Organization of Agreement States

Matthew McKinley, Chair, Kentucky
David Turberville, Chair-Elect, Alabama
Sherrie Flaherty, Past-Chair, Minnesota
Debra Shults, Treasurer, Tennessee
Glenda Villamar, Secretary, Oregon
David Crowley, Director, North Carolina
Jenny Goodman, Director, New Jersey

March 24, 2017

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

RE: OPPORTUNITY TO COMMENT ON DRAFT NUREG-1556, VOLUME 13, REVISION 2, "CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES: PROGRAM-SPECIFIC GUIDANCE ABOUT COMMERCIAL RADIOPHARMACY LICENSES" (STC-17-012)

Dear Mr. McMurtray:

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

1. Page 8-43: Lines 1-3 should be printed directly after page 8-42 lines 36-38 and not be separated by Table 8-3.
2. The Part 37 information is generally not applicable to most radiopharmacies and therefore, would be less distracting as an Appendix in this NUREG.
3. Page J-4: The maximum permissible contamination limits are not correct. In 2014, the US Department of Transportation raised the contamination limits to 240 dpm/cm^2 for beta/gamma/low-toxicity alphas and 24 dpm/cm^2 for other alpha-emitters.
4. Page N-1: Consider either expanding the discussion in lines 10-13 or making it more generic to incorporate other generator systems (e.g., Ge-Ga).
5. Appendix N: Add guidance for compounding alpha-emitting radioisotopes, including contamination control.
6. Page N-5, lines 23-25: OAS supports restricting the minor spill designation to no more than five times the lowest ALI of the material involved in the spill. The list of nuclides should be expanded to include Ga-68 at a minimum.
7. Page O-2 states "All areas where radioactive materials are eluted, prepared, assayed, dispensed, or packaged for transport should be surveyed daily." The guidance should specify whether daily surveys are limited to ambient radiation level surveys or whether they should also include contamination surveys.
8. Page O-3 states "Licensees should establish action levels for the detection of contamination. Typically, licensees establish action levels that are twice the known background radiation level." OAS disagrees with the removal of Table R.1 concerning recommended action levels. Basing action levels on background, that fluctuates with

building material and location will complicate compliance determination. OAS recommends a risk-based action level table based on the ALI, similar to the minor/major spill determination.

9. There is little existing radiopharmacy guidance for alpha surveys, including developing appropriate action levels based on ALARA considerations and the limitations of well counting equipment. Appendix O should provide more guidance specific to alpha surveying. For example, do the action levels apply to each isotope in a decay chain separately or to the decay chain in total? What types of surveys should be performed in areas where alpha radiopharmaceuticals are compounded and how often? This NUREG should emphasize efficiency determination for performing contamination surveys for daughter isotopes in equilibrium with a parent nuclide.

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

Sincerely,

Matthew W. McKinley
OAS Chair
Radiation Health Program Administrator
275 East Main Street
Mailstop HS-1-CA
Frankfort, KY 40621