAL, Executive Vice-President and Chief Regulatory Operations Officer, Canadian Nuclear Safety Commission (CNSC)

Presenters and panellists:

- Ms Silvia GEHRER, Regional Director, ICAO European and North Atlantic (EUR/NAT) Office, United Nations International Civil Aviation Organisation
- Ms Jagoda EGELAND, Advisor to the Secretary-General, International Transport Forum at the OECD
- Mr Christian SCHLEIFER-HEINGÄRTNER, Secretary General, EUROCAE
- Mr Simon MOORE, Assistant Secretary, Safety and Future Technology, Australian Department of Infrastructure, Transport, Regional Development & Communications

- Mr Vassilis AGOURIDAS, UAM Initiative Leader (EU Smart Cities Marketplace) / Head of EU Public Co-Creation & Ecosystem Outreach (AIRBUS Urban Mobility)

KEY CHALLENGES ENCOUNTERED BY THE PANELLISTS INVOLVING REGULATORY APPROVAL OF INNOVATIVE TECHNOLOGIES

Panellists discussed the challenge of developing standardisation due to the complex coordination required when such a large diversity of nations is involved. There is a need to address more than just an aircraft design. Things like pilot certification, environmental impact and security must also be considered when developing standards.

As an example, it takes ten years to certify an aircraft, which is a long timeline and investment. On top of aircraft circulation, many other things like maintenance, engines, and air traffic control are also needed to ensure safety.

Another challenge discussed was that the pace of change and innovation is progressing faster than regulation-making capacity. Regulatory activities need to keep up with the pace of innovation.

During the discussions, it was noted that there are country-specific guidelines to follow, which are in addition to established regulations. Innovative technology needs to get all approvals while satisfying global and local requirements.

There is also a need for social and public acceptance to unlock innovative technology.

Key challenges encountered by the panellists while attempting to facilitate international cooperation and/or harmonisation of requirements

Key challenges in international cooperation and harmonisation of requirements include:

- Connection with the international community
 - Panellists recognised the ongoing importance of staying connected with the international community, and having access to platforms for discussion such as working groups. Global harmonisation needs to be focused in order to be successful.
- Leveraging the benefits of disruptive technologies
 - Policies need to be examined, including both governance and regulation. Consideration should be given to modifying existing regulations, the use of performance-based standards, and a risk-based certification approach.
 - Acceptability by the public often only occurs when the public can relate to benefits or advantages of the technology (social licensing).
 - The integration and role of the technology in the existing aviation regulatory system should be further explored.
- Staffing challenges
 - There is a need for staff with appropriate level of skills and with background in innovation and business.

KEY EXAMPLES OF HOW THOSE CHALLENGES WERE (OR WERE NOT) OVERCOME

Projects such as building or extending airports are very controversial. The costs may be very concentrated, while the benefits are spread out. Sound analysis is key to securing projects of such a nature. Conducting “assessments of needs” demonstrates to the public the evidence of the need for

new capacity, including both positive and negative potential impacts of investment. This process needs to be independent, open, transparent, and must follow all required steps to ensure success.

The emerging drone ecosystem has multiple levels of governance that affect many stakeholders who need to be a part of regulatory and decision-making processes. There is a need to break silos for cross-sectoral collaboration and coordination for:

- Public and private support
- Synergies of air and ground
- Co-creation with stakeholders

To overcome challenges related to social/public acceptance, panellists discussed exploring ways to prove the social utility of the technology. Having a close partnership and working together with the one goal of safety in mind is also critical. An example of this is from Australia, where the public has become generally comfortable with delivery drones as they see direct personal benefit of the technology.

Intellectual property related issues do not appear to be a challenge, as there is already a process in place that addresses it. There is also a process to deal with disagreements in consensus during the standardised process.

Performance-based or objective-based approaches provide greater flexibility to meet objectives of established conventions than follow more prescriptive-based approaches.

