Legal Affairs
2019

Nuclear Law Bulletin No. 103

Volume 2019/2

OECD
BETTER POLICIES FOR BETTER LIVES

NEA
NUCLEAR ENERGY AGENCY

Legal Affairs

Nuclear Law Bulletin
No. 103

NEA No. 7502

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Acknowledgements

In addition to the authors of the articles, the Organisation for Economic Co-operation and Development (OECD) Nuclear Energy Agency (NEA) would like to thank the following individuals for their contributions to this edition of the *Nuclear Law Bulletin*: Mr D. Saumure (Canada); Ms S. Royer-Maucotel and Ms F. Touïtou-Durand (France); Mr M. Hori, Mr R. Ikuma and the Japan Energy Law Institute (JELI) (Japan); Ms U. Adomaitytė (Lithuania); Mr P. Majerus (Luxembourg); Mr A. Dantas and Mr M. Sousa Ferro (Portugal); Mr M. Pospíšil (Slovak Republic); Mr A. Škraban (Slovenia); Ms S. Knopp Pisi (Switzerland); Mr N. Mertz (United States); Mr A. Popov (European Commission); Ms J. Silye (International Atomic Energy Agency); Mr P. Reyners (International Nuclear Law Association); and Ms M. Hanebach (Canadian Nuclear Law Organization). We also would like to thank Mr S.G. Burns for his careful review and support in finalising this edition of the NLB.

The information submitted to the NEA by these individuals represents the opinions of the authors alone and does not purport to represent the official views or the policies of their governments or of any other entity.

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A perspective on key legal considerations for performance-based regulating

*by Emily Dandy**

1. Introduction

The performance-based approach to the regulation of nuclear power generation for civilian use is an approach that requires a certain outcome but provides the regulated entity with the flexibility to determine how it can achieve this outcome.[1] Such an approach is currently being employed, for example, in Canada, France and the United Kingdom. While some have argued that "significant work remains to be done before performance-based approaches can realize their full potential in the regulation of nuclear power plants",[2] a limited number of analyses have been dedicated to the approach.[3] The author was thus inspired to share Canadian expertise in this area, as well as a description of the approach developed in Canada in recent decades.

The article will examine how particular legal approaches may be affected when nuclear regulators choose a performance-based model, without drawing any conclusions on whether performance-based regulating is superior to the prescriptive approach employed in many countries. While the performance-based approach may be effective in Canada, each state is responsible for gauging the appropriateness of a particular approach within its jurisdiction. The article will also examine the merits and particularities of performance-based regulation, as well as whether enforcement practices should differ under a performance-based regime as compared to a prescriptive one. These subjects appear to have attracted little attention from the academic legal community despite what appears to be an increase in interest in the performance-based approach to safety regulation.[4] Enforcement is a critical

* Emily Dandy is Legal Counsel at the Canadian Nuclear Safety Commission (CNSC). An earlier version of this article was submitted as a dissertation towards a University Diploma in International Nuclear Law after the 2018 session of the International School of Nuclear Law (ISNL) in Montpellier. The author expresses thanks to colleagues at the CNSC for sharing their views on performance-based regulating and to the co-ordinators and lecturers of the ISNL for making this valuable academic pursuit possible. The views expressed in this article are those of the author and do not represent any official positions of the CNSC.

1. Youngblood, R. and I. Kim (2005), "Issues in Formulating Performance-Based Approaches to Regulatory Oversight of Nuclear Power Plants", *Nuclear Engineering and Technology*, Vol. 37, No. 3, Elsevier Korea LLC, Seoul, p. 3.
2. *Ibid.*, p. 231.
3. Coglianese, C., J. Nash, and T. Olmstead (2002), "Performance-Based Regulation: Prospects and Limitations in Health, Safety, and Environmental Protection", *Regulatory Policy Program Report No. RPP-03*, Harvard University, Cambridge, Massachusetts, p. 1.
4. Canada employs a performance-based approach to regulating nuclear power plants. The United Kingdom can also be described as employing the performance-based model in its nuclear regulating, as it sets performance goals in its licences authorising nuclear activities but does not prescribe how the regulated must meet these goals. France also employs performance-based methods of regulating, for example, in how it requires licensees to demonstrate the safety case for facilities. The United States takes a more prescriptive approach, although it intends to increase the use of risk-informed, performance-based regulating, as per the Nuclear Energy Innovation and Modernization Act, Pub. L. No. 115-439, sec. 103, 132 Stat. 5565, 5571 (2019), which requires strategies for increased use of the model.

component of nuclear regulation. Indeed, effective enforcement is an international obligation under Article 7 of the Convention on Nuclear Safety (CNS), a convention often cited in this article since it is the source of international nuclear safety requirements for the contacting parties. [5]

The following inquiry was the controlling question for this article: Considering the need to implement international nuclear law obligations, and especially the need for nuclear regulators to be able to enforce regulatory requirements, are there unique legal considerations to be taken into account when regulating with a performance-based approach? The article begins with an explanation of the legal framework for transforming international obligations to domestic regulations. It describes the meaning of performance-based regulation and provides considerations for deciding to implement a performance-based regime. To achieve a better comprehension of how international nuclear safety obligations can be implemented as performance-based regulatory requirements, this article applies an academic expression of the Canadian performance-based model to a real nuclear regulatory example. The article also presents the author's view that performance-based regulating does not call for fundamentally different enforcement practices when compared to the prescriptive model, but seven relevant considerations result from analysing such a question. The considerations may be useful for regulators when establishing, or assessing *post facto*, performance-based regulatory requirements. The considerations are drawn from available academic views on performance-based regulating, and they were then supplemented or tailored to the nuclear context. The seven aforementioned considerations relate to soft law, bureaucratic controls, procedural fairness, inspector training, evidence, regulatory staff expertise and safety culture.

Before studying performance-based approaches, it may be the reflex of lawyers to signal a preference for prescriptive regulation, given that it is the more traditional legal model. However, there are important safety benefits that come with performance-based regulating, as will be explored below. Where performance-based regulating is a model of interest, legal analysis on enforcement topics should be undertaken to minimise legal risk and to ensure that legal approaches keep pace with modern regulatory preferences. It is equally important that modern regulatory preferences are realised with consideration and understanding of the legal perspective. Enforceability of requirements should not be a barrier to implementing a performance-based regime, and considerations to do so effectively are provided in this article.

2. Legal framework for transforming fundamental principles from international obligation to domestic regulation

Nuclear law exists to regulate the conduct of those engaged in nuclear power generation activities, with the risks and benefits that this may involve.[6] The international nuclear law community has accepted some basic concepts as the "fundamental principles of nuclear law".[7] Two such principles are the safety principle and the security principle.[8] The CNS creates international obligations for its contracting parties to ensure the use of nuclear energy is safe and well regulated.

5. Convention on Nuclear Safety (1994), IAEA Doc. INFCIRC/449, 1963 UNTS 293, entered into force 24 October 1996 (CNS).
6. Stoiber, C. et al. (2003), *Handbook on Nuclear Law*, IAEA, Vienna, p. 4.
7. *Ibid.*, pp. 4-5.
8. *Ibid.*, p. 5.

International obligations related to security have sources in other conventions, for example, the Convention on the Physical Protection of Nuclear Material, as amended.[9]

The Vienna Convention on the Law of Treaties states that "Every treaty in force is binding upon the parties to it and must be performed by them in good faith."[10] Accordingly, those states that have become parties to international legal instruments in the nuclear field must design domestic nuclear law in accordance with their international treaty obligations. The *Handbook on Nuclear Law* describes nuclear law as fitting within the state's "normal legal hierarchy":

> This hierarchy consists of several levels. The first, usually referred to as the constitutional level, establishes the basic institutional and legal structure governing all relationships in the State. Immediately below the constitutional level is the statutory level, at which specific laws are enacted by a parliament in order to establish other necessary bodies and to adopt measures relating to the broad range of activities affecting national interests. The third level comprises regulations; that is, detailed and often highly technical rules to control or regulate activities specified by statutory instruments … A fourth level consists of non-mandatory guidance instruments, which contain recommendations designed to assist persons and organizations in meeting the legal requirements.[11]

This legal hierarchy is reflected in Article 4 of the CNS, regarding implementing measures, in that, "Each Contracting Party shall take, within the framework of its national law, the legislative, regulatory and administrative measures and other steps necessary for implementing its obligations under this Convention." As noted in the *Handbook on Nuclear Law: Implementing Legislation*, the basic structure and level of detail adopted in domestic nuclear legislation will vary from state to state.[12]

Canada's legal framework governing nuclear power generation is an expression of this legal hierarchy. Canada's constitution includes provisions that empower the federal jurisdiction to regulate nuclear power generation, by way of two constitutional mechanisms. First, the federal jurisdiction may "make Laws for the Peace, Order and good Government of Canada", which is known as the POGG power.[13] Second, Canada's federal jurisdiction has a constitutional declaratory power to declare provincial works or undertakings to be for the general advantage of Canada and can thereby assert federal authority over works or undertakings that would otherwise be within the jurisdiction of its provinces. The Parliament of Canada exercised this power at the statutory level when enacting the Nuclear Safety and Control Act (NSCA).[14] The NSCA established the Canadian Nuclear Safety Commission (CNSC) to regulate nuclear power generation.[15] At the statutory level, Canada's Parliament is clear that the CNSC is to regulate in a manner consistent with the country's international obligations; one of the stated purposes of the NSCA is to provide for "the limitation, to a reasonable level and in a manner that is consistent with Canada's international obligations, of

9. Convention on the Physical Protection of Nuclear Material, (1980), IAEA Doc. INFCIRC/274 Rev. 1, 1456 UNTS 125, entered into force 8 February 1987 (CPPNM) as amended by the Amendment to the Convention on the Physical Protection of Nuclear Material (2005), IAEA Doc. INFCIRC/274/Rev.1/Mod.1, entered into force 8 May 2016 (ACPPNM).
10. Vienna Convention on the Law of Treaties (1969), 1155 UNTS 332, entered into force 27 January 1980 (VCLT), Art. 26.
11. Stoiber, C. et al. (2003), *supra* note 6, pp. 3-4.
12. Stoiber, C. et al. (2010), *Handbook on Nuclear Law: Implementing Legislation*, IAEA, Vienna, p. 6.
13. Constitution Act, 1867 (UK), 30 and 31 Vict, c. 3, reprinted in RSC 1985, App. II, No. 5, s. 91.
14. *Ibid.*, s. 92(10)(c); Nuclear Safety and Control Act, SC 1997, c. 9, s. 71 (NSCA).
15. NSCA, *supra* note 14, ss. 8-9; the NSCA applies not only to facilities that generate nuclear power for civilian use, but also to the regulation of nuclear substances, prescribed equipment and prescribed information.

the risks to national security, the health and safety of persons and the environment that are associated with the development, production and use of nuclear energy".[16] Likewise, an objective of the Commission is to "achieve conformity with measures of control and international obligations to which Canada has agreed".[17]

The Commission is empowered, with the approval of Canada's Governor in Council (GIC), to make regulations "generally as the Commission considers necessary for carrying out the purposes of this Act and to assist the Commission in attaining its objects".[18] While regulations require GIC approval, promulgating guidance and policies is an inherent power of the regulator. In a decision of the Federal Court of Appeal, a Canadian judge calls this promulgation "communicating prospectively", writing, "an administrative agency does not require an express grant of statutory authority in order to issue guidelines and policies to structure the exercise of its discretion or the interpretation of its enabling legislation".[19] The CNSC has made 13 regulations and approximately 80 guidance documents, most of which are organised into a regulatory document ("REGDOC") series. It is the regulatory approach taken at these latter two levels – regulations and guidance – on which the coming sections of this article will focus.

3. Understanding performance-based regulation

Reviewing the publications available on the performance-based approach to regulating, one finds that it is a fairly well defined concept. There is general agreement on how the approach is distinguishable from prescriptive regulating. The International Atomic Energy Agency (IAEA) recognises prescriptive and performance-based approaches as distinct forms of regulating, and advises that the selection of a method is a step for states establishing their nuclear programmes.[20] The IAEA contrasts the approaches by the differing levels of detail in regulation:

> A *prescriptive regulatory approach* places a great deal of importance on the adequacy of the regulations for safety and requires detailed development. The regulations establish clear requirements and expectations for the regulatory body as well as for the operating organization, and thus can be used to promote systematic interaction between the regulatory body and other parties. The regulations could set detailed technical requirements, or could identify issues that the operating organization and its suppliers should address and present for assessment by the regulatory body. Specific technical requirements can then be taken from relevant international industrial standards (including nuclear specific standards) or industrial standards of other States, as agreed by the regulatory body at an early stage of the licensing process for nuclear power plants. Issuing detailed regulations places a high demand on the regulatory body's resources for their development and updating, which adds to the administrative burden.
>
> A *performance based regulatory approach* allows the operating organization more flexibility in determining how to meet the established safety goals and may require fewer, less detailed regulations. However, this approach requires the establishment of specific safety goals and targets. Verifying that appropriate

16. *Ibid*., s. 3(a).
17. *Ibid*., s. 9(a)(iii).
18. *Ibid*., s. 44(1)(w); The GIC is the Governor General of Canada, who acts on behalf of the Sovereign, Canada's head of state.
19. Thamotharem v. Canada (Minister of Citizenship & Immigration) (F.C.A), 2007 FCA 198 (2007), para. 56, [2008] 1 F.C.R. 385.
20. IAEA (2011), *Establishing the Safety Infrastructure for a Nuclear Power Programme*, IAEA Safety Standards Series, No. SSG-16, IAEA, Vienna, p. 32.

> measures to ensure safety have been identified by the operating organization may be difficult unless the regulatory body's staff, the staff of its external support organization and the staff of the operating organization all have a high level of professional competence and are able to interact to determine whether established safety objectives for each topic are met.[21]

The balance of this section provides an overview of the understanding of performance-based regulation established in academic writing, not necessarily in the nuclear context, and the reasons why less detailed regulations arise under the model. It will elicit the vocabulary that the balance of this article will use to discuss performance-based regulating to implement international nuclear law obligations.

To understand performance-based regulation, it is useful to further dissect what is, for many lawyers, the more familiar model of prescriptive regulation. Prescriptive regulation can be described as "the exact prescription of how to achieve a set objective", where "emphasis is placed on strict adherence to the prescribed rules and standards which in turn is presumed to provide acceptable outcomes".[22] Performance-based regulation, on the other hand, applies performance standards to specify the "outcome required but leaves the concrete measures to achieve that outcome up to the discretion of the regulated entity".[23] One author offers the simple description that performance-based regulation "emphasizes regulating for results".[24] Likewise, another author distinguished the models as follows:

> [R]egulators can direct those they govern to improve their performance in at least two basic ways. They can prescribe exactly what actions regulated entities must take to improve their performance. Or they can incorporate the regulation's goal into the language of the rule, specifying the desired level of performance and allowing the targets of regulation to decide how to achieve that level.[25]

A regulatory system that is performance-based "can be thought of as one using performance as the basis for the legal commands".[26] The legal source of the performance requirement will vary depending on the state's legal system, and where requirements for performance are best placed depends on a state's preferences and unique implementation of the legal hierarchy described earlier in this article. The global nuclear community is arguably already comfortable with the concept of performance-based regulating with regards to the general principle of radiological protection referred to as optimisation; that is, the likelihood of incurring exposure, the number of people exposed and the magnitude of their individual doses should all be kept as low as reasonably achievable (ALARA), taking into account economic and societal factors.[27] According to the principle of optimisation, permissible dose is determined by the level of performance an operator can reasonably achieve.

21. *Ibid*.
22. Owusu, E. (2015), "Regulation of Operational Pollution from Offshore Oil and Gas Activities: A Comparative Analysis of the Norwegian and Ghanaian Regimes", *Asper Review of International Business & Trade Law*, Vol. XV, University of Manitoba, Winnipeg, p. 363. See also May, P. (2003), "Performance-Based Regulation and Regulatory Regimes: The Saga of Leaky Buildings", *Law & Policy*, Vol. 25, No. 4, Oxford, p. 381.
23. Coglianese, C., J. Nash, and T. Olmstead (2002), *supra* note 3, p. 3.
24. May, P. (2003), *supra* note 22, p. 382.
25. Coglianese, C., J. Nash, and T. Olmstead (2002), *supra* note 3, p. vii.
26. *Ibid*., p. 3.
27. International Commission on Radiological Protection (ICRP) (2007), "The 2007 Recommendations of the International Commission on Radiological Protection", *Annals of the ICRP*, Vol. 37, Nos. 2-4, ICRP Publication 103, Elsevier Ltd., Oxford, p. 14.

Performance-based regulation can be thought of as a class of regulations that vary with respect to 1) characterisation of outcomes; 2) standards for desired levels of achievement; and 3) assessment procedures for gauging the level of performance that is obtained.[28] These will be referred to as the three "components" of performance-based regulating and can provide a better understanding of how a performance-based regime may operate.

The first component, characterisation of outcomes, is normally specified in legislation or by regulation.[29] Outcomes can be stated with varying degrees of comprehensiveness or specificity; that is to say, performance can be either loosely or exactly specified.[30] Most loosely specified requirements will call for regulators to make qualitative judgements, while requirements that are more specific may employ quantitative measures of performance.[31] At the drafting stage in particular, attention should be paid to how broadly the goal should be stated, as it will be the goal against which the regulated entity's performance will be measured. For example, one might focus on an ultimate societal objective (e.g. clean water) or a more narrow objective (e.g. limiting effluents).[32] In fact, there can be singular or multiple goals behind a requirement.[33] Drafters might also consider the spatial distribution of the expected performance, as it can be broad or narrow, applying to a system as a whole or just a small part of a system.[34] It is not characteristic of the performance-based model to include technical performance criteria at the goal level.[35]

The second component is "the standard against which compliance is gauged".[36] This component presents the most challenges because "[i]dentifying relevant measures of performance and standards for desired levels of performance are much more difficult than stating performance objectives".[37] Performance requirements may differ according to how their levels of performance are determined.[38] Quantitative requirements might be based on predictions (e.g. computer simulations) or on actual measurements (e.g. emissions).[39] Performance requirements may be based on a determination of the appropriate level of risk or according to the level of performance that is achievable using available technology.[40]

The third component of performance-based regulation is the procedure through which performance is assessed. It may be possible to measure performance through direct observation, or it may not be possible to directly assess outcomes.[41] For example, systems of a nuclear power plant may be too complex to measure directly, and the outcomes to be prevented may be unobservable (i.e. factors that could contribute to a higher probability of a catastrophic accident might not be directly observed, and so safety assessments must be carried out using probabilistic and

28. May, P. (2003), *supra* note 22, p. 384.
29. *Ibid*.
30. *Ibid*.; Coglianese, C., J. Nash, and T. Olmstead (2002), *supra* note 3, p. 4.
31. Coglianese, C., J. Nash, and T. Olmstead (2002), *supra* note 3, p. 4.
32. *Ibid*., p. 5.
33. May, P. (2003), *supra* note 22, p. 384.
34. *Ibid*.
35. Meacham, B. et al. (2002), "Performance System Model – A Framework for Describing the Totality of Building Performance", *Proceedings: 4th International Conference on Performance-Based Codes and Fire Safety Design Methods, 20-22 March 2002, Melbourne, Australia*, Society of Fire Protection Engineers, Bethesda, Maryland, pp. 63, 66 (publication also archived as National Research Council Canada no. 45581).
36. May, P. (2003), *supra* note 22, p. 384.
37. *Ibid*., p. 384.
38. Coglianese, C., J. Nash, and T. Olmstead (2002), *supra* note 3, p. 4.
39. *Ibid*.
40. *Ibid*.
41. May, P. (2003), *supra* note 22, p. 386.

deterministic methods). A challenge in performance-based regimes is to define the performance-based criteria and develop the tools to quantify these criteria.[42]

Another way to dissect the performance-based approach is to apply the terminology of the "performance system model" articulated by Meacham et al.[43] Although their work was completed in the context of building regulation and management, one can view it as a useful framework to apply in the nuclear regulatory context. Their work conceptualises the performance system model as moving through six parts: 1) goals; 2) functional statements; 3) operational or performance requirements; 4) performance or risk level; 5) criteria; and 6) verification.[44] Section 5 of this article will illustrate an example of a performance-based requirement using these six parts.

Accountability is as essential an element in performance-based regulating as it is in prescriptive regulating.[45] Pursuing flexibility without making provision for sufficient accountability could result in an unsound regulatory regime.[46] One author calls accountability "a fundamental and thorny issue for performance-based regulations and as such is the Achilles' heel of this form of regulation".[47] Accountability is an important issue to analyse so as to ensure that a state's performance-based regime is effectively implementing its international treaty obligations in the nuclear field. In the legal context, for this article, accountability is taken to mean compliance verification and enforcement. Well-designed licence application processes and effective compliance verification and enforcement assist in preventing the performance-based model from mirroring industry self-regulation. Self-regulation, which is an industry performing without the oversight of a regulator, is not performance-based regulation, and self-regulation certainly would not meet the obligation to establish a regulatory body under CNS Article 8.

With this understanding of performance-based regulating, it is worth recalling the description of legal hierarchy in the nuclear context, as described in Section 2 of this article. This description says that regulations are detailed and often highly technical rules and that non-mandatory guidance includes recommendations designed to assist persons and organisations in meeting legal requirements.[48] To acknowledge the performance-based model for regulating, this definition could be amended with language that reflects that regulations could contain highly technical rules or performance levels. Likewise, non-mandatory guidance could be described as containing recommendations or performance criteria.

It has been suggested that in addressing performance-based regulating in general, "an important step for future research will be to develop a clearer conceptualization of the different types of performance standards".[49] It may be useful to articulate such different types of performance-based models for the regulation of the nuclear industry, and it could in fact be an interesting academic question for the future.

42. Bénichou, N. et al. (2008), "Review of Current Practices and Knowledge on Performance-Based Design – Focus on the Need of the Nuclear Industry", National Research Council Canada Report No. B4246.1, Ottawa, p. 3.
43. Meacham, B. et al. (2002), *supra* note 35, pp. 64-65.
44. *Ibid*.
45. Blumenauer, E. (2011), "Beyond the Backlash: Using Performance-Based Regulations to Produce Results through Innovation", *Journal of Environmental Law and Litigation*, Vol. 26, No. 2, University of Oregon, Eugene, p. 363; Owusu, E. (2015), *supra* note 22, p. 367.
46. May, P. (2003), *supra* note 22, p. 382.
47. *Ibid*., p. 397.
48. Stoiber, C. et al. (2003), *supra* note 6, pp. 3-4.
49. Coglianese, C., J. Nash, and T. Olmstead (2002), *supra* note 3, p. 5.

4. Deciding to implement a performance-based regime

With the above understanding of the performance-based approach, why might an independent nuclear regulator choose a performance-based regime? As an authority sets out to decide what regulatory approach it wishes to take, it should weigh the objectives of flexibility and innovation with consistency, equity and predictability.[50] The following aptly summarises the tension between the approaches:

> Some say that the answer to regulatory unreasonableness is to give regulators more discretion. Others say that the regulators themselves are the problem and that the solution is to take away their discretion by exerting tighter legislative control. The dilemma is familiar and ages old. Too little discretion provides legalistic, nitpicky behaviour and denies regulators the means to tailor their responses to local or particular circumstances. Too much discretion creates opportunities for corruption and discrimination and opens a regulatory agency to capture by the regulated community.[51]

One view is that, in practice, prescriptive regulation does not place full responsibility for safety with the operators of nuclear power plants.[52] This may be due, for example, to a "lack of incentives for nuclear power plant owners to make plants safer than minimally accepted levels".[53] If this is true, it would frustrate the state's implementation of Article 9 of the CNS, which states that the prime responsibility for safety rests with the licence holder.[54]

In a performance-based environment, the level of safety required need not be deduced based on the regulatory requirements; the level of safety is more explicit in the law and must be specifically addressed by the licence applicant or licensee.[55] In the view of some, "Performance-based approaches measure safety more directly than prescriptive approaches, giving the regulator and other stakeholders more information about the actual safety state than can be inferred from compliance with prescriptive requirements."[56]

The performance-based approach may hold promises for accommodating and even encouraging innovation.[57] Accordingly, the presence or potential for new technologies might also impact the choice of the regulatory approach. A performance-based regime may provide necessary flexibility:

> [P]erformance standards give firms flexibility and make it possible for them to seek the lowest cost means for them to achieve the stated level of performance. Performance standards can also accommodate technological change and the emergence of new hazards in ways that prescriptive technology-based standards generally cannot. However, performance-based standards can sometimes be imprecise, especially when the standards are loosely specified. In addition, in some contexts, measuring performance

50. May, P. (2003), *supra* note 22, p. 387.
51. *Ibid*., p. 387, citing Sparrow, M. (2000), *The Regulatory Craft: Controlling Risks, Solving Problems, and Managing Compliance*, Brookings Institution Press, Washington, DC, p. 238.
52. Golay, M. (2000), "Improved Nuclear Power Plant Operations and Safety through Performance-Based Safety Regulation", *Journal of Hazardous Materials*, Vol. 71, Issues 1-3, Elsevier B.V., Amsterdam, p. 221.
53. *Ibid*.
54. CNS (1994), *supra* note 5, Art. 9.
55. Meacham, B. et al. (2002), *supra* note 35, p. 70.
56. Youngblood, R. and I. Kim (2005), *supra* note 1, p. 242.
57. Coglianese, C., J. Nash, and T. Olmstead (2002), *supra* note 3, p. 20.

