REGDOC-2.7.2 Dosimetry, Volume 2, Technical and QA Requirements for Dosimetry Services
Comments Table for Public Consultation

Comments received from public consultation / Commentaires reçus dans le cadre du processus de consultation

Organization: Radiation Protection Bureau, Health Canada

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1.	Title, cover page and also throughout document.	"Dosimetry, Volume II: Technical and **Management System** Requirements for Dosimetry Services"	"Management system" is too broad; connotes integrated management systems such as ISO 9001 + ISO 14001. Management system can also refer to financial management and marketing, which are out of scope. Recommend "**Quality** Management System".	
2.	1.1 Purpose, 1st para.	"…ensure that licensed dosimetry services meet technical requirements and implement **quality assurance measures**…"	"Quality assurance measures" and (quality) management system requirements/practices/elements are not interchangeable. Recommend "…ensure that licensed dosimetry services meet technical requirements and implement **quality management system requirements**..." Recommend consistent terminology throughout (QMS or QA not both.)	
3.	2. Technical Requirements	Clauses 1 through 8	Section 2 blends the requirements for initial application and the conditions for maintaining the licence into a single section, which is confusing. Moreover, additional conditions for maintaining a licence are stated in the issued dosimetry licence (e.g., ACR, Unplanned Event reporting, etc.), which is confusing. a) Recommend separating the conditions for initial application and licensing into separate sections even if some of the requirements need to be repeated (e.g.,	

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			clause 3.). b) Recommend importing and combining the conditions stated within the issued licence with these Technical Requirements.	
4.	2.5.1 Routine performance tests	2.5.1Routine performance tests, 2nd para. "The dosimetry service shall include provisions for routine performance tests during **every routine dosimeter issue period**. In the case of biweekly issue periods, the test should be completed at least monthly. For extremity dosimetry, performance tests shall be performed at least once every three months. The frequency and **nature of special performance tests shall be specified in the licence application**. For routine performance tests, the dosimetry service shall comply with the following requirements:"	a) Special performance testing is not germane to section 2.5.1. Recommend this be moved to the beginning of section 2.5.2, or preferably a dedicated section for licence application requirements.	
5.	2.5.1 Routine performance tests	2.5.1Routine performance tests, clause "4. Establish, **in consultation with the CNSC, control limits on the test results.**"	Confusing / duplicative. Unless action and alert limits must be established with CNSC, the acceptance criteria in Table 2 is sufficient. Recommend a) Explicitly prescribing control charts for routine performance tests and their format, including control limits.	
6.	2.5.2 Special performance tests, 1st para.	"In addition to the routine performance tests, the dosimetry service shall conduct special performance tests at a minimum of every five years to confirm that the	Anniversary of the special performance tests is unclear / unspecified. The date of the type test and the date of the actual licensing of that service can be protracted.	

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		performance of the dosimetry system remains consistent with the results of the original type tests."	Recommend: "In addition to the routine performance tests, the dosimetry service shall conduct special performance tests at a minimum of every five years **(commencing from the date of the type test submitted during application)** to confirm that the performance of the dosimetry system remains consistent with the results of the original type tests."	
7.	2.5.3 Documentation, Para 4.	"The dosimetry service shall submit the routine performance test procedures to the CNSC **for approval at the licensing application stage**."	Recommend this be moved to a dedicated section dealing with all licence application requirements.	
8.	2.6 Independent testing, clause 1.	"The requirements for independent testing include the following: 1. 1.External dosimetry services shall undergo and pass independent testing of each of its dosimeter designs **prior to licensing.** "	Recommend this be moved to a dedicated section dealing with all licence application requirements.	
9.	2.6 Independent testing, clause 3.	"The dosimetry service shall have the independent tests performed by the relevant reference calibration centre for external dosimetry in Canada (see appendix J)."	Consider the option to use another recognised calibration centre. Recommend rewording: "The dosimetry service shall have the independent tests performed by the relevant reference calibration centre for external dosimetry in Canada (see appendix J) **or another recognized national or international organization, in consultation with the CNSC**"	
10.	4.1	"The internal dosimetry service shall participate in independent tests involving quantities, activities or activity concentrations equal to or greater than the minimum testing levels (MTLs) shown in table 4, up to a maximum of 20 times the relevant	This requirement is too limiting for a potential I-123 performance test program. Health Canada is working towards providing a performance test program for I-123. However, the potential surrogates for I-123 are limited to short-lived radionuclides (Ce-139 or Te-123m). As a	

