From: Wassenaar, Richard <personal information redacted>
Sent: July 15, 2019 11:49 AM
To: Consultation (CNSC/CCSN)
Subject: Nordion Comments on June 15, 2019 Notice, Canada Gazette, part I, Volume 153, Nubmer 24
Attachments: Nordion Comments to RPR revisions.pdf

Good Morning,

Attached, please find Nordion's comments to the proposed revisions to the Radiation Protection Regulations.

Should you have any questions, please don't hesitate to contact me.

Sincerely,
Richard

Richard Wassenaar, PhD, MCCPM, CHP
Director, Regulatory and EHS
Nordion
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Nordion
A Sotera Health company

July 15, 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 Canada Gazette, Part I, Volume 153, Number 24, Notice of June 15 2019

Dear Mr. Torrie,

Nordion wishes to thank the CNSC for the opportunity to comment on the proposal changes to the Radiation Protection Regulations, as outline in the notice of June 15, 2019 in the Canada Gazette, Part 1.

Attached, please find a table of industry comments that Nordion has participated in creating. Specifically, Nordion has concerns over the following:

1) The new regulations propose to provide pregnant and breastfeeding women the decision to self-disclose their situation. Nordion is in agreement with this change. However, the regulations must ensure that any obligations of a licensee with respect to providing accommodating work or emergency response duties for pregnant and breastfeeding women are only applicable once a woman has self-disclosed to the licensee.
2) As part of the change for women to self-disclose their pregnancy, there is an additional requirement being introduced for licensees to inform female nuclear energy workers of the risks associated with exposure of the embryos and fetuses to radiation and risks to breastfed infants from intakes of nuclear substances. There is a significant amount of information surrounding this area of health physics from numerous sources. Many licenses may not be equipped to properly compile this information into something that can be presented in an informative way. The CNSC should assist licensees by providing a summary of such risks.
3) The addition of Subsection 20(3), exempting containers used for temporary storage of radioactive substances from paragraph (1)(b), will help reduce an administrative burden that does not have any clear safety benefits. However, it is not clear exactly how this new regulation will be interrupted by various stakeholders (i.e. inspectors vs. licensees). Further discussions between licensees and the CNSC would be beneficial to ensure this regulation is properly understood.

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

Sincerely,

Richard Wassenaar
Director, Regulator & EHS

Attached: Industry Comments on Canada Gazette, Part 1, Volume 153 Number 24

Nordion
A Sotera Health company

Industry comments on Canada Gazette, Part I, Volume 153, Number 24 Regulations Amending Certain Regulations Made under the Nuclear Safety and Control Act (Radiation Protection)

#	Document/ Excerpt of Section	Industry issue	Suggested Change *[if applicable]*	Major Comment/ Request for Clarification [1]	Impact on Industry, if major comment
1.	RIAS, Section 13	Contrary to the RIAS, the details of how radon progeny are to be calculated in effective dose are not in the current draft of *REGDOC-2.7.2, Dosimetry: Ascertaining Occupational Dose.* This is a significant omission for licensees of uranium mines and mills. Please see related comments 12 and 13.	The regulations should detail the method for how radon progeny is included in the effective dose calculation for uranium mines and mills; specifically, the dose conversion factor between WLM and mSv.	**MAJOR**	For licensees of uranium mines and mills, the removal of how radon progeny is calculated from the regulations (and REGDOC) means there is no clear review and consultation process for any proposed changes to the dose conversion factor from exposure (WLM) to dose (mSv). How radon progeny is included in the effective dose calculation is fundamental to the determination of whether the dose limits are being met. As a result, there is a need for clarity on both the actual calculation and the process or changes. Since there is no cost identified with this change, it is assumed the CNSC intends to continue to accept the current conversion factor of 5 mSv/WLM. However, this is not documented in the current draft of *REGDOC-2.7.2*. If a change to the radon progeny dose conversion factor is proposed in the future, it should undergo a Regulatory Impact Analysis equivalent to that done for regulations. The CNSC committed to a technical review and consultation specific to a change to the dose calculation for radon progeny in *DIS-13-01 Proposal to Amend the Radiation Protection Regulations* (pg. 12).
2.	RIAS, Section 14, para. 1	In 2016, the United States Nuclear Regulatory Commission decided not to proceed with rulemaking in this area because it would result in little, if any, improvement in occupational or public safety. (Please see U.S. Federal Register /Vol. 81, No. 249). In fact, recent scientific research suggests it is not possible to establish a link between radiation exposure and cataract production. These findings call into question whether there is an identifiable threshold for cataract formation.	Amend to read, "Radiation exposure to the lens of the eye, above a threshold dose, has been linked to its opacification (or clouding of the lens, which in its advanced stages, is referred to as a cataract). Data has shown that personnel involved in industrial radiography and medical diagnostic and interventional radiology have a higher risk."	**MAJOR**	Even if the scientific research supported a measureable linkage between dose and cataract formation, Nuclear Energy Workers at most nuclear facilities are largely unaffected by this type of exposure. The CNSC should clarify there are workers in the medical and NDE fields who may not be sufficiently protected and it is these individuals they are targeting with the amendments.
3.	RIAS, Section	Industry has significant concerns with the	Delete the second bullet and	**MAJOR**	The proposed 5-year limit creates a significant administrative burden

