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A Sotera Health company

January 11, 2021

Brian Torrie
Director General, Regulatory Policy Directorate
Canadian Nuclear Safety Commission
P.O. Box 1046
280 Slater Street
Ottawa, Ontario
K1P 5S9

Re: Nordion Comments on Draft REGDOC-2.7.1 Radiation Protection and REGDOC-2.7.2, Volume I, Dosimetry: Ascertaining Occupational Dose

Dear Mr. Torrie,

Nordion would like to thank the CNSC for the opportunity to provide further comments on the draft REGDOC-2.7.1, Radiation Protection and REGDOC-2.7.2, Volume I, Dosimetry: Ascertaining Occupational Dose. We recognize and appreciate the CNSC staff's engagement with industry, and other stakeholders, in developing these REGDOCs.

Nordion has collaborated with industry in reviewing the latest versions and shares continued concerns. These concerns are addressed in the industry comments attached. In addition to these industry comments, Nordion would like to highlight the following:

1) The language in the proposed REGDOCs does not provide clarity on requirements vs guidance. In some instances, provided in the attachments, "expectations" and "should" statements are given as examples or best practices, but are worded in a way that could be interpreted as requirements. It is important that requirements vs. guidance statements are clear and well defined.
2) It is not clear if the concept and CNSC expectations on licensees' use of Action levels changes in this REGDOC 2.7.1. It is important for licensees to properly understand the implications of any such changes before implementation.

We support industry's request for a workshop to discuss these concerns and we look forward to further discussion with the CNSC on this proposal.

Sincerely,

Richard Wassenaar
Director, Regulator & EHS

Attachment 1: Industry Comments: draft REGDOC-2.7.1, Radiation Protection
Attachment 2: Industry Comments: draft REGDOC-2.7.2, Volume 1, Dosimetry: Ascertaining Occupational Dose

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Industry Comments on draft *REGDOC-2.7.1 Radiation Protection*

#	Section	Industry Issue	Suggested Change *(if applicable)*	Major Comment/ Request for Clarification	Impact on Industry, *if major comment*
1.	**General**	Industry appreciates the efforts CNSC staff has made to engage stakeholders in the development of this REGDOC to date, but believe a stakeholder workshop is urgently needed to resolve the remaining concerns before the document is finalized and sent to the Commission for approval. Following two rounds of written submissions, licensees believe a workshop will be the most effective and expedient way for CNSC staff to understand industry's remaining concerns with this draft and the significant operational and resource impacts it will have on key areas such as labelling. During this discussion, industry believes CNSC staff can clarify how Inspectors in the field will interpret many of the "expectations" described in this draft REGDOC to ensure a common understanding. This is of particular concern for expectations like those in section 4.4.3 regarding showers for workers in contaminated areas. As with many other REGDOCs, industry is concerned some CNSC staff view "should" and "may" statements not as guidance or options to consider (as indicated in the Preface), but expectations that must be followed except in rare occasions. While industry will always invest in areas that enhance nuclear safety, some "should" statements in this document will require significant resources to either implement -- or to explain to CNSC staff why it is not implemented – with no commensurate increase in worker safety.			
2.	**4.1.5**	Industry remains concerned with the inclusion of dose constraints in this draft REGDOC considering they were intentionally not included in the revised Radiation Protection Regulations. However, if CNSC staff insists in referencing dose constraints, industry believes additional clarity is required to ensure readers understand the items listed in 4.1.5, are *examples* of measures to consider, not requirements.	Amend the 4th paragraph before the five bullet points to read, "Other measures that may be integrated into day-to-day operations by licensees to help oversee the application of the ALARA principle include the following *examples*:"	**MAJOR**	This proposed change will clarify that these are examples and are not requirements. If dose constraints were to be used to manage work, they could be treated as a de facto regulatory limit.
3.	**4.4.3**	As per comment #1, industry remains deeply concerned with the expectation for workers to "shower and change clothes upon leaving contaminated workplaces." This expectation is overly onerous and unnecessary from a worker safety perspective, particularly in situations in which workers wear additional protective clothing/ equipment and showers are not the main way personnel are decontaminated. Workers have RPPE and are routinely free of contamination upon exit as verified by contamination monitoring. While the authors of this draft REGDOC understand that "should" equates to guidance, experience in the field suggests some Inspectors occasionally view "should" statements as de facto requirements. If that interpretation were applied to this passage, the impact to licensees would be significant with no corresponding improvement to nuclear safety.	Amend this section to indicate that shower facilities are required to be available and that workers should be able to shower and change clothes upon leaving a contaminated workplace, if required. Specifically, amend the 2nd sentence in the last paragraph from "Individuals should shower ..." to "Decontamination facilities should be available …"	**MAJOR**	An expectation is still too strong for a non-standard practice that does not improve safety if contamination monitoring is adequate. The purpose of effective contamination control and monitoring is to ensure workers are not contaminated and can proceed with work without the need for further contamination controls. Taken at face value, the 2nd sentence of the last paragraph sets an expectation that workers shower every time they exit a contaminated area, which equates to an enormous cost with no safety improvement. As an example from just one segment of the industry, this could result in more than 2,000 nuclear power plant workers, making just two work entries per day, having to spend 0.3 hours to shower and change each time. This could result in more than $34 million per year in additional labour costs with no improvement to nuclear safety. It could also require licensees to divert limited resources from other areas to

