SHARED IMAGING

Right Technology • Right Place • Right Time

May 29, 2014

Mr. Robert Gattone
United States Nuclear Regulatory Commission
2443 Warrenville Road Suite 210
Lisle, IL 60532

RE: License # 12-32798-01

Dear Mr. Gattone

Shared Imaging LLC has not performed, or utilized any Fludeoxyglucose F18 within the last 48 months in any non-agreement states. Due to the non-activity, this would not be detrimental or pose any public safety concerns.

At this time Shared Imaging LLC is expanding our PET/CT Nuclear Medicine program and is very interested in continuing F18 with our current NRC license.

Extension Request: Shared Imaging is also requesting to extend the time period of no principle activity for 24 months notification to 6/2/2016.

Corrective Action: Shared Imaging's Compliance & Regulatory Specialist and RSO will conduct annual audits to insure required notification is made to the NRC within the required time period.

Attached are the policies for handling unsealed sources, area ambient surveys, and area wipe tests for contamination, and PET RAM Radiation Safety.

Please contact me with any questions.

Sincerely,

Robert J. Tokarz, M.S., DABR
Medical Physicist/ Radiation Safety Officer
732-424-0909

PET RAM Radiation Safety
And RAM Waste Disposal
Policy and Procedures

Goal

To ensure that all patient and employees are protected from unnecessary radiation and that occupational exposures are minimized. The goal is for staff to assure that occupational exposures that are never more than 10% of the maximum allowed occupational exposure limits established by state and national regulatory agencies. This policy applies to all Shared Imaging PET and CT personnel and patients.

Policies and Procedures

- **PET/CT System**: CT-PET imaging systems have been tested by qualified medical physicist after the installation and the radiation doses and image quality evaluated as appropriate to satisfy applicable radiation safety regulations. The imaging systems are maintained by qualified medical equipment service staff, either OEM staff or other qualified staff and the necessary Preventive Maintenance (PM) is done as recommended by the OEM. Additionally, comprehensive Quality Assurance Programs are in place to assure that the imaging systems perform to recommended OEM levels and when such are not meet, then necessary service is done to assure performance is consistent with clinical expectations. The PET and CT are compliant with applicable state and federal regulations

- **Patient Safety:**
  - Pregnancy warning signs shall be placed in a conspicuous area on each unit that is using radiation.
  - The Ordering Physician, Radiologist and/or Referring Physician approve the diagnostic imaging procedure based on the clinical need and related risks to ionizing radiation.
  - All pregnant patients must have an appropriate consent form signed which details the radiation related risks for the procedure prior to the imaging procedure and the patient must be informed of related risks involved.
  - To ensure the patient is protected as much as possible and applicable for the study, a lead shield shall be used on the front and back of all children, pregnant women, etc. This shield shall be used under the direct supervision of the qualified physician.

- **Employee Safety:**
  - Shared Imaging requires that the ALARA principle be followed by all staff to assure that radiation exposures to staff and patients are as low as reasonably achievable.

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- Shared Imaging personnel are NOT to hold patients during x-ray exposure.

- Individual Personnel Radiation Dosimeter badges must be worn by all Shared Imaging personnel working on mobile CT-PET units.

- Radiation exposure shall be monitored to assure that the radiation exposures to staff are as low as possible and that no staff member receives more than 125 mrem in one calendar month without counseling by the Radiation Safety Officer regarding the radiation exposure and methods to minimize such exposures in the future. In the event that there is an employee who receives in excess of 1250 millirem in a continuous three month period, then this employee will be counseled to determine the cause of the exposure and the necessary action to assure that such exposures do not occur in the future.. In the event of radiation accident or an excessive exposure, the RSO and the appropriate regulatory agency, state or federal, shall be notified and appropriate actions taken including an analysis of the cause of the exposure and the corrective action to prevent such exposures in the future.

- During PET/CT procedures the lead lined door between the patient room and the control room must be closed.

- A Radiation Physicist shall perform appropriate annual testing on the PET-CT systems to assure system performance as well as radiation to patients having imaging procedures and more frequently as required by applicable radiation safety regulations. A copy of the physicist's survey will be kept in the records maintained in the mobile PET-CT as required by regulations and in the Corporate Office.

- As appropriate and applicable, a CT Protocol Dose Committee is or will be established to monitor CT imaging protocols and associated patient doses.

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Radiation Exposure Polices and Records for PET-CT

Policies and Procedures

- All personnel must wear an approved exposure badge at all times when working in the Shared Imaging CT PET/CT units.
- **The exposure badges are exchanged monthly and the monthly staff exposure reports are reviewed with the monitored staff after being audited by the RSO as required by state and federal regulations.**
- The following is the maximum occupational exposure/dose allowed for staff to anyone in a calendar quarter.
  - Whole Body 1.25 rem
  - Extremities 18.75 rem
  - Skin of Whole Body 7.50 rem
- In the event that occupational exposure exceeds the prescribed maximum as described above, a written report shall be made to both the affected employee and to the appropriate regulatory agency. The over exposure report shall be submitted within thirty days.
- Exposure readings will be kept on file in the corporate office.