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	14 para. 3, bullet 2	proposed introduction of a 5-year limit in the section on equivalent dose limits for the lens of an eye. If passed, this new limit would introduce significant operational challenges to licensees with no improved safety benefit to workers. Specially, the 1st bullet in Section 14 sets a target of no single year exceeding 50 mSv. However, the second bullet sets a 5-year limit of 100 mSv, which is effectively a 20 mSv limit for any given year.	recognize that licensees should be expected to minimize dose to the lens of the eye through their ALARA (as low as reasonably achievable) programs.		only to demonstrate that Nuclear Energy Workers are sufficiently protected from a threshold of questionable validity. Also, there could be an impact on the livelihood of tradespeople who will be subject to dose estimates based on overly-conservative surrogate measurements. Boilermakers and other tradespeople who work at multiple licensed sites will receive overly-conservative dose estimates at each of the sites. This will cause them to prematurely approach the permissible dose limits and impact their availability to do radioactive work. Canada already faces an undersupply of talented tradespeople and an overly-conservative 5-year limit will only exacerbate that issue with no corresponding benefit to worker safety. While industry believes it can adapt to the proposed reduction in the current limit from 150 mSv to 50 mSv in a one-year dosimetry period, the 5-year limit does not enhance safety commensurate with its associated challenges and, therefore, is inconsistent with industry's ALARA principles.
4.	RIAS, Regulatory Development, para. 4	Industry concerns went beyond the administrative and financial burden. They questioned the science behind the threshold and limit and the absence of a methodology for measuring lens of the eye dose in mixed radiation fields. Licensees suggest the CNSC conduct an epidemiological or health effects study on Canadian nuclear energy workers regarding radiation-induced lens of the eye opacification/cataracts.	Amend to read, "However, they questioned the benefit of some of the proposed changes given the potential administrative and financial burden. They also specifically challenged the scientific credibility of the linkage between a lens of the eye dose threshold and cataract formation."	**MAJOR**	Worker safety is industry's top priority. As written, this falsely implies that licensees were only concerned with financial impacts. As per comment #3, Canadian industry already faces an undersupply of talented tradespeople and an overly-conservative 5-year limit will only exacerbate that issue with no corresponding benefit to worker safety.
5.	RIAS, Regulatory Development, Section 14, bullet 3	The text suggests that stakeholders are comfortable with workers receiving health effects such as cataracts. Stakeholders were, in fact, opposed to treating, or suggesting that cataracts be treated, as equivalent to cancer-related dose effects.	Amend to read, "claiming that the change in the dose limit is not warranted~~, considering that the health effects (cataracts) are regarded as easily treatable~~;"	**MAJOR**	Worker safety is industry's top priority. As written, this falsely implies that licensees are comfortable with workers receiving health effects such as cataracts.
6.	RIAS, re.	The 4th bullet is incomplete and contextually	Amend to read, "… citing significant	**MAJOR**	Worker safety is industry's top priority. As written, this falsely implies