> presents distinct challenges, something that is especially the case when the standards are based on predictions rather than actual measurable events.[58]

In determining whether to proceed with a performance-based approach, decision makers may need to consider the conditions under which the standard will be applied and the consequences or likelihood of regulatory failure.[59] One view is that a prescriptive approach might be preferred where there is high risk and existing technologies are known to work well.[60] It is important to keep in mind that the activity to which the performance-based standard applies should be an activity that is measurable, evaluable and verifiable.[61]

It is possible that the information requirements relating to a regulatory topic may be so demanding that a performance requirement or a prescriptive requirement, in the end, would be very similar in terms of what the regulator needs to know and the information it requires from a licence applicant or licensee.[62] It may also be the case that there are both prescriptive and performance-based regulations made by the same regulator. The regulator's approach could be blended in the sense that while it takes a performance-based approach in its regulations, it may create detailed performance criteria in regulatory guidance, i.e. "soft law". The defining feature that should be retained for successful performance-based regulating is the opportunity for a licensee to present its case as to why its performance level is satisfactory. In one view, a "pure performance-based approach would measure at the goal level (e.g. public safety)".[63] Regardless of the regulator's appetite for a prescriptive *versus* a performance-based approach, turning one's mind to broad safety goals has merit in that it forces those involved to consider uncertainties:

> [T]he decision to consider using performance standards can offer benefits simply in terms of "shaking things up" or focusing the policy dialogue on the ultimate objectives and the underlying uncertainties. Performance-based regulation may demand more explicit attention to goals and uncertainties, and this attention can be valuable regardless of the specific regulatory instrument selected.[64]

5. Performance-based regulation in Canada

When exercising its regulation-making power, a regulator must look to its empowering legislation (in the legal hierarchy described above, this means looking to the statutory level) to determine the level of discretion it has been provided in terms of the regulatory approach. In Canada, the enabling statute uses deferential language, leaving the regulator free to choose whether it employs a prescriptive or performance-based approach in the making of its regulations. International treaties are not prescriptive so that sovereign states may implement their obligations in a way suited to national considerations and circumstances, and the text of the CNS does not direct contracting parties to take either a performance-based or prescriptive approach.

In making its regulations, it is up to the CNSC to decide whether the NSCA's purposes are better served via a prescriptive approach or via a performance-based approach. Looking at the suite of CNSC regulations, one can conclude that the Commission has chosen not to take a prescriptive approach to the regulation of

58. *Ibid.*, p. 6.
59. *Ibid.*, p. 6.
60. *Ibid.*, p. 8.
61. *Ibid.*, pp. 11 and 20.
62. *Ibid.*, p. 13.
63. Youngblood, R. and I. Kim (2005), *supra* note 1, p. 237.
64. Coglianese, C., J. Nash, and T. Olmstead (2002), *supra* note 3, p. 12.

nuclear power plants in most cases. The following subsections will illustrate the implementation, from a broad safety goal to verification, of an example of a Canadian performance-based nuclear safety requirement at operating nuclear power plants. The illustrations use the terminology set out in Meacham et al.'s performance system model described above as far as applicable.

5.1 Safety goal

The first stage of implementing a performance-based requirement is to define goals or objectives. For nuclear safety, goals and objectives can be found in international treaties – i.e. the international community has already agreed on the minimum objectives for nuclear safety. It is important that, if adopted by a state, each goal and objective set out in the CNS can be traced to a regulatory requirement. Looking at it the other way around, most regulatory nuclear safety requirements will be traceable to a CNS article.

Using CNS, Article 1 as an example, one sees the listed objective "to prevent accidents with radiological consequences".[65] An obligation flows from this objective to Article 14, Assessment and Verification of Safety:

> Each Contracting Party shall take the appropriate steps to ensure that:
>
> […]
>
> (ii) verification by analysis, surveillance, testing and inspection is carried out to ensure that the physical state and the operation of a nuclear installation continue to be in accordance with its design, applicable national safety requirements, and operational limits and conditions.

As stated earlier in this article, requirements can serve singular or multiple safety goals. Accordingly, other safety goals may relate to the requirement analysed here, but this example will focus on a singular goal. The goal, then, for the purposes of this example is ensuring that the physical state and operation of Canadian nuclear power stations continue to be in accordance with their design, applicable national safety requirements, and operational limits and conditions to prevent accidents.

5.2 Functional statement

In its domestic legislation, a contracting party will define functional statements relative to the broad safety goal. A "measure of performance" should be present relative to the functional statement in the performance-based model.[66] The functional statement in the NSCA is in the form of conditions precedent to the issuance of a licence, found in paragraph 24(4)(b):

> 24(4) No licence shall be issued, renewed, amended or replaced — and no authorization to transfer one given — unless, in the opinion of the Commission, the applicant or, in the case of an application for an authorization to transfer the licence, the transferee
>
> […]
>
> (b) will, in carrying on that activity, make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed.

65. CNS (1994), *supra* note 5, Art. 1(iii).
66. Meacham, B. et al. (2002), *supra* note 35, p. 66.

In this case, the measure of performance at its essence is whether the applicant can demonstrate that it will make "adequate provision".

The discretionary language, "in the opinion of the Commission" may not be unique to regulatory frameworks contemplating a performance-based approach, but it is a particularly important element to facilitate the flexibility required for the model.

5.3 Operative requirements

The next step is setting operative requirements, which breaks the functional statement down into more measurable components.[67] In Canada, it is at this stage of the model that the independent regulator begins to exercise its discretion by articulating these operative requirements in the regulations it makes. For the present example, the CNSC, among other actions related to the physical state of a nuclear power plant,[68] sets requirements in the Class 1 Nuclear Facilities Regulations for a licensee's nuclear power plant maintenance:

> 6 An application for a licence to operate a Class I nuclear facility shall contain the following information in addition to the information required by section 3:
>
> […]
>
> (d) the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility.[69]

The operative requirement for this example is to propose (i.e. develop) maintenance programme documents. It is at this level that the CNSC's choice of a performance-based regulatory approach becomes clear. The regulation does not prescribe the elements that proposed measures, policies, methods and procedures must contain. In Canada, the proposed documents submitted by the licence applicant at this stage are an important part of the licensing basis for the facility and will become performance criteria, as discussed in more detail below.[70]

5.4 Performance level

The next level in the model, the performance level, is described as the link between the goals, functional statements and operative requirements.[71] For this example, the performance level can be said to be the licence condition under which performance of the maintenance programme will be assessed. The CNSC issues the following standard licence condition relative to the operative requirement set out in the Class 1 Nuclear Facilities Regulations above: "The licensee shall implement and maintain a fitness for service program." This licence condition is qualitative in nature, which is representative of the performance-based model.[72]

67. *Ibid*.
68. This example is one of many that could be used for this article. The article uses the example of plant maintenance, but safe operation of a nuclear power plant is based on multiple operative requirements.
69. Class 1 Nuclear Facilities Regulations, SOR/2000-204, s. 6(d). Section 3 outlines general application requirements for all Class I facility licence applications in Canada.
70. The "licensing basis" for a facility has three parts: 1) the requirements in applicable legislation and subordinate legislation; 2) the licence conditions and the documents directly referenced in the licence; and 3) the safety and control measures described in the licence application and the documents needed to support the licence application. CNSC (2018), "Glossary of CNSC Terminology", REGDOC-3.6, CNSC, Ottawa, p. 63.
71. Meacham, B. et al. (2002), *supra* note 35, p. 67; the authors indicate that performance level could also be called risk level.
72. *Ibid*. Meacham et al. note that it is possible for quantitative aspects to be incorporated at this level as well.

5.5 Performance criteria

To assess whether the licensee is complying with its licence condition, that is, its performance level, performance criteria must be established. In Canadian nuclear regulation, these are called compliance verification criteria. Meacham et al. indicate that at the criteria level there should be a "measure of pass/fail or range of acceptance", which are sometimes called performance indicators.[73] The authors also indicate that performance criteria should be quantitative in nature,[74] but that may not always be desirable in the nuclear context. At the performance criteria level, standards are useful.[75] Criteria should be selected or designed so that if a licensee meets the criteria, the safety goal to which the regulatory requirement can be traced back to is achieved.[76] Regulators may choose from various sources of standards to apply as performance criteria, for example, industry standards or IAEA guidance, or it may draw from these and others sources to create its own soft law or guidance, which the Canadian regulator calls REGDOCs. The soft law could also describe an approach or technology as a "safe harbour" that will be accepted.[77]

Returning to the example of the fitness for service licence condition (the performance level), for nuclear safety, the CNSC has published its own criteria in REGDOC-2.6.2, "Maintenance Programs for Nuclear Power Plants", which the REGDOC indicates is consistent with IAEA Safety Standard Series.[78] Under the title "Policies, processes and procedures", the CNSC sets out the following:

> When setting out policies, processes and procedures that govern how the maintenance program is to be implemented, licensees should demonstrate that following criteria have been taken into account:
>
> 1. the licensee has a clear high-level maintenance policy statement
> 2. strategic direction for maintaining and improving equipment performance is established
> 3. priorities are clearly communicated to maintenance personnel
> 4. maintenance program and its objectives have been documented
> 5. maintenance management direction, such as goals, initiatives, expectations and priorities, are provided to assist personnel in making decisions and taking actions that contribute to safe and reliable plant operation
> 6. the licensee has procedures that govern how the maintenance program is implemented in respect of the objectives and changing priorities.[79]

The use of the word "should" is meant to "express guidance" to licence applicants.[80] The licensee may propose alternatives to the criteria stated above, but would have to demonstrate how it meets the performance level. The Commission, in its licensing decision, could accept the licensee-proposed criteria or decide to make those criteria set out in REGDOC-2.6.2 a licence requirement. A concise outlook on the status of soft law and its role in the licensing basis is that, "Rules are 'law' to the extent that they are legally enforceable."[81] In Canada, appropriately confirming the performance criteria

73. *Ibid.*
74. *Ibid.*, p. 67.
75. *Ibid.*, p. 68.
76. *Ibid.*, p. 69.
77. Blumenauer, E. (2011), *supra* note 45, p. 354.
78. CNSC (2017), "Maintenance Programs for Nuclear Power Plants", REGDOC-2.6.2, CNSC, Ottawa.
79. *Ibid.*, p. 6.
80. *Ibid.*, p. i.
81. Weeks, G. (2016), *Soft Law and Public Authorities: Remedies and Reform*, Hart Publishing, Oxford, p. 41.

within the licensing structure via the licensing authority's decision is an important step to ensure that the regulator's expectations can be enforced.

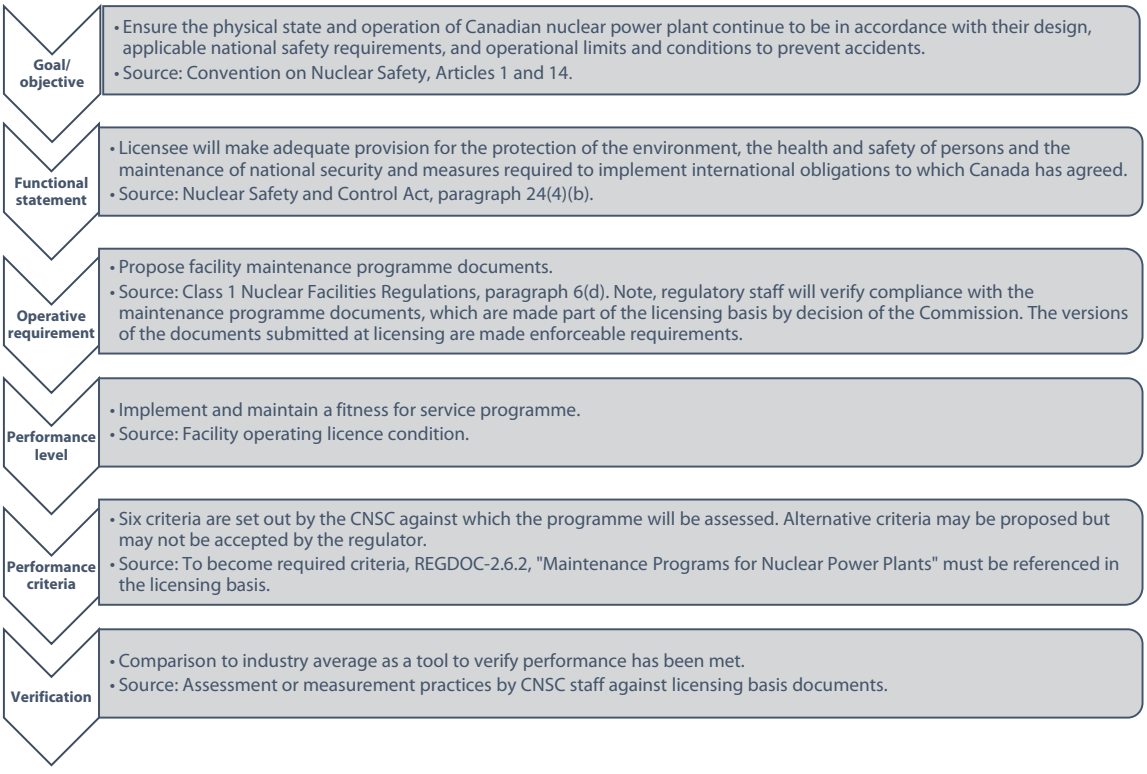
5.6 Verification

The final stage of the performance-based model is the verification that the required performance level is being met.[82] Verification methods include the tools and techniques to be applied to measure performance against the established criteria.[83] This stage may be challenging in the performance-based approach, as it may be difficult to develop the tools necessary to quantify performance criteria into a pass/fail system or acceptability range.[84] Returning again to the fitness for service example, the CNSC may examine, for example, the number of maintenance backlogs a facility experienced over a period of time and compare that number to an industry average to determine how a particular facility is performing.

In Canada, as in many states, the nuclear regulator is a life-cycle regulator. That is, the same authority that issues the licence to operate regulates operation. Accordingly, the verification stage of the performance-based model happens in two phases in the nuclear regulatory context. First, there is verification at the licensing stage, where performance levels and performance criteria are confirmed. Second, once a licensee is operating a nuclear power plant, the regulator conducts activities to verify compliance, such as inspections.

This Canadian example can be summarised as follows:

Figure 1: Summary of Meacham et al.'s Performance System Model as applied to a Canadian nuclear facility



82. Meacham, B. et al. (2002), *supra* note 35, p. 67.
83. *Ibid.*
84. *Ibid.*, p. 67; Bénichou, N. et al. (2008), *supra* note 42, p. 3.

6. Accountability: Considering the enforcement of performance-based requirements

The six stage performance-based model applied to the above Canadian example ends with verification. One finds, after reviewing publications on performance-based regulating, that there is not extensive writing on this final stage of the model, despite accountability recurring as an essential element of an effective performance-based regulation.[85] For the regulated, accountability can be seen as compliance; for the regulator, accountability can be seen as enforcement. In nuclear regulating, accountability is expressed at a high level as the fundamental nuclear law principle of responsibility.[86] Contracting parties to the CNS have an obligation to implement a legislative and regulatory framework that provides for the enforcement of applicable regulations.[87] Likewise, contracting parties are to ensure that the prime responsibility for safety rests with the licence holder and that the licensee meets its responsibility.[88]

The CNS does not define enforcement. The IAEA Safety Glossary indicates enforcement is, "The application by a regulatory body of sanctions against an operator, intended to correct and, as appropriate, penalize non-compliance with conditions of an authorization."[89] In this author's view, enforcement schemes under prescriptive or performance-based models do not necessarily call for substantial differences. Under both models, enforcement actions must be in accordance with powers in the enabling statute and pursuant to the regulations. The unique feature in performance-based regulating is attention required to ensure the behaviour or measures desired by a regulator are properly made legally enforceable requirements. This is not such a concern in prescriptive regulating since the requirements are found in the regulations and have immediate enforcement benefits of "hard law." In the CNSC's performance-based regulating, soft law plays an important role in assessing compliance. The next section provides an overview of the CNSC's approach to enforcement of its nuclear law.

6.1 CNSC's graduated approach to enforcement

The CNSC Glossary of CNSC Terminology defines enforcement as, "All activities to compel a licensee back into compliance and to deter further non-compliances with the *Nuclear Safety and Control Act* (NSCA), the regulations made under the NSCA, and licences, decisions, certificates and orders made by the CNSC."[90] The CNSC uses a graduated approach to enforcement, which provides the regulator with a broad spectrum of options to respond to non-compliance.

The following is an overview of CNSC options to respond to non-compliance. The nature of non-compliance by licensees will be different than the nature of non-compliance by non-licensees, and enforcement action is possible against anyone who fails to comply with the NSCA. Generally, the options are presented from least to most "severe". The regulator may choose to respond with a combination of these responses to elicit the best compliance result in the public interest. Correspondence concerning the "softer" measures makes clear that the regulator may take further regulatory action should the licensee not remedy the non-compliance. This graduation through responses, as appropriate, is the principal feature of graduated enforcement. However, it is critical to note that regulators should not establish a

85. Blumenauer, E. (2011), *supra* note 45, p. 363; Owusu, E. (2015), *supra* note 22, p. 367.
86. Stoiber, C. et al. (2003), *supra* note 6, p. 7.
87. CNS (1994), *supra* note 5, Art. 7(2)(iv).
88. *Ibid.*, Art. 9.
89. IAEA (2018), *IAEA Safety Glossary: Terminology Used in Nuclear Safety and Radiation Protection*, IAEA, Vienna, p. 83.
90. CNSC (2018), REGDOC-3.6, *supra* note 70, p. 39.

regime so that it *must* start with "softer" measures before taking more severe enforcement measures.

Where there is non-compliance, the regulator has discretion to issue a notice of non-compliance, requesting the licensee respond with confirmation that compliance has been restored, or a timeframe for restoring compliance, or a corrective action plan. A warning letter is similar to a notice of non-compliance, but is directed to more senior levels in a licensee's organisation and may be used, for example, in response to recurrent compliance issues. Both of these responses are soft measures created by policy choice of the regulator and, generally, are to be used to respond to non-compliances of lower safety significance. Compliance history of the licensee may affect the decision to issue a notice of non-compliance or warning letter. Notices of non-compliance and warning letters are staff correspondence that are not reviewable. While there is no formal process set out in legislation to challenge the content of the correspondence, discussion and meetings may result as required for those in receipt of the letters to address the compliance issues or to make further information available to the regulator. Generally, these letters are appropriate ways to respond to non-compliances by licensees that have compliance programmes, a compliance history and over which the regulator conducts regular inspections, although such softer responses might also be appropriate for non-licensees in the right circumstances. Poor compliance history may also trigger increased regulatory scrutiny, including such measures as an increased frequency of inspections. Licensees are provided notice of increased regulatory scrutiny for transparency purposes.

The CNSC might choose to order the non-compliant legal or natural person to take any measure necessary to protect the environment, or the health or safety of persons, or to maintain national security or compliance with international obligations to which Canada has agreed. Orders must be referred to the Commission for review to be confirmed, amended, revoked or replaced, and the Commission may designate officers from its staff to perform this review function for inspector orders. The person to whom the order was issued may request an opportunity to be heard before the reviewing authority makes its decision.

To promote compliance with the NSCA, the CNSC may also issue administrative monetary penalties (AMPs) pursuant to the penalty amounts set out by regulation. The NSCA and regulations provide review and appeal processes for AMPs. The person who is served with a notice of violation may request that the Commission review the amount of the penalty or the facts of the violation, or both. The applicable burden of proof on review of the facts of a violation is the balance of probabilities, meaning the decision maker must decide if it is more probable than not that the person named committed the violation. While a licensee is able to make a wide variety of arguments on review or appeal of an order, due diligence or mistake of fact are not defences to a violation resulting in an AMP.[91]

The Commission may revoke certifications or may take licensing actions as a response to non-compliance, meaning that a consequence of non-compliance for the licensee could be licence suspension, amendment, revocation or replacement. This response alters the authorisations enjoyed by the licensee. Finally, any natural or legal person may also be prosecuted for offences under the NSCA, and the regulator may respond to non-compliance with prosecution if it is in the public interest, and there is a reasonable likelihood of conviction. Prosecution requires the state to prove the offence under the NSCA beyond a reasonable doubt.

Safety significance of the non-compliance and compliance history are major factors in determining which response to a non-compliance is appropriate. In

91. NSCA, *supra* note 14, s 65.06.

applying those factors, the application of good professional judgement is necessary to the successful application of the graduated approach to enforcement. Where discretion is broad, it is important that the regulator does not dip into the territory of "selective enforcement", or perhaps better-stated "selective non-enforcement".[92] That is, performance criteria and enforcement from one licensee to the next with facilities of a similar nature should not vary substantially, unless, of course, a licensed facility has a poor compliance history and merits increased regulatory scrutiny.

7. Key considerations for performance-based regulating

An early reaction may be that prescriptive requirements can be seen as more straightforward for assessing compliance and determining penalties for violations.[93] For regulators taking a performance-based approach, some have indicated that there may be a perceived lack of credibility of regulators following through and implementing the regulatory requirements.[94] Accordingly, it is worth considering the particularities of enforcing performance-based requirements. The considerations articulated below may not be applicable exclusively to the enforcement of performance-based regulatory requirements, but they should be considered or assessed when dealing with a performance-based model. These considerations stem from the view of a regulator conducting enforcement activities and not from the view of an operator assessing compliance, although they could inspire considerations of a similar nature for licensees. Taking into account the following considerations should address the concerns of those who believe that enforceability is problematic under performance-based regulating.

7.1 Consideration #1: Draft clear guidance documents in accordance with the rule of law

Guidance or "soft law", and its connection to the exercise of discretion, plays a significant role in the performance-based model. A good description of the role of soft law is, "whereas statutes and regulations are meant to define the boundaries and mandates of public authorities, soft law is intended to ensure coherence and consistency in the implementation of those mandates".[95] In Canada, soft law called REGDOCs are a critical part of the nuclear regulatory framework.

The NSCA gives the Canadian nuclear regulator wide discretion over nuclear safety and security matters. This discretion is an important feature for effective enforcement, but inconsistent exercise of discretion is problematic from a fairness perspective. One could imagine scenarios where inconsistent discretion could negatively impact safety – particularly in a performance-based model where there is more frequent exercise of regulatory discretion on a wider variety of topics. Accordingly, it is important for regulators under legislative schemes granting wide discretion to prioritise rule of law principles. These principles can be summarised as:

1. the requirement to make rules;
2. the requirement to publicise or make rules available;
3. the requirement that rules be workable (understandable and consistent);

92. Weeks, G. (2016), *supra* note 81, at pp. 32-33.
93. Bénichou, N. et al. (2008), *supra* note 42, p. 7.
94. Golay, M. (2000), *supra* note 52, p. 235.
95. Weeks, G. (2016), *supra* note 81, at p. 46, citing Sossin, L. (2004), "The politics of soft law: how judicial decisions influence bureaucratic discretion in Canada", in Hertogh M. and S. Halliday (eds.), *Judicial Review and Bureaucratic Impact*, Cambridge University Press, Cambridge, pp. 129, 139.

