

From: [Nguyen, Janice](#)
To: [Sullivan, Glenn](#)
Cc: [Gomez, Alexis](#)
Subject: NRC Request for Additional Information for Cardinal Health P.R. 120, Inc. (Mail Control Numbers 624561 and 624653)
Date: Thursday, April 1, 2021 10:05:00 AM

Licensee: Cardinal Health P.R. 120, Inc.
License No.: 34-31473-02MD
Docket No.: 030-38569
Control Nos.: 624561 and 624653

PLEASE CONFIRM RECEIPT OF THIS REQUEST FOR ADDITIONAL INFORMATION BY RETURN EMAIL

Dear Mr. Sullivan:

In your letter dated February 1, 2021, you requested to add an authorization for the possession and use of germanium-68/gallium-68 (Ge-68/Ga-68) generators to your NRC License No. 34-31473-02MD. This action is being processed under mail control number 624561. In your letter dated September 15, 2020, you submitted financial assurance information, including a surety bond, to support your request for the Ge-68/Ga-68 generators. The financial assurance action is being processed under mail control number 624653.

In order to continue our review, please provide the following additional information:

1. On your facility diagram, please indicate a brief description of the uses above, below, and adjacent to the Ge-68/Ga-68 use area.
2. The above-referenced letter did not identify who should be authorized for use of the Ge-68/Ga-68 generators. Accordingly, please identify each authorized user (AU) or authorized nuclear pharmacist (ANP) who should be given this authorization, and provide documentation of his/her training and experience in the use of Ge-68/Ga-68 generators. Please note that any individual identified as an ANP on a NRC license will be considered qualified.
3. In the above-referenced letter, only some licensing commitments were made and some commitments were missing specific language.

Accordingly, under the current guidance, please confirm that you commit to the following:

- Following the manufacturer's procedures, including: generator set-up; generator elution; Ge-68 breakthrough testing and frequency when in use; and final disposition;
- After installation, performing the conditioning procedure following the manufacturer's instructions properly disposing of the conditioning eluates prior to the first use of eluate for testing or human use;
- Developing and implementing written procedures for the determination of breakthrough that will detect whether the eluate exceeds the manufacturer's recommended breakthrough limit;

- During the course of breakthrough testing, if the eluate exceeds the manufacturer's breakthrough limits, the eluate will not be distributed or administered to a patient or human research subject;
 - Notifying by telephone the NRC Operations Center (301-816-5100) and the manufacturer/distributor of the generator within 7 calendar days after discovery of a generator that is unable to meet the manufacturer's stated Ge-68 breakthrough limits. A failed generator effective date will be when the breakthrough calculation was performed, which should be no more than 7 days from the date of the previous breakthrough calculation;
 - Include in the report to the NRC Operations Center the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects; when the manufacturer/distributor was notified; and the action taken;
 - Sending a written report to the appropriate NRC Regional Office within 30 days after discovery of a generator that is unable to meet the manufacturer's stated breakthrough limits of Ge-68 on multiple occasions rendering the generator unusable in human patients and research subjects;
 - Include in the written report the action taken by the licensee; probable cause and assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination, and the information in the telephone report made as described above;
 - Conduct surveys of all areas of licensed material use, including the generator storage and kit preparation areas, for contamination each day of use; and
 - Developing and implementing written emergency procedures for leaking or damaged generators.
4. Via memo dated July 13, 2017 (ML17075A487), NRC's Office of Nuclear Material Safety and Safeguards (NMSS) authorized the NRC Region I Office to grant specific exemptions from the 10 CFR 30.35(a)(1) DFP requirement. Please confirm that you are explicitly requesting an exemption from the 10 CFR 30.35 DFP requirement.
5. Please submit an addendum to your surety bond with the following corrections:
- a. Please include the docket number.
 - b. In the last paragraph on the first page of the bond (beginning with "Whereas"), please confirm that the materials fall under Part 30 (and remove Parts 40 and 70 if not applicable).
 - c. The signature section of the bond should be stamped with the corporate seal of the licensee. If the licensee does not have a corporate seal, that should be indicated.
6. Please submit a Certification of Financial Assurance (CFA). It may be helpful to review section A.2 of NUREG-1757, Volume 3, Revision 1, "Consolidated NMSS Decommissioning Guidance – Financial Assurance, Recordkeeping, and Timeliness," which can be found here: <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v3/index.html>. A Model CFA is included on page A-19.
7. Please submit a Standby Trust Agreement (STA) and all supporting documentation (see Section A.12 and attach Checklist 12-A and its supporting documentation from NUREG-

1757, Volume 3, Revision 1).

We will continue our review upon receipt of the requested information. You may respond to my attention in writing by letter, email (if letter is signed by senior management and scanned into a pdf format), or fax (610-337-5269), referencing mail control number 624561 and 624653. Please submit a reply within 30 days, or we will assume you no longer require this amendment. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5006.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Licensee Toolkits, see our toolkit index page**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

Thank you in advance for your help!

Sincerely,

Jan

Janice Nguyen
Senior Health Physicist
U.S. Nuclear Regulatory Commission
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406
Office (610) 337-5006
FAX (610) 337-5269