Nordion
A Sotera Health company

July 19, 2019

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

Re: Nordion Comments on Draft REGDOC-2.7.2, Volume 1 – Dosimetry: Ascertaining Occupational Dose.

Dear Mr. Torrie,

Nordion thanks the CNSC for the opportunity to comment on the draft REGDOC-2.7.2, Volume 1 – Dosimetry: Ascertaining Occupational Dose

Attached, please find a table of industry comments that Nordion has participated in creating.

In general, Nordion is concerned that this REGDOC provides step-by-step methodologies for calculating various quantities (i.e. skin dose) that are mixed in with the regulation and guidance text. The manner in which these are provided indicates they are the only and preferred method for calculating such quantities when there may in fact be other, technically correct means of calculating those quantities. It is recommended that the CNSC ensure "shall" and "should" requirements are clearly defined in the document and consider moving a number of the "step-by-step" methodologies to appendices to better clarify that it is only offered for guidance.

We look forward to further discussion with the CNSC on this proposal.

Sincerely,

Richard Wassenaar
Director, Regulator & EHS

Attached: Industry Comments on Draft REGDOC-2.7.2

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Industry Comments on draft REGDOC-2.7.2, Volume 1 – Dosimetry: Ascertaining Occupational Dose

#	Document/ Excerpt of Section	Industry Issue	Suggested Change (*if applicable*)	Major Comment/ Request for Clarification	Impact on Industry, if major comment
1.	General	As currently written, this draft reads like a mix of a regulation, textbook and guidance document. This makes it very difficult to determine its purpose and what is required versus what is suggested. In its earlier forms, this document was clearly understood to be non-binding guidance for licensees. However, with the change to a REGDOC, there are now requirements in several "shall" or "must" statements. Confusingly, in a number of sections, examples or suggestions are mixed with regulatory commitments. This makes it difficult to differentiate between them. This lack of clarity has been found in other recent REGDOCs and is fueling a growing concern among licensees that CNSC inspectors will, perhaps unintentionally, use this ambiguity to treat guidance as defacto requirements. If the CNSC expects licensees to comply with *all* material in this document, industry has significant issue with the cost versus benefit associated with many of its "suggestions." However, industry believes that is not the CNSC's intent and the comments below assume that only "shall" or "must" statements are enforceable and are merely fleshed out with discussion on guidance, recommendations or best practices for licensees to consider.	Amend the REGDOC to make its purpose clear to all audiences and the differences between requirements and guidance distinct and unmistakable Return to the CNSC's past, effective practice of using only "shall" statements to set requirements rather than "must" references closely tied to a series of "should" or "may" statements. While industry appreciates the CNSC's efforts to provide suggestions to improve our already strong dosimetry programs, the overuse of examples and guidance can inadvertently create more confusion than clarity. Guidance is guidance and should be treated as such. Licensees would appreciate future drafts of this document to more clearly distinguish between what is required and what is suggested.	**MAJOR**	Compliance is best achieved when licensees and CNSC inspectors have a common understanding of what is truly obligatory and what is meant as an option for licensees to consider. Many of the statements in this draft offer singleton solutions to items that have other technically-supported ways of being answered. To be successful, licensees need to be able to manage their operations in ways that satisfy their individual needs and meet the CNSC's requirements. Otherwise, extensive time and effort could be expended to have things done only one way with no corresponding benefit to nuclear safety.