4. the requirement for some stability in rules; and
5. the requirement that rules be impartially interpreted and applied (uniformly enforced).[96]

The exercise of discretion can "be structured through the use of non-binding agency guidelines or directives", in order to mitigate concerns related to the consistency and quality of discretionary decision making.[97] It is also true in Canada that laws must not be vague, and enforcement authorities must not have such unlimited discretion as to apply a "standardless sweep".[98] "Excessive discretion" subverts the rule of law if the manner in which the discretion will be exercised is not "knowable prospectively".[99] The rule of law calls for legal certainty.[100] While guidance may be desired for uniformity and consistency in decision making, and regulators may hold licensees to the guidance in order to be authorised to engage in regulated activities, the Canadian courts have confirmed that decision makers should consider possible good reasons for deviating from guidance where appropriate:

> Nonetheless, while agencies may issue guidelines or policy statements to structure the exercise of statutory discretion in order to enhance consistency, administrative decision-makers may not apply them as if they were law. Thus, a decision made solely by reference to the mandatory prescription of a guideline, despite a request to deviate from it in the light of the particular facts, may be set aside, on the ground that the decision-maker's exercise of discretion was unlawfully fettered ... This level of compliance may only be achieved through the exercise of a statutory power to make "hard" law, through, for example, regulations or statutory rules made in accordance with statutorily prescribed procedure.[101]

Note, as discussed earlier, that if REGDOCs are incorporated either directly into a licence, or the licence applicant has made representations in its licensing basis that it will adhere to a REGDOC as its means to make adequate provision for the protection or the environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed, and the Commission makes a decision to authorise the activity on that licensing basis, the criteria in the REGDOC transform into legally enforceable requirements. Once the Commission members make that licensing decision, the soft law guidance is "hardened". For a REGDOC to be binding on a licensee there must be a Commission decision to make it a part of the licensing basis. Likewise, the programme documents proposed by a licensee become requirements when accepted by the Commission in its licensing decision.

Certainty is an important consideration for compliance verification and enforcement – both the regulator and the regulated benefit from certainty. It has been reported that "regulated entities can be uncomfortable with loosely specified

96. Salembier, P. (2015), *Regulatory Law and Practice*, Second Edition, LexisNexis Canada, Markham, Ontario, pp. 8-13.
97. Macaulay, R., J. Sprague and L. Sossin (2018), *Practice and Procedure Before Administrative Tribunals*, Carswell, Toronto, 5B.4(a). In this context "non-binding" means non-binding on decision makers.
98. Canada v. Pharmaceutical Society (Nova Scotia), [1992] 2 SCR 606, para. 53.
99. Salembier, P., *supra* note 96, p. 10.
100. Canada's former Chief Justice of the Supreme Court of Canada, Beverley McLachlin, remarked in a speech that the principle of legal certainty is, in fact, a "myth of legal certainty", since there are cases without one, obvious answer. McLachlin, B. (2004), "Judging in a Democratic State", Sixth Templeton Lecture on Democracy, University of Manitoba, available at: www.scc-csc.ca/judges-juges/spe-dis/bm-2004-06-03-eng.aspx.
101. Thamotharem v. Canada (Minister of Citizenship & Immigration) (F.C.A), *supra* note 20, para. 62, citing Maple Lodge Farms Ltd. v. Canada, [1982] 2 SCR 2.

performance standards because they believe they give regulators too much discretion when deciding enforcement issues".[102] Regulated entities may react negatively to the lack of predictability if performance-based regulations are inconsistently interpreted, and some feel performance-based standards can be ambiguous.[103] It is often difficult to find the exact words to capture the intended spirit without leaving room for inappropriate interpretation or manipulation, which can create uncertainty.[104] Likewise, the movement from a prescriptive approach to a performance-based one can be daunting for regulators:

> [R]egulators who are accustomed to enforcing relatively straightforward prescriptive standards are frequently uncomfortable with the discretion inherent in loosely specified performance-based standards. Some participants speculated that it may take years (if not a generation or more) for regulators to become accustomed to any such new discretion, though some participants argued that regulators with more professional training (or higher levels of education) might adapt more quickly. It was also noted that regulated entities can be uncomfortable with loosely specified performance standards because they believe they give regulators too much discretion when deciding enforcement issues.[105]

In 2014, the CNSC sought feedback on the question: "Is the CNSC striking the right balance between performance-based regulation and prescriptive requirements?"[106] After review of the responses received from Canadian stakeholders, one can surmise that there is a general acceptance of or preference for the performance-based approach, and stakeholders emphasised the importance of making risk-informed determinations in nuclear regulation. The Canadian nuclear community also said that performance-based guidance should not be drafted or implemented as if it were prescriptive regulation made via the legislative process, as doing so negatively impacts the intended benefits and flexibility of the performance-based model.[107]

Decision making should not be subjective, and performance-based processes should not be murky; that is, "specific, quantifiable outcomes, transparent processes and measurements" are essential for performance-based regulating.[108] To overcome subjectivity, or in legal terms, to overcome the inconsistent exercise of discretion, scrutinised regulatory guidance is desirable. Authors have regarded co-operation among government, industry and public interest organisations as a good practice.[109] A regulator may pursue public consultation using online methods and meetings, and special or tailored stakeholder workshops or meetings can assist in developing soft law. Transparent processes help avert perceived problems as the regulator moves to implementation of a guidance document.[110] The IAEA views consultation with the

102. Coglianese, C., J. Nash, and T. Olmstead (2002), *supra* note 3, p. 10.
103. May, P. (2003), *supra* note 22, p. 388 citing May, P. and R. Wood (2003), "At the Regulatory Frontlines: Inspectors' Enforcement Styles and Regulatory Compliance", *Journal of Public Administration Research and Theory*, Vol. 13. No. 2, pp. 117-139.
104. Coglianese, C., J. Nash, and T. Olmstead (2002), *supra* note 3, p. 12.
105. *Ibid*., p. 10.
106. CNSC (2014), "Modernizing the CNSC's Regulations", Discussion Paper DIS-14-02, CNSC, Ottawa, p. 3.
107. CNSC (2016), "Document History of Discussion Paper DIS-14-02, Modernizing the CNSC's Regulations", available at: www.nuclearsafety.gc.ca/eng/acts-and-regulations/consultation/history/dis-14-02.cfm (accessed 28 Nov. 2019).
108. Blumenauer, E. (2011), *supra* note 45, p. 363.
109. *Ibid*.; Owusu, E. (2015), *supra* note 22, p. 367.
110. May, P. (2007), "Regulatory Regimes and Accountability", *Regulation and Governance*, Vol. 1, Issue 1, Blackwell Publishing, p. 11.

public as part of the role of government, which is a fundamental safety principle.[111] From a pragmatic perspective, thorough, transparent consultation on soft law addresses the criticism that soft law does not go through the rigorous regulation-making process of the legislature.

Regulatory guidance has great utility in the performance-based model by enhancing the comprehensiveness of the regulatory framework. Guidance should always be traceable to a stated, broad safety goal in the law. How a statement manifests in the legislation determines the amount of flexibility available for meeting the safety objective: guidance can only be understood in reference to the ultimate goal.[112] Accordingly, guidance should not be drafted in a way that confuses a reader or significantly overlaps with requirements found in other sources, such as the applicable statutes, regulations or the standards of other organisations that may be referenced within the guidance document. Likewise, soft law should not merely repeat what is stated in legislation in a different way. Soft law must be in accord with its governing legislation, lest it be useless, given that the primary or secondary legislation prevails if in conflict with soft law. Regulatory guidance that is inconsistent with the regulator's governing legislation may result in successful applications for judicial review of a regulatory decision applying it.[113] For example, a party to a proceeding might seek review of a licensing decision if in its view a decision maker acted *ultra vires* with respect to the governing legislation by applying incongruent guidance.

As discussed earlier, regulators may end up implementing very similar requirements to those that would have resulted in prescriptive regulations:

> [Monitoring] may require the government to get so involved that it is "essentially running everything again." In some cases, the information requirements for either a good performance standard or a good prescriptive standard may be so demanding that these two approaches could be very similar in terms of what government needs to know.[114]

It may be true that for some regulatory matters there is only one safe way of doing things; in this sense, guidance can become expectation. What a performance-based model retains, however, is the flexibility for an operator to demonstrate that a new method, measurement, procedure, etc. complies with the performance level (the law) even though it does not meet the performance criteria in guidance. In the interim, it may be true that guidance is relied on in a practical sense as if it were a requirement, because the operator has not demonstrated an alternative that meets the required performance level. Again, a regulator may blend its approaches:

> A programmatic issue for performance-based implementations is that so far, there are no generally accepted equivalents of "compliance" and "non-compliance" with respect to performance goals. One can fail to satisfy a performance goal, but this is different from a violation of a prescriptive requirement. It is easy enough to stipulate that the regulator should intervene when performance declines to a certain level, but what form this intervention should take is difficult to specify a priori [*sic*]. This difficulty is circumvented to some extent by blending prescriptive and performance-based ideas. If both kinds of requirements are in force, then when declining performance is detected, it can be imputed to a compliance issue.[115]

111. IAEA (2006), *Fundamental Safety Principles*, *Safety Fundamentals*, IAEA Safety Standards Series No. SF-1, IAEA, Vienna, pp. 7-8.
112. Coglianese, C., J. Nash, and T. Olmstead (2002), *supra* note 3, p. 5.
113. Weeks, G. (2016), *supra* note 81, at p. 53.
114. *Ibid.*, pp. 13-14.
115. Youngblood, R. and I. Kim (2005), *supra* note 1, p. 238.

One may not agree that the state of "compliance" *versus* "non-compliance" is less applicable to performance-based regulations; and this is certainly not the case in Canada where the CNSC ensures requirements are clear through a careful licensing basis approach. Nevertheless, this binary view of compliance represents a good reason for having strong performance criteria in soft law, so it can be determined with greater ease when a licensee is not in compliance. Performance criteria can be used by the regulator as a prescriptive element within the larger performance-based model, with the level of enforcement response ultimately remaining at the regulator's discretion.

There is also the possibility available to lawmakers of drafting regulations with "equivalency clauses", an interesting alternative to an approach that relies on soft law to contain performance criteria. Under this alternative, specific technologies or prescriptive designs may be prescribed in the law, but an equivalency clause mechanism may be added that allows the regulated entity alternative means of compliance. The provisions would allow licence applicants or licensees to "opt out" of the prescriptive standard if they demonstrate a comparable level of performance through other means.[116]

One downside to the equivalency clause mechanism is that it would signal a return of the limitations of prescriptive regulating that were described at the outset of this article. For example, why would operators opt out when they will be in compliance with the law without spending money to seek improvements? The regulator has done the safety work for them, which, arguably, is not the intent of the CNS. Recalling this potential conflict also serves as a good reason for regulators to avoid making guidance documents more prescriptive than they ought to be. When there is a variety of ways for an operator to perform at a level that meets a safety goal set out in law, it may be best that a regulator avoid belabouring the text of its guidance or mechanically offering what the operator is to do.

Referring back to Meacham et al.'s performance-based model, the soft law or guidance discussed in this section is at the performance criteria level. It may not be the case, however, that all performance indicators are amenable to being static in guidance. For example, in the fitness for service example above, the industry wide data used as a performance indicator against an individual operator changes over reporting periods and may not be amenable to static inclusion. Nevertheless, the fact that it may be applied to assess compliance should be known to the operator.

A performance-based model requires a regulator to continually "collect from industry new and better data on performance and performance indicators".[117] Performance indicators must remain adaptive to keep pace as new information becomes available. However, regulators should not be hyper-sensitive or hyper-reactive. Performance criteria should remain relatively stable where possible so operators have certainty. While performance indicators should indeed change as information becomes available, regulators should not habitually "regulate by letter". That is, performance criteria should be industry wide and in writing in the regulatory framework, unless there is good reason to have facility specific criteria (i.e. a new and unique reactor technology). The next consideration addresses how to treat information that is not amenable to being a part of soft law, but belongs somewhere within bureaucratic control.

116. Coglianese, C., J. Nash, and T. Olmstead (2002), *supra* note 3, p. 8.
117. *Ibid.*, p. 14.

7.2 Consideration #2: Apply bureaucratic controls in a balanced and transparent manner

Under a performance-based regulatory approach, the focus is monitoring for adherence to the performance goals found in regulations, as opposed to the monitoring for adherence to prescriptive regulations. This different approach to monitoring will affect the enforcement practices at the regulator and the tools that it adopts to facilitate its staff enforcement work. The following is a concern regarding the particularity of performance-based regulating:

> [L]oosely specified performance-based standards, by definition, create uncertainty for both regulators and regulated entities with respect to enforcement and compliance issues. Moreover, regulators who are accustomed to enforcing relatively straightforward prescriptive standards are frequently uncomfortable with the discretion inherent in loosely specified performance-based standards.[118]

"Bureaucratic controls" can assist a regulator to ensure regulated entities are in compliance with performance-based regulations.[119] Bureaucratic controls are such things as work instructions, detailed reporting requirements, and compliance verification and enforcement policies and procedures for use by staff – which are not the same as the licensee-facing guidance documents promulgated by the regulator. While bureaucratic controls will be useful to staff whose role relates to compliance verification, a regulator must take a careful approach to their creation. Lacking bureaucratic control in a performance-based regime may lead to "capricious enforcement", which means unpredictability; at the other extreme, too many bureaucratic controls can result in missing larger compliance issues due to "nitpicky enforcement".[120] Internal processes must not be so strict or provide so many levels of bureaucracy as to prevent important, nimble regulatory responses to non-compliance.

We know that in the nuclear field, a graded approach to regulating should be provided for in legislation, which the IAEA Safety Glossary defines as:

> For a system of control, such as a regulatory system or a safety system, a process or method in which the stringency of the control measures and conditions to be applied is commensurate, to the extent practicable, with the likelihood and possible consequences of, and the level of risk associated with, a loss of control.[121]

If the factors to apply the graded approach are not set out in regulations, the process and procedure to apply the graded approach should be captured in a process document. Such a bureaucratic control will help staff apply the graded approach consistently. Likewise, internal guidebooks on applying a regulator's approach graduated enforcement, as summarised above, are an example of a bureaucratic control. Another example is a system that could be developed to guide enforcement

118. *Ibid*., p. 10.
119. *Ibid*., p. 12.
120. May, P. (2007), *supra* note 110, p. 21.
121. IAEA (2018), *supra* note 89, p. 104. The IAEA states in IAEA Safety Standards Series No. SF-1 under fundamental safety principle 3 that "Safety has to be assessed for all facilities and activities, consistent with a graded approach." IAEA (2006), *supra* note 111, p. 9. The application of the graded approach is also included in IAEA's General Safety Requirements as part of several requirements, including "Requirement 29: Graded approach to inspections of facilities and activities". IAEA (2016), *Government, Legal and Regulatory Framework for Safety: General Safety Requirements*, IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), IAEA, Vienna, p. 30.

staff in the selection and effective application of the variety of enforcement tools available to the regulator to correct non-compliance.

In Canada, regulators have received guidance from Canada's federal courts on ensuring formality and transparency in regard to the bureaucratic controls used for regulating. Outside the nuclear context, for example, the decision on an administrative monetary penalty by a federal Canadian regulator was quashed by the Federal Court of Canada (decision upheld on appeal) because a director relied on an unpublished formula to determine the amount of the penalty, which the court called a "secret guideline".[122] At the same time, the court warned Canadian regulators that bureaucratic controls such as a guideline dictating how administrative monetary penalties are assessed must not fetter the discretion concerning that which is set out in legislation.[123] The court warned that unpublished guidelines may be inconsistent with the procedural fairness owed.[124]

7.3 Consideration #3: Consistently consider procedural fairness

Arguably, a procedural fairness discussion could fit under consideration #1 on clear guidance according to the rule of law. However, procedural fairness is of such import to performance-based regulating, and relates to more than just guidance documents, that it merits elevation to a standalone consideration. Regulators should be mindful of how procedural fairness and the rules of natural justice are engaged when verifying compliance and taking enforcement actions in a performance-based regime. While performance-based regulating offers desirable flexibility, outcomes should not be subjective.[125] What follows does not examine every aspect of procedural fairness and the rules of natural justice, which are more expansive than the narrow aspects in this article, but highlights the particularly important topics for performance-based regulating.

The CNSC's graduated approach to enforcement is described above, indicating that review processes provide the subject of an enforcement action with an opportunity to express views on the non-compliance for consideration by the decision maker. Beyond an opportunity to be heard, to be fair to the subject of an enforcement action, careful attention should also be paid to the need for and sufficiency of written reasons for decisions. It is important from a safety perspective that the licensee understand what went wrong with their performance. If a licensee were to challenge an enforcement decision in court, the reviewing court must understand the basis on which the matter was decided given that the review exercise for the judges will not be the statutory interpretation exercise that they may be more accustomed to undertaking.[126] A decision of the Federal Court of Appeal emphasised the importance of articulating the reasons for a decision:

> Without knowing the reasoning behind a decision, it is impossible for a judge to determine if it is founded upon arbitrary reasoning. Thus, in order for a judge to determine whether a decision maker acted lawfully, the decision maker must provide reasons adequate to allow a reviewing judge to determine why the decision maker made the decision they did and whether it followed explicit statutory requirements [or the basis for the decision must be apparent in the record]. If the judge cannot ascertain how the decision was made, then

122. Kabul Farms Inc. v. R., 2016 FCA 143, paras. 36-37, [2016] F.C.J. No. 480.
123. *Ibid.*, para. 41.
124. *Ibid.*, para. 44.
125. Blumenauer, E. (2011), *supra* note 45, p. 363.
126. Kabul Farms, *supra* note 122, para. 33. What will satisfy "adequate reasons" for a particular case will vary greatly.

> the court cannot fulfil this role and decisions made in violation of the rule of law may be sanctioned by the court.[127]

Canadian law provides various factors for consideration when administrative decision makers are determining the content of procedural fairness in a given set of circumstances. The "legitimate expectations" of a party may be such a consideration, which means that where there is a legitimate expectation by a licensee that a certain procedure will be followed, that procedure is required by the duty of fairness.[128] Although reviewing courts in Canada give weight to the choices of expert decision makers on their own procedure, generally, it is considered unfair for regulators to act in contravention of the representations it makes on procedure.[129] The doctrine of legitimate expectations does not, however, create substantive rights.[130] That is, a licensee cannot argue that a regulator is barred from taking its desired enforcement action to correct a non-compliance because of fairness considerations. In this sense, fairness provides procedural protections, not immunity from an outcome. Nevertheless, failing to undertake proper process, resulting in arguments about procedure with a licensee, wastes valuable time for the correction of the non-compliance. A regulator would seek to conduct its affairs in a way that reduces the legal risk of court proceedings due to breaches of procedural fairness so that time and resources remain focused on important safety work.

7.4 Consideration #4: Assess unique needs for inspector training

Inspection and enforcement have a close relationship and should be considered together for the day-to-day work of the regulator: it is why the CNS requires contracting parties to establish a system of regulatory inspection.[131] Likewise, under the fundamental principle of continuous control, it is accepted that "national nuclear legislation must provide for free access by regulatory inspectors to all premises where nuclear material is being used and stored".[132] Being such a fundamental role of any nuclear regulator, it is worthwhile to explore any unique considerations for inspector training in light of a performance-based model.

A merit of performance-based regulation is that it shifts some burden to identify safety issues to the operator, leaving inspectors to focus on noteworthy potential risks.[133] There are particularities to verifying performance-based requirements:

> Inspectors no longer look for particular items to check off boxes that indicate compliance with prescriptions. Instead, they are charged with certifying the adequacy of systems or the adherence to regulatory goals. This requires a different type of expertise and different interactions with regulated entities and as such necessitates a cultural transformation of enforcement. One issue

127. *Ibid*., para. 35; Warchuk, P. (2016), "The Role of Administrative Reasons in Judicial Review: Adequacy and Reasonableness", *Canadian Journal of Administrative Law and Practice*, Vol. 29, No. 1, Carswell, p. 113.
128. Baker v. Canada (Minister of Citizenship and Immigration), [1999] 2 SCR 817, para. 26.
129. *Ibid*., paras. 26-27.
130. Old St. Boniface Residents Assn. Inc. v. Winnipeg (City), [1990] 3 SCR 1170, p. 1204.
131. CNS (1994), *supra* note 5, Art. 7(2)(iii); Stoiber, C. et al. (2003), *supra* note 6, p. 38.
132. Stoiber, C. et al. (2003), *supra* note 6, p. 8. The IAEA General Safety Requirements indicate under Requirement 29 that "Provision shall be made for free access by regulatory inspectors to any facility or activity, at any time within the constraints of ensuring operational safety at all times and other constraints associated with the potential for harmful consequences. These inspections may include, within reason, unannounced inspections. The manner, extent and frequency of inspections shall be in accordance with a graded approach." IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), *supra* note 121, p. 30, para. 4.52.
133. May, P. (2007), *supra* note 110, p. 19.

> is the ability of enforcement personnel to gauge the quality of systems or the adherence to desired performance goals.[134]

A US Nuclear Regulatory Commission white paper on performance-based regulating says the following on inspections:

> [I]f a licensee is unsuccessful in meeting the criteria defined by a performance-based regulation, the inspector should then focus on the licensee's process and method, to understand the root cause of the breakdown in performance, and to understand how future poor performance may be avoided.[135]

Correcting the performance issue requires two-way communication between the regulator's inspector and the operator's staff. Performance-based regulating has a necessarily human component and choosing inspectors with soft skills such as interviewing and good judgement, while maintaining the technical competencies, becomes even more important. In a performance-based regime, one might suggest that not everything an inspector is to do can be summarised in a checklist, nor is that desirable. As discussed under consideration #2, work instructions and procedures for inspectors are bureaucratic controls that can helpfully guide inspection activity and guard against "subjectivity", but should be used after thoughtful consideration to ensure inspectors are also applying the professional judgement necessary.

While it may be true that inspection activities are necessarily more "two-way" than in a prescriptive regime, inspectors must be trained that it is not a collaborative or negotiated exercise. It is, however, a co-operative one. There must be effective separation of a regulator from its licensees.

7.5 Consideration #5: Place a sufficient evidentiary burden on operators

Regulators employing a performance-based model should evaluate particular evidentiary considerations that come with the approach. It is critical that regulatory reviews ensure analyses are not being driven to produce the results desired by the licensee.[136] Such skewing may not necessarily be intentional or malicious:

> [P]erformance standards based on predictive models could lead to "legitimate self-delusion" on the part of regulated entities. In other words, regulated entities may present or interpret their models and data in a way that makes it look as if their proposed approaches will perform well, when in fact a more disinterested examination would find problems with the analysis.[137]

The possibility of such "self-delusion", whatever the motivation, is one reason for the permission principle, fundamental to international nuclear law.[138] Obtaining permission to generate nuclear power in Canada is assessed in terms of the prevention of unreasonable risk.[139] In order to be granted permission from the regulator to operate, operators must provide sufficient evidence to demonstrate that their operation will not pose unreasonable risks. The regulator examines the evidence to make a decision on risk.

134. *Ibid*., pp. 13-14.
135. Memorandum for the Commissioners from L. Callan, Executive Director for Operations (22 June 1998), "White Paper on Risk-Informed and Performance-Based Regulation", SECY-98-144, p. 4, n. 5, available at: www.nrc.gov/reading-rm/doc-collections/commission/secys/1998/secy1998-144/1998-144scy.pdf.
136. Golay, M. (2000), *supra* note 52, p. 235.
137. Coglianese, C., J. Nash, and T. Olmstead (2002), *supra* note 3, p. 11; see also Golay, M. (2000), *supra* note 52, p. 235.
138. Stoiber, C. et al. (2003), *supra* note 6, p. 8.
139. NSCA, *supra* note 14, s. 9(a).

It was noted earlier that certain outcomes cannot be predicted with certainty in the nuclear field because precise data may be unavailable. This makes the regulator's job of making decisions on risk even more challenging, particularly in a performance-based regime where requirements set out in legislation are high-level in nature. Lack of understanding and data present challenges to regulators and may prevent conclusive answers on risk. When making judgements about risk in a performance-based regime, one author recommends that "particular attention must be paid to evidence for the success or failure of current approaches. In order to do this successfully, one needs to establish a standardized process that addresses uncertainty."[140] Also, limits to knowledge must be treated explicitly and formally.[141]

How do these rather academic statements come to life in the day-to-day work of regulatory staff? Let us imagine the following scenario: after the regulator has made a decision to issue a licence to an operator under the performance-based model, the inspection staff will proceed with compliance verification activities. It may be the case that the operator would like to make a change to one of its maintenance management plan documents. The regulator has made it a condition of the licence to obtain permission from a certain level of regulatory staff before changing the current practice, as approved at the time of decision on the licence, to the new process. The regulator decided that a change to the maintenance plan may only be made if the change represents an improvement to the performance of the operator, as this is the very benefit the performance-based model is supposed to encourage. The regulatory staff would be faced with assessing the change and it must be diligent in satisfying themselves that the operator has provided enough evidence to support that its purported change is an improvement in performance.

