

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

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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. Coglianesi, 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 contracting 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

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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.*; Coglianesi, C., J. Nash, and T. Olmstead (2002), *supra* note 3, p. 4.

31. Coglianesi, 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. Coglianesi, 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.

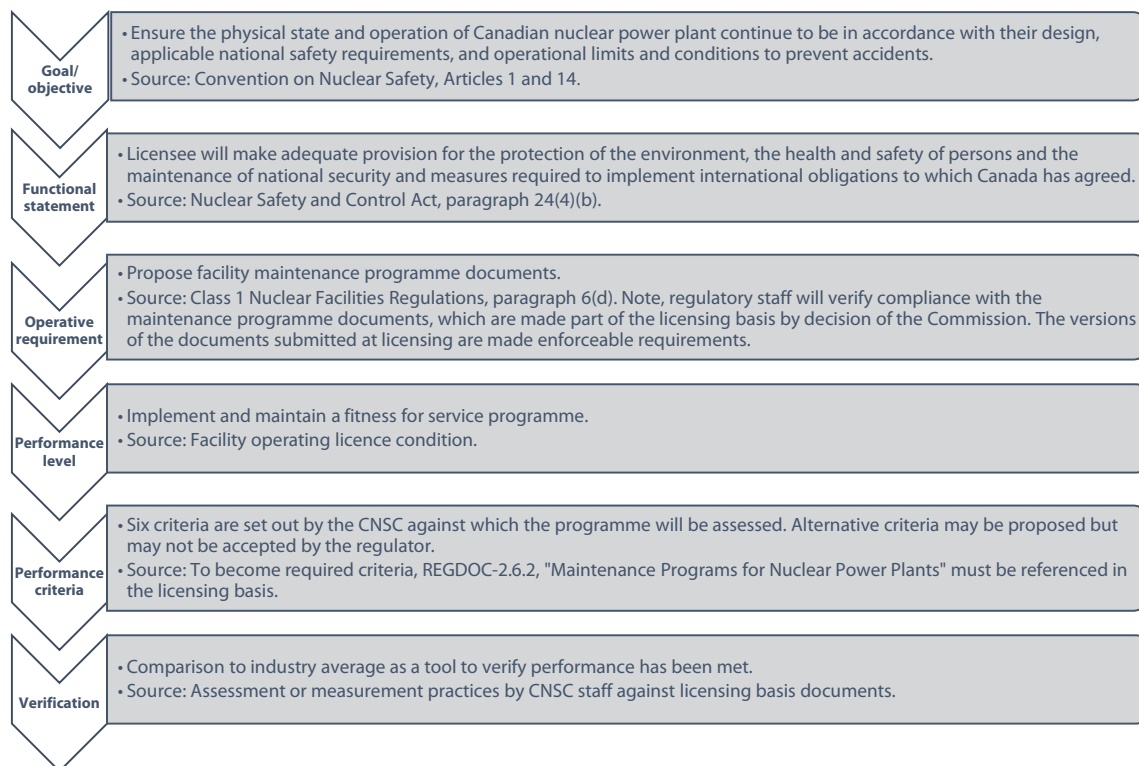
5.6 Verification

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 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, 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. Coglianesse, 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 of 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 knowledgeably 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. Coglianesse, 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.