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October 31, 2016

Donna-Beth Howe, Ph.D.
Office of Nuclear Materials Safety and Safeguards
U. S. Nuclear Regulatory Commission
Washington, DC 20555

RE: Draft Guidance for the Northstar Medical Radioisotopes LLC. Radiogenix Molybdenum-99/Technetium-99m Generator System (RCPD-16-013)

Dear Dr. Howe:

The Organization of Agreement States (OAS) Executive Board (Board) has reviewed the above document and respectfully submits the following comments and recommendations for your consideration.

1. The guidance should include a statement that the generator system is not designed to have multiple "active" vessels. The system is only designed to draw liquid from one molybdenum vessel, until that vessel has decayed below its useful activity. The other three cabinets hold molybdenum vessels for decay-in-storage.

2. The guidance should include a description of how often the user opens the various doors, with typical use. (How much are the users actually interacting with the system?)

3. The guidance should include a statement that eluting Tc-99m from the NorthStar generator is under 35.1000 but medical facilities that use unit doses of NorthStar Tc-99m should be able to administer it under 35.200. Once the drug is in a unit dose, it is handled exactly the same as any other Tc-99m product. At sites that receive unit doses, there should be no need to approve physicians for 35.1000 use.

4. The guidance should include some information on safety equipment that the licensee is required to possess. Does the licensee use tongs to remove vials from the shielded cabinet? Is there a spill kit provided by NorthStar?

5. Is there any daily QA or other routine maintenance that needs to be tied-down? How does tubing get checked, etc.?

6. Page 5: The OAS is concerned about the specificity of requirements for Authorized Nuclear Pharmacists (ANPs). The draft guidance is precedent-setting for how ANPs are named on licenses. There is uncertainty as to whether the RadioGenix generator warrants overhauling the ANP licensing process. The requirements for ANPs in 10 CFR 35.55 do not require documentation of any specific "case studies". ANPs are approved in whole, without limitations or authorizations by task or isotope. For example, regulatory agencies do not approve ANPs to make iodine capsules, even though that task requires additional expertise. The same is true for ANPs who handle PET isotopes, even though that requires familiarity with additional specialized safety equipment. Once being named as an ANP, pharmacists should need no additional written attestation to use the NorthStar generator. OAS recommends removing the requirement for written attestation for ANPs using the NorthStar generator. OAS also recommends removing the requirement to submit documentation of training for ANPs and changing to a licensee commitment that the training will be received prior to their first use of the generator. OAS recommends removing the license condition on p. 16 for ANPs.

7. Page 5: Section B.3 refers to 10 CFR 35.57(b)(2)(i), however this reference does not exist in the regulations.

8. Page 5: Section B.3 allows individuals who are certified by a recognized specialty board and who also complete Section C and D requirements to be listed as an Authorized User to use/elute the RadioGenix generator. It appears that these individuals would not have to be an ANP or physician. This seems to contradict the rest of the guidance which it specifically mentions Authorized Physician User or Authorized Nuclear Pharmacist within the guidance on pages 5, 13, 14, and 16.

9. OAS recommends removing the written attestation for RSOs for the same reasons described above. Documentation of training for RSOs should be retained.

10. Pages 5 and 6: the document should clarify that a "fully loaded" generator has one molybdenum vessel within a certain percentage (20%?) of the maximum loaded activity.

11. OAS recommends the working group justify why annual emergency training should be required. The only other modalities that require this are in 35.600, where there are acute patient care issues. Why is the requirement being extended to the NorthStar generator?

12. Page 10, section 5 "Revision to T&E Criteria Guidance": This paragraph does not apply and should be removed. Licensees who commit to a particular version of the guidance may not use updated T&E guidance until they apply for and receive a license amendment. "Gap training" to existing authorized individuals is not relevant until a licensee applies for an amendment. This should be reviewed by license reviewers prior to issuing the amendment. Licensees cannot and should not commit to this in advance.

13. Page 11, section 2 "Emergency Procedures": High radiation levels alone are typically not reportable. If the working group has particular regulatory reporting requirements in mind, they should be explicitly stated in the guidance. The reference to "action levels" is unclear.

14. Page 12, 7th bullet: "Near" is ambiguous and not inspectable. If there isn't specific guidance in the Operator Manual on where to stand and when, this commitment should be removed. The applicant is already committing to having survey instrumentation present to identify radiation transients, and radiation exposure concerns are already addressed through ALARA.

15. Page 13: Delete references to SSD. The Working Group determined, and OAS agrees, that this is not a sealed source.

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

Sincerely,

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