In deciding to use a performance-based model, there should be consideration of the concepts of risk-informed versus risk-based decision making.[142] Simply distinguished, a risk-based approach is basing a decision solely on the numerical results of an assessment and a risk-informed approach is basing a decision on other factors as well and can "reduce unnecessary conservatism".[143] Whether a regulator takes a risk-informed or risk-based approach to implementing the performance-based model can be said to be representative of the level of conservatism in decision making, and a regulator can make use of both approaches depending on the matter before it. In the view of some, there is a "a very natural relationship between risk-informed and performance-based regulation" because "performance-based regulation requires that performance goals be set, and using risk models is a very natural way to do this".[144]

The intended flexibility for undertaking a performance-based model to regulating should not be undone based on evidentiary considerations, whether during licensing, compliance verification or enforcement activities. The discretion of an operator may be constrained if the regulator chooses to employ an overly strict adherence to a modelling methodology.[145] Nuclear regulators that are new to performance-based regulating may be tempted to pursue highly conservative approaches:

> It may be safer for the career of a decision maker to avoid changing the status quo, as that path avoids the criticisms that are sure to come when a change

140. Golay, M. (2000), *supra* note 52, p. 233.
141. *Ibid*., p. 236. However, it remains a feature of efficient administrative tribunals that they not be bound by the strict rules of evidence and may accept information as, in its discretion, it considers appropriate. In Canada, this has resulted in CNSC licensing hearings that are more inquisitorial in nature, as opposed to adversarial. The NSCA, *supra* note 14, at subsection 20(4) says the Commission is not bound by legal rules of evidence.
142. SECY-98-144, *supra* note 135, p. 3.
143. *Ibid*.
144. Youngblood, R. and I. Kim (2005), *supra* note 1, p. 231.
145. Coglianese, C., J. Nash, and T. Olmstead (2002), *supra* note 3, p. 7.

> turns ou[t] badly (as some surely will). However, to fail to change in some instances also can constitute a regulatory failure to achieve feasible safety improvements.[146]

The policy approach to risk can be reflected, where possible, in the bureaucratic controls discussed under Section 7.2.[147]

All of the above inspires the consideration of the evidentiary burden on operators at the verification stage of the performance-based model, regardless of the approach to risk or level or conservatism applied to decision making. Evidentiary considerations interact with the legal concept of reasonableness, which is the standard that usually applies to the review of CNSC decisions. As a final ancillary thought on evidentiary considerations, it is necessary that a regulator's enabling statute provides the authority to request the information or records it needs from its regulated community.

7.6 Consideration #6: Consider needed expert qualifications of regulator staff

It is not enough in a performance-based regime for a regulator to rely only on developing appropriate bureaucratic controls. The regulation of nuclear energy production and its fuel cycle have special requirements for education and training as well, as explored in detail in the Organisation for Economic Co-operation and Development (OECD) Nuclear Energy Agency's (NEA) 2012 publication entitled *Nuclear Education and Training: From Concern to Capability*.[148] This fact manifests itself as an obligation in Article 11 of the CNS, which states that each contracting party shall take the appropriate steps to ensure that sufficient numbers of qualified staff with appropriate education, training and retraining are available.[149] Capable government actors are critical for performance-based regulating:

> Performance-based standards depend on the ability of government agencies to specify, measure, and monitor performance … When implemented in the wrong way, or under the wrong conditions, performance-based regulation will function poorly, as will any regulatory instrument that is ineffectually deployed.[150]

The aforementioned NEA publication explains that in regards to the competencies necessary to run a nuclear power plant, there are varying degrees of "nuclearisation" across positions, which refers to the extent to which specific nuclear skills and safety culture training are needed to complement other skills.[151] According to the NEA, one becomes more "nuclearised" "as the acquisition of competencies shifts from training focused on a particular job, task or set of tasks, towards education, developing more in-depth underlying principles that, when properly acquired, can be applied to a less predefined set of circumstances".[152] If nuclear education is often necessary for staff working in less predefined circumstances, it makes sense to correlate the implementation of a performance-based regime with a need for trained staff higher on the "nuclearisation" spectrum as well. Indeed, the IAEA indicates in its explanation of the performance-based regulatory approach quoted in Section 3 of this article that staff must "have a high level of professional competence and are able to interact to determine whether established safety objectives for each topic are met". The

146. Golay, M. (2000), *supra* note 52, p. 233.
147. There is extensive writing on the risk-informed approach. For example, see IAEA (2015), *Risk Informed Approach for Nuclear Security Measures for Nuclear and Other Radioactive Material out of Regulatory Control*, IAEA Nuclear Security Series No. 24-G, IAEA, Vienna.
148. NEA (2012), *Nuclear Education and Training: From Concern to Capability*, OECD Publishing, Paris.
149. CNS (1994), *supra* note 5, Art. 11.
150. Coglianese, C., J. Nash, and T. Olmstead (2002), *supra* note 3, p. 2.
151. NEA (2012), *supra* note 148, p. 5.
152. *Ibid*.

inclusion of this statement must be intended to emphasise a particular type of competence especially important to performance-based regulating, as it can be assumed that competent staff is important to regulators applying any model of regulating.

Given that compliance verification and enforcement activities will often focus on an assessment of performance criteria, the staff completing the related tasks may be more likely to employ in-depth principles and more advanced nuclear knowledge more frequently. Accordingly, it can be suggested that the performance-based model may demand formal nuclear education for a greater number of positions.

As discussed under Section 7.5, the regulator must test or challenge the information submitted by operators.[153] While it is critical that licensees have the expertise to meet performance levels, independent consultation of expertise must be accessible to the regulator as well. As topics become more complex, ensuring access to such expertise may become more difficult:

> [M]any people lack the training to use or understand [complex, predictive] models. As a result, the number of people who can knowledgably participate in regulatory decision making declines as the complexity of the analysis increases, thereby causing government either to rely on third-party experts (e.g. academics or consultants) to do much of the analysis or to accept too readily the analysis provided by the regulated entities.[154]

The remedy to this issue requires careful, advanced planning in regards to staffing needs and good foresight by the regulator.

Access to qualified, independent experts is necessary for all nuclear regulators. However, the nature of performance-based regulating, where staff assess licensee proposals and apply performance criteria, suggests that regulators may need more staff with sufficient nuclear education when compared to a prescriptive regime regulating the same volume of activity.

7.7 Consideration #7: Continually pursue strong safety culture

The IAEA indicates that it is a purpose of the management system "To foster and support a safety culture in the regulatory body through the development and reinforcement of leadership as well as good attitudes and behaviour in relation to safety on the part of individuals and teams".[155] Safety culture should be the dominant aspect of organisational culture.[156] Accordingly, it seems fitting that before this article concludes there be recognition of safety culture and its importance to performance-based regulating.

Safety culture permeates every topic of nuclear regulation and ultimately reduces legal risk to the parties involved in the nuclear activity. In the safety context of performance-based regulation, "There seems to be little doubt that a culture of safety is critical to instil to avoid potentially catastrophic consequences."[157] The CNS preamble states that it is the contracting parties' "[d]esir[e] to promote an effective nuclear safety culture".[158] Likewise, the Amendment to the Convention on the Physical Protection of Nuclear Material includes "Fundamental Principle F", which obligates

153. Coglianese, C., J. Nash, and T. Olmstead (2002), *supra* note 3, p. 14.
154. *Ibid.*, p. 14.
155. IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), *supra* note 121, p. 22.
156. IAEA (2002), *Safety culture in nuclear installations: Guidance for use in the enhancement of safety culture*, IAEA-TECDOC-1329, IAEA, Vienna, at p. 8.
157. May, P. (2007), *supra* note 110, p. 20.
158. CNS (1994), *supra* note 5, preamble at (iv).

organisations implementing physical protection to give due priority to "security culture".[159]

It is worth considering whether there is anything unique about safety culture in a performance-based environment. The IAEA indicates that a more evolved or healthy safety culture is one that emphasises continuous improvement:

> Employees were encouraged to develop safety improvement plans and set goals, and monitor progress in achieving them. [This] stage corresponds to an organizational emphasis on continuous improvement and achieving excellence. In pursuit of excellence, organizations have attempted to develop cultures that can cope with frequent change.[160]

We know continuous improvement is a goal of performance-based regulating. It seems, then, that organisations with more mature safety cultures are better suited to operate in the performance-based environment, and one may go as far as extrapolating that a mature safety culture is required for the effective deployment of a performance-based nuclear regime. It may be desirable to develop enforceable safety culture requirements (including monitoring) on the operator to ensure the effectiveness of the performance-based model. Without regulatory oversight of safety culture, the justification for using the performance-based model may be negatively impacted and the intended safety benefits left unrealised, or worse. In Canada, there is regulatory oversight of licensee safety culture. Safety culture can be assessed as a requirement where part of the facility's licensing basis.[161]

In its policy statement on regulatory safety culture, the CNSC indicates, "regulatory safety culture is expressed by the shared attitudes, values and behaviours we demonstrate in meeting our mandated responsibilities".[162] The NEA emphasised the importance of regulators actively scrutinising how their own safety culture impacts that of its licensees.[163] A healthy safety culture at the regulator will "avoid complacency by continuously challenging existing conditions and activities".[164] With that statement, one can see the importance of safety culture to performance-based regulating.

While a critical, questioning attitude from the expert staff is of utmost importance, regulatory decisions must continue to be made. In the nuclear context, "expert opinions and beliefs about possible failure modes and their likelihoods need to be formalized as statements of probability".[165] It is possible that within the regulator there will be disagreements about risk and whether an operator is performing at the level required to meet the safety goal. Disagreement may be an indication of engaged technical experts with a healthy safety culture; however, when experts cannot agree, for example, on the risk level of a certain operator undertaking, such disagreements should be formalised and recorded. This can be done through a differing professional opinion protocol or other formal process. Such explicit acknowledgement of limits in knowledge is important: "As a means of compensating for unavoidable uncertainty as an obstacle to regulatory decision making, limits to knowledge must be treated explicitly and formally."[166]

159. ACPPNM, *supra* note 9, Art. 2A(3).
160. IAEA (2002), *supra* note 156, p. 17.
161. For more on how Canada regulates safety culture, see CNSC (2018), *Safety Culture*, REGDOC-2.1.2, CNSC, Ottawa.
162. CNSC (2019), "CNSC Regulatory Safety Culture Policy", CNSC, Ottawa, p. 2.
163. NEA (2016), *The Safety Culture of an Effective Nuclear Regulatory Body*, OECD Publishing, Paris, p. 7.
164. *Ibid.*, p. 8.
165. Golay, M. (2000), *supra* note 52, p. 233.
166. *Ibid.*, p. 219.

8. Conclusion

This article applied academic expressions of the performance-based model to demonstrate how international obligations related to nuclear safety and security can be implemented via this regulatory approach. Importantly, enforceability of requirements should not be a barrier to implementing a performance-based regime, and this article describes considerations to do so effectively. To create a regulatory environment with effective enforcement of performance-based requirements, seven key considerations emerge:

1. **Draft clear guidance documents in accordance with the rule of law:** Guidance or soft law can provide structure to discretionary decisions and confirm the criteria that will be applied to compliance verification activities. Scrutinised guidance, traceable to a safety goal, allows operators to understand how performance will be measured. Performance criteria should be industry wide and in writing, though facility specific criteria are possible where justified. Regulators should refrain from making guidance documents narrow or "prescriptive-like" when there are many possible ways to meet an operative requirement; on the other hand, it is possible that there may be only one way to meet an operative requirement. It is important for regulators under legislative schemes granting wide discretion to prioritise rule of law principles, particularly as a regulator "hardens" soft law in deciding on a specific facility's performance criteria.
2. **Apply bureaucratic controls in a balanced and transparent manner:** Bureaucratic controls, such as work instructions and procedures, can assist a regulator to ensure regulated entities are in compliance with performance-based requirements. Internal processes must not be so strict or provide so many levels of bureaucracy as to prevent important regulatory actions for safety. Bureaucratic controls used by regulatory staff should be formal and transparent.
3. **Consistently consider procedural fairness:** While performance-based regulating offers desirable flexibility, outcomes should not be subjective. The legitimate expectations of a licensee may be one such procedural consideration, as is the need for adequate reasons for decisions so that licensees understand what went wrong in their performance.
4. **Assess unique needs for inspector training:** Not every task of an inspector can be summarised in a checklist, nor is that desirable, and inspectors may be relied on to exercise more judgement in a performance-based regime as compared to a prescriptive one. Inspection activities may be more "two-way", but inspectors should be trained that the exercise is not collaborative with the operator (as distinct from co-operative), nor is it negotiated.
5. **Place a sufficient evidentiary burden on operators:** Particular attention must be paid to evidence of success or failure of current approaches undertaken by operators. How risk informs regulatory decision making can be captured in bureaucratic controls, and it may be wise for regulators to avoid being so conservative that the benefits of the performance-based approach cannot be realised.
6. **Consider the required level of expertise of regulatory staff:** In a performance-based regime, compliance verification and enforcement activities focus on the assessment of performance criteria. It may be more likely that a regulator's staff will have to employ in-depth nuclear skills and more advanced nuclear knowledge on more occasions when regulating under a performance-based model than if regulating the same number of facilities

under a prescriptive regime. A regulator using the performance-based approach may need a greater number of staff with education higher on the "nuclearisation" spectrum.

7. **Continually pursue strong safety culture:** More mature safety cultures are better suited to operate in the performance-based environment, and may even be required for the effective deployment of a performance-based nuclear regime. It may be desirable to develop enforceable safety culture requirements for operators. Likewise, using a performance-based model necessitates a strong safety culture within the regulator, and explicit acknowledgement of limits in knowledge is important.

There is room for continued legal work on how the deployment of a performance-based regime requires change to enforcement approaches, as compared to a prescriptive approach. It may also be true that the international nuclear law community can revisit the common understanding of the approach to provide more perspective to states that are pursuing the performance-based model. Likewise, a similar "key considerations" exercise could be undertaken from the operator's compliance perspective. The approach has been effective in regulating nuclear power plants in Canada, but it may not be the case that performance-based regulating would work effectively in every nuclear state. Nevertheless, embarking countries and those states regulating prescriptively with a desire to move to a more performance-based approach might inform their decision making with the Canadian example.

Technology-neutral licensing of advanced reactors: Evaluating the past and present NRC framework

*by Maxine Segarnick and Sachin Desai**

I. Summary

Advanced reactors[1] have promise as the future of United States nuclear energy infrastructure. However, licensing these reactors presents many new questions for the nuclear community, particularly around developing a "technology-neutral" framework capable of handling a staggering amount of diversity in technologies and operating models. Congress's enactment of the Nuclear Energy Innovation and Modernization Act (NEIMA) in early 2019 enables the United States Nuclear Regulatory Commission (NRC) to devote substantial resources to developing such a framework. Congress draws a distinction between the existing licensing framework that is focused on light water reactors (LWRs) and the technology-neutral framework that it directs the NRC to establish.

However, to aid in the eventual development of a "technology-neutral" reactor licensing framework, it is important to conceptually understand the history and context of the current licensing framework for commercial nuclear power plants (NPPs). To that end, this study analyses whether the existing licensing framework was ever intended to be fully applicable to advanced reactors.

The study reveals that, while the existing framework did not ignore advanced reactors and is capable of accomplishing the review and licensing of such reactors, the current NRC regulatory framework ultimately was designed primarily for licensing traditional LWRs. This conclusion is reached through a review of regulatory history documents and policy statements of the time and illustrates how the existing framework was not specifically intended to provide a technology-neutral framework. Thus, significant gains may be possible by learning from past experience when exploring a new licensing framework that more substantially addresses technology-neutral licensing concepts.

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1. This study adopts the definition of advanced reactors in Section 3 of the Nuclear Energy Innovation and Modernization Act (NEIMA), Pub. L. 115-439, 132 Stat. 5565 (14 Jan. 2019). NEIMA broadly defines advanced reactors to include reactors "with significant improvements compared to commercial nuclear reactors under construction as of the date of enactment of this Act", including with regard to safety, cost, waste, proliferation and other factors. This definition covers next-generation LWRs as well as fusion systems. Other definitions of advanced reactors include the definition of "Generation IV" reactors, which the Generation IV International Forum (GIF) describes as designs that will "use fuel more efficiently, reduce waste production, be economically competitive, and meet stringent standards of safety and proliferation resistance." GIF, "Generation IV Systems", www.gen-4.org/gif/jcms/c_59461/generation-iv-systems (accessed 25 Nov. 2019).

II. Differences in licensing advanced reactors versus LWRs

Advanced reactors may revolutionise the supply of energy generation in the United States and potentially the world – but, to realise this potential, the NPP licensing framework must address the fundamental technical differences between the operating fleet of large LWRs and advanced reactor designs.

The current commercial nuclear power plant infrastructure in the United States is made up entirely of large LWRs, named as such because they use "light water" (i.e. water that is primarily comprised of protium hydrogen) as the moderator and working fluid. There are two main types of LWRs: pressurised water reactors (PWRs) and boiling water reactors (BWRs). The operating fleet of LWRs in the United States consists of 96 licensed reactors (64 PWRs and 32 BWRs) ranging in thermal output from about 1 600 to 4 500 megawatts thermal (MWt) (thus the inclusion of "large" in the name "large light water reactors").[2]

In contrast to large LWRs that comprise the current US reactor fleet, advanced reactor technologies hold promise to be smaller, simpler and even safer. Advanced reactors are considered safer in large part because of their passive or inherent safety features, which rely on gravity, convection or heat capacity rather than active operational controls in the event of an accident or malfunction. Some of the main differences between large LWRs and advanced reactors are recognised in the NRC's policy statement on advanced reactors, which states that attributes of advanced designs should include:

- "Highly reliable and less complex shutdown and decay heat removal systems", including "inherent or passive" systems;
- "Longer time constants and sufficient instrumentation to allow for more diagnosis and management before reaching safety systems challenge and/or exposure of vital equipment to adverse conditions"; and
- "Simplified safety systems that, where possible, reduce required operator actions".[3]

The result, however, is that advanced reactors present many fundamentally new design features compared to the current LWR fleet, which further present questions of first impression as to safety and licensing. For example, some advanced reactor designs employ and rely on passive safety features like natural circulation and convection, as opposed to actively-managed emergency-core cooling systems that LWRs currently use.[4] Certain passive safety features are also being proposed that would allow reactors to operate at atmospheric pressure, and could reduce or

2. NRC (updated 26 Sept. 2019), "Power Reactors", www.nrc.gov/reactors/power.html (accessed 25 November 2019); NRC (2019), *Information Digest, 2019-2020*, NUREG-1350, Vol. 31, NRC, Washington, DC, Appendix A, "Commercial Nuclear Power Reactors Operating Reactors", Agencywide Documents Access and Management System (ADAMS) Accession No. ML19242D336. Documents referenced in this article with an "ADAMS" number can be retrieved by a search on NRC's Agencywide Documents Access and Management System website at: www.nrc.gov/reading-rm/adams.html#web-based-adams.
3. Policy Statement on the Regulation of Advanced Reactors, 73 Federal Register (Fed. Reg.) 60612 (14 Oct. 2008).
4. See e.g. *Advances in Small Modular Reactor Technology Developments* (Supplement to International Atomic Energy Agency Advanced Reactors Information System) (2016 ed.), IAEA, Vienna, pp. 124, 327, available at: https://aris.iaea.org/Publications/SMR-Book_2016.pdf (describing the convection-based cooling systems of the NuScale Power Module, and a cooling system for the Terrestrial Energy Integral Molten Salt Reactor that relies on heat capacity, thermal radiation and air cooling).

eliminate the need for substantial offsite emergency planning. While such designs may eliminate the risk of a Fukushima-type accident if active cooling systems fail,[5] they represent significant departures from past practice.

Further, as opposed to traditional large-scale plants, advanced reactors may be designed to be "modular", averaging around 50-100 megawatts electrical (MWe) per reactor, meaning that the reactors may be built at factories and shipped to operating sites. This potentially significant opportunity for cost-savings also presents new questions as to licensing of reactors manufactured off-site, which are then transported and installed as complete units where they will be operated. For example, when does NRC direct oversight over construction of nuclear power plants begin for plants built in decentralised construction facilities and later assembled at a plant "site"?

Finally, many advanced reactor designs will use new types of nuclear fuel – including liquid, gaseous and solid fuels. Molten salt reactors, for example, use a liquid fuel that can harden into a solid in case of a reactor coolant failure, thereby trapping the nuclear materials.[6] Some advanced reactor designs also plan to use "fast" neutrons to burn the un-enriched or so-called "depleted" uranium in a fuel rod. This approach reduces the amount of leftover fuel that could become a proliferation or waste concern,[7] but at the same time raises new questions about licensing a type of reactor with different reactor physics and fuel management strategies.[8]

Diversity is also an important characteristic of the advanced reactor movement. Never before have so many fundamentally different ways been proposed to design, build and operate a nuclear power reactor. There are dozens of companies[9] participating in the emerging field of advanced reactors in the United States alone, with many more participating around the world. Regulators need to be prepared to efficiently licence a variety of designs that differ in basic characteristics, such as the fuel, working fluid, reactor shape and neutron spectrum.

Such diversity is likely to push the current regulatory framework in ways that have not been explored in the past. In response to this concern, on 14 January 2019, Congress passed the Nuclear Energy Innovation and Modernization Act (NEIMA), which, in part, requires the NRC to establish by the end of 2027 a technology-inclusive regulatory framework for advanced reactors that accommodates greater technological innovation. While the idea of promulgating risk-informed, technology-neutral, performance-based regulations for reactor licensing has been discussed for over a

5. Martin, R. (Sept. 2015), "Meltdown-Proof Nuclear Reactors Get a Safety Check in Europe", *MIT Technology Review*, Massachusetts Institute of Technology, Boston, p. 4.
6. See e.g. Terrestrial Energy website, www.terrestrialenergy.com (accessed 25 Nov. 2019).
7. See e.g. TerraPower (29 Oct. 2015), "A Solution to the Nuclear Waste Problem", https://terrapower.com/updates/a-solution-to-the-nuclear-waste-problem (accessed 25 Nov. 2019).
8. World Nuclear Association (Sept. 2019), "Fast Neutron Reactors", www.world-nuclear.org/information-library/current-and-future-generation/fast-neutron-reactors.aspx ("Due to the high radiation levels in the core, using simply a core and no blanket gives rise to some new challenges in how the fuel is fabricated and managed.") (accessed 25 Nov. 2019).
9. Allen T., R. Fitzpatrick, and J. Milko (12 Dec. 2016), "The Advanced Nuclear Industry: 2016 Update", Third Way, https://thirdway.imgix.net/downloads/the-advanced-nuclear-industry-2016-update/the-advanced-nuclear-industry-2016-update_032717.pdf (accessed 25 Nov. 2019).

decade,[10] NEIMA presents a new opportunity due to its rulemaking mandate to the agency and accompanying authorisation for funding to be appropriated for the fiscal years 2020 through 2024.[11]

To more fully understand how the current framework would respond to a wave of advanced reactor licence applications, particularly before making modifications to the framework that may be called for under NEIMA, it is important to first understand the historical context of the development of the current reactor licensing framework. Only by knowing where we have come from can we more fully understand how to move forward.

III. NRC licensing: Past and present

A. Where we have come from: A focus on LWRs in licensing

The structure of reactor licensing in the United States has evolved over time from a two-step framework (i.e. the licensing approach in Part 50 of the *Code of Federal Regulations* [10 CFR], as originally promulgated) to an approval process that has encouraged design standardisation and favoured a more predictable "one-step" licensing process. These themes are seen in the development of the general design criteria in 10 CFR Part 50 Appendix A in the 1970s (which focus on LWRs) and more recently in the creation of the 10 CFR Part 52 licensing process.[12]

The applicability of these frameworks to licensing advanced reactors is threaded throughout the underlying regulatory history and policy. However, reviewing the history closely, it becomes apparent that, while passively safe and non-LWR reactor concepts were on the minds of regulators since the dawn of the nuclear era, the regulatory framework was not intended to directly address the design features that embody the advanced reactor designs being introduced today. This article will dive into the underlying history to parse out the intentions for licensing advanced reactors under Parts 50 and 52 to shed light on how the NRC arrived at what may ultimately become "Part 53."