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					meet this expectation, again with no safety benefit.
4.	**6**	The context of the section does not meet the intent of the definition of an action level. Action level is designed as being indicative of a significant loss of RP control. Lowering an action level means more events are to be expected. This may cause unnecessary concern to workers and members of the public. Industry suggests the section should be written such that it's tied to a significant event/incident rather than a continual improvement concept. Industry uses administrative levels (or precursor indicators) to alert potential issues. Also the last sentence of the 3rd paragraph currently says, "If an action level is reached, the specific action under the RPR is establishing the cause for reaching the action level, restoring the effectiveness of the radiation protection program …" This implies that hitting an action level indicates a loss of the effectiveness of the radiation protection program, which conflicts with the early definition that an action level "may indicate a loss of control…"	For clarity, CNSC staff is urged to: • Amend Section 6 to clearly explain that the action level is not the level that should keep changing over time. That is more appropriate for administrative levels or other systems used for optimization. Therefore, the CNSC should consider revising this section to allow flexibility in monitoring the performance. Allowance for administrative levels or other mechanisms can be recommended. • Revise the last sentence of the 3rd paragraph to read, "If an action level is reached, the specific action under the RPR is establishing the cause for reaching the action level, *determining the impact, if any, on the effectiveness of the radiation protection program*, restoring the effectiveness of the radiation protection program *(if required)* …" • Provide further guidance on the use of action levels - what frequency are they expected to be exceeded and what consequences there may be if licensees don't exceed them (as is the current case).	**MAJOR**	Action levels are fundamentally not associated with continual improvement. They are levels that indicate a potential loss of control, requiring investigation and corrective action. They are intended only to be sensitive to programmatic breakdowns. Continual improvement is addressed in many ways other than action levels. Given this, industry feels the CNSC does not accurately address licensees' central issue in its disposition, which reads, "Noted, however action levels are a concept of continual improvement to the RP program and should be reviewed and revised to ensure they remain sensitive indicators. There is guidance on the use of administrative levels provided in section 6 as well. Please note, the text has been revised to reflect significant developments and or fundamental changes in operational and radiological conditions."

