



UNITED STATES
NUCLEAR REGULATORY COMMISSION
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ALL AGREEMENT STATES, VERMONT

NOTIFICATION OF ISSUANCE OF GERMANIUM-68/GALLIUM-68 PHARMACEUTICAL
GRADE GENERATORS LICENSING GUIDANCE (STC-19-048)

Purpose: To inform the Agreement States that updated Germanium-68/Gallium-68
Pharmaceutical Grade Generators Licensing Guidance was published in July 25, 2019.

Background: The U.S. Nuclear Regulatory Commission (NRC) current 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.

Discussion: 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. All sections of this guidance apply to both
medical licensee and commercial nuclear pharmacy licensee use of this generator 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 revision is available online at
<http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

If you have any questions regarding this correspondence, please contact me at 301-415-5804 or the individual named below:

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

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