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2.	**General**	Contrary to the Regulatory Impact Analysis Statement for the Radiation Protection Regulations as published in the Canada Gazette I, the details of how radon progeny are to be calculated in effective dose are not in draft REGDOC-2.7.2. This is a significant omission.	Include the effective dose calculation in the REGDOC- or the amended regulations. This allows a clear process to comment on any proposed changes to the dose conversion factor from exposure (WLM) to dose (mSv). Specifically, industry recommends the dose conversion factor between WLM and mSv be defined in the regulations.	**MAJOR**	The removal of how radon progeny is calculated from the regulations (and REGDOC) means that there is no certainty of a transparent process being used to assess potential changes. Given that how radon progeny is included in the effective dose calculation is fundamental to the determination of whether the dose limits are being met, there is a need for transparency on both the actual calculation and the process for changes.
3.	1.3	Industry believes clarity can be added to the 3rd bullet, specifically that radon progeny dosimetry should apply to exposures occurring as a direct result of a CNSC-licensed activity, such as exposures to radon and radon progeny in uranium mining and milling, as stated in draft *REGDOC 2.7.1, Radiation Protection.*	Amend to read. "… requires every licensee to ascertain and record the magnitude of exposure to radon progeny where applicable…"	Clarification	
4.	2.4	The magnitude of the component of each source should determine if an LDS is needed, not the technology being used. In addition, the controls for the different components (e.g. RnP, LLRD, gamma) are independent of monitoring technologies. These should not be linked.	Remove the final sentence so the 2nd paragraph reads, "Licensed dosimetry should also be used for any components that are a significant contribution to effective doses to workers (e.g. > 1 mSv/year). ~~In cases where a dosimetry device measures more than one source of radiation (e.g., a personal alpha dosimeter for radon progeny and long-lived radioactive dust), these should be treated as a single component for the purposes of determining dosimetry requirements.~~"	**MAJOR**	The technology used to measure a source of radiation does not impact the magnitude of that source. Linking the two through an LDS requirement implies the magnitude of exposure is also linked. This requirement could force licensees and vendors to abandon technologies where not all components have an LDS. In addition, there is no credit given for the widespread use of LDS for gamma. That component typically has an LDS. Therefore, it is the remaining components that should be assessed to determine if addition requirements are necessary for those components.
5.	**2.4**	Industry believes there should be flexibility around the phrase "….expected to contribute the most …." In the 4th sentence.	Amend the sentence to allow for technically-justified surrogates.	Clarification	

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6.	**2.5.1**	Footnote 3 indicates that the "NDR also includes doses received by foreign workers; however, these analyses are not used for analyses of the NDR data."	Clarify : - Whether this will include lens of the eye dosimetry data - How the differences in eye lens dosimetry requirements will be reflected in this database - How Health Canada will be able to notify the CNSC of any records indicating that a dose limit for a NEW has been exceeded if the records are incomplete for workers of foreign origin	Clarification	
7.	**4**	As per comment #1, clarity is needed around the final sentence of the 1st paragraph, which says, "Radiological characterization *should* include, for all locations in a facility:" followed by a set of bullet points. The language is prescriptive and does not read as guidance, or a suggestion. In addition, characterization for "all locations in a facility" is not reasonable. There may be many areas within a facility, e.g. offices, clean shops, etc., with no radiological source term and there is no benefit in characterizing or monitoring these areas.	Clarify whether the bullets are required or whether the "should" statement means there is latitude for licensees. Clarify that only locations where licensed activities are occurring should be characterized.	Clarification	
8.	**4.1**	Industry believes clarity can be added to the 3rd paragraph since beta radiation does not pose a risk to the lens of the eye if energy is < 700 keV.	Amend the 2nd last sentence of the 3rd paragraph to read, "They pose a potential risk to the skin and the lens of the eyes (if beta energy is > 700 keV)."	Clarification	
9.	**4.1**	"Alpha" is not in the title of this subsection, but is referenced in the 2nd paragraph.	Amend the title to read, "4.1 Photon, beta, alpha and electron radiation"	Clarification	