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	Regulatory Development, Section 14 bullet 4	inaccurate as currently written.	financial and administrative burden with the proposed change and the associated impact on their operation, in particular for those exposure situations with non-uniform fields where the lens of an eye dose could be the limiting exposure for workers because of the need to conservatively estimate rather than measure the exposure."		that licensees were only concerned with financial impacts.
7.	RIAS, Regulatory Development, Section 14, 2nd para., last sentence	As per comment #1, the US NRC rendered a decision not to proceed with rulemaking in this area, because of the lack of a clear safety benefit.	Delete the final sentence, ~~"However, it is clear that lens opacities and resulting radiation-induced cataracts are a health effect that can and should be prevented."~~	**MAJOR**	This is a misrepresentation. The results are inconclusive and subject to challenge and that should be reflected here.
8.	**RIAS, Regulatory Development,** Sections 8 and 14	No rational is provided for distinguishing between the skin as a whole, and the skin of the hands and feet. The proposed change to "skin of the hands and feet" could add more confusion than clarity. Section 14(3) states that "when the skin is unevenly irradiated, the equivalent dose received by the skin is the average equivalent dose over the 1 cm^2 area that received the highest equivalent dose." Therefore, all dose received by the "skin of hands and feet" must be included in skin dose, because the skin is unevenly irradiated.	For clarity, remove the term "skins of the hands and feet" for the following reasons: 1) the ICRP has never defined what "hands and feet" mean 2) the limits for "skin" and "skin of the hands and feet" are the same 3) it would close any distinctions that might allow a single location of the skin to receive up to 1 Sv of dose merely because it occurs on a hand or foot	**MAJOR**	It would still not be clear to industry how to apply the equivalent limit to the hands and feet.
9.	**RIAS, Section 20,**	Industry has significant concerns with the section on labelling and believes a workshop with CNSC staff is necessary to ensure common understanding.	Industry requests the CNSC host a workshop to ensure the requirements are clearly understood and key terms defined.	**MAJOR**	For containers intended to be used only within the licensee's facility, like those for waste, adding specifics on radionuclides inadvertently creates a safety risk when staff are trained to evaluate risk based on hazard conditions (dose rates or air concentrations). Waste cans are frequently

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		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 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. Also, the exemption cited in this section does not apply to containers and devices in a designated posted area which imposes measurement requirements that are unnecessary.	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.		emptied by trained and qualified staff. There is also an administrative burden that would require each bag or container to be sampled, analyzed, tags printed and affixed to the item. Also, clear regulations promote better compliance. The absence of definitions can lead to licensees' interpretations which may not meet the intent of the regulation's requirements.
10.	RIAS, Table 1	The analysis does not account for the additional staff that will need to be hired, on-boarded, trained, etc. to take the place of those staff that prematurely approach their permissible dose limits. Also, no formal request has been made for cost information. An informal request was responded to in December 2018, but there has been no follow-up discussion.	As per comment #9, industry requests the CNSC workshop include a review of its cost model and the discrepancies between the RIAS and the impacts provided by industry.	**MAJOR**	Incomplete / inaccurate cost information. Changes to resourcing needs would be significant with no corresponding benefit to nuclear safety. Some licensees estimate the changes could cost an additional $6-12 million for maintenance and major component replacement outages. Other licensees estimate up to $500,000 will be required initially - and $250,000 annually - to amend work practices/procedures to comply with the proposed limits.
11.	One-for-One Rule	Industry disputes the statement, "The CNSC does not expect the proposed Regulations to increase the administrative burden of	Delete this statement.	**MAJOR**	Operating experience confirms that changes of this type have significant impacts on administrative burden as per comment #10.

