

UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON, D.C. 20555-0001

April 21, 2022

Dr. Carol Marcus, Ph.D., M.D.David Geffen School of Medicine of UCLA1877 Comstock AvenueLos Angeles, CA 90025-5014

SUBJECT: LETTER TO DR. CAROL MARCUS FROM KEVIN WILLIAMS REGARDING

NUCLEAR MEDICINE TRAINING AND EXPERIENCE REQUIREMENTS AND

MEDICAL SPECIALTY BOARDS

Dear Dr. Marcus:

I am responding to your letter submitted to the U.S. Nuclear Regulatory Commission (NRC) on November 26, 2021 (Agencywide Documents Access and Management System [ADAMS] Accession No. ML21336A542). On January 27, 2022, the Commission issued a staff requirements memorandum for SECY-20-0005, "Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material (10 CFR Part 35)" (ADAMS Accession No. ML22027A519). The Commission approved the staff's option 1, which maintains the NRC's current training and experience (T&E) requirements for unsealed byproduct material in 10 CFR Part 35. Although the Commission disapproved a T&E rulemaking, the Commission directed the staff to complete other actions related to this effort.

First, the Commission directed the staff to evaluate whether each specialty board still satisfies the board recognition criteria and to report the findings to the Commission within 6 months of the date of the Staff Requirements Memorandum. Specialty boards seeking NRC recognition for their certification program process(es) must meet the NRC T&E requirements in the applicable section in 10 CFR Part 35. The boards must, amongst other requirements, clearly describe the T&E criteria mandated by the specialty board and how the board's criteria compare to the NRC requirements; describe how the board verifies that candidates have met their training and experience requirements, and how examinations assess knowledge and competency in all key topics specified by the regulations. The NRC staff is conducting the assessment of medical specialty boards per NMSS Office Procedure MSST-70-03-2, which is publicly available at ADAMS Accession No. ML20351A389. As part of this assessment, the staff recently issued letters to the medical specialty boards, requesting confirmation within 30 days of satisfaction of board recognition criteria and certificates. The staff will share the results of its assessment with the Commission and the Advisory Committee for the Medical Uses of Isotopes. The staff expects to complete this assessment by July 2022.

Second, the Commission directed the staff to develop implementation guidance to clarify expectations on how individuals fulfill T&E requirements and clarify the roles and responsibilities of persons subject to T&E requirements. And third, the Commission directed the staff to reconsider the full complement of T&E requirements within the current paradigm and obtain stakeholder comments on the knowledge; methods on how knowledge topics should be acquired; and consideration for continuing education, vendor training for new medical uses, and

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training on the NRC regulatory requirements. This action and the development of T&E implementation guidance will be completed as part of the staff's rulemaking to establish requirements for rubidium-82 generators and emerging medical technologies (see the Commission's staff requirements memorandum approving SECY-21-0013, "Rulemaking Plan to Establish Requirements for Rubidium-82 Generators and Emerging Medical Technologies" at ADAMS Accession No. ML22013A266).

If you have any further questions or concerns, please feel free to contact me by e-mail at Kevin.Williams@nrc.gov, or by phone at 301-415-3340.

Sincerely,

Signed by Williams, Kevin on 04/21/22

Kevin Williams, Director Division of Materials Safety, Security, State and Tribal Programs Office of Nuclear Material Safety and Safeguards C. Marcus -3-

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