



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

September 17, 2020

Certification Board of Nuclear Cardiology
ATTN: Edwin Wu, M.D., Chairman
1401 Rockville Pike, Suite 600
Rockville, MD 20852-1402

SUBJECT: TEMPORARY EXEMPTION FROM U.S. NUCLEAR REGULATORY
COMMISSION REGULATION, TITLE 10 OF THE CODE OF FEDERAL
REGULATIONS 35.290

Dear Dr. Wu,

By letter dated June 24, 2020 (Agencywide Documents Access and Management System [ADAMS] Accession No. [ML20231A932](#)), in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 30.11, the Certification Board of Nuclear Cardiology (CBNC), a medical specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission (NRC) under 10 CFR 35.290(a), requested a temporary exemption from the requirement in 10 CFR 35.290(c)(1)(ii)(G). Specifically, CBNC is requesting an exemption from the requirement in 10 CFR 35.290(a)(1) that, for board recognition, the board must require all candidates for certification to 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 stated that most commercial radiopharmacies that typically provide portions of this training are closed to visiting trainees due to the Coronavirus Disease 2019 (COVID-19) public health emergency (PHE). CBNC proposed that, if exempted 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 applicants to complete this part of their training requirement.

The exemption provision in 10 CFR 30.11(a) states:

The Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the requirements of the regulations in this part and parts 31 through 36 and 39 of this chapter as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

The NRC staff reviewed the request in accordance with 10 CFR 30.11(a) and finds that the criteria contained therein are met. The regulation from which the CBNC is requesting exemption is the requirement in 10 CFR 35.290(a)(1) that the licensee require an authorized user for uses authorized under 10 CFR 35.200 to be a physician certified by a medical specialty board whose certification process has been recognized by the NRC or Agreement State that requires candidates to complete 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging

and localization studies, whereby the training and experience must include work experience under the supervision of an authorized user, that involves eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs, in accordance with 10 CFR 35.290(c)(1)(ii)(G).

The regulation in 10 CFR 30.11(a) authorizes granting of exemptions specific to Part 35. The NRC staff has determined that the granting of the requested exemption will not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. The NRC staff, therefore, finds that the granting of the requested exemption is authorized by law.

The requested exemption is to fulfill the supervised work experience described in 10 CFR 35.290(c)(1)(ii)(G) in a manner that is different (other than in-person and hands-on, i.e. by virtual means) than what is currently required. This exemption does not exempt the licensee from obtaining the required work experience. Candidates for certification must obtain virtual, rather than hands-on, work experience involving generator elutions as part of their training to become an authorized user for uses authorized under 10 CFR 35.200.

This training involves radiopharmaceuticals used for diagnostic procedures, which are considered to be lower risk than radiopharmaceuticals used for therapeutic procedures. Additional steps such as calculating, measuring, and safely preparing dosages before medical use, are required prior to administration, and authorized users are required to have work experience on these steps. As such, the risk posed by this exemption does not constitute a significant increase to the risk of administering incorrect dosages to patients. The alternative work experience provided pursuant to this exemption must include live interactive training whereby the candidate can ask questions and receive feedback and cover all the topics listed in 10 CFR 35.290(c)(1)(ii)(G). The NRC also notes that absent the requested exemption, the board may be required to take actions that may be contrary to guidance on preventing the spread of the virus that causes COVID-19. For the reasons stated above, the NRC staff finds that the proposed exemption will not endanger life or property or the common defense and security and is otherwise in the public interest.

Based on the above findings, the NRC grants the following exemption for the specified period of time:

CBNC is temporarily exempt from the NRC recognized medical specialty board work experience requirement in 10 CFR 35.290(c)(1)(ii)(G). Individuals seeking board certification may fulfill this work experience requirement virtually, rather than hands-on, from January 31, 2020, the date the U.S. Department of Health and Human Services declared a public health emergency (PHE) for the United States, through December 31, 2020. Notwithstanding the regulatory relief provided by this exemption, a licensee that uses generator systems should, as soon as is safely possible, provide hands-on work experience involving the tasks described in 10 CFR 35.290(c)(1)(ii)(G) to its authorized users that obtained this work experience virtually.

An environmental assessment for this action is not required, because this action is categorically excluded under 10 CFR 51.22(c)(25)(vi)(E). In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC's Public Document Room or from the NRC's ADAMS.

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 Materials Safety
and Safeguards

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COMMISSION REGULATION, TITLE 10 *CODE OF FEDERAL REGULATIONS*
(10 CFR) 35.290

DATE: September 17, 2020

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***via e-mail**

OFFICE	MSST	MSST	MSST	OGC	MSST
NAME	MAyoade*	LDimmick*	CEinberg*	EHouseman*	KWilliams*
DATE	09/03/2020	09/03/2020	09/09/2020	09/03/2020	09/16/2020

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