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

October 5, 2016

ALL AGREEMENT STATES, VERMONT, WYOMING

ISSUANCE OF ECKERT AND ZIEGLER GALLIAPHARM™ GERMANIUM-68/GALLIUM-68 PHARMACY GRADE GENERATOR LICENSING GUIDANCE (STC-16-079)

Purpose: To inform the Agreement States that the "Eckert and Ziegler GalliaPharm™ Germanium-68/Gallium-68 Pharmacy Grade Generator Licensing Guidance" was published on September 28, 2016.

Background: The Organization of Agreement States and the U.S. Nuclear Regulatory Commission (NRC) created a joint working group to: (1) Confirm and document the need to license the Germanium-68/Gallium-68 (Ge-68/Ga-68) generator used by hospitals under Title 10 *Code of Federal Regulations* (10 CFR) 35.1000 rather than 10 CFR 35.200 or 10 CFR 35.500, and (2) develop a 10 CFR 35.1000 licensing guidance document in accordance with the outcomes corresponding to the above task. Initially, the working group developed the licensing guidance such that it could be broadly applied to any Ge-68/Ga-68 generator. However, it was later decided that the licensing guidance would be narrowed to only address the GalliaPharm™ Ge-68/Ga-68 pharmaceutical grade generator manufactured by Eckert and Ziegler Radiopharma GmbH (hereafter Eckert and Ziegler GalliaPharm™ generator) because it was the only Ge-68/Ga-68 generator that had an approved Drug Master File from the U.S. Food and Drug Administration.

Ge-68/Ga-68 generators are similar to conventional molybdenum-99/technetium-99m (Mo-99/Tc-99m) and strontium-82/rubidium-82 (Sr-82/Rb-82) generators, which are regulated under Title 10 of the *Code of Federal Regulations* (10 CFR) 35.200. Like Mo-99/Tc-99m and Sr-82/Rb-82 generators, potential breakthrough of the parent radionuclide is possible when eluting the generator. This breakthrough could lead to Ge-68 contaminating the Ga-68 radiopharmaceutical, potentially causing an unnecessarily higher radiation exposure to patients. 10 CFR 35.204 provides permissible concentration limits for parent radionuclides for Mo-99/Tc-99m and Sr-82/Rb-82 generators to limit such exposure, but no such limit is specified for Ge-68/Ga-68 generators. Therefore, the working group confirmed that use of a Ge-68/Ga-68 generator to prepare Ga-68 radiopharmaceuticals for imaging and localization studies should be licensed using a customized licensing approach in accordance with 10 CFR 35.1000, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material." The new guidance provides an appropriate limit for breakthrough.

Discussion: This licensing guidance applies only to the use of the GalliaPharm™ Ge-68/Ga-68 pharmaceutical grade generator manufactured by Eckert and Ziegler Radiopharma GmbH (hereafter Eckert and Ziegler GalliaPharm™ generator). All sections of this licensing guidance apply to both medical licensee and commercial nuclear pharmacy licensee use of this generator, unless otherwise specified. This licensing guidance does not apply to licensees or applicants that will receive unit or bulk doses of Ga-68 radiopharmaceuticals rather than use the

Eckert and Ziegler GalliaPharm™ generator themselves. These licensees and applicants will be regulated under 10 CFR 35.200 and, as such, authorized users must meet the requirements in 10 CFR 35.290.

Future Ge-68/Ga-68 radionuclide generators will be addressed in revisions to the licensing guidance.

This licensing guidance may also be found on the NRC Medical Uses Licensee Toolkit at: http://www.nrc.gov/materials/miau/med-use-toolkit.html.

If you have any questions regarding this correspondence, please contact me at 301-415-3340 or the individual named below:

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Enclosure:
Eckert and Ziegler GalliaPharm™
Germanium-68/Gallium-68 Pharmacy
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