**REQUIRED ITEMS FOR GE-68 GENERATOR AMENDMENT**

The information listed below is the minimum information required to amend your license authorizing the possession of the Ge-68 generator. This should be used by radiopharmacy licensees desiring to possess the Ge-68 generator and either distributes the generator or draws and distributes the Ga-68 unit doses. For those medical licensees desiring to possess and use the Ge-68 generator, you also should use this document. If a medical licensee will receive the Ga-68 unit dose, than an amendment is not required as you are already authorized under 12VAC5-481-1920 to receive and use the unit dose.

If you have any questions regarding this process, please contact us at 804-864-8150.

**Radionuclides, Form, Possession Limits, and Purpose of Use**

The applicant shall identify the radionuclides, chemical/physical form, requested maximum possession limit, and purpose of use. For example, the following provides the format for an acceptable request:

Radionuclides (Authorization 6): Germanium-68/Gallium-68 Generator as permitted by 12VAC5-481-2060

Chemical/Physical Form (Authorization 7): Any

Maximum Possession Limit (Authorization 8): X mCi of Ge-68

Authorized Use (Authorization 9): For the use of Ga-68 eluted from a Ge-68 generator to prepare Ga-68 radiopharmaceuticals for imaging and localization studies (medical licensees) or for the use of Ga-68 eluted from a Ge-68 generator to prepare and distribute Ga-68 radiopharmaceuticals (radiopharmacies).

Facility Address and Description: Provide an address of use and submit a facility diagram and description of the location(s) where the generator will be received, used, and stored. If applicable, provide a description of imaging rooms and patient uptake rooms and include shielding information and calculation appropriate for the PET facility. American Association of Physicists in Medicine Task Group 108, “PET and PET/CT Shielding Requirements,” provides guidance on how to design a PET facility and perform associated shielding calculations. The document also provides guidance on appropriate safety equipment to use. If the location of use has already been submitted, no additional information is required, state that the location of use “is as described on the current license.”

**Authorized Users (Medical Licensees)**

Identify each AU and provide documentation of their training and experience, if necessary, in the use of elution of Ga-68 from the Ge-68/Ga-68 generators.

AU should be considered qualified for use of elution of Ga-68 from the Ge-68/Ga-68 generators if the licensee demonstrates that the individual meets the following:

1) Is currently listed as an AU for 12VAC5-481-1920 (or equivalent); on a Virginia, NRC, other Agreement State, Broad Scope or Master Materials license or permit; or

2) Is an AU under 12VAC5-481-1980 and meets the requirements in 12VAC5-481-1940 3 a (2) (g); or

 3) Meets the qualifications in 12VAC5-481-1940 3.

**Authorized Nuclear Pharmacist (Radiopharmacy Licensees)**

Identify each ANP and provide documentation of their training and experience, if necessary, in the use of elution of Ga-68 from the Ge-68/Ga-68 generators.

ANPs should be considered qualified for use of elution of Ga-68 from the Ge-68/Ga-68 generators if the licensee demonstrates that the individual meets the following:

1) Is currently listed as an ANP for 12VAC5-481-1770 (or equivalent); on a Virginia, NRC, other Agreement State, Broad Scope or Master Materials license or permit; or

2) Meets the qualifications in 12VAC5-481-1770.

**Training**

The applicant shall commit to proving training for all AU(s) or ANP(s) using Ge-68/Ga-68 generators to produce Ga-68 for medical use, as well as the RSO for that facility, specific to the manufacturer and model of generator being used.

Such training should include:

(1) Elution and quality control procedures needed to determine Ga-68 activity and the Ge-68 breakthrough levels appropriate for the preparation of radiopharmaceuticals for imaging and localization studies;

(2) Measuring and testing the eluate for radionuclide purity; and

(3) Safety procedures for the use of Ge-68/Ga-68 generator.

The applicant shall commit to provide training in the licensee’s procedures to all individuals involved in Ge-68/Ga-68 generator use, commensurate with the individual’s duties to be performed. This training must be provided to all individuals eluting the generator or preparing, measuring, or administering the Ga-68 dose.