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		MTL, for the radionuclides for which they are licensed."	result, the activities used for the performance test program would be similar year to year if there was a maximum of 20 times the MTL. Health Canada recommends a maximum of at least 50 times the MTL for I-123 independent testing.	
11.	7. Management System Requirements	Heading	Recommend "7. **Quality** Management System Requirements". See comment 1.	
12.	7.1 Management Policy, clause 1.	"1.**Senior** management shall document its quality policy. The quality policy shall be appropriate for a dosimetry service (see section 7**.1**) and shall include a commitment to operate according to its quality assurance program, to regularly review its adequacy, and to **continually improve.**"	a) "(see section 7.1)" is self-referential (typo). b) Senior management is undefined. Recommend re-wording"1. Senior management shall ensure the dosimetry service has a documented quality policy. The quality policy shall be appropriate for a dosimetry service (see beginning of section 7.~~1~~) and shall include a commitment to operate according to its quality management system ~~assurance program~~, to regularly review its adequacy, and to continually improve its processes."	
13.	7.2 Quality assurance program description, Heading	"Quality assurance program **description**"	"Description" implies a characterization of the QMS when this section prescribes "documentation" requirements. Recommend: "7.2 Quality Management System documentation requirements"	
14.	7.2 Quality assurance program	"The **description** of the quality assurance program shall consist of interrelated documents that	See comment 13. Recommend: "The **documented quality**	

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	description, 1st para.	collectively provide clear, comprehensive and accurate **descriptions** of the following information:"	**management system** shall consist of interrelated documents that collectively provide clear, comprehensive and accurate **requirements** of the following ~~information~~:"	
15.	7.3 Management review and self-assessments, clause 1.	"1. Managers shall perform self-assessments of their areas of responsibility at least once per year. These self-assessments shall determine whether the dosimetry service meets standards and **objectives**, and evaluate the effectiveness of processes and procedures..."	a) "Objectives" is ambiguous; does not specify which ones, such as financial. Recommend re-wording with either: "1. Managers shall perform self-assessments of their areas of responsibility at least once per year. **Collectively,** these self-assessments shall determine whether ~~the dosimetry service meets~~ standards and **quality** objectives **have been met**~~. and evaluate the effectiveness of processes and procedures~~..." Or "1. Managers shall perform self-assessments of their areas of responsibility at least once per year. **Collectively,** these self-assessments shall determine whether **process and procedures are effective in meeting** ~~the dosimetry service meets~~ standards and **quality** objectives~~, and evaluate the effectiveness of processes and procedures~~..."	
16.	7.3 Management review and self-assessments, clause 2.	"2.At least **annually**, **senior** management shall conduct a formal review to ensure that processes are **optimized**, under control, and producing accurate results that conform to specifications."	a) "senior" implies the highest tiers of management in a large organization would be in the best position to conduct a formal review of the QMS. Recommend re-wording: a) " 2. At least annually, senior management shall ensure a formal review is conducted to ensure that processes are optimized, under control, and producing accurate results that	

