



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

October 12, 2018

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

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

Troy W. Pruett, Director
Division of Nuclear Materials Safety
Region IV

FROM: Daniel S. Collins, Director
Division of Materials Safety, Security, State, and Tribal Programs, /RA/
Office of Nuclear Material Safety
and Safeguards

SUBJECT: OPPORTUNITY TO COMMENT ON DRAFT LICENSING
GUIDANCE FOR GERMANIUM-68/GALLIUM-68
PHARMACEUTICAL GRADE GENERATORS

Enclosed for your review and comment is draft licensing guidance for Germanium-68 (Ge-68)/Gallium-68 (Ga-68) generators pharmaceutical grade generators. These 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* 35.200, "Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required." Like Mo-99/Tc-99m and Sr-82/Rb-82 generators, potential breakthrough of the parent radionuclide is possible when eluting the generator. This could lead to Ge-68 contaminating the Ga-68 radiopharmaceutical and potentially causing an unnecessarily higher radiation exposure to patients that planned. 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 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."

CONTACT: Said Daibes Figueroa
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The current NRC licensing guidance is specific to the GalliaPharm™ Ge-68/Ga-68 generator from the manufacturer Eckert and Ziegler.¹ The NRC staff, in foreseeing the need to provide licensing guidance for Ge-68/Ga-68 generators made by additional manufacturers, has modified the existing guidance into a non-manufacturer-specific licensing guidance. In this guidance no changes have been implemented in license commitments, breakthrough limit, or radiation safety aspects of the guidance of the Ge-68/Ga-68 generator for generating Ga-68 radiopharmaceuticals.

Please provide any comments that you or your staff, have on this draft document to the point of contact listed below. We would appreciate receiving your comments within 45 calendar days from the issuance of this memorandum.

If you have any questions regarding this correspondence, please contact me at (301) 415-3340 or Said Daibes Figueroa of my staff at (301) 415-6863.

Enclosure:
Draft Germanium-68/Gallium-68
Pharmaceutical Grade Generators
Licensing Guidance

¹ The licensing guidance for the Eckert and Ziegler GalliaPharm™ Germanium-68/Gallium-68 pharmacy grade generator was last published in July 2017 and can be found in the NRC's Agencywide Documents Access Management System (Accession No. ML1705A488).

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DATE	09/25/18	09/25/18	10/12/18

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