



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

Date: 14 - 18 December 2020

Location: Zoom Webinar



Introduction

The OECD Nuclear Energy Agency (NEA) in collaboration with the Canadian Nuclear Safety Commission (CNSC) will host an international, multi-sector workshop on 14-18 December 2020 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. This workshop will 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 is 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 will discuss early observations from those projects.

The workshop will bring together 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 will focus on practical examples of how regulators can address two key challenges:

- **Challenge #1 – How should regulators approach licensing of innovative and disruptive technologies?** Deciding whether to approve 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.

From a policy perspective, countries often have different legal and regulatory standards that they apply to prospective designs. This can 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, this portion of the workshop will explore how countries can leverage bi-lateral or multi-lateral technical work in making their final safety decision.

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

PROGRAM

Day 1 – Monday, 14 December

1300 – 1310 (UTC+1) *Introductory information and Zoom logistics*

Opening remarks, objectives of the workshop, frame the challenges

1310 – 1340 (UTC+1)

- **Mr. William D. Magwood, IV** Director-General of the NEA
- **Ms. Rumina Velshi**, President and Chief Executive Officer of the CNSC



Mr. William D. Magwood, IV, is the **Director-General of the OECD Nuclear Energy Agency (NEA)** since September 2014. Prior to this position, he served from 2010 to 2014 as one of the five Commissioners appointed by the US President and confirmed by the US Senate to the US Nuclear Regulatory Commission (NRC). From 2005 to 2010, he provided independent strategic and policy advice on energy, environmental and technology policy issues. From 1998 to 2005, Mr. Magwood was Director of Nuclear Energy at the US Department of Energy (DOE). During his tenure, he launched several important initiatives including the Generation IV International Forum (GIF) and the formation of the Idaho National Laboratory (INL). He began his career working as a scientist for Westinghouse Electric Corporation and managing electric utility research and nuclear policy programmes at the Edison Electric Institute.

Mr. Magwood, a US national, holds Bachelor's degrees in Physics and English from Carnegie Mellon University and a Master of Fine Arts from the University of Pittsburgh.



Ms. Rumina Velshi is the **President and Chief Executive Officer of the Canadian Nuclear Safety Commission (CNSC)**. Ms. Velshi has had a long association with the CNSC, having been a Commission member from 2011 until her appointment as President and CEO. Ms. Velshi has extensive technical, regulatory and adjudication expertise in the energy industry. Throughout her career, she has worked in various capacities at Ontario Hydro and Ontario Power Generation, the electrical utilities in the province. Ms. Velshi also previously served as a part-time Board member of the Ontario Energy Board, the economic regulator of the province's electricity and natural gas sectors. In February 2020, Ms. Velshi was appointed Chairperson of the Commission on Safety Standards (CSS), established by the International Atomic Energy Agency (IAEA), for a four-year term. Ms. Velshi very actively promotes careers in science, technology, engineering and mathematics (STEM), especially for young women. Since joining the CNSC

as President and CEO, she has launched a women-in-STEM initiative to consider ways to support women in STEM careers at the CNSC and elsewhere, and to further STEM education by working with interested partners. She has also delivered several international keynote addresses about breaking down barriers for women in STEM.

Workshop Moderator



Mr. Ramzi Jammal is Executive Vice-President and Chief Regulatory Operations Officer Regulatory Operations Branch, Canadian Nuclear Safety Commission (CNSC)

Ramzi Jammal has worked for the CNSC since 1998, holding progressively senior positions. He has accumulated over 20 years of experience in the nuclear industry, combining management skills with scientific expertise, and representing the CNSC in various international activities. These include the development and establishment of the IAEA Code of Conduct for the Safety and Security of Radioactive Sources, and the international categorization of radioactive sources. He also played a key role in ensuring that the recommendations of the International Commission on Radiation Protection complemented the CNSC's regulatory needs.

Prior to joining the CNSC, Mr. Jammal was the Technical Manager of the Department of Radiological Sciences Nuclear Medicine Division at the Ottawa Hospital's Civic Campus. Under his leadership, the department became the first filmless nuclear medicine department in Canada.

He has received several academic awards, including the North American Society of Nuclear Medicine's First Place Award for new scientific advancements in nuclear medicine.

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

1340 – 1500 (UTC+1)

The objective of this session is to set the table for the workshop by identifying and explaining the challenges that the nuclear sector has experienced with licensing “innovative” or unconventional technologies. This can occur when licensing new reactors or when licensing innovative technologies that support the existing fleet (e.g. 3D-printed components). The panellists will:

- provide an overview of the process for seeking regulatory approval of nuclear technologies (i.e. the licensing process);
- provide an overview of the role of international organisations and the level of harmonisation of regulatory requirements for nuclear technologies;
- share the most important challenges and successes regarding past cases of licensing innovative nuclear technologies and the related lessons learnt while also opening the discussion to recent/future examples and providing their insights and recommendations.

In discussing these topics, the panellists will address the following questions:

- What role do codes and standards play in the acceptance of new nuclear technologies?
- How are codes and standards developed and to what degree are they harmonised internationally?
- What are the main obstacles for new entrants (i.e., new companies wishing to enter the nuclear field) and how can these obstacles be overcome?
- How can innovative technologies be approved more quickly while still ensuring safety and maintaining public trust?