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5.	**7, 15**	Licensees support the repeal of the provision for a female NEW to self-disclose her pregnancy to the licensee as long as the regulations and this supporting REGDOC are clear with regard to licensees' obligations. This proposal aligns with the international practice of voluntary self-disclosure of pregnancy and nursing. This comment was submitted to the CNSC during the initial consultation round and the CNSC's response was, "Agreed, the text has been revised." However, there have been no changes made to this section to that effect. Similarly, licensees believe additional context is needed for the 2nd last paragraph on page 38, which currently reads, "As per section 15(7) of the Regulations, licensees must not ask pregnant women to participate in the direct control of an emergency." This assumes the licensee knows the woman is pregnant, which may not be the case. Suggested wording was submitted to the CNSC during the initial consultation round and the CNSC's response was, "Agreed, the text has been revised." However, there have been no changes made to this section to that effect.	CNSC is urged to: • Revise the text in Section 7 as per comment #62 in licensees' previously submitted comments table. Specifically, amend the 4th bullet on page 28 to read, "of the female NEW rights once they declare they are pregnant or breastfeeding" • Revise the text in Section 15 as per comment #75 in licensees' previously submitted comments table. Specifically, amend the 2nd last paragraph on page 38 to read, "As per section 15(7) of the Regulations, licensees must not ask women who have declared pregnancy to participate in the direct control of an emergency." Revise the text as per comment #75 in the detailed comments table.	**MAJOR**	Amending Section 7 will clarify that the responsibility lies with the pregnant or nursing NEW to declare their status to the licensee in writing. Until such a declaration is provided, the licensee has no obligation to accommodate work assignment or dose limits associated with pregnant or nursing status. Amending Section 15 will clarify the responsibility lies with the pregnant or nursing NEW to declare their status to the licensee in writing. Until such a declaration is provided, the licensee has no obligation to accommodate work assignment or dose limits associated with pregnant or nursing status.
6.	**20**	All segments of industry, from NPPs to operators of mines and mills, continue to have significant concerns with the section on labelling and believe a workshop with CNSC staff is necessary to ensure common understanding. As per industry's initial feedback, licensees agree containers and devices containing nuclear substances should be labelled to alert persons to the presence of a nuclear substance and the real or potential hazard/risk that exists. However, NEWs are trained to recognize hazard levels and understand the risks when reading posted radiation fields (e.g. mrem/h, mSv/h, MPCa or DAC, cpm, etc.) Given this, listing radionuclides and associated activities on various containers (such as waste containers) intended to stay within a nuclear facility does not improve the safety for personnel. Licensees agree that containers/sources shipped out of the facility should have the appropriate specifics.	As per comment #1, industry requests the CNSC host a workshop to ensure the requirements are clearly understood and key terms defined. Items for discussion could include: • Defining 'container' and 'device'. Does it mean radiation device per NSRD regulations? • Applying the exemption to the labelling requirements for containers or devices in an area subject to the boundary and point of access signs in s. 21. • Revising the following line: "Subsection 20(3) of the RPR applies to containers that are used to temporarily hold nuclear substances, *for example waste*	**MAJOR**	There is a very large volume of equipment and various containers that contain radioactive material in an industrial scale facility like a Nuclear Power Plant. Labeling this material with the minimum of estimated activity (or activity concentration) and group of nuclear substances would be a very large undertaking that would demand significant additional resources to be allocated without any improvement in safety. Radiation workers are not trained to think in the terms being required by the CNSC because these terms do not relate well to hazard levels and generally require a technical knowledge level inappropriate to expect of many staff members. The labelling requirements to identify activity and nuclide should be applied only to material leaving the control of the licensee as is currently practiced. Licensees agree that radioactive material within their control needs to be labeled to identify the radiological

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			containers."		hazard to workers, but insist that the description of the hazard can (and has been) be more effectively communicated in other units. If the CNSC cannot concede this point, a workshop is needed. Given this, industry strongly believes additional dialogue is required with the CNSC to discuss its disposition, which reads, "Noted, and similar concerns were raised with the RPR CG1 consultation. Text has been revised with regards to labelling. Licensees may include radiation dose rate measurements on the label; however, the quantity of the nuclear substances present must also be included. The term "quantity" is activity or activity concentration, in line how the term is used in the Nuclear Substances and Radiation Devices Regulations. Using the primary nuclear substance and a dose rate/contamination measurement, one can approximate the quantity in a unit of activity or activity concentration for inclusion on the label. The REGDOC has also clarified that either each nuclear substance should be identified, or the primary nuclear substance(s) should be identified. Alternatively, the primary group of nuclear substances should be identified; where a group may be denoted as, for example, mixed fission and activation products, transuranics, natural uranium, depleted uranium, enriched uranium, etc. With regards to the term "store", it has been revised to "hold" and the corresponding text was modified in REGDOC 2.7.1. With regards to applying the exemption to labelling requirements for containers or devices in an area subject to section 21 of the RPR; this is beyond the scope of REGDOC-2.7.1, no changes were made to the REGDOC.
7.	**Appendix C**	Industry seeks additional clarity on the following parts of Appendix C: 1. C.2 - The section is unclear. Monitoring is not to confirm that other monitoring was effective. 2. C.7 - This section reads like a work instruction and not guidance on general techniques that can be useful in assisting licensees to	For clarity: 1. Amend C.2 to read: "Contamination monitoring, such as weekly swipe tests, are intended to confirm that operational controls to limit the spread of	**MAJOR**	A lack of clarity can lead to regulatory uncertainty.

