

Harmonising the Nuclear Licensing Process for Emerging Technologies: A Global Path Forward



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878

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GMB

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radical idea, but no more radical an idea than that one day each of us would have a personal computer. Remember the skeptics who once doubt anyone would ever purchase a personal computer.

The Artificial Intelligence (AI) market is predicted to grow in 2016 to in 2021, attaining Compound Annual Growth Rate (CAGR), barriers manufacturers face in evaluating and adopting technologies, and explores how global manufacturing companies can best capitalise on emerging technologies. The study defines exponential technologies as those that enable change at a rapidly accelerating, nonlinear pace facilitated by substantial progress and cost reduction in the areas of computing power, bandwidth, and data storage.

All of this, of course, flies in the face of conventional wisdom that...
The robotics future could look stranger than we ever thought. We need to think beyond the obvious to see us - only a bit stronger, more and fractional...
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When it comes to licensing innovative technologies, what lessons can the nuclear sector learn from other safety-related fields?

Background

Independent safety regulation has been a hallmark of the global nuclear power sector from its beginnings. Industry and government have long understood the importance of a predictable and adaptable regulatory structure and have worked co-operatively to ensure the safety of civilian nuclear energy throughout the lifetime of nuclear power projects – design, construction, operations and decommissioning.

Nuclear energy has benefitted from the adoption of new technologies and regulatory approaches developed by other sectors. Disruptive, innovative and emerging technologies from other industries continue to provide the civil nuclear industry with safety and economic benefits that support existing and planned reactors.

The deployment of advanced reactors incorporating emerging technologies is highly anticipated and will depend on regulatory frameworks that are appropriately positioned to independently analyse and evaluate the safety implications of the new technologies.

Innovation brings new and sometimes unknown risks, for example in the areas of digital instrumentation, data security and privacy. The adoption of new technologies in nuclear energy is also changing the business models that have historically governed the sector. While safety assurance is the primary objective of the regulatory authority, regulators often work at the intersection of safety and economics in that certain regulatory frameworks require a consideration of costs and benefits.

Regulators and industry should work together to protect the public from unnecessary risks while also enabling the benefits of innovation.

These issues were explored in a five-day workshop titled “Multi-Sector Workshop on Innovative Regulation: Challenges and benefits of harmonising the licensing process for emerging technologies”. The workshop was held in December 2020 and jointly sponsored by the Nuclear Energy Agency and the Canadian Nuclear Safety Commission.

The outcomes and conclusions of the event provide valuable insight from other sectors that have managed both the regulation of innovative technologies and global harmonisation. The lessons learnt will help the nuclear sector as it adopts advanced, disruptive technologies in the coming years.



Regulators are very well-suited to adjusting to small incremental changes to technologies they regulate but today they are faced with truly disruptive technologies for the first time since the commercialisation of nuclear energy. Are nuclear safety regulators ready? Are they really ready for SMRs? Are they ready for Generation IV?

Mr William D. Magwood, IV,
NEA Director-General

Why is effective regulation of innovative technologies important to the nuclear sector?

Rapid international scientific, technological, environmental and economic developments are forcing the nuclear sector to rethink its licensing process

Today's advanced reactor industry, comprised of new start-up companies and legacy nuclear vendors, is embracing innovative technologies that support the vision for smaller, safer reactor designs with significantly reduced nuclear material source terms. These reactors can be deployed in non-traditional locations with reduced on-site staffing requirements and can complement the intermittent power generation of renewable energy sources, as well as support hydrogen production and non-power applications such as desalinisation. Innovative technologies are also making it possible to incorporate non-water-based coolant and moderator technologies such as high-temperature gas, molten salt, and sodium, as well as innovative fuel designs to power these new reactors.

The new nuclear industry is being embraced by many governments and private sector power producers seeking to ensure sustainable pathways to decarbonise their economies. As such, the global nuclear regulatory community, a network of national regulators, intergovernmental regulatory authorities and non-government organisations, should be prepared to evaluate these innovative nuclear technologies via a robust regulatory framework that ensures public confidence and safeguards the optionality of advanced nuclear technologies as part of the global solution to climate change. In particular, the licensing process is an important stepping stone towards the deployment of advanced reactors. Nuclear regulators are facing innovative reactor designs that include disruptive technologies not present in the legacy light water reactor-based nuclear power plants deployed over the last 60 years.

