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May 14, 2026

Alessandra Marra
U.S. Nuclear Regulatory Commission
Washington, DC 20555–0001

Dear Ms. Marra,

The OAS Executive Board (Board) appreciates the opportunity to comment on RCPD-26-001, Draft Licensing Memorandum for Alpha Therapy Nuclides. After reviewing the Draft Licensing Memorandum for Alpha Therapy Nuclides, and after receiving comments from our Agreement State partners, the Board has the following comments:

1. The Board agrees that the current licensing requirements under 10 CFR Part 35, Section 35.300 adequately cover these applications. Also, the Board agrees that authorized users who are authorized under 10 CFR 35.390 or 10 CFR 35.396 are permitted to use parenteral alpha-emitting radiopharmaceuticals for patient therapy without the need for additional case-specific training.

2. The Licensing Memorandum should have additional information for licensees and license reviewers for addressing impurities that can be present from the creation of the alpha therapy nuclides, such as:
    a. How are licensees made aware of impurities and radioactive contaminants?
    b. How are licensees going to track those impurities for inventory purposes?
    c. If a manufacturer does not report any impurities, should it be assumed that none are present?
    d. If an impurity profile is unknown, how does a licensee demonstrate that their inventory is less than the requirements for financial assurance.
    e. The licensing memo should include additional information for evaluating alpha generators and how reviewers should evaluate a generator breakthrough and what limits would be acceptable for dose contaminants.

3. Can medical licensees meet regulatory requirements for radiation surveys only using equipment typically found in nuclear medicine departments? From observations made during routine inspections, most (to potentially all) medical facilities do not have a ZnS scintillation detector available.

4. The Dosage Measurement and Calibration section should reference the inherent difficulty in measuring activity of isotopes in decay chains. The NMP already experienced challenges with this when Ra-223 standard was shown to be incorrect and all licensees using Xofigo had to change the calibration factors on their dose calibrators.

5. How do licensees determine if a unit dose has the parent nuclide in equilibrium with the daughter products? For some decay series, this will depend on time period since synthesis.

6. The Spill Procedures section should also include a reference to 10 CFR 30.50(b) for unplanned contamination events. The Part 30 reporting requirement does not depend on potential for intake.

7. There is an apparent conflict between allowing survey instrumentation that relies on detection of beta-gammas in the decay chain and later suggesting there are or may be alpha therapeutics that do NOT have detectable beta-gammas in decay chain. The Radiation Survey section says "these isotopes are part of a decay chain that might also include the emission of beta and photon radiation" but Dosage Measurement section says "Due to technical complexities associated with direct measurement of alpha emissions, especially in the absence of detectable gamma or beta emissions in the decay chain…".

8. The Occupation Safety section includes "The need for facial protection or higher levels of respiratory protection should be considered." The section should include information regarding when facial protection and/or respiratory protection should be part of the medical administration.

9. The Package Receipt section includes a reference to 10 CFR Part 74 (Material Control and Accounting of Special Nuclear Material). It is not clear what this reference is specifically referring to and appears to be in error.

10. The Package Receipt section should include a reference to 49 CFR to point a licensee and the reviewer to the different removable contamination limits for alpha radiation versus beta/gamma radiation.

11. The Authorized User Training section includes "Individuals seeking designation as Authorized Users, Medical Physicists, Pharmacists, Radiation Safety Officers, or related roles must meet the NRC's training and experience requirements outlined in 10 CFR Part 35.390 and 10 CFR 35.396." This is incorrect, 10 CFR 35.390 and 35.396 only addresses training and experience requirements for Authorized Users. Additionally, medical physicists are not required for 35.300 uses; and 'Pharmacists' should be identified as 'Nuclear Pharmacists' if those individuals are being named in the memo to maintain consistency with 10 CFR Part 35.

12. For the Ac-225 Specific Guidance and Radionuclide Impurities section,

    a. The graphic at the end of the decay chain does not match the text. The graphic ends with thallium-205 while the text indicates the decay chain ends at "stable Bi-209".

    b. "Actinium-227 (Ac-227) is the principal radionuclidic impurity found in accelerator produced Ac-225." This is a misleading statement as not all accelerator produced Ac-225 includes Ac-227 impurities.

    c. The statement "Ac-227 impurity can be as high as 2%" needs to be clarified as to when the 2% impurity exists—is this at end of irradiation? Or when administered to patient? The percentage will increase as the Ac-225 decays.

    d. The section should include a statement that reportable spill threshold (5xALI) for Ac-227 is 2 nanocuries. This is lower than the leaking source limit for sealed sources (5 nanocuries). If there is 2% Ac-227 impurity in Ac-225, this corresponds to a spill of 100 nCi of Ac-225.

13. For the At-211 Specific Guidance and Radionuclide Impurities section, there should be some guidance on if or when bioassay is appropriate as astatine is a halogen and may behave similarly to iodine. Does NRC have specific guidance (analogous to Table 2 in RG 8.20) for radioactivity levels above which bioassay is necessary?

14. The guidance should address what "non-carrier added" means and what assumptions can and cannot be made with regard to dose impurities.

15. The Waste Disposal section includes "Once decayed to background levels and verified with a sensitive instrument in a low-background area...". It is not clear what the expectations are for surveying waste, especially waste that might include radioactive materials that do not have detectable gamma or beta emissions in the decay chain. Normal waste is contained in trash bags, biohazard bags, and/or spent syringe containers which will shield alpha emitting isotopes. What level of surveys are expected of licensees for clearing alpha isotopes?

16. The memo references NRC guidance and regulations that will either be superseded or alternative methodologies provided in the upcoming EO 14300 rulemakings. We recommend that the memo is issued in final after the publication of the final regulations currently being revised per EO 14300 to reflect these upcoming changes.

17. The inclusion of the diagrams for the decay chains for the five alpha emitting radionuclides was appreciated but they were hard to follow. Although the narrative explanations were helpful, we recommend that these decay chains be presented with arrows to clearly show the branching that occurs with certain radionuclides. The decay chains on pp. 281 – 285 of The Health Physics and Radiological Health Handbook edited by Bernard Shleien is an example of a better visual way to present this information to the reader.

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

Sincerely,

Sarah Sanderlin

Digitally signed by Sarah Sanderlin
Date: 2026.05.14 12:23:53 -04'00'

Sarah Sanderlin, Chair
Organization of Agreement States
Radiation Physicist 2 | Agreement State Program
New Jersey Bureau of Environmental Protection
Mail Code 25-01, 420, Trenton, NJ 08625
Sarah.Sanderlin@dep.nj.gov