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		licensees or applicants. Therefore the One-for-One rule does not apply to the proposed Regulations."			
12.	1, 5(1), 5(2), 19(f)	The definitions of radon and radon progeny 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 REGDOC 2.7.1	Amend the document to clarify that it applies to exposures occurring as a direct result of a CNSC-licensed activities (e.g. uranium mines and mills) only and that radon and radon progeny from natural sources do not need to be included in effective dose calculations.	**MAJOR**	Without clarity, the inclusion of radon and its progeny could lead some to misinterpret that dose from naturally occurring radon progeny must be ascertained. The concept of effective dose sufficiently captures the whole-body dose from all sources of radiation resulting from licensed activities.
13.	[illegible]	Contrary to what is stated in the RIAS, the definitions of *working level* and *working level month* have not been included in the current draft of *REGDOC-2.7.2* to support the calculation of effective dose.	This term should be defined for uranium mines and mills only throughout the document.	**MAJOR**	Uncertainty and inconsistency.
14.	7 (1) (d) and 10	Bullet (d) of Section 7 (1) changes the requirement to provide a "worker's radiation dose levels" to the "worker's radiation dose levels received on an annual basis." Licensees may not be able to collect workers' personal addresses or other contact information.	Add a bullet to Section 10 on NEW obligations that says, "*(f)* the worker's current mailing and/or email address"	**MAJOR**	Industry needs supporting regulations to require NEWs to provide a current mailing/email addresses so licensees can meet this obligation.
15.	7 (1) (e)	The requirement to inform all NEWs of their duties and responsibilities during an emergency may not be realistic depending on the level of detail expected. Emergencies, by their very nature, are not always predictable and it may not be possible to accurately foresee the emergent conditions.	Amend the requirement to specify providing a general description of expected responsibilities during emergency scenarios and include an explanation of risks with doses up to the emergency dose limits without explaining specific responsibilities.	**MAJOR**	Depending on the level of detail expected, this may be impossible with several thousand nuclear energy workers on some sites at any given time. Without clarity, this could unintentionally create instant and widespread non-compliance.
16.	7 and 11	Industry supports the repeal of the provision for a female NEW to self-disclose her pregnancy to	Amend the regulations to clarify that the responsibility lies with the pregnant or	**MAJOR**	Without this, it is difficult for licensees to comply with the requirement to ensure that pregnant workers are not used in the control of an emergency.

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		the licensee as long as the regulations are clear with regard to licensees' obligations. This proposal aligns with the international practice of voluntary self-disclosure of pregnancy and nursing.	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.		Also, the risks and rights may have been given to the female NEW many years prior to becoming pregnant. Declaring pregnancy to the licensees affords an opportunity to provide her with the most current information and refresh her on the risks.
17.	8, 10 and 18	For the purposes of epidemiological studies using the National Dose Registry (NDR) data, "sex" (i.e. male/female) is the relevant quantity of interest, not "gender." It is unknown whether NDR will be updated to accept data for genders. If this change is made, the acceptable/expected genders should be defined and changes to NDR submission requirements communicated to licensees in advance.	Maintain "sex" as the descriptor.	**MAJOR**	At this time, adopting the term "gender" increases uncertainty since the change is inconsistent with reporting under the NDR.
18.	11 (1) and (2)	The requirement to accommodate workers as described is already covered by existing provincial and federal laws.	Remove the redundant requirements related to accommodations.	Clarification	
19.	11 (2)	As currently written, the regulations do not indicate whether a pregnant NEW can revoke her declaration of pregnancy.	Amend Section 11 to include the following: "A female nuclear energy worker may revoke, at any time, her written declaration that she is pregnant. Upon receipt of this revocation, the licensee must proceed as if it had never been informed of the pregnancy or breastfeeding."	**MAJOR**	Other jurisdictions allow pregnant NEWs to revoke their declaration. With the addition of the ability to voluntarily declare, it gives a female NEW a new method to cope with the psychological pain of spontaneous or induced abortion by simply revoking the declaration instead of informing the licensee of the fate of the foetus.
20.	14	The proposed new dose limits for the lens of an eye will be identical as the WB effective dose	Retain the 5 rem (50 mSv) per year equivalent dose, but remove the	**MAJOR**	There is no scientific consensus for the proposed 5-year equivalent dose of 100 mSv (10 rem), which current research shows is not required. As per