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		determine which techniques are applicable. Providing specific instruction to use a wetting agent and then identifying that a wetting agent can lead to significant underestimation of contamination creates confusion. 3. C.9 - The 2nd paragraph infers that the method set out for the determination efficiency for a mixture is an example only (e.g. in some cases, it may be possible to use a source that contains all the isotopes in mixture. 4. C.11 - This section is not risk based. While use of 2σ uncertainty may be appropriate for comparison to regulatory limits, it is not necessarily required for all measurements. 5. C.12 - This section is not risk based. While use of 2σ uncertainty may be appropriate for comparison to regulatory limits, it is not necessarily required for all measurements.	contamination are effective. Contamination monitoring should be performed at set locations, following a schedule based on the risk of contamination. Follow up monitoring should be performed any time contamination is identified, either through routine monitoring or identified and reported through other means." 2. Provide more general information and remove procedural details. Remove all reference to use of the wetting agent. 3. Revise to, "Examples of acceptable approaches for mixtures of radionuclides include identifying the isotope for which the detector has the lowest response at the applicable contamination limit or use of a source that contains the radioisotope mixture to be measured." 4. Revise to, "Licensees should be in a position to calculate the appropriate uncertainty for any measurement that is made and compared against a contamination criterion. For criterion associated with regulatory limits, a 2σ uncertainty (i.e., 95% confidence) would be appropriate, but may vary for other measurement types." 5. Revise to: "This requires determination of both the MDA for the detector and isotope of interest, and the uncertainty (e.g. 2σ for comparison to regulatory limits).		

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8.	**Appendix D**	Industry continues to have concerns with Appendix D, which details CNSC "expectations" as cited in the title of several of its subsection and their accompanying text. .	Amend the introductory sentence of this Appendix to align with the introduction to Appendix C. Specifically, amend to read, "This appendix provides general guidance for radiation survey meter and DRD calibrations for the purposes of section 25 of the RPR."	**MAJOR**	To many, the word "expectations" reads as "shall" and limits the industry's options to meet the intention of REGDOC.
9.	**D.3**	Industry remains concerned with the following parts of this section: 1. D.3 - There is a significant administrative burden of placing each DRD (e.g. EPD/DCD) on a torso phantom (several thousand per year) requiring additional labour. 2. D.3 - The statement "the jig is at least 1 metre (m) from the floor, the ceiling and any wall" will cause some calibration facilities to no longer be usable. There is no safety impact of using a track that does not meet the 1.0m requirement. 3. D.5 - The statement "distance between any scattering object and the source is at least 0.5 m" appears to state that box calibrators cannot be used for calibration of radiation survey meters even though box calibrators are commonly used across the industry and it is an acceptable method, as long as the correct conversion factors have been determined using a free-in-air style irradiator first. 4. D.6 - In the 2nd paragraph, the requirement to perform dose rate measurements at multiple dose rates does not agree with manufacturer's recommendations to use Irradiators or robots designed for this purpose.	Amend the appendix to: 1. Consider if the DRD is the primary dosimeter used for dose of record (meaning no TLD or OSL dosimeter is used) then torso phantom is required. 2. Make the minimum distance 0.5m from the floor, ceiling and any wall. 3. Add a clarifying statement: "distance between any scattering object and the source is at least 0.5 m, *excluding box calibrators that have been characterized using appropriate survey instruments that have been calibrated on a free in air calibrator.* 4. Include statement to calibrate DRDs per the manufacturer's recommendations.	**MAJOR**	CNSC staff is urged to consider the following impacts: 1. DRDs are primarily used for dose control and are not the primary dosimeter for dose of record. Therefore, they would not need to be put on a phantom. For example, more than 8,500 calibrations are performed annually at OPG using robotics of OEM design. If the CNSC certified radiation device does not meet the CNSC expectations around torso phantom, OPG would be required cease calibrations and develop alternatives methods. This would likely impact the performance of radioactive work in the station. 2. Major resource/labour impact to renovate calibration facilities that do not meet the 1.0m requirement, or commission new calibration facilities that do meet these requirements. 3. Similarly, there would be a major resource/labour impact to calibrate instruments on a free-in-air style track instead of using industry accepted box calibrator. No safety impact of using a box calibrator, when it has been properly characterized. 4. Major resource/labour impact of calibrating thousands of DRDs per year on a phantom instead of in a manufacturer approved irradiator.
10.	**2, 4.5, 5.4.2**	Additional clarity in the following sections would further aid industry's implementation efforts: 1. The interpretation and application section (2) is difficult to follow. The three bullet points associated with "Subsection 2(2) stipulates that the RPR does not apply" are interrupted by explanatory text, placed at the same indentation as the original	For clarity: 1. Indent the explanatory text (i.e., "Medical exposures are confined", "The CNSC issues licences", and "A caregiver is a person") or organizing the section to be clear on application.	Clarification	