Speaker:

- **Mr. William RANVAL**, Director of ENISS (European Nuclear Installations Safety Standards).

Panellists:

- **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

Moderator:

- **Mr. Ramzi JAMMAL**, Executive Vice President and Chief Regulatory Operations Officer, Canadian Nuclear Safety Commission



William Ranval took his duties as ENISS Director in Brussels on 1st January 2018 – ENISS is an association of about 20 European nuclear installation licensees, which interacts with WENRA, IAEA, the European Commission, and other stakeholders on safety and regulatory matters (www.eniss.eu).

He is the EDF member of the EUR Steering Committee, and Member of the Hinkley Point C Nuclear Safety Committee.

From 2014 to 2017 he was Head of the Department Transfers to Environment, Radiation Protection and Severe Accidents at the EDF Design and Technology Branch, delivering to all EDF projects. These positions were preceded by international experiences, as Nuclear Safety Expert in China, and from 2007 to 2012 in the UK, firstly involved in the Generic Design Assessment of the EPR TM then as Safety Case and Reference Design Branch Manager of the Hinkley Point C Project, delivering the PreConstruction Safety Report which supported the Nuclear Site License granted by the ONR in 2012.

Previously his experience, from 1993, has been built on a number of positions as engineer and team manager from R&D to industrial applications in the field of Severe Accidents, leading a number of R&D Programs and providing expertise to the EDF Nuclear Emergency National Team

Mr. Ranval holds a Master of Mechanical and Energy Engineering from Arts et Métiers Paris Tech., which was followed by a research position in 1991-1992 in Thermodynamic System Modelling at the Lawrence Berkeley National Laboratory.



Maria Korsnick is President and Chief Executive Officer of the Nuclear Energy Institute, the nuclear industry's policy organization in Washington, D.C. Drawing on her engineering background, hands-on experience in reactor operations and a deep knowledge of energy policy and regulatory issues, Ms. Korsnick aims to increase understanding of nuclear energy's economic and environmental benefits among policymakers and the public. Before joining NEI, she was senior vice president of Northeast Operations for Exelon, responsible for overseeing operation of the Calvert Cliffs 1 and 2, R.E. Ginna, and Nine Mile Point 1 and 2 nuclear power plants.

Before Exelon, Ms. Korsnick served as chief nuclear officer (CNO) and acting chief executive officer at Constellation Energy Nuclear Group. She began her career at Constellation in 1986 and held positions of increasing responsibility, including engineer, operator, manager, site vice president, corporate vice president, and CNO. Ms. Korsnick holds a bachelor's degree in nuclear engineering from the University of Maryland, and has held a Senior Reactor Operator license. She lives in Maryland with her husband and two children.



Mark Foy is the Chief Nuclear Inspector (CNI) at the United Kingdom's Office for Nuclear Regulation. He is the regulatory head of the organisation and executive member of the ONR Board. During the last 18 years, he has successfully led ONR's regulatory activities across various sectors of the UK's nuclear industry, including civil reactor new build, NPP operations, spent fuel and radioactive waste management and defence. Mark is an accomplished nuclear safety professional, with over 30 years of experience in all aspects of the nuclear lifecycle, from design and commissioning through to operation and decommissioning. He also has extensive international experience, having undertaken various senior roles within the international regulatory community. Mark has a Bachelor's Degree with Honours in Mechanical Engineering, and is a Chartered Fellow of the UK's Nuclear Institute.



Ho Nieh is the Director, Office of Nuclear Reactor Regulation (NRR), U.S. Nuclear Regulatory Commission (NRC). Mr. Nieh joined the NRC in 1997 as a resident inspector and conducted safety inspections at pressurized water and boiling water reactors. His management experience includes responsibilities for the NRC's Reactor Oversight Process, emergency preparedness, licensing and rulemaking, control room operator licensing, operating experience, emergency response, research and test reactor oversight, and decommissioning funding. Mr. Nieh also served as the Chief of Staff for an NRC Commissioner and was the Director of the Division of Reactor Projects in NRC's Region 1 office where he was responsible for the resident inspectors. He also served as the Director of the Division of Inspection and Regional Support in NRR. Most recently and prior to Mr. Nieh's return to NRC, he was Head of the Nuclear Energy Agency's Division of Nuclear Safety, Technology and Regulation, where he was responsible for international cooperation in regulatory policy, safety research, and new reactor regulatory reviews. Mr. Nieh also worked at the International Atomic Energy Agency as a Communications Advisor in the Department of Nuclear Safety and Security.

Mr. Nieh holds a Bachelor's degree in Marine Engineering from the New York Maritime College. Mr. Nieh is a graduate of the United States Naval Nuclear Power School and attended Rensselaer Polytechnic Institute for graduate studies in nuclear engineering. Mr. Nieh also holds a Master of Business Administration from the Johns Hopkins University.



Simon Irish is Chief Executive Officer of Terrestrial Energy. He has 20 years of global investment banking and investment management experience in New York and London, and has a formal education in the quantitative sciences and quantitative finance.

