ARIZONA DEPARTMENT
OF HEALTH SERVICES

LICENSING
BUREAU OF RADIATION CONTROL

October 7, 2024

Dafna Silberfeld, Deputy Director
Division of Materials Safety, Security, State, Tribal
And Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards
U.S. Nuclear Regulatory Commission (NRC)
T8-E18
Washington, DC 20555-0001

Dear Ms. Silberfeld,

Enclosed is a copy of our non-standard license conditions. We believe that adoption of these legally binding requirements satisfies the compatibility and health and safety categories established in the Office of Nuclear Material Safety and Safeguards (NMSS) Procedure SA-200.

If you have any questions, please feel free to contact me at 602-255-4840 or Brian.Goretzki@azdhs.gov.

Sincerely,

Brian D. Goretzki
Chief
Bureau of Radiation Control
Arizona Department of Health Services

Non-Standard license conditions

If using Alpha Dart:

The Alpha DaRT authorized user shall meet the following requirements:

A. Be an authorized user for Group 400 OR Group 1000 specifically for the medical use of the Alpha DaRT.

B. Have successfully completed training in delivery, safety procedures and clinical use of the Alpha DaRT. The licensee shall have documentation of training for three proctored cases of the Alpha DaRT.

For the use of Radium-224 Alpha DaRT manual brachytherapy sources, the licensee shall:

A. Verify that seeds are fully contained within the patient.

B. Report any event in which the seed is implanted directly into a location discontinuous from the treatment site.

C. Evaluate the location of the seeds to determine if the seeds moved during treatment.

D. Perform both ambient radiation and contamination surveys for every administration in the area where seeds were prepared for use or administered.

E. Have a sealed container available where sources are being prepared and used which has been tested by the manufacturer or licensee to ensure the container prevents Rn-220 leakage.

F. Keep the applicator in the labeled container provided by the manufacturer until the applicator is needed for use.

If using Lu-177:

Lutetium-177 waste may be decayed in storage under A.A.C. R9-7-438, "Disposal of Specific Wastes". Small quantities of metastable Lu-177 may be present as a contaminant generated from the production of Lu-177. If Lu-177m is detected by an appropriate survey method, the licensee must dispose of the waste material as low-level radioactive waste in accordance with A.A.C. R9-7-434.

If using Y-90 microspheres:

A. Yttrium-90 microspheres shall be administered in accordance with the manufacturer's procedures and recommendations.

B. The Yttrium-90 microspheres patient dosages shall be measured in a calibration instrument that has been calibrated with:

1. A NIST traceable Yttrium-90 calibration source; and

2. A calibrated source that is contained in a vial or syringe having the same geometric configuration as the vial or syringe used to calibrate the patient's therapy dose.

C. All Y-90 microsphere waste shall be monitored at the surface prior to disposal to determine that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter. If the waste is determined to contain impurities with a physical half-life of greater than 120 days that can be distinguished from the background radiation level, the licensee shall dispose of the waste by:

1. Returning the Y-90 microspheres to the manufacturer, if the manufacturer is authorized to receive Y-90 microspheres; or

2. Transfer the Y-90 microspheres to an authorized recipient pursuant to the requirements in A.A.C. R9-7-434(A).

D. The licensee shall maintain records of each microsphere therapy for three years.

If approved for IND use:

Prepared radiopharmaceuticals, for which the FDA has accepted an IND, and radiopharmaceuticals prepared from generator or reagent kits, for which the FDA has accepted an IND, shall be dispensed and/or distributed:

A. In accordance with the directions provided by the sponsor of the IND; and

B. Only to physicians who have been accepted by the sponsor of the IND to participate in clinical evaluation of the drug; and

C. As described in letter with attachments, dated **[insert date here].**

The licensee shall inform each physician who participates in an IND evaluation that the physician is responsible to the sponsor of the IND for use of the drug in accordance with protocols established by the sponsor and for reporting to the sponsor the clinical information obtained through use of the drug.