ACTION ITEMS THAT WERE IDENTIFIED DURING THIS SESSION

Working at different levels in a layered approach can be very efficient and beneficial in terms of safety and furthering progress, particularly with experts from diverse fields working together. However, consideration needs to be given to the perception of independence when the regulator and industry work together.

Industries should provide their best practices to regulators, who should then consult with stakeholders (including non-users of the technology) to develop standards.

The aviation sector has a large support infrastructure in place, something that is currently lacking in the nuclear industries. For example, there are international aviation committees, organisations, and processes in place to deal with aviation regulations, covering accident investigations, certifications, training, compliance, supply chain, maintenance, etc.

The nuclear sector can benefit from the aircraft industry lessons learnt when combining safety and innovative technologies. This includes:

- Information material, trainings, webinars, online courses, etc., and online availability;
- Accident and incident investigations and role of authorities;
- Accepted Means of Compliance and threshold criteria setting;
- Policy review and role of mergers;
- Certification and licensing, building of innovative items, and regulation of operation;
- Social licensing;
- Living labs;
- Means to leverage benefits of disruptive technologies.

Key takeaways:

- We cannot only look at the design of the technology; we also need to focus on the supporting infrastructure.

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- Harmonisation in this sector is not a simple exercise, given the large international commitment to aviation and the numerous players involved.
 - Everything should start with adoption of core principles (e.g. the Chicago Convention recognising its limitations with respect to innovative technologies, but maintaining its principle of always minimising risk to the public in the aviation industry) and build upon that.

Session 4

The international licensing system for transportation of nuclear material: a success story and a look to the future

DESCRIPTION OF SESSION

The regulations governing transportation of nuclear materials are probably the most harmonised among all the nuclear fields. At the same time, radioactive material transport has an outstanding safety record. During more than half a century of transport according to the IAEA regulations, there has never been a criticality incident nor a case of death, injury, or significant damage to the environment due to radioactivity. More than half a billion packages of radioactive material have been shipped during that period. Such a success encourages the further harmonisation in the nuclear sector.

Nevertheless, there are still challenges encountered when licensing “innovative” or unconventional technologies (e.g. transportable nuclear power plants (NPP)/SMR, shipping unique waste streams from non-light water reactors).

During the session, the panel shared lessons learnt and challenges encountered on the way of harmonising the regulatory approaches for transportation of nuclear materials. It gathered a broad range of different international organisations, industry representatives, and public stakeholders to inform the debate from different perspectives. During discussions, the panellists shared perspectives on regulatory harmonisation, challenges in transportation that were overcome, anticipated regulatory challenges, and areas for collaboration.

Moderator:

Mr Ramzi JAMMAL, Executive Vice-President and Chief Regulatory Operations Officer, Canadian Nuclear Safety Commission (CNSC)

Presenters and panellists:

- Mr Stephen WHITTINGHAM, Head of the Transport Safety Unit, United Nations International Atomic Energy Agency
- Mr Martin PORTER, Secretary General of the World Nuclear Transport Institute
- Dr Jean-Christophe NIEL, Director General of Institute for Radiological Protection and Nuclear Safety, France, Chair of the OECD NEA Committee on the Safety of Nuclear Installations

- Ms Rebecca TADESSE, Head of Radioactive Waste Management and Decommissioning Division, OECD Nuclear Energy Agency
- Mr Serge GORLIN, Head of Industry Cooperation Department at World Nuclear Association (WNA)
- Ms Jennifer NUGENT, Head of Technical, and Member of the International Nuclear Services (INS) Executive Team

KEY CHALLENGES ENCOUNTERED BY THE PANELLISTS INVOLVING REGULATORY APPROVAL OF INNOVATIVE TECHNOLOGIES

The existing prescriptive framework for transport did not discourage innovation in the sector. Organisations were able to work with regulators during the approval process without compromising safety. Panellists discussed challenges faced in transportation of nuclear materials in view of innovative technologies.