Mr. Irish has established and managed multi-billion-dollar alternative investment businesses in North America. Mr. Irish formerly led the investment effort in North America for Man Group Plc, a leading global investment management business. He began his banking career at Credit Suisse in London before moving to New York. In 2010, he focused on investment opportunities in breakthrough energy technologies and specifically nuclear energy given its unparalleled virtues, and the commercial potential of advanced reactors in many industries. Mr. Irish holds an MA in Natural Sciences from Cambridge University and an MSc in Finance from the London Business School.



Anton Moskvina is Vice President for Marketing and Business Development in Rusatom Overseas, front-rank player of the Russian nuclear industry, which brings the exclusive Rosatom Integrated Offer to the global market. Mr Moskvina has over 10 years of professional experience in the Russian nuclear energy industry.

Mr. Moskvina leads Rusatom Overseas activities in international business development and manages the analytics team.

Anton Moskvina holds a degree in International Relations from National Research Nuclear University (MEPhI) and is a Certified IPMA Level “A” Project Director.

Day 2 – Tuesday, 15 December

Session 3: Moving safely from aircrafts to drones: licensing disruptive technologies

1300 – 1310 (UTC+1) *Introductory information and Zoom logistics*

1310 – 1500 (UTC+1)

Speakers and panellists will provide an overview of the many lessons learnt from the aviation sector on their certification process.

They will share the most important challenges and lessons learnt regarding past cases of major innovations and the related lessons learnt. The discussion will be also open to recent and future examples. Speakers will provide their insights and recommendations particularly in the following areas:

- How can we adapt existing regulatory frameworks to new technologies?
- What roles can standards play in international harmonisation?
- How should international organisations facilitate and improve the certification process?
- How can regulators and other stakeholders maintain and even raise a high level of trust?

Speakers:

- **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

Panellists:

- **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)
- **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

Moderator:

- **Mr. Ramzi JAMMAL**, Executive Vice President and Chief Regulatory Operations Officer, Canadian Nuclear Safety Commission



Silvia Gehrler is the Regional Director of the European and North Atlantic (EUR/NAT) Office of ICAO since 01 February 2019. Previously, she was Director General International from 2013 to 31 January 2019 where she was heading the Department of Strategy and International in the Austrian Civil Aviation Authority since 2009. She initially worked with the Ministry for Economic Affairs and joined the Austrian Permanent Representation at the EU in Brussels in 1995, the year of Austria's accession to the EU as Trade Policy Attaché. She also worked at the US Embassy in 1999 before joining the Austrian Ministry for Transport in 2000 where she headed the unit for EU and International Aviation. From 2004 to 2007, she represented Austria on the Council of the International Civil Aviation Organisation as a member of the ABIS Rotation Group (Belgium, The Netherlands, Luxemburg, Ireland, Switzerland and Ireland). Ms. Gehrler received a Master Degree in Business Administration

specialising in Aviation and Trade from Vienna Economic University and also holds a Master Degree in Public Relations.



Jagoda Egeland joined the Organisation for Economic Co-operation and Development (OECD) in 2011. She currently serves as an Advisor in the Office of ITF Secretary-General and leads aviation projects at the International Transport Forum (ITF) at the OECD.

Prior to taking up her role at the ITF, she was in charge of managing strategy and relationships with airlines at the UK Airports Commission, a body set up by the Prime Minister to examine the long-term airport capacity needs in the UK. During her time at the Commission, Ms. Egeland led UK Government's work in the fields of aviation connectivity, airline competition, scenario-based forecasting, hub economics, and the future of global route networks.

Ms. Egeland also worked as a consultant on public policy issues in the private sector, the UN International Labour Organization, and at the London School of Economics where she was also a class teacher. Ms Egeland holds an MSc in Public Policy from Maastricht University and a BSc in Mathematics and Economics from the London School of Economics. She is a British and Polish national.



Christian Schleifer-Heingärtner joined EUROCAE in July 2014 as Secretary General. Since then he is responsible for the operational management and development of the Association. As former President of the Air Navigation Commission (ANC) of the International Civil Aviation Organization (ICAO) he was responsible for developing Standards and Recommended Practices (SARPs) in the field of Air Navigation and Safety. Prior to his posting at ICAO, Mr. Schleifer was in charge of Aircraft and Equipment Certification, Airworthiness and Operational Requirements at the Austrian Civil Aviation Authority. In this role, Christian Schleifer was a specialized Certification and Flight Test Engineer for Avionics, Electrics and Human-Machine interface. After his return from ICAO, he was involved in the strategic development of the

ANS side of Austro Control, contributing to the European and Global Air Navigation modernization programs. Christian has a background in Electronic Engineering and Economics and is also holding an Avionic Maintenance License (AML) as well as a Commercial Pilot License (CPL) and actively flies single and multi-engine aircrafts.



Simon Moore is an Assistant Secretary at the Australian Department of Infrastructure, Transport Regional Development and Communications. He is responsible for aviation safety and future technology.

He previously (2013-2019) was at the Australian Maritime Safety Authority. Prior to that Simon had various roles at the Australian Department of Foreign Affairs and Trade (2005-2013) and the Department of the Prime Minister and Cabinet (2002-2004). He is also a former newspaper and television journalist.