1. The early NRC regulatory framework increasingly focused on LWR licensing

The NRC's original two-step licensing process in 10 CFR Part 50 was applied to all designs put before the Atomic Energy Commission (AEC), the NRC's predecessor agency in licensing the first reactors in the 1950s and 1960s. Some of the first nuclear power plants that the NRC licensed included a 50 MWt BWR licensed in 1957 (General Electric's VBWR, "Vallecitos", shut down in 1963), a 23.5 MWt PWR licensed in 1961

10. See e.g. Memorandum for the Commissioners from L. Reyes, Executive Director for Operations (EDO), NRC (9 Jan. 2006), "Staff Plan To Make a Risk-Informed and Performance-based Revision to 10 CFR Part 50", SECY-06-007 (ADAMS Accession No. ML053420151) ("The staff proposes to achieve the Commission's direction to make a risk-informed and performance-based revision to 10 CFR Part 50 by creating a completely new risk-informed and performance-based Part 50 (to be called Part 53) that is applicable to all reactor technologies. The development of this new Part 53 will integrate safety, security, and preparedness."). Subsequently, the Commission approved NRC staff's recommendation to defer a rulemaking to make 10 CFR Part 50 risk-informed and performance-based. Memorandum to L. Reyes, EDO, from A. Vietti-Cook, Secretary (14 June 2007), "Staff Requirements – SECY-07-0101 Staff Recommendations Regarding a Risk-Informed and Performance-Based Revision to 10 CFR Part 50 (RIN 3150-AH81)" (ADAMS Accession No. ML070790236).
11. NEIMA, sec. 103(a)(6) ("There is authorized to be appropriated to the Commission to carry out this subsection $14,420,000 for each of fiscal years 2020 through 2024.").
12. An in-depth explanation of the structure of licensing under Parts 50 and 52 can be found in Burns, S. (2017), "Reformed and Reforming: Adapting the Licensing Process to Meet New Challenges", *Nuclear Law Bulletin,* No. 99, OECD, Paris, pp. 9-18.

("Saxton", shut down in 1972), and a 600 MWt PWR licensed in 1963 ("Yankee Rowe", shut down in 1992); but also several non-LWR designs, such as a 200 MWt sodium-cooled fast reactor licensed in 1963 ("Fermi 1", shut down in 1972),[13] and a 330-MWe high-temperature gas-cooled reactor (HTGR) that utilised a uranium-thorium fuel cycle ("Fort Saint Vrain", licensed in 1979 and shut down in 1989).[14] However, the vast majority of reactors built during this period were LWRs,[15] with the result being that the licensing standards, and their application within the broader licensing framework, naturally followed suit.

The reasons for the shift towards LWRs in the United States are well-known. One key factor was the military's use of LWRs in naval ships and submarines, and the natural diffusion of this technology into the commercial power sector. The first civilian nuclear reactor ever built was assembled in Shippingport, Pennsylvania, from a military LWR that was converted with help from none other than Admiral Hyman G. Rickover's team (Admiral Rickover was the founder of the US nuclear navy).[16] A second driver was the US government's early push to scale up the nuclear industry at a rapid pace, which cemented around the already-successful LWRs. As stated in a Brookings Institution publication: "[T]he Atomic Energy Commission endorsed a cookie-cutter-like approach to building additional reactors that was very enticing to energy companies seeking to enter the atomic arena. Having a standardised light water reactor design meant quicker regulatory approval, economies of scale, and operating uniformity, which helped control costs and minimise uncertainty."[17]

2. *Licensing reform focused on licensing standards for LWRs over development of a technology-neutral regulatory framework*

In the 1970s, discussion emerged regarding a new generation of reactor designs, which appeared to share similar attributes to modern-day advanced reactors – including a focus on improved safety systems. In 1974, Congress established the NRC from the former AEC,[18] and in doing so, guided the NRC's policy with respect to regulation of advanced reactors. As the NRC explained in its 1985 proposed policy on advanced reactors, Congress instructed the NRC under the amended Section 205 of the Energy Reorganization Act, to provide a "long-term plan for projects for the development of new or improved safety systems for nuclear power plants."[19] The proposed policy listed the NRC's past experience in the regulation of advanced reactors in the 1970s,

13. *NRC Information Digest 2019-2020*, *supra* note 2, Appendix C, "Commercial Nuclear Power Reactors Undergoing Decommissioning and Permanently Shut Down Formerly Licensed to Operate", pp. 116-119.
14. NRC, Office of Nuclear Regulatory Research (Jan. 2004), *Fort Saint Vrain Gas Cooled Reactor Operational Experience*, NUREG/CR-6839, p. 3.
15. In the two decades of the 1960s and the 1970s, apart from licensing of a few non-LWRs such as Fermi 1 and Fort Saint Vrain, over fifty LWRs started commercial operation. See US Energy Information Administration (Feb. 2016), *Nuclear and Uranium*, "Spent Nuclear Fuel", Table 2, "Nuclear power plant data as of June 30, 2013", www.eia.gov/nuclear/spent_fuel/ussnftab2.php (accessed 25 Nov. 2019).
16. Shik Jr., W.L. (2009), "Atoms for Peace in Pennsylvania", *Pennsylvania Heritage Magazine*, Pennsylvania Heritage Foundation, Harrisburg, PA, Vol. 35, No. 2, available at: www.phmc.state.pa.us/portal/communities/pa-heritage/atoms-for-peace-pennsylvania.html (accessed 25 Nov. 2019).
17. Freed, J. (12 Dec. 2014), "Back to the Future: Advanced Nuclear Energy and the Battle Against Climate Change", Brookings Institution, Washington, DC, http://csweb.brookings.edu/content/research/essays/2014/backtothefuture.html (accessed 25 Nov. 2019).
18. Energy Reorganization Act of 1974, Pub. L. 93-438, 88 Stat. 1233 (11 Oct. 1974), codified at 42 United States Code (USC) 5801 *et seq*.
19. 42 USC 5845(f), as amended by Pub. L. 95-209, sec. 4(a), 91 Stat. 1481, 1482 (13 Dec. 1977); see Proposed Policy for the Regulation of Advanced Nuclear Power Plants, 50 Fed. Reg. 11882 (26 Mar. 1985).

including the NRC's review of HTGRs, liquid metal fast breeder reactors (LMFBRs) and a conceptual design for a gas-cooled breeder reactor.[20]

To this end, in 1986 the NRC adopted its final policy statement on the review of, and desired characteristics associated with, advanced rectors.[21] In this statement, the Commission appeared to agree that changes needed to be made to the 10 CFR Part 50 framework to accommodate the potential new licensing wave of non-LWR reactor designs. In its policy statement, for example, the NRC explained that "the Commission intends to develop the capability for timely assessment and response to innovative and advanced designs that might be presented for NRC review."[22] The NRC also stated that new reactor designs "may involve technical problems that must be solved in order to assure adequate protection of the public health and safety", and that it would create a group to "coordinate the development of regulatory criteria and guidance for proposed advanced reactors."[23]

However, this recognition of a need for a technology-neutral framework for advanced reactors did not necessarily lead to a regulatory framework that focused on technology-neutral licensing. Instead, based on industry input, in 1987 the NRC issued a policy statement on the standardisation of reactor designs, which was a precursor to the 1989 promulgation of the combined licensing and design certification approach in Part 52.[24] This shift evidenced that one-of-a-kind licensing was perceived negatively: "Experience has shown that 'one-of-a-kind' approach to reactor design has led to an operating reactor population of great variability and diversity, even among reactors from the same vendor."[25] After remarking on the challenges this variability created, the Commission explained that "standardization of nuclear power plant designs can significantly enhance the safety, reliability and availability of nuclear plants."[26] This policy statement did touch on advanced reactors, noting that the desirable safety characteristics listed in the 1986 Advanced Reactor Policy Statement "are equally as desirable for evolutionary light water reactor standardized designs". However, the NRC's focus was ultimately placed on standardisation of LWRs, reflecting the apparent industry focus on LWRs and the fact that advanced reactor development was still in a nascent stage.[27]

This signals that the NRC drew ideas from advanced reactor safety characteristics (such as those found in HTGRs and LMFBRs.), but drew a distinction between those designs and the "evolutionary light water reactors" that were the apparent primary

20. Proposed Policy for the Regulation of Advanced Nuclear Power Plants, *supra* note 19, p. 11883.
21. Regulation of Advanced Nuclear Power Plants; Statement of Policy, 51 Fed. Reg. 24643 (8 July 1986).
22. *Ibid*., p. 24645.
23. Nuclear Power Plant Standardization, Policy Statement, 52 Fed. Reg. 34884 (15 Sept. 1987).
24. *Ibid*., p. 34884. As background, under the Part 52 process, reactor designers could apply for a design certification that other applicants could later use in their own licensing applications to construct and operate a plant, thus encouraging greater standardisation of reactor designs, and applicants could then also apply for a combined construction and operation licence rather than apply for these in stages. NRC, "Backgrounder on Nuclear Power Plant Licensing Process, Combined License (10 CFR Part 52)", www.nrc.gov/reading-rm/doc-collections/fact-sheets/licensing-process-fs.html#license (accessed 25 Nov. 2019).
25. Nuclear Power Plant Standardization, *supra* note 23, p. 34884.
26. *Ibid*.
27. NRC explained "evolutionary light-water designs" to mean "improved versions of the light-water designs now in operation", and "advanced designs" to mean "designs which differ significantly from the evolutionary light-water designs, or which incorporate, to a greater extent than evolutionary light-water designs do, simplified, inherent, passive, or other innovative means to accomplish their safety functions." Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Reactors, Final Rule, 10 CFR Part 52, 54 Fed. Reg. 15372, 15374 (18 Apr. 1989) (hereinafter Part 52 Final Rule).

focus of the design standardisation effort. The 1987 standardisation policy statement underscores its focus on LWRs by stating that "the reference system designs, at least initially, are expected to be evolutions of existing proven LWR designs …" and "[w]hen an advanced design concept is sufficiently mature, … an application for design certification could be made."[28]

There is further evidence of the acknowledgement – yet lack of direct consideration – of advanced reactor designs in the development of the 10 CFR Part 52 licensing framework in 1988 and 1989, which superseded the 1987 Policy Statement on Nuclear Power Plant Standardization.[29] The 1988 proposed rule for Part 52 responded to the public comments on this 1987 standardisation policy statement, including by providing for certification of advanced designs in the proposed rule. The 1988 proposed rule noted that: "[t]he NRC staff is currently developing safety criteria for application in the review of advanced reactor designs. These criteria will define minimum safety requirements for advanced reactors and will provide for assessment and documentation of the enhanced safety the Commission expects these reactor designs to embody."[30]

In contrast, the 1989 final rule provided for certification of advanced designs, but permitted certification of designs of less than full scope and only in highly restricted circumstances.[31] The NRC instead highlighted its focus on LWR designs: "The Commission's legislative proposals on standardization have always focused on [evolutionary LWR] designs, on the grounds that the light-water designs now in operation provide a high degree of protection to public health and safety."[32] The Commission made this point in the context of describing why prototype testing of advanced designs is required for certification or unconditional final advanced design approval.[33]

The Commission noted that "standardization along these lines may indeed limit some market forces, particularly those which encourage a *highly differentiated range of products*."[34] Later, it added, "there are also uncertainties concerning the costs of the certification process, and the costs of developing the designs themselves, especially the advanced designs, which may require testing of prototypes."[35] Thus, while advanced design applicants could use 10 CFR Part 52 to certify an advanced reactor design, the NRC acknowledged that the design standardisation approach and associated prototype testing might not be economically feasible for advanced reactor designs.[36]

In sum, while the past rulemaking efforts for NPP licensing considered advanced reactors, and the current framework is capable of licensing such reactors, the

28. Nuclear Power Plant Standardization, *supra* note 23, 52 Fed. Reg. at 34885.
29. Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Reactors, Proposed Rule, 10 CFR Part 52, 53 Fed. Reg. 32060, 32061 (23 Aug. 1988).
30. *Ibid*., p. 32063.
31. Part 52 Final Rule, *supra* note 27, 54 Fed. Reg. at 15374.
32. *Ibid*. Note that the final rule draws a distinction between "evolutionary light-water reactors" and "advanced reactors", explaining, "evolutionary light-water designs, that is, improved versions of the light-water designs now in operation, and of 'advanced' designs, that is, designs which differ significantly from the evolutionary light-water designs, or which incorporate, to a greater extent than evolutionary light-water designs do, simplified, inherent, passive, or other innovative means to accomplish their safety functions." *Ibid*.
33. *Ibid*.
34. *Ibid*., p. 15375 (emphasis added).
35. *Ibid*., p. 15385.
36. NRC's licensing regulations contain provisions for additional testing or analysis of "nuclear reactor designs which differ *significantly*" from light-water reactor designs, including provisions for use of a prototype plant for testing, thus demonstrating the NRC's consideration of, but not necessarily additional flexibility for, the licensing of advanced nuclear reactors. See 10 CFR 50.43(e) (emphasis added); see also 10 CFR 52.47(c)(2).

designers of the framework did not specifically aim to create a technology-neutral model that embraced a diversity of advanced reactor designs. The 10 CFR Part 50 standards – i.e. the technical acceptance criteria – crystalised around LWRs, and, albeit after a brief period when advanced reactor licensing was considered at a high-level, the development of 10 CFR Part 52 instead focused on standardisation with the overall goal of streamlining licensing of evolutionary LWRs. While standardisation would assist certain aspects of the review of advanced reactor designs, an explicit focus on the unique needs of advanced reactors, and particularly for a technology-neutral framework, was not at the fore.

B. Where we are now: Working within the existing framework

Today, advanced reactor licensing has returned to the fore, and the NRC has undertaken numerous efforts to prepare for advanced reactor licensing. Given the current LWR-focused regulatory framework, proposals have largely considered "licensing through exemption"[37] approaches and piece-by-piece efforts to develop licensing options for advanced reactors within the existing regulatory framework.[38] But NEIMA requires the NRC to go further and "complete a rulemaking to establish a technology-inclusive, regulatory framework for optional use by commercial advanced nuclear reactor applicants for new reactor license applications" by 31 December 2027.[39] In addition, NEIMA requires, among other things, the NRC to "develop and implement, *within the existing regulatory framework*, strategies for … establishing stages in the licensing process for commercial advanced nuclear reactors",[40] and "strategies for the increased use of risk-informed, performance-based licensing evaluation techniques and guidance for commercial advanced nuclear reactors *within the existing regulatory framework*."[41] The NRC's efforts to carry out the provisions of NEIMA within the existing regulatory framework and through rulemaking are articulated in the NRC's July 2019 report to Congress.[42] Some of these efforts are highlighted below.

Much of the NRC's advanced reactor work is outlined in the key guidance document, *NRC Vision and Strategy: Safely Achieving Effective and Efficient Non-Light Water Reactor Mission Readiness* (Vision and Strategy Statement).[43] In addition, the Non-LWR Vision and Strategy and Implementation Action Plans set forth two phases for advanced reactor licensing preparedness: first, conceptual planning, which the NRC completed in December 2016, and second, detailed work planning efforts and task execution, which are ongoing.[44] As part of these steps, in December 2017, the NRC published its "Regulatory Review Roadmap for Non-Light Water Reactors" (Regulatory

37. See Memorandum for the Commissioners from V. McCree, EDO (23 May 2018), "Achieving Modern Risk-Informed Regulation", SECY-18-0060, Enclosure 5, "Additional Detail on Areas of Transformation", p. 11 (ADAMS Accession No. ML18110A186) (discussing how a technology neutral framework could, "by allowing for greater regulatory flexibility, reduce or eliminate the need for exemptions from regulations under Parts 10 CFR 50 or 10 CFR 52").
38. See Memorandum for the Commissioners from V. McCree, EDO (31 Oct. 2018), "Proposed Rule: Emergency Preparedness for Small Modular Reactors and Other New Technologies", SECY-18-0103 (ADAMS Accession No. ML18134A086).
39. NEIMA, Pub. L. 115-439, sec. 103(a)(4).
40. *Ibid*., sec. 103(a)(1) (emphasis added).
41. *Ibid*., sec. 103(a)(2) (emphasis added).
42. Letter to the Honorable J. Barrasso from NRC Chairman K. Svinicki (12 July 2019) (ADAMS Accession No. ML19128A289).
43. NRC (Dec. 2016), *NRC Vision and Strategy: Safely Achieving Effective and Efficient Non-Light Water Reactor Mission Readiness* (ADAMS Accession No. ML16356A670).
44. NRC (July 2017), "Non-LWR Near-Term Implementation Action Plans" (ADAMS Accession No. ML17165A069); NRC (July 2017), "Non-LWR Mid-Term and Long-Term Implementation Action Plans" (ADAMS Accession No. ML17164A173).

Review Roadmap).[45] This work is consistent with NEIMA's requirement to evaluate options for licensing commercial advanced nuclear reactors under the current regulatory framework, while considering the use of new tools such as licensing project plans.[46]

The Regulatory Review Roadmap provides advanced reactor designers with an overview of the various pathways for the NRC's review of new advanced reactor designs, in order to help the designer select the best option for the design. This document is part of the NRC's "near-term implementation action plan", the development and execution of which constitute Phase 2 of the NRC's vision and strategy for achieving non-LWR readiness. Progress on the implementation of these plans is reported to the Commission annually. For example, in 2019, the NRC staff issued a status update to the Commission on the NRC staff's activities related to advanced reactors, including the progress and path forward on each of the implementation action plan strategies.[47]

In addition, the NRC engaged with industry in the development of the Licensing Modernization Project (LMP), which serves to "develop technology-inclusive, risk-informed, and performance based regulatory guidance for licensing non-LWRs for the NRC's consideration and possible endorsement."[48] The NRC has stated that it plans to issue this guidance in final form in late 2019.[49] Also, in September 2019, the NRC staff completed a draft document called the "Non-Light-Water Reactor Review Strategy – Staff White Paper".[50] This draft white paper would serve to "support the reviews of applications for non-LWR designs submitted prior to the development of the technology-inclusive, risk-informed, and performance-based regulatory framework in 2027" required by NEIMA.[51]

While these existing advanced reactor licensing preparedness efforts are undoubtedly helpful, the NRC's advanced reactor regulatory reform efforts are bounded by existing regulations and require the use of exemptions from existing requirements to address licensing of specific advanced reactor designs. And as described in the previous sections, while the existing framework is usable by advanced reactors, it is not specifically tailored to the diversity of the technical characteristics of advanced reactors.

V. Conclusion

The diversity of advanced reactors calls for a truly technology-neutral framework. The questions regarding efficiency of licensing of advanced reactors within the current NRC framework do not reflect any failure of the current NRC regulatory regime or its implementation, but instead, once the appropriate historical context within which the framework was developed is understood, reflect that the current regime prioritises LWR licensing.

45. NRC, Office of New Reactors (Dec. 2017), "A Regulatory Review Roadmap for Non-Light Water Reactors" (ADAMS Accession No. ML17312B567).
46. NEIMA, sec. 103(a).
47. Memorandum for the Commissioners from F. Brown, Director, Office of New Reactors (4 Feb. 2019), "Advanced Reactor Program Status", SECY-19-0009 (ADAMS Accession No. ML18346A075).
48. NRC, "Advanced Reactors (Non-LWR designs)" (updated 31 Oct. 2019), www.nrc.gov/reactors/new-reactors/advanced.html (accessed 25 Nov. 2019).
49. *Ibid*.
50. Memorandum from S. Lynch, Acting Chief, Advanced Reactor Licensing Branch, Division of Advanced Reactors, Office of New Reactors, to J. Monninger, Director, Division of Advanced Reactors, Office of New Reactors (30 Sept. 2019) (ADAMS Accession No. ML19275E992).
51. *Ibid*.

With Congress's enactment of NEIMA, the NRC is no longer constrained from devoting substantial resources to the development of new or revised regulatory approaches. NEIMA recognises that a key aspect of any framework must be that it is technology-neutral and adaptive to new questions that will arise as part of the licensing process. The authors hope that this article helps to provide historical context for the development of the current NRC licensing framework, to aid in the understanding and development of a technology-neutral licensing framework in the future.

Case law

Japan

Update on lawsuits related to the government responsibility following the Fukushima Daiichi nuclear power plant accident

As previously reported,[1] various lawsuits related to the Fukushima Daiichi nuclear power plant (NPP) accident (hereinafter referred to as "the Fukushima accident") have been filed in Japan. The plaintiffs in these lawsuits sometimes claim that the government has responsibility for failing to exercise regulatory authority over Tokyo Electric Power Company (TEPCO), in addition to the liability of TEPCO itself. As of August 2019, decisions regarding whether the government was liable in the Fukushima accident have been rendered in nine cases. In six of these cases, the courts found that TEPCO and the government were liable and ordered both to pay damages. Conversely, in three decisions, the courts found that TEPCO was liable, but not the government.

In analysing the cases, the courts identified the cause of the Fukushima accident as a station blackout, which was caused by the tsunami, not the earthquake. On that basis, the courts determined government responsibility by analysing the following three questions (though there are slight differences among individual decisions):

1. whether tsunami measures were within the government's regulatory authority;
2. whether the tsunami was foreseeable; and
3. whether the duty to prevent the consequences of the tsunami was breached, which is determined based on whether the accident could have been prevented if the regulatory authority had been exercised, and whether there were any other means of preventing the accident other than by exercising the regulatory authority.

On these issues, all of the court decisions found in the affirmative on the first two questions. That is, the courts stated that the government had the regulatory authority and that the accident was foreseeable (although the decisions varied slightly on their findings regarding the laws that formed the basis for the regulatory authority and regarding the time at which the accident became foreseeable). For this reason, these decisions are considered to be establishing court practice. Accordingly, the finding of government responsibility for failing to exercise the regulatory authority comes down to the third question.

The latest decision rendered in the state redress claim litigation relating to the Fukushima accident is the Nagoya District Court decision.

Nagoya District Court decision (2 August 2019)

The plaintiffs, who claim to have been forced to evacuate and to have suffered mental anguish due to the Fukushima accident, filed a lawsuit seeking a total of JPY 1.44 billion in damages against the government and TEPCO. The court allowed part of the claim

1. NEA (2018), "District court decisions on lawsuits related to state liability following the Fukushima Daiichi nuclear power plant accident", *Nuclear Law Bulletin*, No. 100, OECD, Paris, pp. 87-89.

against TEPCO but denied the government responsibility. The plaintiffs and TEPCO both appealed.

In determining whether the government was responsible, the court analysed the three questions discussed above: whether the government had the regulatory authority; whether the tsunami was foreseeable; and whether the accident could have been prevented if the regulatory authority had been exercised.

- (1) Whether the government had the regulatory authority

The court found that the government had the regulatory authority as claimed by the plaintiffs. That is, the government had the authority to order TEPCO to enact protective measures, such as installing double doors at the entrances and exits of the turbine building, and installing a waterproof housing to protect the seawater pumps installed to cool the emergency diesel generator in the event of a tsunami.

- (2) Whether the tsunami was foreseeable

First, the earthquake prediction published by a government agency in 2002 was not at a level at which a consensus among expert researchers could be reached; however, it at least had a scientific foundation and had a certain degree of reliability. Considering the serious damage that can result from a severe accident at an NPP, requiring knowledge at a level wherein a consensus on foreseeability can be reached might mean ignoring serious risks to citizens' lives and health. Accordingly, the government needed to take the government agency's earthquake prediction into consideration when adopting protective measures against tsunamis at the Fukushima Daiichi NPP.

Second, the government and TEPCO were aware of research in 2006 by a study group comprised of regulatory agencies, TEPCO, and other nuclear operators, among other organisations, which identified the possibility of a station blackout in the event of a tsunami that exceeded the seawalls at the site. Accordingly, at this point, at the very latest, the government had the duty to have TEPCO calculate the potential impact of an expected tsunami, on the basis of the earthquake prediction made by the government agency. Given the science of tsunami assessment as of 2006, it was possible for the government to foresee that a tsunami exceeding the seawalls at the site could occur.

As a general matter, however, foreseeability does not immediately give rise to a duty to prevent the consequence, and the required level of this duty differs based on the degree of foreseeability. In this circumstance, the earthquake prediction by the government agency cannot be considered knowledge that is well enough established as a consensus held by experts, given the limited amount of past earthquake data on which it was based and the insufficiency of its scientific foundation. Moreover, even the government agency that published the prediction itself had described the reliability of the assessment of the areas where earthquakes could occur and the probability of occurrence as "rather low". Therefore, the level of foreseeability was not high.

- (3) Whether the accident could have been prevented if the regulatory authority had been exercised

Because it was foreseeable from the studies in 2006 that a tsunami could exceed the seawalls of the NPP site, the court concluded that TEPCO should have considered measures against this expected tsunami. The plaintiffs asserted that a number of

different measures[2] could have been adopted to protect against a tsunami, but the court found that other measures, such as installing higher seawalls, could also have been adopted to prevent the accident.

Furthermore, even if the measures asserted by the plaintiffs were adopted, construction work was expected to start after at least two to three years, due to various procedures such as applying for permission. In reality, more time may have been needed for public acceptance, design, construction and other matters. In addition, the certainty and accuracy of the earthquake prediction, from which the expected tsunami height was computed, was not very high; therefore, a tsunami exceeding the seawalls of the site was not considered an imminent threat.