- Regulatory flexibility and clarity in requirements for emerging technologies

Despite the flow of innovative technologies in the sector, the panel discussed the lack of flexibility in regulations when it comes to transporting nuclear material. The existing regulatory framework is prescriptive and has limited room for innovation. The pace of technological changes and innovation is progressing faster than regulatory changes. New technologies may end up challenging the rigidity of the current prescriptive regulatory framework, leading to a need for continuous improvement for regulatory activities related to transport.

Panellists discussed the challenges that new technologies face in fitting in to the regulations as presently written. In the current context, there is no clear path to meeting all prerequisites using the existing requirements. Applicants may choose to meet only minimum or baseline requirements, leading to the need for further discussion and clarification.

- Inconsistent regulatory guidance

Another challenge comes from regulatory guidance that varies from country to country. The changes in environment makes the demonstration of safety and security more complex. However, member states have agreed to a broad outline of regulations under IAEA SSR-6, allowing them to retain their sovereignty and adjust the regulations to meet the needs of their country.

- Balance between safety and security

During the discussions, it was noted that the interface between nuclear safety and nuclear security of transport packages is not always mutually inclusive. There is a need to examine the balance between being safe and being secure.

- IAEA SSR 6 Regulations

The SSR 6 regulations aim to minimise interpretation, yet minimising interpretation does not leave a lot of room for innovation. There are also challenges with making changes to SSR 6, given they need to be consensus-based and often take a very long time to amend.

- Transport packages

There are challenges with the transport of fuel enriched to more than 5% (HALEU) and a lack of certified transport packages for emerging technology.

KEY CHALLENGES ENCOUNTERED BY THE PANELLISTS WHILE ATTEMPTING TO FACILITATE INTERNATIONAL COOPERATION AND/OR HARMONISATION OF REQUIREMENTS

The discussions demonstrated that harmonisation is achievable (i.e. the establishment of IAEA SSR-6 and its supporting guidance for interpretation) and confirmed that it takes collaborative effort to achieve harmonisation. The experience from transport also shows that working with a core principle under IAEA SSR-6 is effective and efficient. Regulators adopt and consent to the requirements under IAEA SSR-6 without impediment to innovation.

Another challenge mentioned by the panel concerns collaboration between policy-makers, regulators, and operators. This relationship is key in developing inclusive, fit-for-purpose ways of working. A basis for mutual trust needs to be built within the international community in order to enable harmonisation on a global scale. There is a need to collaborate and agree on the following:

- Characterisation of the transport safety features to ensure the IPR of the reactor design is not compromised;
- Validation that the design of the transport safety features are independently verified;
- Development of prescribed administrative requirements for transportation.

KEY EXAMPLES OF HOW THOSE CHALLENGES WERE (OR WERE NOT) OVERCOME

Over 60 years of regulatory experience has helped achieve harmonisation in regulating the transportation of nuclear materials. This experience has led to increased levels of knowledge and co-operation between Member States. The framework is continuously improving and will continue to overcome the challenges it faces in harmonising internationally.

In addition, the process of developing regulations and guidance is all-inclusive. All Member States are allowed to participate in the process under IAEA SSR-6. This helps ensure consensus is reached before changes are made. It is also best to address harmonisation of requirements by nominating small groups first, rather than tackle the issue as a whole with all member states at once.

ACTION ITEMS THAT WERE IDENTIFIED DURING THIS SESSION

It was suggested that the industry and regulatory bodies should collaborate early, and the importance of having strong and valid technical information to support the approval of innovation technologies was emphasised. In addition, the following are some considerations generated from discussions for promotion and inclusion of innovative technologies within a conventional landscape:

- New approaches should be based on current regulation, and adapt as necessary.
- Harmonisation of regulations does not guarantee harmonisation on the ground. There is a need to develop regulations from bottom (technical bases) up (regulation itself).
- One of the most important challenges for the future is the transport of SMRs and floating NPPs. There is a need for regulation to allow the transport of a “core device” safely and securely. However, it is a challenge to include all stakeholders in the collaboration.
- A process should be developed to harmonise across borders and peer exchanges should be encouraged for continuous improvement.
- Sustained government support must be discussed along with industry engagement in international cooperation.
- The regulatory community should consider exploring new ways of working (the “art of the possible”).

