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Re: Discussion Paper DIS-24-01

To Whom It May Concern,

I am providing comments on the Canadian Nuclear Safety Commission's (CNSC's) proposed changes to the Packaging and Transport of Nuclear Substances Regulations (PTNSR) and the Nuclear Substances and Radiation Devices Regulations (NSRDR), as documented in the Discussion Paper DIS-24-01.

Most of the proposed changes are acceptable as-is: they are not significant changes and should not overly impact anyone's current operations. I would suggest, however, that any changes made to align expectations (remove inconsistencies) be done by referencing the currently accepted text. Duplication of text can lead to issues/conflicts in interpretations, and difficulties when future amendments are proposed. For example, the alignment of the retention period of 5 years for dosimetry records, as noted in Part I, 6.1, could be done by cross-referencing the Radiation Protection Regulations (RPR) in the PTNSR. This would be similar to the note in Part I, 6.2, where the definitions from the RPR will be referenced. Similarly, Part I, 6.8 implies that the text regarding using a licensed dosimetry service provider will be added to the PTNSR, rather than having the PTNSR cite the RPR for this information. These are just some examples; cross-referencing (citations) should be done throughout many of the suggested changes in DIS-24-01, rather than duplicating information.

With respect to the following items, I would ask the CNSC to reconsider these proposed changes:

1) Part I, 6.3 (monitoring of the extremities: skin)
   As already noted by the CNSC, this would primarily affect carriers. However, I believe it is an unnecessary burden to place on carriers to properly analyze which employees could possibly be handling radioactive packages over the course of a year, wherein that extremity dose level (50 mSv) could be exceeded. Although I suspect the CNSC does not

anticipate carriers to actually exceed an extremity dose limit, the regulatory burden still exists. It would require almost a yearly evaluation of the employees handling packages across the country, especially as the quantities, activities, and locations of packages being delivered can be highly variable with time. These people are not actually working *with* radioactive materials; they are handling packages that *contain* the radioactive materials. And the personnel turnover in the transport business is also fairly high, complicating the possible analysis, issuance, and compliance for the wearing of extremity dosimeters.

Historically, the placement of a dosimetric limit to the skin by the International Commission on Radiological Protection (ICRP) was out of concern for cosmetic reasons (ICRP 26)[1 ICRP 26]:

Skin

(63) In comparison with the tissues already discussed, skin is thought to be much less liable to develop fatal cancer after irradiation. However, cosmetically-unacceptable changes in the skin may occur after irradiation with absorbed doses of 20 Gy or more, delivered over weeks or months to limited portions of skin. Therefore, the use of this value, as a limit for exposure over the whole occupational lifetime, should prevent the occurrence of such non-stochastic changes (see also paragraph 103).

At the time, this newly-derived dosimetric system did not include skin as an identified tissue in the weighting factors for stochastic effects. As a result, skin (as a tissue) was included out of concern for non-stochastic effects, leading the ICRP to issue a dose equivalent* limit for the skin. If we assume the dose (especially in the transport setting) is accrued from photon-emitting sources, that 20 Gy (cosmetic concern) over a lifetime (~48 years; ages 18-65) becomes an average annual dose of 417 mSv; this is the basis for the 500 mSv limit for the shallow dose equivalent (SDE). This recommendation has been maintained over the years by the ICRP, despite the inclusion of the skin in the tissue weighting factors, despite the evidence that the relevant sensitive skin cells are found at different depths across the body, and despite the high acute dose threshold for skin reactions (~2,000 mGy). Even the CNSC has altered its tissue depth for the dose conversion factors for the palms of the hands to a more realistic 400 µm[2 CNSC], based on the updated information found in ICRP 89[3 ICRP 89] (making the measurement of the SDE at 70 um an improper tissue depth for the hands).

*the ICRP has since changed the term to equivalent dose

Additionally, in the case of carriers, if we assume the exposure is primarily via photons, the emphasis should be on whole body monitoring. Currently, it appears that of the tens of thousands of carriers across the nation, very few are monitored. The last published

data from Health Canada in 2018[4 HC] indicates 154 ground transport crew were monitored, with an average effective dose of 0.26 mSv and an average non-zero effective dose of 0.67 mSv. This suggests that the analysis already conducted for whole body monitoring has adequately identified the relevant personnel for monitoring purposes, and that there is no need to add the requirement for extremity monitoring.

2) Part I, 6.9 (instrumentation)
I am still concerned with the interpretation that contamination monitoring instruments be "calibrated". I agree that a properly functioning instrument is necessary, but determining an efficiency value every year is not verification thereof (it is simply the determination of a conversion factor per isotope for a specified source-detector geometry). If instruments that measure contamination are used by both licensees and non-licensees (e.g. – carriers) during the transport of dangerous goods, they should undergo proper quality control (QC) tests prior to use (e.g. – the constancy test with a check source, including tracking and trending over time). I would kindly request the CNSC consider emphasizing QC tests rather than efficiencies.