Additionally, in 2006, earthquake measures were a more urgent issue. An earthquake safety assessment was underway in response to the September 2006 amendment of the Regulatory Guide for Reviewing Seismic Design of Nuclear Power Reactor Facilities, and earthquake measures became the focus of the government and TEPCO's resources. Thus, tsunami measures had been assigned a lower priority than earthquake measures. The government and TEPCO have limited financial and human resources, and it is not possible to enact measures to protect against every risk. Therefore, it is not unreasonable to prioritise the enactment of earthquake measures over tsunami measures based on a prediction with insufficient certainty and accuracy.

Taking all of these circumstances into account, even if the regulatory authority had been exercised, implementation of the measures advocated by the plaintiffs is likely to have been incomplete when the Fukushima accident occurred. Therefore, the court found that the station blackout caused by the tsunami exceeding the seawalls at the site could not have been prevented.

- Conclusion

Considering all of the above circumstances, the court did not find that the government acted unreasonably by failing to order the adoption of the protective measures asserted by the plaintiffs. Therefore, the lack of exercise of the regulatory authority cannot be considered to establish liability under the State Redress Act.

United States

Virginia Uranium, Inc. v. Warren, 139 S. Ct. 1894 (17 June 2019), affirming the lower court ruling that the Atomic Energy Act did not preempt a ban on conventional uranium mining on non-federal land

On 17 June 2019, the United States Supreme Court issued a decision in Virginia Uranium v. Warren, which involved a landowner's challenge to the US state of Virginia's ban on conventional uranium mining on private land (an activity that the US Nuclear Regulatory Commission [NRC] does not regulate).[3] The United States submitted a brief asserting that if Virginia Uranium's allegations concerning the motivation for the ban were true (i.e. if the motivation for the ban was a concern for radiological safety of NRC-regulated activities such as milling and tailings management), the ban was "preempted" by the US Atomic Energy Act because it was

2. These were measures to: i) protect the turbine building itself, such as by installing strength-enhancing doors at the entrance and exit; ii) prevent inundation of machinery rooms where important equipment such as emergency diesel generators are installed; and iii) protect the seawater pumps for cooling the existing emergency diesel generators by undertaking measures to waterproof the building in which they were located.
3. For historical information on the case, please see NEA (2018), "Virginia Uranium, Inc. v. Warren, 848 F.3d 590 (4th Cir. 2017)", *Nuclear Law Bulletin*, No. 100, OECD, Paris, pp. 90-92.

an attempt to regulate matters that are within the sole province of the NRC and cannot be regulated by the states.

The Supreme Court rejected this argument by a vote of 6-3 and upheld the ban, holding that it was not appropriate to attempt to ascertain the motivation behind Virginia's ban. The six justices in the majority, however, were not entirely in agreement. A majority of the court agreed that an inquiry into motive was not warranted where, as was the case with Virginia's ban on mining, the state had not imposed any restrictions on activities that the NRC regulates. But the decision did not rule out the possibility that a state's use of its authority that was either intended to interfere, or had the effect of interfering with, matters close to the core of the NRC's authority (such as construction or operation of a nuclear power plant or spent-fuel-storage facility) would still be preempted. As a result, it is likely that state regulation limiting the ability of NRC licensees or NRC licence applicants to take action otherwise permitted by the Atomic Energy Act will be vulnerable to preemption challenges.

NRC Atomic Safety and Licensing Board issues decisions in two consolidated interim storage facility cases

The NRC Atomic Safety and Licensing Board (Board) issued decisions in two cases challenging two different licence applications to build and operate a consolidated interim storage facility (CISF) for spent nuclear fuel and greater-than-Class C waste (collectively, SNF). Both applicants, Holtec International (Holtec) and Interim Storage Partners, LLC (ISP), seek 40-year licences to store canisters of SNF. The applicants seek to undertake these projects as possible temporary solutions for storing SNF from commercial nuclear reactors until a permanent repository is licensed and built. The NRC staff's review of both applications is ongoing.

In the Holtec proceeding, 6 petitioners raised 50 contentions challenging Holtec's application to build a CISF in Lea County, New Mexico. The Board issued its decision in May 2019, denying each petition.[4] Although the Board held that three petitioners demonstrated standing, it determined that none of their proffered contentions (challenges to the licensing) were admissible. Appeals of the Board's ruling by five petitioners, as well as one proposed contention filed after the Board issued its decision, are pending before the NRC Commission.

In the ISP proceeding, 4 petitioners raised 38 contentions challenging ISP's application to build a CISF in Andrews County, Texas. In August 2019, the Board granted the Sierra Club's request for a hearing and petition to intervene and denied the other participants' petitions.[5] The Board ruled that the Sierra Club proffered one admissible contention regarding, in part, the unavailability of ecological studies that ISP relied on in its Environmental Report to describe the project's impacts on two lizard species. Subsequently, ISP provided these studies and requested that the Board dismiss the contention, and Sierra Club filed an amended contention for the Board's consideration. Appeals by the other petitioners and the application are pending before the NRC Commission.

4. Holtec Int'l (HI-Store Consolidated Interim Storage Facility), LBP-19-4, 89 NRC __ (7 May 2019) (slip op. at 135-36) (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19127A026). Documents in ADAMS may be accessed through www.nrc.gov/reading-rm/adams.html.
5. Interim Storage Partners LLC (Consolidated Interim Storage Facility), LBP-19-7, 90 NRC __ (23 Aug. 2019) (slip op. at 106) (ADAMS Accession No. ML19235A165).

National legislative and regulatory activities

Canada

General legislation, regulations and instruments

Impact Assessment Act – Comprehensive changes to the federal environmental assessment process

On 21 June 2019, the Government of Canada adopted the Impact Assessment Act (IAA).[1] The impetus for the changes originated from the government's commitment during the last election campaign to reform federal environmental and regulatory processes to address concerns raised regarding meaningful engagement, inefficiencies, concern for public trust and the need to balance the country's environmental goals with the desire to remain competitive. Following a comprehensive consultation process that included recommendations from an expert review panel, the government tabled its proposed legislation (Bill C-69) on 8 February 2018. Following further reviews by the House of Commons and the Senate, the revised legislation received Royal Assent on 21 June 2019 and it came into force on 28 August 2019.

The focus of the IAA differs significantly from the prior, over 40-year old environmental assessment legislation in Canada. Previously, the focus of the environmental assessment was to determine potential adverse effects and their significance. Before a project in relation to which significant adverse impacts were identified was allowed to proceed, the Governor in Council (GIC) determined whether the "significant adverse environmental effects" could be "justified".

The new approach moves away from focusing on assessing biophysical environmental effects and their significance. The expanded factors,[2] in addition to biophysical environmental effects, include health impacts, purpose and need, economic opportunities, social issues, cultural concerns, Indigenous knowledge and potential impact on the rights of Indigenous peoples. The assessment must also consider how the project contributes to sustainability[3] and the extent to which the effects of the project hinder or contribute to Canada's ability to meet its environmental obligations. Projects must also undergo a gender-based analysis to assess how a project could affect particular groups. The IAA enhances consultation opportunities with Indigenous peoples and recognition of Indigenous rights, interests and knowledge. The IAA also increases consultation and engagement opportunities for Indigenous groups throughout the impact assessment (IA), but notably during the "early planning phase". This approach reflects a shift towards increased Crown-Indigenous consultation earlier in the process, rather than proponent-driven engagement.

1. Statutes of Canada (S.C.) 2019, Chapter (c.) 28.
2. IAA, Section 22 lists more than 20 factors that must be considered as part of an impact assessment of a designated project.
3. IAA, Section 2 defines "sustainability" as "the ability to protect the environment, contribute to the social and economic well-being of the people of Canada and preserve their health in a manner that benefits present and future generations".

Under the new legislation, as was the case in the law it repealed, only designated projects[4] listed in the Physical Activities Regulations[5] (the Project List) or projects specifically designated by the Minister are subject to the IAA. The Project List includes projects determined to have the greatest potential for adverse and complex effects in areas of federal jurisdiction. The Project List includes uranium mines and mills,[6] certain nuclear and storage facilities,[7] and long-term management or disposal facilities[8] of various size, location or characterisation. Nuclear reactors with a combined thermal capacity of more than 900 megawatts thermal (MWt) located within the licensed boundaries of an existing Class IA nuclear facility or reactors with thermal capacity of more than 200 MWt located outside a Class IA nuclear facility boundary are included in the Project List.[9]

The legislation establishes a single federal agency, the Impact Assessment Agency (Agency) to lead or plan all assessments of designated projects. The Agency is responsible to co-ordinate consultations and to ensure opportunities for public participation. It also ensures that the IA is conducted and the IA report is submitted. Under the new legislation, the Canadian Nuclear Safety Commission (CNSC) is no longer the responsible authority for the conduct of impact assessment of designated projects that are regulated under the Nuclear Safety and Control Act (NSCA).[10] Under the former environmental assessment legislation in Canada, the CNSC was the authority responsible for the conduct of the environmental assessment of projects that fell under the NSCA. As explained below, for these projects, the CNSC takes part in the assessment, but is not responsible for decision making on the assessment.

At the initial stage or planning phase, a proponent submits to the Agency an initial description of the intended project. Following a consultation process, the Agency provides the proponent a summary of the issues and comments received. The proponent will then submit a detailed revised project description that will include how it intends to address the issues raised by the Agency. In accordance with section 16 of the IAA, the Agency will then determine whether an assessment is required, taking into account such considerations as the potential adverse effects, as well as comments from the public and Indigenous groups. If an impact assessment of a designated project is required, the Agency has 180 days to provide the proponent with the Notice of the Commencement of the assessment and the information and/or studies that the Agency will require for the impact assessment. Under the new legislation, the Agency determines the scope of the factors to be considered in the impact assessment.

For a project that involves physical activities regulated under the NSCA, the Minister of the Environment must refer the project to a review panel to conduct the impact assessment.[11] Within 45 days after the publication of the Notice of Commencement, the Minister establishes the panel's terms of reference, in consultation with the President of the CNSC. The Agency must appoint within that period the chairperson and at least two other members. At least one panel member, but not the majority of the members of the review panel, is appointed from a roster

4. IAA, Section 2 states that "designated project" means "a physical activity or any physical activity incidental to the physical activity that is carried out in Canada or on federal lands and that is designated by regulations under the Act or designated in an order made by the Minister of the environment".
5. Statutory Orders and Regulations (SOR)/2019-285.
6. *Ibid.*, Sections 20, 21, 22 and 23.
7. *Ibid.*, Section 26.
8. *Ibid.*, Section 28.
9. *Ibid.*, Section 27.
10. S.C. 1997, c.9.
11. IAA, Section 43, "Obligation to refer".

of members of the CNSC.[12] The time limit for the review panel to submit a report must not exceed 600 days, subject to legislated provisions to extend the time limit.

At the end of the IA, the report, together with recommendations on conditions in relation to the adverse effects, is submitted to the GIC for decision. Under the previous assessment regime, the decision whether to approve a project was based on whether there were any significant adverse environmental effects and, if so, whether the effects were justified in the circumstances. Under the new legislation, the decision framework has shifted from whether significant adverse impacts are justified to a determination of whether a project is in the public interest. Section 63 of the IAA stipulates the factors that the GIC must consider to determine whether a project is in the public interest. The determination must consider:

- the extent to which the project contributes to sustainability;
- the extent to which identified adverse effects are significant;
- the implementation of appropriate mitigation measures;
- the impact the project may have on Indigenous groups and on Aboriginal Rights; and
- the extent to which the project hinders or contributes to Canada's environmental obligations and commitments related to climate change.

Should the GIC determine that the project is in the public interest, the Minister of the Environment will issue a decision statement that will include any conditions with which the proponent must comply, including any conditions that the Minister designates as part of the licence issued under section 24 of the NSCA.

Subsection 51(2) of the IAA stipulates that the review panel's report must also include "the information necessary for the licence to be issued" under section 24 of the NSCA in relation to the project that is the subject of the report. This reflects the intention to integrate the assessment process, to the extent possible, with the regulatory process for licensing that will follow a successful assessment. It is important to note that this does not empower the process under the IAA to substitute for the licensing process and decision making under the NSCA, which is conducted by the nuclear regulatory body, the CNSC. As with previous assessment processes, the licensing process for nuclear projects under the regulatory scheme follows the assessment process if it results in a positive decision. Since the review panel's assessment report is to contain the information necessary for licensing, this should facilitate to the extent possible the integration of the assessment with the subsequent licensing process.

The IAA transitional provisions stipulate that projects that commenced under Canadian Environmental Assessment Act, 2012 (CEAA, 2012),[13] for which the notice of commencement was posted, are continued under the CEAA 2012 as if that Act had not been repealed.

12. *Ibid.*, Section 50, "Establishment of roster".
13. S.C. 2012, c. 19, s. 52.

France

Nuclear installations

Decree No. 2019-190 of 14 March 2019 codifying provisions concerning basic nuclear installations, the transport of radioactive substances and transparency in the field of nuclear energy[14]

The Decree codifies in the Environment Code numerous provisions relating to basic nuclear installations (BNI), especially the provisions of Decree 2007-1557 of 2 November 2017 (the so-called "Procedures Decree") concerning BNI and the control of radioactive substances transport in the field of nuclear safety.

Accordingly, Title IX of Book V of the regulatory part of the Environment Code entitled "Nuclear Safety and Basic Nuclear Installations" now has four detailed chapters related to:

- the Nuclear Safety Authority (Autorité de sûreté nucléaire – ASN) and the National Institute for Radiological Protection and Nuclear Safety (Institut national de radioprotection et de sûreté nucléaire – IRSN) (Art. R. 592-1 to R. 592-61); it should be noted that some provisions already existed, but were supplemented and renumbered;
- BNIs (Art. R. 593-1 to R. 593-123): this chapter is divided into 17 sections: nomenclature of BNIs; general provisions; use of external contractors; creation of a BNI; commissioning of a BNI; ASN requirements; amendment of the decree authorising the creation of a BNI; significant modifications during operation coming under the ASN; periodic review; permanent shutdown, dismantling and decommissioning of a BNI; provisions pertaining to installations operating under a grandfather clause; general interest easement; applicable provisions in case of serious risk; installations located in the perimeter of a BNI; particular categories of BNIs; Radiological Protection Adviser; and provisions pertaining to short-term authorisations;
- radioactive substances transport (Art. 595.1 to R. 595.3); and
- controls and sanctions (Art. 596-1 to R. 596-17).

The decree also codifies provisions relating to public information procedures and effective transparency in the field of nuclear energy (Art. R. 125-49), local information commissions (Art. R. 125-50 to R. 125-76) and the High Committee for Transparency and Information on Nuclear Security (Haut Comité pour la transparence et l'information sur la sécurité nucléaire, Art. 125-77 to R. 125-87).

As of 1 April 2019, the date of the decree's entry into force, the following decrees are repealed:

- Decree No. 2007-830 of 11 May 2007 relating to the nomenclature of BNIs;
- Decree No. 2007-831 of 11 May 2007 setting the procedures for the appointment and certification of nuclear safety inspectors;
- Decree No. 2007-1368 of 19 September 2007 relating to the part-time secondment of some civil servants at the Nuclear Safety Authority;

14. *Journal officiel "Lois et Décrets"* [Official Journal of Laws and Decrees] (J.O.L et D.), No. 64, 16 March 2019, text No. 3.

- Decree No. 2007-1557 of 2 November 2007 relating to BNIs and control, in the field of nuclear energy, of radioactive substances transport, except for Art. 65, 66, 67, 67-1, 68 and 69;
- Decree No. 2007-1572 of 6 November 2007 relating to technical investigations on accidents or incidents related to a nuclear activity;
- Decree No. 2008-251 of 12 March 2008 relating to the local information commissions of BNIs;
- Decree No. 2008-1108 of 29 October 2008 relating to the composition of the High Committee for Transparency and Information on Nuclear Security;
- Decree No. 2010-277 of 16 March 2010 relating to the High Committee for Transparency and Information on Nuclear Security; and
- Decree No. 2016-846 of 28 June 2016 relating to the modification, permanent shutdown and decommissioning of a BNI and to subcontracting, except for para. I and II of Article 13.

Decree No. 2019-67 of 1 February 2019 establishing an Interministerial Delegate for the future of the Fessenheim territory and the territories of coal-fired power plants[15]

Decree of 6 February 2019 appointing an Interministerial Delegate for the future of the Fessenheim territory and the territories of coal-fired power plants – Mr David Coste[16]

The Decree of 1 February 2019 establishes, under the Minister for Energy, an Interministerial Delegate for the future of the region near the Fessenheim site (Haut-Rhin) and the regions near coal-fired power plants. Mr David Coste was appointed Interministerial Delegate by the Decree of 6 February 2019. In this capacity, he is in charge of:

- preparing and co-ordinating, under the authority of the Minister for Energy, the operations necessary for the shutdown of the Fessenheim NPP as well as the operations necessary for the shutdown of the coal-fired units of the Gardanne (Bouches-du-Rhône), Cordemais (Loire-Atlantique), Saint-Avold (Moselle) and Le Havre (Seine-Maritime) power plants;
- conducting the development of a reconversion strategy for the livelihood and employment areas concerned, taking into account the impact of the permanent shutdown of these power plants on local economic activities, including contracting, and on the tax revenue of local communities.

In fulfilling this mission, the Interministerial Delegate liaises with the prefects of the departments and regions concerned and can appeal to state administration and national state establishments. The individual ensures that proper social dialogue and consultation take place at every stage with the stakeholders in the living and working areas concerned, especially with local communities, socio-economic actors and operators.

Decree No. 2012-1384 of 11 December 2012 establishing an Interministerial Delegate on the closure of the nuclear power plant and conversion of the Fessenheim site is repealed.

15. J.O.L. et D., No. 29, 3 February 2019, text No. 1, consolidated version in force as of 14 November 2019, available at: www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000038088256&dateTexte=20191114.
16. J.O.L. et D., No. 32, 7 February 2019, text No. 38.

Lithuania

Nuclear safety and radiological protection (including nuclear emergency planning)

Requirements for operating experience

Nuclear Safety Requirements BSR-1.4.4-2019 "Use of the Experience of the Individuals Operating in the Nuclear Energy Sector"[17] were approved by the Head of State Nuclear Power Safety Inspectorate (VATESI) in 2019 and replaced Nuclear Safety Requirements BSR-1.8.1-2010 "Notification on Unusual Events at Nuclear Power Plants" and "Requirements on Operational Experience Feedback in the Field of Nuclear Energy" (P-2009-04). The new requirements were put into place pursuant to changes in legislation and VATESI's regulatory experience and establish provisions on monitoring, evaluating and sharing operational experience in the nuclear energy sector, and also establish obligations for evaluation and reporting of unusual events. The new requirements came into force on 1 November 2019.

Requirements for Maintenance, Surveillance and In-service Inspections of Nuclear Facilities

Nuclear Safety Requirements BSR-1.8.6-2019 "Maintenance, Surveillance and In-service Inspection of Nuclear Facility's Structures, Systems and Components Important to Safety"[18] were approved by the Head of VATESI in 2019. These requirements gather provisions on maintenance, surveillance and in-service inspections within one document and are applicable to all nuclear facilities. The new requirements include provisions regarding planning, maintenance management, surveillance and in-service inspections, analysis of their results, and documentation. The new requirements came into force on 1 November 2019.

Transport of radioactive materials

Requirements for licensing of transport activities

New Nuclear Safety Requirements BSR-4.1.2-2019 "Requirements for the Documents which must be Provided with an Application to Obtain a Licence for Transport of Nuclear Fuel Cycle, Nuclear and Fissionable Materials"[19] were approved by the Head of VATESI in 2019. The goal of this new document is to set requirements for the content of an application for a licence for transport of nuclear fuel cycle, nuclear and fissionable materials. The new requirements came into force on 1 November 2019.

17. Order No. 22.3-148 (4 July 2019) of the Head of State Nuclear Power Safety Inspectorate, "On the approval of Nuclear Safety Requirements BSR-1.4.4-2019 'Use of the Experience of the Individuals Operating in the Nuclear Energy Sector'", TAR, No. 11095 (4 July 2019) available (in Lithuanian) at: www.e-tar.lt/portal/lt/legalAct/4be2d5409e5011e9878fc525390407ce.
18. Order No. 22.3-136 (3 July 2019) of the Head of State Nuclear Power Safety Inspectorate, "On the approval of Nuclear Safety Requirements BSR-1.8.6-2019 'Maintenance, Surveillance and In-service Inspection of Nuclear Facility's Structures, Systems and Components Important to Safety'", TAR, No. 10957 (3 July 2019), available (in Lithuanian) at: www.e-tar.lt/portal/lt/legalAct/50c601109d7c11e9878fc525390407ce.
19. Order No. 22.3-169 (19 July 2019) of the Head of State Nuclear Power Safety Inspectorate, "On the approval of Nuclear Safety Requirements BSR-4.1.2-2019 'Requirements for the Documents which must be Provided with Application to Obtain Licence for Transport of Nuclear Fuel Cycle, Nuclear and Fissionable Materials'", *Teisės Aktų Registras* (TAR – Register of Legal Acts), No. 11968 (19 July 2019), available (in Lithuanian) at: www.e-tar.lt/portal/lt/legalAct/1685a0b0a9e211e9964cdd77475976b0.

Luxembourg

Nuclear safety and radiological protection (including nuclear emergency planning)

Transposition of the Euratom Basic Safety Standards Directive

The new Law of 28 May 2019 on Radiological Protection [*Loi du 28 mai relative à la radioprotection*] and the Regulation of 1 August 2019 on Radiological Protection [*Règlement grand-ducal du 1er août 2019 relatif à la radioprotection*] transposes the Euratom Basic Safety Standards Directive[20] and entered into force on 1 August 2019. The new framework repeals and replaces the former legal framework on those matters, namely the Framework Act of 25 March 1963 concerning the Protection of the Population against the Dangers arising from Ionising Radiation.

The main aspects from the previous framework have been maintained and strengthened, as the previous framework was in conformity with the 2014 amended Nuclear Safety Directive.[21] The new framework also contains some provisions from the 2014 amended Nuclear Safety Directive to further strengthen compliance. The new law mainly aims to:

- modernise the national legislative framework for the control and monitoring of practices that use radiation sources, for example in nuclear medicine departments. The level of control takes into account a graded approach;
- simplify the administrative procedures for low-risk equipment, such as baggage screening scanners. For these practices, the law establishes a system of authorisation, inspections and sanctions by the regulatory body;
- define conditions relating, in particular, to the training and continuing education necessary for the exercise of a practice, the compulsory consultation of experts, the individual protection of workers and the information that must be provided to workers on the potential risks. Concerning experts, the law creates new professions of expert in medical physics and expert in radiological protection;
- specify the responsibilities of the requesting physician and the medical director in the field of medical exposures to radiation so as to ensure the optimisation and justification of any act of nuclear medicine and radiology for the protection of patients;
- broaden the scope of the law to include exposure from natural sources of radiation, including the protection of aircrews from cosmic radiation, radon exposure in dwellings and workplaces, exposure from building materials, and protection of workers from naturally occurring radioactive materials;
- clarify the responsibilities and criteria for the protection of the population in order to cope with the possibility of a nuclear or radiological accident. In this area, it strengthens the implementation of emergency response planning;

20. *Official Journal of the Grand Duchy of Luxembourg*, A389 (7 June 2019) and *ibid.*, A528 (5 Aug. 2019), implementing Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom, *Official Journal of the European Union* (OJ) L 13/1 (17 Jan. 2014) (Euratom Basic Safety Standards Directive).
21. Council Directive 2014/87/Euratom of 8 July 2014 amending Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations, OJ L 219/42 (25 July 2014).

- establish closer collaboration among member states and ensure participation in international peer reviews concerning nuclear safety; and
- forbid some practices, such as the construction and operation of nuclear installations.

Portugal

Nuclear safety and radiological protection (including nuclear emergency planning)

New basic safety standards for protection against the dangers arising from exposure to ionising radiation

Decree Law 108/2018 of 3 December updates the standards regarding radiological protection, adapting them to the Euratom Basic Safety Standards Directive.[22] It also appoints the competent authority and the supervisory authority for radiological protection and establishes its powers.

- Transposition of the Euratom Basic Safety Standards Directive

Decree Law 108/2018 transposes the Euratom Basic Safety Standards Directive, defining the regulatory framework applicable to planned and emergency exposure situations, determining a set of management, control, rapid notification and information mechanisms for the protection of members of the public from the risks of exposure to ionising radiation. Despite some minor arguable inconsistencies between the directive and its transpositions, the only aspects of the transposition that are to be singled out relate to the options of the Portuguese Government in relation to the institutional framework for the enforcement of this legal framework.

