RISK-INFORMED DECISION MAKING AND THE REGULATION OF SMALL MODULAR REACTORS

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ABSTRACT

This thesis argues that small modular nuclear reactors (SMRs) can be regulated within the existing Canadian nuclear regulatory framework in light of existing regulatory principles, and that regulatory flexibility and the development of risk management practices will be crucial to accommodate the many challenges associated with their regulation. SMRs are characterized by their small size, modularity and innovative approaches to design. Though advantageous, these novel characteristics introduce uncertain and novel risks that pose challenges to Canada's risk assessment and risk management practices. The most significant challenge to Canada's regulators is how SMRs can be safely regulated while imposing regulations that have the appropriate scope, detail and content for each proposed SMR project.

This thesis argues that Canada's risk-informed decision-making process must be bolstered to mitigate the variability and uncertain risks of SMRs. Emphasis is placed on the utilization of the graded approach to accommodate the variability of SMR projects and demonstrate that associated risks meet regulatory objectives. In addition to the graded approach, this thesis proposes risk management approaches that may better utilize uncertainty analyses to ensure that conservative measures are appropriate and that regulatory objectives are satisfied. A method to elicit and assess expert judgment for risk-informed decision-making is proposed to alleviate risk uncertainty and fill gaps in risks. Using these tools, regulators may better accommodate the risks of SMRs without relying on conservative measures to justify the satisfaction of regulatory requirements.

This thesis also investigates how type certification of SMR designs can be used to streamline the licensing process to take advantage of their quick construction and installation times. Type certification is the process of certifying a design such that reproductions of that design are assumed to meat regulatory requirements thereby reducing the depth of analysis for subsequent risk assessments of the same reactor. In the type certification process, the assurance that SMR designs can be reproduced by the manufacturer consistently and accurately is a significant concern. The examination of the aviation industry and maritime transport industry yield effective strategies for assuring the reproducibility of SMR designs that may be implemented within Canada.

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TABLE OF CONTENTS

PERMISSION TO USE i
DISCLAIMER i
ABSTRACT ii
ACKNOWLEDGEMENTS iii
Chapter 1: Introduction 1
1.1 Background 1
1.2 Outline 4
1.3 Methodology 6
1.4 Scope 7
Chapter 2: The Regulatory Approach of the CNSC 10
2.1 Introduction 10
2.2 Overview of the role of the CNSC 11
2.2.1 The establishment of the CNSC 12
2.2.2 Licensing phases of SMRs 13
2.2.3 Regulatory Documents 15
2.2.4 Public Involvement 16
2.2.5 Conclusion 19
2.3 Regulatory principles and fundamentals of the CNSC's decision-making 20
2.3.1 Safety objectives of the CNSC 21
2.3.2 Risk-informed decision-making and the regulatory principles that underpin it . 26
2.3.3 The fundamental safety function of "control, cool and contain" 32
2.3.4 Conclusion 34
2.4 The fit of SMRs in Canada's regulatory framework (or the lack thereof) 36
2.4.1 Issues raised by DIS-16-04 37

2.4.2 Responses to DIS-16-04 and consultation with stakeholders 41
2.4.3 Changes in response to DIS-16-04 and consultation with stakeholders 43
2.4.4 Regulatory capture and pursuing recommendations of industry......................... 46
2.4.5 Conclusion.. 48
2.5 Conclusion 49
Chapter 3: Regulating Risks and Uncertainty... 51
3.1 Introduction 51
3.2 Types of regulatory bases 52
3.2.1 Prescriptive-based, performance-based and process-based regulation 53
3.2.2 Performance-based regulation and the standardization of convention................ 55
3.2.3 Conclusion.. 57
3.3 Safety analyses and addressing uncertainty and gaps in risk assessments 58
3.3.1 The uncertainty of SMRs 59
3.3.2 Safety analysis policy of the CNSC 61
3.3.3 Accommodating uncertainty for risk management 68
3.3.4 Conclusion.. 72
3.4 Supporting the elicitation of expert judgement for risk assessment 73
3.4.1 Eliciting expert opinion for quantitative and qualitative risk assessment........... 74
3.4.2 Implementing expert judgement into Canada's regulations............................... 81
3.4.3 The application of the graded approach 87
3.5 Conclusion 92
Chapter 4: The type certification of SMRs 93
4.1 Introduction 93
4.2 The use of type certification by the Federal Aviation Administration of the United States ……………………………………………………………………………94

4.2.1 Criticisms of the FAA: Conflict of interest and Regulatory capture 97

4.2.2 The Canadian perspective 100

4.3 The use of type certification by the Maritime transport industry 102

4.3.1 Criticisms of the Classification Societies: Market pressures and quality discrepancies 106

4.3.2 The Canadian perspective 107

4.4 Type certification of SMRs and accommodating complexity in Canada 109

4.5 Conclusion 113

Chapter 5: Conclusion 115

Bibliography 121

Glossary 129

List of Abbreviations

ABS	American Bureau of Shipping
ALARA	As low as a reasonably achievable
CANDU	Canada Deuterium Uranium, a heavy-water nuclear reactor
CEAA	*Canadian Environmental Assessment Act*
CNSC	Canadian Nuclear Safety Commission
DER	Designated engineering representative
DRDC	Defence Research and Development Canada
FAA	Federal Aviation Administration
IACS	International Association of Classification Societies
IAEA	International Atomic Energy Agency
IMO	International Maritime Organization
MA	Manufacturer Assessment
MWe	Megawatt electric
MWt	Megawatt thermal
NEA	Nuclear Energy Agency
NSCA	*Nuclear Safety and Control Act*
NSR	*Nuclear Security Regulations*
OECD	Organisation for Economic Co-operation and Development
PBMR	Pebble-bed modular reactor
PDA	Product Design Assessment Certificate
RIDM	Risk-informed decision making
SCA	System control area
SMR	Small Modular Reactor
TRISO	Tristructural-isotropic, a fissionable fuel
VDR	Vendor diagram review
vSMR	Very small modular reactor

Chapter 1: Introduction

1.1 Background

Small modular reactors ("SMRs") are nuclear fission reactors with a power generation of 300 MWe or less[1] and are characterized by their modularity, small size, innovative design and approaches to safety. SMRs can vary greatly in design features, size and cooling types.[2] Additionally, the modularity of SMRs provides them with significant advantages, such as reduced durations for on-site construction, increased containment efficiency and increased security and safety. Though the design of SMRs may vary between vendors, many SMRs achieve high levels of safety through their innovation, safety features and approaches to power generation. As a result, many SMRs provide greater levels of safety than traditional large nuclear power plants. The advantages of SMRs make them an inexpensive alternative to conventional nuclear power plants and a viable energy option to replace non-sustainable sources.

SMRs and conventional reactors differ in energy output and size. Canada's smallest commercial reactor in commission is 515 MWe at the Pickering Nuclear Generating Station, though the cumulative net power output of this facility's 6 reactors is 3100 MWe.[3] Comparatively, SMRs at most output 300 MWe and may be deployed as a single reactor or as multiple reactors in a fleet. Additionally, SMRs may employ drastically different technology and approaches to energy production than conventional nuclear reactors used in Canada. All installed commercial reactors in Canada are CANDU reactors, aptly named after its use of a deuterium oxide moderator and (originally) uranium fuel. However, SMRs may be scaled down versions of existing technologies or may be completely new Generation IV technologies.[4]

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[1] See World Nuclear Association, "Small Nuclear Power Reactors" (October 2018) online: World Nuclear Association website <world-nuclear.org/information-library/nuclear-fuel-cycle/nuclear-power-reactors/small-nuclear-power-reactors.aspx> [perma.cc/S6C6-UJ97].

[2] *Dis-16-04, infra* note 120 at 3.

[3] International Atomic Energy Agency, *Nuclear Power Reactors in the World,* Reference Data Series No 2, 2016 Edition (Vienna: IAEA, 2016) at 33.

[4] Giorgio Locatelli, Mauro Mancini, & Nicola Todeschini, "Generation IV nuclear reactors: Current status and future prospects" (2013) 61 Energy Policy 1503 (Generation IV reactors are those that are being researched by the Generation IV International Forum. Generation IV reactors include very high temperature reactors, sodium fast reactors, super-critical water cooled reactors, gas cooled fast reactors, lead cooled fast reactors and molten salt reactors at 1503)

The innovative design features of SMRs can vary significantly and include novel approaches to power generation, safety, security, automation, application and much more. It is unclear how many different SMR designs are currently in development, but Canada's nuclear regulator, the Canadian Nuclear Safety Commission (the "CNSC"), is currently reviewing the designs of ten different SMR reactor types.[5] Other sources have listed more than 40 unique designs.[6]

SMRs have broad applications and are advantageous for Canada's natural resource sector, remote communities and utilities. For example, Bruce Power, the Mining Rehabilitation and Applied Research Corporation, and Laurentian University have signed a five year $1-million agreement to develop strategies to deploy SMRs for remote communities and mining operation that lack sufficient access to power grids.[7] Furthermore, the decreased costs and clean nature of SMRs are advantageous for utilities seeking to offset dependence on greenhouse gas-emitting sources, such as coal and fossil fuels, or to expand their capacity. The applicability of SMRs for Canada is heightened by the Canadian government's acknowledgement of the role of nuclear power in Canada's "greener energy system."[8] SMRs have the potential of filling this role as the energy industry advances, but first Canada must develop effective regulations to accommodate the technology.

Canada currently operates 22 pressurized heavy-water nuclear power plants which are all based on the CANDU reactor design. The CNSC's experience has laid solely with CANDU reactors since the beginning of its development in the late 1950s. Though regulations are developed to be technologically neutral, they are inescapably shaped by the CNSC's experience with CANDU reactors. To appropriately accommodate SMRs, industry and regulators agree that

[5] Canada, Canadian Nuclear Safety Commission, "Pre-Licensing Vendor Design Review" (18 July 2018), online: CNSC website <nuclearsafety.gc.ca/eng/reactors/power-plants/pre-licensing-vendor-design-review/> [https://perma.cc/89CU-677H].

[6] Ux Consulting Company, LLC, "Small Modular Reactor List" (last visited October 21st 2018), online: Ux Consulting website <https://www.uxc.com/smr/uxc_SMRList.aspx> [perma.cc/ZZZ5-9QBF]. See also World Nuclear Association, "Small Nuclear Power Reactors" (September 2018), online: World Nuclear Agency website <world-nuclear.org/information-library/nuclear-fuel-cycle/nuclear-power-reactors/small-nuclear-power-reactors.aspx> [perma.cc/FA4D-GQBX].

[7] Wendi Punkkinen, "Bruce Power signs $1 million MOU for sustainable energy research group" (6 April 2018) online: Bruce Power website <www.brucepower.com/sustainable-energy-research-smr-mou/> [perma.cc/JRS2-ST4H].

[8] Canadian Nuclear Association, "Canada's Nuclear Energy Future" (2017) 3:1 Public Newsletter, online: Canadian Nuclear Association website <cna.ca/news/canadas-nuclear-energy-future/>.

regulations need to be restructured to provide additional flexibility to account for their variability of design.

The CNSC has commenced regulatory plans to ready themselves for the regulation of SMRs. Consultation between the CNSC and the nuclear industry has yielded insight into the regulation of SMRs within the Canadian regulatory framework. Notably, the CNSC and the nuclear industry agree that regulations need further clarification for their application to SMRs and that regulations need to be less prescriptive so that they can better accommodate all types of SMRs.

The CNSC has broadly characterized the challenges of regulating SMRs into two categories: "Novel technologies" and "Novel approaches to deployment."[9] Both categories address significant challenges that will vary with each reactor design. The novel risks and deployment strategies of SMRs pose challenges to the CNSC's decision-making process and licensing strategies. Canada needs to address these challenges so that SMRs are effectively and efficiently regulated to meet Canada's energy needs.

The risks posed by SMRs can be categorized into novel risks and uncertain risks. Novel risks are those that may be adequately quantified but are unfamiliar to the CNSC and may require unconventional approaches to mitigate. For example, the safety assessments performed by Canadian regulations are developed based on its experience with CANDU reactors and thus poorly consider the inherent safety of SMR designs. Uncertain risks are those that are not quantified or are encumbered with significant uncertainty and challenge the CNSC's ability to make decisions confidently. Risk uncertainty is common for SMRs as many designs are still under development.

The novel deployment and modularity of SMRs pose challenges to conventional licensing practices. For instance, the deployment of SMRs in fleets, on the same site or separated by large geographic areas, is not capable of being considered within current licensing structure. Furthermore, the inspection of the reactor and components of SMRs is difficult as the pre-construction and modularity of the reactor limit the access of inspectors.

Overall, SMRs provide improved safety features, economic advantages, broad application to various industries and are advantageous for Canadians. However, Canada's current regulatory

[9] Kevin Lee, "Canadian Nuclear Safety Commission: Readiness for SMRs" (presentation delivered at the International SMR and Advanced Reactor Summit 2018, 17-18 March 2018) [unpublished].

regime is shaped by the CNSC's expertise with the regulation of CANDU reactors. This thesis aims to show that these challenges can be overcome through regulatory flexibility and by bolstering risk management approaches. That is, to successfully regulate SMRs within the existing framework, the CNSC must provide regulatory flexibility so that SMRs can be evaluated within the scope of their design. Additionally, regulatory tools to appropriately and proportionally assess the risks associated with SMR designs are needed to streamline the assessment under the current framework. Finally, licensing strategies are needed to accommodate the novel deployment strategies of which SMRs are capable. A list of abbreviations at page vii and a glossary at page 129 are provided for the reader's reference for when terms and abbreviations become difficult to keep track of, or where further information is needed.

1.2 Outline

This thesis argues that SMRs can be regulated within the existing Canadian nuclear regulatory framework, in light of existing regulatory principles, and that challenges associated with that regulation can be accommodated through regulatory flexibility and by bolstering risk management approaches. The chapters are aligned first to set out the framework of Canadian regulations and the challenges that arise with the application of the framework to SMRs. Second, the analysis of this thesis investigates how some of these challenges can be mitigated by providing additional regulatory flexibility, risk management strategies and expert judgement. Finally, the thesis concludes with the examination of licensing strategies of the aviation industry and maritime transport industry to accommodate mass-produced complex technologies.

Chapter 2 of this thesis introduces Canada's nuclear regulatory regime, the challenges of regulating SMRs and important regulatory fundamentals that underpin Canada's regulations. It is important to establish the regulatory framework so that the readers understand how the CNSC develops nuclear regulations, what objectives inform those regulation and how they apply regulatory principles for the safe regulation of nuclear power facilities. This chapter also explains in detail what constitutes risk-informed decision making and how it applies to SMRs. Risk-informed decision-making forms the foundation for the regulatory strategies and tools suggested within this thesis.

Chapter 3 discusses the approaches to address the risks and variability of SMRs within regulations and is broken down into three segments. The first segment recommends the use of performance-based regulation and the graded approach to achieve the regulatory flexibility necessary to regulate SMRs. The second segment suggests the use of uncertainty analysis within risk management practices to ensure the prudent application of conservatism by the graded approach and other regulatory principles. Uncertainty analysis is an integral tool for regulators to ensure the economical application of conservatism – i.e. without over or under confidence – and the satisfaction of regulatory objectives. The final segment develops and recommends an expert elicitation method capable of being integrated within current policies to quantify uncertain risks of SMRs. Expert elicitations can produce accurate risk distributions that can be relied upon within probabilistic and deterministic risk assessments.

The final chapter examines how type certification can be integrated into Canada's regulatory regime to accommodate the novel deployment strategies of SMRs. Type certification is the regulatory activity of certifying designs and ensuring their reproducibility for future assessments, thereby reducing assessment duration and workload. The maritime transport industry and the aviation industry are studied for this purpose, as they lend insight into the type certification of complex products with high-consequences events. This chapter also provides surprising insight into the regulation of complex designs produced in mass and has instructional value for the CNSC if they choose to add a type certification regime into their regulatory framework.

The approach of this thesis is not to address the challenges of SMRs on an individual basis, but to bolster regulatory approaches so that regulations can accommodate all SMRs, despite the specifics of their design. In this way, the regulation of SMRs avoids an *ad hoc* process. This approach also avoids prescriptive requirements which increase the rigidity of regulations.

This thesis is novel because it argues at length that Canadian regulations can regulate SMRs successfully within existing regulatory principles economically and expediently. The CNSC has made broad statements regarding the regulations of SMRs but has not delved into their regulation with any specificity. This thesis presents an in-depth and never before completed assessment of the regulation of SMRs. This thesis has advantages and application for Canada as it provides regulatory strategies for the safe and effective regulation of SMRs. Although this thesis is aimed at how Canada can accommodate SMRs within their regulations specifically, the strategies suggested provide regulatory flexibility employable for all reactor types including advanced reactors, such as Generation IV reactors, and other established designs.

1.3 Methodology

This thesis aims to develop regulatory strategies within the existing policies of the CNSC and consults materials published by the CNSC and international bodies, and examines regulatory theory generally. The regulatory documentation, licensing strategies and other materials published by the CNSC are heavily consulted to provide both the skeletal framework of Canada's nuclear regulation applicable to SMRs and to provide insight into what strategies may be inserted to improve the regulation of SMRs. Furthermore, material published by international nuclear agencies such as the International Atomic Energy Agency and the Nuclear Energy Agency are consulted to provide additional perspective on how to regulate nuclear power plants. These materials are germane to Canada's regulation as Canada has entered into many conventions and agreements with these bodies which inform fundamental aspects of Canada's regulations. Thus, these international materials provide persuasive insight into Canada's regulations.

Regulatory theory, in the general sense, is consulted to expound on the principles and doctrines adopted by the CNSC. Regulatory theory provides insight into the advantages and disadvantages of regulatory principles adopted by the CNSC, and is used to assess the methods and strategies suggested within this thesis. Regulatory theory as it applies to nuclear regulation is also consulted; however, the literature in this area is limited. For this reason, regulatory theory is examined where applicable.

Finally, this thesis consults with literature on the type certification approaches taken by the Federal Aviation Administration of the United States and by the maritime shipping industry. The aim of reviewing this literature is to provide insight into type certification approaches of other regulatory bodies governing complex domains. In particular, literature criticizing the type certification structures of these industries are examined to illustrate some of the challenges and pit falls of this type of regulation. The aim of this study is not to develop a detailed type certification structure of Canada's nuclear industry, but to highlight its strengths and weaknesses.

The claims made in this thesis are supported by the material relied upon and mentioned above. Though attempts are made to support claims using academic and other objectively neutral literature, such material, as it applies to the nuclear industry, is limited. As a result, many claims of this thesis are informed and supported by materials provided by the CNSC, international organisations and stakeholders within Canada's nuclear industry. Though this thesis intends and attempts to provide an objective discussion of the material, it is acknowledged that some material relied upon may knowingly or unknowingly be biased towards private interest. To balance competing interests, this thesis examines the material relied upon in an objective and fair manner, with a close eye on the intention, influence and actions of the authors where appropriate.

1.4 Scope

This thesis examines Canadian nuclear regulations to bolster them for the regulation of SMRs. This thesis relies primarily on the regulatory documentation of the CNSC to develop a framework to safely and appropriately regulate SMRs. Additionally, this thesis examines literature on regulation generally and specific to nuclear regulation to develop strategies to regulate novel and complex nuclear technology. Additionally, this thesis examines risk assessment, risk management and risk elicitation literature to develop regulatory strategies to mitigate the challenges arising with the risks associated with SMRs. Finally, literature regarding the maritime transport industry and the aviation industry are consulted to illustrate how type certification can be implemented into Canadian nuclear regulation and the complications it may create with Canada's nuclear regulations.

The CNSC has authority over all aspects of nuclear regulation and provides extensive regulatory documentation of their expectations. Extensive analysis is conducted on the CNSC's regulations to provide a framework in which to make recommendations for the regulation of SMRs. This analysis is integral as regulatory strategies and recommendations made within this thesis are evaluated based on their impact on the regulation of SMRs and their integration within the existing framework.

This thesis does not aim to develop regulations for specific SMR designs but aims to bolster regulations so that they may regulate all SMRs without any specificity. By maintaining a broad scope, this thesis avoids inflexible prescriptive requirements that would hinder the regulation of SMRs generally. To otherwise develop regulations specific to each SMR design would be an insurmountable task considering the number of SMR designs currently in development. Any reference to specific SMR designs within this thesis is done only to provide examples and should not be taken as developing regulations specific to that design.

This thesis does not examine the approaches taken to regulate SMRs in other countries because of the limitations to the length of this thesis and the lack of specificity the regulations of other countries may have to Canada's regulatory framework. However, it is noted that SMRs have gained international popularity as evidenced by the yearly held International SMR & Advanced Reactors Summit, and that many countries have begun considering the deployment of SMRs. The United Kingdom[10] and the United States[11] , for example, are two countries where the industry is pushing for the deployment of SMRs. This thesis suggests that the CNSC look into the approaches taken by other countries for the regulation of SMRs, if it has not already, to ensure it employs the most effective approach.

This thesis considers the guidance provided by the Nuclear Energy Agency of the Organisation for Economic Co-operation and Development and the International Atomic Energy Agency. These international bodies provide valuable insight into Canada's regulations and the regulation of nuclear power generation generally. Additionally, Canada's regulations embody the international commitments entered into with these international bodies. Thus, the guidance provided by these bodies provide persuasive insight into Canadian regulations.

This thesis examines the use of type certification by the Federal Aviation Industry of the United States and by international maritime transport. These two industries are used as examples for the type certification process of complex systems that risk catastrophic failure for the purpose of considering what approaches may be appropriate for the certification of SMR designs. This thesis does not perform a case study on these industries but use them as an example of how type certification may be carried out for complex systems and the challenges that arise. The two

[10] See World Nuclear News "UK institute proposes SMR deployment schedule", World Nuclear News (29 September 2016) online: <www.world-nuclear-news.org/Articles/UK-institute-proposes-SMR-deployment-schedule> [perma.cc/RFK8-H5VE].
[11] See World Nuclear News "US group Calls for SMR support", World Nuclear News (12 October 2017) online: <www.world-nuclear-news.org/Articles/US-group-calls-for-SMR-support> [https://perma.cc/Q69P-67HC].

industries provide dissimilar approaches to assessment for type certification and outline challenges of implementing a similar system in Canada.

This thesis examines in depth how SMRs may be better accommodated within Canadian regulations but is limited by the maximum page amount and the complexity of the subject matter. The subject matter of this thesis is complex and discusses engineering, regulatory theory, regulatory law, and statistics. This thesis attempts to present these subjects to the reader in a digestible manner and therefore may lack in-depth discussions of some aspects. Additionally, this thesis deliberately does not address the legal issues relating to the consultation or involvement of Indigenous peoples that may arise during the assessment, licensing, or planning of SMR projects, but recognizes that some may exist.

Chapter 2: The Regulatory Approach of the CNSC

2.1 Introduction

The *Nuclear Safety and Control Act* charges the CNSC with the duty to establish and enforce national standards in the areas of health, safety and the environment and to fulfill Canada's international obligations.[12] To achieve these objectives, the CNSC is provided broad powers to regulate nuclear activities within Canada, including the power to develop regulations.[13] As such, the CNSC has developed a regulatory framework that aims to satisfy the objectives of the *NSCA.* This framework embodies "performance-based regulation" and "risk-informed decision-making" to assess nuclear activities, which are integral regulatory aspects for the regulation of SMRs and are explained thoroughly in the following section.

The following analysis discusses how the regulatory framework ensures the safety objectives of the *NSCA* are satisfied and how SMRs pose challenges to that process. An overview of these objectives, the nuclear licensing process of Canada, and the regulatory principles that underpins Canada's regulatory framework is provided to define the backbone of Canada's nuclear regulatory framework. The analysis provides an in-depth discussion of the important regulatory principles used by the CNSC to make risk-informed decisions to provide fundamental insight into how regulations may be expanded and developed to accommodate SMRs. The discussion illustrates the challenges SMRs pose to regulation and the regulatory principles in which SMRs must submit.

The purpose of this chapter is to outline Canada's regulatory framework and how SMRs are to be regulated therein. The analysis demonstrates the dissonance between SMRs and the current regulatory framework. Novel risks and alternative deployment strategies of SMRs pose challenges to Canada's nuclear regulatory framework because of the specificity of Canada's regulations to CANDU reactors – that is Canada's regulations promulgate requirements, objectives and expectations specific to CANDU technologies. Conversely, SMR designs may implement

[12] Arslan Dorman, Robert W Morrison, & GB Doern, *Canadian Nuclear Energy Policy: Changing ideas, institutions, and interests* (Toronto: University of Toronto Press, 2001) at 103. See also *Nuclear Safety and Control Act*, SC 1997, c 9, s 8(1) [*NSCA*].

[13] Dorman, *ibid.*

automation, be safe by design, be premised on fundamentally different approaches to nuclear power generation or use other novel and innovative technologies. As a result, some expectations may not apply, such as containment requirements, exposure to radiation, and waste disposal practices. Additionally, the CNSC may face risks unfamiliar to them or that lack certainty. This Chapter argues that regulatory flexibility and bolstering of the framework may aid to address the differences between the technologies and accommodate the challenges posed by SMRs to Canada's regulations.

2.2 Overview of the role of the CNSC

The regulatory framework developed by the CNSC is a mixture of performance and prescriptive-based regulation.[14] Prescriptive regimes provide specific requirements for the issuance of licenses or certificates approving the regulated activity to be carried out.[15] Performance-based regimes place the onus on the operators to prove that set targets are satisfied.[16] Set targets are typically aspirational goals such as reducing risk as low as reasonably achievable, or ensuring that risks are reasonable.[17]

Under the *NSCA*, the CNSC is empowered to develop regulatory requirements as it sees fit. The CNSC determines the regulatory requirements to be met by applicants seeking to obtain a licence to site, construct, operate, decommission or abandon a nuclear facility. Licences and certificates set out binding conditions to which licensees must comply. The requirements of licenses are set out in the regulations developed by the CNSC, whereas regulatory documents are supplementary and provide greater detail on what must be achieved by the licensee or an applicant seeking a license. These regulatory documents provide in-depth guidance on how to successfully meet the regulatory requirements of the CNSC.

[14] Kevin Lee, "The Canadian Nuclear Safety Commission: Readiness Activities to regulate Small Modular Reactors" (Paper delivered at the 26th International Conference on Nuclear Engineering, 22–26 July 2018) [unpublished] at 3.

[15] Nuclear Energy Agency Organisation for Economic Co-Operation and Development, *The Characteristics of an Effective Nuclear Regulator*, Nuclear Regulation NEA No 7185 (Paris: OECD Publishing, 2014) [Nuclear Energy Agency, *Characteristics of an Effective Regulator*] at 25.

[16] Dorman, *supra* note 12 at 98.

[17] *Ibid.*

2.2.1 The establishment of the CNSC

The CNSC is established by the *NSCA* to regulate all nuclear activities within Canada. In this role, the CNSC is required by the *NSCA* to limit risk to a reasonable level, to provide licenses only to those who are qualified to carry on the nuclear activity and ensure the satisfaction of Canada's international obligations. To achieve these objectives, the CNSC is given a broad set of powers including the authority to develop regulations, issue licenses and to enforce those licenses. The discussion of how the CNSC derives its authority and objectives provide fundamental background information on how the CNSC impose their regulations and make their decisions.

As Canada's nuclear regulator, the CNSC embodies the fundamental purpose of the *NSCA* to "limit to a reasonable level … 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" and to implement the measures Canada has agreed to respect through its international obligations.[18] To accomplish this, the CNSC has devised an extensive regulatory framework that assesses the safety of nuclear activity applications based on a myriad of goals, objectives, risk management practices and risk assessments. The onus is on the proponent to demonstrate that their proposed activity satisfies regulatory expectations, upon which the proponent will be issued a license.

Section 24(4)(a) and (b) of the *NSCA* authorize the CNSC to issue or otherwise provide a license to an applicant where the applicant is "qualified to carry on the activity that the licence will authorize the licensee to carry on" and where the applicant makes "adequate provisions 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."[19] Section 24(4)(a) and (b) place the onus on the applicant to prove that the activity being licensed meets the objectives and requirements of the *NSCA* and Canada's international obligations. Section 24(4)(a) and (b) is fundamental to Canada's regulatory framework and forms the basis for its mixture of performance and prescriptive-based regulation.[20]

Canada's international obligations provide imperative regulatory requirements for the applicant. Canada has ratified many treaties and conventions, most of them arising out of

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[18] *Supra* note 12 s 3(a)–(b).
[19] *Ibid*, s 24(4)(a)–(b).
[20] Lee, *supra* note 14 at 3.

agreements of safeguards and measures entered into with the International Atomic Energy Association (the "IAEA")[21] and the Nuclear Energy Agency.[22] These agreements and other international commitments are embodied within the nuclear regulations.

The regime set out by the *NSCA* establishes the CNSC as an arms-length government regulatory agency to ensure that Canada's international commitments are met and that national standards in the areas of health, safety and the environment are enforced.[23] Through this authority, the CNSC has devised an extensive regulatory framework to ensure that licenses are issued to proponents who demonstrate that their activity pose reasonable risk.

2.2.2 Licensing phases of SMRs

Under Canadian regulations, SMRs are considered a Class IA nuclear facility and thus must meet the regulatory requirements promulgated within regulations regarding those types of facilities. Under the *Class I Nuclear Facilities Regulations* there are five licensing phases within the life cycle of a Class IA reactor.[24] Additionally, applicants are required to obtain licenses to possess, use, transport and store nuclear substances. The following is an overview of the licensing process applicable to SMRs.

A license is required for the site preparation, construction, operation, modification, and decommissioning or abandoning of a Class IA facility.[25] Such licenses are issued to an applicant depending on whether the applicant has met the conditions set by the *NSCA* and the requirements prescribed by the regulations. The onus is on the applicant to demonstrate that they are qualified to carry on the activity that the licence authorizes and that there are adequate provisions for maintaining the objectives of safety, security and standards required by Canada's international obligations.[26] In assessing an application for a license, the CNSC places scrutiny on the activity

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[21] The IAEA is an autonomous organisation established independently of the United Nations and serves as an intergovernmental for nuclear cooperation amongst countries.

[22] The NEA is a specialised agency within the OECD that promotes development of nuclear energy for peaceful purposes.

[23] Dorman, *supra* note 12 at 103-104.

[24] *Class I Nuclear Facilities Regulations*, *SOR/2000-204*, ss 3–8.

[25] *NSCA*, *supra* note 12 ss 9, 21(1), 26(e). See also *ibid*, ss 4–8.

[26] *Ibid* s 24(4)(a)–(b).

commensurate with its risk, which is an exercise of the graded approach and is discussed further in the following section.

An environmental assessment (EA) must be performed before obtaining a license for the siting of a reactor; however, a proponent may complete an EA and the application for a license to site simultaneously. Currently, the *Canadian Environmental Assessment Act, 2012,*[27] is the governing legislation for the completion of EAs. Under the *CEAA* the CNSC is the responsible authority for carrying out environmental assessments. However, this responsibility will soon be reduced to a minor consultative role as the *CEAA* will be repealed once Bill C-69 receives Royal Assent and enacts the *Impact Assessment Act.*[28] Under the *IAA*, assessments of nuclear activities regulated under the *NSCA* are referred to a joint review panel consisting of members appointed by the Minister of the Environment, rather than to the CNSC.[29]

Vendor design reviews (VDRs) is an optional pre-licensing process established in 2008 by the CNSC and provides a preliminary assessment of reactor designs to inform the vendor of the overall acceptability of the design.[30] The determinations made in a VDR do not bind or influence the later decision to issue or otherwise provide a licence.[31] The VDR evaluates whether the design complies with applicable regulations and provides certainty by providing clear feedback, identifying technical issues, reducing significant changes to the design later on in the application process and reducing the amount of time to assess the design during the review of applications.[32] The objective of pre-licensing engagement is to increase regulatory clarity for applicants.