Workshop participants were asked to consider four challenges:

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

From the opening remarks provided by Rumina Velshi, President and Chief Executive Officer, Canadian Nuclear Safety Commission (CNSC)

Over the course of the workshop, the speakers and panellists, all world-renowned experts in their respective industries (aviation, communications, medicine and medical devices, nuclear material transport, shipping, and others) provided insight and recommendations on the content and structure of world-class regulatory regimes. From their insight, four critical lessons were identified that can assist in the commercial deployment of advanced nuclear reactors:

1. Regulating innovative nuclear technologies should be a more participatory process. Other sectors involve the industry and other stakeholders early and often.
2. To sustain independence and transparency, it is essential to enhance trust between the public, regulators and industry.
3. Maintaining regulatory excellence requires that regulators evolve with the technology.
4. The nuclear sector should pursue global regulatory harmonisation.

The key lessons identified at the workshop

Regulating innovative nuclear technologies should be a more participatory process. Other sectors involve the industry and other stakeholders early and often.

A key lesson learnt that the workshop participants identified was that sectors with strong international collaboration had intentionally set the groundwork early on to establish harmonisation and international recognition of safety standards. For example, the Chicago Convention on International Civil Aviation, signed in 1944, states that “certificates of airworthiness, certificates of competency and licences issued or validated by the state in which the aircraft is registered, shall be recognised as valid by other states.” By committing to this principle, the signatories of this treaty (which now includes 193 countries) committed to an international framework where countries acknowledge the air safety decisions of other countries. For this to be effective, the airline industry recognised that these standards must reflect a sound international consensus and must be based on the best available technical information. Therefore, the Chicago Convention also establishes international minimum standards and states that the requirements for issuing certificates of airworthiness, certificates of competency, or licences must be equal to or above these standards.

The International Telecommunications Union (ITU), a specialised agency of the United Nations, provides another example of how stakeholder involvement is important, particularly as a sector evolves over time. The ITU has existed since the 1860s and has evolved from an organisation focused on radio communications to one that considers all forms of communication including satellite. The ITU has evolved with a continuously changing and increasingly diverse group of participants and radically changing issues and tools. Engagement from these stakeholders has helped the ITU adapt its framework to include technologies, such as satellite communications, that its founders could not have comprehended in the 1860s.

Stakeholders in advanced nuclear technologies should consider the lessons that can be learnt from these sectors.

For example, a group of countries interested in advanced reactors could develop a common set of safety principles and possibly a more detailed common set of codes and standards. They could also agree to accept some portion of the overall licensing review conducted by another country, in a manner similar to the commercial air sector.

In addition, stakeholders (including industry) in the nuclear sector should engage regulatory authorities to seek their thoughts on innovative, disruptive technologies that are under consideration for adoption prior to proceeding too far along the design and development pathway.

This early engagement between regulatory authorities and industry proponents should help develop an “art of the possible”, to find ways of working within existing requirements where possible and to develop new requirements if necessary.



The ITU is an intergovernmental body at its core, but it has over the years managed to incorporate not just industry players but academia, research institutions and other standards development bodies into the fold. What it is trying to do is to create a structure by which different stakeholders can come and develop standards, highlight best practices and also negotiate frequency spectrum use.

Ms Kathryn Martin, Director,
Asia and United States, Access Partnership



Industry needs to engage with us and ask for our view. Don't believe you will know what we think and, therefore, fail to engage us. It is society that will lose out as the best solution may never be proposed.

Mr Mark Foy,
Chief Nuclear Inspector,
UK Office for Nuclear Regulation



We believe strongly that any regulatory framework must be technology-inclusive, risk-informed and performance-based.

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

When it comes to safety regulation, independence should not be confused with isolation. The historic independence of the regulatory authority should not deter industry or the regulator from early technical and regulatory engagements as they may prove beneficial to all parties. The structure of these engagements may include introductory briefings on the technologies of interest and/or discussions of regulatory options for industry adoption of innovative technologies. The meetings may be interactive or purely informational. In those jurisdictions where regulators operate on a cost-reimbursement basis, industry may seek a cost waiver for these introductory meetings and the regulator may accept such a request considering the benefits which accompany such technical exchanges, including human capital development. Some countries have implemented grant programmes or organisation plans to provide funding to industry to cover the cost of early engagement with the national regulator. These programmes can be valuable to newer vendors that do not have alternate revenue streams to help them fund the licensing process.

