



May 29, 2015

Brian Torrie
Director General
Regulation Policy Directorate
Canadian Nuclear Safety Commission
280 Slater Street
Ottawa, ON
K1P 5S9

Canadian Nuclear Association Comments on DIS-14-02, Modernizing the CNSC's Regulations

The purpose of this letter is to provide feedback, as requested, on CNSC Discussion Paper DIS-14-02, Modernizing the CNSC's Regulations [1]. We are also going to provide comments concerning Regulatory Documents that the CNSC publishes as well as comments on the process on how these documents are developed.

The Canadian Nuclear Association (CNA) has approximately 100 member companies, representing over 60,000 Canadians employed directly, or indirectly, in exploring and mining uranium, generating electricity, and advancing nuclear medicine. We represent the full spectrum of nuclear technologies that mean quality of life for Canadians, from medical imaging for faster diagnosis, to more efficient and less invasive therapies, to sterilizing pharmaceuticals and food and medical supplies, to testing the sophisticated materials that underlie all advanced manufacturing, to generating affordable power without greenhouse gases, to mining uranium, to safely transporting and decommissioning the materials we use.

This letter is to express the CNA members concerns with the current regulatory environment. Simply stated, our members feel that the distinction between CNSC Regulations and Regulatory Documents (RegDocs) has become blurred. Whereas it is our belief that Regulatory Documents should be concise documents that clarify how Regulations are to be met; increasingly they form a mode of regulation in and of themselves. When a RegDoc is referenced in a Licence Condition Handbook it effectively carries the rule of a regulation. But yet the RegDoc has not undergone the same development and review process that is required of a regulation.

In general, our members' experience is that the system is too complex with too many different kinds of regulatory instruments. Our members do not find clear links to the governing regulations because of the development process for Regulatory Documents that maps them to the CNSC's internal Safety and Control Areas. The Regulatory Documents themselves often suffer from a lack of clarity in their presentation. It is difficult for our members to determine what elements are new requirements and what is restating existing CNSC practice.



We wish to highlight that our concerns stem from the overlap between various regulations and Reg Docs. As such our letter will address both, and in addition will speak to CSA Standards where appropriate.

The Response to Industry Comments by the CNSC President

Several of the themes and concerns articulated in this letter have previously been communicated directly from a number of our members to the President of the CNSC. I have chosen to include them in this letter to reinforce that they are items of strong and on-going concern for our members. In addition, these concerns extend beyond the power generation sector from which the earlier correspondence arose. Indeed, the issue of providing a clear and transparent regulatory environment, without undue punitive rules for the nuclear sector, is of concern to all of our members regardless of their business focus.

President Binder has responded to similar industry comments [2]. The CNA was pleased to see that the use of a Regulatory Impact Analysis Statement (RIAS) -like statement will be explored by CNSC staff. The CNA and its members urge the adoption of a RIAS, or effective equivalent, as a standard component of Regulatory Documents. This is discussed further later in this letter.

Given the manner in which Regulatory Documents are being referenced in operator's licences, the Reg-Doc has increasingly become a *de facto* form of regulation. As such it is imperative that all RegDoc be given the same level of scrutiny as a Regulation. This includes a complete cost-benefit analysis and adherence to the governments "one-for-one" policy.

The CNA feels that an accurate cost-benefit analysis is an important component of any new regulatory instrument; whether Regulation or RegDoc.

The comments [2] outlining the updating and replacement of earlier document series (the old R-, S-, P-documents, etc) are acknowledged by the CNA. However, our members still find that considerable overlap exists between various Regulations, RegDocs and CSA standards. Having duplication of requirements does not always appear to be in keeping with the spirit of the governments Red Tape Reduction strategy. Our members believe that that purpose of RegDocs and CSA Standards should be to clarify how Regulations are met, not duplicate or introduce requirements. We would also like to point out that where an appropriate Standard exists, it would be simpler if a Regulatory Document were to only reference the Standard rather than attempt to duplicate it.

The Need for Regulatory Impact Analysis Statements

The CNA recognizes the effort put forward by CNSC staff to bring clarity and predictability to issuing new RegDocs by publishing a forward looking regulatory development plan [3]. We note, however, that while several Regulations have been amended, the majority of changes, or introduction of new requirements, occur at the level of RegDocs or Guidance Documents. The experience of some of our members has been that an increasing number of these RegDocs are being incorporated either directly into their Licence or into their Licence Condition Handbook. A member has reported that they have experienced a 10-fold increase in the number of RegDocs incorporated into their licence over the previous decade.



The introduction of new regulatory requirements often causes increased operating expenses and resource demands for our members. The specific costs of implementation are issue and member specific; however, the increased burden generally will fall into one of three broad categories:

1. A one-time cost to establish a new or upgraded capacity or capability that is required by the document.
2. On-going costs required to maintain this capability in perpetuity into the future.
3. Overhead costs associated with implementing the new requirement within the member's management system; ongoing compliance; control changes; monitoring performance; reporting on results; and supporting CNSC staff with inquiries and inspections.