The CNSC may issue, renew, amend, replace or suspend a license. Additionally, the CNSC may prescribe and enforce licensing conditions to satisfy the requirements of the *NSCA*. However, the onus is on the applicant to demonstrate that regulatory requirements are satisfied and that they have adequate provisions to meet the objectives of the *NSCA*. To make this determination, the

[27] *Canadian Environmental Assessment Act, 2012,* SC 2012, c 19, s 52.
[28] Canada, Bill C-69, *An Act to enact the Impact Assessment Act and the Canadian Energy Regulator Act, to amend the Navigation Protection Act and to make consequential amendments to other Acts*, 1st Sess, 42nd Parl, 2018 [*Bill C-69*].
[29] *Ibid,* cl 43(a).
[30] Canada, Canadian Nuclear Safety Commission, *Pre-licensing Review of a Vendor's Reactor Design*, GD–385 (Ottawa: CNSC, May 2012) at 1.
[31] *Ibid.*
[32] *Ibid.*

CNSC has produced regulatory documents that outline its policies, which include measures, procedures and requirements that applicants must demonstrate or otherwise satisfy.

2.2.3 Regulatory Documents

Regulatory documents detail and provide guidance on what licensees and applicants must accomplish to satisfy regulatory requirements. Regulatory documents are produced through a transparent and consultative process between the CNSC and stakeholders and form the foundation of licensing assessments. Regulatory documents produced by the CNSC are numerous and amount to more than 70 documents, with more continuously being developed. Regulatory documents provide guidance for all nuclear activities including SMRs.

Important regulatory documents for the regulation of SMRs include *RD-367: Design of Small Reactor Facilities,*[33] *Design of Reactor Facilities: Nuclear Power Plants*[34] and the *Licence Application Guide: Licence to Construct a Nuclear Power Plant.*[35] *RD-367: Design of Small Reactor Facilities* provides design specifications and safety requirements for facilities containing a reactor with a power level of less than 200 megawatts thermal, which only some SMRs may fall within.[36] Though *Design of Reactor Facilities: Nuclear Power Plants*[37] and *Licence Application Guide: Licence to Construct a Nuclear Power Plant*[38] provides guidance specific to commercial water-cooled nuclear power plants, some aspects are also applicable to SMRs.

Licence application guides outline the information that should be submitted by the applicant in support of the licence sought. Common to all license application guides are the safety and control areas ("SCAs"), which are technical topics the CNSC employs to "assess, review, verify and report on regulatory requirements and performance across all regulated facilities and

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[33] Canada, Canadian Nuclear Safety Commission, *Design of Small Reactor Facilities,* RD-367 (Ottawa: CNSC, June 2011) [Canada, *Design of Small Reactor Facilities*].

[34] Canada, *Design of Reactor Facilities*, *infra* note 75.

[35] Canada, Canadian Nuclear Safety Commission, *Licence Application Guide: Licence to Construct a Nuclear Power Plant*, RD/GD-369 (Ottawa: CNSC, August 2012).

[36] *Supra* note 33 at 1.

[37] *Supra* note 34

[38] *Supra* note 35 at i.

activities."[39] The 14 SCAs specify considerations to be addressed by license applicants. In their assessments of license applications, the CNSC considers the measures taken by the applicant to address the SCA proportionate to the risk associated with the activity. This approach to assessment is known as the graded approach and is discussed further in this chapter.

There are numerous types of regulatory documents produced by the CNSC that provide information and guidance for applicants attempting to license SMRs. Licence application guides are one type of regulatory document and provide direct guidance on what needs to be addressed and considered in a licence application. Other regulatory documents may consider aspects of regulation such as regulatory fundamentals, probability safety assessment practices, public involvement and more. Regulatory documents provide the foundational information and guidance of the CNSC's expectations for the regulation of nuclear activities.

2.2.4 Public Involvement

The CNSC considers the views of the public and stakeholders in all licensing decisions in accordance with their mandate to regulate in the best interest of Canadians. There are three primary areas where the public is engaged to address their concerns regarding a nuclear project or activity. First, the public is involved in environmental impact assessments according to the *CEAA.* Second, public hearings are held prior to granting licences by the CNSC. Finally, the CNSC requires that proponents engage in a public information disclosure program that necessitates public engagement commensurate with the complexity of the project and public perspective. These public engagement strategies are consistent with the objectives of the *NSCA* and the duties of the CNSC.

The CNSC is mandated by the *NSCA* to regulate in the interest of the public, which includes addressing the concerns of the public and informing them of the effects of nuclear activities on the environment, and the health and safety of the public.[40] The *Regulatory Policy: Regulatory Fundamentals* further outlines the objectives of the CNSC's engagement with the public, and directs the CNSC to:

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[39] Canada, Canadian Nuclear safety Commission, Glossary of CNSC Terminology, REGDOC-3.6 (December 2016) at 100 [Canada, *Glossary of Terminology*].

[40] *NSCA, supra* note 12 s 9(b).

1. Carry out its mandate in the interest of Canadians;
2. Communicate openly and transparently with stakeholders in an objective fashion while respecting Canada's access to information and privacy laws;
3. Provide stakeholders with the opportunity to be heard in accordance with the prescribed rules of procedure;
4. Consult with stakeholders when establishing priorities, developing policies, and planning programs and services;
5. Interact with foreign nuclear regulators and appropriate national and international organizations, and cooperate with other jurisdictions; and
6. Operate in an effective and efficient manner.[41]

Currently, environmental impact assessments are governed by the *CEAA*, which provides opportunities for the public to engage with proponents and government agents. The *CEAA* requires notices or reports to be made available to the public at numerous points during the assessment process and invites public participation during the screening phase,[42] the completion of the impact assessment[43] and when making the decision to refer assessments to a review panel.[44] Additionally, as the responsible authority for impact assessments under the *CEAA,* the CNSC must establish a participant funding program to facilitate the participation of the public in environmental assessments of nuclear activities.[45] The requirement to establish a participant funding program is echoed within the *NSCA.*

Proponents are instructed by regulations to develop a public information and disclosure program to facilitate the participation of the public.[46] The aim of the program is "to ensure that information related to the health, safety and security of persons and the environment, and other issues associated with the lifecycle of nuclear facilities are effectively communicated to the public."[47] The proponent determines the development of the objectives, strategy, protocol and scope of the program; however, the program is overseen and approved by the CNSC.[48]

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[41] Canada, Canadian Nuclear Safety Commission, *Regulatory Policy: Regulatory Fundamentals*, P-299 (Ottawa: CNSC, April 2015) at 2 [Canada, *Regulatory Fundamentals*].

[42] *CEAA*, *supra* note 27 s 9(c).

[43] *Ibid* ss 24, 19(1).

[44] *Ibid* s 38(2)(b).

[45] *Ibid* s 58(1).

[46] *NSCA*, *supra* note 12 ss 21(1)(b.1) and (e).

[47] Canada, Canadian Nuclear Safety Commission, *Public and Aboriginal Engagement: Public Information and Disclosure*, REGDOC-3.2.1 (Ottawa: CNSC, May 2018) at 2.

[48] *Ibid*.

Importantly, the level of public engagement by the proponent is commensurate with the complexity of:

- the level of public interest they generate
- the design, construction and operation of the nuclear facility and activities being licensed
- the risks to the health and safety of persons and the environment associated with the facility and activities.[49]

Further requirements specific to the engagement of Indigenous Peoples are found in *Public and Aboriginal Engagement: Aboriginal Engagement.*[50]

In addition to the public information and disclosure program, the CNSC provides an opportunity for the public to participate in a public hearing with respect to the granting of a licence, or where it is in the public interest to do so.[51] Public hearings allow the public and stakeholders to learn about the nuclear activity and provide an opportunity to be heard in front of the CNSC.[52] In keeping with their mandate to regulate within the best interest of the public, the CNSC must address the concerns raised during the public hearing, and elsewhere, before deciding to grant a licence.

The weight given to public and stakeholder concerns can be ambiguous. The *NSCA* requires that all issues or comments raised during public hearings be addressed by the CNSC and includes hearings conducted during environmental assessment as per the CNSC's responsibility under the *CEAA*. However, it is not clear whether a review panel exercising the powers of the CNSC when conducting an impact assessment under *IAA* will have this same obligation. Furthermore, acting in the interest of the public may not always coincide with public concern or opinion. The public may be biased, have incomplete information, or be poorly informed of the risks involved in the deployment and operation of a nuclear facility.[53] The CNSC balances the public's interest with objective assessments and information, and will rely on expert opinion when

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[49] *Ibid* at 4.

[50] Canada, Canadian Nuclear Safety Commission, *Public and Aboriginal Engagement: Aboriginal Engagement*, REGDOC-3.2.2 (Ottawa: CNSC, February 2016).

[51] *NSCA, supra* note 12 s 40(5)(a)–(b).

[52] Canada, Canadian Nuclear Safety Commission, *Information Dissemination: Licensing Process for Class I Nuclear Facilities and Uranium Mines and Mills*, REGDOC-3.5.1, Version 2 (Ottawa: CNSC, May 2017) at 3.

[53] See Cass R Sunstein, "Beyond the Precautionary Principle" (2003) 151 U PA L Rev 1003 (Sunstein explains that public concerns of nuclear power are not linked to the actual risk of those hazards and that those concerns are unproportionate to the quite low risks associated with the technology at 1045 and 1051).

faced with uncertainties.[54] The balancing of these considerations in the assessment of a nuclear activity is done under the risk-informed decision-making model employed by the CNSC, which employs a myriad of regulatory principles to ultimately make decisions regarding the granting of licenses.

Acting in the interest of the public is a paramount obligation of the CNSC and forms an important aspect of the regulatory framework. The CNSC achieves public participation through multiple levels of public consultation, discourse, and disclosure. This practice aims to ensure that the public is informed of the proposed projects and its risks. In the regulation of SMRs, public opinion poses significant, though necessary, challenges, especially considering that literature has concluded that the public is more opposed to the regulation of novel technologies than pre-existing and more familiar technologies, products or activities.[55] Thus, public engagement becomes increasingly more important when regulating SMRs to ensure that the public is accurately and well informed of its novelty and risks. Additionally, the public's trust may be bolstered where SMRs are regulated under a robust and effective regulatory framework. Proposed regulations of SMRs must, therefore, embody and consider these aspects in order to successfully deploy SMRs.

2.2.5 Conclusion

The above provides a brief outline of the structure of Canada's nuclear regulatory framework. The CNSC plans to proceed with the regulation of SMRs under the same framework, albeit with minor variations. To ready Canada for the deployment of SMRs, the CNSC plans to release additional regulatory documents to inform proponents of their expectations on how to satisfy the regulatory requirements.

Public opinion poses significant challenges and concerns for proponents. Early and thorough engagement of the public by proponents will be imperative to achieving favourable public opinions of their nuclear activities. Nuclear power plants already have an established public bias, while the novelty of SMRs inspires additional concern. For SMRs to be successfully and effectively deployed in Canada, public engagement must form an important consideration of the regulations. Regulatory theorists have addressed these issues in different ways and have proposed

[54] Canada, *Regulatory Fundamentals*, *supra* note 41 at 2.

[55] See generally Sunstein, *supra* note 53 (Sunstein discusses the precautionary principles, its misuse by the public and how its use has been criticized for stifling progress).

regulatory measures to address these issues; however, the matter remains problematic. It remains that this issue should be considered when evaluating regulatory approaches to SMRs to ensure effective measures are implemented.

To accommodate SMRs in the regulation, the above outlined regulatory process may remain the same; however, supporting regulatory documents may be developed or adjusted for this purpose. Not all regulatory documents need to be evaluated, but the regulatory principles employed within them may be. Approaches to risk-informed decision-making implemented by the CNSC may be expanded and re-purposed to accommodate SMRs. These approaches include the graded approach, the precautionary principle deterministic and probabilistic risk assessments and the reproducibility principle. These approaches are discussed in the following section.

2.3 Regulatory principles and fundamentals of the CNSC's decision-making

The CNSC practices risk-informed decision-making (RIDM) which is an overarching deliberative process that measures risk against a set of performance or safety objectives, along with other considerations, to inform their decisions.[56] RIDM contemplates whether activities meet regulatory requirements while recognizing the relevant role of human judgement, technical assessment and best available information.[57] RIDM is an overarching organizing philosophy that implements a myriad of decision-making tools and risk assessment approaches. Its application is not directly expressed by any of the CSNC's regulatory documents but may be gleaned by considering the CNSC's overarching decision making process.

The CNSC employ RIDM so that they may confidently make decisions in light of the safety objectives provided within the *NSCA* and other relevant legislation. Notably, these safety objectives are aspirational in nature and thus are not easily demonstrated. For example, the primary safety objective of the *NSCA* requires that risks to the environment and the public are kept at reasonable levels, while others center on keeping radiation exposure as low as reasonably achievable, ensuring that there is no adverse impact to the environment, and that all reasonably practical measures are taken. As aspirational goals do not outright provide prescriptive regulatory

[56] Enrico Zio & Nicola Pedroni, Fondation pour une Culture de Sécurité Industrielle, *Risk-informed decision-making processes,* (Toulouse, France: FONCSI, December 2012) at 4.
[57] *Ibid.*

requirements, the CNSC employs RIDM to assess the safety of proposed activities to ultimately arrive at a decision they believe qualitatively meet these objectives.

The regulatory documents produced by the CNSC provide insight into the administration of RIDM and the principles its process employs. Regulatory principles such as grading, probabilistic and deterministic risk assessment, the precautionary principle, defence in-depth, control cool and contain and others permeate throughout the CNSC's regulation and form integral aspects of the RIDM process. These principles help the CNSC assess the risk of proposed projects and whether applicants satisfy the safety objectives.

The following discussion explains how the safety objectives of the *NSCA* are met within the RIDM structure prescribed by the CNSC's regulations. Importantly, the discussion illustrates how the graded approach is administered and its implications to the regulation of SMRs.

2.3.1 Safety objectives of the CNSC

The *NSCA* and other pertinent legislation provide safety objectives that are aspirational in nature. These safety objectives consist of a primary objective and three complementary safety objectives. The primary safety objective requires that the risk of nuclear activities be limited to those that are reasonable, while complementary safety objectives provide aspirations in the areas of radiation exposure, environmental effects and technology. Both the primary and complementary safety objectives permeate all aspects of nuclear regulation, such as regulatory standards, behaviour modification or enforcement, and information gathering.[58] The CNSC employs RIDM to assess the safety of proposed activities and to ultimately arrive at a decision they believe qualitatively meet these objectives.

The primary safety objective is prescribed within the *NSCA* and mandates that risk be limited "to a reasonable level and in a manner that is consistent with Canada's international obligations, of the risks to national security, the health and safety of persons and the

[58] Robert Baldwin, Martin Cave, & Martin Lodge *The Oxford handbook of regulation* (Oxford New York: Oxford University Press, 2010) at 358.

environment..."[59] Limiting risk to a reasonable level imparts no prescriptive requirements for how this objective is met, but is an aspirational objective of performance-based regulation.

Whether the risk of a proposed project is mitigated to a reasonable level is determined discretionally by the CNSC on best practices and the performance of the proposed project.[60] The safety objective of "reasonable risk" is interpreted by the Organisation for Economic Co-operation and Development (the "OECD") as a qualitative criterion revealed in practice over several years.[61] The CNSC takes the same approach, citing the Federal Court of Appeal decision of *Canada v Berhad* as guidance on the statutory mandate regarding safety.[62] *Canada v Berhad* explains that safety is not measured quantitatively, rather "[i]t is judged according to an assessment of an acceptable risk: ... [a]n acceptable risk is essentially a value-based proposition determined by policy and/or by those authorized by governments to judge safety and/or by those exposed to the risk..."[63] The CNSC provides *Berhad* as support and justification for reliance on best practices and performance-based considerations for making regulatory decisions.

The CNSC prescribes three additional safety objectives that are complementary to the primary objective. These objectives are the radiation protection and acceptance safety objective, the environmental protection safety objective, and the technical safety objectives.[64] These complimentary objectives must be satisfied before the CNSC may grant a license and inform the overall primary objective of whether risks are limited to a reasonable level.

The radiation protection and acceptance safety objective originates from the *Radiation Protection Regulations,* which provides that the exposure of radiation within the reactor facility during anticipated operational occurrences, or any planned release of radiation, be kept as low as reasonably achievable (ALARA), taking into account social and economic factors, through the

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[59] *Supra* note 12 ss 3(a), 24(4).

[60] Canada, Canadian Nuclear Safety Commission, "How does the CNSC define safety?" (11 August 2014) [Canada, *Defining Safety*], online: <nuclearsafety.gc.ca/eng/resources/educational-resources/feature-articles/how-does-the-cnsc-define-safety> [perma.cc/252D-8JQJ].

[61] Nuclear Energy Agency Organisation for Economic Co-Operation and Development, *Nuclear Regulatory Decision-making*, (Paris: OECD Publishing, 2005) [Nuclear Energy Agency, *Nuclear Regulatory Decision-making*] at 17.

[62] Canada, *Defining Safety*, *supra* note 60. See also *Canada v Berhad*, 2005 FCA 267, [2005] FCJ No 1302 [*Berhad*].

[63] *Berhad*, *ibid* at para 122.

[64] Canada, *Design of small reactor facilities*, *supra* note 33 at 4.

implementation of different control processes and planning.[65] The CNSC has published a regulatory guide for keeping radiation exposure ALARA.[66] This guide explains that ALARA is achieved not only by respecting appropriate dose limits, but requires explicit efforts to reduce radiation exposure below dose limits where practical.[67] Whether measures are practical will depend on social and economic factors. The fundamental safety function of "control, cool and contain" is an important factor in assessing whether this safety objective is satisfied and is discussed further in section 2.3.3.

The environmental protection safety objective finds its impetus in the *CEAA* and the *NSCA* and requires applicants to demonstrate that their proposed nuclear activity poses no significant adverse effects to the environment during normal operation and anticipated operational occurrences, and where design basis accidents occur.[68] This complementary safety objective will persist when the *IAA* replaces the *CEAA* despite the removal of the CNSC as the responsible authority to perform impact assessments because the *IAA* continues to proscribe detrimental effects to the environment.[69] However, it is unclear how the CNSC will satisfy itself that this objective is met once it is removed as the responsible authority for impact assessments. Under the *IAA* the CNSC will have a far more limited capacity to assess whether this safety objective is satisfied and will rely upon the determinations of a review board who may not be as experienced as they are with the evaluation of nuclear activities.[70]

Finally, the technical safety objective prescribes that the design of facilities take all reasonably practical measures to prevent all accidents in the reactor facility and that appropriate measures are in place to mitigate those accidents if they occur.[71] This includes risks of very low

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[65] *Radiation Protection Regulations*, SOR/2000-203 s 4(a). See also *Packaging and Transport of Nuclear Substances Regulations*, 2015, SOR/2015-145, s 18(1).

[66] See Canada, Canadian Nuclear Safety Commission, *Keeping Radiation Exposures and Doses 'As low as Reasonably Achievable (ALARA)'*, G-129, Revision 1 (Ottawa: CNSC, October 2004).

[67] *Ibid* (Licencees are expected to reduce doses ALARA proportional to the magnitude of projected or historical doses, where relevant social and economic factors, and the views of the public are balanced with the benefits obtained at 2–3, 7).

[68] *Ibid* at 14. See also *CEAA*, *supra* note 27, s 52.

[69] Bill C-69, *supra* note 28 (the *IAA* maintains that there be no significant adverse effects to the environment at Part 1 cl 15(a)).

[70] See Andrew Dusevic, "The role of the CNSC under the proposed Impact Assessment Act" (2018) 6:3 Energy Regulation Quarterly 33 at 33–35.

[71] *Ibid*.

probability.[72] In practice, this safety objective is met primarily through the practice of defence-in-depth. The CNSC has a defence-in-depth framework for this purpose and is discussed more thoroughly in section 2.3.3.

As the name suggests, the complementary safety objectives support the primary objective of limiting risk to reasonable levels. Complementary safety objectives impart appropriate aspirational goals to the areas of environmental, radiological and technical safety, which form important consideration for ensuring the primary goal that the proposed activity does not introduce unreasonable risk. This interaction is illustrated by the SCAs which cover various aspects of environmental, radiological and technical control. The assessment of these SCAs by the CNSC ultimately determines whether the risk of the proposed activity is reasonable. Thus, complementary safety objectives promote the broader objective of preventing unreasonable risk.

The lack of operational history and gaps within risk assessments of SMRs frustrates that ability of proponents to demonstrate that risks meet safety objectives. When addressing SCAs, applicants must demonstrate with determinability that risks are mitigated to a reasonable level[73] which becomes difficult where there are gaps in risk assessments or where novel approaches outside the scope of the CNSC's experience are used to address the SCAs. The traditional method of managing these risks is to implement conservative measures like the use of defence-in-depth and safety margins. However, these measures may employ a level of conservatism disproportionate to the actual risk, or may not actually be necessary for the safe operation, but are required by regulations.

Additionally, the CNSC has developed prescriptive qualitative and quantitative safety goals for radiation protection and technical safety. These safety goals aim to limit the risks posed by the operation of the plant through quantitative assessments of the frequency of radiological release and frequency of core damage. To limit the societal risks posed by the operation of a small reactor facility two qualitative safety goals have been established:

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[72] *Ibid.*

[73] Canada, Canadian Nuclear Safety Commission, *Licence Application Guide: Licensing Small Modular Reactor Facilities (DRAFT)*, REGDOC-1.1.5 (Ottawa: CNSC, October 2017) [Canada, *REGDOC-1.1.5*] at 14.

1. Individual members of the public are provided a level of protection from the consequences of reactor facility operation such that there is no significant additional risk to the life and health of individuals.
2. Societal risks to life and health from reactor facility operation should not significantly add to other societal risks.[74]

The qualitative safety goals are achieved upon the demonstration of the accompanying quantitative safety goals.[75] Quantitative safety goals are a measure of the plant's accident preventive capabilities characterized by the frequency of core damage and release of radioactive material.[76] Core damage frequency is a sum of all event sequences that may result in significant core degradation. The small release frequency and large release frequency metrics are the sum of all events that may require temporary or long-term evacuation of the local population, respectively.[77] Expression of core damage frequencies are expressed by the chance of event per year and exclude malevolent acts but include events that may occur during operation and external events such as earthquakes.[78] The CNSC's regulatory documents provide guidance on how these calculations are to be completed and prescribe maximum release frequencies.[79]

The safety objectives are aspirational goals informed through years of practice and expectations found within the regulatory documents. The basic level of the CNSC's safety objectives are paramount and must be satisfied regardless of any cost or consideration.[80] However, challenges arise with the determination of whether SMRs meet these safety objectives, as there is no historical data on which to judge these novel reactors. Additionally, Canada's regulatory regime has been tested, for the most part, only by commercial CANDU reactors and has little experience in regulating other types. It is argued that the novel and unprecedented risks associated with SMRs cannot be addressed in full using conventional risk assessment mitigation practices designed for heavy water-cooled reactors, such as the CANDU. Re-evaluation of the regulatory framework is

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[74] Canada, *Design of Small Reactor Facilities*, *supra* note 33 at 7. See also Canada, Canadian Nuclear Safety Commission, *Design of New Nuclear Power Plants*, RD-337 version 2 (Ottawa: CNSC, 2011) [Canada, *Design of New Nuclear Power Plants*] (this source provides the same qualitative goal; however, it explains that for larger reactor facilities the "plant operation shall be comparable to or less than the risks of generating electricity by viable competing technologies, and shall not significantly add to other societal risks" at 4).

[75] Canada, Canadian Nuclear Safety Commission, *Design of Reactor Facilities: Nuclear Power Plants*, REGDOC-2.5.2 (Ottawa: CNSC, May 2014) [Canada, *Design of Reactor Facilities*] at 4.

[76] Canada, *Design of Small Reactor Facilities*, *supra* note 33 at 7.

[77] *Ibid.*

[78] *Ibid.*

[79] Canada, *Design of Reactor Facilities*, *supra* note 75 at 4–5.

[80] Nuclear Energy Agency, *Nuclear Regulatory Decision-making*, *supra* note 61 at 18.

necessary to overcome issues related to SMRs. To do this, the CNSC has begun adapting and expanding its regulatory documents and regulatory procedures to accommodate SMRs. The belief is that these safety objectives may be still met by re-considering the regulatory practices that underpin it.

2.3.2 Risk-informed decision-making and the regulatory principles that underpin it

RIDM is implemented by regulators to ensure confident decisions and is an overarching organizing philosophy that implements a myriad of decision-making tools and risk assessment approaches. Cornerstones of the RIDM process applied by the CNSC include risk assessment, conservative decision-making and the principle of proportionality. These key elements are not themselves expressly prescribed within the regulatory documents; rather, they are espoused within the regulatory measures such as the precautionary principle, deterministic risk assessment, probabilistic risk assessment, and the graded approach. Understanding how these principles are implemented to inform the decision-making process provide insight into how the regulatory framework may be adapted or developed to address concerns of regulating SMRs.

The RIDM model integrates both deterministic and probabilistic risk assessment and other relevant factors to assess proposed nuclear activities objectively and to make appropriate decisions.[81] More specifically, RIDM "ensures that the significant risks associated with the decisions are identified, understood, and characterized and that appropriate measures are taken to control these risks."[82] Unlike risk management, RIDM considers all relevant factors, such as cost-benefit arguments, regulatory documents, experience, codes and standards in the areas of licensing, compliance, planning and resource allocation.[83] RIDM considers all perspectives on an objective basis but also "[r]ecognizes the role of professional judgement, especially in areas where there is a lack of standards."[84] The CNSC makes its assessments on a thorough assessment of factual

[81] Enrico Zio, *supra* note 56 at 4.

[82] A Bujor, *Risk-informed Decision-making – Approach for Consideration of Time-at-Risk*, (Ottawa: Canadian Nuclear Safety Commission, 2010) at 1.

[83] *Ibid* at 4.

[84] Canada, *Regulatory Fundamentals*, *supra* note 41 at 2. See Canada, "REGDOC-1.1.5", *supra* note 73 ("[t]he Commission recognizes the role of professional judgement, particularly in areas where no objective standards exist… [and] its independence and transparency in decision-making are supported by fair, open, transparent and predictable regulatory processes at 13).

evidence, but also emphasizes the judgement of experts when faced with uncertainty.[85] The RIDM model integrates deterministic risk assessments and probabilistic risk assessment with other consideration to form a robust decision-making model.

RIDM is an advantageous model for regulating SMRs. The RIDM process acknowledges the utility of human judgement in decisions and avoids technocentrism as a basis for decision-making.[86] RIDM avoids inevitable technical gaps in information through human judgement,[87] which is advantageous for novel technologies that are encumbered by gaps in their risk assessments such as SMRs. This approach is more effective and robust than its predecessor which was mostly a deterministic assessment and relied heavily on the conservative regulation of system designs and operation.

The utility of the RIDM model will depend on how it is implemented by the regulator. The approach taken by the US Nuclear Regulator, for example, employs a structure built upon mandatory and legal requirements, such as plant specifications; deterministic requirements, which ensures the satisfaction of defence-in-depth measures and the maintenance of safety margins; probabilistic risk insights, which assesses all initiating events and estimates risk; and other factors which include costs-and-benefits analyses and more.[88] The RIDM model employed by the CNSC is much the same, except that the Canadian regulator places additional emphasis on the perspectives of stakeholders.

A mainstay of the RIDM model is its integration of deterministic risk assessment and probabilistic risk assessments, and thus necessitates comment. The deterministic approach assesses risk on less quantifiable criteria such as political or security considerations and focuses on engineering principles such as safety measures, redundancy and diversity to prevent the consequences of an event.[89] The purpose of the deterministic approach is to identify a group of failure event sequences leading to credible worst-case accident scenarios, predict their consequences and design safety measures to prevent and mitigate those consequences.[90] In

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[85] Canada, *Regulatory Fundamentals*, *supra* note 41 ("[t]he CNSC . . . [r]ecognizes the role of professional judgment, especially in areas where there is a lack of standards" at 2).

[86] See Enrico Zio, *supra* note 56 at 4.

[87] *Ibid.*

[88] *Ibid* at 23–24.

[89] *Ibid* at vii.

[90] *Ibid* at 3.

contrast, probabilistic risk assessments employ quantitative, or semi-quantitative methods, to estimate the likelihood of all accidents and are not limited to assessments of worst-case scenario accidents such as the deterministic approach.[91] Probabilistic risk assessments do not supplant deterministic assessments; rather they are used to support them.[92] The integration of both assessment types by the RIDM model provides a rational and quantitative approach to uncertainty.

An integral approach to address uncertainty and risk within the RIDM model is to make conservative decisions. Conservative decision-making underpins many regulatory principles employed within RIDM such as deterministic assessments, the precautionary principle and the graded approach. Conservative decision-making aims to place the reactor and its facilities in a condition known to be safe or that have reasonable risks. Deterministic risk assessment, the precautionary principle and the graded approach each provide a different aspect to conservative decision-making that significantly affects how the risks of a proposed project are to be mitigated and assessed.

Elements of conservative decision-making are exemplified within deterministic approaches where the assessment mandates the necessity of measures such as defence-in-depth, safety margins or other like-wise precautionary practice to mitigate risks to reasonable levels.[93] Invocation of conservative decision-making assures that risks are reasonable and that regulatory objectives are satisfied. Regulatory objectives necessitate the application of conservative decision-making despite the impact it may have on the costs of the proposed project.[94]

The precautionary principle is used by policymakers to justify conservative decision-making where the risks of the activity remain unknown. Though the principle is not expressly mandated within the *NSCA* as it is in the *CEAA* and *IAA,* it is woven throughout the framework developed by the CNSC.[95] Continuous improvement, adoption of best practices, transparency and

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[91] J Fischer, P Giuliani, "Probabilistic Methods Used in NUSS" (Paper delivered at the proceedings of an International Symposium on Safety Codes and Guides (NUSS) in the Light of Current Safety Issues, 29 October – 2 November 1984), (Vienna: International Atomic Energy Agency, 1985) at 145.

[92] E P O'Donnell, "Use of Quantitative Safety Goals and Probabilistic Risk Assessment in Regulatory Decision-Making" (Paper delivered at the proceedings of an International Symposium on Safety Codes and Guides (NUSS) in the Light of Current Safety Issues, 29 October – 2 November 1984), (Vienna: International Atomic Energy Agency, 1985) at 175.

[93] See Enrico Zio, *supra* note 56 at 26.

[94] Nuclear Energy Agency, *Nuclear Regulatory Decision-making, supra* note 61 at 18.

[95] See Lee, *supra* note 14 ("elements of the graded approach are already woven through the fabric of the CNSC's regulatory framework" at 9).

public scrutiny are aspects of the principle that form paramount features of Canada's nuclear regulations.[96] Under the *CEAA* the CNSC, or a review panel as will be the case under the *IAA*,[97] is expressly mandated to conduct environmental impact assessments in a manner that applies the precautionary principle.[98] It is noted, however, that the *IAA* and *CEAA* do not specify or provide guidance on the strength or variety of the principle to be used.