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RADIOACTIVE MATERIAL RECEIPT AND DISPOSAL PET/CT

Policy

To establish Policies and Procedures directing and documenting the ordering, receipt, use and disposal of radioactive materials (RAM). These guidelines and polices apply to all staff working in the PET/CT unit

Policies and Procedures

- All PET procedures will be done using Unit Dose RAM's
- All RAM materials ordered, received, used on patients and disposed of including RAM waste must be documented with files maintained on the mobile unit
- All RAM unit doses must be ordered by an approved authorized physician user, APU and the order documented and records maintained on the mobile unit
- The use of each unit RAM dose must be documented and such records maintained, this includes any unit doses returned, not used, stored as waste etc. and the documentation signed by the person dong the documentation
- A record of the ordered RAM unit doses including the APU and the staff member that actually orders the RAM unit doses
- The primary location of unit dose RAM delivery will be to the hot lab located in the mobile unit.
- The delivery of unit dose RAM must be documented and signed by the person receiving the RAM on site. A staff member MUST be on site on our coach when any RAM is delivered to our medical coach.
- A secondary or alternative backup unit dose RAM delivery location may be identified in the client facility
- The multiple unit dose RAM Packages must be surveyed at the time of deliver or as soon as there is a staff member on site. The multiple unit dose RAM package must be surveyed at the surface and at one meter from the package surface and exposure values logged in the RAM activity receipt and usage log sheet
- Wipe tests are done and the activity measured and recorded on any RAM Package determined to require additional survey
- If the package is damaged or emits greater activity than identified by the package label, immediately notify the RAM supplier and the RSO.

Disposal guidelines for RAM Injection Devices:

- Needles used for RAM injections shall NOT be recapped
- Used RAM injection related devices including syringes, needles, tubing and wipes shall be disposed of in RAM Waste. The needles must go in a RAM Infectious Waste Sharps Container with needle attached into an appropriate rigid puncture proof infectious waste container.
- When the RAM SHARPS container is two-thirds full, securely cap container, remove the lower "cold" sharps container, and place a new container in the top of the RAM sharps shield.
- Store the RAM Sharps Container in the hot waste secured area for a minimum of two weeks and then survey each filled and stored SHARPS container to confirm that the

activity is at background level. If the activity is above background, return the RAM Sharps Container to Hot was storage for another week and then repeat the RAM Sharps container survey to assure the container is at background. Record the radiation exposure survey results in the Decay-in-Storage Log and then dispose of decayed out or background level filled SHARPS container in the location designated by the client facility for disposal of used Sharps waste. This waste is not RAM waste since it has decayed to background, but it is necessary to document the disposal of the waste with a signature from the client site receiving the waste material.

- Gloves are to be worn at ALL times when handling RAM and the gloves must be disposed of in RAM waste for decayed storage.
- The RAM unit dose transport containers/pigs are routinely picked at the next delivery of RAM unit doses by the RAM supplier.

Safe Use of Radiopharmaceuticals

We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposable gloves at all times while handling radioactive materials.

3. Either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area with a survey meter or camera.

4. Use syringe shields for routine preparation of multi-dose vials and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins, infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).

5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

6. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.

7. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer. When not being worn to monitor occupational exposures, personnel monitoring devices should be stored in the work place in a designated low-background area.

8. Wear a finger exposure monitor during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals; and when holding patients during procedures.

9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.

10. Never pipette by mouth.

11. Wipe-test byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for decay.

12. Survey with a radiation detection survey meter, radionuclide storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate.

13. Confine radioactive solutions in shielded containers that are clearly labeled. Radiopharmaceutical multidose diagnostic vials and therapy vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation. A log book should be used to record the preceding information and total prepared activity, specific activity as mCi/cc at a specified time, total volume prepared, total volume remaining, the measured activity of each patient dosage, and any other appropriate information. Syringes and unit dosages should be labeled with the radiopharmaceutical name or abbreviation, type of study, or the patient's name.

14. Assay each patient dosage in the dose calibrator before administering it. Do not use a dosage if it deviates more than 20 percent from the prescribed dosage, except for prescribed dosages of less than 10 microcuries. When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle. Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering.

15. Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.

16. Because even sources with small amounts or radioactivity exhibit a high dose rate on contact, you should use a cart or wheelchair to move flood sources, waste, and other radioactive material.

Surveys

Area Survey Procedures

Ambient Dose Rate Surveys

We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.

1. Survey Areas
   a. A survey will be performed at the end of each workday of the radiopharmaceutical preparation and administration areas with a radiation detection survey meter.

   b. A map of the areas to be surveyed is posted.

   c. Areas to be surveyed include waste containers, radiopharmacuetical storage, waste storage, radiopharmaceutical and administration.

2. Notify the RSO if unexpectedly high or low levels are found.

Removable Contamination Surveys

1. Survey Areas
   a. In radiopharmaceutical preparation and administration areas, survey weekly for removable contamination.

   b. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly removable contamination.

2. The wipe sample assay procedure will be done with a NaI(Tl) well-type detector capable of detection level of less than 200 dpm/100cm^2.

3. Notify the RSO if you find unexpectedly high levels.

Records

1. A record will be kept of dose rate and contamination survey results. It will include the following:
   a. The date, area surveyed and equipment used.
   b. The name or initials of the person who made the survey.
   c. A drawing of the areas surveyed with contamination and dose rate action levels.
   d. Measured dose rates in mR/hr or contamination levels in dpm/100cm^2 as appropriate.
   e. Actions taken in the case of excessive dose rates or contamination and follow-up survey information.

2. The RSO or consultant will review and initial the record.