November 1, 2021

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Washington, DC 20555–0001

Dear Dr. Tapp:

The OAS Executive Board (Board) appreciates the opportunity to comment on the Nuclear Regulatory Commission's (NRC) Draft Regulatory Guide 8.39, *Release of Patients Administered Radioactive Materials,* Revision 2 (RG 8.39) (RCPD-21-007). The Board offers the following questions and comments:

1. There is no doubt this will likely require additional effort on the part of the licensees regarding release. Has the NRC considered how many or what percentage of I-131 administrations are at or just below the current 33 mCi threshold and the impact this may have to the facilities who may be in a rural setting and not have the same level of access to a medical physicist who would be best suited to assist with release calculations? Could this create a health care equity problem regarding rural vs urban facilities?

2. Page 6, *Consideration of International Standards*: "The IAEA guidance is based on retained activity in the patient such that doses to a bystander would not exceed a few mSv (rem)." This seems like it is equating a "few mSv" to a few rem. This is not correct, or at least not a good way, of expressing dose equivalency.

3. Page 9, *Table 1. Basic Activity Thresholds for Radionuclides* (Table 1): Has there been any consideration to include any of the known alpha-emitting radionuclides that are in the research phase now, such as Ac-225, Th-227, and Pb-212 in the table?

4. Page 9, Table 1: With the significant change in the release threshold for I-131, i.e., from 33 mCi to 8.6 mCi, will there be any consideration regarding the threshold for Authorized User (AU) training requirements in 10 CFR 35.392 and/or 35.394? Although it is not specifically stated, there seems to be a correlation to the patient release threshold and the training requirements for AU's who administer I-131.

5. Page 11, Section 1.1 d. *Release of Patients Based on the Administered Activity*: Will a "hold time" trigger the requirements of 35.310 Safety instruction and or 35.315 Safety precautions?

6. Page 11, Section 1.2 *Release of Patients Based on the Measured Dose Rate* (Section 1.2): It may be appropriate to provide specifics on measurement of dose rate such as, "1 meter from the highest point on the patient with no shielding in between the patient and the potentially exposed member of the public" rather than just, "…if the measured dose rate at 1 meter from the patient…"

7. Page 11, Section 1.2: It may be appropriate to provide more information regarding the possibility of caregivers dealing with multiple patients, or the same patient who may have multiple treatments. For example, if a patient was 35 mrem/hr from an F-18 procedure, they can be released without instructions because the caregiver likely won't exceed 500 mrem. But what if there are multiple patients released to a nursing home with the same amount of activity, and those patients had the same caregiver? The caregiver could receive more exposure than allowed.

   Additionally, it may be appropriate to expand on the discussion including information on patients that are released from the nuclear medicine area but are still in-patients within the facility for other reasons. The release might be good enough for caregivers helping them to the bathroom, but not take into account blood draws or other medical tasks for the "released" patient.

8. Page 11, *Table 2. Basic Measurement Thresholds for Radionuclides* (Table 2): Some of the dose rate values in the table are less than background. These entries (C-14 and Sr-90) should have a footnote saying that patients may not be released based on measured dose rate.

9. Page 13, Section 1.3 *Release of a Patient after a Hold Time*: This section has licensees hold a patient for a period of time to allow for physical decay of the isotope. It's a lot of math for little benefit. The bystander dose drops much more by using effective half-life than by simply holding a patient and calculating physical decay. Why would a licensee choose to hold a patient instead of using effective half-life to release them? In practice, any licensee that holds a patient is going to do a calculation based on effective half-life to account for biological elimination of activity and then base release on retained activity or measured dose rate.

10. Page 15, *Table 3. Breastfeeding Activity Thresholds Assuming No Breastfeeding Interruption* (Table 3): Some of the activity values are in the nanocurie range. The tables should instead include a footnote for these isotopes saying the calculated activity is <1uCi and breastfeeding record retention is required, and instructions must be given.

11. The data in Tables 1, 2, and 3 should include commonsense cut-off values. For example, in Table 1 some of the isotopes have exceedingly high values, exceeding any dose that would ever be given in a medical setting. For practicality it seems like at some point RG 8.39 could generally state the patient can be released, i.e., for isotopes with Column 1 values that exceed 1000 mCi. As an extreme case, Rb-82 has a half-life of 75 seconds. By the time the patient is released, there is no activity remaining, why bother calculating the mathematical possibility of administering 26 curies to a patient?

12. Page 23, Section 4.2.2 *Patient Instructions* (Section 4.2.2): "It is understood that once a patient is released, the licensee has no control of the patient." Is the converse true, i.e., if the patient is an inpatient in the facility for reasons not related to the radiologic procedure and under the control of the licensee are, they then considered "not released"?

13. Page 23, Section 4.2.2: If an inpatient has a diagnostic scan and remains in the hospital are there any requirements analogous to 10 CFR 35.310 Safety instruction and/or 35.315 Safety precautions? It appears that these only apply to those procedures that require a written authorization.

14. Page 30, Section 6. *Material Separated from the Patient*: "Licensees must evaluate unique patient-specific situations following radiopharmaceutical therapy which could result in increased exposure

from radioactive material in body fluids, excreted in urine or feces to ensure dose limits are not exceeded." It would be helpful to add more to the discussion regarding the difference between the limits on public exposure from a released patient and the limits on public exposure from materials that may be excreted from that same released patient.

15. *Appendix B Patient-Specific Modifying Factors and Methods* (Appendix B): The page numbers of this appendix are listed as "Appendix C, Page C-1" etc.

16. Appendix B: As written, licensees who want to do patient-specific calculations must justify each of the four modifying factors. The patient-specific modifying factors for attenuation and geometry are complicated. For example, Appendix B, *Figure B-1. Example Patient Questionnaire for Determining Patient-Specific Modifying Factors*., how does a licensee estimate the patient's overlying tissue for attenuation and buildup? Even with the isotope-specific attenuation factors referenced, the licensee will still have to combine that information with an estimate of the patient's tissue thickness. The real gain with patient release is to minimize the dose in the few hours following release based on occupancy. It doesn't seem practical to put forth effort into the attenuation factor. It would be more practical to provide default values the factors that would allow licensees to collect patient-specific information only for biokinetics and occupancy.

17. *Appendix C Example Calculations:* Consider adding additional examples i.e., a patient release where the patient is breastfeeding, a patient release where licensee did not calculate the overlying tissue thickness and used a default value for attenuation, an example where the patient's return trip home is via public transit, etc.

Once again, the Board appreciates this opportunity to comment. We are available should you have any questions or need clarifications to our responses.

Sincerely,

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