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- In order to overcome the challenge with innovation, transportation needs to be considered early so it can be seen as an enabler instead of a constraint during the lifecycle process.
 - Interactions between stakeholders must be enhanced (TRANSSAC, PATRAM, technical meetings, etc.). International harmonisation is an ongoing effort.
 - Investigate the use of innovative technology, such as robotics, to monitor casks and equipment.
 - Consideration needs to be given to the WNA/CORDEL report.
 - It is best to address harmonisation of requirements by nominating small groups of member states.
 - The transportation community needs to address the challenges of attracting a new generation of people and attaining gender parity.

Session 5

Innovation without borders: challenges and successes of international cooperation on emergent medical technologies

DESCRIPTION OF SESSION

The medical sector played an important role in this workshop because it faces several challenges that are relevant to the nuclear sector today. First, medical technology is a rapidly developing field so regulators are often tasked with making safety decisions about new and innovative products. Second, in order to ensure the safe and efficient use of medical technologies, it is often advantageous for countries to work together on harmonising standards.

This session consisted of medical experts with experience in vaccines, medical devices (e.g. pacemakers, prosthetics), and pharmaceuticals sharing lessons learnt on regulatory approvals of new medical technologies including but not limited to medical devices and vaccines. The panellists discussed challenges on medical devices during the response to COVID-19 pandemic and regulatory approval of new medical technologies, harmonisation and collaboration in regulatory requirements for medical technologies across countries as well as lessons learnt from COVID-19 pandemic with recommendations of areas for future work.

Panellists also shared best practices supporting the development of emerging technologies, how innovative products could be approved quickly while ensuring safety and maintaining public trust, and challenges and successes of international co-operation on emergent medical technologies.

Moderator:

Mr Ramzi JAMMAL, Executive Vice-President and Chief Regulatory Operations Officer, Canadian Nuclear Safety Commission (CNSC)

Presenters and panelists:

- Ms Adriana VELAZQUEZ BERUMEN, Team Lead Medical Devices and In Vitro Diagnostics, MDD, Health Product Policy and Standards Department, HPS, Access to Medicines and Health Products Division, MHP, World Health Organization (WHO)
- Ms Francesca COLOMBO, Head of the Health Division, Organisation for Economic Co-operation and Development (OECD)

- Dr Harald ENZMANN, Chair of the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), Head of Section "European and International Affairs" at the German Federal Institute for Drugs and Medical Devices. German Federal Institute for Drugs and Medical Devices, Head of Section "European and International Affairs"
- Dr William HEETDERKS, Consultant, United States National Institutes of Health, Former Senior Regulatory Official at the United States Food and Drug Administration
- Dr Emmanuelle VOISIN, Founder & CEO, Voisin Consulting Life Sciences
- Dr Carlos PEÑA, Director, Office of Neurological and Physical Medicine Devices (OHT5), Office of Product Evaluation and Quality (OPEQ) in the Center for Devices and Radiological Health, U.S. Food and Drug Administration

KEY CHALLENGES ENCOUNTERED BY THE PANELLISTS INVOLVING REGULATORY APPROVAL OF INNOVATIVE TECHNOLOGIES

Science and innovation are changing rapidly, but the regulations are not adapting at the same pace. Given innovative technologies are often complex, not only does the regulatory approach need to keep up, but also does the training and skill of regulators. This will ultimately lead to timely and efficient processes, while ensuring safety and maintaining public trust.

Public trust is another challenge when introducing emergent technologies (in the creation of a vaccine, for example). Trust is a key component in improving regulatory reliance and efficiency. When an immediate problem requires an innovative solution, rapid advancement of the regulatory process is also required. Approval of innovative technologies can become problematic without the completeness of data sets. There are times where parallel approval is required, which brings up the challenge of additional monitoring post-approval.

