



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

August 1, 2017

ALL AGREEMENT STATES, VERMONT, WYOMING

NOTIFICATION OF CLARIFICATION THAT GRANTING AN EXEMPTION FROM THE DECOMMISSIONING FUNDING PLAN REQUIREMENTS IN TITLE 10 OF THE CODE OF FEDERAL REGULATIONS PART 30 DOES NOT EXEMPT LICENSEES FROM OTHER FINANCIAL ASSURANCE REQUIREMENTS, UPDATE OF LICENSING GUIDANCE, AND COMPATIBILITY DETERMINATION FOR GERMANIUM-68/GALLIUM-68 GENERATORS (STC-17-057)

Purpose: To inform Agreement States that the U.S. Nuclear Regulatory Commission (NRC) staff has updated its information concerning Germanium-68 (Ge-68)/Gallium-68 (Ga-68) generators. First, the NRC staff has revised the technical basis for granting a specific exemption from the decommissioning funding plan (DFP) requirement for Ge-68/Ga-68 generators. Specifically, the technical basis clarifies that the DFP exemption does not exempt financial assurance. The enclosed memorandum (Agencywide Documents Access and Management System (ADAMS) Accession No. ML17075A487) provided to the NRC regions on July 13, 2017, updates a July 29, 2016, NRC memorandum (ADAMS Accession No. ML16082A415). Second, the Ge-68/Ga-68 generator licensing guidance has been revised to include the criteria needed for the DFP exemption. Last, the NRC staff has provided a compatibility determination for the DFP requirement.

Background: The Advisory Committee on the Medical Uses of Isotopes (ACMUI) evaluated the DFP requirement for Ge-68/Ga-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 (ADAMS Accession No. ML15231A047). The ACMUI recommended that the NRC staff exempt Ge-68/Ga-68 generator licensees from DFP requirements under certain conditions. The NRC staff analyzed the ACMUI report and agreed that 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, possession of 50 mCi of Ge-68 exceeds the threshold quantity above which a DFP is required. The NRC staff determined that this exemption will ensure public health and safety and allow access to the radiopharmaceuticals developed from this generator until a permanent regulatory solution is reached through rulemaking.

Discussion: The July 29, 2016, memorandum delegated authority to the NRC regions to grant an exemption from the DFP requirement in 10 CFR Part 30 for possession and use of Ge-68/Ga-68 generators. The technical basis for the exemption relieved a licensee from the requirement for a DFP (10 CFR 30.35(a)(1)) when certain conditions were met. Specifically, the memorandum authorized the NRC regions to issue an exemption for Ge-68/Ga-68 generators when requested, only if a legally binding agreement was in place for the licensee to return the generators to the manufacturer or distributor when the generators were no longer used. The technical basis for the exemption did not remove the financial assurance requirements in 10 CFR 30.35.

The revised memorandum issued to the NRC regions on July 13, 2017, contains the technical basis for granting a specific exemption from the DFP requirement for the Ge-68/Ga-68 generators and provides (1) a clarification that granting an exemption from the DFP requirement in 10 CFR Part 30 does not exempt licensees from financial assurance requirements; (2) a list of specific elements that should be in a legally binding agreement for the return of generators to the manufacturer or distributor; and (3) a minor revision to the licensing condition that specifies that the licensee must return the Ge-68/Ga-68 generators to the manufacturer or distributor when they are no longer being used.

Lastly, the enclosed revisions to the technical basis and guidance will not impact existing granted Ge-68/Ga-68 generators DFP exemptions by NRC or the Agreement States.

The NRC has updated its licensing procedure for the use of the Ge-68/Ga-68 pharmaceutical grade generator manufactured by Eckert and Ziegler Radiopharma GmbH dated July 13, 2017, (ADAMS Accession No. ML17075A488) to include items noted above.

