Industry Comments on draft REGDOC-2.7.2, Dosimetry, Volume II: Technical and Management System Requirements for Dosimetry Services

	Document/ Excerpt of Section	Industry Issue	Suggested Change (*if applicable*)	Major Comment/ *Request for Clarification*	Impact on Industry, ***if major comment***
1.	**2.5.1**	Although Section 2.5.1 states that routine performance tests should be conducted monthly for bi-weekly issue periods, performance tests currently conducted every 13 weeks by some licensees are effective and typically accepted by the CNSC.	Specify that a different frequency can be approved by the CNSC, as per Section 1.3, item 2. Alternatively, remove the requirement for bi-weekly return of a licensed dosimeter for radiographers as identified in Nuclear Substance and Radiation Devices Regulations 31.(2).	**Major Comment**	Without the option for a different frequency, licensees face a significant increase in burden to comply with monthly tests with no corresponding increase in safety. This is especially true for licensees where bi-weekly badge issue is done for a small subset of workers (i.e. Radiographers) and quarterly issue is done for the large majority of other workers. Request for amendment to licence required if different frequency needs to be defined in the licence.
2.	**2.5.2**	Industry seeks clarification as to why the draft REGDOC refers to special performance testing "every five years" in the first paragraph? All testing done to meet requirements beyond this section are more frequent and demonstrate any performance decline.	Industry recommends leaving the wording as, "on occasion."	*Request for Clarification*	
3.	**2.5.2**	Industry seeks clarification as to why this draft uses the phrase, "original type tests" in the first paragraph? Licensees believe it is better to refer to the most recent CNSC-approved type test, not the original test.	Amend to say, "… remains consistent with the results of the most recent-CNSC-approved type test ~~the original type tests~~."	*Request for Clarification*	

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4.	**3.2**	There is an incorrect reference beneath Table 3 which says the requirement for an annual independent test may be combined with the requirement described in Section 2.7. There is no Section 2.7.	Correction needed to reference for Table 3.	*Request for Clarification*	
5.	**4.1 Table 4**	Plutonium (TIMS[f]). The rest of Table 4 refers to isotopes and this refers to a test.	Industry recommends the CNSC remove TIMS and the associated test level specific for TIMS and add a line following Table 4 stating, "Licensees may be tested at a level less than the MTL after consultation between the CNSC, the test provider and the licensee to ensure an appropriate level has been selected."	**Major Comment**	CNL is likely the only provider, which would allow for the use of a CNSC and CNL agreed-upon level. The established MTLs are specific to the analyte and not to the test method. This establishes a precedent that more sensitive test methods (like TIMS) should be expected to demonstrate better performance during independent testing, instead of allowing the licensee to demonstrate superior performance to less-sensitive test protocols for the same test radionuclide. This is not done for other analytes with different test methods (e.g. uranium). Test providers will encounter difficulties in providing reliable spiked samples at such low levels (near the proposed MTL). The recommended additional line allows for flexibility to test closer to the actual performance level of the test without setting a defined parameter that may be unnecessarily difficult to achieve.

