

September 26, 2016

Canadian Nuclear Safety Commission P.O. Box 1046, Station B 280 Slater Street Ottawa, Ontario K1P 5S9

Re: Nordion Comments on Discussion Paper DIS-16-02

Nordion wishes to thank the CNSC for this the opportunity to comment on the proposal to consolidate a number of guidance documents into two new documents. We have reviewed CNSC's proposal and have a number of comments and suggestions which we have attached.

In general, consolidation of a number of stand-alone documents can provide better clarity to licensees. However, there is concern that the scope of the two new documents may be too broad and runs the risk of resulting in difficult and cumbersome documents. In addition, it is not clear what new requirements may result from this proposed work. Nordion currently has a robust radiation safety program and is concerned that the addition of new requirements would only provide addition restrictions on Nordion's procedures, create a significant financial and administrative impact to Nordion, and it would do so without any added benefit to the safety of people or the environment.

We look forward to further discussion with the CNSC on this proposal.

Sincerely,

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Nordion's Comment on DIS-16-02

Nordion has reviewed DIS-16-02 and has a number of comments and suggestions. We have formatted our comments and suggestions based on the DIS-16-02 section headings.

Section 3.2

Comments on the CNSC's assessment of each existing documentation for inclusion in the regulatory documents and the proposed updates:

G-91 – Nordion has no specific comments. As a general practice and due to the nature and scope of work, Nordion directly measures all employees with access to the active areas, so further clarification is not needed. However, Nordion can understand that there could be a number of licensees where further clarification of direct vs indirect dose assessments and the need for the use of licensed dosimetry services would be helpful.

G-121 – An update of this document, if for no other reason but to remove reference to the AECB, would be worthwhile.

G-129 – The use of dose constraints was discussed in DIS-13-01. The "What We Heard" report for DIS-13-01 states, "*There was also general support of CNSC's position that introducing a requirement for dose constraints is unnecessary at this time,…*". Based on this, it is unclear the reasoning for the proposal to add guidance in the use of dose constraints to G-129.

In addition, Section 6 of G-129 states, "*Licensees are expected to reduce doses where this can be done without significant expenditures.*". Section 7.4.1 states "*For work projects in areas where the existing or potential radiation hazards may result in workers accumulating significant doses, …*". The terms "significant expenditures" and "significant doses" are ambiguous. What does the CNSC consider significant? Clarification should be given, based on a graded approach that allows the licensee to propose level of significance based on what is most reasonable for the given situation.

G-147 – Nordion has no comments with respect to this document. The document provides a very high level response to abnormal radionuclides update. It is not clear what further guidance the CNSC believe could be added.

GD-150 – The CNSC seems to be proposing that GD-150 be updated to reflect current international recommendations. Although aligning CNSC requirements with the international standards is typically a good idea, it is not clear what changes this will entail. Nordion would need to see the proposed changes before comment on them. As well, it is not clear whether these changes would remain as guidance or become requirements of licensees. Nordion, along with many other licensees, have robust bioassay programs that have been approved by the CNSC. Any changes to GD-150 should not impose further requirements on licensees that currently have robust and accurate bioassay programs.

G-228 – This document provides a clear overview of action levels and their role. It is not clear what further improvement on the concept of action levels the CNSC is proposing. Further guidance on the development of meaningful action levels would be welcome. However, such



guidance must not further restrict licensees. Currently, there seems to be a push to continue to decrease action levels as licensees implement improved ALARA programs. However, this adds significant burden on licensees to continue to implement even stronger ALARA programs to prevent from hitting ever increasingly restrictive action levels. Such undue hardships may not be warranted given the low doses regime many licensees appear to be operating in.

RD-58 – This document currently provides a good technical review for thyroid screening program. Again, alignment with international standards is often welcomed. However, Nordion would need to understand the proposed changes before being able to make specific comments.

S-260 – Improvements to this document to include changes not currently covered would be helpful.

Section 3.3

Nordion does not believe further guidance is needed. There is currently a wealth of information and standards (ANSI, ICRP, etc) that are used with respect to many of the topics listed. Where possible, the CNSC should look at referencing external standards where doing so provides added benefit.

Section 4.1

It is not clear from the discussion paper, but based on our reading, the CNSC is planning on consolidating the information from the various documents listed into two new documents on Radiation Protection and Dosimetry, thus obsoleting the old documents? This should be clarified.

This is significant content that is being consolidated. Although this reduces the number of CNSC documents a licensee must keep track of, it has the potential to create a long, difficult, and cumbersome document that is less helpful to the licensee. This is seen in the proposed table of contents listed in the appendices of the discussion paper. Although the table of contents seem to logically layout the material, they are quite lengthy. There will be a significant administrative burden for licensees to review any new documents. A gap analysis will likely be needed if such documents are to be listed on our license or otherwise applied. A significant implementation time frame will be needed.

Section 4.2

Guidance on the new requirements stemming from the amendments to the *Radiation Protection Regulations* would be welcomed.

However, it is not clear to as to the requirement for additional guidance on a number of the other topics. Content such as radiological hazard control, dose control devices, radiation work planning, etc is very facility specific. It is not clear how the CNSC could provide guidance in a single document for all licensees.



Section 5.1 and 6

It is important for licensees to understand any new requirements vs guidance that will result for this exercise. It is not clear at this point what the potential impact to Nordion will be without further assessment of the specifics of the content of the two new documents.

Many of the documents being consolidated are guidance documents. It is important that the guidance currently provided in these documents does not change into requirements in the new, consolidated documents.

As previously discussed, the CNSC is proposing to consolidate a number of documents into two new documents, with the inclusion of new material. Although these documents may provide better long-term clarity and guidance to licensees, there will be a significant administrative burden to review the documents and ensure compliance. Nordion's current procedures and practices will need to be assessed in light of the proposed documents, likely through a gap analysis. The CNSC should consider a long implementation period, similar to that undertaken with the implementation of RegDoc-2.12.3, to ensure licensees have sufficient time to review and implement the requirements of the new documentation.

Nordion does not feel that the benefit of the proposed consolidation work matches the administrative and financial impact expected to result from implementation of the changes. Current CNSC guidance documents have provided sufficient guidance to enable Nordion to implement a robust radiation protection program that has ensure the safety and security of people and the environment.