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			conform to specifications."	
17.	7.3 Management review and self-assessments, clause 2., sub clause b.	"b. analyses of **inspection and test** results"	a) Although this clause is unchanged from S-106 rev.1, that document had not defined "inspection" in the Glossary. REGDOC-3.6 defines inspection as, "For **maintenance** purposes, an examination, observation, measurement or test undertaken to assess the condition of a structure, system or component." and defines **maintenance** as, "The organized activities, both administrative and technical, to keep **Class II prescribed equipment and radiation devices**, as well as structures, systems and components, in good operating condition. Note: For reactor facilities, maintenance includes repair aspects." In other words, the new reference to REGDOC-3.6 in the Glossary section of REGDOC-2.7.2 has completely altered the context of "inspection". Recommend ""b. analyses of **verifications (see 7.11)** and the results of performance testing." or Adding a third sub definition for "inspection" in REGDOC 3.6 which addresses the situation of quality inspection of procured goods or services.	
18.	7.3 Management review and self-	"c.analyses of non-conformances (e.g., frequency, **significance**, consequence, **causes and accountability**), **of corresponding**	The scope of analysis is unclear. a) Clause 7.13 does not require cause analysis for non-conformances that are	

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	assessments, clause 2., sub clause c.	**corrective and preventive measures**, and of deficiency trends"	not deemed "significant" or "recurring". As such, only a subset of non-conformances have "corrective and preventive measures." b) "Accountability" encourages "blame game" and is widely discouraged in the quality paradigm. c) "preventive measures" is redundant since corrective action includes "take to prevent repetition" in 7.13 clause 1. d) "measures" is inconsistent terminology. Clauses "7.12 and 7.13 already refer to "remedial **actions**", "corrective **actions**". Recommend: "c.analyses of non-conformances (e.g., frequency, **significance**, consequence, **causes**), **of corresponding corrective and preventive measures**, and of deficiency trends as applicable"	
19.	7.6 Procurement, clause 2.	2.Purchasing procedures shall ensure that purchased equipment, material and services conform to specified purchase requirements. **Specified purchase requirements shall include** a clear description of the item on a requirement or technical data sheet that includes measuring accuracy and repeatability, traceability of calibration to national standards, inspection and testing specifications, acceptance criteria, the quality assurance program specifications that the supplier shall meet, and recording specifications.	The list of purchase specifications is not appropriate for every kind of purchase (e.g., some services). Recommend: 2.Purchasing procedures shall ensure that purchased equipment, material and services conform to specified purchase requirements. **S**pecified purchase requirements shall include **(as appropriate)** a clear description of the item on a requirement or technical data sheet that includes measuring accuracy and repeatability, traceability of calibration to national standards, inspection and testing specifications, acceptance criteria, the quality assurance program specifications that the supplier shall meet, and recording specifications.	
20.	7.6 Procurement, clause	"3. Suppliers shall be evaluated and selected based on their ability to meet specifications. **A vendor or supplier**	The requirement for a vendor or supplier list is over prescriptive and the requirement could be met by alternate means. The quality industry has	

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	3.	**list shall be maintained**."	been moving away from vendor/supplier lists for quite a while now. The requirement already states that suppliers must be evaluated. If a record is kept of the evaluation which deems them qualified to offer the good or service, there is no added benefit of a supplier list. Recommend: "3.Suppliers shall be evaluated and selected based on their ability to meet specifications. **Records of selected suppliers** shall be maintained."	
21.	7.7 Work control, Heading	"7.7 **Work** Control"	Inconsistent terminology: work vs process vs activity. Recommend: "7.7 Process Control"	
22.	7.7 Work control, clause 1.	"1.All work or activities that can influence the **assignment of the correct dose** to the right individual and the maintenance of an effective dose record system shall be controlled by established procedures that provide details of the following items:"	"assignment of the correct dose" expresses a compound requirement, which can lead to confusion or omission. Recommend: "All work or activities that can influence**: dose accuracy, the correct assignment of dose** to the individual and the maintenance of an effective dose record system…"	
23.	7.8 Change Control, clause 6.	"6.Where changes involve a revision to approved procedures and instructions, the specifications of section 7.11, Document control, shall be met."	Redundant. Changes to procedures would (should) automatically trigger the Document Control process and training, possibly internal audits, management review. Etc. Ergo clause 6. detracts from the need to perform comprehensive impact analysis. Recommend deleting clause 6 and extending clause 4: "Records shall include an analysis of the impact of the change to the QMS, including documents, products, processes, services, plans, infrastructure, equipment.	