If using CardioGen Sr-82/Rb-82 generator:

When using the CardioGen-82® rubidium-82 generator with the Infusion System manufactured by CTI, Inc.:

A. Use only additive-free Sodium Chloride Injection USP to elute the CardioGen-82® generator. The use of any other type of saline is prohibited.
   a. If the additive-free 0.9% Sodium Chloride Injection USP is replaced during a day of clinical use, the licensee shall perform an additional quality control test with the new saline.
B. The licensee shall follow all of the requirements in manufacturer's CardioGen-82® Infusion System User Guide, its supportive documents and updates. The licensee shall maintain and follow updates to the manual provided by the manufacturer. Copies of this manual, its supportive documents and updates shall be available to each person using and persons having responsibility for the use of, the device and shall be available for inspection by the department.
C. The licensee shall comply with the safety precautions and limitations established in the package insert for the generator.

D. For each generator, the licensee shall maintain an on-going record of all eluate volumes (washing, testing and patient infusions) including a summary of the cumulative volume of eluate. The on-going daily records of volume usage shall be maintained for at least three years and be available for inspection by the Department.

E. The licensee shall measure and calculate the strontium-82 / rubidium-82 and strontium-85 / rubidium-82 concentrations by using a dose calibrator set on the rubidium-82 or cobalt-60 setting (with correction formula if using cobalt-60) and on its most sensitive microcurie scale and recording all values with at least one significant figure and at least two places to the right of the decimal place according the schedule as detailed below. Records of these tests shall be kept in accordance with the manufacturer's user manuals, and its supportive documentation.
    a. Daily eluate tests on days of use prior to administration; and
    b. Additional daily eluate tests performed at every 750 milliliters eluate use for that day (i.e., one additional test when 750 milliliters of eluate is used during the day, a second additional test when 1,500 milliliter of eluate is used during the day and an additional test for each 750 milliliters of eluate used during the day) when:

        i. the initial test concentrations of strontium-82 reach 0.002 microcuries per millicurie of rubidium-82; or
        ii. the initial test concentrations of strontium-85 reach 0.02 microcuries per millicurie of rubidium-82; or
        iii. 14 liters of total elution volume has passed through the generator column.

F. The licensee shall immediately stop using the generator to treat patients at the expiration limits listed below:

    a. 17 liters for the generator's cumulative eluate volume; or
    b. 42 days post generator calibration date; or
    c. An eluate concentration of strontium-82 of equal to or greater than 0.01 microcuries per millicurie of rubidium-82; or
    d. An eluate concentration of strontium-85 of equal to or greater than 0.10 microcuries per millicurie of rubidium-82.

G. The licensee shall follow the manufacturer's annual preventative maintenance schedule for the CardioGen-82® Infusion System and complete all of the recommended corrective actions. This shall include checks on infusion pump flow rate for consistency and accuracy and the performance of the radiation detector as compared to the manufacturer's specifications. The licensee shall retain copies of all infusion system calibration records, preventative maintenance checks, corrective actions taken and any manufacturer's quality review audits for inspection by the Department.

H. The licensee shall participate in the manufacturer's generator and CardioGen-82® Infusion System monitoring programs to determine use or stability of these products.

I. The licensee shall immediately report to the department each occurrence when the eluate concentration of strontium-82 equals or exceeds 0.02 microcuries per millicurie of rubidium-82 or the eluate concentration of strontium-85 equals or exceeds 0.20 microcuries per millicurie of rubidium-82.

J. The licensee shall use the activity measured by the detector on the infusion cart as the activity of the administration. This activity determination will be acceptable to satisfy the activity determination requirements.

If using Ruby-Fill Sr-82/Rb-82 generator:

When using the RUBY-FILL® rubidium generator and RUBY Rubidium Elution System:

A. Use only additive-free 0.9% Sodium Chloride Injection USP to elute the rubidium-82 generator. The use of any other type of saline is prohibited.

1. If the additive-free 0.9% Sodium Chloride Injection USP is replaced during a day of clinical use, the licensee shall perform an additional quality control test with the new saline.

B. The licensee shall follow all of the requirements in the manufacturer's RUBY Rubidium Elution System User Manual, its supportive documents, and updates. The licensee shall maintain and follow updates to the manual provided by the manufacturer. Copies of this manual, its supportive documents, and updates shall be available to each person using, and persons having responsibility for the use of, the device and shall be available for inspection by the Department.