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6.	**4.1 Table 4**	Plutonium (TIMS[f])	Remove footnote	*Request for Clarification*	
7.	**4.1 Table 4**	0.02 pg/L Minimum testing level should not be pre-defined and expected to meet existing statistical parameters	Remove 0.02 pg/L. Suggest using, "to be determined by service provider in consultation with CNSC."	*Request for Clarification*	
8.	**4.1 Table 4**	MTL for natural uranium in lung at 10 mg The new limit is too low when the independent test provider (Health Canada) applies the test with thicker lung overlays.	Change back to 20 mg.	**Major Comment**	Industry will not be able to meet the proposed new requirements.
9.	**4.2 and 4.5**	The terms B and SB are not defined in the text or Glossary of this draft or in REGDOC-3.6. The definition of these terms is required for clear performance testing criteria.	For definitions not found in REGDOC 3.6, use the corresponding definitions in S106 Rev 1 Glossary.	**Major Comment**	The use of non-defined terms has the potential for non-compliance to REGDOC 2.7.2 expectations for performance testing.
10.	**4.5**	As currently written, in vivo accuracy and precision specifications RMSE are such that the root mean squared error (RMSE) of B and SB must be less than or equal to 0.25, as follows: RMSE= ... ≤0.25	Industry requests clarification on the calculation. Does the accuracy and precision calculation apply to individual radionuclides, per instrument, etc.? How is Health Canada applying this calculation? Expectations on application of the calculation to independent testing need to be made more clear. If the limits are expected only to apply to the suite of tests and not to individual tests (which may include "challenge" tests as described in the Impact on Industry section), this needs to be stated in the document, along with associated limitations on the number of "challenge" tests which may be assigned in the	**Major Comment**	Very unlikely to meet for all isotopes (e.g. in vitro tests with interferences added, lung counting, whole body counting with activity in lung only, whole body counting of 95th percentile male). If the limit on RMSE of 0.25 was applied to these "challenge" tests, licensees would be unable to meet the new limits for independent testing.

			performance testing. Otherwise, allowing some additional margin on the precision for these tests and leaving the bias at 0.25 would be warranted.		
11.	**4.5**	There is an incorrect use of terms in the third sentence.	Correct third sentence to read, "The in vivo …" instead of "~~The in vitro …~~"	*Request for Clarification*	
12.	**4.6**	The document still requires the use of physical phantoms. Licensees believe the CNSC should consider the use of virtual phantoms as an option for all energy ranges.	Consider adding the use of computed phantoms as an option	*Request for Clarification*	
13.	**7**	There is duplication of management system requirements within draft REGDOC-2.7.2, Section 7. Licensees who already comply with a mature management system, for example N286-12, meet the intent of management system requirements outlined in Section 7 of REGDOC-2.7.2. Introducing a separate set of management system requirements appears to be contrary to the industry direction towards an integrated management system, which integrates all components/processes of a business into one coherent system to enable achievement of purpose and mission. Specifically, for facilities which already have management system compliance requirements linked to the implementation of CSA N286 in their Licence or Licence Condition Handbooks, these separate requirements do not appear to be fully	For future drafts of this REGDOC, industry recommends the CNSC: 1. Revise Section 7 from "Management System Requirements" to "Guidance for establishing a Management System" 2. Remove "Management System Requirements" from the title of REGDOC-2.7.2 3. Ensure Section 7 is reworded to remove "shall" statements that imply a requirement.	**Major Comment**	Duplication of management system direction with potential for confusion and inconsistency within organizations.

		aligned with the N286 requirements. For example, there is no mention of the management system principles, nuclear safety culture or the application of a graded approach within the management system requirements in REGDOC-2.7.2, Section 7. To eliminate potential conflicts and confusion in compliance, it is suggested that REGDOC-2.7.2, Section 7 be reworded as guidance and suggested framework for licensees who do not already comply with a mature management system such as N286-12. This would be aligned with the scope of REGDOC-2.1.1, which states that dosimetry services licensees do not have a management system as a condition of their CNSC licence, but may consult REGDOC-2.1.1 for information on management system.			
14.	**7.3**	Industry believes any additional requirements for the dosimetry licence not already captured as part of CSA N286 should be stated specifically outside the management system requirements. (e.g. requirement to perform annual self-assessment on dosimetry service). N286-12, clause *4.11.2 Self-Assessment* states that, *"management shall conduct self assessments to identify opportunities for continual improvement and to confirm that work meets the*	Move section 7.3 out of the Management System Requirements section into its own section, for example, "<u>8.0 Requirements for review and self-assessments</u>"	**Major Comment**	Explicit statements of requirements outside of CSA N286 will clarify expectations.