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10.	**5**	Industry has concerns with the line in the 4th paragraph on page 10, which reads, "At least one control dosimeter should be kept in each dosimeter storage area during the wearing period."	Amend to read, "At least one representative control dosimeter of the same type should be kept in each dosimeter storage area during the wearing period"	**MAJOR**	To correct for non-occupational doses, the same type of representative dosimeter needs to be used for personal dose monitoring.
11.	**5.1.5**	Portable neutron survey meters are calibrated for a specific dose conversion coefficient. This is a large problem because that coefficient varies over two orders of magnitude.	Insert a note into the section to say neutron energies must be well known for neutron survey meters or set for a conservative value of dose conversion rate.	Clarification	Without clarification, neutron survey meters could be improperly deployed.
12.	**5.3.1, Table 2.**	Flexibility is necessary if new recommendations/changes are minor in nature and do not improve safety. 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.	Include some flexibility in the REGDOC to allow licensees to continue using the factors 0.11 and 0.89 for head and trunk.	**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. The change is not commensurate with the safety benefit.
13.	**5.5**	There is no technical basis provided for 15 mSv/year regarding lens of the eye dosimetry	Amend the final paragraph on page 16, to read, "~~If doses to the lens of the eye have a reasonable probability of exceeding 15 mSv per year, direct monitoring with a passive dosimeter should be carried out.~~ The operational quantity measured (Hp(3), Hp(10) or Hp(0.07)) will depend on the exposure situation, which should be assessed as part of the workplace hazard assessment."	**MAJOR**	The technical basis for this 15 mSv level is not explained. The proposed dose limits provide the framework. The addition of this requirement for a direct measurement should be removed and licensees will determine whether a direct measurement is required or not to maintain exposures below the regulatory limits.

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14.	**5.5 and 6.1.1**	There is no dosimetry method reasonably accessible to licensees capable of accurately measuring dose to the lens of the eye in mixed beta and gamma radiation fields. Eye lens dosimeters tend to be overly responsive to beta. Also, surrogate measurements are overly conservative.	Clarify how lens of the eye dose should be measured / calculated.	Clarification	
15.	5.6	Use of the maximum measured dose rate is not an appropriate method for estimation of dose. By definition, it overestimates the dose to workers as they are rarely, if ever, in the maximum dose rate for the entire time.	If the intent is dosimetry, industry recommends removing the statement requiring use of "the maximum." Doses should be accurate, not conservative.	**MAJOR**	There is potential for significant dose overestimation.
16.	**5.6**	It is impractical to implement the final sentence in the draft, which currently reads, "If neutron fields are non-uniform, personal dosimeters that measure Hp(10) from neutron radiation may be worn near the eyes to provide a conservative estimate for dose to the lens of the eye. Note that this is in addition to neutron dosimetry used to monitor dose to the whole body.	Remove this reference from the REGDOC	Clarification	
17.	**6**	In the 1st sentence, *RPR* is in italics. Is this intentional, or just a typo?	Remove the italics for RPR	Clarification	

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18.	**6.2 and 7**	Licensees have practical concerns with passages in both sections that suggest current information published by the ICRP should be used. Software (such as IMBA) that incorporates the most recent ICRP recommendations significantly lags the publication of those recommendations, which creates significant challenges for licensees to implement and update programs. Specifically, - Section 6.2 says, "The latest dose coefficients published by the ICRP should be used when available." As indicated, this would require significant time and resources to implement. - Section 7 reads, "When such data are not available, the values may be obtained from current ICRP publications and should be based on conservative assumptions of solubility." The reference to "conservative assumptions" is not appropriate. - Footnote 8 in Section 7 states "ICRP Publications 119 or more recent publications when published"	For future drafts of the REGDOC, the CNSC is encouraged to: - Recognize the practical challenges licensees face to obtain the most current ICRP information owing to software limitations. It can be several years before there are computational tools available to incorporate the newest versions. - Consequently, decide on now best to adopt new ICRP guidance and allow licensees a transition period for implementation. - Note that dose conversion factors referenced in Section 7 should be based on ICRP defaults when site-specific solubility is not known, not the "conservative assumptions."	Clarification	
19.	**6.2**	The final sentence in this section cites "the CNSC's Radionuclide Information Booklet" but gives no proper reference to it.	Include a proper reference to the booklet in the REGDOC's reference page.	Clarification	
20.	**6.3**	The final bullet point in this section contains a new requirement since only licensed activities listed in a dosimetry service licence are required to be reported to the NDR. Assessing dose from skin contamination events is performed and dose records are maintained in licensees' system. Currently, dose change requests are required only for doses previously reported to the NDR. The licensee may be able to assess the equivalent dose within routine NDR reporting cycles.	Clarify whether the NDR will identify these records different from the records that are submitted arising from TLDs. If yes, then DCR not required.	Clarification	

