



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**  
REGION III  
2443 WARRENVILLE RD. SUITE 210  
LISLE, IL 60532-4352

April 6, 2023

Craig Kinne  
Radiation Safety Officer  
Jubilant DraxImage Inc.  
d/b/a Jubilant Radiopharma  
790 Township Line Rd.  
Suite 325  
Yardley, PA 19067

Dear Craig Kinne:

This letter is regarding your request dated December 27, 2022 to renew your NRC Materials License No. 09-32781-04MD

Following review of your licensing request I have identified the following areas requiring additional or clarifying information. Please reference NRC Guidance Document NUREG-1556 Vol. 13 Rev. 2 in preparing your response. This guidance is available on the U.S. NRC website at: <https://www.nrc.gov/docs/ML1907/ML19079A207.pdf>

1) 5. Materials to be Possessed - Sealed Sources

- a.) Confirm that each sealed source, device, and source/device combination is registered as an approved sealed source, device, or discrete source by the NRC or an Agreement State and will be possessed and used in accordance with the conditions specified in the registration certificate. Provide the SSD registration certificate number, if available;
  - i) For each sealed source, device, and source and device combination that is not registered provide the applicable information, as described in 10 CFR 30.32(g) and 32.210;
- b.) Confirm that the activity per source and maximum activity in each device will not exceed the maximum activity listed on the approved certificate of registration issued by the NRC or by an Agreement State;

2) 6.1 Distribution and Redistribution of Sealed and Unsealed Materials

For all transferred, distributed, and redistributed sealed and unsealed materials:

- a.) Provide a statement that, "We have developed and will implement and maintain written procedures to meet the license verification requirements specified in accordance with 10 CFR 30.41(d).
- b.) Describe procedures to ensure that sealed and unsealed materials are securely and safely provided to mobile medical licensees if they are transferred, distributed, or redistributed to a mobile medical licensee's mobile van or coach, where there is no permanent structure for byproduct material storage. For example, procedures should

ensure that delivery directly to the van or coach will only occur if the van or coach is occupied by mobile medical licensee personnel at the time of delivery.

For radiopharmaceuticals:

- c.) Confirm that radiopharmaceuticals will be prepared under the supervision of an Authorized Nuclear Pharmacist (ANP) or will be obtained from a supplier authorized pursuant to 10 CFR 32.72, or under equivalent Agreement State requirements.

For redistribution of used generators:

- d.) Describe the procedures and instructions for safely repackaging the generators, including the use of the manufacturer's original packaging and minimization of migration of radioactive fluids out of the generator during transport.
- Confirm that the manufacturer's packaging and labeling will not be altered;
  - Confirm that the generator will not be distributed beyond the expiration date shown on the generator label;
  - Confirm that the redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator;
  - Confirm that only generators used in accordance with the manufacturer's instructions will be redistributed.

For redistribution of sealed sources for brachytherapy or diagnosis:

- e.) Confirm that the sealed sources for brachytherapy or diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy or diagnosis in accordance with a specific license issued pursuant to 10 CFR 32.74 or under equivalent Agreement State requirements.
- f.) Confirm that the manufacturer's packaging, labeling, and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

For redistribution of prepackaged units for in vitro tests to specific licensees:

- g.) Confirm that the labeling on redistributed prepackaged units for in vitro tests will conform to the requirements of 10 CFR 20.1901, "Caution signs" and 20.1904, "Labeling containers."

### 3) 6.2 Preparation of Radiopharmaceuticals

Respond to the following:

For radiopharmaceutical preparation we will perform:

- Compounding of Iodine-131 capsules;
- Radioiodination;
- Chemical synthesis of Positron Emission Tomography (PET) radiopharmaceuticals;
- Technetium (Tc)-99m kit preparation;
- Other, specify

- 4) 7.2 Authorized Nuclear Pharmacist(s)
  - a.) Please confirm that Jonathan Vaught, R.Ph should be removed from the license.
  
- 5) 8.2 Training for Personnel Involved in Hazardous Materials Package Preparation and Transportation
  - a.) Submit the following statement, "We have developed and will implement and maintain written records and written procedures for training personnel involved in hazardous materials package preparation and transport that meet the requirements in 49 CFR 172.700, 49 CFR 172.702, and 49 CFR 172.704, as applicable."
  
- 6) 9. Facilities and Equipment
  - a.) Provide a response indicating if permanent shielding is installed in the facility aside from shielding installed in equipment such as the DRAXIMAGE Smart-Fill.  
  
If applicable, provide a facility diagram with sufficient detail to indicate locations of shielding, the shielding thickness, and the materials used for shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. Please specify areas where PET isotopes are use and any additional considerations for shielding in these areas.
  
- 7) 10.2 Radiation Monitoring Instruments:
  - a.) Submit the following statement: "We reserve the right to upgrade our monitoring instrumentation as necessary, as long as the instruments are adequate to measure the type of radiation and energy range of the radiation for which they are used."
  