		requirements of the management system". However, if there is a specific annual frequency requirement within the Dosimetry license for conducting self-assessments, this should be stated explicitly.			
15.	**7.8**	Licensees request clarity regarding the standing of CNSC regulatory standard S-260. Although more information on how to request the CNSC to change dose records is being developed in *REGDOC-2.7.2, Volume I, Ascertaining Occupational Exposure*, it is not yet published. The current version (S-106) says, "To request the CNSC to change dose records, users of dosimetry services follow the requirements of CNSC regulatory standard S-260."	It is recommended that clarification be provided stating that S-260 be followed for guidance on changes to dose records until REGDOC-2.7.2 Volume I is published.	*Request for Clarification*	
16.	**A.3.2**	Formula is incorrect	(u/R) should be squared not cubed	**Major Comment**	Incorrect formula. Current wording inaccurate
17.	**A.3.2**	Inaccurate reference: "The mean response, *R,* is defined…", the letter R should read $\bar{R}$	Change: "The mean response, *R,* is defined…" To: "The mean response, $\bar{R}$ is defined…"	**Major Comment**	Incorrect formula. Current wording inaccurate
18.	**A.4.4 formulae (2A) and (8A)**	*R= 1* r D* r E*θ ** r H rT* (2A) u2= 12* r2D* r2Eθ * rH2 rT2 - (R)2 (8A)	Consider changing multiplication symbol from *, for consistency with other formulas.	*Request for Clarification*	
19.	**B.6**	"…Hp(0.07) and He."	Consider changing to subscript for Hp and He, consistency for example (Kr) versus Kr, etc. for consistency	*Request for Clarification*	
20.	**D.3**	90.0 mGy	Change to 90 mGy. What is the purpose for extra significant digit? It is inconsistent with other examples	*Request for Clarification*	

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21.	**E.2 and E.3**	Americium-241-Beryllium	Consider changing to AmBe to be consistent with other examples in the document and commonly used terminology	*Request for Clarification*	
22.	**E.2 and E.3**	Incorrect reference: "In order to pass this test, reported results shall lie within the criteria described in section 2.7, Requirements for routine neutron dosimetry services." Section 2.7 does not exist.	Correct/clarify reference.	*Request for Clarification*	
23.	**G.2**	Incorrect reference: "Table 9, section 5.6, Accuracy specifications of radon gas" does not exist	Clarify reference to table	*Request for Clarification*	
24.	**I.3.2**	…to the NDR by indicating the radionuclide…	Remove reference to the radionuclide. The dosimetry service providers submit doses consistent with categorization and details expected by the National Dose Registry. Additional levels of detail are maintained by the service provider within in-house reports, which can be quite detailed and are retained to ensure the necessary information is available should it be requested. These reports may include details such as an array of isotopes that by separately reporting dose contributions, would not add value to the NDR reports.	*Request for Clarification*	
25.	**2.1.2, Appendix A (A.3), and Reference #2**	This draft REGDOC refers to "the ICRP" in section 2.1.2 and ICRP 60 in Appendix A (A.3), which is inconsistent with reference #2 on page 57.	Change the reference to ICRP 60 throughout the document instead of ICRP 103. ICRP 60 is the current ICRP that the CSNC enforces	**Major Comment**	Align with current requirements and clarify compliance references.

Bruce Power

July 31, 2018

NK21-CORR-00531-14592
NK29-CORR-00531-15279
NK37-CORR-00531-03034

Mr. B. Torrie
Director General, Regulatory Policy Directorate
Canadian Nuclear Safety Commission
P.O. Box 1046
280 Slater Street
Ottawa, Ontario
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Dear Mr. Torrie:

Bruce Power comments on draft REGDOC-2.7.2, Dosimetry, Volume II:
Technical and Management System Requirements for Dosimetry Services

The purpose of this letter is to provide Bruce Power's comments on draft *REGDOC-2.7.2, VII*, which details requirements and guidance to ensure licensed dosimetry services meet technical requirements and implement quality assurance measures.

As always, Bruce Power appreciates the CNSC's efforts to seek input from licensees to ensure requirements in this important document are fully understood. Following a collaborative review of the draft REGDOC with our industry peers, we have compiled a set of suggestions and requests for clarification in Attachment A for the CNSC's consideration.