3) Part I, 7.1 (exempted medical isotopes)
Although the CNSC may not directly regulate contaminants included with the purchase of a source, they may be present within our medical isotopes at purchase, and they may hinder the disposal of medical waste (e.g. – Lu-177m with Lu-177). In terms of packaging and transport, it would be preferable that the contaminants present at production be included in this section. Additionally, the daughter productions should also be noted. Finally, the text in part 2(2)(n) should be written correctly and similarly as compared to part 2(2)(o). For example:

(2) These Regulations, except for sections 6 and 7, do not apply to the packaging and transport of a nuclear substance
(n) that is present in a load of waste, if
(i) that load is in transport,
(ii) it is not classified as radioactive material,
(iii) it has triggered a radiation monitor alarm,
(iv) there is no loss or dispersal of the material during transport, and
(v) the nuclear substance in the load has been determined only to be one or more of the following medical isotopes and/or their production contaminants and/or their daughter products: Chromium-51, Copper-64, Gallium-66, Gallium-67, Indium-111, Iodine-123, Iodine-124, Iodine 131, Lutetium-177, Radium-223, Radium-224, Rhenium-186, Technetium-99m, Thallium-201, Yttrium-90, or Zirconium-89.

4) Part II, 10.1 (definitions)
- Uniformly distributed.
It is difficult to comment when there is no definition provided; allow for comments once a definition is provided.

- Radiation device.
  Do not change the definition. This definition and the regulations regarding radiation devices are already somewhat vague and difficult to interpret, but in its current state, anything containing less than 1 exemption quantity (EQ) is *not* a radiation device. This means that servicing licenses are not required to service the device under this limited condition, technically allowing the department to dismantle the device (assuming the source it contains is less than 1 EQ and the device has been removed from the license). Pertinent text from the NSRDR:

radiation device means

(a) a device that contains more than the exemption quantity of a nuclear substance and that enables the nuclear substance to be used for its radiation properties; and

(b) a device that contains a radium luminous compound. (*appareil à rayonnement*)

servicing in respect of radiation devices, means any maintenance of a device, including installation, repair, or dismantling, other than maintenance that

(a) constitutes routine operating procedures as indicated in the manufacturer's operating manual for the device; or

(b) is authorized in the licence issued in respect of the possession or use of the device. (*entretien*)

General Exempted Activities

5 (1) A person may carry on any of the following activities without a licence:

(a) possess, transfer, import, export, use, mine, produce, refine, convert, enrich, process, reprocess, manage or store a radioactive nuclear substance if the activity or the activity concentration of the substance does not, at any one time, exceed

(i) its exemption quantity,

(ii) its conditional clearance level, or

(iii) its unconditional clearance level;

(b) possess, transfer, import, export, store, use, abandon, produce or service a sealed source that contains less than the exemption quantity of a radioactive nuclear substance;

(c) possess, transfer, import, export, store, use or abandon a radiation device, other than an exposure device, if the quantity of the nuclear substance or substances contained in the device is less than 10 times the exemption quantity;

Certification of Radiation Devices

Certification Requirement

11 (1) No person shall use a radiation device unless

(a) it is a certified model; or

(b) it is used in accordance with a licence that authorizes its use for development purposes.

(2) No person shall transfer a radiation device for use within Canada unless it is a certified model.

In Nuclear Medicine, the gamma cameras that house sealed sources for attenuation correction or for automatic QC testing are deemed to be radiation devices, and the manufacturers certify them as such. These sources decay and are replaced within the clinic under an expensive service contract, with the manufacturer holding the servicing license. With the current definition, a Nuclear Medicine department may choose to allow the source(s) to decay below 1 EQ, remove the device from the license, and dispose of the source properly (and possibly sell or transfer the gamma camera in whole or in part through a third

party vendor). Another option is to have the source(s) removed under the servicing contract, then the department may remove the device from the license, and again dismantle, sell, or transfer the gamma camera*. These devices *can* be used in clinical operations without the source(s). These are just a few examples of the possible disposition of a gamma camera that is also a radiation device. If the CNSC changes the definition with the intent to regulate a radiation device as "still a radiation device even though it may contain less than the exemption quantity" (only requiring *certification* if it can hold greater than an EQ), then how does the CNSC intend to handle a radiation device with no source? There is no direct text about using or servicing a radiation device with no source. I am not sure the CNSC has analyzed the impact of this change on Nuclear Medicine's gamma cameras that are radiation devices, but that can also be operated, serviced, dismantled, transferred, etc without being a radiation device.

*although the source housing/assembly is likely what is qualified as the "radiation device", departments buy/sell/transfer/dispose of the *entire* gamma camera, which includes that portion of it

5) Part II, 10.13 (instrumentation)
   As with Part I, 6.9, I would again emphasize that the emphasis should be on proper QC, for both contamination monitors and direct reading dosimeters (DRDs). As for DRDs, the CNSC has not allowed them to be used for legal dose records, and so sites use them for secondary purposes. Some of the DRD models may no longer be supported for calibration by vendors, especially the pocket ion chambers. Requiring formal calibration of DRDs may force cites to stop using these devices as additional tools within their radiation protection programs, which would not be best practice.

Sincerely,
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[1] International Commission on Radiological Protection (ICRP). Recommendations of the ICRP. ICRP Publication 26. Pergamon Press, Oxford, 1977.
[2] Canadian Nuclear Safety Commission. Radionuclide information booklet. 2018; accessed Apr 16, 2024 at https://api.cnsc-ccsn.gc.ca/dms/digital-medias/radionuclide-information-booklet-2018-eng.pdf/object?subscription-key=3ff0910c6c54489abc34bc5b7d773be0).
[3] International Commission on Radiological Protection (ICRP). Basic anatomical and physiological data for use in radiological protection reference values. ICRP Publication 89. Pergamon Press, Oxford, 2002.
[4] Health Canada. National Dose Registry. Report on occupational radiation exposures in Canada 2018. Government of Canada, Ottawa, 2019.