The CNSC does not explicitly define the version of the precautionary principle it aims to employ; however, it is evident that the CNSC's regulations have adopted a weak form of the principle. Stewart has identified four versions of the precautionary principle that are prominent throughout legal instruments, government and international declarations and other documents.[99] They are as follows:

1. The Non-Preclusion Precautionary Principle: Scientific uncertainty should not automatically preclude regulation of activities that pose a potential risk of significant harm.
2. The Margin of Safety Precautionary Principle: Regulatory control should incorporate a margin of safety; activities should be limited below the level at which no adverse effect has been observed.
3. The Best Available Technology Precautionary Principle: Activities that present an uncertain potential for significant harm should be subject to best technology available requirements to minimize the risk of harm unless the proponent of the activity shows that they present no appreciable risk of harm.
4. The Prohibitory Precautionary Principle: Activities that present an uncertain potential for significant harm should be prohibited unless the proponent of the activity shows that it presents no appreciable risk.[100]

[96] See generally Canada, Canadian Nuclear Safety Commission, *DIS-16-01, How the CNSC Considers Information on Costs and Benefits: Opportunities to Improve Guidance and Clarity*, (Ottawa: CNSC, 24 April 2017) at 8–9.

[97] *Bill C-69, supra* note28, cl 6(2).

[98] *Supra* note 27, s 4(2).

[99] Richard B Stewart, "Environmental Regulatory Decision-making Under Uncertainty" (2002) 20 Research in L & Economics 71 at 76, 77.

[100] *Ibid.*

Of these definitions, Stewart's second definition, the "Margin of Safety Precautionary Principle," most closely resembles the precautionary principle embedded in the regulations of the CNSC because it is consistent with the use of conservative decision-making to ensure reasonable risks. Stewart characterizes this definition on the weaker end of the continuum because of its failure to specify the form of regulation that should be adopted but instructs that margin of safety should be adopted.[101] This definition is consistent with Canada's regulations which aim to limit risk to reasonable levels through different measures including the requirement of safety margins.

Measures carried out by conservative decision-making are to be inversely proportional to the level of understanding of risk and safety, which is an application of the principle of proportionality.[102] The proportionality principle is most notably utilized within the graded approach. The graded approach, as applied by the CNSC, is a framework of decision-making tools and rules consistent with principles espoused by the IAEA. The graded approach assures the administration of regulatory requirements in proportion to the risks of the associated nuclear activity.[103]

The graded approach instructs that regulatory requirements be applied in accordance with the circumstances, and the "likelihood and possible consequences of, and the level of risk associated with, a loss of control."[104] The circumstances considered are those presented within the 14 SCAs mentioned previously. These include the relative risks to health, safety, security and the environment, and characteristics of the activity, such as reactor power, fuel design and more.[105] Moreover, the degree of scrutiny placed on the nuclear activity by the CNSC is informed by a number of considerations, including the technical assessments of submissions, relevant research and information supplied by the parties, cooperation with other regulators and the safety history

[101] *Ibid.*

[102] See e.g. Canada, *Glossary of Terminology, supra* note 39 ("[the graded approach is a] process by which elements such as the level of analysis, the depth of documentation and the scope of actions necessary to comply with requirements are commensurate with . . . the relative risks to health, safety, security . . . characteristics of a nuclear facility or licensed activity" at 53). See e.g. Enrico Zio, *supra* note 56 ("system redundancy, independence, and diversity are preserved commensurate with the expected frequency and consequences of challenges to the system, and associated uncertainties" at 26).

[103] Canada, *Glossary of Terminology, ibid.*

[104] International Atomic Energy Agency, *Use of a Graded Approach in the Application of the Safety Requirements for Research Reactors*, Specific Safety Guide No SSG-22 (Vienna: IAEA, 2012) (the guide provides general definition and purpose of the graded approach at 2).

[105] Lee, *supra* note 14 at 8.

of the licence applicant.[106] From the perspective of the CNSC, the goal of the graded approach is to ensure the satisfaction of fundamental safety objectives in a risk-informed manner commensurate with the risk complexity and novelty of the project.[107]

The primary responsibility for safety remains with the licensee and those conducting the regulated activities at all times.[108] Accordingly, the graded approach allows for applicants to propose alternative methods of meeting regulatory requirements so long as they can demonstrate a reasonable level of risk and that regulations are satisfied.[109] The onus of proving and demonstrating that measures proportionally address risk is placed on the applicant. Thus, the graded approach provides the opportunity for SMR proponents to deviate from conventional risk practices, so long as they can proportionally demonstrate the activity's safety.

The CNSC determines the safety of a project by applying the graded approach which considers the degree of novelty, complexity and potential harm posed by the activity commensurate with the measures used to reduce risk to a reasonable level.[110] Industry and the CNSC have highlighted the graded approach as an important regulatory tool for regulating SMRs. However, many vendors and proponents of SMRs have called for more clarity on the principles application to SMRs, as they point out that SMRs often lack historical operational data which is an important consideration in its application.[111]

RIDM is an effective model for nuclear regulators to make well-informed decisions regarding nuclear activities. Its application to SMRs is beneficial because it strikes a balance between many inputs and implements the graded approach which provides a technological neutral assessment of safety commensurate with the degree of novelty, complexity and potential harm. The graded approach is an effective model because it supports transparency and robustness within the regulatory process, and considers the best available information arising from research and

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[106] *Ibid* at 4.

[107] *Ibid* at 8.

[108] *Ibid.*

[109] *Ibid*.

[110] Canada, *REGDOC-1.1.5*, *supra* note 73 (the degree of scrutiny is informed by technical assessments of submissions; safety performance history of the licencee; relevant research; information supplied by parties relevant to Commission proceedings; international activities that advance knowledge in nuclear and environmental safety; and co-operation with other regulatory bodies at 14).

[111] Canada, Canadian Nuclear Safety Commission, "What We Heard Report – *DIS-16-04*" (18 September 2017) [CNSC, "What We Heard Report"], online: CNSC website <nuclearsafety.gc.ca/eng/acts-and-regulations/consultation/completed/*DIS-16-04*.cfm> [perma.cc/B42X-SER8].

stakeholder input. In addition, the graded approach provides a balance with conservative decision-making which naturally has an implicit bias against novelty and innovation. However, to effectively regulate SMRs there must be a balance struck between the graded approach and conservative decision-making that moves away from conventional approaches and accommodates novel designs, automation, modularity, and other innovative features.

2.3.3 The fundamental safety function of "control, cool and contain"

The fundamental safety principles of "control, cool and contain" are a safety philosophy that minimizes risk to the public and environment through the implementation of design measures. These measures include the application of defence-in-depth and containment barriers which may not be effectual for SMRs. Conventional approaches to obtaining the fundamental safety functions assume ubiquitous application to all reactor designs. Proponents claim that this approach may cause compatibility challenges depending on the design of the SMR.

The application of the fundamental safety function of "control, cool and contain" refers to the control of the reactor power, the cooling of the reactor fuel, and the containment of radioactivity using safety mechanisms and measures to achieve safety objectives. Achieving this safety function requires that risks of radiation are ALARA and that measures implemented are independent, diverse, separate and redundant.[112] An important strategy to achieve the functions of "control, cool and contain" is the execution of defence-in-depth in conjunction with the CNSC's regulatory expectations.

Not only is defence-in-depth a tool of deterministic and conservative regulation, but its administration is a fundamental safety function of "control, cool and contain."[113] Defence-in-depth is administered through overlapping measures to prevent and mitigate risks to design related safety and security activities.[114] The CNSC has defined five levels of safety objectives pertinent to

[112] Canada, Canadian Nuclear Safety Commission, "Nuclear Power Plant Safety" (20 January 2016), online: CNSC website <https://nuclearsafety.gc.ca/eng/reactors/power-plants/nuclear-power-plant-safety-systems> [perma.cc/A2YD-VJNN].

[113] Lee, *supra* note 14 at 3.

[113] Canada, *REGDOC-1.1.5, supra* note 73 at 14.

[113] Lee, *supra* note 14 at 4.

[113] *Ibid.*

[114] Canada, *Design of Small Reactor Facilities*, *supra* note 33 at 4.

establishing defence-in-depth. Level one prevents deviations from normal operation and prevents failures of systems, structures and components. Level two prevents anticipated deviation occurrences in normal operation from escalating to accident conditions through detection ant interceptive systems. Level three minimizes the consequences of accidents. Level four ensures that any release of radioactive material by severe accidents is ALARA. Level five mitigates the consequences of radioactive releases that may result from accident conditions.[115] Each level of defence should be effective independent of each other.

Furthermore, each level is achieved through multiple and diverse provisions.[116] Regulations and related documents leave little ability for proponents to deviate from conventional approaches of defence-in-depth. Additionally, difficulty arises for SMRs as approaches to defence-in-depth are discretionally assessed by the CNSC based on operational history, which may be lackiong, and the complexity and novelty of the technology.

A mainstay of defence-in-depth is the erection of multiple physical barriers to prevent and contain the uncontrolled release of radioactive materials. Physical containment is conventionally considered necessary for the overall success of the practice of defence-in-depth.[117] Physical barriers include physical containment but may also take the form of a fuel matrix, cladding or other additional barrier types.[118]

However, barriers pose unique challenges for some SMR designs. Some vendors have claimed physical barriers are unnecessary where reaction mechanisms are incapable of resulting in the release of materials, with some claiming that they may also impede heat transfer thereby increasing risks.[119] The practice of defence-in-depth presupposes that conventional approaches of this measure are ubiquitous, which arises from the CNSC's exclusive experience with CANDU reactors.

The fundamental safety function of "control, cool and contain" has traditionally been achieved through robust precautionary systems such as defence-in-depth, physical barriers and

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[115] *Ibid.*
[116] *Ibid.*
[117] *Ibid* at 5.
[118] *Ibid.*
[119] E S Lyman, "The Pebble-Bed Modular Reactor (PBMR): Safety Issues" 30:4 Physics and Society 16 ("PBMR promoters claim that a robust containment is unnecessary . . . [and] [t]hey argue further that such a containment would actually be detrimental to safety because it would inhibit heat transfer" at 17).

other practices. The rigidity of the current framework and the invocation of conservatism creates a pseudo prescriptive regime which leaves little room for innovation. To combat this, regulatory flexibility is necessary so that precautionary measures can be specifically tailored for each reactor design. Flexibility may be added to the fundamental safety principle by using the graded approach to determine the scope, content and details of "control, cool and contain." The application of the graded approach for this purpose would consider the research and development, documentation and other proof of safety of the reactor commensurate to the complexity, risks and claims of the proponent.

2.3.4 Conclusion

The nuclear regulatory framework of Canada is developed with the focus on the safety objectives promulgated within the *NSCA* and other relevant regulations and legislation. The CNSC is established as Canada's nuclear regulator to carry out the mandate of the *NSCA* and its safety objectives. To do this, the CNSC assesses the license applications by considering whether the applicant is qualified to carry on the activity sought and whether the applicant has made adequate provisions for the protection of the environment, the health and safety of persons and national security, and that they maintain Canada's international obligations. The regulatory framework developed by the CNSC implements a hybrid prescriptive and performance-based regulatory scheme to achieve these objectives.

The CNSC resolves license applications within the RIDM process developed through their regulatory expectations. RIDM produces well-informed decisions through the consideration of many inputs and the application of both deterministic and probabilistic risk assessment, as well as regulatory principles such as proportionality and conservative decision-making. The principle of proportionality is a mainstay of the graded approach. Conservative decision-making is embodied within the practices of the precautionary principle, the graded approach and deterministic risk assessment. These principles form integral aspects of the RIDM and have implications on the deployment of SMRs.

The novelty and unfamiliarity of SMRs imply risk uncertainty and complexity untested by Canada's nuclear regulations. Conservative decision-making directs regulators to be especially precautious of nuclear activities with uncertain risk, which it attempts to mitigate using conventional approaches traditionally used for heavy water reactors. For SMRs, these conventional approaches may not be practical or applicable. However, the graded approach provides flexibility for those attempting to license SMRs and may be used to offset conventional regulations and demonstrate that SMR activities meet the safety objectives of Canada's regulations.

The graded approach provides SMRs with the opportunity to incorporate novel and innovative design features to address risks. However, the lack of referential operational history creates difficulties for grading SMRs. Difficulties are exacerbated as proponents will need to document and demonstrate the safety of SMRs to a higher degree, as it must be proportional to its complexity and novelty. To ensure that grading is not applied disproportionaltely, it is suggested that the CNSC clarify the graded approach's application to SMRs and that risk management practices employ measures to ensure that scrutiny is applied proportionally. Additionally, methods to mitigate risk uncertainty should be considered, such as the use of expert elicitations to fill gaps within risk assessments.

Furthermore, conservative decision-making approaches, such defence-in-depth and other precautionary measures used to obtain fundamental safety function of "control, cool and contain," should be more flexible to accept novel and innovative approaches to risk. The graded approach is indispensable for providing regulatory flexibility, and its application should consider the research and development, documentation and other proof of safety of the reactor commensurate with the complexity and claims of the proponent.

The fundamental regulatory principles discussed in this section must also be respected when making recommendations and suggestions later in this thesis. Recommendation of risk management approaches, such as the use of uncertainty analyses and expert judgement for risk assessment discussed Chapter 3, and type certification, discussed in Chapter 4, must respect and be capable of being integrated with these principles. The purpose of this thesis is to not modify or remove these underpinning principles, but to make recommendations that develop and bolster them so that they may better accommodate SMRs.

Canadian regulations have been developed to be technology neutral; however, their development is skewed towards the regulation of CANDU reactors. Canadian regulations attempt to be sufficiently broad to anticipate alternative approaches to power generation. However, Canada's regulations have been developed based on the CNSC's expertise with heavy water reactors because of their experience with CANDU technologies. Thus, despite attempts to create technologically neutral regulations, elementary aspects of the regulations may not be applicable to reactor designs that implement fundamentally different technology. Many of these issues raised above are echoed in some capacity by the stakeholders and proponents. As a result, the CNSC has begun a campaign to ready its regulations for SMRs and other advanced reactors.

2.4 The fit of SMRs in Canada's regulatory framework (or the lack thereof)

The CNSC has made significant efforts to consult with industry on how to appropriately regulate SMRs. In May of 2016, the CNSC published the discussion paper "*DIS-16-04*: Small Modular Reactors: Regulatory Strategy, Approaches and Challenges" to commence a discourse with industry and stakeholders to address the growing interest in deploying SMRs in Canada.[120] *DIS-16-04* raised key regulatory challenges for licensing and deploying SMRs in Canada and called for comments from industry and stakeholders. On January 31st, 2017, the CNSC held a workshop with those who commented on *DIS-16-04* and other interested stakeholders, which is summarised within the Stakeholder Workshop Report: Periodic Review of the Nuclear Security Regulation in December 2017.[121] Additionally, in September 2017, the CNSC summarized and responded to the comments received on *DIS-16-04* with the "What We Heard Report."[122]

In the "What We Heard Report," the CNSC outlines the concerns raised by stakeholders in response to *DIS-16-04* and addresses how it aims to improve and clarify regulations. A clearer explanation of the graded approach and how it will apply to SMRs was a common concern amongst industry stakeholders. As a result, the CNSC hosted a workshop in November 2017 to consult stakeholders and advise them of the application of the graded approach to SMR facilities. The

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[120] Canada, Canadian Nuclear Safety Commission, *Discussion Paper DIS-16-04, Small Modular Reactors: Regulatory Strategy, Approaches and Challenges*, (Ottawa: CNSC, May 2016) [Canada, *DIS-16-04*].

[121] Canada, Canadian Nuclear Safety Commission, "Stakeholder Workshop Report: Periodic Review of the Nuclear Security Regulations" (30 November 2017), online: CNSC website <nuclearsafety.gc.ca/eng/acts-and-regulations/consultation/history-regs/stakeholder-workhop-report-periodic.cfm> [perma.cc/E293-JX5H].

[122] Canada, Canadian Nuclear Safety Commission, "What We Heard Report – *DIS-16-04*" (18 September 2017), [CNSC, "What We Heard Report"], online: CNSC website <nuclearsafety.gc.ca/eng/acts-and-regulations/consultation/completed/*DIS-16-04*.cfm> [perma.cc/5N4J-U48K].

synopsis of the November 2017 workshop is published; however, the bulk of it reiterates what is discussed previously in this chapter regarding the RIDM process.[123]

Notwithstanding the CNSC's acknowledgment that SMRs pose unique challenges for Canada's regulations and RIDM, they purport that Canada's regulatory framework is sufficiently robust to accommodate SMRs and seemingly ignore the proponent's calls for more certainty and clarity. The CNSC claims that the graded approach provides a technologically neutral and competent solution for addressing risk. However, this thesis argues that Canada's regulations can be further developed to more effectively regulate the deployment of SMRs through the balancing of conservative decision-making and the graded approach. Additionally, approaches to mitigate and manage novel risks and risk uncertainties of SMRs are required.

It is common for regulators of complex domains, such as nuclear power generation, to work closely with industry so that regulation is developed with sufficient expertise. THowever, care must be taken so that the regulator continues to make decision in the public interest and not in the private interests of the industry. Thus, the recommendations made by industry and the results of the discussions between the CNSC and industry are scrutinized within this section objectively to ensure that the intentions and effects remain in the interest of the public. This section also discusses how regulatory capture may occur and how transparency, accountability and clarity and other tools are important to stave off capture when pursuing the points raised by industry.

2.4.1 Issues raised by DIS-16-04

DIS-16-04 raises seventeen key challenges of regulating SMRs, which are primarily attributed to the uncertainty accompanying the novel approaches and technology implemented by SMRs. The bulk of the seventeen key challenges can be summarized into five categories. These regulatory challenges are specific to SMRs, but not every SMR will have the same regulatory challenges. Upon outlining these regulatory issues, it becomes clear that the most effective approach to regulating SMRs is to develop a flexible and robust framework that address SMRs on a case by case basis.

[123] Lee, *supra* note 14 at 8.

The 17 key regulatory challenges raised in *DIS-16-04* may be categorized into the following:

- Novel fuels and refuelling processes
- Gaps in the safety claims of vendors
- Overseeing the design, manufacturing, and installation of SMRs
- Reduction in staff and automation of the processes
- Relocatable and replaceable reactors, or reactors used in fleets

Novel fuels and refuelling processes encapsulate issues regarding cooling of novel fuels, methods of refuelling, and the management of the waste produced by such fuels. Novel fuel types vary and may include metallic and graphite-based fuel concepts, which consist of a fuel kernel encased in a carbon or metallic matrix, fuels dissolved within the coolant, or subcritical fuels. The traditional model of refuelling a nuclear reactor is to perform individual fuel element replacement on site.[124] However, refuelling approaches will vary with each fuel type. For example, pebble bed reactors utilizing graphite fuel designs may be refuelled during operations, while heavy water reactors such as CANDU reactor designs will be required to be shut down.[125] In addition, graphite fuels propose significant challenges to waste management due to the difficulty of separating wastes from its carbon matrix, and approaches to cooling the fuel during operation and in the event of an accident.[126] These challenges are exacerbated as designs and safeguards may not be fully proven by vendors or the proponent, creating additional uncertainty.

Gaps in the safety claims of vendors pose significant challenges for regulating and assessing SMRs because it is difficult to demonstrate that performance-based regulations are satisfied. The *General Nuclear Safety and Control Regulations* require that an application for a licence provide "a description and the results of any test, analysis or calculation performed to substantiate the information included in the application."[127] Extensive documentation is needed to demonstrate "the credibility of a safety claim, effectiveness of a safety approach or the informing

[124] Canada, *DIS-16-04, supra* note 120 at 12.

[125] Lyman, *supra* note 119 at 17.

[126] See generally F Guittonneau, A Abdelouas & B Grambow, "HTR Fuel Waste Management: TRISO separation and acid-graphite" 407 Journal of Nuclear Materials 71.

[127] *General Nuclear Safety and Control Regulations*, SOR/2000-202, s 3(1)(i).

of long-term considerations in the conduct of licensed activities."[128] Though the CNSC makes deference to expert opinion in the face of uncertainty, it will be difficult to overcome the scrutiny applied by the graded approach and conservative decision-making because of the prevailing complexity of SMRs. Additionally, the gaps in the claims of vendors may affect many different considerations of a reactor facility, such as the reliability of novel construction materials and the risks associated with automation.

A significant advantage of SMRs is its reduction in staff, offsite monitoring, increase in automation and other passive features; however, current regulations are incapable of appropriately appreciating the risks associated with those advantages. The practice of "minimum complement of qualified workers" in a nuclear facility ensures that the plant is operated safely and assures that emergency response is adequate.[129] Proponents of SMRs that incorporate these advantages will be required to demonstrate with a high amount of confidence that the facility can be operated safely commensurate with the risks and complexity of the automated system.

The CNSC also highlights the challenges involved with overseeing the design, manufacturing and installation of SMRs due to the modularity of the facility.[130] SMRs are to be installed on site using modules manufactured offsite, thus frustrating the CNSC's ability to perform inspections of the reactor and facility. Sealed reactor modules pose significant challenges as inspectors are unable to conduct inspections of the reactor to permit its installation.[131] Modularity increases the quality of construction, lowers manufacturing times and overall reduces the time required to bring the facility into operation.[132] For Canada to take advantage of SMRs, modularity must be accommodated for within the regulations.

The size and modularity of SMRs provide unique deployment capabilities for SMRs, such as deployment in fleets, and use as a relocatable and replaceable reactor.[133] There are two central regulatory issues raised for these unique deployment strategies. First, environmental assessments become complicated where SMRs are deployed as fleets over a large geographical area, or where

[128] Canada, *DIS-16-04, supra* note 120 at 35
[129] *Ibid* at 11.
[130] *Ibid* at 33, 10.
[131] *Ibid* at 10.
[132] Lee, *supra* note 14 at 2.
[133] Canada, *DIS-16-04, supra* note 120 at 7, 17, 9.

the reactor may be relocated or replaced.[134] Though the *IAA* removes the CNSC as the responsible authority for impact assessments, the CNSC must still ensure the protection of the environment in satisfaction of the objectives of the *NSCA*. Second, conventional licensing strategies for decommissioning and waste management are set up for individual and stationary reactors but are not equipped for transportable reactors and multiple reactor sites.[135] To accommodate the novel deployment approaches the CNSC may require new approaches to decommissioning and waste management. For example, transportable SMRs may perform site decommissioning and reactor decommissioning as separate activities and under separate licenses.[136] Additionally, multiple reactor sites may seek to replace complete reactor modules as a refurbishment exercise considered under normal waste management operations.[137]

Challenges raised by the discussion paper not capable of being categorized in the above classes include the risks associated with using alternative construction material, what emergency zones are appropriate, whether existing defence-in-depth regulations are clear and appropriate for the prevention and mitigation of accidents, updating regulations for demonstration reactors and the appropriateness of the regulations for fusion reactor systems.[138]

The above is not an exclusive list of challenges posed by SMRs. The SMR industry is in its infancy but boasts more than 50 designs currently in development.[139] Thus the issue is not how to regulate in response to the above issues, but how to set up a framework that can accommodate all nuclear technologies, including those yet to be conceived, and in any deployment strategy. As one respondent puts it, the "prominent concerns with the regulation of SMRs is how can the regulatory process be aligned to permit offsets in regulatory requirements for such aspects … while acknowledging the burden of proof on the proponent to establish the effectiveness of the novel technology."[140] Regulatory flexibility was a common concern of the feedback received from stakeholders and was addressed by the CNSC in the "What We Heard Report." In this report, the

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[134] *Ibid* at 9, 7.
[135] *Ibid* at 25.
[136] *Ibid.*
[137] *Ibid.*
[138] *Ibid* at 5, 16, 14–15, 8–9, 27–28.
[139] Ux Consulting Company, *supra* note 6.
[140] V G Snell, T Aziz, E Kittel & G Raiskums, "Comments on 'Small Modular Reactors: Regulatory Strategy, Approaches and Challenges', CNSC Discussion Paper DIS-16-04," (May 2016) Terrestrial Energy Working Paper Response to *DIS-16-04*.

CNSC proposes a robust grading system where the adaption of regulatory expectations can be demonstrated as safe by the proponent.

2.4.2 Responses to DIS-16-04 and consultation with stakeholders

The "What We Heard Report" summarizes the responses by stakeholders to *DIS-16-04*. A common theme among responses was the lack of clarity in the licensing process for SMRs and how the graded approach will apply. Additionally, responses criticized precautionary measures such as defence-in-depth and made recommendations to how regulations may improve, such as the addition of reproducibility and safety in design. Overall, the consensus was that the challenges posed by SMRs were not insurmountable and that the current regulation can be amended to accommodate the challenges posed by SMRs by using the graded approach effectively.[141]

Stakeholders raised concerns about how the graded approach is to apply to SMRs and how its implementation may create a common understanding. Additionally, stakeholders suggested that emphasis should be given to the research and development programs of vendors where there is a lack of historical operational data.[142] The CNSC agreed that the graded approach must be clarified for its application to SMRs. The CNSC also emphasized that the onus is on the proponent to demonstrate the safety of the activity, which can be achieved through extensive supporting information and documentation.

Stakeholders also criticized the application of defence-in-depth, accident mitigation, and emergency planning zones for SMRs based on their obvious relevance to water-cooled reactors.[143] SMRs emphasize the prevention, control and protection levels of defence-in-depth and on inherent passive safety features and safety by design.[144] On this note, the CNSC was less interested in amending conventional approaches, stating that there already exists a level of flexibility within these measures.[145]

[141] Canada, "What We Heard Report", *supra* note 111.
[142] *Ibid.*
[143] *Ibid.*
[144] *Ibid.*
[145] *Ibid.*

Additionally, stakeholders recommended the principle of reproducibility as an approach to streamlining SMR licensing. The principle of reproducibility can be a practical approach to the siting, licensing and regulation of SMRs as the SMR business may operate in a standardized and repeatable manner.[146] The successful verification of reproducibility by the aerospace and shipbuilding industry provides insight into how it may be affirmed for the production of SMRs.[147] On this note, the CNSC responded that they would remain open to discussing alternative approaches to licensing to increase efficiencies, however, reiterated that the demonstration of the safe operation of the facility remains paramount.[148]

The workshops and consultations carried out by the CNSC are discussions carried out amongst industry stakeholders, including the CNSC, SMR vendors, utilities and groups representing the interests of the public. Although most issues are acknowledged by all stakeholders, recommendations and suggestions made by industry are balanced by the CNSC's regulatory approach. The CNSC regulates transparently, are accountable to the public and other stakeholders and provide clarity for their regulations so that they may be administered fairly and consistently.

Overall the feedback given by stakeholders regarding the critical challenges of regulating SMRs raised in *DIS-16-04* was that regulations need to be clarified and that there must be an ability to offset conventional regulatory practices to safety and risk by demonstrating the innovative and novel approaches taken by SMRs. On this point, the CNSC held that the graded approach would be a sufficient means to offset conventional regulatory practice and that the acceptance of safety claims will rely heavily on the quality of information to support the claims, especially where assessing passive features, variation to defence-in-depth practices and emergency planning zones of the proposed facility.[149] Additionally, the CNSC suggest that the utilization of vendor design reviews and workshops administered by the CNSC can help resolve these challenges.[150]

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[146] Lee, *supra* note 14 at 6.
[147] *Ibid.*
[148] CNSC, "What We Heard Report", *supra* note 111.
[149] *Ibid.*
[150] *Ibid.*

2.4.3 Changes in response to DIS-16-04 and consultation with stakeholders

The CNSC has begun marketing themselves as an SMR friendly regulator and has been working with stakeholders to bolster their technical knowledge and to make regulations more accommodating for SMRs. The CNSC's strategy to ready themselves for SMRs is to increase regulatory certainty, raise awareness and establish technical readiness and priorities.[151] As a part of this strategy, the CNSC has held two workshops on improving and clarifying regulations, and have drafted a Licence Application Guide for Small Modular Reactors. These are small steps in the overall accommodation of SMRs.

January 31st, 2017 the CNSC held a workshop regarding potential amendments to the *Nuclear Security Regulations,*[152] resulting in the report "Stakeholder Workshop Report: Periodic Review of the Nuclear Security Regulations" the following month.[153] Consultations with stakeholders determined that both the industry and CNSC agreed that revisions and amendments made to the *NSR* should be framed to be consistent with performance-based regulations.[154] Also, regarding defence-in-depth, it was suggested that the CNSC apply the graded approach consistent with the recommendations of the IAEA. Discussion regarding clarity also arose, with participants suggesting that emphasis be placed on "security by design" and that regulators provide clarity to what is expected to achieve objectives and what evidence is needed to support proposals.[155] Other discussions centred on security response forces, offsite monitoring, and additional guidance related to detection, delay and response options for SMRs located in remote locations.[156] The CNSC has not yet begun to make these amendments.

The CNSC also held a workshop to provide greater clarity on the application of the graded approach on November 24th, 2017. The information workshop provided guidance on how the graded approach would apply to SMRs and focused on the application of the graded approach

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[151] Ramzi Jammal, "Readiness for Regulating Small Modular Reactors" (Lecture delivered at the International Nuclear Regulators Association, 19 September 2017, [unpublished] online: CNSC website <nuclearsafety.gc.ca/eng/pdfs/Presentations/VP/2017/2017-09-19-ramzi-jammal-presentation-small-modular-reactor-eng.pdf>.

[152] *Nuclear Security Regulations*, SOR/2000-209 [*NSR*].

[153] Canada, Canadian Nuclear Safety Commission, "Stakeholder Workshop Report: Periodic Review of the *Nuclear Security Regulations"* (30 November 2011), online: CNSC website <nuclearsafety.gc.ca/eng/acts-and-regulations/consultation/history-regs/stakeholder-workhop-report-periodic.cfm> [perma.cc/YFH5-BVZW].

[154] Lee, *supra* note 14 at 6.

[155] *Ibid.*

[156] *Ibid.*

within the RIDM process. The content of the workshop follows closely the discussion in the previous section regarding the graded approach. Emphasis was placed on how the CNSC articulate requirements and guidance within their regulatory documents and that it is ultimately the onus of the proponent to demonstrate proportionality of the measures taken to mitigate the corresponding risks.

The CNSC is developing a Licence application guide for SMRs. REGDOC-1.1.5, *Licence Application Guide for Small Modular Reactor Facilities* sets out the guidance for proponents making applications to the CNSC to obtain a licence to prepare a site, construct and operate an SMR in Canada.[157] This document identifies the SCAs and other considerations that are to be taken into account during the assessment of licence applications.[158] However, at this time REGDOC-1.1.5 remains in draft form and is currently out for public consultation.

REGDOC-1.1.5 identifies the 14 SCAs and raises considerations for applications to construct or operate an SMR.[159] Each description of the relevant SCA includes reference to relevant regulatory documents and remains, for the most part, consistent with other licence application guides. However, REGDOC-1.1.5 acknowledges that conventional approaches to SCAs may be incompatible for some SMR designs, and provides the opportunity for applicants to offer unconventional approaches where:

1. The alternative approach would result in an equivalent or superior level of safety to that of the approach stated in the requirement
2. The application of one or more CNSC requirement(s) would conflict with other rules or requirements.
3. The application of one or more CNSC requirement(s) would not serve the underlying purpose of the requirement(s) or is not necessary to achieve the underlying purpose of the requirement(s).[160]

REGDOC-1.1.5 requires that "alternative approach[es] must demonstrate equivalence to the outcomes associated with the use of the requirements set out in this regulatory document."[161]

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[157] Canada, *REGDOC-1.1.5, supra* note 73 at 1.
[158] *Ibid.*
[159] See generally, Canada, *REGDOC-1.1.5, supra* note 73.
[160] *Ibid* at 14.
[161] *Ibid* at 15.