Simon has a Master of International Law from the Australian National University. He also has a Graduate Certificate in International Relations and Asian Politics, a Bachelor of Arts with majors in journalism and philosophy, and a Bachelor of Science majoring in Earth sciences.

Simon was awarded an Australian Service Medal in 2003.



Vassilis Agouridas is leading the EU Public Co-Creation & Ecosystem Outreach activities at AIRBUS (Urban Mobility). Vassilis is, on behalf of Airbus, the Urban Air Mobility (UAM) Initiative Leader that was launched in October 2017 within the Smart Cities Marketplace supported by the European Commission. Forty-two (42) cities and regions across Europe have joined the initiative to explore through mobility demonstrators the 3rd dimension in urban and peri-urban mobility. In addition, Vassilis is Chairman of the UAM Working Group of ASD Europe (AeroSpace & Defence Industries Association of Europe).

Day 3 – Wednesday, 16 December

Session 4: The international licensing system for transportation of nuclear material: a success story and a look to the future

1300 – 1310 (UTC+1) Introductory information and Zoom logistics

1310 – 1500 (UTC+1)

The objective of this session is to share the lessons learnt and challenges encountered on the way of harmonising the regulatory approaches for transportation of nuclear materials. This session will also identify and explain the challenges that are encountered when licensing “innovative” or unconventional technologies (e.g. transportable NPP/SMR, shipping unique waste streams from non-light water reactors, etc.).

The speaker and panellists will:

- provide an overview of the role of international organisations and the level of harmonisation of regulatory requirements for transportation of nuclear materials;
- provide a brief overview of the process for seeking regulatory approval of new technologies or initiation of review of regulations for the new technologies;
- share the most important challenges and successes regarding past cases of reviewing and approving innovative technologies and the related lessons learnt while also opening the discussion to recent/future examples and providing their insights and recommendations.

In discussing these topics, the panellists will address the following questions:

- What role do safety standards and requirements play in the acceptance of new technologies in terms of transportation of nuclear materials?
- How can international regulations be transferred to national, considering different technical approaches?
- What are the current and anticipated challenges that industry and regulators encounter within the existing regulatory framework?
- What are the key areas for international collaboration in order to overcome those challenges?
- What are the main obstacles for new entrants (i.e. new companies wishing to enter the field of nuclear transportation) and how can these obstacles be overcome?
- How can innovative products be approved more efficiently while still ensuring safety and maintaining public trust?

Speakers:

- **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 Director of ENISS (European Nuclear Installations Safety Standards).

Panellists:

- **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
- **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

Moderator:

- **Mr. Ramzi JAMMAL**, Executive Vice President and Chief Regulatory Operations Officer, Canadian Nuclear Safety Commission



Stephen Whittingham joined the nuclear industry in 1980 working on the design and development of a BWR spent fuel cask design, compilation of the PDSR and was responsible for the submission for competent authority design approval and European validations. Subsequently he was responsible for the package design safety cases and submissions for package design approval for a fleet of PWR and BWR spent fuel casks operated in Europe for the delivery of spent fuel to the reprocessing plants in France and the UK.

Stephen joined the UK Competent Authority in 2004 where he developed the compliance inspection programme for non-nuclear operators. He was a member of the UK Government decommissioning and waste strategy groups and has represented the UK in many international meetings. During this time, he served for two terms as Chairman of the European Association of Competent Authorities, which was formed in 2008 with a membership of 23 European States.

Stephen joined the IAEA in 2013 and is the Head of the Transport Safety Unit, he is the scientific secretary of the Transport Safety Standards Committee (TRANSSC) and his Unit is responsible for the management of the IAEA SSR-6 Transport Regulations, associated IAEA guidance documents, and transport safety regulator capacity building in IAEA Member States.



Martin Porter joined the UK nuclear industry in BNFL at Sellafield in 1983 to take up a post in the emerging health science of Occupational Hygiene.

Martin is a University of Manchester Occupational Health Post-Graduate and worked for 26 years in the field of Occupational Hygiene and Chemical Safety at Sellafield. In 2008 his work as a senior event investigator introduced him to radioactive material transport and a change of career ensued when Martin was appointed Head of Operations for nuclear transport at Sellafield Limited. In this position, he

was responsible for many fuel, high-level waste and reprocessed product shipments around the globe. During his time at Sellafield, he was a Board Member and Chair of the UK nuclear industry transport committee (RAMTUC), a Board Member of the UK radioactive transport emergency response mutual aid scheme (RADSAFE), Chair of the World Nuclear Transport Institute (WNTI) Back-End Working Group and a member of the World Nuclear Transport Institute (WNTI) Advisory Committee.

In April 2020, Martin took up his current role of Secretary General at the World Nuclear Transport Institute, based in London, UK. In his WNTI role, Martin will be focussed on helping ensure that future nuclear missions are transport-enabled with the appropriate capability and fit-for-purpose international regulations.



Dr. Jean-Christophe Niel has a long experience in the control of nuclear safety and radioprotection through various positions at the French technical safety organization IRSN and at the French nuclear safety authority ASN.