Nuclear regulators should approach innovative, disruptive technologies from a technology-inclusive, risk-informed and performance-based perspective.

When introducing a new, innovative technology the first step should be to determine if it can be adopted within existing regulations. If existing regulations are sufficient, no change is needed. If the existing regulations are insufficient for the new technology, the regulator should seek to modify the existing regulations or develop new ones with an outlook towards harmonisation within the global nuclear regulatory community.



Regulation is almost always focused on minimising risk associated with new innovations and in this context it is very important that the regulator is provided with a reasonable level of understanding of how an innovation behaves in a variety of states: normal, abnormal and failure.

Ms Silva Gehrer,
International Civil Aviation Organization
Regional Director

To sustain independence and transparency it is essential to enhance trust between the public, regulators and industry

Regardless of the industrial sector, national regulators operating in a transparent and effective manner are critical to achieving a social licence to operate. It is also imperative to build and maintain trust among regulators, industry and the public while seeking harmonisation in regulations and licensing processes.

Successful regulation of innovative technologies in the telecommunications industry has been driven by the diversity of participants reviewing and updating existing regulations: governments, industry, academic observers, international and regional organisations, and non-government organisations all work together.

Within the nuclear power sector, trust is required between innovative technology proponents, national nuclear regulators, government policymakers, and the public. A technically proficient, independent, credible regulator is vital to public confidence and acceptability. Building a basis for mutual trust involves inviting the public and non-government organisations (NGOs) to collaboratively participate in the review,

revision and promulgation processes for regulations. Stakeholder engagement is critically important and must occur early, often and continuously. Both positive and negative aspects of innovation must be discussed in full transparency to build a robust regulatory system and licensing process recognised by all parties.



It starts with building trust among regulators so that we have confidence that we are each on the road to harmonisation for the right reasons and with the right intentions. It ends with building trust with proponents and the public in us as regulators and in the licensing processes we have in place and the decisions we make.

Ms Rumina Velshi,
President and CEO,
Canadian Nuclear Safety Commission

Maintaining regulatory excellence requires that regulators evolve with the technology

Innovation requires nuclear regulators to evaluate their processes, standards, and requirements to determine whether they are appropriate for the new technologies available to industry. While regulatory authorities are typically risk averse, it is incumbent on them to maintain operational awareness of rapidly changing technologies and their potential applications in civil nuclear energy. Regulators need to be flexible, accessible, enabling, and willing to work in a collaborative manner both domestically and internationally.

If regulators do not maintain awareness and understanding of the innovations, they will be unprepared for any attempt by industry to adopt the technologies. The adoption of emerging technologies within the nuclear sector will slow or stop and the regulatory gap between current regulations and those necessary for the new technology will continue to grow as the technology matures outside the regulatory context.

Policymakers and national regulators should ensure nuclear licensing and regulations are not impediments to technical progress. Regulators should balance privacy, safety, security and environmental sustainability and



The question is how do we achieve the right levels of standards, the standards of quality and performance in these products in a way that is conducive with the scale and rate of deployment that we need to address our climate challenges.

Ms Kirsty Gogan,
Terra Praxis

should establish a constructive environment for innovation and the inclusion of potentially disruptive technologies. Existing regulatory structures should not hinder the adoption of technical innovation and new nuclear requirements should be risk-informed and allow for innovation and technical advancement. If regulators overregulate, they risk creating an environment that stifles innovation, negatively impacting safety.

The establishment and maintenance of an agile regulatory system that is conducive to the introduction of innovative technologies requires the regulator to consider the existing regulatory framework before developing new regulations and also to take into consideration any lessons learnt from other national and international regulators in other industrial sectors. An agile regulator defines responsibilities across public authorities

to clarify regulatory roles, assesses the adequacy of national regulations, and engages experienced personnel from industry early in the regulatory development process. Effective communication with industry is also required to ensure regulatory approaches are appropriate and conducive to innovation.

The establishment of competence and credibility are prerequisites to a good regulatory framework as it builds confidence in the regulator's capabilities and in the public's perception of the maturity of the regulatory process. To ensure regulatory competence and enhance public trust, national regulators should maintain a close relationship with the international technical community, engage in a graded approach to training, have a system to register professional credentials, adopt a code of ethics, and establish a continuing professional development system.