- Termination of COMRSIN

The previously existing Regulatory Commission for the Security of Nuclear Facilities (Comissão Reguladora para a Segurança das Instalações Nucleares – COMRSIN), created by Decree Law 30/2012 of 9 February 2012, is terminated and its powers are transferred to two public authorities under the new legal framework: the Portuguese Environment Agency (Agência Portuguesa do Ambiente – APA) and the Inspectorate-General for Agriculture, Sea, Environment and Territorial Planning (Inspeção-Geral da Agricultura, do Mar, do Ambiente e do Ordenamento do Território – IGAMAOT).

- Portuguese Environment Agency

The APA is now one of the two authorities responsible for ensuring the existence of a high level of radiological protection and of nuclear safety, the safe management of spent fuel and radioactive waste, as well as the issue of registrations and licences for practices or activities covered by the decree law. It has, in essence, received all the powers previously held by COMRSIN and by the Directorate General for Health, except those relating to control and inspections. In other words, it regulates and licenses, but does not verify compliance with the law.

Other than the powers received under Decree Law 108/2018, the APA's key roles are proposing, developing and implementing environmental and sustainable development policies, combating climate change, preserving nature, protecting air quality and restoring contaminated soils.

22. *Diário da República* (Official Register), Series 1, No. 232, p. 5490 (3 Dec. 2018). The Decree Law implements Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom, OJ L 13/1 (17 Jan. 2014) (Euratom Basic Safety Standards Directive).

- Inspectorate-General for Agriculture, Sea, Environment and Territorial Planning

Decree Law 108/2018 transferred inspection powers relating to radiological protection, nuclear safety, spent fuel and radioactive waste to IGAMAOT. IGAMAOT is thus entrusted with ensuring compliance with this legal framework. To this extent, it can order corrective measures, including the modification or revocation of issued permits and registrations, as well as operating conditions and procedures, and the temporary or permanent closure of installations.

Slovak Republic

General legislation, regulations and instruments

Draft Decree amending Decree No. 52/2006 Coll., on professional competence as amended by Decree No. 34/2012 Coll.

The Draft Decree of the Nuclear Regulatory Authority of the Slovak Republic (NRA SR) amending Decree No. 52/2006 Coll. on professional competence as amended by Decree No. 34/2012 Coll. was the subject of the approval procedure on 19 August 2019 by the Standing Working Commission on technical legal provisions of the Legislative Council of the Government of the Slovak Republic. Subsequently, this draft was open for comment in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.[23] The draft decree was made available within the EU Technical Regulation Information System database through 23 November 2019. No comments were received from the European Commission or any other member states; therefore, the decree was published in the Official Journal of Law of the Slovak Republic on 29 November 2019 as Regulation No. 410/2019 Coll., and it came into force on 1 January 2020.

Quadrilateral meeting with the Czech, Hungarian and Slovenian regulatory authorities

The Slovenian town Ptuj hosted the quadrilateral meeting of the Czech, Hungarian, Slovak and Slovenian regulatory authorities from 3 to 4 April 2019. Meeting participants exchanged information on changes and current developments of their regulatory authorities and on the most important activities undertaken from the last meeting. Topics of discussion included issues of nuclear power plant (NPP) safety, legal and regulatory frameworks, international issues and safety culture. Part of the meeting included a consultation on international projects conducted within the common consortium.

Bilateral meeting with Austrian authorities

The bilateral meeting between Austria and the Slovak Republic was held in Piestany, Slovak Republic, from 17 to 19 June 2019. As stipulated in the bilateral treaty concluded between both countries, the topic of the meeting was issues related to nuclear safety and radiological protection. The Slovak delegation was led by Chairwoman Marta Žiaková of the Nuclear Regulatory Authority of the Slovak Republic. As the part of the official programme, the expert meeting on Mochovce NPP, units 3 and 4, was held on 17 June 2019. Heads of both delegations noted their appreciation for these regular

23. Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, OJ L 241/1 (17 Sept. 2015).

meetings as well as the opportunity for discussion on, and exchange of, current information, which reinforce confidence between both countries in the nuclear field.

Slovenia

Nuclear safety and radiological protection (including nuclear emergency planning)

New regulations adopted on the basis of Ionising Radiation Protection and Nuclear Safety Act from 2017

As reported previously,[24] on the basis of the 2017 Ionising Radiation Protection and Nuclear Safety Act,[25] four government decrees (denoted by the abbreviation "UV"), two Rules of the Minister responsible for the Environment (denoted by the abbreviation "JV") and six Rules of the Minister responsible for Health (denoted by the abbreviation "SV") were adopted by the end of July 2018.

The following additional regulations were recently adopted to implement the same act:

- Decree on verification of radioactivity of shipments that may contain radioactive sources of unknown origin (UV11), in February 2019 (*Official Gazette of the Republic of Slovenia*, No. 10/2019, 15 Feb. 2019); and
- Amendments to the Decree on the content and elaboration of protection and rescue plans, in April 2019 (*Official Gazette of the Republic of Slovenia*, No. 26/2019, 26 April 2019). Although the amended decree was actually adopted to implement the Protection against Natural and Other Disasters Act, it is important because it transposed some provisions of the Euratom Basic Safety Standards Directive.[26]

With these two regulations, the process of transposition of the Euratom Basic Safety Standards Directive into the Slovenian legal system was completed. The Slovenian Nuclear Safety Administration continues to work on amendments to other regulations issued under the 2017 Ionising Radiation Protection and Nuclear Safety Act, which will be adopted in the coming months and years.

24. For more information, see NEA (2018), "New regulations adopted on the basis of Ionising Radiation Protection and Nuclear Safety Act from 2017", *Nuclear Law Bulletin*, No. 101, OECD, Paris, pp. 87-88.
25. Ionising Radiation Protection and Nuclear Safety Act (ZVISJV-1), *Official Gazette of the Republic of Slovenia*, No. 76/2017 (22 Dec. 2017).
26. Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom, OJ L 13/1 (17 Jan. 2014) (Euratom Basic Safety Standards).

Switzerland

Nuclear installations

Opening of the cooling water discharge authorisation procedure for the Beznau nuclear power plant[27]

Under the new legal provisions, the existing discharge authorisation for the two units of the Beznau nuclear power plant (NPP) should be reviewed for possible amendment or replacement. The Swiss Federal Office for Energy (Office fédéral de l'énergie – OFEN), which is the responsible authority, initiated a procedure for the possible amendment or replacement of the existing cooling water discharge authorisation for the Beznau NPP. On 4 July 2019, the OFEN also notified the Beznau NPP of provisional measures with immediate effect regarding cooling water discharge. By virtue of the OFEN decision, the Beznau NPP should henceforth observe the 25° C compulsory limit set for waterways as defined by the Order on water protection. Should the 25° C limit be exceeded or be at risk of being exceeded, the operating power should be lowered or the NPP should be temporarily shut down. During the 2018 heatwave, areas of the Aar River close to the NPP at times greatly exceeded the 25° C limit, sometimes for several days. The provisional measures aim to prevent this situation from reoccurring until the end of the procedure. Consequently, any appeal against the aforementioned measures will not suspend the procedures.

Radioactive waste management

Paul Scherrer Institute's Eastern Storage Area (OSPA): Entry into force of the combined construction and operation licence

The Paul Scherrer Institute (PSI) operates on its eastern site (Würenlingen, Argovie canton) the interim storage installation for packaged radioactive waste managed by the Swiss Confederation (waste from medical, research and industrial activities) and for radioactive waste generated by PSI's decommissioning activities. A new building dedicated to interim storage is now necessary for existing and future low and intermediate level radioactive waste until a deep geological repository is available in Switzerland to dispose of this waste. The PSI filed an application before the Confederation for a combined construction and operation licence in 2014. On 13 September 2018, the Federal Department for Environment, Transport, Energy and Communication (DETEC) granted the combined licence for the new interim storage building. The licence has now come into force.

United States

Nuclear safety and radiological protection (including nuclear emergency planning)

The NRC issues a final rule related to beyond-design-basis events

On 9 August 2019, the US Nuclear Regulatory Commission (NRC) published a final rule that amended its regulations to establish requirements for nuclear power reactor applicants and licensees to mitigate beyond-design-basis events.[28] The final rule made generically applicable the requirements in NRC orders for mitigation of

27. Swiss Federal Office for Energy (4 July 2019), "Interlocutory Decision with regard to proceedings concerning the possible adaptation or new approval of the Federal Council's approval of 15 December 1997 concerning the discharge of cooling water for the Beznau I and II nuclear power plants", available at: www.newsd.admin.ch/newsd/message/attachments/57706.pdf (in German).
28. Mitigation of Beyond-Design-Basis Events, Final Rule, 84 Fed. Reg. 39684 (9 Aug. 2019).

beyond-design-basis events[29] and for reliable spent fuel pool instrumentation[30] that were issued following the March 2011 Fukushima Daiichi nuclear power plant accident. Under the Final Rule, operating nuclear power plants must have mitigation strategies (also called "FLEX strategies") to address beyond-design-basis events. Plants must also provide a reliable means to remotely monitor wide-range water level for each spent fuel pool, so that they can effectively prioritise event mitigation and recovery actions in the event of a beyond-design-basis external event with the potential to challenge both the reactor and spent fuel pool. Plants that have begun decommissioning only need to have mitigation strategies associated with maintaining or restoring spent fuel pool cooling capabilities, and they need not maintain the means to remotely monitor spent fuel pool water levels. When the spent fuel in a pool at a decommissioning plant has cooled sufficiently such that ad hoc action in response to an event can be taken to sustain the spent-fuel-pool cooling function indefinitely, licensees will not need to maintain mitigation strategies. The final rule went into effect on 9 September 2019.

Radioactive waste management

NRC issues regulatory basis for disposal of "Greater-than-Class-C" radioactive waste

On 22 July 2019, the NRC published in the Federal Register a notice requesting public comment on a draft regulatory basis[31] to support the development of rulemaking for the disposal of greater-than-Class-C (GTCC) waste in a near-surface disposal facility.[32] Under its regulations in Part 61 of Title 10 of the *Code of Federal Regulations* (10 CFR), the NRC classifies low-level radioactive waste (LLRW) into three classes based on the radiological hazard as determined by the concentration of radionuclides prescribed for each class, namely, Class A, Class B and Class C wastes. Class C is the most hazardous of the three categories, and LLRW streams that contain radionuclide concentrations exceeding the limits for Class C waste (and thus are more hazardous than Class C waste), are referred to as "greater-than-Class C" (GTCC) waste. Currently, NRC regulation 10 CFR 61.55(a)(2)(iv) directs that GTCC waste be disposed in a geological repository, although the Commission, on a site-specific basis, may approve a proposal to dispose of GTCC waste in a facility licensed under 10 CFR Part 61 (i.e. a "land disposal facility").[33]

In 2015, the Commission directed the NRC staff to develop a draft regulatory basis that would analyse whether all or some GTCC waste streams could be disposed of in a near-surface disposal facility, which is a facility in which LLRW is disposed of within the upper 30 metres of the earth's surface.[34] The Commission further directed that the

29. NRC (12 March 2012), "Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond Design-Basis External Events (Effective Immediately)", EA-12-049, 77 Fed. Reg. 16091 (19 March 2012).
30. NRC (12 March 2012), "Order Modifying Licenses with Regard to Reliable Spent Fuel Pool Instrumentation (Effective Immediately)", EA-12-051, 77 Fed. Reg. 16082 (19 March 2012).
31. A draft regulatory basis is a pre-rulemaking document used by the NRC staff to develop a regulatory position on a given matter and to solicit public and other stakeholder comment as to whether the NRC should proceed with a notice-and-comment rulemaking, and if so, the scope of such rulemaking.
32. Greater-Than-Class-C and Transuranic Waste, 84 *Federal Register* (Fed. Reg.) 35037 (22 July 2019). The draft regulatory basis is available through the NRC's Agencywide Documents Access and Management System (ADAMS) and is designated as ADAMS Accession No. ML19059A403. ADAMS may be accessed at www.nrc.gov/reading-rm/adams.html.
33. Land disposal facilities are used for the disposal of LLRW. LLRW buried at a land disposal facility would be disposed of at much shallower depths than if disposed of in a geological repository.
34. A "near surface disposal facility" is a type of "land disposal facility". Both terms are defined in 10 CFR 61.2, "Definitions."

staff consider whether Agreement States[35] could license near-surface disposal facilities that can accept GTCC waste, or whether there were any GTCC waste streams that were so hazardous that the disposal of such waste should be reserved solely to the NRC's regulatory oversight. The NRC staff's preliminary technical analyses found that most GTCC waste streams were potentially suitable for disposal in a near-surface disposal facility that could be licensed by an Agreement State. The presence of transuranic radionuclides in many GTCC waste streams, however, presents a regulatory issue as the current definition of low-level radioactive waste in 10 CFR 61.2 excludes transuranic waste.[36]

As described in the draft regulatory basis, a potential rulemaking could remove the 10 CFR 61.55(a)(2)(iv) direction that the default disposal path for GTCC waste be in a geological repository, revise the definition of LLRW by removing the transuranic waste exclusion, and make other regulatory changes to accommodate an expanded licensing role for Agreement States. In addition to a potential rulemaking, the draft regulatory basis considered the no-action alternative and a guidance-only option, in which the NRC staff would issue guidance on GTCC waste disposal but no rule.

The public comment period ran until 19 November 2019.[37] The NRC staff will consider all written comments received and make a recommendation to the NRC Commission. If the NRC staff recommends, and if the Commission approves, proceeding with a GTCC waste disposal rulemaking, the NRC will then issue a proposed rule for public comment in accordance with the Administrative Procedure Act, 5 USC 553.

35. Section 274b of the Atomic Energy Act, as amended, 42 *United States Code* (USC) 2021(b), authorises the Commission to enter into an agreement with the governor of a state whereby the Commission relinquishes its regulatory authority, and the state assumes that authority, for the regulation of certain radioactive materials. A state that has entered into such an agreement with the NRC is defined as an "Agreement State".
36. The regulation defines the term "waste" as meaning:
    > those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs (2), (3), and (4) of the definition of *Byproduct material* set forth in [10 CFR] § 20.1003 of this chapter.
37. In response to multiple requests, the NRC extended the public comment period by 60 days, from 20 September 2019 to 19 November 2019. Greater-Than-Class-C and Transuranic Waste, 84 Fed. Reg. 48309 (13 Sept. 2019).

Intergovernmental organisation activity

European Atomic Energy Community

Published reports

Euratom Supply Agency Annual Report 2018

The *Euratom Supply Agency Annual Report 2018*[1] takes note of the conclusion of negotiations on eight major legislative acts aimed at ensuring clean energy for all Europeans. The report states that the Euratom Supply Agency (ESA) has continued to assume responsibility for the common supply policy in the interest of regular and equitable access to nuclear material for Euratom Community users. To ensure security of supply for European users in the medium and long term, ESA has been consistently encouraging the diversification of sources. ESA welcomes steps towards licensing an alternative fuel supplier in the member states using VVER technology and encourages continued efforts in this area.

ESA pursued its co-operation with the United States (US) Department of Energy's National Nuclear Security Agency to implement the high-enriched uranium (HEU) exchange programme, as provided for in a 2014 memorandum of understanding.[2] The aim is to provide European research reactors and producers of radioisotopes with the necessary amounts of HEU in conformity with the policy of minimising its use. A dedicated working group of the ESA's Advisory Committee resumed its work on the supply of high-assay low-enriched uranium (HALEU), which is currently not produced in Europe and is intended to replace HEU in nuclear medicine applications as well as in other areas. The ESA Advisory Committee produced its report in May 2019 (see below).

2018 was also a year of unique challenges. In preparation for the withdrawal of the United Kingdom from Euratom, ESA analysed all the supply contracts that it had concluded involving United Kingdom entities and took appropriate measures to ensure that those contracts continue to remain valid after the withdrawal of the United Kingdom from the European Union (EU). ESA liaised with the EU-27 (the 27 remaining EU member states engaged in the negotiations with the United Kingdom) stakeholders to help raise awareness of the need to be prepared and to address, in the appropriate fora, issues related to the future supply of medical radioisotopes.

Euratom Supply Agency (ESA) Advisory Committee Report

In May 2019, the ESA Advisory Committee produced its revised report,[3] which it endorsed and approved in its session of 21 March 2019.

1. Euratom Supply Agency (2019), *Euratom Supply Agency Annual Report 2018*, Publications Office of the European Union, Luxembourg.
2. "Memorandum of Understanding (MOU) between the Department of Energy National Nuclear Security Administration of the United States of America and the Euratom Supply Agency concerning the exchange of highly enriched uranium needed for supply of European research reactors and isotope production facilities" (Dec. 2014).
3. Euratom Supply Agency (2019), *Securing the European Supply of 19.75% enriched Uranium Fuel: A Revised Assessment*.

The report provides an updated view of HALEU needs, including potential global demand. It also takes account of developments in recent years, specifically realistic scenarios for the conversion of HEU fuelled high-performance research reactors, new concepts for power reactors and fuel design, the current geopolitical situation, and issues relating to the shipping and transport of HALEU. It also addresses the pressing issue of US stocks of HEU available for downblending to HALEU, since these are only sufficient to cover needs until 2030-2040.

HALEU is not currently produced in any western country. The material used in research reactors is obtained either by downblending US HEU stocks, or from Russia. If no action is taken, there is a risk that the supply of this critically important material cannot be guaranteed after 2030-2040. This could jeopardise European research technological applications and the production of the most vital medical radioisotopes. It is now recognised that HALEU production could be of major importance for the future of nuclear technology, science using nuclear technology and nuclear medicine.

The report contains an overview of the demand for HALEU in the coming decades, a discussion on the potential future needs of small and medium-sized reactors using advanced HALEU fuel, and a description of issues related to the metallisation, deconversion and transport of HALEU. The core part of the report presents a business model to build European capacity for the production of metallic HALEU, based on three different market demand scenarios. The report concludes that building such a facility in the EU is feasible but that its economic viability would depend on certain conditions, in particular production volumes, price and financing.

By providing an overview of the current situation while looking ahead to the future, this report contributes to the European and international discussion on the future secure supply of HALEU and provides policymakers with a basis for making informed decisions on related initiatives.

Published studies

Study on the impact of the ITER activities in the EU, final report

On 4 April 2018, Trinomics B.V. completed a study on the impact of the ITER project activities on behalf of the Commission's Director-General for Energy.[4] The report presents an analysis of the impacts of the spending on ITER by the joint undertaking Fusion for Energy. The study provides a detailed analysis of the in-kind contributions funded by Fusion for Energy and an analysis of future payments. It shows that spending on ITER is already delivering significant benefits, almost equivalent to the spending by Fusion for Energy. It has also generated around 34 000 job years between 2008-2017. These impacts are expected to increase, along with spending, in the next five years. So far, the geographical distribution of impacts largely corresponds to the size of an economy, with a weighting towards France as the host country.

Potential impacts of spin-offs further increase the economic impact. A survey of contracted firms and a series of case studies confirm these impacts and demonstrate the multiple, other economic benefits to firms.

The study also provides a cross-cutting analysis of the aggregate impact of ITER spending, in the context of the future EU energy system and EU energy research spending. An analysis of ITER compared to other big science projects, especially the Large Hadron Collider at the European Organization for Nuclear Research (CERN) and the European Space Agency is provided. The analysis finds that the economic impacts of ITER follow a similar pathway and may deliver a positive net return on investment in the future, that there are synergies for firms working across big science projects

4. Trinomics B.V. (2018), *Study on the impact of the ITER activities in the EU: Final report*, Rotterdam.

and that there are lessons to be learnt by Fusion for Energy on technology transfer and public dissemination and opinion.

The study concludes that it remains highly valuable to keep open the ITER fusion power option, as a large-scale, low-carbon, clean, low environmental impact energy technology in which Europe can be self-sufficient. Although fusion power will only play a major role in the energy system post-2050, it is thought by most experts, and in the opinion of the authors of the report, that it is highly valuable to keep open the ITER fusion power option. While the risks associated with the project are high, the benefits are also potentially very high for ITER to act as a catalyst for the sustainable energy transition that will be necessary in the coming decades.

According to the study, ITER should be seen as a big science project investment rather than energy research. The study recommends already beginning to systematically invest in technology transfer because a technology transfer system takes time but is crucial to enhancing the impact of the public investment. It makes clear that it is also important to reduce the chances that EU investments in technology development result in sustainable economic gains instead of (as in the case of solar photovoltaic) EU money kick-starting the development of the technology although the industrial production and benefits largely occur elsewhere. Further work to examine the best option for such a mechanism for Fusion for Energy and ITER would be beneficial as the approaches taken by the European Space Agency and CERN differ considerably and each have particular strengths. The study states that steps should be undertaken as soon as possible to build up a technology transfer system, so that it can support innovation and guarantee the continued generation of societal benefits at ITER through its operational phase.

The study further recommends developing a strategy to create a positive public image of ITER and fusion energy. It states that it is very important to create a positive public image of fusion energy for the future success of the project. This is something that other big science projects such as CERN and the European Space Agency have managed to achieve, and which helps in budget discussions. ITER and Fusion for Energy should plan more clearly what they will do to engage the public in this way. According to the study, important routes for doing so are:

- being clear about the time horizon for ITER. Positioning fusion as much as possible as a major science project that contributes to fundamental human knowledge next to already delivering concrete spin-offs and benefits to society;
- positioning fusion as a fossil-free (baseload) energy source complementary to, and not a competitor with, already existing intermittent renewable energy sources;
- being as open as possible about benefits and the real and perceived risks of the technology; and
- dedicating substantial budget to informing the public about fusion energy, not only developing dissemination fact sheets, but also engaging and organising public debate that discusses potential risks and drawbacks, organising site visits, etc.

International Atomic Energy Agency

Nuclear safety

Convention on Nuclear Safety: Officers' Meeting

The International Atomic Energy Agency (IAEA) facilitated an additional Officers' Meeting in Vienna in September at which officers for the Eighth Review Meeting of

the Convention on Nuclear Safety[5] agreed on and approved a number of templates to further enhance the peer review process to be used at the Eighth Review Meeting scheduled from 23 March to 3 April 2020. At the meeting, the officers also discussed the organisation of topical sessions on safety culture and ageing management and considered the possibility of utilising an electronic tool to ask questions and streamline them during the topical sessions. In this context, they requested the Secretariat to inquire into the technical possibility for this tool.

Open-ended Meeting of Technical and Legal Experts for Sharing Information on States' Implementation of the Code of Conduct on the Safety and Security of Radioactive Sources and its Supplementary Guidance

The IAEA held an Open-ended Meeting of Technical and Legal Experts to Share Information on States' Implementation of the Code of Conduct on the Safety and Security of Radioactive Sources[6] and its Supplementary Guidance[7] in Vienna, from 27 to 31 May 2019. The meeting provided an opportunity for a wide exchange of information among member states and identified current needs to ensure the safe and secure management of radioactive sources during import and export worldwide. At the meeting, a revised version of the "formalised process" was also agreed upon for sharing information related to states' implementation of the Code of Conduct and its Supplementary Guidance. The meeting concluded that the national papers submitted prior to the meeting and the presentations made during the meeting showed progress in implementing the provisions of the Code and its Supplementary Guidance.

Nuclear security

Meeting of Legal and Technical Experts in Preparation for the 2021 Conference of the Parties to the Amendment to the Convention on the Physical Protection of Nuclear Material (CPPNM)

From 22 to 26 July 2019, the IAEA convened a Meeting of Legal and Technical Experts in Preparation for the 2021 Conference of Parties to the Amendment[8] to the CPPNM.[9] The purpose of this event was to facilitate the preparations for the 2021 Conference with a view to the implementation and adequacy of the amended convention, as foreseen in Article 16(1) thereof.

Nuclear liability

During the reporting period, the Secretariat continued to assist member states, upon request, in their efforts to adhere to the relevant nuclear liability instruments in the context of its overall legislative assistance programme. Also, a follow-up IAEA International Expert Group on Nuclear Liability (INLEX) mission to Saudi Arabia was conducted in August 2019.