Born in 1961, graduate of Ecole Polytechnique (class of 1980) and Ecole Nationale des Ponts et Chaussées (class of 1985), Dr Jean-Christophe Niel holds a PhD in Theoretical Physics from the University of Paris VI and is a general civil engineer of Pont, water and forests. He held various positions in the field of control of nuclear safety and radiation protection. From 1991 to 1995, he was in charge of the control of the fuel cycle, radioactive waste and control facilities at the Department of Safety of Nuclear Installations (DSIN) of the CEA. From 1995 to 2005, he held various functions at IRSN, notably Head of the safety assessment department and Director of strategy, development and external relations. From 2005 to 2006, he was Head of the strategy mission at the Ministry of equipment and transport. Dr Jean-Christophe Niel was Director General of the French nuclear safety authority (ASN) for almost 10 years.

The President of the French Republic appointed Dr Jean-Christophe Niel at the head of French Institute of Radiation Protection and Nuclear Safety (IRSN) in April 2016. Before becoming DG of IRSN in 2016, he was DG of ASN for almost 10 years.

He currently chairs the CSNI, the Committee of safety of nuclear installations of the Nuclear Energy Agency.



Rebecca Tadesse joined the NEA in January 2019 and is responsible for advancing information exchange and studies in the fields of radioactive waste management, nuclear facility decommissioning and legacy management.

Prior to joining the NEA, Ms Tadesse served as Chief of the Radiation Protection Branch at the United States Nuclear Regulatory Commission. She has over 27 years of domestic and international experience in operation and radiation safety of research reactors, fuel fabrication facilities, nuclear power plants and biomedical research facilities. Ms Tadesse holds a B.S. in Radiation Physics from Purdue University and an M.S. in Environmental Science/Policy from Johns Hopkins University.



Serge Gorlin is Head of Industry Cooperation at the World Nuclear Association, the international trade association for nuclear energy based in London, England. He holds responsibility for the Association's Working Groups, forums through which the enterprises of the global nuclear industry share leading practice, conduct analysis, and develop consolidated positions on economic, safety and environmental issues. Several of these groups act as the interface for industry at organisations, such as the International Atomic Energy Agency (IAEA), the International Commission for Radiological Protection (ICRP) and the Nuclear Energy Agency (NEA) of the OECD.

Serge is a member of the IAEA's Transport Safety Committee (TRANSSC), as well as co-Chair of the Transport Facilitation Working Group, a multi-stakeholder group that proposes strategies and activities to facilitate the transport of radioactive material. In 2005, he published a textbook for learners of English working in the nuclear field entitled Nuclear English – Language Skills for a Globalizing Industry (WNU Press), which was revised in 2013. It remains widely used at companies, research institutes and universities worldwide. Serge is a regular speaker at World Nuclear University (WNU) events, and has led WNU short courses in China and South Korea. His career in nuclear began as a translator and interpreter at British Nuclear Fuels (1996 – 2000).



Jennifer Nugent has been working in the arena of international nuclear transport for nearly 20 years, where she is Head of Technical for INS, leading a team of engineers, scientists and regulatory specialists delivering package design and licensing solutions to the nuclear industry. Working to develop and influence the national and international transport regulations of the future.

Early career was focused on the international consignment of front-end fuel cycle materials (Uranium Ore Concentrate (UOC), Uranium Hexafluoride (UF₆), Uranium Oxides and Enriched Uranic fuels). This progressed into transport package design, safety case development and securing regulatory approvals covering the full nuclear fuel cycle from front end through to Mixed Oxide (MOX) fuels, separated plutonium (Pu) High Enriched Uranium (HEU), irradiated wastes and also supporting transport of radioactive sealed sources.

Working with Competent Authorities in the UK, France, Germany, Netherlands, Belgium, Japan, Russia and the US to gain transport approvals. Recent significant accomplishments to deliver novel solutions for the transport of exotic nuclear materials resulted in the approval of the UK's first Multiple Water Barrier transport safety case.

Day 4 – Thursday, 17 December

Session 5: Innovation without borders: challenges and successes of international co-operation on emergent medical technologies

1300 – 1310 (UTC+1) *Introductory information and Zoom logistics*

1310 – 1500 (UTC+1)

The speakers and the panel will:

- provide a brief overview of the process for seeking regulatory approval of new medical technologies;
- provide an overview of the role of international organisations and the level of harmonisation of regulatory requirements for medical technologies.

Panellists will share the most important challenges and successes regarding past cases of reviewing and approving innovative medical technologies and the related lessons learnt but also to open the discussion to recent/future examples and provide their insights and recommendations; particularly in the following areas:

- What role do safety standards play in the acceptance of new medical technologies? How are safety standards developed and to what degree are they harmonised internationally?
- What are the main obstacles for new entrants (i.e. new company wishing to enter the medical field) and how can these obstacles be overcome?
- How can innovative products be reviewed quickly while still ensuring safety and maintaining public trust?

