

June 13, 2010

Toye Simmons  
U. S. Nuclear Regulatory Commission  
Materials Licensing Section  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

**RE: Control Number 319041**

Ms. Simmons:

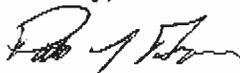
Please allow this letter to serve as a response to questions you had concerning a request to amend the Materials License of C & G Technologies, number 13-32739-01. Information will be provided in the order it was requested in your letter dated May 21, 2010.

1. The Fluorine-18 (F-18) will be used to calibrate and test Positron Emission Tomography (PET) scanners. The F-18 will not be administered to humans or animals and will not be used medically. Please reduce the amount of the maximum possession to one Curie instead of ten Curies. Only milliCurie amounts are needed to calibrate the equipment but we are requesting one Curie to account for receiving dosages of the rapidly decaying F-18 at far greater activities than will be used.
2. The F-18 will be ordered from a radiopharmacy in unit dosage form, calibrated for the activity amounts that will be utilized for calibration. The F-18 will remain in the unit dosage shielding (pigs) provided by the radiopharmacy until being used. In addition, the pigs containing the F-18 will be stored in a lead box when not in use.
3. The F-18 will be used by Dale McGuire, who is currently listed on the Materials License as an Authorized User. In addition, service engineers may use F-18 under the supervision of an Authorized User and the Radiation Safety Officer. Before first use of the unsealed F-18, I as the Radiation Safety Officer, will provide training with the use of unsealed radioactive materials, including spill response.
4. Enclosed is a diagram showing the areas where the F-18 will be used and stored. Please note that there is not a significant change in the unrestricted and restricted areas.
5. F-18 will only be received during normal working hours. The facility is secured from access during non-normal working hours. A procedure for receiving packages containing radioactive materials was previously approved for this licensee and a copy of that procedure is enclosed.
6. Pertinent radiation safety policies are enclosed.

7. Currently, staff members wear whole body personnel dosimeters. Any staff members that may work with unsealed radioactive materials will be issued ring badges to measure their extremity doses.

If there are any questions concerning this information, please feel free to contact me at 877-317-5811 or directly on my cell phone.

Sincerely,



Patrick J. Byrne, DABR, CHP, DABSNM  
Radiation Safety Officer

## **EMERGENCY SPILL PROCEDURES**

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### **Minor Spills (less than 25 mCi of F-18)**

1. **NOTIFY:** Notify persons nearby that a spill has occurred.
2. **PREVENT THE SPREAD:** Cover the spill with absorbent paper.
3. **CLEAN UP:** Use disposable gloves and remote handling tools. Carefully fold the absorbent paper with the clean side out and insert in a plastic bag for transfer to a radioactive waste container. Also place the contaminated gloves and any other contaminated disposable material in the bag.
4. **SURVEY:** Survey the area with a low-range, GM survey meter. Check the area around the spill, hands, clothing, and shoes for contamination.
5. **REPORT:** Report the incident to the RSO who will supervise the cleanup of the spill and complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey. The RSO may delegate the actual clean-up and survey performance to a trained technologist. However, the RSO will retain the ultimate responsibility to ensure that the Report and Survey are completed properly.

### **Major Spills (greater than 25 mCi of F-18)**

1. **CLEAR THE AREA:** Notify all persons not involved in the spill to vacate the room.
2. **PREVENT THE SPREAD:** Cover the spill with absorbent paper, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.
3. **SHIELD THE SOURCE:** This should be done only if it can be done without further contamination or a significant increase in radiation exposure.
4. **CLOSE THE ROOM:** Leave the room and lock the door(s) to prevent entry.
5. **NOTIFY:** Notify the RSO immediately.

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6. **PERSONNEL DECONTAMINATION:** Decontaminate personnel by removing contaminated clothing and flushing the contaminated skin with lukewarm water and then washing with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination released by the perspiration.

