PharmaLogic
Take The Lead

17 December 2023

Jason VonEhr
U.S. Nuclear Regulatory Commission, Region I
Division of Nuclear Materials Safety
2100 Renaissance Blvd Suite
100 King of Prussia, PA 19406

Subject: Additional Items for License Renewal 47-253075-01MD PharmaLogic, WV, Ltd.

Mr. VonEhr:

PharmaLogic West Virginia respectfully submits the additional license commitments that were requested regarding Ga/Ge-68 generator licensing.

Item 5: License Commitments

We commit to the following.

- Providing instructions and/or training on the manufacturer's procedures to all individuals involved in Ge-68/Ga-68 generator use, commensurate with the individual's duties to be performed;
- Not opening, breaching, or physically modifying the Ge-68/Ga-68 generator in any way;
- Following the manufacturer's procedures, including: generator set-up; generator elution; Ge-68 breakthrough testing and frequency when in use; and final disposition;
- Eluting the generator in accordance with the manufacturer's stated frequency and procedures to minimize the concentration of Ge-68 in the eluate;
- Not using an expired generator for preparation of materials that will be administered to patients or human research subjects;
- Only using a generator that has a clearly marked expiration date;

- 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;

- Maintaining a record of the breakthrough tests for at least 3 years. These tests should include the ratio of the measured activity of Ge-68 per Ga-68 corrected for the time of elution, time and date of the elution, time and date of the measurement, and the name of the individual who made the measurement;

- 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.

Item 6: Radiation Protection Program Changes

We request to incorporate a change process similar to 10 CFR 35.26 that will allow minor changes to our radiation safety program. Such a change process can allow some future changes to radiation safety programs without the need to request a license amendment.

Examples of acceptable changes include,

- The revision does not require a license amendment under 10 CFR 35.13;

- The revision is based upon NRC's current guidance for use of the Ge-68/Ga-68 generator to prepare Ga-68 radiopharmaceuticals for imaging and localization studies under 10 CFR 35.1000 posted on the NRC Medical Uses Licensee Toolkit;

- The revision has been reviewed and approved by the licensee's Radiation Safety Officer and management;

- The affected individuals are instructed on the revised program before the change is implemented;

- We shall retain a record of each change for 5 years; and

- The record will include a copy of the current guidance for use of the Ge-68/Ga- 68 generator to prepare Ga-68 radiopharmaceuticals for imaging and localization studies under 10 CFR 35.1000, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management representative who reviewed and approved the change.

If you should need any additional information, please do not hesitate to contact me.

Respectfully submitted,

Frank Plastini

Frank Plastini
Corporate Radiation Safety Officer
PharmaLogic Holdings, Corp.