



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

September 18, 2020

American Society of Nuclear Cardiology
Society of Nuclear Medicine and Molecular Imaging
American College of Radiology
American Society for Radiation Oncology
ATTN: Sharmila Dorbala, MD, MPH
Vasken Dilsizian, MD
Howard B. Fleishon, MD, MMM, FACR
Laura Thevenot
Presidents, Chair of Board of Chancellors, and Chief Executive Officer

SUBJECT: RESPONSE TO MEDICAL PROFESSIONAL SOCIETIES REQUEST FOR REGULATORY RELIEF FROM U.S. NUCLEAR REGULATORY COMMISSION REGULATION, TITLE 10 OF THE *CODE OF FEDERAL REGULATIONS* 35.290

Dear Drs. Dorbala, Dilsizian, Fleishon and Ms. Thevenot,

By letter dated June 11, 2020 (Agencywide Documents Access and Management System [ADAMS] Accession No. [ML20231A931](#)), the American Society of Nuclear Cardiology, the Society of Nuclear Medicine and Molecular Imaging, the American College of Radiology, and the American Society for Radiation Oncology, requested that the U.S. Nuclear Regulatory Commission (NRC) consider Title 10 of the *Code of Federal Regulations* (10 CFR) 35.290(c)(1)(ii)(G), "Training for Imaging and Localization Studies," as a potential area for regulatory relief during the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE). Your letter states that most of the commercial radiopharmacies that supply portions of this training are closed to visiting trainees because of the COVID-19 PHE and may not reopen for the foreseeable future. Your letter further states that you believe that this experience requirement can be satisfied virtually, via demonstrative educational webinars during the duration of the public health emergency.

The NRC staff is prepared to consider, on an expedited basis, requests for an exemption from the requirement to obtain the hands-on work experience described in 35.290(c)(1)(ii)(G). These exemptions may be requested in accordance with in 10 CFR 30.11, "Exemptions." The requirement in 10 CFR 35.290(c)(1)(ii)(G) applies to NRC licensees and specialty boards whose certification processes have been recognized by the NRC. As such, any requests for an exemption from the requirement in 10 CFR 10 CFR 35.290(c)(1)(ii)(G) must be submitted by a licensee or an NRC recognized specialty board.

The attached table, *Medical Use Licensee Temporary Exemptions* (ADAMS Accession No. [ML20233B145](#)) provides a list of the Title 10 *Code of Federal Regulations* (10 CFR) Part 19, 20, 30, and 35 requirements, for the which the NRC may consider expedited requests for temporary exemption. The table includes the requirements for generator elution training and experience under 10 CFR 35.290(a)(1) and 10 CFR 35.290(c)(1)(ii)(G). Licensees or specialty boards may seek a temporary exemption from these requirements to address the challenges licensees or candidates for board certification may face during the PHE. This table may be updated as the

NRC identifies additional requirements for which the NRC may consider expedited requests for temporary exemption.

As you may be aware, the NRC received a letter dated June 24, 2020 (ADAMS Accession No. [ML20231A932](#)), from the Certification Board of Nuclear Cardiology (CBNC), a medical specialty board whose certification process has been recognized by the NRC under 10 CFR 35.290(a). By this letter, CBNC requested relief from the regulatory requirement in 10 CFR 35.290(c)(1)(ii)(G). Specifically, CBNC requested relief from 10 CFR 35.290(a)(1), which requires, in part, that all candidates for certification have training and experience that includes supervised work experience involving eluting generator systems as described in 10 CFR 35.290(c)(1)(ii)(G). In its request, CBNC also stated that most commercial radiopharmacies that typically provide portions of this training are closed to visiting trainees due to the COVID-19 PHE. CBNC proposed that if relieved from the specific requirements in 10 CFR 35.290(c)(1)(ii)(G), it would modify its policies and procedures to reflect the option for virtual training for candidates for certification to complete this part of their training requirement. The NRC processed CBNC's relief request as a request for an exemption and granted CBNC's request in a letter dated September 17, 2020 (ADAMS Accession No. [ML20252A174](#)).

If you have questions, please contact Maryann Ayoade at Maryann.Ayoade@nrc.gov.

Sincerely,

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosures:

1. Medical Use Licensee Temporary Exemptions
2. NRC Letter to CBNC – Temporary Exemption from U.S. NRC 10 CFR 35.290

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DATE: September 18, 2020

ADAMS Accession No.: ML20231A930

***via e-mail**

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