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21.	**6.3.3**	Industry has concerns with the 5th sentence, which indicates the process for measurement of skin contamination places "the detector as close to the skin as possible without direct contact." This is an issue because then dose rates cannot account for air attenuation or even geometry without a known distance.	Amend the sentence to read, "The measurement should be taken with the detector placed to a ~~as~~ close, known distance to the skin (e.g. 0.5 cm) as possible without direct contact."	**MAJOR**	Calculation of accurate skin dose requires a controlled geometry.
22.	**6.3.3**	Industry believes the final sentence could be clarified since radiation safety officers are not required in most cases.	Amend the final sentence to read, "The radiation safety officer or equivalent radiation protection authority should be consulted for specific guidance."	Clarification	
23.	**6.3.4**	The area assumed for contaminated skin must be 1 cm^2 for dose purposes, as per the Radiation Protection Regulations	Correct the formula to only allow the highest contaminated 1 cm^2 area of skin.	**MAJOR**	The REGDOC does not conform to the *Radiation Protection Regulations*.
24.	**6.3.4, Table 4**	As per comment #1, it is unclear if the CNSC is mandating the use of these DCFs in dose assessment.	Confirm this is a suggestion/recommendation and not a requirement.	Clarification	
25.	**7**	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. In addition, there is an inconsistent use of the sub-script in the ALIinh formula in this section. The subscript, e_{in} should be written as e_{inh}	Amend the formulae to conform to all relevant regulations. Use the subscript e_{inh}	**MAJOR**	The REGDOC does not confirm to all relevant regulations, including the *Radiation Protection Regulations*.
26.	**7**	Licensees believe the final paragraph should reflect the ICRP 103 breathing rate of 1.1 m^3 per hour.	Amend to read, "The derived air concentration (DAC) is the concentration of a radionuclide in air, that when inhaled at a breathing rate of 1.~~1~~2 m^3 per hour for 2,000 working hours per year, results in …"	Clarification	

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27.	**8**	Licensees seek clarity on the following passage and associated bullets: "The radiological characterization relating to internal dosimetry and bioassay should provide a comprehensive description of the nature, extent and variability of surface contamination, airborne radioactivity and other potential sources of intakes, as appropriate, at all work locations. Including: • their chemical forms and related respiratory tract clearance types • the particle size (e.g., expressed as the AMAD), if applicable"	Please clarify what is applicable/ appropriate. Determining chemical forms, particle size, clearance types is not generally practical.	Clarification	
28.	**9.1**	Industry has significant concern with the 2nd sentence in the 3rd paragraph on page 27, which reads, "Urine bioassay programs designed for the purpose of dosimetry should be designed … to collect and analyze samples collected over a period of 24 consecutive hours."	Remove this statement.	**MAJOR**	This recommendation places significant burden on the licensee around submission and collection of samples. More sensitive test methods should permit analysis of smaller volumes and correction to Reference Person models for the purposes of screening, and urine volume corrections made where appropriate/required.
29.	**9.1**	Industry seeks clarity on the use of the phrase "chemical toxicity associated with nuclear substances…" in the 2nd sentence of the 1st paragraph. Chemical toxicity is commonly the domain of conventional safety, not radiation protection. It is not feasible to use activity measurements/monitoring to verify protection from chemical toxicity.	Amend the sentence to read: "More specifically, individual intake monitoring aims to ascertain workers' doses, to serve as an indicator of potential intake~~, to verify that workers are adequately protected from the chemical toxicity associated with nuclear substances~~, and overall, to support the licensee's radiation protection program."	Clarification	
30.	**9.1**	The last two bullets are indented on page 27. Though just a typo, it implies that creatinine concentration measurement alone must be combined with normalization by specific gravity.	Align the list so all bullets appear to carry equal importance.	Clarification	