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24.	7.9 Document control, clause 1.	"1.Procedures shall be established for the preparation, review, approval, issue, distribution, and revision of documents and procedures. **This includes documents and procedures that contain** technical specifications or prescribe activities for the achievement and verification of technical specifications; for example, technical standards, dosimetry manuals, specifications and procedures for dose records, operating procedures, **software programs**, calibration techniques, and analytical methods. It also includes quality assurance program procedures."	Confusing. Software programs may be construed as a document or procedure. While there is overlap in configuration management practices for both documents and software, there are also important differences such that they should not be aggregated into one section. Recommend deleting "software programs" from the list of examples.	
25.	7.9 Document control, clause 3.	"3. Documents shall be removed from use when obsolete, or be clearly identified as obsolete if **retained** for reference purposes."	Obsolete versions should be retained by default to enable dose recreation (see 7.14 clause 3 and 4; see 7.7 clause 4) and root cause analysis. Recommend: Documents shall be removed from use when obsolete or be clearly identified as obsolete if **kept in distribution** for reference purposes."	
26.	7.10 Calibration and maintenance, clause 9	"9.When equipment is found to be inaccurate (see section 7.**14**, Non-conformance), reviews shall be conducted to determine the validity of previous data or results and corrective action is to be taken (see section 7.**15**, Corrective action)."	Incorrect references. "9.When equipment is found to be inaccurate (see section 7.**12**, Non-conformance), reviews shall be conducted to determine the validity of previous data or results and corrective action is to be taken (see section 7.**13**, Corrective action)."	
27.	7.14 Records, clause 5.	5.A **list of records** that relate to the licensed operation shall be maintained…."	A QMS can produce a considerable variety of records of various formats. Maintaining an (up-to-date) list is onerous and is arguably useful only to an auditor.	

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			Recommend deleting this requirement and adding to Document Control: "Procedures shall reference the record(s) they generate in accordance with 7.14 records, Clause 2.".	
28.	7.15 Audits, clause 1.	"1.Management shall have an audit program. The audit shall determine whether procedures and processes are being **effectively implemented** and are **resulting in the satisfactory performance of the dosimetry service**."	"effectively implemented" is a compound requirement. The audit should separately determine whether a procedure or process is: 1) compliant to regulatory and other requirements; 2) implemented; 3) effective in achieve stated outcomes; 4) continually improving. "resulting in the satisfactory performance of the dosimetry service" is a determination that management should make during management review. Also "satisfactory performance" is undefined. Recommend replacing with: "1. Management shall have an audit program. The audit program shall consist of determinations of whether the documented QMS is: 1) compliant to regulatory and other requirements; 2) implemented; 3) effective in achieve stated outcomes; 4) improving.	
29.	7.15 Audits, last para.	Note: See the CSA Group publication **CAN/CSA-ISO 19011:03** CAN/CSA-ISO 19011:12 (R2017) [3] for guidance.	Outdated reference to a standard. Replace: "Note: See the CSA Group publication **CAN/CSA-ISO 19011:12 (R2017)** [3] for guidance."	
30.	Appendix J, J.2 Independent test specifications for in vitro measurements, in vivo	https://www.canada.ca/en/health-canada/services/environmental-workplace-health/occupational-health- safety/occupational-radiation.html	Broken hyperlink and likely incorrect contact information. See: https://www.canada.ca/en/health-canada/corporate/contact-us/national-calibration-reference-centre-bioassay-in-vivo-monitoring.html	

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	measurements, and interpretation of bioassay data			
31.	References, 3rd ref.	3. CSA Group, CAN/CSA-ISO 19011-03, Guidelines for Quality and/or Environmental Management Systems Auditing, (Adopted ISO 19011:2002), 2002.	Outdated standard. CAN/CSA-ISO 19011:12 (R2017) - Guidelines for auditing management systems (Adopted ISO 19011:2011, second edition, 2011-11-15)	
32.	General		The CNSC should include guidance on what constitutes an unplanned event as per licence conditions 2430-2 and 2431-1.	
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