SNMMI Submits Comments to NRC on Radioactive Materials

On November 14 SNMMI announced that it had submitted comments to the Nuclear Regulatory Commission (NRC) on its open petition for rulemaking, addressing regulation revisions for radionuclides and their corresponding activities on the NRC list of "Quantities of Licensed Material Requiring Labeling." The NRC also received a petition for rulemaking from Matthew McKinley on behalf of the Organization of Agreement States (OAS) earlier in the year, making the same request. The petition was docketed by the NRC on June 21, 2017, and assigned Docket No. PRM–30–66. The NRC is examining issues raised in PRM–30–66 to determine whether they should be considered in rulemaking. SNMMI's comments addressed 4 questions raised by NRC in response to the earlier petition.

Question 1. What products or technologies, other than the ^{68}Ge generators cited in the petition, are being or could be negatively affected because the radioactive materials required for these products or technologies are not currently on the table in appendix B of 10 CFR part 30? *From the SNMMI comments:* The society listed 7 radionuclides currently under investigation or being considered for possible use as radiopharmaceuticals: ^{227}Ac, ^{228}Th, ^{32}Si, ^{44}Ti, ^{22}Na, ^{26}Al, and ^{177m}Lu.

Question 2. Please provide specific examples of how the current NRC regulatory framework for decommissioning financial assurance (FA) has put an undue hardship on potential license applicants. Explain how this hardship has discouraged the development of beneficial new products, or otherwise imposed unnecessarily burdensome requirements on licensees or members of the public (e.g., users of medical diagnostic or therapeutic technologies) that depend on naturally-occurring or accelerator-produced radioactive materials (NARM). *From the SNMMI comments:* The society responded by first citing the hardships that the framework for decommissioning funding plan (DFP) imposes on medical license applicants, particularly those with multiple locations. Examples of these hardships can be found in the Advisory Committee on the Medical Uses of Isotopes (ACMUI) *^{68}Ge Decommissioning Funding Plan Final Report* of August 12, 2015. These hardships would be extended to other radionuclides and generators cited in the DFP. The comments also addressed potential increases in expense and special hardships for commercial radiopharmacy networks, as wells as limitations and delays in patient care under the current DFP trigger amounts of 1–10 mCi. The society provided a specific example of a hardship to a licensee with ^{177m}Lu, which is not currently listed in appendix B of 10 CFR part 30.

Question 3. Given NRC's current regulatory authority over the radiological safety and security of NARM, what factors should the NRC take into account in establishing possession limits for any of these materials that should be listed in appendix B of 10 CFR part 30? *From the SNMMI comments:* The society recommended that NRC consider the unique medical nature of the radionuclides used in radiopharmaceuticals and the fact that these have already undergone extensive evaluation before they are approved for use in humans by the U.S. Food and Drug Administration (FDA). The limits in appendix B from the DFP were originally developed primarily for nuclear facilities (e.g., power reactors, fuel cycle facilities, etc.), and the evolution of the medical use of radionuclides was not considered during their development. The scope and use of radioactive materials at nuclear facilities is quite different from that at medical facilities; for this reason radionuclide generators should be considered as a separate category from sealed and unsealed sources of radionuclides and should qualify for additional relief from restrictive DFP activity limits. The society provided examples of the reasons and potential benefits of adding a third category of radioactive material to 10 CFR 30.35. FDA oversight of radionuclide generators was also cited as an additional layer of safety, as well as the requirement to return the generators to the manufacturer for disposal. The society also supported development of appropriate DFP and FA for decommissioning amounts for medical isotopes at medical licensees. Given the substantial differences between a medical licensee and a nuclear facility, a one-size-fits-all approach is not consistent with the principles of good regulation.

Question 4. Does this petition raise other issues not addressed by the questions above about labeling or decommissioning financial assurance for radioactive materials? Must these issues be addressed by a rulemaking, or are there other regulatory solutions that NRC should consider? *From the SNMMI comments:* The society noted that the latest licensing guidance (July 13, Revision 1) and its related memorandum are a welcome improvement, adding that, although newer and larger ^{68}Ge/^{68}Ga generators are on the market, a 100-mCi generator would pose no more hazard than 2 50-mCi generators. It should be clear that calculations in the guidance for determining FA amounts should focus on the total amount of ^{68}Ga used by a medical licensee. New guidance should be developed to promote consistent regulatory implementation across all medical licensees for the use of these new generators.

SNMMI agreed with the OAS petition for rulemaking, stating in its comments letter that "this petition is well supported by the findings of the ACMUI ^{68}Ge DFP Final Report of August 12, 2015." The complete comments are available at: http://snmmi.files.cms-plus.com/docs/hpra/Non_Searchable_Folder/OAS_petition_SNMMI_comment_FINAL.pdf.