



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

October 19, 2016

ALL AGREEMENT STATES, VERMONT, WYOMING

NOTIFICATION OF ISSUANCE OF A REVISION TO THE ECKERT AND ZIEGLER
GALLIAPHARM™ GERMANIUM-68/GALLIUM-68 PHARMACY GRADE GENERATOR
LICENSING GUIDANCE (STC-16-083)

Purpose: To inform the Agreement States that a revision to the Eckert and Ziegler GalliaPharm™ Germanium-68/Gallium-68 (Ge-68/Ga-68) Pharmacy Grade Generator Licensing Guidance was published in October 2016.

Background: The licensing guidance for the Eckert and Ziegler GalliaPharm™ Ge-68/Ga-68 Pharmacy Grade Generator Licensing Guidance was initially published on September 28, 2016. This revision to the guidance was issued to update the breakthrough limit example due to a conversion error made in the original guidance document. The document is intended to be used as guidance in licensing the Eckert and Ziegler GalliaPharm™ Ge-68/Ga-68 Pharmacy Grade Generators for applicants, licensees and NRC staff, and is also available to the Agreement States for their use.

Discussion: This revision to the licensing guidance was issued to update the Ge-68 to Ga-68 ratio example provided to illustrate the 0.001 percent breakthrough limit because the original example contained a conversion error. The example, as stated in the revised document, is a ratio of 0.01 μCi Ge-68 per mCi Ga-68. The example ratio is located on page 6 of the document.

This licensing guidance revision is available at
<http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

If you have any questions regarding this correspondence, please contact me at 301-415-3340 or the individual named below:

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Daniel S. Collins, Director
Division of Material Safety, State, Tribal
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Eckert and Ziegler GalliaPharmTM
Ge-68/Ga-68 Pharmacy Grade
Generator Licensing Guidance

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***via email**

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