The nuclear sector should pursue global codes, standards and regulatory harmonisation

The goal of harmonisation is not to have minimal standards and regulations, but standards and regulations that can be applied consistently. Harmonisation seeks functional equivalency in the regulations promulgated by sovereign authorities. The pursuit of global harmonisation of nuclear energy regulations is an ambitious undertaking and can benefit from looking to other industrial sectors that have been successful in this regard. The drivers for harmonisation and standards convergence (e.g. the need for aircraft to cross international borders) have not traditionally applied to large, stationary light water reactors. That said, there may be parallels for advanced reactor technologies, some of which are intended to be transported throughout the world.

The global aviation industry has a well-developed regulatory system comprised of a global framework (i.e. Chicago Convention), regional regulatory bodies, and national authorities. Within the aviation industry's regulatory framework, industry and government work collaboratively to ensure passenger safety and the reliable delivery of an essential service to all areas of the globe. The aviation industry and its international, regional and national regulators are productively engaged in the rapidly growing

transformational sector of remotely piloted aircraft systems (drones) and associated national and international regulations. A similar harmonisation of national regulations across the medical industry has been



In some ways, nuclear energy is very much in the 21st century. Nuclear understands risk better than most other industries. Nuclear has been focused on performance-based regulations for decades. But in other ways, nuclear is still in the 1950s and I do think that one case where we are in the 1950s is in international harmonisation. I believe this is the most difficult challenge we face. I think the structure of the industry and the structure of the regulatory infrastructure makes it more difficult to harmonise than perhaps it has been in other commercial areas.

Mr William D. Magwood, IV,
NEA Director-General

achieved through the alignment of national standards, work sharing between industry and regulators, the adoption of work done in other jurisdictions, and a recognition of decisions made by other competent regulatory authorities.

Collaboration within the global nuclear regulatory community allows for the sharing of knowledge, best practices, and lessons learnt. Collaboration on how to regulate innovation in nuclear applications with the goal of harmonisation should be a key priority of national nuclear regulators. With the emergence of an international advanced reactor industry that is being embraced by governments and private sector power producers seeking to ensure sustainable pathways to decarbonise power generation, there is an urgent need for agreement and co-operation among national nuclear regulatory authorities so that approved designs can be more easily adopted internationally. Regulatory requirements should be sufficiently harmonised so that minimal design changes are required to meet specific national regulations and the technical reviews of a lead national authority can be validated in a straightforward manner by other competent regulatory authorities.

A necessary initial step in the harmonisation of global nuclear regulations is the establishment of draft definitions and frameworks. Multi-national panels of nuclear regulators operating in a stand-alone fashion or under one of the existing international agencies could take the lead in developing these initial guidance documents.



You must start to establish definitions and frameworks, even if they are draft, so that people can come together and talk about these frameworks.

Dr Carlos Pena,
US Food and Drug Administration

Moreover, convergence of requirements could be initiated through an evaluation of which codes and standards – if harmonised – would be most beneficial to the deployment of advanced nuclear technologies. In the long term, the harmonisation of codes and standards will require the co-operation and co-ordination of standards developing organisations, the nuclear industry (e.g. vendors, designers, manufacturers and owners) and regulators on an international scale. It is achievable if one acknowledges that code harmonisation is a continual process.



Align regulation nationally and internationally by engaging a broader set of players across the ecosystem.

Mr Bruce Chew,
Deloitte

Regulatory harmonisation could begin with a small number of countries working together to harmonise their licensing and regulatory requirements with an initial focus on a limited number of cases, technologies or activities.

As more organisations are directly involved in harmonisation, the process will become more difficult to co-ordinate and require more time. A mechanism or platform to facilitate the exchange of information could be of great benefit. Chief among the obstacles to effective collaboration between national regulatory authorities are legacy regulatory practices.

A prioritised path forward for policy makers

The value proposition for civil nuclear energy in the global clean-energy economy has never looked brighter but increased international co-operation and global harmonisation of nuclear regulations is imperative.

Today's nuclear regulatory regimes have structural challenges in managing the pace of innovation, the scaling of innovative technologies, and the disruption of traditional business models resulting from innovation. These challenges, while daunting, are not insurmountable.

One important way to address these challenges is to align and harmonise regulatory requirements for advanced nuclear technologies. To do this, regulators should endorse common codes and standards for innovative features and should work together towards common acceptance of existing international standards to the extent that they are available. A central tenet of the harmonisation effort among national authorities is the willingness of participants to embrace practices and protocols that may differ from those of their home organisations or from those the regulators themselves have followed or espoused during their professional careers. A risk-informed philosophy that focuses on safety outcomes, rather than process or prescriptive requirements, can assist in this effort.