**Alterations to the Generator Unit**

The applicant shall commit to not open, breach, or physically modify the Ge-68/Ga-68 generators in any way.

**Permissible Ge-68 Concentrations**

The applicant shall commit to elute the generator in accordance with the manufacturer’s stated frequency and procedures to minimize the concentration of Ge-68 in the eluate. The applicant shall commit to only use a generator that has not expired for the preparation of Ga-68 radiopharmaceuticals that are used for patients or human research subjects. An applicant shall commit to not administer to a patient or research subject a Ga-68 radiopharmaceutical that exceeds the manufacturer’s stated breakthrough limits of Ge-68. An applicant shall commit to measure the concentration of Ge-68 to demonstrate compliance with the above maximum concentration limits at least once per week. Applicant shall commit to develop and implement written procedures to measure the Ge-68 breakthrough in the generator eluates. These procedures must be capable of determining the Ge-68 concentration at the maximum permissible concentration limits described above. The applicant shall commit to remove a generator from use if the measured Ge-68 breakthrough exceeds the manufacturer’s stated breakthrough limits of Ge-68. The breakthrough shall be measured again in a new elution and must be below the maximum permissible concentration limits before the generator may be placed back into use. The applicant shall describe the equipment used to determine the concentrations.

**Transfer or Sharing of Ge-68/Ga-68 Generator**

If the Ge-68/Ga-68 generator is transferred between locations, the licensee shall commit to measure the concentration of Ge-68 breakthrough to demonstrate compliance with the above maximum Ge-68 concentration limits. This measurement will be of either the first elution or the first elution after the generator is flushed, if necessary, from the Ge-68/Ga-68 generator at the new location. The licensee shall commit to not using the first eluate after the transfer for preparing Ga-68 radiopharmaceuticals.

**Radiation Protection Program Changes**

An applicant initially applying for authorization for medical use of Ga-68 radiopharmaceuticals that are prepared with Ga-68 from a Ge-68/Ga-68 generator may request to incorporate into its license a change process similar to 12VAC5-481-1700 F. Such a change process can allow some future changes to radiation safety programs provided that the change process requires the following conditions to be met for revisions to the radiation safety program:

1. The revision is in compliance with the regulations; and

2. The revision is based upon current guidance for use of Ga-68 radiopharmaceuticals that are prepared with Ga-68 from a Ge-68/Ga-68 generator under 12VAC5-481-2060; and

3. The revision has been reviewed and approved by the licensee’s Radiation Safety Officer and licensee’s management; and

4. The affected individuals are instructed on the revised program before the change is implemented; and

5. The licensee will retain a record of each change for 5 years; and

 6. The record will include a copy of the appropriate Web site guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

If approved, these conditions for use of updated guidance will be incorporated as license conditions in the licensee’s license. Notes to Licensees Labeling Syringes and unit dosages must be labeled in accordance with 12VAC5-481-1850.

**Waste Disposal**

Due to breakthrough, the eluate may contain small activity of Ge-68, which has a half-life of greater than 120 days. Depending on the activity of Ge-68, composition of waste, and local regulations, the licensee may need to:

1) Dispose the waste by release into sanitary sewer in accordance with 12VAC5-481-930. Please note that the waste generated during elution and dose preparation is acidic. For final disposal, the acidic solution may need to be placed into a chemical waste container; or

2) Transfer the waste to an authorized recipient. For applicants that are requesting to use this generator at a mobile facility, the applicant should address how waste will be processed and additional shielding considerations in order to show compliance with 12VAC5-481 Part IV.

**Returning Generators to the Manufacturer or Distributor**

Used generators may be returned to the manufacturer or distributor. This permission does not relieve licensees from the requirement to comply with 12VAC5-481 Part XIII and DOT regulations.

Perform the following actions when returning generators:

1) Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container.

2) Assemble the package in accordance with the manufacturer’s instructions.

3) Perform the dose-rate and removable-contamination measurements.

4) Label the package and complete the shipping papers in accordance with the manufacturer’s instructions.

5) Retain records of receipts and transfers.