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31.	**9.1.1**	The 2nd last sentence in this section should read as 1mSv/year.	Amend to read, "The criterion set for the bioassay participation is 1 mSv /year."	Clarification	
32.	**9.1.5**	The cited formulae for MDA are only correct if data is Gaussian, which leads industry to question whether the formulae are correct for low counts. Licensees recognize the true equations are complicated. However, 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.	Licensees strongly encourage the CNSC to review the formulae for MDA to ensure it is appropriate for low-level counting. The Gaussian formula is more sensitive to errors at low background levels than the MDA formula. The Poisson version should be included.	**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. Please see MARLAP Attachment 20A *Low-Background Detection Issues*.

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33.	**9.2**	Industry believes clarity is needed for the following parts of this section: - As currently written, there is a poor correlation in the 3rd paragraph between personal air sampler (PAS) and static air sampler (SAS) and a poor correlation between SAS and bioassay. The text establishes that SAS results should be used with caution, but the caution is then extended to PAS without a logical connection. - In the 6th paragraph, specific international standards/guidelines should be cited in the passage "The calibration methods should be based on a current method recommended by the American Conference of Governmental Industrial Hygienists or the U.S. Occupational Health and Safety Administration. - In the 7th paragraph, a minor edit would clarify the intent.	For clarity: - In the 3rd paragraph, remove PAS so it reads, "SAS ~~and PAS~~ results should be used with caution…" - Revise the 6th paragraph to include specific document number(s). - Amend the 7th paragraph to read, "The licensee should demonstrate that the air sampled is representative of breathing zone air when the ~~whenever one or more of the following conditions exist: (i)~~ personal air samplers are not worn within 30 cm of the worker's head and one or more of the following conditions exists: (ii) the workers' doses will be ascertained on the basis of air monitoring, and/or (iii) annual exposures are likely to exceed 100 DAC-hours (or the annual CED resulting for inhaled radionuclides is likely to exceed 1 mSv)."	Clarification	
34.	**10.1**	Clarity is sought for the following: - Is the statement that the IL should not exceed 5 mSv accurate? The document earlier states measurement is required where the potential for dose exceeds 1 mSv.	The disconnect between the IL statement here and what is required for potential dose should be corrected.	Clarification	

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35.	11	The basis for the recommendation to modify fr, and Ss, but not Sr, to get a proper fit is unclear. Generally, the ICRP 66 factor that should not be altered is f1, not the material solubility parameters. Is there a typo in this section? Industry recognizes this is a way to change the fit, however, there are other parameters and factors that can be varied (e.g. intake time, intake pathways, etc.) that would appear to be more appropriate to start with.	Add further referencing and/or justification for this method or consider revision.	Clarification	
36.	**11&14**	The use of the word "intake" appears to be applicable to both the terms "intake" and "uptake" in ICRP 119.	Please confirm if industry's understating Is correct.	Clarification	
37.	14	Step 4 of the steps for monitoring a contaminated wound states that equivalent dose to the skin should be ascertained from measurements of contamination in the wound. While this is part of the input data, it is not the only input and for some radionuclides may not be overly useful.	Amend Step 4 to say the equivalent dose to the skin should be determined using data from Steps 2 and 3.	Clarification	The direction is not appropriate for all radionuclides.
38.	14	The formula $I \times e_{inj}(50)$ is not applicable for a NEW below the age of 18.	Include a footnote to remind readers this formula applies to 18 years and older (NEW) consistent with Radiation Protection Regulations and ICRP.	Clarification	
39.	14, Table 11	No units are cited. Also, it's unclear whether or not wound dose assessment must be performed using NCRP Report 156 recommendations or other models.	Cite the units, which reviewers suppose are Sv/Bq intake? Confirm if wound dose assessment must be performed using NCRP Report 156 recommendations or other models.	Clarification	