Furthermore, the evidence required to demonstrate the satisfaction of regulatory requirements must increase proportional to the uncertainties in the risk.[162] Thus, REGDOC-1.1.5 provides that applicants may offset regulatory requirements where the desired outcome is demonstrated under the scrutiny of the principle of proportionality.

At the International SMR and Advanced Reactor Summit 2018, the CNSC raised the issue of the application of defence-in-depth to SMRs and conceded that conventional approaches might not apply; however, they reiterated that applicants must demonstrate that defence-in-depth is assured.[163] They determined that shutdown requirements of some SMR designs, for example, are not required to prevent fuel failure because of inherent safety features and, thus, do not need a graded safety shut down system.[164] Moreover, some SMR designs do not require an emergency core cooling system as residual nuclear heat from the reactor can be removed passively during operation and accident events.[165] Some vendors claim that traditional concrete physical containment is unneeded and may interfere with the heat transfer of the reaction thereby increasing risk rather than alleviating it.[166] The CNSC reframed the issues for control, cooling and containment to the question of what is needed from vendors or proponents of these novel technologies to demonstrate the intent of these design requirements.[167]

Overall the CNSC asserts that the key to developing a supportive and effective regulatory framework for SMR deployment is to actively work and consult with proponents to provide transparency, certainty and clarity while adapting the framework to be increasingly performance-based to accommodate the innovative approaches of SMRs. The CNSC emphasizes the use of the graded approach for assessing SMR applications that deviate from conventional methods to safety. In this approach, proportionality is used to ensure that the novel safety features of SMRs meet the safety objectives of the CNSC. An increased use of grading reflects the agreement of both the

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[162] *Ibid.*

[163] Doug Miller, "Canadian Perspective on Risk-informed Regulation of Small modular Reactors*"* (Presentation delivered at the International SMR and Advanced Reactor Summit 2018 in Atlanta Georgia, 27–28 March 2018) [unpublished], online: CNSC website <nuclearsafety.gc.ca/eng/pdfs/Presentations/CNSC_Staff/2018/20180328-doug-miller-international-smr-advanced-reactor-eng.pdf> [perma.cc/Y8RH-7UJH].

[164] *Ibid.*

[165] *Ibid.*

[166] Lyman, *supra* note 119 at 17. See also Miller, *ibid.*

[167] Miller, *supra* note 163.

CNSC and stakeholders that amendments to the *NSR* should be more performance-based because performance-based regulation necessitates the use of the graded approach.

2.4.4 Regulatory capture and pursuing recommendations of industry

The Fukushima nuclear accident that occurred in 2011 has been largely attributed to oversights arising from regulatory capture, corruption, collusion and nepotism.[168] The Fukushima accident serves as warning for all nuclear regulators as nuclear regulators are uniquely susceptible to capture because of the closeness at which they work with industry. For the regulation of SMRs, the risk of capture is heightened as regulators must work even closer with industry because of their unfamiliarity and lack of expertise with SMR technologies. Therefore, it is useful to understand briefly how regulatory capture arises, whether pursuing the suggestions made by industry and the CNSC heightens those risks, and what the CNSC can do to avoid that capture.

Regulators of complex domains are inevitably affected by weak regulatory capture arising from the need of the regulator to work with industry.[169] This cooperation is needed so that the regulator can obtain the expertise or training only available from the industry to competently govern over the complex activities being regulated.[170] Weak capture occurs where regulation remains positive overall, that is the interest of the public is maintained, except that the net social benefits of the regulation are diminished as a result of special interests.[171] Studies of regulatory models indicate that as the complexity of the actions being regulated increase, the more prone the regulator is to industry influence.[172] Thus, as the CNSC embark on the regulation of SMRs, their lack of expertise in the area heighten the potential of industry influence.

The co-operation of industry with the regulator is not *prima facie* capture – in fact, some models suggest that, in the regulation of complex domains, pro-firm biases may be part of an

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[168] See generally Richard Tanter, "After Fukushima: A Survey of Corruption in the Global Nuclear Power Industry" (2013) 37 Asian Perspective 475.

[169] Nolan McCarty & Susan Dod Brown, "Complexity, Capacity, and Capture" in Daniel Carpenter & David A. Moss, eds, *Preventing Regulatory Capture: Special Interest Influence and How to Limit It,* (New York: Cambridge University Press, 2013) 99 at 119.

[170] *Ibid.*

[171] Daniel Carpenter & David A. Moss, "Introduction" in Daniel Carpenter & David A. Moss, *ibid*, 1 at 12.

[172] Nolan McCarty & Susan Dod Brown, "Complexity, Capacity, and Capture" in Daniel Carpenter & David A. Moss, *ibid,* 99 at 119.

optimal regulatory design where public interest is preferred.[173] To determine if regulatory capture is present, the intention of policy must be examined to determine the true intentions, which may be deduced from the actual effects of the regulation.[174]

The cooperation between the CNSC and the industry and acting upon the suggestions of industry does not itself constitute regulatory capture. Whether capture is introduced is determined by how the CNSC implement the suggestions and what interests those suggestions benefit. For example, suggestions that the CNSC clarify how the graded approach and the principle of proportionality apply to SMRs will indicate capture where it is extended to prioritize private interest over that of the public. However, clarity may help alleviate capture, as it also helps to hold all proponents to the same standard and is open to the public to see and criticize. It is argued that the clarification of these two principles has little regulatory capture value.

On the other hand, suggestions of type certification of SMR technology is in the interest of the industry as it expediates licensing times and is decreases licensing costs. However, there is concern that relying on the suggestions of industry presents opportunities for regulatory capture. Thus, the CNSC must ensure their decision making remains independent from the industry's influence and that the interests of the public are maintained. Whether capture exists will depend on the effects the policy has on the public interest. Chapter 4 discusses how type certification may be implemented within the current framework in a manner that does not obscure licensing objectives and is in the interest of the public.

In the circumstances, the lack of expertise poses the largest potential for capture. It is suggested that the CNSC expand their expertise in SMR technologies in manner that relies on the industry as little as possible. This can be done by increasing the base salary to attract experts and compete with the private sectors, developing career paths and educational opportunities for key personnel independent of industry.[175]

The CNSC already have an existing ethics policy that prevent biases towards industry and promote transparency, accountability and clarity. Examples of the practice of transparency by the

[173] *Ibid.*

[174] Daniel Carpenter & David A. Moss, "Introduction" in Daniel Carpenter & David A. Moss, *ibid*, 1 at 8.

[175] Nolan McCarty & Susan Dod Brown, "Complexity, Capacity, and Capture" in Daniel Carpenter & David A. Moss, *ibid*, 99 at 119.

CNSC include the publishing of discussion papers and workshops completed with stakeholders, and the involvement of the public and Indigenous peoples within the process. Accountability is a value embedded within the CNSC code of ethics, which states that the CNSC is committed to exercising their authority in a responsible manner that maintains public trust and confidence and being accountable for their "decisions, actions and advice."[176] Clarity is promoted through the CNSC's dealings with industry and its robust library of regulatory documents outlining their expectations.

The CNSC's cooperation with industry does not by itself indicate capture but is a common and possibly critical method for the regulation of complex domains. CNSC is not immune to capture and has been criticized in the past for introducing possible capture.[177] Additionally, the complexity of SMRs and the lack of the CNSC's familiarity with the technology motivates further cooperation with industry, thereby introducing more potential for capture. For this reason, suggestions considered within this thesis are explored objectively and with consideration of the interests they benefit. Additionally, it is suggested that the CNSC build up their expertise, preferably without deference to industry, and to continue and bolster their practice of accountability, transparency and clarity.

2.4.5 Conclusion

DIS-16-04 created discourse between industry stakeholders and the CNSC to facilitate the transparent development of regulations for SMRs. The result of *DIS-16-04,* and the subsequent workshops and readiness activities, illustrate two critical points for the regulation of SMRs. First, the graded approach for SMRs is a significant consideration when offsetting pre-existing regulatory requirements, the success of which will depend on the quality and credibility of supporting information. The lack of clarity on how this approach will accommodate SMRs poses

[176] Canada, Canadian Nuclear Safety Commission, *CNSC Values and Ethics Code*, (Ottawa: CNSC, 2012) at 4.

[177] See Theresa McClenaghan, Chris Rouse & Shawn-Patrick Stensil, Greenpeace, "Re: Opposition to restrictions on public participation proposed in Discussion Paper DIS-13-02" (21 March 2014) (In response to DIS-13-02, Greenpeace argued that the CNSC's changes to limit public participation at hearings to those who "who [are] directly affected by the carrying out of the designated project" introduced capture at 1) online: Canadian Environmental Law Association website <http://www.cela.ca/sites/cela.ca/files/REGDOCparticpationletterCNSC.pdf> [perma.cc/ZMN2-X6E9]

challenges, but the CNSC plans to resolve this issue through continued consultation with industry and the participation of proponents in the pre-licensing vendor design review program.[178]

Second, the CNSC is open to implementing additional regulatory approaches where appropriate. In their response, the stakeholders suggested that the principle of reproducibility would be effective for the regulation of SMRs in Canada and streamlining the licensing process. On this point the CNSC appears to be open to alternative approaches to licensing; however, the CNSC is concerned about the implementation of those methods within the framework.[179] Notwithstanding, the CNSC has stated no plans of implementing alternative regulatory procedures at this time.

The CNSC believes that Canada will be able to safely regulate SMRs once they have developed the expertise and have made the appropriate amendments to the current regulations. However, it is unclear on what steps the CNSC plans to take to reduce licensing times and take advantage of the SMRs' fast manufacturing and installation times. Arguably, by bolstering the current framework with the implementation of the graded approach, adding regulatory flexibility, implementing reproducibility and assuring that conservatism is implemented commensurate with the risks, SMRs can be regulated effectively and their advantages can be exploited for the benefit of Canadians. In making these changes, it will be important to promote impartiality and independence from the industry to avoid capture by developing their own expertise, clarifying their requirements and being transparent and accountable to the public.

2.5 Conclusion

The current Canadian regulatory framework, though aimed to be technologically neutral, was developed to fit the conventions of CANDU reactors and creates dissonance with the regulation of SMRs. Though the underpinning regulatory principles and approaches of Canada's regulations are applicable to SMRs, such as probabilistic and deterministic risk assessments, RIDM, the graded approach and others mentioned in this chapter, the execution of these principles

[178] *Ibid.* See e.g. Canada, "What We Heard Report", *supra* note 111 (the report is an example of how the CNSC works with the industry).

[179] Canada, "What We Heard Report", *Ibid.*

are done in accordance with the CNSC's experience with CANDU technology. That is, regulatory objectives are formed with CANDU reactors in mind, which may not be applicable to SMRs.

The dissonance between SMRs and current regulatory policies create challenges for proponents trying to license novel SMR designs. Aspects of Canada's regulations may not be capable of being met by SMRs as they consider extraneous considerations made irrelevant by the SMRs design. As the proponent may not be able to demonstrate the satisfaction of these objectives, the proposed designs are met with conservatism and precaution that may be irrelevant or disproportionate to the actual risks. To alleviate these issues, there needs to be sufficient regulatory flexibility so that SMRs can be assessed with appropriate scope and detail.

Furthermore, Canada's regulations poorly manage novel and uncertain risks, which exacerbates the precaution and conservatism applied. It is not suggested that Canada abandon its risk averse approach to regulation. However, it is argued that Canadian regulation may better manage risk using other risk management approaches and by bolstering already existing regulatory principles. In this way the CNSC may better accommodate SMRs without imposing disproportionate amounts of conservatism.

The CNSC has not made attempts to provide a framework specifically for SMRs. Instead, it has attempted to shoehorn the regulation of the technology within the existing framework. Stakeholders and the CNSC agree that the current framework may regulate SMRs in a manner that ensures the safety and protection of the public and the environment. However, whether this is the most effective approach for deploying SMRs is questionable as regulations are tailored to the regulation of CANDU reactors.

This thesis argues that SMRs can be successfully regulated within the existing framework in light of existing regulatory principles and regulatory bias towards CANDU reactor types. This can be accomplished by adjusting regulations to embrace regulatory flexibility and alternative risk management techniques so that SMRs may be regulated according to their design. Chapter 3 discusses how Canada's regulation can become increasingly flexible to accommodate SMRs and suggests risk management practices to help mitigate risks associated with SMRs. Chapter 4 discusses type certification and how the CSNC can employ type certification to streamline the licensing of SMRs and how type certification can be integrated within the existing framework.

Chapter 3: Regulating Risks and Uncertainty

3.1 Introduction

SMRs impart a new frontier for Canada's nuclear industry but are accompanied by uncertainty, novel and complex technology and other regulatory hurdles. These aspects impose difficulties for the CNSC who attempt to make decisions within the RIDM process confidently. To overcome these issues, the CNSC must investigate alternative approaches to regulation, safety assessment and uncertainty.

Regulators and the nuclear industry promote performance-based regulation as a critical approach for the regulation of SMRs. Accordingly, the CNSC has begun shifting regulations to reflect that sentiment. The goal of this shift is to do away with conventional prescriptive practices and develop a more performance-based regulatory regime. Performance-based regulations allow for the assessment of new nuclear reactor designs according to their specification and not expectations relevant to CANDU reactors. Industry and the CNSC have begun this shift with amendments made to the *NSR*. However, this shift needs to be pervasive throughout regulations and regulatory expectations.

The CNSC provide regulatory expectations for the probabilistic and deterministic risk assessment of all nuclear activities. However, the scope, content and details of these expectations are specific to CANDU reactors and are not fully appropriate for SMRs. The reliance on convention creates significant difficulties for SMR proponents attempting to deploy reactors that implement novel safety approaches. For example, SMRs may not require the same practices applied to CANDU reactors such as defence-in-depth, barriers or other precautions because they are safe by design. This thesis argues that the scope, detail and content of safety assessment should be specific to the reactor to in accordance with promoting regulatory flexibility.

To mitigate risk uncertainty, the CNSC applies comprehensive conservative measures without considering other risk management tools. However, uncertainty can be used strategically within risk management for purposes advantageous to the overall assessment of SMRs. Uncertainty may be used to compare and analyze risk management approaches, ensure that safety objectives are met, provide credibility to decisions and determine the amount of conservatism needed. Using uncertainty in this way provides regulators confidence when regulating SMRs and ensures that conservatism is being fairly applied to mitigate risks.

Another approach to mitigate uncertainty is the use of expert judgement. The use of expert judgement within the regulation of nuclear activities is not new.[180] However, the elicitation of expert judgment to produce probabilistic risk distributions is not contemplated within current regulations. Expert elicitations may be relied upon where there are gaps in risk assessments, where mathematical models inaccurately characterize the novelty of nuclear reactors, where parameters are unknown or where there is no operating data.[181] This chapter proffers a two-step process for eliciting risk distributions from experts and demonstrates how it may interact within Canada's regulatory framework.

The following discussion raises attempts to alleviate the fundamental challenges of regulating SMRs. The discussion of flexibility highlights how the CNSC may be more adaptable to SMR variation so that all designs may be appropriately regulated. Additionally, it is suggested that risk management utilize uncertainty analyses and the use of expert elicitation to fill gaps where they exist to address the challenges of uncertainty. Under a flexible regulatory structure, the combination of these suggestions allows the CNSC to appropriately consider all aspects of SMR designs without bias and with confidence.

3.2 Types of regulatory bases

In its current state, Canada's nuclear regulations impose both prescriptive and performance-based regulations.[182] Prescription-based frameworks prescribe comprehensive and detailed standards applied equally to all activities regulated within that framework.[183] Alternatively, performance-based schemes set out aspirational objectives and impose safety criteria that conform to those objectives rather than imposing prescriptive requirements.

[180] Early on in the history of nuclear regulation, regulators relied on expert judgment to generate prescriptions resulting in substantial safety margins, and experts are still relied upon intermittently throughout Canada's nuclear regulations.

[181] National Research Council, *Science and Judgment in Risk Assessment*, *Infra* note 210 at 165.

[182] Dorman, *supra* note 12 at 96.

[183] *Ibid* at 97–98.

There are multiple bases for nuclear regulatory frameworks in addition to prescriptive and performance-based schemes. The three most common for nuclear regulations are prescriptive-based, performance-based and process-based regulations.[184] Frameworks such as outcome-based and self-assessment based are less common in the nuclear industry. Each basis has advantages and disadvantages and applicability for different scenarios. The following is a discussion of the regulatory basis Canada currently administers, the implications that arise when shifting regulation to embody a more performance-based regulatory framework and the advantages and disadvantages of different regulatory bases for SMRs.

3.2.1 Prescriptive-based, performance-based and process-based regulation

The nuclear regulations of Canada utilize a mixture of performance-based and prescriptive-based regulation. With the enactment of the *NSCA* in 1997, Canada introduced increasing prescriptive regulation, a noted trend within Canadian regulation at the time.[185] Since its enactment, Canada has maintained this mixture, which has served the industry well. However, with the anticipation of SMRs and other advanced reactors, the CNSC has begun shifting regulations towards performance-based approaches. An overview of the strengths and drawbacks of these regulatory bases are important for determining what aspects of the current mixture produce challenges for the regulation of SMRs.

Barraclough and Carnino have classified nuclear regulation into three overall approaches: process-based, performance-based and prescriptive-based.[186] The regulation regime favoured by the CNSC's regulatory predecessor, the AECB, was largely performance-based. However, the enactment of the *NSCA* provided approaches that were more prescriptive than in the past, with a noted trend towards increased prescription-based regulations.[187] Since then, the CNSC has maintained a regulatory approach that mixes all three approaches.

[184] *Ibid.*
[185] Dorman, *supra* note 12 at 96.
[186] Ian Barraclough & Annick Carnino, "Safety Culture Keys for Sustaining Progress" (1998) 40:2 IAEA Bulletin – Quarterly QJ Intl Atomic Energy Agency 27 at 29–30.
[187] *Ibid.*

Process-based regulation hinges safe operation of the nuclear power plant on effective organizational processes of the licensee for the operation, maintenance, modification and improvement of the facility.[188] The organizational system is developed from the perspective of the facility's internal logic and remains flexible so that the facility may adapt operations to their history, culture and business strategy.[189] This approach can provide an in-depth understanding of the licensee's performance and may be used by regulators to identify key processes that lead to safe performance.[190] However, process-based regulations face difficulties in evaluating and defining adequate processes for complex systems, such as those associated with SMR facilities. Additionally, processes are only effective where linked to process outcomes, which are not always straightforward to determine.[191] Though process-based regulations provide flexibility for SMR licensees to accommodate the novelty and innovations of their facilities, risk uncertainties of SMR designs increase the complexity of the facility. As a result, this creates challenges of evaluating and defining appropriate processes.

Performance-based regulation forms the primary structure of Canada's nuclear regulatory framework and provides licensees flexibility due to safety criteria conforming to safety objectives rather than prescriptive requirements. Performance-based regimes set out targets for reactors with the onus on the operators to meet them – prevention of unreasonable risk and ALARA are examples of this.[192] This approach is especially suited for the design phase of nuclear power plants as it provides flexibility for demonstrating the safety of the design.[193] For these reasons, industry and the CNSC has supported this regime as the best approach to regulating SMRs. The flexibility available within the design phase provides applicants with the ability to deviate from the convention so long as they comply with safety objectives.

Prescription-based regulation provides a comprehensive and detailed regime based on standards and regulations that apply equally to every nuclear installation.[194] Under this regime, regulation occurs through inspection and reporting to ensure compliance, where penalties are

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188 International Atomic Energy Agency, *Regulatory control of nuclear power plants Part A (Textbook)*, Training Course Series No 15 (Vienna: IAEA, September 2002) [IAEA, *Regulatory Control*] at 35.

189 *Ibid.*

190 Dorman, *supra* note 12 at 99.

191 IAEA, *Regulatory Control*, *supra* note 188 at 35.

192 Dorman, *supra* note 12 at 98.

193 *Ibid.*

194 *Ibid* at 97.

imposed for non-compliance.[195] Prescriptive regulations provide difficulties for operators as regulations are inflexible to accommodate modifications or unconventional operations.[196] Prescriptive regulations are challenging for regulating SMRs because it provides not only inflexibility for applicants to meet the requirements but also difficulties for the decision-maker to anticipate the wide variety of requirements needed to regulate the plethora of possible SMR designs.

Canada implements process-based, performance-based and prescription-based regulations for different aspects of their regulatory regime, with the predominant approach being performance-based. Performance-based regulation is being further encouraged with the revision and amendments of regulation as the Canadian nuclear industry prepares for the deployment of SMRs and other advanced reactors. This regulatory shift finds impetus from the challenges posed by prescriptive-based regimes to unconventional reactor designs and operation. The inflexibility of prescriptive systems provides little ability for proponents to approach regulatory requirements in novel and innovative ways. The flexibility provided by performance-based regulation provides the most favourable regulatory strategy for SMRs out of the three most common approaches.

3.2.2 Performance-based regulation and the standardization of convention

Despite being touted as technologically neutral, Canadian nuclear regulations have developed with the CANDU reactor as the single point of reference, and, thus, existing regulations have an inherent bias against other nuclear generation bases. This bias is exacerbated by Canada's long history of regulating CANDU reactors and the nuclear industry's tendency to impose conservative decision-making on uncertain or unfamiliar technologies. This bias towards convention poses a significant challenge for the regulation of SMRs, despite attempts to make regulations performance-based. To mitigate this bias, the CNSC must continuously develop as a regulator and develop risk management procedures that do not solely rely on conservative measures.

[195] *Ibid.*
[196] *Ibid.*

Inexperience with alternative reactor designs encourages biases in favour of conventional approaches, and at its extreme may standardize conventional approaches within the regulatory framework. Since the initial deployment of the CANDU reactor in 1962, Canada's experience with nuclear reactors has been specific to CANDU reactor designs which have not only shaped Canadian regulations but has established conventions for mitigating and ensuring reasonable risk. The CNSC's inexperience of novel reactor designs may provide challenges to proponents who attempt to destabilize those conventions through innovative and novel approaches. This challenge is bolstered by the systematic bias created by the principle of proportionality and conservative decision-making.

Conservative decision-making and proportionality favour conventional approaches to address risks because it places greater scrutiny on innovative approaches and restricts the exposure of the decision-maker to new technologies. The graded approach scrutinizes nonconventional approaches according to their complexity and novelty. As a result, convention is favoured over novel measures to address safety. Favouring convention also sustains regulatory inexperience and maintains the dependence of the regulator on conventional measures as there is less incentive to deploy novel designs. This cyclical conservatism can result in a deadlock that may mirror the challenges of prescriptive-based regulatory regimes.

Prescriptive-based regulatory regimes impose an inflexible framework of requirements that create challenges for proponents who try to license novel products.[197] The inflexibility that may arise out of conservative decision-making and the dependence on conventions create similar challenges.[198] This issue may impact the application of the graded approach as regulators are inclined to impose greater conservatism than is necessary because of their lack of experience with the technology. This fear is present in the industry's concern that the lack of operating experience with novel designs will result in the misapplication of the graded approach.[199]

The lack of diversification of nuclear reactors within the United States exemplifies this concern. The U.S. Nuclear Regulatory Commission traditionally relied on prescription-based regulations which placed a heavy burden on proponents to conform reactors to their regulatory

[197] *Ibid* at 97.
[198] *Ibid.*
[199] Canada, "What We Heard Report", *supra* note 111

requirement and provided little freedom to modify reactor operations.[200] Prescription-based regulation is the primary reason why American utilities have ordered no new power reactors since the 1970's.[201] For this reason, the U.S. has been shifting towards more risk and performance-based regulations.[202]

To address these concerns, the CNSC has affirmed that they will develop their internal knowledge and understanding of nuclear technologies while also increasing performance-based regulation.[203] The development of expertise and knowledge of novel nuclear technologies will aid with redefining reference points and developing an understanding of the regulation of SMRs. However, the substantial number of SMRs and the continual progression of the nuclear industry pose challenges for the advancement of the expertise necessary to regulate SMRs. Furthermore, experience and knowledge of this technology do not offset the inclination of the regulator to practice what they are most familiar with. Arguably, promoting more performance-based regulation an ensuring that appropriate levels of conservatism are applied is the best approach to reduce bias and encourage innovative and novel designs.

3.2.3 Conclusion

The CNSC and industry agree that performance-based regulation is the most suitable regulatory base to regulate SMRs. Performance-based regulations evaluate applications on whether they meet overarching safety objectives on a case by case basis. Performance-based regulations provide flexibility for applicants who attempt to adapt SMR designs to meet safety objectives in novel ways. However, conservative decision-making, proportionality and the graded approach in addition to lack of experience create the fear that regulators will be biased towards conventional approaches to safety and design, rather than being open to novel and innovative design.

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[200] Dorman, *supra* note 12 at 97.
[201] *Ibid.*
[202] See Dorman, *supra* note 12 at 99.
[203] Lee, *supra* note 14 at 3.

The OECD remarks that experience, transparency, clarity and continuous self-improvement are key characteristics for balanced and unbiased decisions.[204] However, this does not address the possible systematic bias created by conservatism. Instead, regulators must further investigate how performance-based regulations can further the directives of RIDM and what risk management strategies are available to the regulator for regulating SMRs. In addressing these issues, the CNSC has acknowledged that they are open to alternative regulatory strategies.

3.3 Safety analyses and addressing uncertainty and gaps in risk assessments

Performance-based regulation is the most effective bases for regulating SMRs; however, the regime is only as robust as the regulatory practices it embodies. The RIDM process is an essential element to performance-based regulations because it informs the regulator of whether the proponent has met relevant safety objectives. If not, the current framework seeks to apply precautionary measures in reaction to uncertainty. It is important to evaluate what aspects of the RIDM process are deficient in its application to SMRs for the development of a more robust system.[205]

A significant concern is how uncertainty may be correctly addressed within the RIDM process to ensure that measures, and the extent of their application, are appropriately applied.[206] The novelty and complexity of SMRs in addition to the uncertainty inherent within many designs suggests that the graded approach will highly scrutinize them. To overcome these issues this section discusses the uncertainty that SMRs pose, the shortcoming of the risk assessment policies, and how to employ uncertainty as a risk management tool. The resulting discussion explores how risks are currently used in risk assessment policies of the CNSC and make recommendations on how current approaches can accommodate SMRs.

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[204] Nuclear Energy Agency, *Characteristics of an Effective Nuclear Regulator*, *supra* note 15 at 15–18, 19, 25.

[205] See generally Nuclear Energy Agency, *Characteristics of an Effective Nuclear Regulator*, *supra* note 15 (A drawback of a risk and hazard informed regulatory framework is that there is a possibility that some regulatory areas may receive inadequate or too much attention due to the limitation of risk analysis methods at 26).

[206] See Canada, “What We Heard Report”, *supra* note 111.

3.3.1 The uncertainty of SMRs

The CNSC has outlined the uncertainties associated with SMRs and how they pose challenges to regulation in *DIS-16-04*. Uncertainty creates significant concern for regulators because of the need for certainty and predictability in their decisions. Nuclear regulators have relied on conservatism and other precautionary measures to accommodate uncertainty. However, this approach sheds very little light on the issues at hand and neglects other available recourses.

DIS-16-04 identifies risk uncertainty as a key challenge for regulating SMRs.[207] Uncertainty impacts the accuracy and confidence of regulatory decision-making as regulators cannot be certain of the risks involved with the plant performance under normal operating conditions and accident conditions.[208] Fundamentally, two aspects of these challenges pose a concern for regulators. First, risks may be unknown, inaccurate or incomplete thus affecting the certainty of safety analyses on which regulatory decision-making depends.[209] Second, management of risks become challenging, even where risks are sufficiently certain, as the content and extent of measures taken to manage those risks may not be clear or may be unconventional and, therefore, beyond the experience and expertise of the regulator.

Uncertainty may arise because of gaps within risk assessments or inaccurate analysis models and parameters. Gaps within risk analysis arise because of a lack of research and development into the design. Model uncertainty may be significant depending on the novelty and complexity of the reactor technology and system design. Model uncertainty arises from oversimplification of reality, relationship errors, neglect or exclusion of relevant variables, and failure to account for correlations that cause seemingly unrelated events to occur much more frequently than would be expected by chance.[210] Thus, model uncertainty will vary with the level of understanding of the system and may be significant for proposed SMR facilities that have a high level of complexity and novelty. Parameter uncertainty arises from a lack of accurate data for use within risk models. Where accurate and practical data is missing, risk assessors may use less

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[207] Canada, *DIS-16-04*, *supra* note 120 at 4.

[208] *Ibid.*

[209] *Ibid* (For example, the lack of "technical information, including research and development activities used to support a safety case" poses significant difficulty for demonstrating and "supporting the credibility of safety claims made by an applicant both in the licensing process and during conduct of licensed activities" at 5).

[210] National Research Council, *Science and Judgment in Risk Assessment*, (Washington: National Academies Press, 1993) at 165.

accurate data derived from theory or expert judgement.[211] Parameter uncertainties are common within risk assessments and increase with novelty and complexity.

The OECD outlines in their article "Nuclear Regulatory Decision-making" strategies for regulators when making decisions in the face of uncertainty.[212] The article explains that it is common for regulators to face unreliable safety analyses because of risk uncertainty or lack of data for the technology, and provides a series of steps to follow in such circumstances.[213] The article first suggests that the regulator do its best to collect and assess available information, which may require solicitation of additional information from the operator or vendor.[214] Second, it suggests that the regulator assess where gaps occur and raise implications that may result from not filling those gaps.[215] The article recommends that regulators explore conservative bounds to overcome data uncertainties.[216] Finally, the article suggests the use of conservative actions such as defence-in-depth and safety margins, and the judgement of experts and senior regulatory staff to accommodate uncertainty.[217] Though the suggestions made by the article are helpful, they do very little to develop a robust and experienced scheme.

"Nuclear Regulatory Decision-making" provides regulators with a sensible yet impotent outline of steps to manage uncertainty. The outlined steps provide no real depth and do not develop the issues. For example, the approach fails to address the amount of conservatism in the application within step two and three, or how much reliance to place on expert judgement. The outline fails to consider different types of uncertainty such as model and parameter uncertainty or gaps within risk assessments. Instead of developing risk management strategies, the article ultimately suggests the use of conservative measures to address uncertainty.

To address the uncertainties presented by SMRs the CNSC must promote further performance-based regulation within safety assessment policies. Currently, the policies are framed to address the safety of CANDU reactors and rely heavily on conservative or precautionary

[211] Canada, Canadian Nuclear Safety Commission, *Safety Analysis: Deterministic Safety Analysis, REGDOC-2.4.1* (Ottawa: CNSC, May 2014) [Canada, *REGDOC-2.4.1*] at 22.
[212] Nuclear Energy Agency, *Nuclear Regulatory Decision-making, supra* note 61.
[213] *Ibid* at 24.
[214] *Ibid*.
[215] *Ibid*.
[216] *Ibid*.
[217] *Ibid*.

measures to address uncertainty. Though reliance on conservative measures is not misguided, this thesis argues that the current regulatory policy overlooks alternative methods of addressing uncertainty conducive to the regulation of SMRs while giving deference to practices specific to the regulation of CANDU reactors. Overall, this creates needless and disproportionate difficulty for SMRs projects to meet regulatory expectations. However, by providing more flexibility within regulatory expectations and practices using performance-based approaches, the unique qualities of SMRs may be appropriately accommodated and regulated within Canada's regulatory framework.