Of particular note, there is concern that Section 7 of this draft duplicates management system requirements for licensees who already comply with *CSA N286-12, Management System Requirements for Nuclear Facilities.* Introducing a separate set of management system requirements in this document appears contrary to the industry direction towards an integrated system which pulls all business components/processes into one coherent management system. To reduce confusion and duplication, Bruce Power suggests Section 7 be clearly labelled as guidance to offer a suggested framework for licensees who do not already comply with a mature management system standard such as *N286-12*. This would also align with the scope of draft *REGDOC-2.1.1, Management System,* which says dosimetry services licensees do not have a management system as a condition of their CNSC licence, but may consult *REGDOC-2.1.1* for information on management systems. For additional clarity, the CNSC is also encouraged to remove the phrase *"Management System Requirements"* from the title of *REGDOC-2.7.2, VII* in future versions.

Bruce Power Maury Burton, Senior Director, Regulatory Affairs
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If you require further information or have any questions regarding this submission, please contact Steve Cannon, Department Manager, Nuclear Oversight and Regulatory Affairs, at (519)-361-6559 or steve.cannon@brucepower.com.

Yours truly,

Maury Burton
Senior Director, Regulatory Affairs
Bruce Power

cc: CNSC Bruce Site Office (Letter only)
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Attach.

NK21-CORR-00531-14592
NK29-CORR-00531-15279
NK37-CORR-00531-03034

2018 July 31

Mr. Brian Torrie
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Canadian Nuclear Safety Commission
280 Slater Street
P.O. Box 1046, Station B
OTTAWA, Ontario K1P 5S9

COMPLIANCE
Regulatory Affairs

Dear Mr. Torrie:

Comments on Draft REGDOC-2.7.2, Dosimetry, Volume II: Technical and Management System Requirements for Dosimetry Services

Canadian Nuclear Laboratories (CNL) has reviewed the proposed REGDOC-2.7.2, Dosimetry, Volume II: Technical and Management System Requirements for Dosimetry Services and has consulted with its industry partners to produce a set of consolidated comments, which are presented in Attachment A.

One of the major themes of the comments is that wording for regulatory requirements should be exactly as written in the regulations to avoid imprecise interpretations and potential confusion. Also, there needs to be clear delineation between requirements and guidance.

CNL appreciates the opportunity to provide comments during the development of this regulatory document.

If you require further information or should have any questions regarding this submission, please contact me directly.

Yours sincerely,

Solly Karivelil, Manager
Regulatory Affairs
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SK/mj
Attachment (1)

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July 25, 2018

Mr. Brian Torrie, Director General
Regulatory Policy Directorate
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Dear Mr. Torrie:

Subject: NB Power Comments on REGDOC 2.7.2, Dosimetry, Volume II – Technical and Management System Requirements for Dosimetry Services.

The purpose of this letter is to provide NB Power's comments on REGDOC 2.7.2, Dosimetry, Volume II – Technical and Management System Requirements for Dosimetry Services (Reference 1). NB Power's Point Lepreau Nuclear Generating Station (PLNGS) has collaborated with industry to review the proposed regulatory document in detail.

PLNGS appreciates the opportunity to provide input to strengthen the licencing process. Comments are provided in Attachment 1 recommending changes for improving the regulatory guidance.

NB Power is prepared to clarify our comments and concerns. If you require additional information please contact Brian Thorne at 506 659-6264 or brthorne@nbpower.com.

Sincerely,

Brett Plummer
Vice President Nuclear and Chief Nuclear Officer

BP/bt

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cc. Bruno Romanelli, Isabelle Gingras, Josée Giguère , Nathan Kline, Carleigh Zelmer (CNSC - Ottawa)
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References:

1. CNSC draft REGDOC 2.7.2 Dosimetry, Volume II: Technical and Management System Requirements for Dosimetry Services, April 2018

Attachments:

1. NB Power Comments on draft REGDOC-2.7.2, Dosimetry, Volume II: Technical and Management System Requirements for Dosimetry Services