AMERICAN SOCIETY OF HEMATOLOGY
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January 28, 2019

May Ma
Office of Administration
Mail Stop: TWFN-7-A60M
United States Nuclear Regulatory Commission
Washington DC 20555-0001

RE: Docket ID NRC-2018-0230, Training and Experience Requirements for Different Categories of Radiopharmaceuticals

Dear Ms. Ma:

The American Society of Hematology (ASH) is pleased to provide input on the Nuclear Regulatory Commission's (NRC) request for comments regarding the NRC's current training and experience requirements for different categories of radiopharmaceuticals as included in Subpart E of 10 CFR Part 35.

ASH represents over 17,000 clinicians and scientists worldwide, who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions such as sick cell anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the field of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy. ASH membership is comprised of basic, translational, and clinical scientists, as well as physicians providing care to patients in diverse settings including teaching and community hospitals, as well as private practice.

The Society's comments are limited to the use of radiopharmaceuticals such as alpha- and beta- emitters, that are prepared at a licensed specialty (radio) pharmacy and delivered to a hematology/oncology practice in a patient-ready dose where it is intravenously administered. Ibritumomab tiuxetan is an example of a beta-emitter that is a treatment option for patients diagnosed with non-Hodgkin lymphoma. This clinical therapeutic radio-immunopharmaceutical is delivered to physician practices immediately prior to administration for a specific patient in a patient-ready dose (in a pre-filled syringe). Given the nature of this therapeutic and the sequence for its administration, it would seem that the extensive didactic training required by current NRC regulation would be impossible for the vast majority of clinical centers that deliver these therapeutics. We believe that this could have the potential effect of disenfranchising patients in need from timely and uninterrupted access to this potentially life-saving treatment.

The regulation's alternate pathway to administer radiopharmaceuticals is 700 hours of training and experience (200 classroom hours and 500 hours of supervised work experience). We believe this requirement is aimed at training and certifying physicians in the use of an array of radioactive substances in the diagnosis and treatment of disease. While this may be appropriate for clinicians who seek to be certified for all uses of

radioactive materials, we believe that it is not appropriate for hematologists who simply seek to administer a very **limited** set of therapeutic radio-immunopharmaceuticals, such as ibritumomab tiuxetan. As such, the Society strongly supports a more tailored training approach for different categories of radio-labeled/radio-emitting pharmaceuticals, as suggested by the NRC in its request for comments, especially for alpha- and beta-emitters that are prepared and packaged in a licensed specialty (radio) pharmacy and easily administered as a patient-ready dose in the hematologist/oncologist office setting. Further, as new radiopharmaceutical products come to market, ASH would be happy to provide thoughts on whether enhanced training and experience should be required. It is noted that prior to a 2002 rulemaking, 80 hours of classroom and laboratory training was deemed sufficient for purposes of licensing authorized users to safely administer beta-emitting radiopharmaceuticals.

ASH supports a reasonable and limited change in the regulations that would allow for more appropriate training and experience requirements with regard to alpha- and beta-emitters. This would significantly improve patient access to lifesaving treatments in the community hematology/oncology setting, while also addressing important safety considerations.

Thank you for your consideration of our comments. Please contact Suzanne Leous, ASH Chief Policy Officer at 202-292-0258 or sleous@hematology.org, with any questions concerning this letter.

Sincerely,

Roy L. Silverstein, MD
President