Speakers:

- **Dr. Adriana VELAZQUEZ BERUMEN**, MSc., Biomedical Clinical Engineer, 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
- **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

Panellists:

- **Dr. Carlos PEÑA**, Ph.D., M.S., Director, Office of Neurological and Physical Medicine Devices (OHT5), Office of Product Evaluation and Quality (OPEQ), Centre for Devices and Radiological Health, U.S. Food and Drug Administration
- **Dr. William HEETDERKS**, PhD, MD, Consultant to the United States National Institutes of Health, Former Senior Regulatory Official at the United States Food and Drug Administration
- **Dr. Emmanuelle VOISIN**, PhD, Founder & CEO, Voisin Consulting Life Science

- **Dr. Adriana VELAZQUEZ BERUMEN**, MSc., Biomedical Clinical Engineer, 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
- **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

Moderator:

- **Mr. Ramzi JAMMAL**, Executive Vice President and Chief Regulatory Operations Officer, Canadian Nuclear Safety Commission

Dr. Adriana Velazquez Berumen, Team Lead Medical Devices and In Vitro Diagnostics, WHO. (tbp)



Francesca Colombo, M.Sc., is Head of the Health Division at the Organisation for Economic Co-operation and Development. She oversees OECD work on health, which aims at providing internationally comparable data on health systems and applying economic analysis to health policies, advising policy makers, stakeholders and citizens on how to respond to demands for more and better health care and make health systems more people centred. Major activities of the OECD Health Division cover the response to the COVID-19 crisis and solutions to make health systems more resilient; trends in health spending; measuring of health care outcomes, activities and inputs; health care quality policies; assessing health system efficiency and value for money; health workforce; long-term care systems and ageing; the economics of public health; pharmaceutical policies, new technologies, big data and Artificial Intelligence in health. Mrs Colombo has over 20 years of experience leading international activities on health and health systems. Over her career, she travelled extensively in Europe, South America and Asia, advising governments on health system policies and reforms.



Dr. Harald Enzmann has experience in academic, corporate and regulatory settings. A physician by training (graduation 1985), he received his MD “summa cum laude” from the Karl Rupprechts University, Heidelberg, Germany. Subsequently, he held positions at the German Cancer Research Center, at the Institute of Pharmacology and Toxicology at the University of Erlangen, at R&D at Bayer AG, Wuppertal and at the American Health Foundation in Valhalla, NY, USA. In 2002, he joined the German Federal Institute for Drugs and Medical Devices (BfArM).

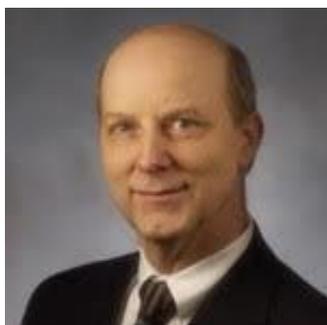
H. Enzmann received the Award of the German Cancer Research Center for Outstanding Research in 1987 and the Animal Welfare Research Award of the German Ministry of Health in 1995. He received the Master of Science Degree for Experimental Pathology from the New York

Medical College 1996, the title “Privatdozent” and the *venia legendi* in Experimental Pathology from the University of Heidelberg in 1999.

H. Enzmann is a fellow of the International Academy of Toxicologic Pathology, member of the European Society of Toxicological Pathology, of the Society of Toxicology and of the European Association for Cancer Research. Member of the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) since 2005, Harald was elected vice chair of CHMP in October 2016 and chair of CHMP in September 2018.



Dr. Carlos Peña is Director for the Office of Neurological and Physical Medicine Devices, in the Center for Devices and Radiological Health (CDRH), at the U.S. Food and Drug Administration (FDA). Dr. Peña is involved in all aspects of the safety and effectiveness review of neurostimulation, neurodiagnostic, neurosurgical, neurotherapeutic, and physical medicine devices. Prior to joining CDRH, Dr. Peña served on detail as Assistant Director for Emerging Technologies in the Office of Science and Technology Policy (OSTP), in the Executive Office of the President of the United States. His areas of expertise included science, technology, policy, analysis, and regulatory matters related to biology, neuroscience, biotechnology, emerging technologies, and agriculture. Before joining OSTP/FDA, Dr. Peña served at the National Institute of Neurological Disorders and Stroke, National Institutes of Health. He completed his neurosciences doctoral training at Case Western Reserve University in Cleveland, Ohio. He also attended the University of Connecticut for the Masters in Comparative Physiology, and the City College of New York, City University of New York, where he received a Bachelors specializing in Developmental Biology.



Dr. William Heetderks is currently a Senior Advisor at the National Institute of Biomedical Imaging and Bioengineering (NIBIB) at the US National Institutes of Health (NIH). There he is working on the RADx program, an effort to radically increase the availability of COVID testing in the US by scaling up existing test manufacturing capacity and by developing new diagnostic tests. Before retiring 2 years ago, he was the Director of Clinical Studies in the Division of Neurological and Physical Medicine Devices (DNPMD) at the US Food and Drug Administration (FDA). Prior to going to the FDA he was the Director of the extramural sciences program at NIBIB for many years where he directed a diverse program for support of Biomedical Imaging and Bioengineering research at several hundred universities and medical centers. He is board certified in Internal Medicine and received his PhD in Bioengineering.



Dr. Emmanuelle Voisin founded Voisin Consulting Life Sciences (VCLS) in 1997. The firm has become a leading advisor to Biotech, Pharma and Medtech manufacturers for the development, registration and launch of innovative medical technologies across international markets.

