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General Comment

See attached file(s)

Attachments

Draft Regulatory Guide 8_39 OAS Comments (approved)

Organization of Agreement States

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September 26, 2019

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RE: Draft Regulatory Guide 8.39 (DG–8057) RELEASE OF PATIENTS ADMINISTERED RADIOACTIVE MATERIAL

To Whom It May Concern:

The Organization of Agreement States (OAS) Executive Board (Board) reviewed draft regulatory guide (DG), DG-8057, "Release of Patients Administered Radioactive Material" and offers the following comments.

1. Section A. Introduction
The DG states that 10 CFR 35.75 permits the release of a patient that has been administered unsealed byproduct material or implants containing byproduct material if the TEDE to any individual from exposure to the released individual is not likely to exceed 5 mSv. The footnote explicitly says this is a per treatment limit not a yearly limit.
Draft revision 3 of NUREG 1556 Volume 9 stated: Although the regulations are not explicit, licensees should consider implementing the 5 mSv 22 [0.5 rem] as an annual limit for multiple administrations during a calendar year. For more information on this topic see Regulatory Issue Summary (RIS) 2008-07, "Dose Limits for Patient 24 Release Under 10 CFR 35.75," March 27, 2008. However, this language is missing from final NUREG 1556 Volume 9, and now instructs readers to go to RG 8.39 for guidance. The OAS Board objects to changing the guidance from a yearly limit to a per treatment limit without any discussion or justification.

Do the values in Table 1 assume only one administration per year? If yes, this should be noted so that the licensee can adjust them accordingly if more than one treatment is expected or planned.

2. Section B. Discussion
Page six contains a formatting error. There should be a space between the third and fourth bullets.

3. Section C. Release of Patients Based on Measured Dose Rate Section 1.2, Table 1
The entries for Y-90 in Columns 1 and 2 refer to footnote "c," which states "Activity and dose rate limits do not apply because of minimal exposures to members of the public..." This contradicts the current "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Licensing Guidance" (February 12, 2016, Revision 9), found in the NRC's Medical Toolkit. On page ten of the guidance, it states licensees "...should commit to develop procedures that describe measures taken to ensure that radiation emissions, which may include bremsstrahlung, from each patient or human research subject permits his or her release in accordance with 10 CFR 35.75."

4. Activities and Dose rates That Require Instructions Section 2.1, Table 2
Similar comment to number three above. Y-90 value in table refers to footnote "b," which again states activity and dose rate limits are not applicable. This contradicts the commitment statement from the current Y-90 toolkit guidance.

Either the medical toolkit guidance should be revised to align with the Regulatory Guide, or the Regulatory Guide should align with the Medical Toolkit.

5. Pretreatment Discussions on the Administration of Radiopharmaceuticals Section 2.3.1
The last two sentences of the first paragraph and the two sentences that comprise the second paragraph are the same.

6. Staff Regulatory Guidance Section 2.3.2
Because the waste facility usually does not know the cause of the alarm, these loads are rejected and typically sent back to their point of origin, which triggers additional action by the waste hauler, state personnel, and the point of origin. This is a drain on available resources, time and money for the involved parties. Agreement State staff spend hours completing forms to issue Department of Transportation exemptions and contacting other states to inform them that loads will be returning to their state or passing through their state. Because these alarms have also resulted in actual hazards unrelated to medical waste, Agreement State staff must treat all alarms as if they are a potential public health risk.

To help reduce the number of responses to municipal waste alarms, the Board recommends that the guidance say that, while not required by regulation, licensees may want to provide instructions about holding waste to all patients.

7. Section 2.3.2 Patient Instructions
The Board suggests more details in the instructions to patients. Here are a few examples that some states have added for I-131.

- Drink plenty of clear liquids (water, juice, tea, etc.)
- Always sit when using the toilet.
- Empty your bladder at least once every hour for the first 8 hours.
- Get up at least once during the first night and empty your bladder.
- Flush the toilet twice to remove any radioactivity from the toilet bowl.

- Minimize your time with others and keep at least six feet away, especially from infants, children and pregnant women.
- Shower 2 - 3 times a day for the first two days.
- If whole fruits (e.g. apples, pears, etc.) are eaten it is recommended that sections be sliced off the core, rather than biting into the fruit whole. This prevents contamination of portions of the food that will be thrown away. In general, minimize the amount of uneaten food that has come into contact with your saliva. After five days of use, replace the toothbrush. The old one is to be placed with the trash being held for a month prior to disposal.
- Wash linen, personal clothing, towels, etc. separately from those items used by family members. A second rinse cycle is recommended.
- Avoid using disposable items, such as plastic utensils and cups, to minimize the amount of potentially contaminated waste generated. (Note that this conflicts with this draft which recommends using disposable utensils.)
- Limit close personal contact; keep approximately six feet of distance between yourself and others.

The Board recommends revising the wording on page 16 (10). Collect anything that is disposable and possibly contaminated in a strong plastic bag that won't easily leak or tear. Store these collected items for at least one month [or other time period specific to the radionuclide] before taking out to the curb or to the waste disposal facility in your town. This would include tissues, napkins, sanitary products such as incontinence pads, and scraps of food that came into contact with your saliva. The bag should be tightly closed and secured in a remote area of the garage, basement, etc. away from food, people and pets.

Also, the first sentence of the section states "The licensee should consider following precautions/measures for most patients…" It seems as though there should be the word "the" between "consider" and "following," so that the sentence reads "The licensee should consider the following precautions/measures…"

We appreciate the opportunity to provide these comments and stand ready to answer any questions you may have.

Sincerely,

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