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		heading. As a result, each bullet point's explanatory text loses the link on application. 2. In 4.5, the overlap and relationship between emergencies and unusual situations is unclear. 3. In 5.4.2, personal air sampling can also be performed to accurately estimate breathing zone concentrations of radionuclides and in turn, can be used for internal dose assignment. Use of personal air sampling equipment includes the following elements: equipment worn or located in an appropriate environment and position; a quality control program; a preventive maintenance program; and appropriate minimum detection limits.	2. Include a sentence in Section 4.5 to indicate when an unusual situation becomes an emergency. 3. Amend the 2nd sentence of the 4th paragraph to read, "If personal air sampling is used for internal dose assignments, use of the equipment includes the following elements…." This would further clarify that the additional requirements would not necessarily be required if the personal air sampling was used for screening only and not for assigning dose.		

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Industry comments on draft REGDOC-2.7.2, Volume I, Dosimetry: Ascertaining Occupational Dose

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1.	Preface	As with many other REGDOCs, industry is concerned with the potential interpretation of "should" and "may" statements in this draft. Some CNSC staff view "should" and "may" statements not as guidance or options to consider (as indicated in the Preface), but expectations that must be followed except in rare occasions.	Industry urges CNSC staff to host a stakeholder workshop as the most effective and expedient way for CNSC staff to understand industry's remaining concerns with this draft REGDOC.	**MAJOR**	While industry will always invest in areas that enhance nuclear safety, some "should" statements in this document will require significant resources to either implement -- or to explain to CNSC staff why it is not implemented – with no commensurate in-crease in worker safety.
2.	2.6	As per the CNSC staff comments: "the NDR can accept lens of eye dose records, but have no records currently since only licensed dosimetry services may input data into the NDR and there are currently no LDS for lens of eye" How will lens of eye dose be reported in 2021 if there is no LDS?	Arrange for the NDR to accept lens of eye dose records from others. Otherwise, provide an alternative path for dose reporting.	**MAJOR**	There remains no LDS for lens of the eye. Many licensees do not have this as a licensed activity in their DSL. Industry notes Ap-pendix A now provides guidance on using surrogate methods. Will this be considered licensed dosimetry? Will licensees be required to submit their approach to the CNSC for review, approval and reference in the dosimetry service licence?
3.	4.5	It is impractical to implement the revised sentence in this draft, which currently reads, "When non-uniform neutron fields are present and preferentially expose the eye, personal dosimeters that measure Hp (10) worn near the eyes provide a conservative estimate of the neutron dose to the lens of the eye. Note that this is in addition to neutron dosimetry used to monitor dose to the whole body (as described in section 5.6)."	Remove this reference from the REGDOC.	Clarification	
4.	4.3	The 7th paragraph reference the incorrect section when it says, "Section 5.3.1 provides guidance …" Section 5.3.1 is on the topic of contamination meter efficiencies.	Replace text with: "Section 4.3.1 provides guidance…"	Clarification	
5.	4.3.1	The compartment factors presented in Table 2 of this draft imply the factors used to calculate WB effective dose when wearing a head and trunk dosimeter are 0.12 and 0.88, respectively. Current factors used by some licensees for head and trunk dosimeters are 0.11 and 0.89, respectively.	CNSC staff is urged to: • Clarify that other factors may be used if a technical basis exists. • Include some flexibility in the REGDOC to allow licensees to continue using the factors 0.11 and 0.89 for head and trunk. • Revise the text as per comment #19 in the detailed comments table submitted by licensees during the initial round of consultation.	**MAJOR**	The changes made in the REGDOC are relatively small in dose consequence but will require significant resources to revise procedures, update training and replace software for calculations. These changes are not commensurate with the safety benefit.

