



AMERICAN SOCIETY OF HEMATOLOGY

2021 L Street, NW, Suite 900, Washington, DC 20036 ph 202.776.0544 fax 202.776.0545 e-mail ASH@hematology.org

July 3, 2019

Office of Administration
Mail Stop: TWFN-7-A60M
U.S. Nuclear Regulatory Commission
Washington, DC 20555-001
ATTN: Program Management, Announcements and Editing Staff

RE: Docket ID NRC-2018-0230 Draft Approaches for Addressing Training and Experience Requirements for Radiopharmaceuticals Requiring a Written Directive

To Whom it May Concern:

The American Society of Hematology (ASH) is pleased to provide input on the Nuclear Regulatory Commission's (NRC) draft approaches for addressing training and experience requirements for radiopharmaceuticals requiring a written directive. ASH appreciates NRC's attention to this matter as it relates to hematologists who administer patient-ready doses to patients with hematologic malignancies.

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 sickle cell disease, 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 concerns are limited to the use of radiopharmaceuticals such as alpha- and beta-emitters, that are prepared at a licensed specialty pharmacy and delivered to a hematology/oncology practice in a patient-ready dose where it is intravenously administered. An example of the limited kind of radiopharmaceutical administered by hematologists is ibritumomab tiuxetan, a therapeutic option for patients diagnosed with non-Hodgkin lymphoma.

The Society does not support the "Status Quo" approach outlined in docket ID NRC-2018-0230; ASH has previously commented that the current requirements under 10 CFR 35.390 which include 700 hours of training and experience (200 classroom hours and 500 hours of supervised work experience) are too onerous and not appropriate for hematologists who seek to administer such therapeutic radio-immunopharmaceuticals mentioned above.

ASH supports modifying current regulations, including the approach outlined in the "Tailored Training and Experience Requirements" (Section B.1), "Limited AU for Alpha- or Beta-Emitting Radiopharmaceuticals" and (Section B.2) "Limited AU for Unit-Dose, Patient-Ready Radiopharmaceuticals." In both sections B.1 and B.2, ASH appreciates that

2019

President

Roy Silverstein, MD
Medical College of Wisconsin
Clinical Cancer Center
9200 W. Wisconsin Avenue
Milwaukee, WI 53226
Phone 414-805-0518

President-Elect

Stephanie Lee, MD, MPH
Fred Hutchinson Cancer Research Center
1100 Fairview Avenue N, D5-290
PO Box 19024
Seattle, WA 98109
Phone 206-667-5180

Vice President

Martin Tallman, MD
Memorial Sloan-Kettering Cancer Center
1275 York Avenue
Howard Building 718
New York, NY 10065
Phone 212-639-9842

Secretary

Robert Brodsky, MD
Johns Hopkins University
Ross Building, Room 1025
720 Rutland Avenue
Baltimore, MD 21205
Phone 410-502-2546

Treasurer

Mark Crowther, MD
McMaster University
50 Charlton Avenue East
Room L-301
Hamilton, ON L8N-4A6
Canada
Phone 1-905-521-6024

Councillors

Steven Allen, MD
Belinda Avalos, MD
John Byrd, MD
Cynthia Dunbar, MD
Arnold Ganser, MD
Agnes Lee, MD, MSc, FRCPC
Joseph Mikhael, MD, FRCPC, Med
Jane Winter, MD

Executive Director

Martha Liggett, Esq.

Deputy Executive Director

Matthew Gertzog, MBA, FASAE

the NRC is recommending a reduction in the number of hours required to be an authorized user to a total of 400 hours (200 hours of classroom and laboratory training, and a minimum of 200 hours of supervised work experience). The Society believes that reducing the overall number of training hours may be more appealing to community hematology/oncology practices around the country that want to offer such therapies, while addressing important safety issues. Ultimately, this will help improve patient access to these potentially lifesaving treatments in the community setting.

Additionally, ASH supports the recommended approach in Section B.4, Emerging Radiopharmaceuticals, that the NRC conduct individual reviews of each new emerging radiopharmaceutical to determine training and experience requirements specific to the new radiopharmaceutical. This seems to be a reasonable tactic that keeps safety considerations in check for potential administrators of any new radiopharmaceutical therapy.

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,

A handwritten signature in black ink, appearing to read "Roy L. Silverstein". The signature is fluid and cursive, with the first name "Roy" being particularly prominent.

Roy L. Silverstein, MD
President