



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

August 18, 2016

ALL AGREEMENT STATES, VERMONT, WYOMING

NOTIFICATION OF ISSUANCE OF AUTHORIZATION FOR GRANTING SPECIFIC  
EXEMPTION FROM DECOMMISSIONING FUNDING PLAN REQUIREMENT FOR  
GERMANIUM-68/GALLIUM-68 GENERATORS (STC-16-065)

**Purpose:** To inform the Agreement States of the attached memorandum (Agencywide Documents Access and Management System (ADAMS) Accession No. ML16082A415) provided to the U.S. Nuclear Regulatory Commission (NRC) Regions on July 29, 2016, delegating authority to the regions to grant a specific licensing exemption from the decommissioning funding plan (DFP) requirement for medical Germanium-68 (Ge-68)/Gallium-68 (Ga-68) generators.

**Background:** The Advisory Committee on the Medical Uses of Isotopes evaluated the DFP requirement for Ge-68 generators that arise from Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30 regulations and concluded that the DFP requirement was too restrictive and would prevent or deter the use of promising Ga-68 diagnostic imaging agents for patients (ML15231A047). Concerns were raised with respect to the resources needed to develop and maintain a DFP for the medical Ge-68/Ga-68 generator. After analysis, staff agreed the DFP requirement could impede or limit patient access to the radiopharmaceuticals developed from this generator.

A typical new Ge-68/Ga-68 generator contains 50 mCi at its calibration date; under the NRC regulations, the possession of a single generator triggers the need for a DFP. Even with the proposed exemption, licensees must continue to provide financial assurance in amounts described in 10 CFR 30.35 if they possess other radionuclides in quantities requiring financial assurance or a DFP. The amount is based on their license to possess other (i.e., non Ge-68) unsealed byproduct material as described in 10 CFR 30.35(a)(1).

Staff determined this exemption will ensure public health and safety, at the same time allowing access to the radiopharmaceuticals developed from this generator until a permanent regulatory solution is reached through rulemaking. A direct final rule process has been initiated.

**Discussion:** The attached memorandum authorizes NRC regions to issue, when requested, an exemption to 10 CFR 30.35 (a)(1), just for medical Ge-68/Ga-68 generators, and only if a legally binding agreement is in place for the licensee to return the generators to the manufacturer or distributor when the generators expire and are no longer used to prepare Ga-68 radiopharmaceuticals for patients, or if the licensee ceases its preparation of Ga-68 radiopharmaceuticals. The legally binding agreement between the licensee and generator manufacturer or distributor must highlight licensee commitments to return expired generators back to the manufacturer or distributor and also must include a manufacturer or distributor

commitment to take expired generators back. The regions are instructed to consult with regional counsel or the Office of General Counsel to confirm that a legal binding agreement is in place prior to issuing the exemption.

The NRC licensing staff may issue an exemption from the 10 CFR 30.35 DFP requirements to a licensee or applicant for authorizations who apply for possession of Ge-68/Ga-68 medical use generator(s), under Part 35.200 (medical facility) or 10 CFR Part 32.72 (nuclear pharmacy), if the licensee or applicant submits and maintains for NRC inspection, a legally binding agreement that ensures the generator will be returned to the manufacturer or distributor at the end of use. The NRC licensing staff will add the following condition to the license:

“Notwithstanding the requirements of 10 CFR 30.35 (a)(1), the licensee is exempt from the requirement to have a decommissioning funding plan needed for the possession and use of Ge-68/Ga-68 medical use generators (make/model # of generators), based on the commitments between the licensee and manufacturer (name of manufacturer/distributor), described in the letter/application dated \_\_\_\_\_.”

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

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Division of Material Safety, State, Tribal  
and Rulemaking Programs  
Office of Nuclear Material Safety  
and Safeguards

Enclosure:  
Authorization for Granting Specific  
Exemption From Decommissioning  
Funding Plan Requirement for  
Germanium-68/Gallium-68 Generator

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Enclosure:  
Authorization for Granting Specific  
Exemption From Decommissioning  
Funding Plan Requirement for  
Germanium-68/Gallium-68 Generator

**ML1622A4273**

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