



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

October 21, 2016

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

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

Mark R. Shaffer, Director
Division of Nuclear Materials Safety
Region IV

FROM: Daniel S. Collins, Director */RA Pamela Henderson for/*
Division of Material Safety, States, Tribal
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

SUBJECT: ISSUANCE OF A REVISION TO THE ECKERT AND ZIEGLER
GALLIAPHARM™ GERMANIUM-68/GALLIUM-68 PHARMACY
GRADE GENERATOR LICENSING GUIDANCE

This memorandum is to inform you that a revision to the Eckert and Ziegler GalliaPharm™ Germanium-68/Gallium-68 (Ge-68/Ga-68) Pharmacy Grade Generator Licensing Guidance was published on October 17, 2016.

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.

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

Enclosure:
Eckert and Ziegler GalliaPharm™
Germanium-68/Gallium-68 Pharmacy
Grade Generator Licensing Guidance

CONTACT: Katie Tapp, Ph.D., NMSS/MSTR
(301) 415-0236

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

The licensing guidance revision may be found on the NRC Medical Uses Licensee Toolkit at:
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(301) 415-0236

DISTRIBUTION:

Pamela Henderson, NMSS
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Vered Shaffer, RIII

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OFC	MSTR/MSEB	MSTR/MSEB	MSTR
NAME	KTapp	DBollock	PHenderson for DCollins
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