June 22, 2016

Sophie Holiday
Office of Nuclear Materials Safety and Safeguards
U. S. Nuclear Regulatory Commission
Washington, DC 20555

RE: Opportunity to Comment on Draft Revision to the Radioactive Seed Localization (RSL) Licensing Guidance (RCPD-16-008)

Dear Ms. Holiday,
The Organization of Agreement States (OAS) Executive Board (Board) has reviewed the above document and respectfully submits the following comments. The Board has significant concerns with the proposed guidance, particularly concerning seed accountability and the elimination of the written directive.

General Comments:

1. The Board finds the guidance to be lacking on information concerning source accountability.
    a. Requirements for training and procedures should include more robust information regarding the loss of a seed in a patient.
    b. The patient should not be cleared/released until every single seed is verified/accounted for and an energy discriminating survey of the patient shows no seed activity remaining. There may be presence of other radionuclides in patient that could mask a standard survey.
    c. All staff involved in RSL procedures need to be trained. The training should emphasize identification of seeds both within patients and in tissue samples.
    d. Information should be added to the guidance to indicate that an X-ray of tissue sample is not enough to conclude on its own that the seeds were removed. There exist cases where this gives the impression that a seed was removed but instead it turns out to only be a surgical clip. Also, multiple angles may need to be taken if multiple seeds are used that obscure one another on a radiograph. If multiple seeds are used, licensees need to account for each and every seed.
    e. Procedures for surveying/finding lost seeds should include more than just your typical GM pancake; something more sensitive to low energy gamma would be ideal.
    f. Emergency procedures should be added on steps to be taken when a source is unaccounted for. The Board recommends listing some important pieces of

emergency response equipment in the guidance. Although these sources do not pose an immediate health risk, they can cause serious effects if a patient has an unintentional prolonged exposure.

2. The Board recommends adding an appendix which includes isodose/dose rate maps surrounding some of the various common seeds in a mostly homogeneous fatty tissue (since non-palpable breast lesions are where this is used frequently). The Board highly recommends some type of dose mapping around an arbitrary, say 200 uCi, source of the various isotopes/manufacturers. This way regulators can more easily discern dosages delivered, and through superposition can add cumulative doses to one another if multiple seeds are present.
3. The document title is unnecessarily wordy. The Board recommends changing to "Radioactive Seed Localization Licensing Guidance"
4. The guidance contains ambiguous information about seed removal. For example, page 1 says seeds may be removed in surgery or in pathology. Then, page 2 firmly indicates that the pathology location must be identified as a location of use.
    a. Recommend changing the last sentence of the "Radioactive Seed Localization" paragraph on page 1 to say "The tissue specimen containing the seed(s) is typically sent to pathology for removal of the seed and analysis of the tissue."
    b. Recommend changing the "Facility Address and Description" to say "If" instead of "Because."

Authorized Individuals (pages 2-5):

1. Preceptor attestations are seemingly not required for the first two authorization pathways? This seems like it should be there for consistency.
2. In 3) ii) H) 10 CFR 25.290 should be changed to 10 CFR 35.290
3. Is there a difference between 10 CFR 35.490 AUs who must be "currently listed" on a license and 10 CFR 35.290 AUs who only need to be "listed" on a license (page 3)? Why isn't the wording the same?
4. Why is there a pathway for a surgeon to be named as an authorized user? Radioactive material handling is not an area of expertise for a surgeon; it does not seem appropriate to permit surgeons to sign preceptor attestations for RSL use.
5. The authorized user section references "manufacturer's representative." The RSO section references "manufacturer's representative vendor". These references should be the same.

Written Directive (page 6):

1. The first paragraph under "Written Directive" would be more appropriately placed under "Medical Event Reporting."
2. The seeds used for radioactive seed localization are designed for therapeutic use. They are capable of delivering therapeutic doses, and therefore must require a written directive. The Board recommends retaining a written directive limited to:
    a. Pre: patient name, radionuclide, treatment site, number of seeds intended, maximum seed activity, signed and dated by AU.
    b. Post: radionuclide, treatment site, number of seeds implanted, activity per seed, signed and dated by AU.

c. Post Excision: number of seeds recovered, method they were verified (i.e. visual, by radiograph, survey of tissue, etc.), name of individual or department who assumed responsibility for control/disposal. If not all recovered, this would be place for documenting reason (i.e. patient did not return for removal, health complications precluded surgery, source migrated or not located, etc.).
d. It is critical to have a record of how many seeds were implanted, due to accountability issues mentioned in the general comments, above. A written directive is the customary process for recording this information.

Medical Event Reporting (pages 6-7):

1. Without a written directive, how does a licensee determine a wrong radionuclide was used? How does a licensee determine the wrong number of seeds were used?
2. Line d) under "Medical Event Reporting" is not necessary. The reporting requirement is based on a 50 rem organ or tissue dose, to any organ or tissue (whether or not it was outside the treatment site).
3. The Board recommends changing e) to add "or if the licensee performs the explantation while failing to excise all RSL seeds."
4. The Board supports the medical event threshold of 50 rem.

Specific Information on Radiation Safety Precautions and Instructions for Radioactive Seed Localization (pages 7-8):

1. The Board recommends adding the name of the rules that are being listed instead of just numbering them in 2 columns (i.e. "10 CFR 35.67 Requirements for possession of sealed sources and brachytherapy sources.").
2. The Board recommends adding 35.75 to the list of requirements that must be met for RSL procedures.
3. The Board recommends deleting the recordkeeping requirement in §35.2310. The licensee is not required to meet §35.410 because RSL patients can be released under §35.75.
4. The Board fully agrees that all personnel involved in RSL procedures, must be trained on routine and emergency procedures.
5. The Board recommends that procedures for patient verification be added to the commitments that the applicant must confirm are in place.

Survey and Source Localization Instrumentation (page 10):

1. Survey equipment must identify low activity, but also lower energy gammas. Additionally, unless the licensee commits to not perform sentinel node biopsy or other nuclear medicine procedures concurrently with the RSL procedure, then it must be able to select energy windows to discriminate between these isotopes.

Inspection Frequency (page 10):

1. Inspection frequency should be no less than 3 years which is the same frequency as manual brachytherapy. From the Board's NMED review, there were nearly as many misplaced/lost seed events with RSL as brachytherapy implants. There are also an increasing number of leaking source events with RSL.

We appreciate the chance to comment on this subject, and stand ready to answer any questions you may have.

Sincerely,

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