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

September 29, 2016

MEMORANDUM TO: James M. Trapp, Director
Division of Nuclear Materials Safety
Region I

John B. Giessner, Director
Division of Nuclear Materials Safety
Region III

Mark R. Shaffer, Director
Division of Nuclear Materials Safety
Region IV

FROM: Daniel S. Collins, Director ***/RA Pamela Henderson for/***
Division of Material Safety, State, Tribal
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

SUBJECT: ISSUANCE OF ECKERT AND ZIEGLER GALLIAPHARM™ GERMANIUM-68/GALLIUM-68 PHARMACY GRADE GENERATOR LICENSING GUIDANCE

This memorandum is to inform you that on September 28, 2016, the U.S. Nuclear Regulatory Commission, in conjunction with the Agreement States through a joint working group, issued the enclosed licensing guidance entitled, "Eckert and Ziegler GalliaPharm™ Germanium-68/Gallium-68 Pharmacy Grade Generator Licensing Guidance."

Germanium-68/Gallium-68 (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 use of a Ge-68/Ga-68

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generator to prepare Ga-68 radiopharmaceuticals for imaging and localization studies is regulated under 10 CFR 35.1000, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material."

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.

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.

Enclosure:
Eckert and Ziegler GalliaPharm™
Germanium-68/Gallium-68 Pharmacy
Grade Generator Licensing Guidance

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Enclosure:
Eckert and Ziegler GalliaPharm™
Germanium-68/Gallium-68 Pharmacy
Grade Generator Licensing Guidance

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