- 8) 10.6 Safe Use of Radionuclides and Emergency Procedures
  - a.) Provide the following response:  
"We have developed and will implement and maintain written procedures for the safe and secure use of radioactive materials that address:
    - Facility and personnel radioactive contamination minimization, detection, and control.
    - Performing molybdenum-99 breakthrough measurements of each eluate from a molybdenum-99/technetium-99m generator.
    - Reporting under the requirements in 10 CFR 30.34(g) if there is more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m) in the eluate.
    - Performing breakthrough measurements on each eluate of other generators (e.g., Ge-68/Ga-68 generators).
    - Using protective clothing and equipment by personnel to support meeting the requirements in 10 CFR 20.1101.
    - Securing licensed material during use and storage (10 CFR 20.1801, 10 CFR 20.1802)

- Conducting Mo-99/Tc-99m generator Mo-99 breakthrough tests and conducting Sr-82/Rb-82 generator breakthrough tests for Sr-82 and Sr-85 contamination in accordance with 10 CFR 30.34(g) and 10 CFR 35.204
  - Posting the operating procedures applicable to commercial radiopharmacies (10 CFR 19.11(a)(3))
- b.) Provide the following statement:  
We have developed and will implement and maintain written procedures for identifying and responding to emergencies involving radioactive material, including:
- Lost, stolen, or missing licensed material.
  - Exposures to personnel and the public in excess of NRC regulatory limits.
  - Releases of licensed materials in effluents and the sanitary sewer in excess of NRC regulatory limits.
  - Excessive radiation levels or radioactive material concentrations in restricted or unrestricted areas.
  - Radioactive spills and contamination.
  - Fires, explosions, and other disasters with the potential for the loss of containment of licensed material.
  - Routine contacts with local fire departments and LLEA to meet the requirements in 10 CFR 20.1101, 10 CFR 20.2201- 20.2203, and 10 CFR 30.50, 10 CFR 37.45, 10 CFR 40.60, and other requirements, as applicable.

9) 10.8 Dosage Measurement Systems

- a.) For each dosage measurement system used to measure the amount of radioactivity in alpha-, beta-, gamma-, and photon-emitting radioactive drugs, state: "We have developed, and will implement and maintain, a written procedure for the performance of dosage measurement system checks and tests that meet the requirements in 10 CFR 32.72(c)."
- b.) If applicable, include a description of the methodology and equipment to be used for the assay of alpha-emitting radionuclides.

10) 10.11 Radioactive Drug Labeling for Distribution

- a.) Confirm that required labels will be affixed to all "transport radiation shields" and each container used to hold the radioactive drugs.

Germanium-Gallium Generators:

10 CFR 35.1000 Licensing Guidance: <https://www.nrc.gov/docs/ML1910/ML19106A367.pdf>

11) Commit to the following:

- a.) 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;
- b.) 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;

- c.) Confirm that the following actions will be performed when returning a Ge-68/Ga-68 generator to the manufacturer.
- Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container;
  - Assemble the package in accordance with the manufacturer's instructions;
  - Perform the dose-rate and removable-contamination measurements; and
  - Label the package and complete the shipping papers in accordance with the manufacturer's instructions. Retain records of receipts and transfers in accordance with 10 CFR 30.51, "Records."

Financial Assurance Documents

- 12) Submit an originally signed duplicate of the financial assurance mechanism. Please mail your response to our Region III office located at 2443 Warrenville Road, Suite 210, Lisle, IL 60532.
- 13) Include a Model Certificate of Events with your response. A copy is attached for your convenience.
- 14) Include a Model Certificate of Resolution with your response. A copy is attached for your convenience.

In accordance with Title 10 Code of Federal Regulations 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

Laura B. Cender  
Health Physicist  
Materials Licensing Branch

License No. 09-32781-04MD  
Docket No. 030-38280

**A.12.6 Model Specimen Certificate of Events**

[*Insert name and address of trustee*]

Attention: Trust Division

Gentlemen:

In accordance with the terms of the Agreement with you dated \_\_\_\_\_, I, \_\_\_\_\_, Secretary of [*insert name of licensee*], hereby certify that the following events have occurred:

1. [*Insert name of licensee*] is required to commence the decommissioning of its facility located at [*insert location of facility*] (hereinafter called the decommissioning).
2. The plans and procedures for the commencement and conduct of the decommissioning have been approved by the United States Nuclear Regulatory Commission, or its successor, on \_\_\_\_\_ (copy of approval attached).
3. The Board of Directors of [*insert name of licensee*] has adopted the attached resolution authorizing the commencement of the decommissioning.

\_\_\_\_\_  
Secretary of [*insert name of licensee*]

\_\_\_\_\_  
Date

### **A.12.7 Model Specimen Certificate of Resolution**

I, \_\_\_\_\_, do hereby certify that I am Secretary of [*insert name of licensee*], a [*insert State of incorporation*] corporation, and that the resolution listed below was duly adopted at a meeting of this Corporation's Board of Directors on \_\_\_\_\_, 20\_\_\_\_.

IN WITNESS WHEREOF, I have hereunto signed my name and affixed the seal of this Corporation this \_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_.

\_\_\_\_\_  
Secretary

RESOLVED, that this Board of Directors hereby authorizes the President, or such other employee of the Company as he may designate, to commence decommissioning activities at [*insert name of facility*] in accordance with the terms and conditions described to this Board of Directors at this meeting and with such other terms and conditions as the President shall approve with and upon the advice of Counsel.