3.3.2 Safety analysis policy of the CNSC

The CNSC has developed their deterministic safety assessment policy within *REGDOC-2.4.1, Deterministic Safety Analysis.*[218] *REGDOC-2.4.1* outlines the scope, detail and content of the safety analysis, which aims to demonstrate the safety and adequacy of the design and performance of nuclear power plants. Though *REGDOC-2.4.1* is developed to be technologically neutral, its application to SMRs leaves much to be desired. *REGDOC-2.4.1* implements a bifurcated process for the assessment of nuclear power plants and small reactor facilities. As a result, SMRs may be divided based on their power level into two different safety analysis regimes; the first provides little flexibility for variation and the second employs the graded approach to determine the scope, detail and content of the safety analysis. It is suggested that SMRs should be regulated similarly to small reactor facilities, where the graded approach is implemented to determine the depth of scope, content and details necessary for their safety analysis so that they may be appropriately regulated. This approach transforms the prescriptive and conventional nature of *REGDOC-2.4.1* to a more flexible approach.

The objective of a safety analysis is to evaluate event consequences concerning the siting, design, commissioning, operation or decommissioning of nuclear facilities to confirm and demonstrate its safety in all lifecycle phases.[219] Deterministic safety assessment, probabilistic safety assessment and hazard analysis are assessment tools implemented within the safety analysis

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[218] Canada, *REGDOC-2.4.1, supra* note 211 at 22.

[219] Canada, Canadian Nuclear Safety Commission, *Safety Analysis: Deterministic Safety Analysis, REGDOC-2.4.1* (Ottawa: CNSC, May 2014) [Canada, *REGDOC-2.4.1*] at 4.

to determine the likelihood and consequences of various events and to identify complementary design features that address those events.[220]

A safety analysis implements a systematic process to identify events, event sequences and event combinations (collectively referred to as "events") that pose risks to the safe function of nuclear power plants.[221] *REGDOC-2.4.1* provides an inclusive list of factors to consider within the analysis;[222] however, this list may not apply to SMRs because of the specificity of the listed factors to CANDU reactors. For example, the factors list operating experience and events specific to nuclear power plants relevant to the regulation of CANDU reactors. However, as noted prior, these factors are inapplicable to the safety analysis of SMRs because SMRs typically lack operating data and are dissimilar to most other reactor types. Where these factors are assessed with insufficient data, the CNSC are compelled to act conservatively according to their experience and past practices. In this instance, it is suggested that performance-based factors and other approaches to risk management be implemented. This may include the use of expert-judgement and the use of the graded approach to determine scope and content, which are all discussed in more depth later in this chapter.

Consideration is given to expert judgement within the safety analysis when grouping and prioritizing events for analysis, however, the overall safety analysis relies heavily on objective risk assessment techniques. Engineering judgement is implemented within *REGDOC-2.4.1* primarily to provide reference and support for grouping and prioritizing of risks.[223] Overall, *REGDOC-2.4.1* provides expert judgement with a minor role in the safety analysis and relies heavily on deterministic safety assessment, probabilistic safety assessment and hazard analysis for performing safety analysis.

REGDOC-2.4.1 achieves high levels of confidence using three statistical methodologies. First, the conservative analysis method is used to achieve appropriate conservative limits relative to the specified acceptance criteria. Second, the estimate-plus-evaluation-of-uncertainties method is used to determine initial and boundary conditions with all uncertainties defined to a high level

[220] *Ibid* at 5.
[221] *Ibid* at 8.
[222] *Ibid* at 9.
[223] *Ibid* at 12.

of confidence. Finally, the best estimate method is employed to obtain realistic results.[224] Notably, the methodologies listed implement conservatism to achieve high levels of confidence when faced with uncertainty.

Regulations employ conservatism in both the conservative analysis method and estimate-plus-evaluation-of-uncertainties method.[225] The conservatism within safety analysis is defined as the "[u]se of assumptions … about a phenomena or behaviour of a system being at or near the limit of expectation, which increases safety margins or makes predictions regarding consequences more severe than if best-estimate assumptions had been made."[226] This approach to conservatism assumes worst case scenarios, and without more is in danger of applying excess conservatism. REGDOC-2.4.1 provides no discussion as to how this conservatism may be applied commensurate to uncertainty.

REGDOC-2.4.1 is split into two parts which have differing approaches for determining the scope, detail and content of the safety analysis. Part I applies to nuclear power plants with a power level above 200 MWt and Part II applies to small reactors facilities that have a power level of 200 MWt or less.[227] Small reactor facilities include those "used for research, isotope production, steam generation, electricity production and other applications."[228] As a result, SMR projects may be assessed differently based on their power level.[229] The most significant difference between Part I and Part II is the invocation of the graded approach for determining the scope, detail and content of the safety analysis of small reactor facilities within Part II.

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[224] *Ibid* (best-estimate-plus evaluation of uncertainties method, conservative analysis method and best-estimate analysis methods are the "three main analysis methods used in deterministic safety analysis" at 22, 63, 64).

[225] *Ibid* at 22.

[226] *Ibid* at 64.

[227] *Ibid* at i.

[228] *Ibid*.

[229] See Nuclear Power, "Thermal Efficiency of Nuclear Power Plants" (last visited 23 October 2018), (Very small modular reactors (vSMRs) will be assessed under Part II of *REGDOC-2.4.1* as they range from 45.5 MWt or less, assuming a power output of <15 MWe and an "overall thermodynamic efficiency [of] one-third (33%)"), online: Nuclear Power <https://www.nuclear-power.net/nuclear-engineering/thermodynamics/laws-of-thermodynamics/thermal-efficiency/thermal-efficiency-of-nuclear-power-plants/> [perma.cc/4SCK-QBRV]. See also M Moore, "The Economics of Very Small Modular Reactors in the North" (Paper delivered at the 4th International Technical Meeting on Small Reactors, 2–4 November 2016), (Chalk River: Canadian Nuclear Laboratories, 2016) ("However, several very small modular reactor (vSMR) concepts are under development, which have an electrical capacity of <15 MWe and are specifically designed for remote communities" at 1) online: Canadian Nuclear Laboratories http://www.cnl.ca/site/media/Parent/Moore_ITMSR4.pdf> [perma.cc/5S77-92NJ].

The distinction between Part I and Part II is important because the policy expressly acknowledges the need for the graded approach to define the scope, content and detail for safety assessments of small reactor facilities.[230] The policy explains that the use of the graded approach in this way is needed for small reactor facilities because for some facilities "[d]ifferent accident scenarios may apply and some scenarios may need only limited safety analysis."[231] That is, the policy acknowledges that the graded approach is needed to anticipate the variability of nuclear activities encompassed within the definition of "small reactor facilities." Conversely, the policy does not apply the graded approach for safety analysis of nuclear power plants assessed under Part I because of its conventional application to CANDU reactors.[232]

REGDOC-2.4.1 is presented as technologically neutral, but it's failure to acknowledge the graded approach in Part I suggests it is not drafted with the anticipation of applying to power generation facilities other than CANDU reactors. Instead of defining the depth, content, and detail of the safety analysis using the graded approach, Part I sets out analysis criteria relevant to CANDU technologies. This criteria includes "the selection of events to be analyzed, acceptance criteria, deterministic safety analysis methods, and safety analysis documentation, review and update, and quality control."[233] It is clear that *REGDOC-2.4.1* was drafted using CANDU reactors as a reference point as much of the technical criteria and requirements are exemplified using references to how they apply to CANDU reactors.[234] Thus, the safety analysis developed within *REGDOC-2.4.1* is not flexible to other reactor types and may not be effective for the regulation of SMRs.

The CNSC has already acknowledged the need for the graded approach for the regulation of SMRs.[235] For example, the CNSC has integrated the graded approach into the draft licence application guide for SMRs to provide applicants with the opportunity to address SCAs using alternative approaches.[236] In doing so, the CNSC recognizes that "many requirements were originally written to reflect experience from water-cooled reactor designs, [and] that a graded

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[230] Canada, *REGDOC-2.4.1*, *supra* note 211 at 42.
[231] *Ibid.*
[232] See *ibid* at 1.
[233] *Ibid.*
[234] See *Ibid* at 14–16, 29–30, 57–58.
[235] Canada, "What We Heard Report", *supra* note 111.
[236] Canada, *REGDOC-1.1.5*, *supra* note 73 at 14.

approach may be applied, or alternative approaches used, to meet the intent of some requirements or to make a compelling case that the application of the requirements would not serve the underlying purpose or is not necessary to achieve the underlying purpose."[237] It is sensible to implement the graded approach to determine the scope, depth and content of risk assessments of SMRs so that their assessment does not consider irrelevant consideration and so that risks are appropriately considered.

DIS-16-04 posed the questions whether "the regulatory requirements and guidance clear for the kinds of alternatives that might be proposed for Deterministic/probabilistic safety analyses for SMR facilities? Do the existing requirements permit the establishment of a suitable level of probabilistic safety analysis for different novel designs?"[238] In their response to *DIS-16-04*, industry consistently recommended that safety analyses include alternative techniques to probabilistic safety assessment[239] and requested the consideration of key features of SMRs that render traditional events and scenarios insubstantial.[240] Industry also explained that the extent of applicability of current deterministic and probabilistic policies are limited by the (1) focus of safety analysis policy on water-cooled reactors; (2) absence of sufficient procedure for dealing with passive systems and inherent safety; and (3) inability to identify potential accidents for designs with little or no operating experience.[241] The nuclear industry has suggested that policies should reduce prescriptive elements and provide flexibility within the policy to combat these limitations.

Industry suggests that a system to define scope, content, detail and depth on a case-by-case basis for non-water cooled reactors within safety analyses would offset the limitations of the safety

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[237] *Ibid.*

[238] Canada, *DIS-16-04, supra* note at 14.

[239] SNC Lavalin, "SNC-Lavalin Nuclear Comments on Draft *DIS-16-04* Small Modular Reactors: regulatory Strategy, Approaches and Challenges" (18 September 2018) at 26 online: CNSC website < nuclearsafety.gc.ca/eng/pdfs/Discussion-Papers/16-04/DIS-16-04-comment-received-SNC-Lavalin.pdf> [perma.cc/2HBG-A9XP]. See also Ontario Power Generation, "OPG Comments on Discussion paper DIS 16-04 'Small Modular Reactors: Regulatory Strategy, Approaches and Challenges'," (18 September 2018) at 26, online: CNSC website <nuclearsafety.gc.ca/eng/acts-and-regulations/consultation/history/DIS-16-04.cfm>[perma.cc/34LT-2KLH]. See also Bruce Power, "Bruce Power Comments on Discussion paper *DIS-16-04* - Small Modular Reactors: Regulatory Strategy, Approaches and Challenges," (18 September 2018) at 12 online: CNSC website <nuclearsafety.gc.ca/eng/pdfs/Discussion-Papers/16-04/DIS-16-04-comment-received-bruce.pdf > [perma.cc/KEJ3-6QZ7]. See also Canadian Nuclear Laboratories, "Canadian Nuclear Laboratories Comments on Draft Discussion Paper *DIS-16-04* Small Modular Reactors: Regulatory Strategy, Approaches and Challenges," (18 September 2018) at 29 online: CNSC website <nuclearsafety.gc.ca/eng/pdfs/Discussion-Papers/16-04/DIS-16-04-comment-received-CNL.pdf> [perma.cc/86LC-5GZG].

[240] SNC Lavalin, *ibid*.

[241] *Ibid* at 27.

analysis of SMRs. Regarding the first limitation, industry suggests that vendors be able to review the CNSC's safety analysis requirements before analysis and exclude or add requirements where applicable.[242] This addition would require the vendor to address the safety intent of underlying requirements and ensure their satisfaction. Additionally, vendors will have to identify requirements for phenomena latent within their reactor designs but not addressed within Canada's safety analysis policies. However, this approach is precarious as it leaves it to the vendor to develop potentially significant aspects of the safety analysis that may not be within the scope of the expertise of the CNSC. The principle of proportionality may be employed to help curtail this issue as vendors will be required to provide documentation and support commensurate with the risk and novelty of the alternatives implemented.

To address the second limitation, industry suggests providing vendors and proponents the opportunity to be credited for the inherent or passive safety features of their design. In this way designs with a high degree of passive or inherent safety can forego unneeded extensive analyses.[243] This approach eliminates the need for backup safety functions and the need to include reactor vessel failure within design basis events.[244] For example, the inherent safety of molten salt reactors make it a popular and advantageous reactor design for nuclear power generation.[245] Molten salt reactors have a strong negative temperature coefficient of reactivity, use a stable coolant, operate at low pressures, are easy to control, have passive decay heat cooling, and do not require expensive containment. Canada's nuclear policies provide little flexibility for accepting these inherent safety features without requiring extensive assessment. By providing a crediting system, nuclear regulators can not only accommodate the passive features of SMRs but may serve to streamline aspects of the safety analysis. Crediting proponents for the safety of their reactors is expanded upon within chapter 4, where this thesis discusses the use of type certification to certify reactor designs for more streamlined regulation.

The third limitation applies to any new design as identifying events typically requires operating experience.[246] Though there are techniques to derive a list of events, conventional

[242] *Ibid* at 27.
[243] *Ibid.*
[244] *Ibid.*
[245] Badawy M Elsheikh, "Safety assessment of molten salt reactors in comparison with light water reactors" (2013) 6:2 J Radiation Research & Applied Sciences 63 at 63.
[246] SNC Lavalin, *supra* note 239 at 27.

probabilistic safety assessments do not integrate well with passive systems.[247] Industry suggests that vendors initiate the development necessary where needed, which the CNSC may accumulate for its use.[248]

Upon making these recommendations, industry notes the utility of the graded approach for providing flexibility and supporting the recommendations made above. They explain that, although no new regulatory requirements are needed, acknowledgement of the graded approach within the process would be useful for demonstrating safe deviation or alteration of the safety analysis requirements.[249]

The use of the graded approach for the safety analysis of SMRs is not without difficulty as the lack of operational history, uncertainty and insufficient expertise available may complicate determinations of scope, detail and content. That is not to say that the graded approach would provide a streamlined and simpler risk assessment procedure for SMRs. In fact, the graded approach may dictate more stringent and greater depth within assessments because of the level of complexity, risk and uncertainty associated with some SMR designs. Notwithstanding, the graded approach may provide a suitable and appropriate assessment of SMRs, and the extent of its scrutiny will decrease as uncertainty, expertise and operational history improve as the industry develops. Ultimately, the graded approach provides the necessary flexibility to the regulatory regime to assess SMRs.

Development of *REGDOC-2.4.1* has occurred based on the CNSC's experience with CANDU reactors and is not technologically neutral as purported by it's policy guides. Grading should be implemented within the safety analysis so that all reactor designs may be evaluated fairly and appropriately, and not just those premised on light water reactor technology. Grading implements flexibility, allowing the regulator to accommodate the unconventional, novel and innovative approaches taken by SMRs. The application of the graded approach will invoke additional documentation, increased risk mitigation and other conservative approaches to curtail the novelty of SMRs, at least during the outset of their use within Canada. In addition to the graded approach, other regulatory methods may be used to offset the stringency of conservatism and

[247] *Ibid.*
[248] *Ibid.*
[249] *Ibid.*

uncertainty within safety analysis. For example, statistical analysis of uncertainty and conservatism may provide insight into what amount of conservatism is sufficient. Additionally, expert opinion and judgement may be used to provide insight to reduce uncertainties. Risks may be more accurately represented by applying these approaches to safety analyses.

3.3.3 Accommodating uncertainty for risk management

Current nuclear regulatory policy utilizes uncertainty as an indication for the amount of conservatism needed. However, uncertainty has greater applications within risk management and may be used to inform whether decisions meet objectives, whether cost-benefit requirements goals are satisfied and is indispensable for prioritizing risks. Using uncertainty analysis in this way is useful for SMRs because it provides additional considerations when comparing the risks of novel technologies and may be used to inform decision-makers of the amount of conservatism that is appropriate. Current regulatory policies consider uncertainty analyses when applying conservative measures, but fail to utilize those analyses in other aspects of risk management.

Canadian nuclear regulatory documents consider uncertainty distributions primarily to account for the amount of conservatism their decisions should embody. For example, *REGDOC-2.4.1* requires frequency of accident occurrences characterized by significant uncertainty to be classified into a higher frequency class where more stringent precautions will apply.[250] Other precautionary measures such as safety margins or safety factors are to be taken by designers "to account for uncertainty in experimental data and relevant models" when establishing quantitative acceptance criteria for anticipated operational occurrences and design-basis accidents.[251] Notably, *REGDOC-2.4.1* prescribes a degree of conservatism be incorporated within the analysis "to demonstrate a level of confidence in conformance with the analysis objectives"[252] and "is often necessary to cover the potential impact of uncertainties."[253] *REGDOC-2.4.2* prescribes sensitivity and uncertainty analysis to be included within probabilistic safety assessments[254] and describes an

[250] Canada, *REGDOC-2.4.1, supra* note 211 at 13, 45.
[251] *Ibid* at 20.
[252] *Ibid* at 48.
[253] *Ibid* at 37.
[254] Canada, Canadian Nuclear Safety Commission, *Probabilistic Safety Assessment (PSA) for Nuclear Power Plants*, REGDOC-2.4.2 (Ottawa: CNSC, May 2014) [Canada, *REGDOC-2.4.2*] at 4.

uncertainty analysis as a "process of identifying and characterizing the sources of uncertainty in the safety analysis, evaluating their impact on the analysis results, and developing, to the extent practicable, a quantitative measure of this impact."[255]

The CNSC uses uncertainty to justify safety margins and precautionary measures within their policy and neglect its benefits for assessing conservatism. Uncertainty may be used to identify where conservative decisions are overconfident by identifying the flaws in risk estimates that result in a greater skew towards prudence than is intended.[256] In the report "Science and Judgment in Risk Assessment" by the National Research Council, the Committee on Risk Assessment of Hazardous Air Pollutants (the "Committee") recommended the use of uncertainty to determine whether a risk assessment generates a point that is too "conservative," which exaggerates the magnitude of harm.[257] This recommendation highlights the short comings of *REGDOC-2.4.2*'s use of uncertainty as justification for the application of conservatism "to demonstrate a level of confidence in conformance with the analysis objectives."[258] Conversely, this thesis recommends that uncertainty analysis be used to determine whether such applications of conservatism overestimate the magnitude of harm for SMRs.

Uncertainty distributions may also be used to optimally weigh probabilities and consequences, compare alternatives, identify compatible control options, and develop mechanisms to reduce it.[259] Uncertainty analysis used in these ways is beneficial for regulating SMRs as safety assessment would be able to compare designs, accurately identify alternative measures and calibrate conservative measures appropriately. Consider the assessment of whether structural barriers for containment are necessary for packed bed nuclear reactors using tristructural isotropic (TRISO) fuels. TRISO fuels are engineered to inhibit the release of harmful materials and prevent meltdowns because of its high-temperature resistance.[260] Proponents of this technology claim that containment is not necessary and that containment may impede heat transfer, therefore, increasing

[255] *Ibid* at 6.

[256] National Research Council, *supra* note 210 (A common example of overconfidence occurs where scientific inferences account for conservatism within estimates and decisions are made with additional margins of safety resulting in a greater amount of conservatism than was intended at 604).

[257] *Ibid* at 180.

[258] *Supra* note 254 at 48.

[259] National Research Council, *supra* note 210 at 166–167.

[260] Lyman, *supra* note 119 at 17.

risks rather than decreasing them.[261] On this issue, uncertainty may provide additional information for decision-makers for assessing alternatives to conventional practices and completing a full evaluation of these claims. At present, policy avoids novelty and variation and prefers conventional precautions.

Unlike point estimates, the comparison of uncertainty distributions can account for overestimation and underestimation of risks and reduce non-uniform outputs caused by conservative probabilities.[262] Point estimates are unable to account for the ambiguities inherent within risk probabilities and, hence, are silent on whether the differences between two value estimates exceed the uncertainties of the estimates together.[263] That is, decision-makers cannot ensure that the lower risk is not being underestimated and the higher risk is not being overestimated by comparing point estimates alone.[264] Conservatism exacerbates this issue because it may be hidden within estimates resulting in non-uniform outputs as some estimates may represent differing worst case scenarios.[265] For example, an estimate that represents the worst case scenario and another that represents a realistic scenario are incomparable because they are based on varying levels of conservatism.[266] However, comparing uncertainty analyses under the examination of statistical methods may account for overestimation and underestimation and promote uniform outputs despite differing levels of conservatism.

Furthermore, comparing uncertainty distributions is beneficial because it provides insight into the variation of risk magnitude important for decision-making. For example, consider the risks of two hypothetical chemicals, chemical A and chemical B, at an upper confidence limit of 95 percent and that have 86 and 119 deaths/year, respectively.[267] However, at a 97 percent confidence level, the uncertainty of chemical A and B have a corresponding risk of 580 and 340 deaths/year.[268] This example illustrates how uncertainty can affect the magnitude of risks at different levels of confidence. With the appropriate statistical tools, uncertainties may be compared to determine

[261] *Ibid.*
[262] Adam M Finkel, "Confronting Uncertainty in Risk Management: A Guide for Decision-Makers," (Washington: Center For Risk Management for the Future, 1990) at 60.
[263] *Ibid.*
[264] *Ibid.*
[265] *Ibid.*
[266] *Ibid.*
[267] *Ibid* at 61.
[268] *Ibid.*

where risks may exceed one another and yield more information to form decisions.[269] Ranking based on point estimates alone may lead to decisions that rank chemical A higher than chemical B despite chemical A having a non-trivial worse outcome than the other at a 97 percent confidence limit.[270] To effectively rank risks using uncertainty, decision-maker must weigh the probabilities and the costs of error.[271]

In addition to uncertainty distributions, bottom-line summaries of risks are critical for determining risks that are acceptable and within the safety objectives of the CNSC.[272] Uncertainty distributions and bottom-line summaries provide decision-makers with the ability to assess the amount of "conservatism" inherent within the risks, determine whether benefits exceed costs and whether other objectives are met.[273]

Though *REGDOC-2.4.2* prescribes the completion of uncertainty analyses within probabilistic safety assessments to identify and characterize the sources of uncertainty and evaluate their impact on the analysis results, *REGDOC-2.4.1* does not develop a policy that implements uncertainty analysis to compare and rank alternatives or to investigate the magnitude of conservatism inherent within the risk distributions. Uncertainty distributions are an excellent tool for risk management and should be utilized by decision-makers to make decisions. The Committee found that uncertainty distributions and bottom-line summaries are effective for ensuring decisions meet objectives and are acceptable as it provides insight about the amount "conservatism" inherent within the risks, whether benefits exceed costs, and whether safety objectives are met. Additionally, the Committee recommended the completion of uncertainty analyses for all risk estimations including low-tier risk assessments as the inherent difficulties associated with uncertainty should be expressed, despite difficulties and costs.[274] It was the Committee's opinion

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[269] *Ibid* ("the proper way to compare uncertain risks is to look at the [probabilistic distribution function] for the ratio of one to the other – one can derive this [probabilistic distribution function] analytically in special cases, or by Monte Carlo methods… [chemical B] is indeed 10 times worse… [and] substituting [chemical A] for [chemical b] is indeed likely to lower risk. But there is a significant (23 percent) chance that the true risk of [chemical A] exceeds that of [chemical B], perhaps by more than 50-fold") at 61-62.

[270] *Ibid* at 62.

[271] *Ibid*.

[272] National Research Council, *supra* note 209 (to be effective, bottom-line summaries should include least three types of information: (1) fractile-based summary statistics; (2) estimate of the mean and variance of the distribution; and (3) a statement of the potential for errors and biases of fractiles, means and variance) at 180.

[273] *Ibid.*

[274] *Ibid* at 184.

that "explicit treatment of uncertainty is critical to the credibility of risk assessments and their utility in risk management."[275]

3.3.4 Conclusion

The CNSC must be proactive within their RIDM process to accommodate the uncertainty and novel risks associated with SMRs and their variability. Conventionally, the CNSC employ conservatism to address uncertainty and novel risks. Conservatism is a risk averse practice to mitigate risks, but where left unchecked and under a conventional mindset may unnecessarily increase costs and assessment delays for proponents. SMRs are particularly vulnerable to conservatism because of their complexity, and uncertain and novel risks. The bias of regulations for CANDU technology exacerbates the use of conservatism for regulating SMRs and provide little flexibility for novel technologies. Therefore, to effectively regulate SMRs, the CNSC must implement more flexibility and proactively manage uncertainty.

The graded approach should be applied to SMRs of all sizes to determine the scope, content and detail for their deterministic risk assessments. Industry and the CNSC both agree that the graded approach is essential for accommodating the variability of SMR designs. Furthermore, the flexibility offsets assessment expectations developed based on the CNSC's experience with CANDU technology. The use of grading in the risk assessment of SMRs improves regulatory flexibility and reduces reactionary tendencies to rely on conservatism to accommodate SMRs within a fixed regulatory framework.

The literature on the management of risk uncertainty perpetuates conservatism as the primary risk management tool to accommodate uncertainty or risk gaps. This thesis recommends the use of risk uncertainty as a resource for decision-making rather than just the impetus for precaution. Risk uncertainty analyses may be used to determine whether regulatory objectives are met, whether benefits exceed costs and the amount of conservatism already within risks. The use of uncertainty analysis within risk management is encouraged by the Committee who assert that it is critical to the credibility of risk assessments and risk management.[276]

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[275] *Ibid.*
[276] National Research Council, *supra* note 209 at 180.

3.4 Supporting the elicitation of expert judgement for risk assessment

Inadequate scientific understanding and lack of data may be responsible for gaps within risk assessments, thereby hindering objective assessment;[277] however, subjective quantification of expert opinion can be a suitable alternative.[278] Experts may assign probability weights to scenarios or models according to their best judgement and available scientific judgement which may form a risk distribution where objective assessments are unavailable.[279] Though there are advantages to objective risk assessment such as impartiality, there is no rule that objective estimates are always preferred to subjective estimates.[280]

Canada implements expert opinion within its deterministic assessments to evaluate determined risk. Expert judgement is used in conjunction with sensitivity analyses "to help identify and rank the parameters by assessing their influence on analysis results for each acceptance criterion."[281] Regulatory documents indicate that the CNSC may weigh heavily expert opinion where faced with no standard[282] and employ best-estimate analysis and assumptions in conducting deterministic assessments.[283] Accordingly, Canadian nuclear regulations do not emphasize the use of expert judgement for eliciting probabilities for assessment but use it primarily for the evaluation of risks within deterministic risk assessment.

Elicitation of expert judgement can produce qualitative and quantitative risk assessments for new, rare, complex or poorly understood phenomena, and can include failure rates, incidence rates, or weighing factors for combining data sources.[284] For proponents of SMRs, expert judgement can provide another resource to fill risk gaps or relieve uncertainty where objective probabilistic safety assessment cannot accurately do so. Defence Research and Development Canada [the "DRDC"] has consolidated much of this literature and have reviewed methods and

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[277] *Ibid* at 177.
[278] *Ibid* at 170.
[279] *Ibid*.
[280] *Ibid* at 171.
[281] Canada, *REGDOC-2.4.1*, *supra* note 211 at 22.
[282] Canada, *Regulatory Fundamentals*, *supra* note 41 at 2.
[283] Canada, *REGDOC-2.4.1*, *supra* note 211 at 22.
[284] *Ibid* at 4.

procedures for the preparation, training, aggregation, scoring and verification of expert judgement to elicit probabilities based on expert judgement successfully.[285]

Though the DRDC lays out the process and procedures for obtaining accurate elicitation of expert judgement, challenges remain regarding how it may be implemented within Canada's current nuclear policies and how it may be relied upon within the RIDM structure. The reliance on elicited risks for determining proportional amounts of conservatism poses the greatest challenge as it will be explained that elicited risks are only as accurate as the procedures in which they are generated.

3.4.1 Eliciting expert opinion for quantitative and qualitative risk assessment

The use of expert judgement to overcome risk uncertainty is not contemplated by Canadian policy but may benefit the regulation of SMRs. Expert elicitation may be used to produce risk distributions for new, rare, complex or poorly understood phenomena associated with SMRs. The DRDC has consolidated literature on how to effectively elicit expert judgement for risk assessment. Their article outlines the elicitation process, inherent biases, evaluation of expert elicitations, how to improve elicitations, and how to aggregate multiple elicitations to generate accurate risk assessments.

The DRDC reviews the literature on how to effectively generate probabilities based on expert judgement.[286] The aim of the article is to "synthesise models and techniques for eliciting and aggregating expert judgements, together with methods to evaluate the accuracy of elicitation and the quality of the risk assessment, in order to assist [branches of the DRDC] and other public security partners with essential tools to conduct sound risk assessments."[287] The result is a set of procedures, consideration and approaches for decision-makers to implement within regulations to effectively elicit expert judgement.

[285] Canada, Defence R&D Canada - Centre for Operational Research & Analysis, *Expert Judgement in Risk Assessment,* DRDC CORA TM 2007-57 (December 2007) [Canada, *Expert Judgment in Risk Assessment*] at 1, online (pdf): Defence R&D Canada website <cradpdf.drdc-rddc.gc.ca/PDFS/unc88/p529083.pdf> [perma.cc/P4C5-K7H6].

[286] Canada, *Expert Judgment in Risk Assessment*, *supra* note 285 at 1.

[287] *Ibid* at 2.

Expert judgement for eliciting quantitative and qualitative risks is useful for determining risks of SMRs where there exist risk gaps or uncertainty in risks. The DRDC suggest the use of expert judgement where objective probabilities are sparse, and experimentation is impractical.[288] In particular, expert judgement may be used to provide estimates for new, rare, complex or poorly understood phenomena, and can include failure rates, incidence rates, or weighing factors for combining data sources.[289] Additionally, the process can form both qualitative and quantitative judgements. Quantitative estimates "can be expressed in the numerical value of probabilities, ratings, odds, uncertainty estimates, weighting factors, physical quantities of interest."[290] On the other hand, qualitative estimates can be "textual descriptions of the expert's assumptions in reaching an estimate, reasons for selecting or eliminating certain data or information from the analysis, and natural language statements of physical quantities of interest."[291] Expert judgement, therefore, can be employed to develop risk distributions for SMRs where objective probabilistic assessments are unavailable or uncertain.

There are five roles within the elicitation process: (1) the decision maker; (2) the facilitator; (3) the normative expert; (4) the domain experts; and (5) the stakeholders.[292] The decision-maker, or the CNSC, is embodied with the responsibility to set out objective outcomes and decision criteria.[293] Though legislation, regulations, and regulatory documents set out broad objectives of safety analysis already, the CNSC may develop a regulatory document that sets out its expectations regarding elicitation of expert judgement and how to consider resulting probabilistic data within existing policies and the graded approach.

The facilitator acts as the medium between the domain expert and the decision maker and is responsible for selecting domain experts and describing the case to them.[294] The applicant, or an agent thereof, should fill the role as a facilitator because the applicant has the onus to demonstrate the safety of their application. Furthermore, the applicant would have the best insight into the

[288] *Ibid* at 1.
[289] *Ibid* at 4.
[290] *Ibid* at 6.
[291] *Ibid.*
[292] *Ibid* at 4.
[293] *Ibid* at 5.
[294] *Ibid.*

subject matter for which risks are being elicited and thus would be better capable of describing it to the domain expert.