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6.	6	The formula provided in this section does not apply in all circumstances. In fact, it will not apply if a NEW of the age of 17 has an ingestion of radionuclides, which is legal in the federal jurisdiction. All provinces appear to allow even younger NEWs. Please see comment #34 in licensees' submission during the initial round of consultation. CNSC staff agreed with the comment and said the text has been revised to include two footnotes. However, there have been no changes made to this section to that effect.	Add the missing footnotes as per comment #34 in the detailed CNSC comments disposition table, which reads: "Specifically, a footnote will be added at the end of the 2rd paragraph of section 7: For persons that are less than 18 years of age, the committed equivalent dose is the equivalent dose received by an organ or tissue from a radionuclide from the time of intake to age 70 years. And another footnote to be added at the end of the 3rd paragraph: For persons that are less than 18 years of age, the CED is the effective dose received from the time of intake to age 70 years."	**MAJOR**	The REGDOC does not conform to all relevant regulations, including the Radiation Protection Regulations.
7.	7.1.1 E.2.1 E.6.3 G.2	REGDOC-2.7.1 and Section 2.1 refers to "non-NEWs" as "persons who are not NEWs"	CNSC staff is urged to use consistent terminology between the two REGDOCs or define the term "non-NEW" in this REGDOC. Consistent terminology improves clarity in the REGDOCs.	**Clarification**	
8.	7.2	Limiting confirmatory monitoring to bioassay samples is unnecessarily restrictive and inconsistent with NUREG 1400 and US NRC Regulatory Guide 8.25, which is referenced in NUREG 1400.	This may be accomplished by confirmatory monitoring using personal air sampling in the breathing zone or bioassay. In order for the air sampling to be considered representative of breathing zone air, the ratio of intakes calculated from air monitoring to the intakes calculated from either personal air samples or confirmatory bioassays, averaged over all workers participating in the confirmatory monitoring, should be more than 0.7. The same ratio for each individual worker should be more than 0.5. For further information, consult NUREG-1400, *Air Sampling in the Workplace* [20] and/or US NRC Regulatory Guide 8.25 Rev 1 June 1992.	**MAJOR**	A lack of clarity can create regulatory uncertainty.
9.	15	The 2nd paragraph reads, "The licensee should demonstrate that every effort was made to inform each worker of the change and that each worker agrees to the proposed changes(s) to *his or her* dose records."	In alignment with the updates to the RPRs, "his or her" should be replaced with "the worker" (or "their"). Consistent terminology improves clarity in the REGDOCs.	Clarification	

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10.	E.8.4	The cited formulae for MDA are only correct if data is Gaussian, which leads to question whether the formulae are correct for low counts. While the true equations are complicated, applying these Gaussian equations results in errors greater than 10% when background (blank) counts are less than 3 counts. This would also imply the CNSC accepts a 14% deviation between the Poisson discrete counting and the Gaussian approximation for nominal alpha counting. In its disposition table, CNSC staff says text was added to clarify that the formula may not be applicable to low counts. However, there have been no changes made to this section to that effect.	As per comment #44 in the detailed CNSC comment disposition table, add a note that states that the formula may not be applicable to low counts. Also, recommend including Poisson version so it is applicable for low-level counting.	**MAJOR**	The result of using equations that are not appropriate for low-level counting is magnified the lower the background levels. If not described correctly, alpha detection by licensees will be inadequate
11.	E.8.3, E.5	Though referenced in these areas, “Section 9.1.5” does not exist. Is this supposed to be Section 7.1.5?	Update section reference	Clarification	