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		limits. Industry supports the reduction of the annual dose limit from 150 mSv (15 rem) to 50 mSv (5 rem), but opposes the proposed 100 mSv over a 5-year dosimetry period.	proposed 10 rem (100 mSv) over 5 years.		comment #3, the proposed 5-year dose would introduce operational complexities and administrative challenges to demonstrate that workers are below regulatory dose limits. In the absence of accurate dosimetry for lens of the eye in beta radiation fields, surrogate measurements would be used to provide a conservative estimate of dose. In turn, these conservative estimates would lead to the premature removal of workers from performing radioactive work.
21.	14	The proposed changes to the table to subsection 13 (1), Item 1 Column 1, does not convey that a pregnant NEW can revoke her pregnancy declaration.	This is not an issue if the suggested change for Section 11 is incorporated	**MAJOR**	A licensee would be forced, by the letter of the regulations, to maintain the special dose limit for a pregnant NEW unless the pregnant NEW has the ability to revoke her declaration.
22.	14	In the table to subsection 13 (1), the proposed dose limits allow for a lower dose limit for a child of a breastfeeding worker (1 mSv) (i.e. Person who is not a nuclear energy worker) than a foetus (4 mSv), when the foetus is more radiosensitive.	Amend to include the following note, "Subsection (1) does not apply in respect of a child of a breastfeeding NEW."	**MAJOR**	Without clarity, for I-131 for example, this would cause a disparity where a pregnant NEW could receive 4 mSv effective dose and her foetus would receive 11 mSv CED. But the same NEW with the now child, born on January 1st, would be limited to receiving 0.38 mSv effective dose per year because her child would be limited to 1 mSv CED (assuming I-131).
23.	15	The proposed change to subsection 14(1) provides no definition of equivalent doses. Having one is important in the context of the dose limit regarding the lens of the eye.	Define equivalent doses in Section 14 (1) (i.e. the equivalent dose for the lens of the eye is Hp(3), or accepted alternative).	**MAJOR**	Without a definition, particularly in mixed radiation fields, there is uncertainty around measurements of true Hp(3) doses and potential for significant overestimation. In addition, a definition would require dosimetry providers to show how estimation algorithms estimate the Hp(3) dose, as opposed to what they would consider an "eye dose".
24.	15	While there are no proposed changes to *Section 15, Emergencies*, licensees believe there is an opportunity to add clarity to this section while the regulations are being amended. Please see the requested change in the next column, which is an expectation/interpretation mentioned in other regulatory documents (*REGDOC 2.10.1, Emergency Management and Fire Protection, Volume II* and *REGDOC 2.7.1, Radiation*	Include a statement in Section 15 of the amended regulations to read: "Dose received from emergency response activities should be treated separately from regular occupational doses."	Clarification	

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		Protection). Reinforcing this in the RPRs would create additional clarity.			
25.	**15**	Regarding the table for Section 15 of the regulations, given that the equivalent dose limits for items 2 and 3 are the same, and they both refer to skin equivalent doses, it is not obvious why they need to be differentiated.	If the separate listing of dose limits for items 2 and 3 is meant to force different reporting and dosimetry requirements, that should be clarified somewhere in the RPR, potentially in Section 5.	Clarification	
26.	**18**	The definition of "management system" cannot be found in the regulations. Also, industry has no issue with the replacing paragraphs 18 (b) and (c) in the regulations as long as the changes in terminology do not introduce new requirements.	Include a definition for "management system" and confirm the terminology changes in 18 (b) and (c) carry no new requirements.	Clarification	
27.	**20**	Licensees have concerns with proposed changes to Section 21. For licensees with facilities designed for the purpose of processing large volumes of radioactive material, e.g. uranium mills, there is little benefit to putting signage on every entrance to those facilities indicating that the radioactive material is present.	Add a subsection to exempt the application of s. 21(1) to facilities whose purpose is the bulk processing and handling of radioactive materials. Also, licensees request the rationale behind the change to posting to vehicles in Section 21. Industry believes this better covered by a REGDOC.	**MAJOR**	Maintenance of a significant number of signs creates an administrative burden with no corresponding safety benefit. Operating experience shows too many signs can actually create confusion, not clarity.
28.	**22**	Industry has significant concerns that Section 24.1 is overly broad as currently written. This concern also relates to RIAS Section 22: *Proposed new section on radiation detection and measurement instrumentation.*	Industry believes the subtleties of language are very important in this area and propose this be discussed as part of the workshop proposed in comment #9. Specifically, licensees urge the CNSC to amend 24.1 to read, "Every licensee must ensure that instruments and equipment ~~that are~~ used for radiation measurements related to direct, personnel protection are selected, tested	**MAJOR**	"Radiation measurements" include in-core flux detectors and other detectors related to radiation processes not related to radiation protection. As written, it would be illegal to have a licenced fixed gauge out of calibration because it would not be "calibrated for" its intended use (because it 'measures radiation'), having nothing to do with Radiation Protection.