The concept of risk is measured and balanced differently in the medical sector compared with the nuclear sector. There are common standards that apply to both sectors, but risk is weighed differently from region to region and is population-based. The measure of success is also a factor that varies between the medical and nuclear sector.

There are new models and tools such as artificial intelligence and machine-learning that pose challenges due to data privacy and security. It is unclear how the current regulation can be safely applied.

KEY CHALLENGES ENCOUNTERED BY THE PANELLISTS WHILE ATTEMPTING TO FACILITATE INTERNATIONAL COOPERATION AND/OR HARMONISATION OF REQUIREMENTS

One of the main challenges in harmonisation is when consensus cannot be reached in international or multinational bodies. There is an aim to strive for consensus, but falls back on "majority rules".

Other challenges discussed by the panel include the desire for sovereignty in decision-making, along with the investment and resources needed to harmonise and collaborate. Additionally, it requires "like-minded" participation in order to establish co-operation, build confidence and set shared standards. The right instruments also need to be in place to allow for valuable information sharing (working groups, forums, frameworks, organisations, etc.).

KEY EXAMPLES OF HOW THOSE CHALLENGES WERE (OR WERE NOT) OVERCOME

Streamlined or fast tracked approval processes are key in urgent situations. Rapid approvals can be obtained by revising the very definition of “approval”. A conditional approval can be granted and withdrawn by regulator if not meeting required approved conditions. This allows approval of product without completeness of data. In addition, adequate resources were allocated to facilitate with prioritisation of work and parallel reviews.

To achieve better harmonisation, a multinational network of regulators uses a consensus-building approach. There is also the need to be open and promote interactive exchanges between all stakeholders, including regulators and publics, to overcome challenges with collaboration.

Additional guidance is helpful in overcoming challenges with innovation. For example, guidance was created to provided clarity and predictability for manufacturers of mobile medical applications.

There is a need to provide “reasonable assurance” for safety and effectiveness, but it is also a key to balance risks and benefits during the approval process.

A cost free pre-approval process is beneficial to enable an open dialogue between industry and regulators.

ACTION ITEMS THAT WERE IDENTIFIED DURING THIS SESSION

During the discussion, many observations were noted by the panellists:

- It is important to align standards, recognise commonalities, and develop a level of like-mindedness.
- Being transparent with the public is imperative when fast tracking approvals.
- The pandemic has demonstrated efficiencies in speeding up the regulatory process, and has shown that many approvals can be done in parallel.
- Regulatory approval is often a national decision, but the sharing of medical information and data amongst various countries should be increased.
- The medical sector utilises a 5-staged approach to building consensus that could be explored by other sectors :
 1. Consensus Building - Technical Document;
 2. Consensus on technical document - draft guideline adoption by regulators;
 3. Regulatory consultation and discussion;
 4. Consensus - guideline adoption by regulators;
 5. Implementation.

Session 6

Harmonisation of licensing: beyond regulators and licensees, how do the other stakeholders view the situation?

DESCRIPTION OF SESSION

The purpose of this session was to gather a broad range of different stakeholders (other than just regulators and regulated entities) from the various sectors who interact with decision-makers dealing with innovation. They shared insights and experiences in seeking regulatory approval, challenges observed, and lessons learnt.

This session touched on the structural phenomena that tend to drive new innovations including rapid scaling up of existing technologies and disruptive or paradigm-breaking technologies. Panellists noted that disruption is not only about new technologies but also about business models that apply. The convergence in different industries is also a source of this disruptive/new business model. Panellists also discussed the need of regulators to deal with this broad and more rapid, more frequent, more disruptive innovation. Furthermore, the panellists discussed management and assessment of global risk; how to qualify an acceptable level or risk for “everyday life”, how emerging innovations can raise emergent risks and how to identify new sources of risk. Finally, panellists noted that new technologies may also provide new tools to regulators to enhance and make regulation more effective and it is an exciting opportunity.