C. The licensee shall comply with the safety precautions and limitations established in the package insert for the generator.

D. For each generator, the licensee shall maintain an on-going record of all eluate volumes (flushing, testing, and patient infusions) including a summary of the cumulative volume of eluate. The on-going daily records of volume usage shall be maintained for at least three years and be available for inspection by the Department.

E. The licensee shall use the dose calibrator that is integrated into the RUBY Rubidium Elution System to perform mandatory eluate testing (i.e. quality control tests) to determine rubidium-82, strontium-82, and strontium-85 levels:

1. Daily, before administering rubidium-82 chloride injection to the first patient each day;

2. Immediately after detection of the volume alert limit (20 L); and

3. After every 4 patients when an alert limit has been detected. Alert limits are:

a. 20 L total elution volume has passed through the generator column; or

b. The strontium-82 level reaches 0.004 uCi per mCi (kBq per MBq) of rubidium-82; or

c. The strontium-85 level reaches 0.04 uCi per mCi (kBq per MBq) of rubidium-82.

F. The licensee shall immediately stop using the generator to treat patients at the expiration limits listed below:

1. A total elution volume of 30 L has passed through the generator column; or

2. The expiration date of the generator (60 days post-manufacturing) has passed; or

3. An eluate concentration of strontium-82 of equal to or greater than 0.01 uCi per mCi (kBq/MBq) of rubidium-82; or

4. An eluate concentration of strontium-85 of equal to or greater than 0.10 uCi per mCi (kBq/MBq) of rubidium-82.

G. The licensee shall follow all manufacturers' guidance for use, maintenance, and disposal of activities related to the RUBY-FILL® generator and elution system. This would include all commitments in the Jubilant system user manual, package insert, and any associated current and future amendments to the documents including product recalls. The licensee shall keep records for all system quality and safety requirements as required by the manufacturer and be able to produce them within a reasonable time frame during an inspection. The licensee is responsible for all adverse event reporting requirements related to the use of the Jubilant system.

H. The licensee shall immediately report to the Department each occurrence when the eluate concentration of strontium-82 equals or exceeds 0.02 uCi per mCi of rubidium-82 or the eluate concentration of strontium-85 equals or exceeds 0.20 uCi per mCi of rubidium-82.

I. The licensee shall use the activity measured by the detector on the elution cart as the activity of the administration. This activity determination will be acceptable to satisfy the activity determination requirements

If using Ga-68/Ge-68 generator AND requested DFP exemption:

A. Based on the documentation received with the letter dated (enter date of letter here), the Department grants the license a specific exemption from the decommissioning funding plan (DFP) requirements for Ge-68/Ga-68 generators.

B. The licensee shall submit financial assurance for the possession and use of Ge-68/Ga-68 generators as described in the letter dated (enter date of letter here).

C. The licensee shall return the generators to the manufacturer/distributor in accordance with the generator return agreement described in the letter dated (enter date of letter here).

National Source Tracking System

In accordance with the National Source Tracking System referenced in A.A.C. R9-7-454, each licensee who is regulated under Title 9, Article 19 shall reconcile the licensee's sealed source inventory with the NRC at the end of each calendar year of operation

A. The licensee shall comply with the requirements in the document entitled "National Source Tracking of Sealed Sources".

B. A licensee who receives, transfers, or disposes of a nationally tracked sealed source shall complete and submit to the Nuclear Regulatory Commission's (NRC) National Source Tracking System and the Department a National Source Tracking Transaction Report that contains the information required in 10CFR 20.2207(b), (c), and (e). The Report shall be submitted before the close of the next business day after the transaction in a reporting form specified in 10CFR 20.2207(f).

C. A licensee shall correct any error in previously filed National Source Tracking Transaction Reports or file a new report for any missed transaction within five business days of the discovery of the error or missed transaction in accordance with 10CFR 20.2207(g).

D. A licensee who receives a nationally tracked sealed source shall not disassemble the source unless specifically authorized to do so by the Department.