The normative expert is responsible for eliciting judgements from domain experts and instructing them how to perform inferential estimations, and therefore require expertise in the generation of risk distributions.[295] Additionally, the normative expert also combines elicited domain expert judgements and forms conclusions from the results. To avoid industry bias and regulatory capture, it is suggested that the normative expert be independent from the applicant.

Stakeholders are those affected by the decision and provide feedback to affirm the scope and completeness of the issues.[296] The decision-maker identifies the stakeholders and is given the opportunity to affirm the quality of the results. The scheme considers the input of stakeholders crucial for the qualification of risk assessment and divides engagement amongst the decision-maker, the facilitator and the normative expert.[297] Conversely, Canadian regulations engage stakeholders through mandatory public hearings, notices and engagement programs carried out by proponents with the public and indigenous peoples. Though the current scheme may achieve the participation of stakeholders within the elicitation process through engagement requirements, it may be appropriate for the CNSC to outline their expectations of this engagement regarding the elicitation of expert opinions. This approach not only satisfies the suggestions made by the DRDC but clarifies expectations for proponents.

Domain experts are those who are qualified to provide respected judgments. Elicitation involves the extraction of inferential opinions based on the expert's knowledge and experience within a controlled process to minimize error. [298] To determine qualified expertise, consideration is given to the special knowledge and skill of the expert relevant to the particular domain, which may be determined through peer assessment, ability and length of experience.[299] The obligation to select experts is on the applicant because they have the onus to demonstrate to the CNSC that their project is safe and within regulatory requirements. Independence of the experts is ensured through

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[295] *Ibid.*

[296] *Ibid.*

[297] Tony Rosqvist, "On the Use of Expert Judgement in the Qualification of Risk Assessment," (Espoo: VTT Technical Research Centre of Finland, 2003) at 14–15.

[298] DRDC, s*upra* note 285 at 4.

[299] *Ibid.*

a nomination system and the oversight of the CNSC. How the CNSC may ensure the independence of the experts is discussed further in the following section.

Literature outlines five critical stages conducive to a favourable elicitation process with preparation being an underpinning factor.[300] The first stage, "Background and Preparation," requires the normative expert and facilitator to identify variables to be assessed by the domain experts and plan the elicitation process. Next, literature recommends a nomination system to appoint domain experts and suggests that nominations include public interest groups and professional organizations to balance perspectives, and recommends six criteria for selecting appropriate domain experts.[301] The third stage involves motivating and training experts.[302] At this stage, domain experts undergo training on probability and overcoming biases, and practice elicitation.[303] The final two stages, the "Structuring and Decomposition" stage and "The Elicitation" stage represent the actual elicitation of judgement. Structuring and Decomposition define what risks are to be quantified and on what evidence those quantities are to be drawn.[304] Elicitation solicits probability distributions through an iterative procedure which repeats until assessments are adequate.[305] The process outlined by the DRDC is methodical and deliberate to build a foundation of accuracy and impartiality for elicitations.

Training domain experts to overcome biases is important because of the limitations of human memory, and information processing regularly produce probabilities that are poorly calibrated or inconsistent.[306] Research suggests that human ability to assess probabilities or predict future quantities are limited, which introduces uncertainty into the assessment through psychological biases.[307] Literature finds that bias is minimized where the expert has a high level of expertise, adequate preparation, adequate instruction on the process and face-to-face

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[300] *Ibid*.

[301] *Ibid* (when selecting experts, consider the "(i) Tangible evidence of expertise; (ii) Reputation; (iii) Availability and willingness to participate; (iv) Understanding of the general problem area; (v) Impartiality; and (vi) Lack of an economic or personal stake in the potential findings" at 5)

[302] *Ibid* at 5–6.

[303] *Ibid.*

[304] *Ibid* (The two final stages are best carried out face-to-face between experts and the facilitator, whereas well-planned and structured interaction will minimize expert biases at 6).

[305] *Ibid.*

[306] *Ibid* at 8.

[307] *Ibid* (psychological biases include the availability heuristic, the representativeness heuristic, and the anchor-and-adjustment heuristic at 8–11).

interactions with the facilitator and normative expert.[308] Additionally, alerting experts to what biases influence elicitation and how they are introduced is found to be the most effective approach to reducing inaccuracies.[309] The use of behavioural and mathematical aggregation techniques of multiple domain experts are also recommended to bolster results and ensure accuracy.[310]

Following elicitation, calibration curves, scoring and feedback are used to evaluate the performance of domain experts based on whether their elicited risks accurately reflect both the their opinion and reality.[311] Calibration curves graphically represent the accuracy of elicitation over a range of confidence levels,[312] where poor calibration may result from the domain expert's poor ability to accurately reduce their beliefs or the operation of the domain expert on inaccurate knowledge.[313] Calibration curves can conclude if estimates are overconfident or underconfident and are used to calibrate the elicitation process to improve accuracy.[314] Calibration curves are developed during the training stage of elicitation where testing, practice and feedback are used systematically to produce and improve calibration.[315] Scoring uses a statistical approach to compare the expert's performance against reality and is applicable to both discrete and continuous probability distributions.[316] Additionally, scoring provides an incentive for experts to perform their elicitations well and help train them to quantify judgements accurately.[317] Feedback of the domain experts is the most effective method of improving accuracy and calibrations.[318] Feedback should be structured to avoid apathetic responses to feedback[319] and anchoring effects[320] of the domain

[308] *Ibid* at 5.
[309] *Ibid* at 11.
[310] *Ibid* at 7.
[311] *Ibid* at 12–18.
[312] *Ibid* at 12.
[313] *Ibid* at 14.
[314] *Ibid* (overconfidence occurs where the mean subjective probability of probed experts over predict risks and is the most common bias in assessing probability whereas underconfidence occurs where the actual frequency is higher than the mean subjective probability, and occurs less frequently then over confidence at 12).
[315] *Ibid* at 13.
[316] *Ibid* at 14.
[317] *Ibid.*
[318] *Ibid* at 18.
[319] *Ibid* ("[o]ne problem with feedback is that experts may be too willing to accept that a proposed value is representative of their opinions, since this is the first option, and avoid having to revise the value").
[320] *Ibid* (upon receiving feedback, experts may use the previous estimate as an anchor resulting in insufficient adjustments) at 18. See also *ibid* (anchoring occurs where experts anchor an estimate "on what seems to them to be the most likely value of the quantity, and underestimate the variability or uncertainty of their estimate" at 10).

experts. The DRDC suggest the implementation of an iterative feedback procedure during training which counteracts apathetic responses and anchoring and encourages accurate elicitation.[321]

Random variation of estimates can be offset by aggregating multiple expert judgements into a single distribution using behavioural or mathematical aggregation techniques.[322] Statistically, aggregating judgements from multiple experts produce a better appraisal than individual distributions and provides practicality and feasibility when assessing risks as the single distribution represents a consensus.[323] Both aggregative approaches provide effective conclusions, and debate over which approach is most effective is inconclusive. However, literature recommends using behavioural aggregation initially because of its simplicity and ability to coordinate the synthesis of knowledge and analysis through group interaction.[324] Conversely, mathematical aggregation is used where behavioural aggregation fails to yield a consensus as it can be complex and time-consuming.[325]

Behavioural aggregation facilitates collaboration between multiple experts to generate a single probability distribution through various methods of interaction that promotes the exchange of knowledge, information, and interpretations.[326] There are many behavioural aggregation methods to consider, such as the Delphi Method,[327] Nominal Group Technique,[328] and Kaplan's Approach,[329] but their application will depend on the circumstances of the process.[330] The type of interaction, the nature of the interaction, individual reassessment post interaction, and the role of the facilitator in the process are some, but not all, of the elements to consider when choosing a behavioural aggregation method.[331]

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[321] *Ibid.*

[322] *Ibid* at 19.

[323] *Ibid.*

[324] *Ibid* at 22.

[325] *Ibid* at 22–23.

[326] *Ibid* at 19.

[327] *Ibid* (in the Delphi Method, "[e]xperts first make individual judgements after which judgements are shared anonymously. They may then revise their probabilities, and the process is repeated for a few rounds. The final probability distributions are aggregated mathematically" at 19-20).

[328] *Ibid* (in the Nominal Group Technique, experts assess judgments independently and share their findings to other members in a group discussion facilitated by the facilitator. After the discussion, experts may revise their probabilities which may be aggregated mathematically at 20).

[329] *Ibid* (in Kaplan's approach, the facilitator first leads a group discussion for experts to present their evidence and arrive at a consensus. The facilitator proposes a distribution based on that consensus at 20).

[330] *Ibid* at 19–20.

[331] *Ibid* at 20.

Where domain experts fail to reach a consensus within behavioural aggregation attempts, mathematical aggregation may be used to combine elicitations into a single distribution through mathematical methods.[332] However, mathematical aggregation tends to be complex, time-consuming and difficult to implement and thus should be applied as an adjunct to behavioural aggregation. For example, Bayesian methods[333] require sophisticated elicitation practices by the decision-maker and create complexity and difficulties of implementation.[334] Additionally, Cooke's method,[335] though significantly accurate, is substantially more complex than other methods and requires a well-structured and thorough elicitation process.[336] Linear and logarithmic pooling,[337] though simpler and widely used in practice, also relies on a thorough elicitation process.[338] Additional complications arise as the choice of what method to use is dependent on a myriad of considerations which are not always obvious.[339] In the interest of simplicity and time, mathematical aggregation approaches should be considered supplementary upon the failure of behavioural aggregation attempts because of their associated complexity and comparable results.

The article recommends that a risk assessment framework be developed within the RIDM processes to verify the quality of the elicitations and to promote the regulatory qualities of completeness, credibility, transparency and fairness.[340] A framework developed by Rosqvist built upon peer review, accountability and quality characteristics implement "yes" or "no" criteria to satisfy the four regulatory qualities, albeit upon the judgement of the decision-maker.[341] The effectiveness of Rosqvist's framework depends on the experience of the individual performing the verification, which in the Canadian context would be the CNSC.[342] Rosqvist's step by step procedure is as follows: (1) "scope definition," which ensures that stakeholders are informed of

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[332] *Ibid* at 21.

[333] *Ibid* (Bayesian methods have experts and the decision-maker individually assess an unknown quantity and uses Bayes' Theorem to generate a single probability distribution at 20-21).

[334] *Ibid.*

[335] *Ibid* (Cooke's Method is similar to pooling but proposes that "it is desirable to weight heavily those experts who are perceived to have more expertise." The method assigns "weights on the basis of the performance of each expert in a separate elicitation exercise utilizing seeding variables" at 22)

[336] *Ibid* at 23.

[337] *Ibid* (Linear pooling is the weighted average of individual distributions and logarithmic pooling is a weighted geometric mean of the distributions at 21).

[338] *Ibid* at 21.

[339] *Ibid.*

[340] *Ibid* at 25.

[341] *Ibid.*

[342] *Ibid.*

decision rules and criteria; (2) "hazard identification," which ensures hazard identification process is adequately surveyed and verified by stakeholders and domain experts; (3) "risk estimation," verifies that parameter uncertainty, model uncertainty and bias are sufficiently addressed; (4) "risk evaluation," which verifies that resolutions are consistent; (5) "analysis of options," which ensures that control options are adequately surveyed from stakeholders and domain experts; (6) "recommendation for the decision-maker," which requires that a peer review be completed.[343] Upon the completion of the verification, the decision-maker may make decisions based on the risk assessment and verification results, or request modifications or other adjustments.[344]

The DRDC outline effective procedures to elicit expert judgment and evaluate the accuracy and quality of the resulting elicitations. Canada's nuclear regulations do not contemplate the use of expert judgement as a method to assess risk and produce risk probabilities. However, its use for SMRs may be an alternative method to provide estimates for new, rare, complex or poorly understood phenomena. Though the DRDC outline procedures and steps for obtaining accurate elicitations, regulators must investigate how elicited expert opinion may be implemented successfully within current policies. Points of consideration for this task include how the graded approach should apply to elicitations, whether regulatory expectations should outline procedures for choosing domain experts, what aggregations methods are best for nuclear power generation risk assessments, whether there are conflicts with existing policies, and complications arising out of the relationship between proponents and the decision-maker.

3.4.2 Implementing expert judgement into Canada's regulations

This thesis suggests that the CNSC produce an adjunct regulatory document that outlines its expectations of how elicitations are to be performed and how elicited risks are to be relied upon amidst established policies and regulatory principles. The article by the DRDC sets out a well-informed elicitation process, a summary of appropriate aggregative methodologies, and procedures for the evaluation and verification of elicited risk distributions that may be drawn upon by the CNSC for this task. However, when implementing these procedures, the CNSC must consider the compatibilities with their policies and their international commitments. Important considerations

343 *Ibid* at 26.
344 *Ibid* at 25.

include potential modifications to the CNSC's public engagement policies, and the adherence to safety standard policies of the IAEA that prescribe conditions for elicitations.

The CNSC will need to develop policy that expresses their expectations for the elicitations of risks and how it may be relied upon within their risk assessment. The CNSC's *REGDOC-2.4.1* and *REGDOC-2.4.2* follow the standards for deterministic and probabilistic risk assessments outlined by the IAEA. However, the IAEA does not outline a specific regime for the elicitation of expert judgment or how it may be relied upon. Accordingly, the CNSC must develop their own elicitation policy.

Such a regulatory document would specify, among other things, procedural expectations of the elicitation process, acceptable behavioural and mathematical aggregative methods, calibration and scoring requirements, stakeholder engagement expectations and require extensive documentation throughout the process. The elicitation process proposed by the DRDC is sufficiently thorough to act as the bare bones standard for elicitations, whereas the CNSC may expound on areas they see fit within regulations. Additionally, the CNSC may provide proponents opportunities to refine further elicitation procedures where such variation or addition may improve elicited judgement accuracy while maintaining the independence of the experts and where documented heavily. The expectations of the elicited process may also be a point of discussion during the optional pre-licensing stage of vendor diagram review.

The regulatory document developed for elicitation of expert judgement will be an adjunct to *REGDOC-2.4.1* and *REGDOC-2.4.2*. Thus, elicitations are to be carried out in accordance with existing regulatory expectations including the IAEA's Safety Standards documents, Level 1 and Level 2 PSA.[345]

The IAEA Safety Standards contemplate the use of expert elicitation, which requires expert judgement to be accompanied by an appropriate justification, extensive documentation[346] and strict

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[345] Canada, *REGDOC-2.4.2*, *supra* note 254 (the following safety standard documents provide general guidance for conducting high-quality PSAs: IAEA Safety Standard SSG-3, Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants; and IAEA Safety Standard SSG-4, Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants at 1). See also International Atomic Energy Agency, *Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants,* (Vienna: IAEA, April 2010) [IAEA, *Level 1 PSA*] at 3.

[346] *Ibid* at 42, 83, 99. See also at International Atomic Energy Agency, *Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants,* (Vienna: IAEA, May 2010) [IAEA, *Level 2 PSA*] at 11, 36.

conditions. The IAEA Safety Standard document Level 1 PSA requires that the elicitation of expert judgement embody "a formal, highly structured and documented process" with the following conditions:

> (a) Qualified experts capable of evaluating the relative credibility of multiple alternative hypotheses in order to explain the available information are selected.
> (b) Independence of the experts' opinions is maintained.
> (c) The uses, rationale and background information for expert judgement are documented in a way that is traceable and reproducible.
> (d) Uncertainties and variabilities in expert judgement are stated. The impacts or effects of these uncertainties and variabilities are assessed.
> (e) The conclusions that are based on the results of the process have a sound basis[347]

Though *REGDOC-2.4.2* cites the IAEA Safety Standard documents as "guidance,"[348] it is recommended that these considerations be included in the Canadian regulatory documents developed for elicitation of expert judgement.

The five-stage elicitation process recommended by the DRDC is compatible with the conditions of elicitation set out by the IAEA's safety standards, though some aspects may require reinforcement and support within the policies developed by the CNSC. Condition (a) is met within Stage 2: Identification and Recruitment of Experts of the DRDC's suggested process. Stage 2 implements a nomination system set out by Hora and von Winterfeldt, which was developed for the elicitation of risks for nuclear waste repositories, to ensure the quality and capability of experts.[349] In the nomination system, proponents, and any other interested parties, pool experts identified through literary searches, registries of professional organizations, contacts with consulting firms, research laboratories, governmental organizations and universities.[350] For matters that are controversial or have alternative viewpoints, such as nuclear regulation, Hora and von Winterfeldt recommend that public interest groups and professional organizations both be invited to submit nominations to avoid criticisms of bias.[351] From this pool, domain experts are selected according to six criteria: (1) tangible evidence of expertise; (2) reputation; (3) availability

[347] IAEA, *Level 2 PSA*, *ibid* at 99.
[348] Canada, *REGDOC-2.4.2*, *supra* note 254 at 1.
[349] DRDC, *supra* note 285 at 5. See also Stephen C Hora & Detlof von Winterfeldt, *Nuclear Waste and Future Societies: A Look into the Deep Future*, (1997) 56:2 Technological Forecasting and Social Change 155 at 158.
[350] Hora, *ibid* (in the authors study, they pooled nominated experts as a neutral party but also invite many professional organisations and public interest groups to also nominate experts to create a well-balanced pool of experts at 158).
[351] *Ibid.*

and willingness to participate; (4) understanding of the general problem area; (4) impartiality; and (6) lack of an economic or personal stake in the potential findings.[352] In their case study, Hora and von Winterfeldt implemented a committee to select experts made up of professionals and members of a university. For SMRs, this thesis suggests the selection of experts should be made by a committee of neutral members to avoid partiality when selecting experts, with at least one member being from the CNSC. This selection process ensures the selection of qualified and capable experts for elicitations.

Condition (b), which advocates that experts provide an independent opinion, is a significant concern because of the potential partiality introduced by the proponent carrying out the elicitation process. However, measures may be introduced to mitigate partiality and encourage independence, such as implementing the nomination process recommended by Hora and von Winterfeldt, requiring extensive documentation for all stages of elicitation, and designing procedures that encourage independence. Nominating domain experts using the recommendations of Hora and von Winterfeldt encourages a balanced pool of experts, deters conflict of interest and rejects experts who have an economic or personal stake in the potential findings. Additionally, extensive documentation of the elicitation process, which is required by IAEA Safety Standards and condition (c), (d) and (e),[353] provides content reviewable by the CNSC to ensure the independence of the experts. This documentation should include the scientific evidence being relied upon by the experts for their determinations. Where documentation is found unsatisfactory, the CNSC may reject the findings or request refinements or adjustments to elicitations. Finally, requiring multiple experts to arrive at a consensus using behavioural aggregation limits the influence of rogue experts within the process. Where experts fail to arrive at a consensus and mathematical aggregation techniques are used, the CNSC may review documentation, the basis for the elicited expert's opinions and the qualification of the domain experts to rule out impartiality and ensure independence.

Conditions (c) through (e) are substantive requirements to be met within the completion of elicitations and the probabilistic safety assessment. The verification of these, and preceding conditions, is carried out by the CNSC within their safety assessment regulations, which are

[352] *Ibid.*
[353] IAEA, *Level 1 PSA*, *supra* note 345 at 42, 83, 99. *See also* IAEA, *Level 2 PSA*, *supra* note 346 at 11, 36.

informed by the IAEA's "A Framework for a Quality Assurance Programme for PSA."[354] The IAEA's Quality Assurance Programme describes elements and principles necessary to develop adequate quality assurance programmes for probabilistic safety assessments of nuclear facilities.[355] This framework is delineated within two methodological aspects: (1) probabilistic safety assessment quality characteristics;[356] and (2) quality verification tasks.[357] Rosqvist argues that the Quality Assurance Programme provides little detail for how quality assurance tasks should be linked to quality characteristics.[358] Furthermore, in his analysis of other probabilistic safety assessment quality assurance literature, Rosqvist determines that, overall, quality assurance for risk assessments is still "in the stage of conceptual development" and that for elicitation purposes a "mature conceptual framework relating to quality characteristics, peer review organization and its tasks, and accountability" is necessary to serve its aim in the RIDM process.

Rosqvist develops a framework built upon "an independent peer review process for consolidating the decision-maker's confidence in the results and recommendations of risk assessment."[359] This framework implements the quality characteristics of completeness, credibility, transparency, fairness, which encapsulates the same quality characteristics promoted within the IAEA's Quality Assurance Programme.[360] Rosqvist links quality characteristics to a six-step risk assessment framework: (1) Scope Definition;[361] (2) Hazard Identification;[362] (3) Risk

[354] International Atomic Energy Agency, "A Framework for a Quality Assurance Programme for PSA" (1999) 1101 Tecdoc Series 1.

[355] *Ibid* at 1.

[356] *Rosqvist, supra* note 297 (the quality characteristics embodied by the IAEA's Quality Assurance Programme are completeness, consistency and accuracy at 35).

[357] *Ibid* at 35.

[358] *Ibid*.

[359] *Ibid.*

[360] *Ibid* ("[t]he following quality characteristics are presented [in the IAEA's Quality Assurance Programme]: Completeness, Consistency and Accuracy" at 35).

[361] *Ibid* (Scope Definition "verifies that the stakeholders have been informed about adopted decision rules and criteria" and embodies the quality of transparency at 38).

[362] *Ibid* (Hazard Identification "verifies that the stakeholders' and the domain experts' feedback on the completeness of hazard identification process is adequately surveyed" and represents the quality of completeness at 38).

Estimation;[363] (4) Risk Tolerability;[364] (5) Analysis of Options;[365] and (6) Recommendations for the decision-maker.[366] Though the IAEA may provide an adequate standard for quality assurance of elicitations, Rosqvist's framework not only links tasks to quality characteristics but represents a framework that represents the culmination of literature on the subject.

REGDOC-2.4.1 and *REGDOC-2.4.2* embody the quality assurance framework of the IAEA; however, the question is whether they should adopt the more rigorous model of Rosqvist and how that will affect the reliability of expert elicitation. The differences between the verification processes of *REGDOC-2.4.1* and *REGDOC-2.4.2* and Rosqvist's framework are minimal. Rosqvist's verification steps of Hazard Identification, Risk Estimation and Risk Tolerability are already, in one way or another, represented within *REGDOC-2.4.1*. The most significant difference is the inclusion of stakeholders' feedback throughout the elicitation process and the verification of that participation.[367] The verification process ensures that stakeholders provide feedback on the completeness of hazard identification, provide feedback on the completeness of risk control options and are informed about decision rules and criteria during the verification steps of Hazard Identification, Analysis of options, and Scope Definition respectively.[368] The inclusion of stakeholders in this way is a result of the culmination of literature on the subject.

The elicitation process recommended by the DRDC provides for extensive stakeholder feedback and interaction with normative experts and facilitators [369] and engages the proponent's obligations to consult with the public and indigenous peoples under regulatory policies. Literature

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[363] *Ibid* (Risk Estimation "verifies that sensitivity studies, based on parameter uncertainty, are adequate; … verifies that model uncertainty and direction of bias of risk model is adequately addressed" and represents the quality of credibility at 38).

[364] *Ibid* (Risk Tolerability "verifies that the conclusions drawn as based on the decision rules are consistent" and represents the quality of credibility at 38).

[365] *Ibid* (Analysis of options "verifies that the stakeholders' and the domain experts' feedback on the completeness of risk control options is adequately surveyed" and represents the quality of completeness at 38)

[366] *Ibid* ("[Recommendations for the decision maker] verifies that the stakeholders' and the domain experts' feedback on the completeness of risk control options is adequately surveyed" at 38).

[367] *Ibid* (Rosqvist lists the roles of parties involved in the elicitation process and their responsibilities to engage with stakeholders, i.e. the Facilitator is required to question stakeholders on the quality of results and whether any issues have been neglected; Normative experts are responsible for eliciting "preferences and the development of utility functions" of stakeholders; and Stakeholders give feedback during the risk assessment process at 14).

[368] *Ibid* at 38.

[369] *Ibid* (Rosqvist lists the roles of parties involved in the elicitation process and their responsibilities to engage with stakeholders, i.e. the Facilitator is required to question stakeholders on the quality of results and whether any issues have been neglected; Normative experts are responsible for eliciting "preferences and the development of utility functions" of stakeholders; and Stakeholders give feedback during the risk assessment process at 14).

explains that the input of stakeholders is crucial for the qualification of risk assessment and that the public should be involved within the nomination process of domain experts. Implementation of this engagement should not only be addressed within safety assessment but should also be outlined within public engagement policies of the CNSC so that proponents understand the full scope and content of their obligations.

REGDOC-3.2.1 and REGDOC-3.2.2 require proponents to develop a public information and disclosure program and engage with the public and indigenous peoples early and throughout project development. It is suggested that these regulatory documents include the CNSC's expectations for how the proponent should involve the public in eliciting risks. These expectations would include the goals and objectives of that engagement and require the proponents to develop a program outlining how they aim to achieve those goals and objectives. Proponents will be required to identify points where stakeholder engagement is necessary to provide feedback, and how and when the public is to interact with the facilitator and normative experts. When determining whether the objectives and goals of public engagement are met, it is suggested that the CNSC also consult the verification process framework by Rosqvist as the first questionnaire asks whether stakeholders are informed of decision rules and criteria.

The integration of the elicitation process recommended by the DRDC produces minimal conflicts with Canadian policies and conforms with the standards of the IAEA`s Quality Assurance Programme. Dovetailing the elicitation process within the current safety assessment policy is possible, but additional regulatory documents should be established to outline expectations. Though the mechanisms of this elicitation process can easily be integrated, regulators must consider the impact this will have on regulatory policies such as the graded approach and conservative decision-making.

3.4.3 The application of the graded approach

The decision-makers must consider how the graded approach will apply to elicited risks, not only for their assessment but also so that proponents may be informed of their expectations. Traditionally, decision-makers have dealt with subjective risks using conservatism as exemplified by the heavy use of margins of safety during the advent of the nuclear industry which heavily relied on expert judgement.[370] However, elicitations have the potential to be well-informed and statistically interpreted to yield accurate and informative risk distributions because of advancements in elicitation methodologies.[371] This section recommends a two-step process to appropriately characterize elicited risks for the purpose of applying the graded approach.

In the advent of nuclear power generation, expert judgement was relied upon to develop regulatory requirements for safety features, operations and quality assurance; however, this resulted in a strong dependence on conservative decision-making philosophies resulting in substantial safety margins.[372] The fear of subjective risk analysis has remained and is exacerbated by the public fear of nuclear technology. This analogy serves as a cautionary tale for considering expert elicitations. However, since then elicitation processes have developed robust methodologies to account for bias and error, understanding of nuclear technology and safety has progressed, and technology has advanced. Regulators must consider elicited risks objectively and avoid disproportionate conservatism.

The graded approach is a significant consideration in the RIDM process and embodies regulatory principles such as proportionality and conservatism to make decisions. This thesis recommends the implementation of a two-step process to account for the accuracy of elicitations for RIDM. First, elicitations are assessed for their accuracy by assessing the process used by the proponent to elicit the risk distributions and whether they conform to the expectations promulgated within the CNSC's to be developed regulatory documents. From this assessment, the CNSC will score the performance of elicitations proportional to the performance of the elicitation process. The performance score should also consider the effectiveness of the elicitation process, what methodologies are applied, the accuracy of elicitations as characterized by calibration curves and probability scoring, the probabilistic coherence of elicitations and whether elicitations are successfully verified. Second, the graded approach is applied normally but applies conservatism proportionally to the uncertainty of the risk distribution and the performance score. By framing

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[370] Nuclear Energy Agency, *Nuclear Regulatory Decision-making, supra* 61 (in the infancy of nuclear regulation, expert judgement was relied upon to develop requirements for safety features, operations and quality assurance which was supplemented by conservative decision-making philosophies and resulted in substantial safety margins at 27).

[371] See generally W P Aspinall *et al*, "Evaluation of a Performance-Based Expert Elicitation: WHO Global Attribution of Foodborne Diseases" (2016) 11:3 PLOS ONE 1 at 1.

[372] Nuclear Energy Agency, *Nuclear Regulatory Decision-making, supra* 61 at 27.

the process in this way, elicited risks may be treated alongside other risks in the overall evaluation of the design.

It is important to note that step one determines a performance score which reflects the performance of the elicitation process and does not account for the subject matter of the risk or the value of the risk. A performance score is determined by setting goals, expectations and objectives within regulatory documents and evaluating applicants based on how effectively they meet those targets. Step two assesses risks and afford elicited risk distributions weight proportional to the performance score assigned by the decision maker. Poor performance scores are an indication of the reliability of elicited risk distributions and can also be used to indicate the amount of conservatism that should be applied. For example, elicitation of the frequency of occurrences attributed with *notable* uncertainty and a poor performance score may be classified into a higher frequency class then the reported estimation of frequency alone may suggest. This approach is similar to the practice implemented by *REGDOC-2.4.1*, which requires frequencies of occurrences characterized by *significant* uncertainty to be classified into a higher frequency class.[373] How performance scores affect decision making will depend on the score given and the decision-maker

The DRDC's report presents three methods to evaluate the uncertainty of elicitations to be considered in step-one – calibration curves, probability scoring and coherence. The degree of agreement between the expert's judgement and reality is quantified using calibration curves.[374] Calibration curves quantify the "quality of subjective judgements elicited from experts … over a range of confidences."[375] The calibration curve does not demonstrate the actual accuracies of elicited judgement as there is no way to compare elicitations to observed frequencies but identifies whether experts are overconfident or under-confident due to bias or poor understanding of the statistics. Scoring quantifies how well the expert's elicitations match their true beliefs.[376] Strong scores represent a positive correlation between reality and the elicitations.[377] Additionally, coherence is checked to affirm the maintenance of the laws of probability.[378] Good calibration, probability scores and coherence indicate unbiased results that obey the laws of probability and

[373] Canada, *REGDOC-2.4.1*, *supra* note 211 at 13.
[374] DRDC, *supra* note 285 at 27.
[375] *Ibid* at 12.
[376] *Ibid* at 14.
[377] *Ibid.*
[378] *Ibid* at 27.

are a good representation of the expert's beliefs based on substantive evidence, and vice versa. Within regulatory documents calibration curves, probability scores and coherence can be used as quantitative targets for proponents completing elicitations and can be used to determine uncertainty and margins of safety.

The verification proposed by Rosqvist ensures credibility, completeness and transparency using a "yes" or "no" response rubric. A "no" on any of the questionnaire indicates an inadequate risk assessment and the need for more detail.[379] A decision-maker who awards a "no" during the verification process should reject the elicitation or award it a significantly poor performance score.

The accuracy of elicitations increases with the number of experts elicited and should form a consideration of step one. Studies have found that the accuracy of elicitations increases with the number of experts and that there is little improvement beyond five or six.[380] The performance score should represent the number of experts elicited, especially where the number of experts involved is less than five. However, elicitations with greater than six experts should not call for increased deference due to the accompanied plateau of accuracy. The performance score should consider the number of experts to ensure that perspectives, knowledge, and interests are balanced, and that impartiality and independence is maintained. These aspects are important for emulating objectivity within elicitations.