Dr. Emmanuelle Voisin has 30+ years' experience in drug development. Her expertise lies in non-conventional development strategies, maximizing the use of regulatory mechanisms and innovative approaches, to bring innovative technologies to patients. She has a particular interest in the in silico clinical development leading to expedited approval of drugs and biologics. Emmanuelle also provides strategic advice for interacting with FDA and EMA. She participates in due diligences and negotiations for licensing and acquisitions. Previously, Emmanuelle launched the operations for Quintiles (now IQVIA) in France, Spain and Italy. Prior to this, Dr. Voisin held a position as Reviewing Pharmacologist and Toxicologist at the US FDA CDER Division of Antiviral Drug Products, where she was in charge of reviewing applications for new AIDS therapies. She gained industry experience both from the Laboratoires Servier in France and Laboratoires Besins Iscovesco (now Besins International) in the USA. Dr. Voisin acquired her background in academic research in the USA at the National Institute of Mental Health, NIMH, Neuroscience Branch, and in France with national research units, CNRS/INSERM, at Institut Gustave Roussy, Villejuif, where she obtained her Ph.D. in Pharmacology studying the bioactivation of a novel anticancer molecule. Emmanuelle holds a pharmacy degree and was a Resident in the Paris Hospital Authorities (Ancien Interne des Hôpitaux de Paris).

Dr. Voisin has published a number of articles in international peer-reviewed journals, covering various scientific and regulatory aspects of innovative drug development, as well as global challenges of the biotechnology industry. Emmanuelle is a member of the Avicenna Alliance and leads the Policy Development Working Group of the Alliance. She is a member of organisations of professionals in Regulatory (Eucope, TOPRA, RAPS, DIA), as well as an active member of France Biotech and other industry associations. She is a member of the Advisory Board of the Swiss-based biopharmaceutical company, leader in Alzheimer's disease, AC Immune. Dr Voisin is also on the Board of Endodiag, developing an innovative diagnostic for endometriosis. Dr. Voisin is regularly invited as a key expert speaker in international conferences.

Day 5 – Friday, 18 December

Session 6: Harmonisation of licensing: beyond regulators and licensees, how do the other stakeholders view the situation?

1300 – 1305 (UTC+1) Introductory information and Zoom logistics

1305 – 1445 (UTC+1)

The presenters will provide a brief overview of their interactions with decision-makers dealing with innovation and they will describe the process for seeking regulatory approval. They will share the most important challenges and lessons learnt regarding their own experiences and provide their insights and recommendations, particularly in the following areas:

- How should decision-makers consider innovative technologies that need to be approved while still ensuring safety and maintaining public trust?
- How can enhancing international cooperation in licensing benefit not just industry but society in general?
- What does a risk-benefit or cost-benefit analysis for international licensing could look like considering your perspectives?

Speakers:

- **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

Moderator:

- **Mr. Ramzi JAMMAL**, Executive Vice President and Chief Regulatory Operations Officer, Canadian Nuclear Safety Commission
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Bruce Chew is the Federal Research Leader for Deloitte’s Center for Government Insights (DCGI) and a Managing Director in Deloitte Consulting’s Government and Public Services (GPS) practice. In his role with DCGI his research focuses on trends in government including new technologies, new business models, and disruptive forces. As a founding member of the Monitor Deloitte Strategy practice for GPS, Bruce helps government clients anticipate and effectively respond to their changing and challenging environment.

For twenty-plus years, Bruce has served clients across industries and sectors including manufacturing, aerospace and pharmaceutical firms, universities, non-profits and intelligence, defense, health, and civilian government agencies. His professional focus has always been on helping historically successful organizations respond effectively to new mission requirements and opportunities, outside pressures or technology disruptions. In 2015 and 2016, Bruce was on the Advisory Board for the Federal Government’s “President’s Customer Service Awards”.

Prior to entering consulting, Bruce was an Associate Professor at the Harvard Business School (HBS) where he was an award-winning teacher. While at HBS, Bruce developed and taught courses including Operations Strategy, Technology and Operations Management and a variety of Executive Development programs. He continues to teach, developing and delivering development courses and transformational Labs for Deloitte and its clients. He has published in the Harvard Business Review, Sloan Management Review, Brookings Papers and elsewhere.

Bruce received an MBA from HBS and a PhD in Economics from Harvard University after receiving his Bachelor of Science in Computer Science from the University of Michigan. He lives with his wife Margie on the coast of Maine.



Kirsty Gogan is an internationally sought-after advisor to governments, industry, academic networks and NGOs. Kirsty is co-founder of TerraPraxis, a new non-profit organisation focused on designing strategies that leverage science, technology and energy innovation for a prosperous planet. TerraPraxis’ special focus is on enabling high-impact rapid transitions for neglected parts of the decarbonization challenge. Kirsty is also managing partner of LucidCatalyst, a highly specialized international consultancy offering thought leadership, strategy development and techno-economic expertise focused on multiplying and accelerating zero carbon technology options available for large-scale, affordable, market-based decarbonization of the global economy over a wide range of future scenarios. Kirsty chairs the UK Government’s Nuclear Innovation Research and Advisory Board (NIRAB) Cost Reduction Working Group. Kirsty’s

other board appointments include US-based NGO, Nuclear Innovation Alliance, as well as Energy for Humanity, an environmental NGO focused on large scale deep decarbonisation and energy access, which Kirsty co-founded and led, as Executive Director, for six years.