The Government of Canada, through the Treasury Board Secretariat, has provided guidance [4] to departments and agencies to better understand the regulatory impact analysis requirements of the *Cabinet Directive on Streamlining Regulation* [5] and to improve the quality of regulatory impact analysis statements (RIAS) prepared in support of their regulatory proposals. In the guidance document [4] the Treasury Board states that a Regulatory Impact Analysis Statement (RIAS) "describes what the government will deliver, benefits and costs of the proposal, the consultation that has taken place, and opinions expressed during that consultation." The RIAS should address [4]:

1. Potential impacts of the regulation on health, safety, security, the environment, and the social and economic well-being of Canadians;
2. Costs or savings to government, businesses, or Canadians and the potential impact on the Canadian economy and its international competitiveness;
3. Potential impacts on other federal departments and agencies, provincial or territorial governments in Canada, or on Canada's foreign affairs; and
4. Degree of interest, contention, and support among affected parties and Canadians.

The RIAS is, in effect, a public accounting of the need for each regulation [4, 6]. The CNA has noted that, recently, RegDocs are becoming increasingly prescriptive in nature. Instead of simply clarifying and providing guidance on existing requirements, Reg-Doc's now being issued by CNSC staff include new requirements and overly prescriptive discussions concerning how the requirements are to be met. This inherently limits the licensee's ability to determine the most appropriate manner to meet the requirements. In so doing, the CNSC may in fact inhibit the licensee from adopting a more cost-effective solution.

Obtaining Licensee and Other Stakeholder Views in Advance of Drafting Regulatory Documents

Only in infrequent instances are operator and other stakeholders views solicited prior to the writing and release of a draft RegDoc. Yet it is this time, before views and requirements are formalized, when discussion is most important for the CNA's members. We recognize that a small number of workshops have been held in consultation with interested stakeholders. However such workshops are the exception and not the rule when developing new regulatory instruments. In addition, many of these workshops with interested stakeholders are held late in the process. Workshops held in the early stages of the RegDoc production are far more effective. Issuing a RegDoc in draft format and soliciting public feedback is not the most effective way of discussing alternative solutions. By the time a RegDoc is released for public review the content is fixed with extremely limited scope for alteration; especially where it involves systemic issues considering a new proposed rule. Engagement with stakeholders earlier in the process would allow for a more efficient, and more meaningful, consultative process.



What is the New Regulatory Document Addressing?

When reviewing new RegDocs, it is often unclear what need, or what gap in oversight, is being addressed by the proposed document. All CNSC documents would benefit by the inclusion of a specific section detailing: a) the gap that is to be addressed by the document, and b) a description of what is new in a document if it is designed to replace an existing document. The expected benefits of a new document should be highlighted along with potential alternatives that would include taking no new regulatory action.

Comments on Discussion Paper DIS-14-02

In addition to the general comments above, the CNA would like to provide the following comments and information to CNSC staff concerning the questions posed in Discussion Paper 14-02, *Modernizing the CNSC's Regulations* [1].

1. *"Could the CNSC's regulations be changed to make them more efficient and effective in ensuring protection of the health, safety, security and the environment? How?"*

Yes, the CNSC regulations can be changed or adjusted to be more efficient and effective in ensuring the health, safety, security and the environment or for workers and the public. Regulations do not recognize the widely varying conditions, or capabilities between licensees, resulting in requirements that can be confusing or difficult to apply in some cases. Regulations should explicitly provide for flexibility of implementation between different licensees, even within the same class of licence.

Improved consistency between the *General Nuclear Safety and Control Regulations* and other regulations would improve the licence application process for organizations holding multiple licences.

2. *"Is the CNSC striking the right balance between performance-based regulation and prescriptive requirements? Are there specific regulatory requirements that do not seem to have the correct approach?"*

Industry is supportive of a performance-based approach that allows licensees to demonstrate how they meet health, safety, security and environmental objectives. Our members find that there are instances, however, where the regulations are too prescriptive, or are prescriptive in a manner that does not benefit health, safety, security or the environment.

We acknowledge the need for prescriptive requirements or hard limits under certain circumstances. However, where a specific requirement is necessary, regulations should be developed or amended, and where objectives are appropriate, guidance should be provided in the form of a RegDoc.

3. *"Are you aware of opportunities for the CNSC to reduce administrative burden, without compromising safety?"*

A key consideration in achieving the right balance between performance-based regulation and prescriptive requirements is the avoidance of duplication. Where prescriptive requirements already exist in other jurisdictions, equivalency and authorizing regulations should be pursued, as opposed to new regulatory requirements or duplicating regulatory requirements.