Moderator:

Mr Ramzi JAMMAL, Executive Vice-President and Chief Regulatory Operations Officer, Canadian Nuclear Safety Commission (CNSC)

Presenters and panelists:

- Mr Bruce CHEW, Federal Research Leader for Deloitte’s Center for Government Insights (DCGI) and Managing Director in Deloitte Consulting’s Government and Public Services (GPS), Deloitte
- Ms Kirsty GOGAN, Co-Founder, TerraPraxis and Managing Partner of LucidCatalyst, Chair of the UK Government’s Nuclear Innovation Research and Advisory Board (NIRAB) Cost Reduction Working Group, and Co-Founder Energy for Humanity (EFH)
- Ms Marie-Françoise RENARD-GONDINET, Offshore Sales and Marketing Director

- Mr Denis BOURGUIGNON, Nuclear Development and Technical Manager, BUREAU VERITAS
- Ms Kathryn MARTIN, Director, Asia & US Access Partnership
- Mr Jean-Jacques DOREAU, Executive Manager of the Agriculture Insurance Market, ALLIANZ France

KEY CHALLENGES ENCOUNTERED BY THE PANELLISTS INVOLVING REGULATORY APPROVAL OF INNOVATIVE TECHNOLOGIES

Panellists shared their perspectives and experiences working with regulators in non-nuclear sectors. It was noted from presentations and discussions that innovation brings new and sometimes unknown risks. Safety can be a fundamental challenge.

As with previous sessions, keeping pace with the rate and scales of innovation is difficult (i.e. hyper-growth). Innovation is also changing traditional business models and introducing challenges of data, digital privacy, and security.

The cost of a first-of-a-kind project is high and it is not clear who will be responsible for the risk liability. Insurance companies and governments are less willing to accept risks associated with technology.

Public acceptability is another area of challenge, and panellists noted that having a robust framework will gain more public and domestic confidence.

Regulatory approval in a single country may not be insurmountable. However, regulating the international commercial marine transportation industry provides an insight into just how complicated international harmonisation of the nuclear industry can be. The complexity and number of players that will be required should not be underestimated.

KEY CHALLENGES ENCOUNTERED BY THE PANELLISTS WHILE ATTEMPTING TO FACILITATE INTERNATIONAL COOPERATION AND/OR HARMONISATION OF REQUIREMENTS

It is a long and often slow process to reach harmonisation. It was suggested that regulators could utilise new regulator tools to increase effectiveness in regulation. To overcome the challenges in cooperation, the right forum is needed.

Public acceptability is a challenge because public may not see the need for proposed new technologies.

It was observed that the nuclear sector integrates Disruptive, Innovative, and Emerging Technologies (DIET) from other industries which means international co-operation between nuclear regulators will also require co-operation with a wide range of international regulatory bodies. From a technology developer's point of view, regulatory approval may not be as much of an obstacle as obtaining insurance. Co-ordinating the number of players necessary to bring about success (not just from the nuclear industry) is a very important challenge.

KEY EXAMPLES OF HOW THOSE CHALLENGES WERE (OR WERE NOT) OVERCOME

In the energy sector, climate change is seen as the driver for increasing public acceptance.

Success in regulating innovative technology requires collaboration amongst industry, policymakers, and regulators. A centralised regulatory process will help with standardisation, compliance and quality control, and harmonising equipment for economies of scale. The role of regional bodies is also critical to ensuring that global solutions are applicable at local levels. The voice of industry is vital to ensuring that regulatory approaches are appropriate and conducive to innovation. It was noted that in order to

encourage innovation and protect consumers, an iterative process for innovative technology could be considered:

1. Pre-regulatory: what do we have now?
2. Testing and evaluation: when to regulate?
3. Regulatory approach: how to regulate?
4. Revisit: what has changed?

