



Chairman

Edwin Wu, MD

June 24, 2020

Vice-Chairman

Jeffrey Rosenblatt, MD

Maryann O.N. Ayoade
Medical/Health Physicist
Medical Radiation Safety Team
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Examination Panel

Paul Cremer, MD
Matthew Harinstein, MD
Shivda Pandey, MD
Aseem Vashist, MBBS

Reference: COVID-19 PHE Regulatory Relief request for 10 CFR Part 35.290 (c)(1)(ii)(G)

Dear Ms. Ayoade:

The Certification Board of Nuclear Cardiology (CBNC) respectfully requests that the Nuclear Regulatory Commission (NRC) consider 10 CFR Part 35.290 (c)(1)(ii)(G), *Training for imaging and localization studies* as a potential area for regulatory relief during the COVID-19 Public Health Emergency (PHE). The regulation reads:

Chief Assessment Officer

Kathy Kelly

“Work experience must involve: 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”.

We understand that a number of organizations have requested that CBNC applicants be allowed to complete the elution generator training requirement virtually rather than in-person. These organizations include:

- The American Society of Nuclear Cardiology (ASNC)
- The Society of Nuclear Medicine and Molecular Imaging (SNMMI)
- The American Society of Radiation Oncology (ASTRO)
- The American College of Radiology (ACR)

We further understand that the reason for their request is that most of the commercial radiopharmacies that typically provide portions of this training are closed to visiting trainees due to the PHE. If approved by the NRC, CBNC will modify our policies and procedures to reflect this option for applicants to complete this part of their training.

The CBNC welcomes the opportunity to discuss with the NRC how virtual training might be able to be included as an option for elution generator training on an ongoing basis and any other areas where simulation or virtual training may be of a benefit. To this end, we would be happy to set up a meeting to discuss.

We appreciate the NRC’s commitment to expeditious review of regulatory relief requests during the COVID-19 pandemic. This issue is critical to the CBNC as we want to ensure that the applications we are currently receiving and processing meet NRC’s requirements. To that end, we will await further guidance from the NRC. Please let us know once the NRC has made a determination so that we can proceed accordingly.



Please contact Kathy Kelly, Chief Assessment Officer at Kathy.kelly@inteleos.org should you have any questions.

Sincerely,

A handwritten signature in black ink that reads "Kathy A. Kelly".

Kathy Kelly, Chief Assessment Officer

CC: Edwin Wu, MD, Chair, CBNC Assessment Committee
Dale Cyr, Chief Executive Officer and Executive Director
Tom Fitzgerald, Principal, Groom Law Group and Inteleos General Counsel