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40.	Appendices	As per comment #1, the appendices in this draft REGDOC are overly prescriptive. Often, it is difficult to decipher what is required versus suggested. In general, requirements should not appear in appendices if they have not already identified in the main text of the document.	Review all appendices and ensure the differences between requirements and guidance is distinct and unmistakable	**MAJOR**	Many of the statements are offering singleton solutions to things that have other technically supported ways of answering. Extensive time and effort needed for no reason to have things done only one way. Makes document hard to critique because could be major implications or none.
41.	Appendix B.1 & E.2.1	The potential intake fraction does not mention the role and place of respirators in reducing intakes. Most intakes are further protected by the donning of respiratory protection. Without this factor, the PIF is significantly reduced in effectiveness.	Include a note on respirator factor equal to the reciprocal of the respirator's protection factor.	**MAJOR**	Most intakes are further protected by the donning of respiratory protection. Without this factor, the PIF is significantly reduced in effectiveness.
42.	Appendix C.5	The provided curves in Figures C-1 and C-2 are not normalized to any provided intake or discernable information. The charts are confusing and could be applied incorrectly by licensees. They do not provide appreciable value without comparison to detection limits.	Remove charts. Or, if it is felt the charts support readers' comprehension of the text, consider removing the units from the y-axis and replace with "log scale" or something similar to convey the message.	**MAJOR**	As currently depicted, the charts may cause confusion.
43.	Appendix C.8.4	Failure to maintain the samples refrigerated does not degrade the activity contained in the sample. Therefore, this should be a "may"? Maintenance of fecal samples as frozen has typically been a matter of worker comfort and not a regulatory issue.	Replace the word "must" with "may" or remove this passage completely.	Clarification	
44.	Appendix C.8.5,	Failure to maintain the samples refrigerated does not degrade the liquid radio bioassay samples. This statement is not needed. Also, as per comment #1, it is unclear as written if the information in Table C-1 is a recommendation or a requirement. This follow up sampling regime is not currently implemented in licensee bioassay programs.	Remove the statement regarding "frozen state during transport" and confirm the information in Table C-1 is a recommendation, not a requirement.	Clarification	

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45.	Appendix D.2	There is no specific reference provided for the criteria that is detailed.	Include the reference used for the criteria so the technical basis can be better understood. Ensure there is wording to permit this practice and do not mandate the calculations or references that must be used, since CNSC staff have the ability to "approve" the proposed method and grant licenses based on the approved program technical bases.	**MAJOR**	Licensees with approved, well established dosimetry programs for ascertaining tritium doses may not have exactly the same equations or calculation method documented in their programs and may use other references.
46.	Appendix D.3	The accumulated dose, E_k, received during the reporting period k, should be calculated from a series of N measurements of tritium in urine made during period k, as shown below. There is no reference provided for the equations provided. Also, the equation used by licensees to calculate tritium CED differs slightly from that provided in this document. This is primarily due to slightly different methodologies used (e.g. ICRP vs first principles from beta energy).	Include the reference that was used for equations 25, 26 and 27. As per comment #1, please confirm that it is not a regulatory requirement that the same equations be used by all licensees if the method of calculation here is approved by the CNSC.	**MAJOR**	Licensees with approved, well established dosimetry programs for ascertaining tritium doses may not have exactly the same equations or calculation method documented in their programs and may use other references. Ensure there is wording to permit this practice and do not mandate the calculations or references that must be used, since CNSC staff have the ability to "approve" the proposed method and grant licenses based on the approved program technical bases.
47.	Appendix E.2.2	It is not clear why a threshold of 1 kBq was selected for a screening of 2 meters from a suspected exposure.	Provide the rationale for this selection.	Clarification	
48.	Appendix E.5	Is this section intended to be applicable to routine iodine work? For routine iodine related work, for example an iodine facility or filter test using radioiodines, the guidance for needing the thyroid screening as per the suggested monitoring period becomes too onerous and not practical to implement.	Suggest mentioning that licensees can determine a different monitoring period for routine iodine work.	Clarification	
49.	Appendix E.8.3,	"Section 9.1.6" does not exist. Is it "Section 9.1.5"?	Clarify	Clarification	