Marie-Françoise Renard-Gondinet is graduate as Aerodynamic Engineer from Conservatoire National des Arts & Métiers in Paris. She started her career in 1980 with Bureau Veritas and joined the Research and Development team specialised in the hydrodynamic field. There she was involved in many naval architecture, marine and offshore engineering designs. In 1988, she took up Project Manager duties in TECNITAS, Bureau Veritas Subsidiary, in the marine and offshore fields. In 1990, she joined TRANSOFT International as Principal Engineer for developing studies and software applications in the Mechanical Analysis field, particularly in the Aeronautics, Military and Environmental sectors. She was later on appointed as Commercial Manager for that same company. After 7 years she joined Bureau Veritas Head Office again, within the VeriSTAR Hull team as Commercial Manager. She is now in charge of the Offshore activity as the Sales Director. The Offshore market covers the traditional Oil & Gas sector, but also the various energy transition initiatives happening today including Gas to Wire and Renewables applications.



Denis Bourguignon is Nuclear Development and Technical Manager for BUREAU VERITAS. With more than 25 years' experience working on various nuclear projects, Denis is an expert in a broad scope of engineering activities, manufacturing and surveillance of the supply chain, nuclear codes and regulations. Before joining BUREAU VERITAS, Denis worked for Edf-Energy as engineering manager for the Manufacturing Inspection Team on the EPR Hinkley Point C project in the UK. Denis also worked on Research Reactor projects for the French Alternative Energies and Atomic Energy Commission - CEA. Denis has an electro-mechanical engineering degree. Denis is General Secretary of the Nuclear Quality Standard Association (NQSA) promoting the new ISO19443 quality management system and supporting the implementation of a "Nuclear Industry Controlled Certification Scheme".



Kathryn Martin is co-founder of Access Partnership, an international technology, consultancy, Kathryn obtains spectrum and service rights in foreign markets for a variety of commercial clients. She has broad experience negotiating with commercial and government entities to secure operating licenses, spectrum rights and interconnection agreements. An engineer by training, she represents clients' technical interests at international fora such as the International Telecommunication Union (ITU), Organization of American States (OAS) and the International Civil Aviation Organization (ICAO). She has served on US delegations to several International Telecommunication Union conferences covering spectrum and satellite issues and has developed strategies and successfully executed multi-year WRC campaigns since 1995. She currently serves on the board of the United States ITU Association and is an alternate member of the Satellite Industry Association board. In the past, while at Access Partnership, she supported the Department of Commerce's efforts on broadband deployment in the United States and a separate Presidential initiative on spectrum.

Kathryn joined Access Partnership in 2000 from Iridium LLC, where she secured global country codes for a global voice and data network. Kathryn also served five years at the U.S. Department of State, where she led delegations of government and industry representatives to spectrum and standards-setting bodies at the ITU and the Asia-Pacific Economic Cooperation (APEC). Kathryn holds a B.S. in Electrical Engineering from Brown University and a Master of the Arts degree in Telecommunications from George Washington University.



Jean-Jacques Doreau is Executive Manager of the Agriculture Insurance Market in Allianz France. Mr. Doreau has developed during 33 years a large experience in various insurance and reinsurance Markets, from Property and Casualty industrial risks, to Construction or Financial Risks. His chemical engineering background has helped him to build technical rules to secure the underwriting policies while working for various insurance leaders like UAP (AXA), GAN, GROUPEAMA and now ALLIANZ.

Before joining the Insurance sector, he worked 5 years for Commissariat à l’Energie Atomique in the reprocessing of spent fuel Division.

Session 7: Recommendations to the nuclear sector, the path forward

1445 – 1545 (UTC+1)

This final session will feature at least one speaker or panellist from each previous session. The moderator will join these individuals to spark a discussion on key takeaways from the workshop. It is expected that this panel will identify clear, tangible, and actionable insights that workshop attendees can take home to apply in their organisations. The panel may also identify areas of future collaborative work on the topics that were discussed in the workshop.

*Panel and Q&A session lead by Moderator: **Mr. William D. MAGWOOD, IV**, Director-General of the Nuclear Energy Agency*

Mr. Petteri TIIPPANA, Director General of the Radiation and Nuclear Safety Authority (STUK), Finland, Chair of the OECD NEA Committee on Nuclear Regulatory Activities

Mr. Mark FOY, Chief Nuclear Inspector for the Office for Nuclear Regulation in the UK

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

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

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

Mr. Ramzi JAMMAL, Executive Vice President and Chief Regulatory Operations Officer, Canadian Nuclear Safety Commission

Closing remarks

1545-1600 (UTC+1)



Ms. Rumina VELSHI, President and Chief Executive Officer of the Canadian Nuclear Safety Commission



Mr. William D. MAGWOOD, IV, Director-General of the Nuclear Energy Agency