Behavioural and mathematical aggregative techniques are equally effective for arriving at a single elicited probability distribution. However, documentation should be reviewed to ensure that the correct methods employed under the circumstances and that training and preparation of experts are satisfactory. Behavioural aggregation methods rely heavily on the facilitator to carry out the process. The appropriateness of the behavioural aggregation methods employed will depend on whether interactions occur face-to-face, and the nature of the interaction (e.g. sharing information).[381] The appropriateness of mathematical aggregative methods will also differ based on the circumstances, with different methods having varying accuracies. Cooke's Method is the most complex mathematical aggregation technique but also provides the best results and provides the most information to form conclusions.[382] Targets and expectation for aggregation should

[379] Rosqvist, *supra* note 297 at 37.
[380] DRDC, *supra* note 285 at 14.
[381] *Ibid* at 20.
[382] *Ibid* at 22.

consider the appropriateness of the methods chosen, the effectiveness of the aggregation technique used, any additional information that may result from aggregation and the actions of the facilitator and the normative expert to improve the accuracy during behavioural aggregation methods – i.e. the use of feedback and training.

Upon the completion of step one, the overall assessment of the nuclear activity continues as normal, whereas performance scores are considered within the application of the graded approach to elicited risks. Elicited risks are treated the same as objectively determined risks, and conservatism is introduced to mitigate events in response to the evaluated risk probability, uncertainty and performance score determined in step one. However, when applying the graded approach there are additional considerations that are pertinent to elicited risks. Decision-makers must consider additional conservatism where:

- a significant number of risks are elicited or otherwise subjectively determined;
- there is conflict or incongruity between elicited risks and other risks;
- stakeholders strongly oppose use of elicited risks;

The two-step process is advantageous because it contemplates elicited risk as any other risk. Step one operates on the assumption that an elicitation formed with perfect execution with sufficient evidence is comparable to risks formed objectively using accurate models and parameters. However, the uncertainty of the elicited distribution and the performance score temper this assumption so that it can be appropriately considered within the RIDM process. Scoring, calibration curves and analysis of probabilistic coherence indicate the amount of uncertainty in the elicitation. On the other hand, the performance score accounts for circumstances within the performance of the elicitation that may result in ineffective results. In practice, the addition of the performance score may overestimate the necessary amount of conservatism due to the subjective determination of the performance score and the evaluations of elements that may or may not have a bearing on the accuracy of the results. However, by evaluating the elicitations on their ability to meet established goals and objectives, decision-makers can break down the evaluation into manageable quantifiable chunks thereby minimizing superfluous conservatism.

3.5 Conclusion

Regulatory flexibility is needed to effectively regulate SMRs within Canada's current regulatory framework so that their variability, novel technology and novel applications are addressed appropriately without prejudice. Performance-based regulation is advantageous for this purpose as it provides aspirational goals for which SMRs must adhere, instead of immovable prescriptive requirements. Though performance-based regulations improve regulatory flexibility, Canada's experiences with CANDU reactors inevitably constrain the assessments of SMRs. However, the use of the graded approach to define the scope, content and detail of risk assessment will help negate any preferences for CANDU technology. The graded approach will ensure that regulatory expectations are adjusted based on the design of the reactor on a case-by-case basis.

Canada's regulatory response to risk uncertainty is to mitigate its effects using conservatism. However, uncertainty may be used in risk management practices to provide insight into the amount of precaution needed to meet safety objectives and can be used to ensure that appropriate conservatism is applied. Additionally, uncertainty can be used to prioritize risks, ensure safety objectives are met, and provide credibility to the decisions being made. In this way, the risk uncertainty of SMRs may play a beneficial role within risk assessment and may help reduce conservative responses.

Expert judgement may also be used to help fill risk gaps to provide accurate risk distributions on which the CNSC may confidently rely to form decisions. The CNSC may score the performance of the elicitation to be used as a weighting factor when considering elicited risk distributions within risk assessments. The weighting factor operates on the fact that there is a strong link between the accuracy of elicitations and the methods used to procure those elicited risks. Elicited risks are a powerful tool to produce risk distributions that will become increasingly necessary as technology becomes progressively complex.

Chapter 4: The type certification of SMRs

4.1 Introduction

Type certification or type approval is the process of certifying a design and approving its manufacturing process such that productions of that design are assured to meet regulatory requirements without further proof. Industries that regulate products produced in mass use type certification to ensure their safety without having to certify each individual product. Accordingly, the nuclear industry has raised reproducibility and, by association, type certification to take advantage of the modularity and mass production benefits of SMRs. However, Canada regulates nuclear activities on a case-by-case basis and does not currently have a type certification framework in place

The CNSC raised the issue of how to effectively regulate SMRs deployed in fleets, either on the same site or across Canada, in *DIS-16-04*.[383] On this issue, the nuclear industry suggested that the CNSC employ reproducibility similar to the maritime and aviation industries.[384] Reproducibility refers to the assurance that the vendor is capable of producing products that are consistent to a high degree with the original design. Reproducibility is an essential element of type certification and is thus an important consideration in this chapter.

This chapter examines how type certification is employed by the U.S. Federal Aviation Administration (the "FAA") and by classification societies within the maritime industry. These two industries provide pedagogical value for the CNSC because both industries regulate complex products that can have catastrophic consequences upon the realization of a risk event. Examination of these industries provides insight into type certification practices and its application to complex products. Notably, the complexity of the products has compelled both industries to rely on third parties for assessment and, in the case of the FAA, key regulatory functions.

The FAA's approach to type certification is afflicted with conflict of interest and possible regulatory capture as members of the industry are depended on to perform regulatory functions. Conversely, the maritime industry is able to maintain impartiality in the administration of risk

[383] See Canada, *DIS-16-04*, *supra* note 120 at 9.
[384] Lee, *supra* note 14 at 2. See also Canada, "What We Hear Report", *supra* note 122.

assessments because it relies upon third-party classification societies who have an insignificant stake in the maritime transport market.

The FAA and the maritime industry provide surprising insight into the type certification of complex products. Both industries found it necessary to depend on private enterprise to perform important regulatory responsibilities because of insufficient resources to effectively regulate complex products. The reliance of the aviation and maritime industry in this way exemplifies the difficulties of regulating increasingly complex technologies and serves as a cautionary narrative for the regulation of SMRs as their complexity and popularity increase. This chapter serves not only to indicate how Canada's nuclear regulation can implement type certification but also to provide caution as Canada embarks on the regulation of increasing complex nuclear reactors.

4.2 The use of type certification by the Federal Aviation Administration of the United States

The Federal Aviation Administration of the United States is responsible for the regulation of aviation safety and for granting type certificates, referred to as production certificates, to aircraft designs that have been demonstrated to meet applicable rules and regulations.[385] The production certificate is advantageous because aircraft produced thereunder are axiomatically determined airworthy, thus avoiding further assessment for individual products. However, due to the complexity of aircraft design, the FAA rely heavily on designated representatives of the manufacturer to review the multitude of supporting documentation. Many have criticized this reliance for introducing regulatory capture into the industry and serves as a cautionary tale for the CNSC.

Production certificates certify that produced aircrafts meet regulatory requirements and are produced consistently and accurately to design schematics. The FAA award production certificates to manufacturers after the completion of two steps. First, the aircraft design undergoes an assessment to ensure that it meets regulatory requirements and standards. The assessment ensures

[385] National Research Council, Committee on Airliner Cabin Air Quality, *Airliner Cabin Environment: Air Quality and Safety*, (Washington (DC): National Academies Press, 1986) at 65 [National Research Council, "Airliner Cabin Environment"].

that the aircraft design is airworthy. Second, the manufacturer is audited to ensure that the aircraft design can be produced accurately and consistently to specifications.

The audit ensures that the manufacturer's organization, production facility, quality system and design data follow regulatory requirements and expectations.[386] Where corrective actions are needed, the manufacturer is notified in writing. The correction may include additional audits or meetings with the manufacturer.[387] The production certificate is effective "until surrendered, suspended, revoked, or the FAA otherwise establishes a termination date"[388] and cannot be transferred.[389] Additionally, notification must be given to the FAA where the manufacturer makes any changes to the facilities that affect quality systems, inspection, conformity or airworthiness of the product, which are subject to review by the regulator.[390]

The auditing process requires extensive documentation from the applicant. Materials include a description of how the organization will ensure compliance, the responsibilities of management overseeing the quality of production, and the identification of a manager with authority over production operations.[391] The manager acts as a liaison to confirm that the procedures in place comply with regulations. Most importantly, the manufacturer must provide a written description of their facility's quality system to demonstrate the conformity of the production to the approved design. Federal regulations list fourteen quality systems that must be maintained to demonstrate the adequacy of the manufacturer's quality systems.[392] The documentation provided by the manufacturer and the compliance of their quality system to regulations are used to demonstrate the reproducibility of the product.

Aviation safety relies on the cooperation and mutual exchange between the FAA and manufacturers.[393] There is a strong incentive for the manufacturer to continue to produce according to the certified design because modifications that affect the quality, organization or airworthiness

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[386] United States of America, Federal Aviation Administration, "Production Certificate Application and Approval Process" (22 March 2016) online: FAA website <https://www.faa.gov/aircraft/air_cert/production_approvals/prod_cert/prod_approv_proc/> [https://perma.cc/C77H-AQPE].

[387] *Ibid.*

[388] 14 CFR § 21.143 (2009).

[389] 14 CFR § 21.144 (2009).

[390] 14 CFR § 21.150, 21.122 (2009).

[391] 14 CFR § 21.135 (1)–(3) (2009).

[392] 14 CFR § 21.137 (a)–(c) (2009).

[393] National research Council, "Airliner Cabin Environment", *supra* note 385 at 66.

of the aircraft require resubmission for certification.[394] This pattern of interaction emphasizes inspection and enforcement rather than the review of design specifications and production.[395] This characterization becomes increasingly evident when considering the FAA's reliance on representatives from the manufacturer to assess their designs.

The FAA relies heavily on Designated Engineering Representatives (the "DERs") to assess aircraft. DERs are typically employees of the manufacturer who have been selected by the FAA to perform assessments of their design because of the growing complexity of aviation technology, the significant amount of documentation that needs to be considered within the assessment, and the familiarity of the employees with their design.[396] Though DERs are not supposed to perform key regulatory tasks of the FAA, government audits of the regulator indicate that DERs are relied upon for the bulk of the FAA's regulatory work, including work that is meant to be completed by FAA staff. As a result, many have analogized the FAA as a human resource manager, as they ensure the impartiality and competency of DERs rather than directly perform safety assessments.[397]

The type certification of aircraft by the FAA provide insight for the nuclear industry as both industries are tasked with regulating complex products with the potential for catastrophic failures. It is recommended that the CNSC type certify designs upon the satisfaction that the design of the SMR meets regulatory expectation and its manufacturing process ensures reproducibility just as the FAA does. However, not all aspects of the approach of the FAA are comparable. It is recommended that the CNSC avoid relying upon representatives for regulatory tasks, as it removes their direct involvement of ensuring the safety of the designs. The challenges associated with the FAA's approach to type certification is discussed in the following section.

[394] *Ibid* at 65.

[395] *Ibid* at 66.

[396] John Downer, "Trust and technology: the social foundations of aviation regulation" (2010) 61:1 The British Journal of Sociology 83 at 85. See also *ibid* at 65.

[397] *Ibid* at 95.

4.2.1 Criticisms of the FAA: Conflict of interest and Regulatory capture

The FAA relies on DERs for most of their assessment responsibilities due to the complexity of the aircraft designs and their familiarity with the technology. As a result, the tacit knowledge of DERs has become indispensable for aviation regulation. Many have criticized the relationship between the FAA and DERs for introducing a conflict of interest between manufacturers and the regulator and the potential for regulatory capture. Conflict of interest arises from the DERs service to two masters: their employer (the manufacturer) and the FAA. The FAA is exemplary for its assurance of reproducibility, but its reliance on DERs is a cautionary tale that should be carefully examined if the CNSC chooses to implement their own type certification framework.

DERs are employees of the manufacturers, usually senior employees, who are deputized by the FAA to act as surrogates for the oversight of the design, test calculations and compliance with aviation regulations.[398] The FAA choose DERs to perform assessments because of their tacit in-depth knowledge of the design.[399] As a result, DERs perform the bulk of regulatory obligations of the FAA, including key regulatory responsibilities of FAA staff. Thus, DERs serve two masters: the FAA and the manufacturer. To effectively administer this regime, the FAA reportedly go to great lengths to train DERs with sufficient expertise and impartiality.[400]

The FAA's approach to regulation is characterized as "second-order" regulation because it functions as a resource manager of DERs.[401] In this role, the FAA assesses the integrity and expertise of its DER workforce to ensure that technical assessments of aircraft are performed honestly by qualified and credible people.[402] That is, the FAA cannot assess the technological claims directly, but assess the creditworthiness of the people who make them.[403] This approach is characterized as "second-order" regulation because the FAA is intimately involved in the oversight of "representatives who conduct, interpret and frame the tests," and not the direct assessment of the design.

[398] *Ibid* (DERs are employees of the manufacturer chosen by the FAA, though usually they are nominated by the manufacturer, to become designees at 85).

[399] *Ibid* at 88.

[400] *Ibid* at 88.

[401] *Ibid* at 95.

[402] *Ibid*.

[403] *Ibid*.

Critics chastise the FAA's reliance on DERs because it places the primary responsibility of ensuring the safe design, maintenance and operation, and ultimately the guarantee of aviation safety, with the manufacturer.[404] In principle, DERs are to conduct routine functions while the FAA staff administers key elements of certification.[405] In practice, however, DERs have increasingly been delegated key aspects of the certification and assessment process because of the growing complexity of aircraft designs.[406] In 1993, the US Government Accountability Office found that DERs are delegated 90-95 percent of the FAA's regulatory activities.[407] A delegation of significant regulatory tasks to DERs has been noted since 1989, where the FAA delegate nearly all certification processes to Boeing for assessment of their advanced flight management system because of the unfamiliarity of the system.[408] As a result, conflict of interest and regulatory capture are significant concerns.

DERs are in a clear conflict of interest as they serve two masters: the manufacturer and the FAA.[409] The conflict arises as the manufacturer's interest lies in corporate gain and the FAA's interest lies in ensuring the safety of civil aviation. These interests are incompatible as regulation by definition is the control or maintenance of industry, irrespective of private interest, for some objective that might not otherwise occur.[410] Supporters of the FAA argue that the concerns of conflict of interest are unjustified because the FAA and aircraft manufacturers share the same interest to design safe, reliable aircraft.[411] However, this interest fails on two points. First, it neglects the parallel economic interest of the manufacturer that is influenced by market pressures.[412] For example, certification failures can be extremely expensive with some manufacturers literally "betting the company" on its success.[413] Under these stresses, the refined

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[404] *Ibid* at 83.

[405] *Ibid.*

[406] *Ibid.* See also US, United States Government Accountability Office, Report to the Chairman, Subcommittee on Aviation, Committee on Public Works and Transportation, House of Representatives, *Aircraft Certification: New FAA Approach Needed to Meet Challenges of Advanced Technology,* (Washington, DC: GAO, September 1993) [GAO, *Aircraft Certification*] at 22.

[407] GAO, *Aircraft Certification*, *ibid* at 17.

[408] Aerospace Industries Association of America, Inc, *Maintaining a Strong Federal Aviation Administration: The FAA's Important Role in Aircraft Safety and the Development of U.S. Civil Aeronautics* (Washington, DC: Aerospace Research Center, September 1989) at 49.

[409] Downer, *supra* note 396 at 91.

[410] *Ibid*.

[411] *Ibid* at 92.

[412] *Ibid* at 93.

[413] *Ibid.*

impartiality of the DER in their assessment is dubious as they strive to rise through the corporate ranks and maintain their employment through the success of their employer.[414] Second, this fails to consider non-nominal legal obligations such as the fiduciary accountability of the DERs to the manufacturer and the FAA that may arise. Academics have raised the question as to why regulation is needed at all if the interests of the FAA and the manufacturers align.[415]

Critics of the relationship between manufacturers and the FAA are also concerned with the potential for regulatory capture. Regulatory capture occurs where, "over time, powerful industries come to dominate the agencies that regulate them."[416] The arrangements between manufacturers and the FAA are exemplary of regulatory capture pathology as the FAA's dependence on manufacturers provides a power imbalance which the manufacturers may abuse to achieve their interests.[417] Many academics have named the FAA as particularly vulnerable to regulatory capture,[418] and some agency veterans have confirmed that manufacturers have significant influence within aviation regulation.[419] Regulatory capture threatens good regulation because it is "a method of subsidizing private interests at the expense of the public good.[420]

The type certification regime of the FAA serves as a caution for the regulation of complex technology that requires extensive assessment. Moving forward with the regulation of SMRs, the CNSC must ensure they have sufficient resources to accommodate nuclear activities. Reliance on representatives to assess designs and audit the quality system of the manufacturer poses significant risks of conflict of interest and regulatory capture. Proponents of the FAA have suggested that the criticisms are moot because of the lack of alternative approaches available and that the imperfection of the process is embraced.[421] However, the CNSC may avoid this through preparation and fortification of their expertise and resources.

[414] *Ibid.*

[415] *Ibid.*

[416] *Ibid* at 91.

[417] *Ibid.*

[418] See e.g. David Dana & Susan P Koniak, "Bargaining in the Shadow of Democracy" (1999) 148:2 U Pa J L Rev 473 at 497. See especially Mark C Niles, "On the Hijacking of Agencies (and Airplanes): The Federal Aviation Administration, "Agency Capture," and Airline Security" (2002) 10:2 J Gender, Social Policy & L 381 at 384, 442.

[419] Niles, *ibid* ("at least one agency veteran was quoted in a national news magazine in 1995 as saying: 'To tell the truth, the industry, they really own the FAA'" at 384).

[420] John Shepard Wiley Jr, "A Capture Theory of Antitrust Federalism" (1986) 99 Harv L Rev 713 at 723.

[421] Downer, *supra* note 396 at 93.

4.2.2 The Canadian perspective

The reliance on third party representatives not only introduces regulatory capture and conflict of interest into regulation, but it also contradicts the ideology that RIDM embodies. The power imbalance resulting from the reliance on DERs for the performance of risk assessments contradicts the heart of RIDM. Furthermore, the conflict of interest arising from the reliance on DERs is potentially a breach of the DERs fiduciary obligation to their employer under Canadian jurisprudence. Fortunately, with informed and careful policy the CNSC may be able to avoid the challenges faced by the FAA if a similar licensing structure is put in place.

There is no doubt that the CNSC should avoid the type certification process imposed by the FAA, not only because of the fear of regulatory capture but also because it is inoperable within the RIDM policies of the CNSC. The latent power imbalance of the FAA's regulatory approach places significant responsibility on industry to make regulatory decisions, sharing the responsibility with the CNSC, and potentially obscuring informed decision-making. Additionally, it is difficult for organizations, other than the CNSC, to have sufficient experience to administer performance-based criteria based upon aspirational objectives. Decisions formed under a conflict of interest by definition signals that the values of RIDM are not maintained.

Not only is there a conflict of interest between DERs and the FAA but, in the context of Canadian jurisprudence, there is also the potential for a breach of fiduciary obligations owed by the DER to its employer. In *Can. Aero v O'Malley,* the Supreme Court of Canada recognized senior management officers as status fiduciaries owing a strict duty of loyalty to their employer requiring them to put the interest of the corporation ahead of their own.[422] It is also noteworthy that the court left open the opportunity for junior employees to be found as a fact-based fiduciary where their duties have a confidential nature.[423] As a regulator, expertise is a commodity when choosing designated representatives and, therefore, there is a preference for employees who have tacit knowledge and years of experience.[424] Though their position will determine whether they are a fact-based or a status-based fiduciary, it is probable that designated representatives owe a fiduciary

[422] *Can Aero v O'Malley*, [1974] SCR 592, 1973 CanLII 23 at 610.

[423] See *ibid* (though the court analysed whether employees are status-based fiduciaries, the analysis does not preclude the finding that employees of all nature may be found as a fact based fiduciary).

[424] Dower, *supra* note 396 at 88.

duty to their employers because of the confidential and senior nature of their employment. Notably, some academics have argued that all employees are accountable as fiduciaries.[425]

It may be also possible for the DER to be a fiduciary of the regulator in addition to the manufacturer. Such a characterisation will depend on the nature of the relationship of the DER with the regulator. The characterization of the DER as an employee of the regulator is unlikely because of the regulator's lack of sufficient control over the DER[426] and thus cannot create a fiduciary relationship. However, the finding of a fact-based fiduciary relationship remains possible. Thus, the failure to find the DER as an employee of the regulator does not preclude the fiduciary accountability of the DER to the regulator.[427]

Fiduciary accountability is strict and is breached where the fiduciary uses their limited access to the employer's assets opportunistically.[428] As discussed previously, some argue that there is no conflict of interest between the regulator and the manufacturer because they share the common interest to produce a safe and reliable product. However, this is an economic justification and should not be conflated as a justification for the legal duty of loyalty. The duty of loyalty is strictly applied and acting in the "best interest" of the beneficiary is not a defence. Expressed consent is the only defence to a breach of a fiduciary obligation. Thus, despite being ostensibly a justification economically or politically, the justification is not defensible legally.

Issues arising out of fiduciary accountability of the employee are complex, and the complete discussion of those challenges is beyond the scope of this paper. Not only are there issues

[425] Robert Flannigan, "Employee Fiduciary Accountability" (2015) 3 J Bus L 189 (Flannigan uses conventional fiduciary analyses to determine that all employees are fiduciaries to their employer because of their limited access undertaking with their employer at 189).

[426] See *Wiebe Door Services Ltd v Canada (Minister of National Revenue)*, [1986] 2 CTC 200, [1986] 3 FC 553(CA), (to determine whether the contract is for service or of services, consider (1) the degree or absence of control, exercised by the alleged employer; (2) ownership of tools; (3) chance of profit and risk of loss; and (4) integration of alleged employees work into alleged employers business at para 3).

[427] See *Frame v Smith*, [1987] 2 SCR 99, 42 DLR (4th) 81, (a fact-based fiduciary relationship possess three general characteristics: "(1) [t]he fiduciary has scope for the exercise of some discretion or power (2) [t]he fiduciary can unilaterally exercise that power or discretion so as to affect the beneficiary's legal or practical interests. (3) [t]he beneficiary is peculiarly vulnerable to or at the mercy of the fiduciary holding the discretion or power" at para 60). Contra Robert Flannigan, "The Boundaries of Fiduciary Accountability," (2004) 83:1 The Canadian Bar Rev 35 (Flannigan argues that the characterisation of a fiduciary has been distorted by courts and legislation over the last century, but remains at the heart of the issue, and that conventionally, parties (including employees) are accountable fiduciaries where they have "access to the assets (and opportunities) of the beneficiaries" at 37–54).

[428] See Robert Flannigan, "The Strict Character of Fiduciary Liability" (2006) New Zealand LR 209 at 209–210.

of the breach of an employee's fiduciary obligations to the employer, but the CNSC can be held accountable where those breaches are committed as a result of their relationship with the employee. Dishonest assistance, or knowing assistance, is a third-party liability in trust law for knowingly assisting the breach of a fiduciary duty.[429] Accordingly, this thesis highly recommends that reliance on designated employees be avoided, not only because of the threat of regulatory capture and the conflict of interest but also because of the issues arising out of the fiduciary accountability of the employees to their employer.

The dependence on DERs by the FAA is not the result of some irreconcilable elements of type certification but is a consequence of the complexity of the technology and the FAA having insufficient resources to accommodate it. In addition to regulatory capture and conflict of interest, a similar approach implemented within Canada would potentially breach the employees' fiduciary duty to their employer. Despite these issues, the FAA provide an example for how to ensure reproducibility of the manufacturer. Auditing the manufacturer facilities, ensuring the quality systems and having a manager as a liaison may simply be implemented within the current regulatory regime of the CNSC.

4.3 The use of type certification by the Maritime transport industry

The maritime transport industry is regulated according to international standards, with deference to state requirements where appropriate. Independent organizations, or classification societies, heavily influence maritime transport and oversee the construction and manufacturing of vessels and accompanying components. The US relies on the American Bureau of Shipping (the "ABS")[430] for the certification, including type-approval, of maritime transportation. Although they are a third-party certification process made up of members of industry, they avoid regulatory capture and conflict of interest through their organizational structure. The certification processes

[429] See *Gold v Rosenberg*, [1997] 3 SCR 767, 35 OR (3d) 736.

[430] American Bureaus of Shipping, *Type Approval Program: Practical and Effective Approval Solutions*, (Houston: ABS, 2015) (ABS is instrumental within the certification of ships for national and international shipping within the U.S provide, and provide review on behalf of the U.S. Coast Guard, perform conformity assessment for equipment for certification of the European Union Marine Equipment Directive and European Union Mutual Recognition at 4).

practiced by the maritime industry relay conducive regulatory approaches useful for the type certification of SMRs.

The maritime transport industry is regulated according to international standards and state requirements.[431] The International Maritime Organisation (the "IMO") is a specialized agency established by the United Nations tasked with regulating shipping. The IMO has produced 22 conventions or treaties, 17 codes and resolutions containing guidelines and recommendations for maintaining comprehensive shipping regulations.[432] International requirements are imposed by the vessels originating jurisdiction, or "flag state," that has ratified the international agreements.[433] A vessel is awarded a certificate for every convention for which it complies. A certificate is valid for five years, provided that the vessel is inspected annually.[434] After five years, the ship undergoes a major inspection whereby certification is renewed pending any necessary maintenance or renovation to meet standards.[435] Though traditionally inspection of vessels has been conducted by government agencies, such as the coast guard in both Canada and the U.S., there is increasing reliance on classification societies who are contracted by flag states to perform inspections and enforce regulations.

Classification societies are independent organizations relied upon by the maritime industry for their assurance of vessel safety. Classification societies establish basic minimum standards for the design, construction and maintenance of the hull and components of vessels.[436] Classification societies issue certifications of the class which are relied upon throughout the maritime industry as an affirmation that the vessels are fit for its intended use.[437] Prominent classification societies such as ABS are members of the International Association of Classification Societies (the "IACS"), which prescribe minimum requirements for classification.[438] The IACS standardizes classification practices to deter, to the greatest extent possible, classification society shopping by

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[431] National Research Council, Committee on Tank Vessel Design, Marine Board, *Tanker Spills: Prevention by Design*, (Washington, DC: National Academy Press, 1991) [National Research Council, *Tanker Spills*] (the U.S. may ensure that all ships sailing within their jurisdiction, including foreign ships, are in compliance with international agreements through inspection while in a port or terminal within their jurisdiction at 46).

[432] *Ibid* at 39.

[433] *Ibid* at 43.

[434] *Ibid.*

[435] *Ibid.*

[436] See Machale A Miller, "Liability of Classification societies from the Perspective of United States Law" (1997) 22 Tul Mar LJ 75 at 77.

[437] See *Ibid.*

[438] See *Ibid.*

ship-owners and promote public confidence by discouraging economic gains regarding seaworthiness requirements.[439]

Like the FAA, the maritime industry relies on classification societies because of the complexity of the vessels being regulated. The complexity and continual advancement of the technology is an ever-moving target too ambitious for governments to maintain with specificity.[440] The rules of classification societies are continuously reviewed and developed to meet advancing technology. However, unlike the FAA, classification societies, mostly remain impartial in their assessments.

Though classification societies are independent third-parties, the system avoids regulatory capture and partiality through the competition between societies, enforcement of standards and oversight by the IACS, insulation from the market pressures of the shipping industry and the practice of publishing the findings of their assessments. Classification societies compete amongst each other to deliver the best services to their clients who include shipping companies and governments.[441] In the U.S.,[442] Canada[443] and other countries, governments have legislated the use of classification societies for the regulation of their vessels and shipping industry, where impartiality and transparency are integral.[444] Impartiality is also encouraged by the IACS, who instil public confidence through safety standards and inhibit gains awarded to classification societies for bias dealings with ship-owners.[445] Furthermore, classification societies do not share the same interests as ship-owners because they have a distinctively different role within the

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[439] See *Ibid.*

[440] See Laihui Sun, *A study of the roles of classification societies under the new maritime atmosphere,* (MSc Thesis, World Maritime University Faculty of Maritime Safety and Environment Protection, 1999) [unpublished] at 7.

[441] See Hartmut Hormann, "Classification Societies – What is Their Role, What is Their Future" (2006) 5:6 WMU J Maritime Affairs 5 at 6.

[442] See example 46 CFR § 3316(a) (1983) ("[e]ach department, agency, and instrumentality of the United States Government shall recognize the American Bureau of Shipping as its agent in classifying vessels owned by the Government and in matters related to classification"). See also National Research Council, *Tanker Spills*, *supra* note 431 (The U.S. Coast Guard is responsible for the "safety of life and property at sea and protection of the marine environment," however incorporate the rules of the ABS and rely on the ABS to perform inspections and design reviews and delegates a significant amount of its regulatory responsibility to the ABS at 47).

[443] See e.g. Canada, Transport Canada, *Guidelines for the Construction, Inspection, Certification, and Operation of Tugs < 24 Metres in Length*, 1st ed, TP 15180E (Ottawa: Transport Canada, 2013) ("Transport Canada has entered into formal agreements with certain Classification Societies, under the authority of the Act. These agreements cover the delegation of statutory inspection and certification functions and product approvals" at 15).

[444] See Sun, *supra* note 440 at 39.

[445] Miller, *supra* note 436 at 77.

industry. Therefore, classification societies are unmoved by the market pressures experienced by ship-owners and have minimal to no incentive for regulatory capture.[446] Furthermore, unlike DERs, classification societies rely on surveyors[447] who do not have an economic stake in the performance or maintenance of the vessel.[448] The IACS requires that surveyors be impartial and require member societies to ensure the independence of their personnel performing class surveys and audit activities.[449] Finally, classification societies attempt to remain transparent and accountable by publishing their findings so that ship-owners, authorities, insurers and other interested parties may consult it.[450]

Using the ABS as an example, type approval certification for vessels is awarded upon the successful evaluation of the vessel design and the quality standards of the manufacturer. The "Type Approval Certificate" is granted upon the completion of the "Product Design Assessment Certificate" (the "PDA") and the "Manufacturer Assessment" (the "MA"). To begin the process, a PDA is first applied for and completed. The ABS issue a PDA upon the verification of the product's compliance with the manufacturers' specifications, ABS rules, national standards and international standards.[451] Next, the ABS conducts an MA which requires the inspection of the product during manufacturing to assess the quality control system and the manufacturing processes of the plant.[452] The quality system check is similar to that of the FAA, where the ABS conducts an audit of the quality control systems and the facility. The IACS provides quality assurance standards and guidance depending on the product.[453] A "Type Approval Certificate" is axiomatic upon PDA certification and a successful MA.

The maritime industry and the FAA both employ third parties to aid in the regulation of complex technology. However, the maritime industry manages to maintain impartiality using

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[446] *Ibid* at 85.

[447] Hormann, *supra* note 441 (Though surveyors are required to be employees of a technical organisation, they may still act as independent experts for projects not pertaining to their employment at 11).

[448] *Ibid.*

[449] See Laihui Sun, *supra* note 440 at 35.

[450] See *ibid* at 7.

[451] American Bureau of Shipping, "Type Approval Procedure" (last visited 23 October 2018) online: ABS website <https://ww2.eagle.org/en/Products-and-Services/type-approval/type-approval-procedure.html> [https://perma.cc/8W3S-N2SG].

