Comments from Health Canada / Radiation Protection Bureau

CNSC Discussion Paper DIS-16-02
Radiation Protection and Dosimetry
September 2016

The following contains a compilation of comments from staff of Health Canada's Radiation Protection Bureau.

Section 3.2: Strengthening existing CNSC documents:

The proposed change to incorporate and revise S-106, Rev 1, Technical and Quality Assurance Requirements for Dosimetry Services will have an effect upon the performance test programs that Health Canada's National Calibration Reference Centre (NCRC) provide to licensed dosimetry service providers on behalf of the CNSC. The adoption of new performance criteria based on the ANSI 13.30 -2011- Performance Criteria for Radiobioassay - has been anticipated for some time and its adoption will require a change in the evaluation criteria for our clients.

Another point specified is that a clarification regarding CNSC expectations with regards to quality assurance programs for licensed dosimetry service providers will probably have an effect upon National Dosimetry Services and perhaps also on the NCRC. If the new clarifications require the implementation of an internationally recognized standard such as ISO 17025 then this would require considerable effort and resources.

Please see Annex 1 for more detailed comments on proposed revisions to S-101, Rev 1 with respect to external dosimetry service providers, and the potential impact on Health Canada's National Dosimetry Services.

Section 3.3: Improvement Opportunities Identified Through Regulatory Experience:

The CNSC proposes to provide formal guidance for radionuclide-specific methods for internal dosimetry. This is an area where Health Canada has some expertise and will certainly look forward to providing input, if solicited.

Section 4.2: New Content

The bullet starting with "Provide guidance for principles of worker dose control" includes a statement that emergency situations will be included as new content. However, nowhere in *Section 3.2: Strengthening existing CNSC documents* or *Section 3.3: Improvement opportunities identified through regulatory experience* is a gap regarding emergency situations identified or discussed. There is not enough information provided in the Discussion Paper to identify what the improvements to emergency situation guidance might be and therefore their implication cannot be assessed. Even based on the draft table of contents for REGDOC 2.7.1 Radiation Protection, it cannot be discerned whether the emergency situation guidance will be applicable only to NEWs and Non-NEWs working on-site at CNSC licensed facilities or if it will apply to other types of emergency workers (e.g. first responders). If the guidance will apply to other types of emergency workers then it is important that CNSC guidance aligns with other Canadian standards and guidance materials including *CSA N1600-16* and *Health Canada's draft Canadian Guidelines for Protective Actions during a Nuclear Emergency*.

Guidance for Emergency Helpers, which is a new addition in IAEA GSR Part 7, should also be considered..

Appendix A: Proposed Table of Contents / A.1 REGDOC-2.7.1, Radiation Protection

Given the importance of effective and timely information sharing in an emergency situation, a section on data sharing with offsite authorities should be added in the chapter on Control of Radiological Hazards.

Annex: Detailed comments for possible revisions to S-106, Rev 1

Reference (Section No., Figure No., Table No....)	**Issue**	**Proposed Solution**
S-106 Section 5.0	Prefer Quality Management System and replace references to Quality Assurance, Quality Assurance Program.	Replace Quality Assurance with Quality Management throughout.
S-106 Section 5.2.2	Prefer Quality Manual to Quality Assurance Program Description	Replace Quality Assurance Program Description with Quality Manual.
S-106 Section 5.2.2	Include references as an alternative to descriptions	Replace existing test with: and accurate descriptions *or references to* the following
S-106 Section 5.2.3 #1	Prefer reviews instead of self-assessments, to avoid inconsistent terminology.	Replace self-assessments with *reviews*
S-106 Section 5.2.3 #2	Suggest deleting the word optimized. Process optimization usually means cost minimization or maximum throughput. "producing accurate results that conform to specifications is sufficient."	Delete the word *optimized*
S-106 Section 5.2.3 #2 b)	Word inspection requires clarification. Is this pertaining to verifications or purchase inspections? Test results are something different and therefore should not be conflated with inspection.	Provide clarification
S-106 Section 5.2.3 #2 b)	The term non-conformance has been deprecated by ISO/TC176 in preference to nonconformity. Suggest replacing with new term. Suggest deleting the word accountability. Accountability is seldom used in the quality vernacular as it implies punishment for non-conformance.	Replace the term non-conformance Delete the word *accountability*
S-106 Section 5.2.3 #2 b)	Overlaps with c)…"of corresponding corrective and preventive measures". Recommend deleting g).	Delete g)
S-106 Section 5.2.4	External communications should be	Provide clarification and consider

