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Subject: REGDOC 2.7.2, *Dosimetry, Volume II: Technical and Management System Requirements for Dosimetry Services*

Thank you for the opportunity to provide comment and feedback on the draft version of REGDOC 2.7.2, Volume II, published in April 2018.

As a holder of a dosimetry service licence, SRBT anticipates that REGDOC 2.7.2 will impact our activities, once published and referenced in our licence.

As such, SRBT is pleased to provide the following comments on the draft document, which are limited to the applicable parts of the document that affect our activities.

Section 4: Technical Requirements – Dosimetry Services for Internal Radiation

- Comment 1: Maximum quantities for independent testing (Section 4.1)

For tritium urinalysis performance testing (TUPT) conducted each year, typically, three blind spiked sample sets are provided to dosimetry service providers by Health Canada, with some spiked samples routinely in excess of 40,000 Bq/L. For example, the 2017 'high' sample spike was certified as 2,505,000 Bq/L, and the 'medium' sample spike as 45,850 Bq/L.

These activity concentrations exceed 20 times the minimum testing level identified in Table 4 (for tritium, 2,000 Bq/L). The draft REGDOC establishes a maximum concentration permitted for independent testing that would not be complied with if current testing practices were to continue. The samples provided by Health Canada would need to be restricted to less 20 times the minimum testing level (i.e. equal to or less than 40,000 Bq/L) in order to meet the REGDOC requirements.

Precision and accuracy at higher concentrations of uptake is an important consideration for any radionuclide. What is the regulatory goal in restricting the maximum concentration of radionuclide incorporated in an independent test?

- Comment 2: Use of RMSE as specification (Section 4.2)

Currently, S-106 defines a successful test in terms of the results obtained when calculating mean relative bias and relative precision values from the set of data obtained. REGDOC 2.7.2 would seemingly eliminate this method of evaluating the data in favour of a combined statistical approach.

It would be helpful if the technical rationale for this approach were discussed – why is this method of data analysis expected to improve upon the current method?

- Comment 3: Definitions of statistical terms (Section 4.2, Glossary)

In S-106, the calculations implemented to determine 'B' and 'S_B' are explicitly laid out in the Glossary. Neither is addressed in REGDOC 2.7.2, and only the bias ('B') is described in the text, while 'S_B' is undefined. These terms would benefit from at least the same treatment in REGDOC 2.7.2 as in S-106 for ease of use and clarity for the reader.

- Comment 4: CNSC approval of method to ascertain dose (Section 4.7)

It is appreciated that there are likely numerous methods of calculating dose for the range of internally deposited radionuclides that workers may be exposed to; however, some guidance on the approval process to be implemented by CNSC would be helpful. For example, an in-line reference to any technical standards or guidance that would be used to evaluate and approve a submitted method for determining dose would ensure transparency.

It is also noteworthy that, of the eighteen references included in the draft version of REGDOC 2.7.2, the vast majority appear to deal either with the measurement of external radiation exposure, or with statistical analysis. There does not appear to be any references to technical information focused on internally deposited radionuclides, and the derivation of dose from this exposure route.

Section 7: Management System Requirements

- Comment 5: Opportunity for alignment with CSA Standard N286-12

Most of the content included in Section 7 is based upon the requirements established in S-106, with some minor alterations. Considering the advancement of management system requirements in other areas that are, for the most part, quite aligned with the spirit of what is laid out in S-106, the publication of REGDOC 2.7.2 offers an opportunity to further align and harmonize terminology and guidance in this area.

Class I nuclear facilities such as SRBT are typically required to implement a management system which complies with CSA Standard N286-12. Although it is appreciated that dosimetry service providers may not be required to comply with this standard, requiring explicit treatment of expectations within REGDOC 2.7.2, having two different sets of expectations for key elements in both systems can be cumbersome and confusing, despite similarities.

The more alike the management system elements are between N286-12 and REGDOC 2.7.2, the better it will be, especially for those licensees that hold both dosimetry service and nuclear facility operating licences.

- Comment 6: Procurement (Section 7.6)

Where dosimetry services represent a subordinate component of a larger operating organization, requiring procurement procedures to be 'established by the dosimetry service' can introduce confusion where procurement processes are already in place and comply with standards focused on ensuring nuclear safety and quality.

The text (which remains unchanged from S-106) should be altered to ensure that procedures for procurement of equipment and material need not necessarily have been established by the dosimetry service, but must include input from licensee experts in this area (i.e. dosimetry service technical specialists and management).

The addition of a requirement to maintain a supplier/vendor list is acknowledged as being in line with best practices.

- Comment 7: Records (Section 7.14)

The 'relevant applicable legislation' referenced in subclause 7 could be specified to avoid ambiguity and ensure a clear understanding of the regulatory expectations in this area.

- Comment 8: Audits (Section 7.15)

The requirement to audit 'the entire quality program' annually is not clear – what is intended by the use of this terminology? What exactly is meant by the 'entire' program? For example, if an audit did not cover procurement one year, would this be out of compliance with the requirements of section 7.15?

As well, the reference for CAN/CSA-ISO 19011:03 is out of date, as the most recent version of this standard was first published in 2012, and was reaffirmed in 2017.

- Comment 9: Section designations

Several of the section references are incorrect throughout section 7 of the draft REGDOC.

In conclusion, SRBT appreciates the opportunity to provide comments on this draft REGDOC, and hopes that our feedback assists in the development of regulatory requirements and guidance in the area radiation protection and dosimetry.

Should further information be required please do not hesitate to contact me directly.

Sincerely,

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