Reducing duplication would also reduce the administrative burden introduced by overlaps with other jurisdictions, such as with the Ministry of the Environment, Fisheries and Oceans Canada, the Ministry of Labour, Employment and Social Development Canada, without compromising safety. Where there are appropriate provincial or federal requirements in place, the CNSC should accept those regulations as equivalent, rather than duplicating the requirements.

Along these same lines, industry would see a benefit to improving the consistency of approach among the various CNSC licensing divisions. This could be taken a step further by allowing for the consolidation of multiple licences that a single organization holds.

4. *“Is the CNSC making effective use of existing standards? Are there additional opportunities for the CNSC to reference standards in its regulations?”*

Referencing standards such as IAEA Standards in Regulations may be appropriate in some cases. However, caution must be applied. Regulations are very time consuming to revise, and thus may not be appropriate whereas codes and standards, which may be updated more frequently are a potentially better avenue.

Standards such as CSA standards are readily included in licences (or Licence Conditions Handbooks). As new standards are introduced or updated, the licence / LCH process is flexible enough to capture changes.

Although the CNSC has improved in the referencing of other standards in lower tier documents such as CNSC RegDocs or licences / LCHs, there is still a tendency to repeat those requirements. It would be much more efficient to reference the appropriate standard, and then identify within the CNSC RegDoc or licence only the differences in requirements that must be applied.

5. *“Is the relationship between the CNSC regulations and the obligations set forth in licences clear and straightforward? Would it be clearer to prescribe some standard licence conditions in regulations rather than in licences? If so, which ones?”*

It would not be beneficial to prescribe more standard licence conditions in the Regulations as they are currently already repeated in the licences. Instead, industry sees many opportunities to streamline the Class 1 Nuclear Facility Operating Licences and to provide greater clarity in the associated Licence Condition Handbooks.

Furthermore, the inclusion of more licence conditions in Regulations would be problematic because it would be much more difficult and time consuming to make necessary changes to Regulations than the licence / LCH. This would inhibit change and introduction of learning. It would also not allow for any flexibility for different licensees. Licence conditions for large corporations with multiple licence types may be different from those of smaller licensees, but embedding conditions in the Regulations removes flexibility from staff and licensee, potentially forcing more administrative burden on one or the other.

In this regard, the *Nuclear Security Regulations* as well as a number of related federal regulations continue to be out of step with the expected operating security regime for nuclear power plant security. Industry suggests that a workshop be set up to discuss the changes required in the *Nuclear Security Regulations*, to ensure these gaps are properly addressed.



6. *“Are there opportunities where the CNSC can provide greater assistance to applicants and licensees (to) understand what they must do to comply with the CNSC’s regulatory requirements?”*

The industry has previously expressed concerns with the regulatory framework process for deciding on the creation of and revision to RegDocs, CSA standards, or changes to regulations. We would advocate for a more robust process to include:

- a) Engagement with the industry and other stakeholders for determining the need for a RegDoc, CSA standard or changes to regulations,
- b) A cost-benefit analysis to support new requirements in RegDocs, CSA standards or changes to regulations, and
- c) Initial engagement of industry subject matter experts and other stakeholders as a part of fact finding support for new or revised RegDocs, CSA standards or changes to regulations.

The CNA, and its members, would like to suggest that the regulatory process have a forum to discuss possible interpretations to clarify new requirements and what exactly the change will look like. Having an end goal and consistent approach among the industry will permit better change management and further dialogue on feasibility.

The industry would appreciate more proactive discussions on the development of exactly what changes would be made to existing regulations, and on the development of new regulatory documents. There has been a significant increase in the development of regulatory requirements. The CNA feels the need for better balancing of new regulatory requirements and reduction of regulatory burden in other areas.

We thank you for your consideration of this matter. If you or your staff requires further clarification on any of the above information, please do not hesitate to contact me at 613-237-4262.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Peter Poruks', with a horizontal line underneath.

Dr. Peter Poruks
Manager of Regulatory Affairs
Canadian Nuclear Association

Cc.

Dr. John Barrett, President, Canadian Nuclear Association

References

- [1] Canadian Nuclear Safety Commission, *Modernizing the CNSC's Regulations*, DIS-14-02, 2014 November.
- [2] M. Binder, Letter to F. Saunders, L. Swami and S. Granville, 2014 December 16.
- [3] Canadian Nuclear Safety Commission, *Forward Regulatory Plan 2014-16*, retrieved from <http://nuclearsafety.gc.ca/eng/acts-and-regulations/regulatoryplan/forward-regulatory-plan-details/index.cfm>.
- [4] Treasury Board of Canada Secretariat, *RIAS Writer's Guide 2009*, BT53-16/2009E-PDF, 2009.
- [5] Treasury Board of Canada Secretariat, *Cabinet Directive on Streamlining Regulation*, BT22-110/2007, 2007.
- [6] Privy Council Office, *Guide to Making Federal Acts and Regulations*, 2nd edition, page 181, 2001.