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			and calibrated for their intended use."		
29.	25	Compliance for using new dose factors (0.12 and 0.88) should align with the effective implementation for new eye dose limits which is Jan 1, 2021.	Revise to align with the new lens of the eye dose limits.	**MAJOR**	Without adequate time for implementation, industry could be in non-compliance with the new regulations upon their publication.
30.	25	Compliance with s. 15(2) within the proposed transition period is not possible. Industry notes that in Europe, this took five years to implement.	Section 15(2) should not come into effect until January 1, 2024 to allow for dosimetry services for mixed radiation fields to become available for monitoring of Hp(3). This is consistent with the implementation period in Europe.	**MAJOR**	This is currently an evolving field, and there are no certified dosimetry services in North America that provide Hp(3) for mixed radiation fields.
31.	Part 3	Industry has concerns with a subjective concept such as ALARA (as low as reasonably achievable) being explicitly tied to administrative monetary penalties as they are in Items 2-5 in Part 3.	Remove the phrase "as low as reasonably achievable" from Items 2, 3, 4, 5.	**MAJOR**	It is inappropriate to link a subjective concept with a monetary penalty.
32.	Part 3	Industry has concerns with Item 34, provision 15(7), "Requesting a pregnant woman to participate in the control of an emergency"	Amend to read "Requesting a NEW who has declared pregnancy to participate in the control of an emergency."	**MAJOR**	Unless a pregnant woman was required to declare pregnancy, it is possible that a licensee could unknowingly request a pregnant woman participate in the control of an emergency.
33.	Schedules 1 and 2	Changing the tissue weighting factors and the radiation weighting factors to match ICRP 103 recommendations would invalidate all previous dose conversion coefficients. The ICRP has yet to release all dose coefficients based on the 2007 recommendations.	Retain the weighting factors from the ICRP 60 recommendations until all current dose coefficients are updated to the new recommendations. The other option would be to treat either set of weighting factors as equally valid.	**MAJOR**	Industry would have to self-fund the development of dose conversion coefficients for all radionuclides and situations, something the international community of Health Physicists has yet to do. This cost is not considered in the regulatory impact statement.
34.	**Schedule 2**	It is assumed that a spelling error is present in item 3 of schedule 2, and such the correct reading is "Protons and charged pions."	Change the first instance of "neutrons" to "protons" as per ICRP 103.	**MAJOR**	Without a change, the regulations would not provide a radiation weighting factor for protons.
35.	**Schedule 2**	Column 1 specifies "all energies" for some types	Remove "energy range" and "all	**MAJOR**	Leaving the table as proposed would make items 3 through 5 technically in

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		of radiation so that "energy range" does not appear necessary.	energies" as they are redundant. See ICRP 103.		error because column 1 does not denote an energy range.
36.	Schedule 2	As currently written, the industry could lawfully use *any* "continuous function of neutron energy" as a weighting factor.	Reference the continuous function of neutron weighting factor from ICRP 103. The alternatives would be to provide a graph like schedule 3 of the RPR or include the equations directly to reconstruct the function.	MAJOR	Industry would not be able to follow the same standard without this clarification.