63rd session of the IAEA General Conference

The 63rd regular session of the IAEA General Conference was held in Vienna, Austria, from 16 to 22 September. A total of 3 034 participants attended the conference,

5. Convention on Nuclear Safety (1994), IAEA Doc. INFCIRC/449, 1963 UNTS 293, entered into force 24 October 1996 (CNS).
6. IAEA (2004), *Code of Conduct on the Safety and Security of Radioactive Sources*, IAEA Doc. IAEA/CODEOC/2004.
7. IAEA (2012), *Guidance on the Import and Export of Radioactive Sources*, IAEA Doc. IAEA/CODEOC/IMO-EXP/2012.
8. Amendment to the Convention on the Physical Protection of Nuclear Material (2005), IAEA Doc. INFCIRC/274/Rev.1/Mod.1, entered into force 8 May 2016 (ACPPNM).
9. Convention on the Physical Protection of Nuclear Material (1980), IAEA Doc. INFCIRC/274 Rev. 1, 1456 UNTS 125, entered into force 8 February 1987 (CPPNM).

including delegates from 152 of the IAEA's 171 member states. Throughout the week, delegates were able to attend 43 exhibitions, 96 side-events showcasing activities and special programmes by the IAEA Secretariat, as well as by several member states.

Resolutions of the conference

A number of resolutions were adopted by the conference. As in previous years, resolution GC(63)/RES/7 on Nuclear and Radiation Safety, as well as resolution GC(63)/RES/8 on Nuclear Security, include sections that are of legal relevance. All resolutions adopted during the 63rd regular session of the General Conference are available on the IAEA website at: www.iaea.org/about/policy/gc/gc63/agenda.

Nuclear and Radiation Safety (GC(63)/RES/7)

Regarding the CNS, the General Conference urged "all Member States that have not yet done so, especially those planning, constructing, commissioning or operating nuclear power plants, or considering a nuclear power programme, to become Contracting Parties to the CNS". Concerning the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management,[10] the conference likewise urged "all Member States that have not yet done so, particularly those managing radioactive waste or spent fuel, to become Contracting Parties to the Joint Convention".

The conference stressed "the importance of CNS and Joint Convention Contracting Parties fulfilling their respective obligations stemming from these Conventions and reflecting these in their actions to strengthen nuclear safety and in particular when preparing National Reports, and actively participating in peer reviews for CNS and Joint Convention Review Meetings". In addition, the conference requested "the Secretariat to provide full support for the CNS and Joint Convention Review Meetings, and to consider addressing their outcomes in the Agency's activities, as appropriate and in consultation with Member State".

The conference further urged "all Member States that have not yet done so to become Contracting Parties to the Early Notification Convention and the Assistance Convention", and stressed "the importance of Contracting Parties fulfilling the obligations stemming from these Conventions, and actively participating in regular meetings of the Representatives of Competent Authorities". In this context, the conference requested "the Secretariat, in collaboration with regional and international organisations and Member States, to continue its activities to promote the importance of conventions concluded under the auspices of the IAEA and to assist Member States upon request with adherence, participation and implementation as well as strengthening of their related technical and administrative procedures".

With respect to the Code of Conduct, its Supplementary Guidance and its Guidance on the Management of Disused Radioactive Sources,[11] the General Conference encouraged *inter alia* all member states to make "political commitments", and to implement them, as appropriate, "in order to maintain effective safety and security of radioactive sources throughout their life cycle". The conference also requested the Secretariat to continue supporting member states in this regard.

Similarly, the conference encouraged member states "to apply the guidance of the Code of Conduct on the Safety of Research Reactors at all stages in their life, including planning" and "to freely exchange their regulatory and operating information and

10. Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (1997), IAEA Doc. INFCIRC/546, 2153 UNTS 357, entered into force 18 June 2001 (Joint Convention).
11. IAEA (2018), *Guidance on the Management of Disused Radioactive Sources*, IAEA Doc. IAEA/CODEOC/MGT-DRS/2018.

experience with regard to research reactors". In this context, the conference requested the Secretariat "to continue to support member states, upon request, in [the] application of the guidance of the Code of Conduct on the Safety of Research Reactors".

With regard to civil liability for nuclear damage, the General Conference encouraged "Member States to give due consideration to the possibility of joining the international nuclear liability instruments, as appropriate, and to work towards establishing a global nuclear liability regime". In this context, the conference requested the Secretariat, in co-ordination with the OECD Nuclear Energy Agency when appropriate "to assist Member States, upon request, in their efforts to adhere to any international nuclear liability instruments concluded under the auspices of the IAEA or the OECD/NEA, taking into account the recommendations of the INLEX in response to the IAEA Action Plan on Nuclear Safety".

In addition, the conference recognised "the valuable work of INLEX"; took note "of its recommendations and best practices on establishing a global nuclear liability regime, including through the identification of actions to address gaps in and enhance the existing nuclear liability regimes"; encouraged "the continuation of INLEX, especially for its support for the IAEA's outreach activities to facilitate the achievement of a global nuclear liability regime"; and requested "that INLEX, via the Secretariat informs Member States on a regular and transparent basis about the work of INLEX and its recommendations to the Director General".

Nuclear Security (GC(63)/RES/8)

In the context of nuclear security, the conference affirmed "the central role of the Agency in strengthening the nuclear security framework globally and in coordinating international activities in the field of nuclear security, while avoiding duplication and overlap".

The conference called upon the Secretariat "to continue to organize [International Conference on Nuclear Security: Sustaining and Strengthening Efforts] ICONS every three to four years" and welcomed "the ongoing preparations for the 2020 ICONS". It encouraged all member states "to participate at ministerial level" and called upon them "to strive towards a substantive outcome of ICONS in the form of a consensual Ministerial Declaration, and a successful technical and scientific programme which could contribute to further strengthening nuclear security".

In addition, the conference welcomed "the ongoing preparatory process for the 2021 Conference, which is being convened in accordance with article 16.1 of the CPPNM, as modified by its 2005 Amendment", and encouraged "all States Parties and EURATOM to engage actively". The conference also encouraged "all Parties to the CPPNM and its 2005 Amendment to fully implement their obligations thereunder" and encouraged "States that have not yet done so to become party to this Convention and its Amendment". It encouraged "the Agency to continue efforts to promote further adherence to the Amendment with the aim of its universalization".

The conference welcomed "the organization by the Secretariat of CPPNM meetings" and encouraged "all States Parties to the Convention to participate in relevant meetings".

IAEA Treaty Event

The yearly Treaty Event took place during the 63rd session of the IAEA General Conference in September 2019. During the event, Bolivia deposited instruments of accession to the CNS and to the Joint Convention; Chad deposited an instrument of accession to the CPPNM and of ratification of its 2005 Amendment; Ecuador deposited instruments of accession to the Convention on Early Notification of a Nuclear

Accident[12] and to the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency;[13] and Lesotho deposited an instrument of acceptance of the Agreement on the Privileges and Immunities of the IAEA.

Legislative assistance

The IAEA continued to provide legislative assistance to its member states to support the development of adequate national legal frameworks and to promote adherence to the relevant international legal instruments. Specific bilateral legislative assistance was provided to several member states through written comments and advice on drafting national nuclear legislation. Assistance in gaining a better understanding of the relevant international legal instruments was also provided to member states through awareness missions and workshops conducted in member states.

In addition, the IAEA continued to organise a number of regional and training events in nuclear law, such as the Subregional Workshop on Nuclear Law held in August in Jakarta, Indonesia, for member states of Asia and the Pacific, and the Meeting on the Role of the Legal Advisor in a Nuclear Regulatory Body held in August at IAEA headquarters in Vienna, as well as the ninth Session of the Nuclear Law Institute (NLI) held in October in Vienna, which was attended by 65 participants from 58 member states.

OECD Nuclear Energy Agency

Fourth International Workshop on the Indemnification of Damage in the Event of a Nuclear Accident

The Fourth International Workshop on the Indemnification of Damage in the Event of a Nuclear Accident was organised by the OECD Nuclear Energy Agency (NEA) in co-operation with the Instituto Superior Técnico and the Faculty of Law of the University of Lisbon (Portugal) on 8-10 October 2019 in Lisbon, Portugal. The event was a unique opportunity to continue exploring the practical application of the international nuclear liability conventions and national legislations in case a nuclear incident occurs at a nuclear installation that causes transboundary nuclear damage. More specifically, the workshop assessed the determination of the nuclear damage to be compensated and transboundary claims handling, in order for the participants to understand the challenges involved and discuss views and options to ensure an adequate compensation of victims in case such a nuclear incident were to occur.

With regard to the determination of nuclear damage, the aim was to discuss in different sessions the meaning of each of the following heads of damage that have been included in the post-Chernobyl versions of the nuclear liability conventions:

1. loss of life or personal injury;
2. loss of or damage to property;
3. economic loss (arising from damage 1 and 2, loss of income deriving from an economic interest in any use or enjoyment of the environment, loss caused by preventive measures, and any other economic loss);
4. costs of measures of reinstatement of impaired environment; and

12. Convention on Early Notification of a Nuclear Accident (1986), IAEA Doc. INFCIRC/335, 1439 UNTS 276, entered into force 27 October 1986 (Early Notification Convention).
13. Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency (1986), IAEA Doc. INFCIRC/336, 1457 UNTS 134, entered into force 26 February 1987 (Assistance Convention).

5. costs of preventive measures.

The meaning to be given to each head of damage may in practice depend on the circumstances of the accident, the international convention(s) applicable (if any), the national legislation and case law, and the interpretation that the competent court may have. The purpose of the workshop was to identify:

- what could be considered in practice as "nuclear damage",
- the challenges that could be raised by some heads of damage that are difficult to determine or may potentially be compensated under different heads of damage (to avoid double payment), and
- whether a system to determine what nuclear damage is should be set up in case of a nuclear accident to help avoiding disputes and litigations (which would be time consuming and costly for all parties involved and would delay the payment of compensation to the concerned victims).

The workshop also addressed the administrative challenges of handling nuclear damage compensation claims to set forth the complexity of such process, which would require, among many others, national and international co-ordination between several governmental authorities and private actors, an adequate claims handling procedure put in place in case the countries concerned (i.e. the country of the installation and the affected states) would not have treaty relations, and a common understanding of the applicable legal framework between the countries concerned. It clearly demonstrated the need to be prepared beforehand as much as feasible by, for example, setting up in advance whatever is possible (e.g. IT system, website, co-ordination between fund providers), clarifying the responsibilities between all the actors involved (which would certainly change from one country to another and from one operator to another) and carrying out international nuclear claims handling exercises.

A group of experts from different fields and backgrounds (e.g. legal, economics, radiological protection, insurance) was constituted for each head of damage and for the claims handling. Such variety of experts ensured a holistic analysis of each topic. There were in total 42 experts from 16 member and non-member countries involved in such groups. They prepared notes and relevant supporting documents for each topic, which were made available to the participants before the workshop. This approach ensured an active and collaborative discussion between the panel of experts and the participants who came prepared.

A total of 140 participants attended the workshop from 24 NEA member countries, 5 non-member countries, the European Commission and the IAEA. They represented governments, regulatory authorities, technical support organisations, academia, judiciary, operators, suppliers and law firms, as well as nuclear insurance pools. The Secretariat is now preparing a report with practical outputs that should facilitate countries to be prepared with regard to the determination of nuclear damage and claims handling in case a nuclear accident with transboundary damage occurred.

Nuclear Law Committee meeting

The NEA Nuclear Law Committee (NLC) met on 27-28 June 2019 to review the ongoing activities of the NEA Office of Legal Counsel and of the NLC working parties on nuclear liability and transport, deep geological repositories and nuclear liability, and the legal aspects of nuclear safety. The meeting was attended by nearly 70 participants representing 25 NEA member countries, 4 non-NEA member countries, the IAEA, the European Commission (EC) and the insurance industry. Participants discussed the organisation of the Fourth International Workshop on the Indemnification of Damage in the Event of a Nuclear Accident, a forthcoming report on legal frameworks for the long-term operation (LTO) of nuclear power reactors and the implementation of

international conventions with regard to public participation in nuclear-related activities. Reports on the latest national developments in nuclear law were provided by Japan, Sweden, the United Kingdom and the United States.

Two working group meetings took place on the margins of the NLC meeting. The NEA Working Party on the Legal Aspects of Nuclear Safety held a meeting on 25 June 2019 with 34 participants from 18 NEA member countries, 2 non-NEA member countries and the EC. Reports on national licensing processes were provided by Finland and the United States, while Spain and Sweden gave presentations on latest national developments related to the legal aspects of nuclear safety. Participants finalised a forthcoming report on the legal framework for the LTO of nuclear power reactors. They also discussed the legal aspects of licensing small modular reactors, legal challenges to licensing decisions, and the enforcement of nuclear safety related laws and regulations.

The NEA Working Party on Nuclear Liability and Transport (WPNLT) met on 26 June 2019 with 38 representatives from 19 member countries, two non-NEA member countries, the EC, the IAEA, the nuclear insurance industry and the International Nuclear Law Association (INLA). At this meeting, participants discussed the preliminary results of an enquiry regarding national legislation and rules applicable to nuclear transport and transit, and agreed to make the potential final deliverables publicly available. A topical session examined, through legal, technical and insurance perspectives, the challenges relating to the qualification of nuclear substances to be transported. Participants also worked on theoretical case studies.

Contracting Parties to the Paris Convention

The Contracting Parties to the Paris Convention on Third Party Liability in the Field of Nuclear Energy met on 24 June 2019 to discuss the interpretation and implementation of this Convention and the Brussels Convention Supplementary to the Paris Convention. During this meeting, the Contracting Parties continued preparing for the entry into force of the 2004 Protocols to amend both conventions. The Contracting Parties have not been able to ratify the 2004 Protocol to amend the Paris Convention due to a decision of the Council of the European Union (EU) that requires EU member states that are Contracting Parties to the Paris Convention (except Denmark and Slovenia) to deposit their instruments of ratification of the Protocol simultaneously.[14] The last EU member state that needs to finalise its national legislative process to be able to ratify the 2004 Protocols is Italy, which has made some progress lately. After its approval by the Council of Ministers on 28 November 2018, a draft bill authorising the ratification of both Protocols has been submitted to the Chamber of Deputies in December 2018 and has been posted on the website of the Chamber of Deputies. The consideration of the bill has been jointly assigned to the Standing Committee of Foreign and European Community Affairs and the Standing Committee of Environment, Territory and Public Works. Since 13 May 2019, both Committees have examined the draft bill in three sessions, the last one taking place on 3 July 2019.

2019 International School of Nuclear Law (ISNL)

The 19th session of the NEA International School of Nuclear Law (ISNL) was held from 26 August to 6 September 2019 in Montpellier, France, bringing together a diverse group of graduate students and professionals from across the world to learn more

14. Council Decision 2004/294/EC of 8 March 2004 authorising the member states which are Contracting Parties to the Paris Convention of 29 July 1960 on Third Party Liability in the Field of Nuclear Energy to ratify, in the interest of the European Community, the Protocol amending that Convention, or to accede to it, *Official Journal of the European Union* (OJ) L 97 (1 Apr. 2004).

about the legal framework and major issues affecting the peaceful uses of nuclear energy. Organised by the NEA and the University of Montpellier, the ISNL is a unique educational programme that offers participants from the academic, private and governmental sectors an in-depth look at international nuclear law, focusing on areas such as nuclear safety, environmental law, security, safeguards and nuclear liability. A total of 60 participants from 33 countries, including numerous non-NEA member countries, attended this year's session. Many of these participants received support to attend the ISNL from the IAEA, which also provided several lecturers. The ISNL has attracted since 2001 more than 1 000 participants from an increasingly diverse range of countries, many of whom are now experts in the nuclear law field.

Second NEA International Radiological Protection School (IRPS)

The second session of the NEA International Radiological Protection School (IRPS) was held on 19-23 August 2019 at the Centre for Radiation Protection Research (CRPR), Stockholm University, with the support of the Swedish Radiation Safety Authority (SSM). This year's session brought together 31 participants from 14 countries. The five-day training featured lectures and dialogues by renowned radiological protection experts on the history of the development and implementation of the international system of radiological protection.

News briefs

2020 International Nuclear Law Essentials (INLE) course in Paris

The next session of the NEA International Nuclear Law Essentials (INLE) will take place in Paris, France, from 17-21 February 2020. The five-day INLE course is designed to provide participants with a practical and comprehensive understanding of the various interrelated legal issues relating to the safe and peaceful use of nuclear energy. This intensive course in international nuclear law addresses the needs and interests of lawyers working in either the public or the private sector, but will also be of interest to scientists, engineers, policymakers, managers and other professionals working in the nuclear field.

24th Nuclear Inter Jura Congress, October 2020

Every two years, the International Nuclear Law Association (INLA) organises a congress entitled "Nuclear Inter Jura" in which nuclear lawyers from around the world participate. The 24th INLA Congress will take place in Washington, DC, United States, from Sunday 25 October to Thursday, 29 October 2020 at the Willard InterContinental Washington.

The theme of this year's Congress is "INLA and The Nuclear Industry: The Next 50 Years", and the goal of the 2020 Congress is to draw that theme into the individual papers and presentations. This will provide insights as to how each topic represents or will be influenced by developments impacting nuclear power's future. Such factors may reflect a positive contribution to, or potentially detract from, the evolution of key aspects of nuclear power's role in our societies throughout the world. Abstract submissions for papers should be made by 30 January 2020 and final papers will be due by 1 September 2020.

The second announcement will contain all relevant information in terms of registration fees, various events, the venue, accommodation options, travel packages prepared for participants, instructions about visas and important dates to bear in mind. The main lines of the provisional scientific programme will also be included.

Certificate Course on "Nuclear Law and Energy", TERI School of Advanced Studies, New Delhi, 2-6 March 2020

The 7th edition of the Nuclear Law Association, India and TERI School of Advanced Studies Certificate Course on "Nuclear Law and Energy" will be held between 2-6 March 2020 at the TERI School of Advanced Studies, New Delhi, India. This week-long course includes a site visit to the Narora nuclear power plant on the last day. All information is available at: https://nuclearlaw.wordpress.com/2019/10/24/7th-certificate-course-on-nuclear-energy-and-law-monday-2-friday-6-march-2020/. Inquiries and participation forms should be sent to: secretary@nlain.org

3rd Canadian Nuclear Law Organization Nuclear Law School

The 3rd Canadian Nuclear Law Organization (CNLO) Law School was held in Toronto, Canada on 19-20 September 2019. The CNLO Nuclear Law School is a two-day event

that provides a comprehensive overview of the significant legal issues and important developments of consequence to the nuclear industry in Canada. This intensive course has been designed for lawyers practicing nuclear energy law in both the private and public sectors. The course consisted of 10 topical sessions with 32 speakers from organisations including Ontario Power Generation, Bruce Power, the Canadian Nuclear Safety Commission, NuScale, Cameco, Torys, Blakes, Gowling WLG, and Fogler, Rubinoff LPP. Participants from 22 organisations included representatives from licensees and proponents, regulatory bodies, government officials, corporate lawyers and academics. The sessions addressed the latest developments pertaining to relevant topics including cross-border considerations on nuclear liability, nuclear decommissioning and legacy waste management, labour issues, the Canadian Impact Assessment Act and environmental assessments, export control and technology transfer, consultation and Indigenous relations, procurement and contracting, medical isotopes and small modular reactors.

Recent publications

Legal Frameworks for Long-Term Operation of Nuclear Power Reactors (2019), by the NEA

In July 2019, the world's oldest operating nuclear power reactor passed 50 years since it was first connected to the electricity grid. Four other nuclear power reactors will also have passed 50 years of operation since they were first connected to the electricity grid before the end of 2019. With almost 70% of the world's operating reactors over 30 years of age, countries around the world are assessing whether to allow reactor operation to continue past the 50- to 60-year mark and potentially up to 80 years. Ensuring a proper legal framework for the long-term operation (LTO) of nuclear power reactors is a key component of such considerations. While there are numerous reports that address LTO from a technical standpoint, and some of these also incorporate a review of regulatory frameworks for LTO, *Legal Frameworks for Long-Term Operation of Nuclear Power Reactors* is the first report of its kind to comprehensively address the legal and policy aspects involved in a decision to allow or authorise long-term operation.

The aim of the report is to provide insight into the various laws, regulations and policies that contribute to different countries' approaches to LTO around the world, without any judgement as to the merits of one approach over another. The report is thus intended for a wide audience who may wish to better understand both the current state of international approaches to LTO and the detailed approaches of one or many countries.

Official information was provided by 25 countries (collectively referred to as the "reporting countries"), 24 of which are Nuclear Energy Agency (NEA) member countries, and by an additional country that participates in certain NEA activities.[1] In total, the report covers 359 (or 80%) of the world's operating nuclear power reactors.

With information collected from countries that have both experience in and plans for LTO, the report highlights some of the commonalities that emerge and the possible reasons for some of the variations. The overall review of different legal frameworks for LTO in these countries illustrates how even among countries with similar approaches, small distinctions can ultimately amount to major differences. A comprehensive analysis of the information provided by reporting countries draws the following main conclusions:

- Differences among reporting countries in the initial licensing frameworks for nuclear power reactor operation have a substantial impact on the legal frameworks for LTO. Initial authorisations for nuclear power reactor operation may be granted either for a specific, time-limited term or for an indefinite duration. This variation most often, but not systematically, determines whether a specific decision is taken to authorise the LTO of a nuclear power reactor.

1. It should be noted that not all reporting countries operate nuclear power reactors and not all countries that operate nuclear power reactors are pursuing LTO.

- All reporting countries require a review of nuclear safety related aspects of LTO by their national regulatory bodies, although authorisation or approval for LTO is in some instances granted by a ministry or by the government, rather than the regulatory body.

- Regulatory approaches to LTO are often described as either a periodic safety review (PSR) or a licence renewal. For reporting countries, however, the usual PSR and/or licence renewal dichotomy was not the most suitable distinction. Instead, the safety review in reporting countries is performed by either carrying out a PSR, an LTO-specific review or a combination of the two. It should be noted that such reviews do not necessarily lead to a formal licensing decision to authorise LTO.

- Of the reporting countries that require a specific authorisation for LTO, approaches vary in terms of the requirements for a new licence, a renewed licence, an amended or updated licence and a ministerial order.

- A legal requirement exists in the majority of reporting countries to perform a review of the environmental impacts prior to LTO, although the nature and extent of such reviews vary.

- In all reporting countries, new safety requirements related to LTO can be imposed through the LTO-review process. The ability to impose new safety requirements is, however, not always specifically linked to an LTO-approval process; in many reporting countries, new safety requirements may be imposed as part of the PSR process or in some cases at any time during reactor operation.

- Most reporting countries' legal frameworks provide rights to the public to access LTO-related information held either by public authorities, or, in some reporting countries, by licensees. Typically, these rights are provided under the general, environmental or national nuclear laws and therefore are not specific to LTO.

- The legal frameworks for LTO-related public participation vary among reporting countries. While not all reporting countries provide for public participation, for those that do, such requirements typically rest with the nuclear regulatory body or another decision-making authority (e.g. the public authority in charge of environmental protection or a local authority) and may entail public hearings, written comments and/or the dissemination of draft decisions for public consultation, as well as requirements for the decision-making authority to take into account comments received when reaching its final decision.

- Nearly all reporting countries allow legal challenges to the LTO process (often concerning the authorisation, approval or other type of decision made in the context of the LTO-review process). In most instances, the procedures for such challenges are determined by civil or administrative procedures that are not unique to the nuclear energy sector.

A detailed review of national approaches to LTO is also provided in the report. In many ways, the country reports are the central part of *Legal Frameworks for Long-Term Operation of Nuclear Power Reactors*. Each country report is drafted so that it can be read and understood separately from the report as a whole. When applicable, each country report provides key data regarding the status of nuclear power reactor operation, important details about the designed and authorised periods, terminology, main laws/regulations/documents for initial operation and LTO, responsible government bodies, application and review timing, scope of review (both safety and

environmental), new safety requirements and transboundary notification. Each country report concludes, as far as applicable, with a review of the available avenues for access to information and public participation during the LTO-approval process in the individual reporting country, as well as the opportunities and procedures to initiate legal challenges.

With the information gathered for this report, it can ultimately serve as a resource for future exchanges concerning the legal aspects of LTO, with a view to further developing and strengthening the collective understanding of these issues.

The report can be downloaded at: http://oe.cd/nea-lto-npp.

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Nuclear Law Bulletin No. 103

The *Nuclear Law Bulletin* is a unique international publication for both professionals and academics in the field of nuclear law. It provides readers with authoritative and comprehensive information on nuclear law developments. Published free online twice a year in both English and French, it features topical articles written by renowned legal experts, covers legislative developments worldwide and reports on relevant case law, bilateral and international agreements as well as regulatory activities of international organisations.

Feature articles and studies in this issue include: "A perspective on key legal considerations for performance-based regulating" and "Technology-neutral licensing of advanced reactors: Evaluating the past and present NRC framework".

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