The Standing Committee on Compatibility (SCC) has reviewed this matter and agrees that the exemption from the DFP requirements and its conditions outlined in the technical basis for licensees who possess and use Ge-68/Ga-68 generators are a matter of compatibility. An Agreement State should adopt and implement the essential objectives of this program element. With regard to meeting the financial assurance requirements in 10 CFR 30.35(b), this portion of the regulations is designated as Category Health & Safety. An Agreement State has a number of options to meet the essential objective of this requirement including:

1. Use the financial assurance monetary values from the attached technical basis document of \$1,125,000 for licensees who possess more than 2 generators but less than 20 (>100 to 1000 mCi) or \$225,000 in financial assurance for licensees possessing one or two Ge-68 generators (50 to 100 mCi) accompanied by a legally binding agreement for the return of the generator(s) to the manufacturer or distributor at the end of use.
2. Use the financial assurance monetary values listed in the Agreement State regulations for the quantities of Ge-68 possessed by the licensee in the generator(s) accompanied by a legally binding agreement for the return of the generator(s) to the manufacturer or distributor at the end of use.
3. Although licensees are exempt from the requirement to submit a DFP, a licensee may still choose to submit a DFP to support a different amount of financial assurance. After review and approval by the Agreement State, the licensee would provide financial assurance for the amount in the DFP.
4. Exempt their licensees from the financial assurance requirements based on a health and safety evaluation conducted and documented by the Agreement State that should include a legally binding agreement for the return of the generator(s) to the manufacturer or distributor at the end of use.

Consequently, the SCC also agrees that the licensing procedures for Ga-68/Ge-68 generators are an essential component of a licensing program and it is a matter of compatibility (see Appendix A in *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements - SA-200*). The NRC will review the NRC Regional and Agreement State radioactive materials programs' implementation through the Integrated Materials Performance Evaluation Program (IMPEP) under the performance indicator, Technical Quality of Licensing Actions. An Agreement State can demonstrate meeting this compatibility requirement by implementing written procedures for the licensing of Ge-68/Ga-68

generators that include one of the financial assurance options described above and a legally binding agreement for the return of the generator(s) to the manufacturer or distributor at the end of use if the DFP exemption is used. An example of a Ge-68/Ga-68 generator licensing guide is enclosed.

In accordance with Part VI of Management Directive 5.9 *Adequacy and Compatibility of Agreement State Programs*, an Agreement State must implement this requirement within 6 months of the date of this letter.

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

TECHNICAL POINT OF CONTACT: Said Daibes, Ph.D.

E-MAIL: Said.Daibes@nrc.gov TELEPHONE: (301) 415-6863

COMPATIBILITY AND IMPEP POINT OF CONTACT: Duncan White

E-MAIL: duncan.white@nrc.gov TELEPHONE: (301) 415-2598

/RA Kevin Williams for/

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

Enclosures:

1. Revision of Technical Basis for Granting Specific Exemption from Decommissioning Funding Plan Requirement for Germanium-68/Gallium-68 Generators
2. Eckert and Ziegler GalliaPharm™ Germanium-68/Gallium-68 Pharmacy Grade Generator Licensing Guidance, Rev. 1 (July 13, 2017)

SUBJECT: NOTIFICATION TO CLARIFY THAT GRANTING AN EXEMPTION FROM THE DECOMMISSIONING FUNDING PLAN REQUIREMENTS IN 10 CFR PART 30 FOR GERMANIUM-68/GALLIUM-68 GENERATORS DOES NOT IMPLY THAT OTHER FINANCIAL ASSURANCE REQUIREMENTS ARE EXEMPTED (STC-17-057)

ML17075A484

OFC	MSTR	MSTR	MSTR	OGC	MSTR	MSTR
NAME	SDaibes	MFuller	DBollock	EHouseman	PMichalak	KWilliams for DCollins
DATE	3/29/17	3/29/17	4/6/17	5/15/17	7/28/17	8/1/17

OFFICIAL RECORD COPY