There is good reason for policymakers to be optimistic with respect to harmonisation. National nuclear regulators from Canada are currently working in a bi-lateral, collaborative manner with their counterparts from the United Kingdom and the United States to reach a higher degree of harmonisation in their approach to innovative technologies exemplified by small modular reactors (SMRs). The European Union (EU) is developing a vision for European SMRs in a decarbonised energy sector, including an assessment of a common standardised and streamlined licensing process for the national nuclear safety authorities of EU member states. In a similar fashion, other national nuclear regulators could pursue bi-lateral collaboration with countries seeking to harmonise regulations in support of nuclear trade.

Policymakers may also seek to engage their domestic industries and seek their insights regarding harmonisation of nuclear regulations with respect to innovative technologies. As advanced reactors continue to emerge as a viable alternative to traditional energy sources and legacy nuclear technologies in addressing climate change, the new reactor developers envision their designs for global export. The harmonisation of regulations is critically important to this vision. Policymakers would be well served to engage industry and regulators in identifying those technical areas where efforts to harmonise requirements would provide the greatest national benefits.

Consistent with its Strategic Plan for 2023-2028, the Nuclear Energy Agency (NEA) can assist in the harmonisation efforts by engaging with industry and academia across member countries to facilitate the identification of areas for future collaboration.

Starting to investigate topics of highest priority

In its unique role as both an independent technical and regulatory authority and intergovernmental organisation, the NEA is well positioned to convene subject-specific workshops to solicit input from national regulators and the nuclear industry and to encourage an multi-national convergence of codes, standards and safety goals. The NEA Multinational Design Evaluation Programme (MDEP), which facilitates co-operation between regulators on the design reviews of new reactors, is an example of how these NEA-facilitated discussions could lead to specific joint undertakings by member countries involved in the use of nuclear energy.

The NEA has a unique organisational authority to engage the national regulatory authorities and leading nuclear industry organisations of its member countries. The NEA can secure the necessary commitments of resources from member countries to advance regulatory harmonisation through the participation of experts in joint undertakings. The NEA can also hold workshops to identify regulatory processes for unlicensed technologies as well as for technologies previously licensed by regulatory authorities from other member countries. The NEA's engagement with the advanced reactor industry of member countries would be valuable to ascertain industry's views on the key technical and regulatory issues and the near-term and long-term priorities of industry with respect to regulatory harmonisation.

As evidenced by a comprehensive list of issues already identified by the regulatory community, the challenge of harmonising the regulatory requirements of independent national nuclear regulators is massive. The steadfast leadership of an organisation like the NEA will be required to oversee and manage the required collaborative development efforts over the next decade, based on a work plan that identifies the high priority technical and regulatory topics to be addressed first as well as the longer-term discussions to be held between all stakeholders. Such an undertaking will require the active participation and collaboration of numerous experts from regulatory organisations, industry, academia, and research laboratories and would be consistent with the NEA's strategic vision.

The NEA looks forward to working with its member and partner countries to take on this challenge.



The most important thing is we have to get this done quickly. If our objective is to meet the climate change challenge, we need to move very quickly. Decisions by governments and industry around the world are being made today and if we don't have the technologies and regulations in place to support advanced nuclear over the next decade it is going to be too late... This is not a long-term project. We have to do this now. We have to do it by working together.

Mr William D. Magwood, IV,
NEA Director-General



The Nuclear Energy Agency (NEA) is an intergovernmental agency established in 1958.

Its primary objective is to assist its member countries in maintaining and further developing, through international co-operation, the scientific, technological and legal bases required for a safe, environmentally sound and economical use of nuclear energy for peaceful purposes. It is a non-partisan, unbiased source of information, data and analyses, drawing on one of the best international networks of technical experts.

The NEA has 34 member countries: Argentina, Australia, Austria, Belgium, Bulgaria, Canada, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Korea, Luxembourg, Mexico, the Netherlands, Norway, Poland, Portugal, Romania, Russia, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The NEA co-operates with a range of multilateral organisations, including the European Commission and the International Atomic Energy Agency.



Nuclear Energy Agency (NEA)

46, quai Alphonse Le Gallo
92100 Boulogne-Billancourt, France

Tel.: +33 (0)1 73 21 28 19

nea@oecd-nea.org www.oecd-nea.org

NEA No. 7616