[452] *Ibid.*

[453] See e.g. International Association of Classification Societies, *No. 17 Guidelines for the Acceptance of Manufacturer's Quality Assurance Systems for Welding Consumables*, (London: IACS, 1987). See e.g. International Association of Classification Societies, *No.47 Shipbuilding and Repair Quality Standard*, (London: IACS, 1996).

classification societies. Over the last few centuries, this system has developed a market consisting of many societies that promote impartiality through competition, regulatory oversight and independence from the market pressures of the shipping industry. This approach drastically reduces conflict of interest and potential for regulatory capture. Another similarity between the FAA and the maritime industry is how they ensure reproducibility through audits and inspections of the manufacturing facilities, organization and quality systems. The maritime industry provides an example of an international inspection system that may be employed to streamline the licensing of SMRs being mass-produced. However, this system has its own flaws that should be considered and addressed before it is implemented for the regulation of SMRs.

4.3.1 Criticisms of the Classification Societies: Market pressures and quality discrepancies

The literature on classification societies criticizes their internal decision-making methods, but focus little discussion on their regulatory structure and approach. A pouring of criticism came during the mid to late 1990s after a string of accidents resulted in the loss of life and extensive pollution.[454] Academics point out poor risk assessment methodologies, standards, and failures to address human factors in safety as the cause for the surge in maritime accidents.[455] Though critics are silent on the reproducibility and type approval approaches of the maritime industry, their discussion of market pressures and competition amongst societies provide insight into additional difficulties of developing a third party assessment regime.

The competitive nature of the classification society market has been called the Achilles heel of the industry.[456] Delegating certification and assessment tasks to third-party organizations promotes competition. Competition for market share incentivizes societies to cut costs of services

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[454] See Laihui Sun, *supra* note 440 ("[i]n 1990, the trend of increasing disasters was [*sic*] dramatically emerged … 20 bulk carriers sank with 94 lives lost, and in 1991, 24 sank with 154 dead" at 28, 18).

[455] *Ibid* (human factors, natural occurrences and poor risk assessment methodologies were blamed for the poor safety record of the maritime industry in the late 1980's to early 1990's, which was addressed through the development of safety standards by the IMO and IACS – though Sun also suggests that additional research and development, continuous development of rules, publishing of rules and accelerated uniformity of standards are needed to further improve the industry's safety record at 18, 20–26, 28, 49).

[456] J M Silos *et al*, "The role of the Classification Societies in the era of globalization: a case study, Maritime Policy & Management" (2013) 40:4 Maritime Policy & Management 384 at 398.

to remain competitive [457] and decreasing the quality of service.[458] Though 12 prominent classification societies are members of the IACS, there are countless others who operate out of the association. As a result, many societies are reporting annual losses, with some contemplating merging with other entities to remain profitable.[459]

Market pressures are generally corrosive to good regulation – the aviation industry is a good example of that. Though classifications societies are not regulators per se, they do play an extensive role within the regulation of the shipping industry and are subject to their own market pressures. The IACS and IMO are important organizing institutions that ensure the standards of classification societies are satisfactory and instil confidence within the system. Despite the countermeasures placed by the IACS and IMO, however, classification societies' capitulation to market pressures is inevitable, which typically incentivizes classification societies to reduce their costs and thus diminish their quality of assessment.

4.3.2 The Canadian perspective

As SMRs increase in popularity and begin deployment, regulators such as the CNSC may find themselves struggling to perform regulatory tasks competently and economically without reliance on outside resources. The maritime industry suggests that regulators may rely on independent third parties for the assessment of complex designs which are capable of maintaining their impartiality unlike the DERs relied upon by the FAA. It is suggested that this approach may be effective for the CNSC. However, the such a regime will require a sizeable SMR industry in order to eb effective.

Classification societies such as those in the maritime industry are impartial because of their unique placement within the maritime industry. Market independence, oversight by an international body, competition amongst classification societies, and publication of their findings are key aspects that hinder regulatory capture within the maritime industry. Unlike the FAA who

[457] Robert Koenig, "Classification Societies Encounter Rough Seas" (2 July 2000) Journal of Commerce - Maritime News online: Journal of Commerce of website <https://www.joc.com/maritime-news/classification-societies-encounter-rough-seas_20000702.html>.

[458] Silos, *supra* note 456 at 398.

[459] Koenig, *supra* note 457.

obscures the significance of their reliance on DERs,[460] classification societies practice transparency and accountability to obstruct regulatory capture. Transparency aids in mitigating regulatory capture, encouraging complete and accurate information, and ensuring that decision-makers are accountable for their decisions.[461] Accountability has a significant impact on the promotion of effective decision-making in two ways. First, it holds the decision-maker accountable for their actions.[462] Second, it holds regulators accountable for their inactions and elicits improved regulations where such regulations are inadequate.[463]

Were the CNSC to depend on third parties for regulatory assessments, classification societies would be exemplary for how to maintain impartiality and reduce the potential for regulatory capture. However, Classification societies are also exemplary of how regulation may develop to accommodate the proliferation of SMRs internationally. International oversight over nuclear activities already exists as the IAEA and the UN provide standards and guidelines for member countries. Thus, the IAEA, or if they so choose third-party organizations organized within the IAEA (like the IACS), may become a standard source for assessing reproducibility and certification of SMR designs. International oversight would be in line with already mobilized efforts to standardize nuclear regulations internationally.

An international certification and reproducibility process may operate similarly to the maritime industry, where the assessment of SMR designs and quality assurance of the vendor occur in accordance with the regulatory guidelines of the IAEA. Under such a regime, states would defer to the assessments of the IAEA but would still need to assess SMRs according to their regulatory laws. For example, assessment for licenses to prepare a site, construct, operate, etc. would still have to be satisfied by the CNSC. This regime would reduce costs for regulators who otherwise must conduct the assessment of the manufacturer, while also reducing costs and licensing durations for the vendor.

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[460] Downer, *supra* note 396 (the FAA are criticised for ‘white boxing’ technology where “regulators purport to make the inner workings of a technology publicly visible and accountable even whilst obscuring the messy realities of technological practice” at 90).

[461] Judith Kurland, “The Heart of the Precautionary Principle in Democracy” (2002) 117:6 Public Health Reports 498 at 499.

[462] *Ibid* (An issue of regulatory capture is the disbursement of false, misleading, or inaccurate information to the public, or other such activities by the decision-maker to advance the interests of private groups at 499).

[463] *Ibid.*

The maritime industry and aviation industry are examples of how regulators have integrated expert and third parties to regulate complex systems. As the Canadian nuclear industry begins to expand their regulation to accommodate SMRs, a significant amount of consideration must be given to their resources and whether they have the capacity to accommodate the technology. Though the reliance on third parties to perform regulatory functions has resulted in a conflict of interest and potential regulatory capture for the FAA, the maritime industry illustrates that, under the correct structure, regulators may rely on third parties for the assessment of products for the purposes of type certification. However, before such a regime can be introduced, the SMR industry will have to grow substantially, which may occur as SMRs gain in popularity because of their safe operation, economics, range of applications, and as countries take measures to offset their emission.

4.4 Type certification of SMRs and accommodating complexity in Canada

Though the substance of the regulation of SMRs will differ greatly from the aviation and maritime regulation, the two industries provide insight into how regulators can implement type certification and maintain reproducibility. This thesis recommends that the CNSC exercise type certification of SMRs in a two-step process similar in structure to type certification by the FAA and classification societies. The first step is the assessment of the design. This step administers design relevant expectations for assessing the design of the SMR. Following a successful assessment, step two ensures the reproducibility capabilities of the vendor. If vendors are successful in step two, their designs will receive type certification. In theory, this approach would mirror the approach taken by classification societies and the FAA. However, the implementation of type certification may be challenging due to the entangled and lengthy licensing process.

This thesis argues that the assessments conducted for type certification should embody relevant regulatory expectations conducive to the overall licensing process. In this way, type certification may occur during or before the licensing process without unnecessarily using regulatory resources. Another advantage of this approach is that it avoids implementing an *ad hoc* regulatory scheme for SMRs[464] and acknowledges the industry's desire to regulate SMRs within the existing framework.[465]

The scope of assessment for type certification will be limited to that of the reactor and components of the facility that are standard to the respective SMR design. This assessment will include deterministic and probabilistic safety assessment, defence-in-depth considerations, personnel needed and other considerations specific to the safety of the facility and reactor. Additionally, the scope, content and details of the assessment should be tailored to each design using the graded as suggested in the previous chapter. This approach will also require the CNSC to extricate criteria and requirements entangled within the broad licensing phases of nuclear power plants and synthesise those requirements into a single assessment phase.

The CNSC requires licences for the five phases of the nuclear power plants lifecycle, three of which are pertinent to the deployment of the reactor: (1) license to prepare a site; (2) license to construct; and (3) licence to operate. These licensing phases consider aspects beyond just the design of the reactor such as consultation with the public, environmental assessment, personnel requirements and more. Though applicants may obtain these three licences in parallel, the total duration from applying for a licence to prepare a site to the grant of a licence to operate is 9 years.[466] The licensing duration may be increased by the limitations of the CNSC's resources, and the complexity and unfamiliarity of SMRs.[467]

The pre-licensing vendor design review already synthesizes an assessment procedure useful for type certification. The pre-licensing step can "verify, at a high level, the acceptability of a nuclear power plant design with respect to Canadian nuclear regulatory requirements and expectations, as well as Canadian codes and standards."[468] Though the conclusion of the review is

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[464] See Tristano Sainati, Giorgio Locatelli & Naomi Brookes, "Small Modular Reactors: Licensing constraints and the way forward" (2015) 82 Energy 1092 (the authors discourage the creation of an ad hoc regulatory framework to regulate SMRs because of three primary challenges: (1) "[i]t requires a significant review of the legal and regulatory framework"; (2) "[i]t implies a complete re-think of the [licensing process] that implies a redefinition the institutional framework; (3) "[i]t implies a reduction of the licensing guarantees in intuitional and democratic terms (e.g. exemption of circumstances for the public inquiry)" at 1094).

[465] See Canada, "What We Heard Report", *supra* 122.

[466] Canada, *Design of New Nuclear Power Plants*, *supra* note 74 at 14.

[467] *Ibid.*

[468] Canada, Canadian Nuclear Safety Commission, *Pre-licensing Review Vendor Design Review*, GD-385 online: CNSC website <https://www.nuclearsafety.gc.ca/eng/reactors/power-plants/pre-licensing-vendor-design-review/> [https://perma.cc/9VVY-8Z83].

intended not to be binding, it demonstrates that designs may be assessed outside of normal licensing procedures to a high degree.

The second stage of the type certification assesses the reproducibility of the design by the manufacturer. This step assures that the manufacturer will produce its design consistently and accurately to its design specifications. Using the FAA as an example, the assessment of the manufacturing process is broken into two phases. First, the FAA requires that the manufacturer describe how its organization will ensure its compliance with productions standards and describe the quality management strategies implemented therein.[469] Second, the FAA ensures that the quality system of the plant is sufficient to ensure that "each product and article conforms to its approves design."[470] The FAA's regulations identify fourteen control measures to be included within the quality system which provide an excellent reference for the CNSC when implementing a similar approach.[471]

Quality assurance also requires that the regulator inspect the manufacturing premises that build the product. Before the FAA grants a production certificate, they inspect the manufacturing process on site. Classification societies do the same for vessels and other components. This inspection is necessary if the CNSC wishes to ensure the reproducibility of the manufacturer. Additionally, an on-site inspection may alleviate difficulties associated with the inspection of modular reactors during installation on site as inspectors may assess the inside of the vessel during its manufacturing. Upon type certification, the inspection of a single certified unit may be sufficient for all units designed to that specification.

The CNSC may grant type certifications with conditions at their discretion. Common conditions by the FAA and maritime industry include the voiding of certification or license upon any unauthorized changes to the design or the manufacturing facilities. The FAA requires approval for any minor[472] and major changes to aircraft designs.[473] Additionally, the manufacturer must notify the FAA of any changes to the manufacturing process that affects inspection or conformity

[469] 14 CFR § 21.135 (2009).

[470] 14 CFR § 21.137 (2009).

[471] *Ibid.*

[472] 14 CFR § 21.93 (2009) (a minor change being one that does not affect "the weight, balance, structural strength, reliability, operational characteristics, or other characteristics affecting the airworthiness of the product").

[473] 14 CFR § 21.97 (1964) (major changes are approved upon the receipt of substantiating and descriptive data and demonstration that the changes comply with regulations).

of the product.[474] The maritime industry requires that certified vessels be re-examined every five years to ensure that designs are up to standards.[475] Additionally, conditions may be appended to type certification as the CNSC sees fit similar to how they provide conditions to the license they grant.

It is possible to integrate type certification into the Canadian nuclear industry without adverse effects or challenges to RIDM and associated regulatory principles such as the graded approach. In the first step of type certification, designs will be scrutinized as if being assessed within the normal licensing procedures. The second step of type certification, the audit of the manufacturer and its quality assurance systems, is heavily prescriptive-based and, thus, insignificantly engages with performance-based principles such as the graded approach. The graded approach may apply, however, during the assessment of documentation provided by the manufacturer concerning their quality assurance program. The extent of documentation must satisfy the quality assurance claims of the vendor proportional to the complexity and novelty of the process (not the design of the reactor). This is in line with other regulatory requirements of the CNSC which requires that the amount and content of documentation be proportional to the complexity and novelty of the activity.

The CNSC can avoid regulatory capture through transparency, accountability and clarity which should be maintained in the practice of type certification. Examples of the practice of transparency by the CNSC include the publishing of discussion papers and workshops completed with stakeholders, and the involvement of the public and Indigenous peoples within the process. Accountability is a value embedded within the CNSC code of ethics, which states that the CNSC is committed to exercising their authority in a responsible manner that maintains public trust and confidence and being accountable for their “decisions, actions and advice.”[476] Clarity is promoted through the CNSC’s dealings with industry and its robust library of regulatory documents outlining their expectations. It is suggested that licenses granted on the basis of type certification be subject to these values and practices to avoid regulatory capture. The involvement of stakeholders and the

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[474] 14 CFR § 21.139 (2009).
[475] National Research Council, *Tanker Spills*, *supra* note 431 at 43
[476] Canada, Canadian Nuclear Safety Commission, *supra* note 177 at 4.

transparency of that involvement will be important as the Canadian nuclear industry is diverse and contains many different stakeholders who are influential within the process.

The exact scope and content of the type certification are beyond this thesis. It involves intimate regulatory considerations developed through years of practice and expertise familiar only to the CNSC. However, the above discussion does its best to highlight a structure for type certification that may be expanded upon by the CNSC to be used within it's regulations. When implementing the system, the CNSC must be sure that the structure remains economical for vendors to take advantage of, while remaining sufficiently robust for the CNSC to rely upon. The pre-licensing vendor design review already does a similar assessment that verifies at a high level the acceptability of the SMRs design and can act as a reference for the development of a type certification assessment phase.

4.5 Conclusion

Industry suggests the implementation of type certification for SMRs to take advantage of its modularity and to streamline the deployment of SMRs in fleets or otherwise across Canada. The FAA and the maritime industry provide a comparable approach to type certification and reproducibility. Additionally, both industries rely on non-governmental organizations for conducting key regulatory responsibilities, which have contrasting results pertinent to Canada's potential advancement into the type certification of complex and unfamiliar reactor designs.

As Canada begins regulating SMRs, industry and regulators alike raise their complexity and uncertainty as a significant challenge to their effective regulation. The FAA and maritime industry foreshadow the difficulties of administering the type certification of complex products and illustrates the need for resources and expertise to ensure their effective regulation. The CNSC have implied that they the sufficient capacity to regulate SMRs. However, the maritime industry and the FAA show that regulating mass produced complex technologies is an overwhelming task and casts doubt on whether the CNSC could ever be ready for such a task.

There are no significant challenges or impediments to the implementation of type certification within Canada's nuclear regulations. Assessment criteria of the reactor may be extricated from regulations, as done by the pre-licensing vendor design review. Reproducibility is an important phase of the type certification process and regulators must assess the quality assurance, organization and the facilities of the manufacturer to ensure that products conform to standards. Reproducibility is a significant concern for type certification of SMRs because of the high consequence events that can result. Thus, the quality assurance programs of vendors must be held to a high standard, and the documentation of quality assurance and other reproducibility claims should be proportional to the complexity of the manufacturing process.

Chapter 5: Conclusion

SMRs are characterized by their small size and modularity, which provide them with applications unavailable to conventional large nuclear power plants. SMRs provide advantages for Canada's natural resource sector, remote communities and utilities. SMRs have gained international popularity because of these advantages, and the CNSC has begun activities to ready themselves for their regulation. However, SMRs pose unique challenges for their regulation in Canada arising from the risks they pose and the familiarity of the CNSC with CANDU reactors.

The CNSC and the nuclear industry aim to regulate SMRs within Canada's existing regulatory framework. To address the variability and novel designs of SMRs, the nuclear industry and the CNSC agree that Canada's regulations require additional flexibility. Flexibility can be improved by structuring regulations to be performance-based. Performance-based regulations are predicated on regulatory requirements in the form of aspirational objectives, where the onus is placed on the proponent to demonstrate their satisfaction. Additional flexibility can be provided to Canada's regulation by the graded approach.

The graded approach encourages flexibility while ensuring the satisfaction of regulatory objectives. Regulators use grading to determine the amount of conservatism proportional to the uncertainty, complexity and novelty of the assessed activity. Grading will be indispensable for SMRs. However, most SMR designs lack operational history for which to judge the safety of the design. The challenges posed by the lack of operating history are exacerbated by the CNSC's lack of expertise with the advanced technologies common within SMR designs. The lack of expertise forces the CNSC to rely on conservatism to ensure the safety of SMRs. There is no clear solution to this issue. Though increasing the knowledge and familiarity of the CNSC with SMR technologies would be beneficial, the variability of SMR designs and innovation employed can be significant.

The uncertain risks posed by SMRs also pose significant regulatory challenges. The graded approach indicates that the greater the uncertainty, the greater amount of conservatism needed. Care must be given to ensure that conservatism is applied proprotionally. The use of risk uncertainty analysis, though already a staple in risk assessment, can be used in novel ways to ensure that the amount of conservatism being applied is proportional and ensures the confidence of the regulator's decisions.

The CNSC employs risk uncertainty analyses only as a means to indicate conservatism and fail to employ it to its full potential within risk management practices. Uncertainty analysis can assure that the amount conservatism is proportional to the risk by considering the conservatism inherent in the risk distribution itself. Additionally, uncertainty analyses can ensure that regulatory objectives are met and provide regulators confidence in their decisions. The Committee on Risk Assessment of Hazardous Air Pollutants of the National Research Council has recommended the completion of uncertainty analyses for all risk estimations including low-tier risk assessments, despite difficulties and costs.

The use of uncertainty analysis for determining whether risk assessments generate points that are too conservative, thereby exaggerating the risk of harm, is beneficial to the application of the graded approach to SMRs. The complexity, uncertainty and novelty of SMR designs will invoke high levels of conservatism, and the use of uncertainty analyses can ensure that it is not applied with overconfidence. This is economically beneficial to proponents who will already have a high cost of deployment, especially where the SMR being deployed is a first of a kind technology.

Risk uncertainty can arise from inaccurate parameters and models used to generate risks, or from gaps within risk estimates. Risk uncertainties are a significant challenge for risk-informed decision-making. However, the elicitation of expert judgement to produce risk distributions and uncertainty distribution can be used to fill risk gaps or relieve uncertainty where objective probabilistic safety assessment cannot. Elicitation of expert judgement can produce qualitative and quantitative risk assessments for new, rare, complex or poorly understood phenomena, and can include failure rates, incidence rates, or weighing factors for combining data sources. The DRDC has consolidated and reviewed methods and procedures for the preparation, training, aggregation, scoring of expert’s conduct and verification of expert judgement to produce accurate risk distributions.

This thesis reccomends the use of performance scores are used to represent the accuracy of elicited risks within the RIDM process. Performance scores are determined based on how well the performance of the elicitations meets regulatory expectations and considers the methods and procedures illustrated by the DRDC. Performance scores operate on the finding that there is a strong link between the performance of elicitations and the accuracy of the results. A strong performance score indicates greater accuracy and reliability of the elicitation. Within assessments, grading may consider the score as an indication of whether the risk is reasonable or whether precautionary steps are needed.

The *IAEA Safety Standard document Level 1 PSA* provides standards for expert elicitations that must be included within the CNSC's regulatory expectations. *REGDOC-2.4.*2 requires that proponents comply with *IAEA Safety Standard document Level 1 PSA*. *IAEA Safety Standard document Level 1 PSA* requires that the elicitation of expert judgement embody "a formal, highly structured and documented process" and provides conditions for expert elicitations. The DRDC's suggested procedures and outline fulfill to a high degree the conditions of *IAEA Safety Standard document Level 1 PSA*; however, the CNSC may wish to develop policy to ensure their compliance further.

The accuracy of expert elicitation is informed by multiple evaluative tools, such as the scoring of expert's conduct, calibration, verification, coherence, the number of experts elicited, the amount of preparation, feedback and more. Performance scores simplify the entire performance of the elicitation into a single estimate for which the CNSC can rely on for its deterministic risk assessment and RIDM. The CNSC will need to develop a regulatory document informing proponents of their expectation regarding expert elicitation. This document must illustrate in detail how performance scores are determined, the weighting each factor considered in determining the performance score is given, and how performance scores are used in the CNSC's risk assessment.

The amalgamation of the performance of an elicitation into a single score may ostensibly seem discriminatory as one poor evaluation can have a significant impact on the value of the score. However, the amalgamation will encourage proponents to ensure the quality of all aspects of the elicitation process to ensure accurate and representative results. Additionally, performance scores do not consider all aspects of the performed elicitated equally but weigh each consideration according to their impact on the accuracy of the elicitation. For example, the verification process should be heavily weighted as a failure of any of its criteria calls for a revision of the elicitated risk distribution. How the CNSC wishes to weigh these considerations is at their discretion informed by the recommendations made in this thesis and the literature on the subject.

The DRDC is a useful source for the CNSC when developing an expert elicitation policy. The DRDC aim to deliver technical solutions and advice to federal departments such as the CNSC. Accordingly, it may be constructive for the CNSC to consult with the DRDC regarding the development of regulatory expectations for expert elicitations.

Type certification is a design certification process that can help the CNSC accommodate the novel deployment strategies of SMRs. Type certification requires the assurance that the design of the SMR meets the safety requirements of the CNSC and is capable of being reproduced consistently and to the specification of the original design. type certification can be implemented as a parallel certification regime that is conducive to the overall licensing process. It may be conducted during or prior to the licensing of the SMR at the discretion of the vendor. To achieve certification, performance of the assessment of SMRs will occur according to the requirements of the normal licensing process. The CNSC already provide an optional pre-licensing vendor diagram review that can assess to a high degree the safety of reactor design. The pre-vendor diagram review provides a basis for what criteria should be considered within the certification. However, the certification process will require a more substantive assessment of the demonstrated safety of the SMR than the vendor diagram review process to be binding.

The CNSC must conduct audits of the vendor's manufacturing facilities to confirm that designs are reproducible. The U.S. aviation regulations provide an inclusive list of quality assurance criteria to consider for assuring the reproducibility of aircraft and may lend direction on the matter for the CNSC.[477] Audits of the manufacturer's facilities may also provide the CNSC with the opportunity to inspect the physical reactor and accompanying components of the SMR design in question during its manufacturing process, which becomes challenging once completed as the finished unit may obstruct access for inspectors. Without the assurance of the design's reproducibility, the CNSC cannot be sure that the deployed unit conforms to the original design or the inspected unit.

The maritime shipping industry and the FAA provide insight into how type certification may operate. Both industries approach type certification in a two-step process of assessing the design and assuring the reproducibility of the vessel. Though both industries use independent

[477] Regulations list 14 criteria to consider when auditing a manufacturers quality system, see 14 CFR § 21.137 (a)–(c) (2009).

bodies to perform assessments, they provide two different perspectives into how type certification can be employed and provide insight into how industries regulate mass produced and complex products. Due to the complexity of aircraft designs and the amount of work required in each assessment, the FAA relies heavily on the manufacturer's employees to perform assessments and other key regulatory tasks. This approach is heavily criticized because it creates a conflict of interest and the potential for regulatory capture and should be avoided by the CNSC when developing a type certification regime.

The maritime transport industry relies on classification societies to assess whether vessels conform to the specifications required by maritime shipping laws. Classification societies can remain neutral in their performance of assessments because of their independence from the shipbuilders. Additionally, the oversight and standards of the IACS help to ensure the independence of classification societies. However, the competition among classification societies can affect the quality of assessments. This competition can force classification societies to reduce their prices so that they can compete within the market. Reducing costs can affect the quality of the assessment performed.

The maritime shipping industry and the FAA rely on third-party assessments because of the complexity of the designs they review and the large amount of work each assessment entails. In the infancy of the SMR industry, it is unlikely that the CNSC will need to rely on third parties for the assessment of SMRs because the number of SMRs being deployed are manageable within the CNSC's resources. It is true that the lack of expertise of the CNSC with SMR technologies will be challenging. However, the deployment of SMRs will not occur at any great numbers incapable of being handled by the CNSC.

However, as the popularity of the technology grows it is possible that SMRs will become widespread across Canada. Proponents of SMRs assert that SMRs must become widespread to benefit from their advantages fully. In this case, assessment activities could surpass the resources of the CNSC to administer regulatory oversight. If this were to occur, the CNSC should take precaution not to follow the direction of the FAA. Instead, the CNSC should consider independent bodies capable of performing the necessary assessments. In this case, the IAEA may administer assessments, either directly through themselves or as a governing body similar to the IACS. This would be beneficial as it reduces the costs of individual regulators. Additionally, this is in line with efforts to standardize nuclear regulation internationally, creating a bigger market for proponents to deploy SMRs.

This thesis argues that SMRs can be regulated within the existing Canadian nuclear regulatory framework, in light of existing regulatory principles, and that challenges associated with that regulation can be accommodated through regulatory flexibility and by bolstering risk management approaches. Regulatory flexibility provides adaptability to Canada's regulations so that the variability and novel design of SMRs can be appropriately assessed. The improved risk management techniques and elicitations of expert judgement to generate risk distributions mitigate novel and uncertain risks commonly associated with SMRs. Finally, type certification provides an adjunct but parallel certification process to address novel deployment strategies of SMRs and mitigate the challenges of inspecting reactors caused by their modularity.

However, this thesis does not alleviate all of the regulatory challenges posed by SMRs. For one, the lack of operational history will be a significant challenge for the deployment of new SMR designs. Additionally, challenges raised by *DIS-16-04* such as the reduction of exclusionary zones, whether physical barriers are needed, the consultation with indigenous peoples, the use of automation, and the decreased number of personnel still pose challenges and will need to be dealt on a case-by-case basis. It is the hope that the suggestions made in this thesis will help regulators address these issues within the appropriate scope, detail and content according to the assessed design.

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Glossary

ALARA, as low as reasonably achievable	is an aspirational objective common among nuclear regulators within the OECD and is revealed through years of practice. It is imposed within the CNSC's *Radiation Protection Regulations* and is an important objective of their radiation protection and acceptance safety objective. ALARA is achieved not only by respecting appropriate dose limits, but also by explicit effort take measures to reduce doses beyond those limits where practical.
Aspirational objective	is a performance-based regulatory objective determined discretionally by the regulatory by considering the best practices and the performance of the proposed project. Aspirational objectives are a as a qualitative criterion revealed in practice over several years. Aspirational objectives used by the CNSC include keeping radiation exposures ALARA and the prevention of unreasonable risk.
Best-estimate method	is used within probabilistic and deterministic safety assessments to generate realistic results.
Complementary safety objectives	include the radiation protection and acceptance safety objective, the environmental protection safety objective and the technical safety objective. Complementary safety objectives are subordinate to the primary safety objective to prevent unreasonable risks.
Conservative analysis method	a method deliberately leading to results that are intended to be limiting relative to specified safety acceptance criteria.
Conservative decision making	Fundamental regulatory principle underpinning nuclear regulatory decision-making. Conservative decision-making aims to place the reactor and its facilities in a condition known to be safe or that have reasonable risks

Defence-in-depth	is a regulatory principle administered through overlapping measures to prevent and mitigate risks to design related safety and security activities. The CNSC administer defence-in-depth through five levels of differing safety objectives.
Deterministic risk assessment	may refer to the regulatory guidance provided by the CNSC in its regulatory document *Safety Analysis: Deterministic Safety Analysis* also referred to as *REGDOC-2.4.1*, or the risk assessment strategy. As a risk assessment strategy, deterministic risk assessment assesses risk on less quantifiable criteria such as political or security considerations and focuses on engineering principles such as safety measures, redundancy and diversity to prevent the consequences of an event.
Expert elicitation	Is a scientific consensus methodology to generate risk distributions or uncertainty distributions for risk events.
Fundamental principle of "control, cool and contain"	refers to the control of the reactor power, the cooling of the reactor fuel, and the containment of radioactivity using safety mechanisms and measures to achieve safety objectives. Defence-in-depth is indispensable in achieving this principle.
Graded approach	ensure the satisfaction of fundamental safety objectives in a risk-informed manner commensurate with the risk complexity and novelty of the project. The graded approach instructs that regulatory requirements be applied in accordance with the circumstances, and the likelihood and possible consequences of, and the level of risk associated with, a loss of control.
Performance-based regulation	is regulatory basis that sets out targets with the onus of the proponent to demonstrate, rather than prescriptive requirements.
Precautionary principle	is the principle that the introduction of a new product or process whose ultimate effects are disputed or unknown should be resisted or handled with precaution. There are various strengths of the precautionary principle, of which the CNSC adopt a weak one closely

	resembling the "Margin of Safety Precautionary Principle" which requires regulatory control to incorporate a margin of safety and activities to be limited below the level at which no adverse effect has been observed or predicted.
Prescriptive-based regulation	Is a regulatory basis that provides a comprehensive and detailed regime based on standards and regulations that apply equally to every applicable activity
Primary safety objective	is the primary objective of the *Nuclear Safety and Control Act.* See unreasonable risk
Probabilistic risk assessment	is a comprehensive and integrated assessment of the safety of the reactor facility. It considers the probability, progression and consequences of equipment failures or transient conditions, to derive numerical estimates that provide a consistent measure of the safety of the reactor facility.
Process-based regulation	is a regulatory basis that hinges safe operation of the nuclear power plant on effective organizational processes of the licensee for the operation, maintenance, modification and improvement of the facility.
Proportionality principle	is the principle that requires measures carried out by conservative decision-making to be inversely proportional to the level of understanding of risk and safety.
Reproducibility principle	is the assurance that the vendor or manufacturer can and does produce products that are consistent with the original design.
RIDM, Risk-informed decision-making	is a deliberative process that measures risk against a set of performance or safety objectives, along with other considerations, to inform decisions.
Risk distribution	is a probabilistic distribution that provides the probabilities of occurrence of different outcomes of a risk event.
Safety by design	is the prevention of harm through design. Achievement of safety by design occurs at early stages of design to minimize hazards.

Type approval	See type certification
Type certification	is the process of certifying a design and approving its manufacturing process such that productions of that design are assured to meet regulatory requirements without further proof.
Uncertainty analysis	is the process of identifying and characterizing the sources of uncertainty in an analysis, evaluating their impact on the analysis results, and developing, to the extent practicable, a quantitative measure of this impact.
Unreasonable risk	is a primary objective of the *Nuclear Safety Control Act*.