



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

July 25, 2019

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

David L. Pelton Director
Division of Nuclear Materials Safety
Region III

Linda Howell, Acting Director
Division of Nuclear Materials Safety
Region IV

FROM: Andrea L. Kock, Director
Division of Materials Safety, Security, State, /RA/
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

SUBJECT: ISSUANCE OF GERMANIUM-68/GALLIUM-68
PHARMACEUTICAL GRADE GENERATORS LICENSING
GUIDANCE

This memorandum is to inform you that on July 25, 2019, the U.S. Nuclear Regulatory Commission (NRC) issued the enclosed revised licensing guidance entitled, "Germanium-68/Gallium-68 Pharmaceutical Grade Generators Licensing Guidance."

The current NRC licensing guidance under Title 10 *Code of Federal Regulations* (CFR) 35.1000 for Germanium-68/Gallium-68 generators [Ge-68/Ga-68 generators] (Revision 1) was issued on July 13, 2017 and can be found in NRC's Agencywide Documents Access Management System (ADAMS) (Accession No. ML17075A488). At that time, the only Ge-68/Ga-68 generator approved by the U.S. Food and Drug Administration (FDA) and available on the market was the Eckert and Ziegler GalliaPharm® generator. Now that additional Ge-68/Ga-68 generators (IREs [Institute of Radio Elements] Galli Eo™ generator and others) are becoming commercially available, the Ge-68/Ga-68 generator licensing guidance has been revised to eliminate reference to any specific generator manufacturer or product.

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All sections of this guidance apply to both medical licensee and commercial nuclear pharmacy licensee use of these generators unless otherwise specified. This guidance does not apply to licensees or applicants that will receive unit or bulk doses of Gallium-68 (Ga-68) radiopharmaceuticals.

This guidance provides applicants with an acceptable means of satisfying the requirements for a license for the use of Ge-68/Ga-68 generators to prepare Ga-68 radiopharmaceuticals. It is not intended to be the only means of satisfying the requirements for a license.

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

Enclosure:
April 2019, Germanium-68/
Gallium-68-Pharmaceutical Grade
Generators Licensing Guidance

SUBJECT: ISSUANCE OF GERMANIUM-68/GALLIUM-68 PHARMACEUTICAL GRADE GENERATORS LICENSING GUIDANCE

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ADAMS Accession Package No. ML19108A145

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