	clarified. Also, it may be better situated under 5.2.2.	moving
S-106 Section 5.2.6	Prefer “Purchasing” instead of Procurement, for consistency of terminology.	Replace Procurement with *Purchasing*
S-106 Section 5.2.7 #5	“method of transferring dose data” is not really a Work Control item. Recommend moving to 5.2.14 Records.	Move *method of transferring dose data* to Section 5.2.14
S-106 Section 5.2.8 #1	Including changes to dose records under change control is a compound/conflated requirement. Recommend moving changes to dose records to 5.2.14 Records.	Move changes to dose records to Section 5.2.14
S-106 Section 5.2.8 #5	“prescribe standards” should be clarified	Provide clarification
S-106 Section 5.2.8 #6	Agreed in principle but this is a redundant requirement. Changes to documents can be triggered by several things (non-conformance/ corrective action, etc.)	Consider removing
S-106 Section 5.2.8 Note	Move to records section or create a new subsection for this topic.	Consider moving or creating a new subsection
S-106 Section 5.2.9	The control of software programs is definitely needed, but should not be conflated with document control. I recommend this be separated out into its own clause, e.g., Infrastructure	Separate clause for control of software programs
S-106 Section 5.2.10	“data or results” should be clarified with, “previously gathered data or results”.	Provide clarification
S-106 Section 5.2.11 #4	Overlaps with clause 1. Recommend combining.	Combine clauses 1 and 4
S-106 Section 5.2.12	Recommend that some licence conditions, such as Unplanned Event, be moved here and deleted from the licence.	Move some licence conditions to this section and delete from licence.
S-106 Section 5.2.12 #2	“ and remedial actions identified, executed, verified and recorded” overlaps with 5.2.13 Corrective Action. Recommend deleting or combining with 5.2.13.	Remove or combine with 5.2.13
S-106 Section 5.2.12 #4	“Backup arrangements” should be moved to a new section, e.g., Infrastructure.	Move to a new section
S-106 Section 5.2.13 Note	“an undetected overexposure, an incorrect dose being assigned to an individual” are really the same issue: inaccurate dose	Recommend replacing with *Significant non-conformances are those that lead to, or could lead to an inaccurate dose, an incorrect dose being assigned to an individual…*
S-106 Section 5.2.15 #1	The effectiveness of a procedure and its degree of implementation are different things. The audit should draw separate conclusions about each.	Include both the effective of a procedure and its degree of implementation

S-106 Section 5.2.15 #2	Literally taken “entire” is impractical. The audit program should demonstrate appropriate coverage of representative areas. Also the emphasis should be placed on “status and importance”, i.e., a risk-based audit programme.	Remove entire and replace with risk-based audit program
S-106 Section 5.2.15 #3	Prefer audited. Assessed has slightly different meaning in the conformity assessment industry.	Replace assessed with *audited*
S-106 Section 5.2.15 Note	CAN/CSA-ISO 19011:03 has been superseded by a newer version.	Add reference to new version of the standard
S-106 Section 5.0	Compounded/conflated requirements should be avoided. Integration with generic licence conditions and applicable regulatory clauses is highly desirable so that all the normative requirements are centralized. ISO terminology and concepts should be adopted wherever possible to improve harmonization and integrated management systems approach.	General comments
S-106 Section 4.1.6 #3	Allow the option to use other approved labs for independent testing for external dosimetry providers.	Suggest identifying requirements for a lab to be considered for independent testing for external dosimetry providers and allowing licencees to submit labs for review and acceptance by the CNSC.
S-106 Section 4.1.6 Note	Suggest providing information on required methodology. This type of analysis lends itself to a difference of means test which requires independent data sets. Since the tested unit is a subset of the full set of units, the data is not truly independent.	Provide guidance or example of expected analysis.