ACTION ITEMS THAT WERE IDENTIFIED DURING THIS SESSION

Although specific follow up actions were not discussed, it was suggested that regulators should create clear requirements to enable innovative technologies. Other observations included:

- To address challenges with regulating innovative technologies, regulators may choose a more responsive and iterative approach (i.e. adaptive) and create regulatory sandboxes, adapting outcome/performance based regulation, risked informed regulation (such as the pre-certification model) and collaborative regulation.
- Regulators should consider ongoing and planned investments.
- Regular, centralised collaboration amongst countries is critical to strengthening co-operation with policymakers, regulators, manufacturers, operators, and academia.
- For innovative products, clarity is needed in order to accelerate deployment of products and support from policy makers and stakeholders.
- There are opportunities for regulators to develop an envelope to reduce the regulatory risk and enable a more standardised approach, create competition, leverage costs, and increase innovation and focus on core business.
- Use of new regulatory tools can improve effectiveness of regulations.
- A more global perspective is needed in the design of products that can be deployed where demand is greatest.
- Innovation can be achieved through innovative delivery and deployment models.
- It was acknowledged that while the nuclear sector is different from oil and gas sector, there are still similarities. For example, both are high-risk sectors and need independent and accredited parties. But the nuclear sector is regulated by national regulatory bodies while vessel is certified by specialised companies and national statutory bodies.
- Everyone must assess the level of risk and evaluate what is acceptable.

Session 7

Recommendations to the nuclear sector, the path forward

DESCRIPTION OF SESSION

This final session was structured with one panellist or speaker from each previous session providing an overall summary of session they participated in, followed by a panel discussion. Mr. Ramzi Jammal who moderated the previous sessions, joined the panel discussion and shared his observations based on discussions throughout the week, where the four questions from Ms. Rumina Velshi, CNSC President and Chief Executive, were touched upon.

Moderator:

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

Presenters and panellists:

- Mr Mark FOY, Chief Nuclear Inspector, UK Office for Nuclear Regulation
- Mr Christian SCHLEIFER-HEINGÄRTNER, Secretary General, EUROCAE
- Dr Jean-Christophe NIEL, Director General of Institute for Radiological Protection and Nuclear Safety, France, Chair of the OECD NEA Committee on the Safety of Nuclear Installations
- Mr Christopher Joseph (“C.J.”) FONG, Deputy Head for Regulation, Division of Nuclear Safety Technology and Regulation, NEA Nuclear Energy Agency (NEA)
- Mr Bruce CHEW, Federal Research Leader for Deloitte’s Center for Government Insights, and Managing Director in Deloitte Consulting’s Government and Public Services (GPS), Deloitte
- Mr Ramzi JAMMAL, Executive Vice President and Chief Regulatory Operations Office, Canadian Nuclear Safety Commission (CNSC)

OBSERVATIONS AND KEY DISCUSSION POINTS FROM THE SESSION

- The nuclear sector does not have a universal framework as other sectors do, which causes challenges in international harmonisation.
- There are international organisations such as NEA and IAEA whose mandates aim to support and facilitate harmonisation across the sector, but obtaining collective agreement on a large scale is difficult.

