



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
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July 25, 2019

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:

POINT OF CONTACT: Said Daibes, PhD  
TELEPHONE: (301) 415-6863

E-MAIL: [Said.Daibes@nrc.gov](mailto:Said.Daibes@nrc.gov)

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Paul Michalak, Chief  
State Agreement and Liaison Programs  
Division of Materials Safety, Security, State  
and Tribal Programs  
Office of Nuclear Material Safety  
and Safeguards

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

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

DATED: JULY 25, 2019

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NAME	SDaibes	LDimmick	CEinberg	PMichalak
DATE	04/24/19	04/26/19	05/02/19	07/25/19

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