- Regulators cannot do this alone. Support is needed from governments and the whole of the industry to harmonise successfully.
- The harmonisation of transportation regulations shows that the nuclear sector can be successful. However, a better framework is needed to support harmonisation of innovative technologies.
- Harmonisation in the transport sector came from necessity. It was needed in order to allow cross-border shipments to be completed, and there was a desire for collaboration. For innovative technologies, industries are trying to protect their intellectual property, leading to difficulties in harmonisation.
- MDEP was ambitious, but it did show success in focused working group settings.
- Nuclear was a purely national programme and the idea of export was not at the core of the mission, therefore harmonisation was not considered. In aviation, the nature was always to export around the world and cross borders, leading to a need to harmonise from the outset.
- In aviation, modernisation and innovation are built on existing structures. Partnerships start quite early with industry, operators, end users, R&D, and regulators with common goals of safety and acceptable risk. The collaborative spirit has always been there. If compliance is demonstrated by meeting the performance objectives of safety without OPEX, then a technology is accepted as safe. Regulatory updates will take place, if required, based on the operational experience as it becomes available.
- Aviation industry engages very early on and educates the regulatory authorities. Collaboration exists without the fear of perception of institutional capture or of influence by the industry. This collaboration ensures safety being the outcome and leads to the approval of the technology. This is something the nuclear sector can learn from the aviation sector.
- A regulator's mandate is safety first and foremost. Regulators are not prohibited from adopting information from other bodies in the regulatory decisions. Harmonisation can be accomplished without taking away from regulatory sovereignty and decision-making. It is possible to collaborate and still retain national regulatory requirements.
- Although international collaboration is not part of a regulator's mandate, it is important to regulate in the most efficient way possible, and use all credible scientific and technical information at our disposal. It is to everyone's benefit to work together and share information.
- Innovation is moving at a very fast pace, and the nuclear sector cannot wait for international standards to be developed. Regulatory bodies need to continue to prepare for regulation of new technologies in their own ways.
- Part of the barrier to harmonisation is cost, and is proving detrimental to developing nations.
- In some ways, the nuclear sector is at the forefront. We understand risk better than some industries. In other ways, the industry is quite far behind. International harmonisation is the most difficult challenge we face. The structure of the industry makes it a challenge. But if our objective is to meet climate challenges, we need to move quickly and all work together.

VIDEO TIMING GUIDE

[Multi-sector workshop on innovative regulation - Closing session - YouTube](#)

- Introductory remarks from Mr William D. MAGWOOD IV (01:45)
- Mr Mark FOY (03:44)
- Mr Christian SCHLEIFER (10:50)
- Dr Jean-Christophe NIEL (18:28)

- Mr Christopher Joseph FONG (25:24)
- Mr Bruce CHEW (32:20)
- Mr Ramzi Jammal (40:30)
- Panel discussion (46:46)

Session 8

Closing Remarks

In the closing session, Ms Rumina Velshi, CNSC President and Chief Executive Officer, provided the following key highlights in her remarks:

- Readiness and preparedness for crises are important, but the nuclear sector should collaborate toward harmonisation without being driven by a crisis.
- Insights and discussions from the workshop provide a foundation for actions within the nuclear sector in our future efforts of advancing harmonisation and collaboration.
- The CNSC will continue to lead the effort in harmonisation, and we will encourage other countries and organisations to join this effort.
- SMRs are getting more support and interest from the Canadian government. Hence, readiness in regulation of SMRs is critical and harmonisation in this initiative is one of the priorities for the CNSC.

Summary of the closing remarks from Mr William D. Magwood IV, NEA Director-General:

- Thanked CNSC for partnering with NEA on this workshop;
- Nuclear is different from other sectors but there are lessons to be learnt;
- In some ways, nuclear is very much in the 21st century. For example, the nuclear sector has an advanced risk-informed framework and tools and has been implementing performance-based regulation for decades.
- In other areas (e.g. international harmonisation) nuclear is still in the 1950s. This is the most difficult challenge that we face and it is due in part to the structure of the industry and the regulatory framework.
- NEA is a platform for co-operation and we can assist with this.
- NEA is equipped to support and we look forward to working with our member countries (and perhaps even some non-member countries) in this area.
- The most important thing is that we have to act quickly. If our objective is to meet the climate challenge, we must move now. If we do not have the technologies and regulations in place to deploy advanced nuclear in the next 10-15 years, it will be too late.

VIDEO TIMING GUIDE

[Multi-sector workshop on innovative regulation - Closing session - YouTube](#)

- Closing remarks from CNSC President and Chief Executive Officer, Ms Rumina Velshi (01:13:24)
- Closing remarks from NEA Director-General, Mr William D. Magwood IV (01:21:02)