**REPORT:** The RSO will supervise the cleanup of the spill and complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey. The RSO may delegate the actual clean-up and survey performance to a trained technologist. However, the RSO will retain the ultimate responsibility to see that the report and the survey are completed properly.

## AREA SURVEY PROCEDURE

1. All areas where unsealed radioactivity is handled, used, and prepared will be surveyed at the end of each day of use for ambient radiation exposure rates.
2. Surveys for ambient exposure rates will be performed with a radiation detection survey instrument. For example, a Geiger-Mueller meter able to detect as low as 0.1 mR/h.
3. All measurements will be made on the lowest scale, unless exposure rates exceed this scale.
4. Trigger level exposure rates will be determined for each area that is to be surveyed.
5. Survey results greater than the trigger levels will result in decontamination or shielding procedures necessary to reduce the exposure or contamination levels to background on repeat surveys. **Any result that exceeds the trigger level must be reported to the RSO.**
6. A record shall be kept of all survey results. These records will be retained for a period of three (3) years. The record **MUST** include:
  - a. Date of the survey
  - b. Results of the survey
  - c. Instrument used to make the survey
  - d. Name of the person conducting the survey.
7. The RSO or their designate will review the survey results on a quarterly basis for conformance to certain action levels.

**Item 10****Operating and Emergency Procedures**

Procedures for picking up, receiving, and opening packages containing licensed materials, in accordance with 10 CFR 20.1906.

1. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop and notify the RSO.
2. Measure and record the exposure rate from the package at 1 meter and at the package surface. If the rate is greater than 10 mR/hr, stop and immediately notify the RSO, the final delivery carrier and by telephone and fax the regional office of the NRC.
3. Measure and record the exposure rate on the surface of the package in the same orientation as the data taken in step 3 above. If greater than 200 mR/hr stop the procedure and immediately notify the RSO, the final delivery carrier and by telephone and fax the regional office of the NRC.
4. Wipe 300 cm<sup>2</sup> external surface area of the package in compliance with 10 CFR 20.1906. Assay the wipe sample with a suitable instrument sufficient to detect 2200 dpm to determine if there is any removable activity. If there is any contamination in excess of 6600 dpm/cm<sup>2</sup>, immediately notify the RSO, the final delivery carrier and by telephone and fax the regional office of the NRC.
5. Follow the steps listed below when opening the package.
  - a. Remove the packing slip.
  - b. Open the outer package following the supplier's instructions, if available.
  - c. Open the inner package and verify that the contents agree with the packing slip.
  - d. Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
  - e. If anything unusual is noticed, stop and notify the RSO.
6. Verify that the material received is the material ordered.
7. Verify that the manufacturer receives the material being returned.
8. Monitor the packing material and the empty packages for contamination with a GM survey meter before discarding. If contaminated, treat as radioactive waste. If not contaminated, deface all radiation labels before discarding.
9. Record the receipt and all readings taken.

The diamond label used is determined by the exposure measurements noted below. Make sure your package conforms to these exposure levels / label pairings.

	<u>Surface</u>	<u>One Meter</u>
<b><u>WHITE I</u></b>	<0.5 mR/hr	Background
<b><u>YELLOW II</u></b>	0.5 - 50 mR/hr	< 1 mR/hr
<b><u>YELLOW III</u></b>	50 - 200 mR/hr	1 - 10 mR/hr
<b><u>YELLOW III</u></b> Exclusive Use Only	200 - 1000 mR/hr	> 10 mR/hr

## **WASTE DISPOSAL**

### **Liquids**

Liquids may be disposed of by release to the sanitary sewer release to the atmosphere.

1. Disposal to the sanitary sewer system will be made in accordance with 10 CFR 20. A record will be kept of the following: date, radionuclide, estimated activity released, and place where material was released.
2. Permissible concentrations in effluents will be kept within the limits enumerated in 10 CFR 20. A record will be kept of the date, radionuclide, estimated activity released, estimated concentration, and vent site at which the material was released.

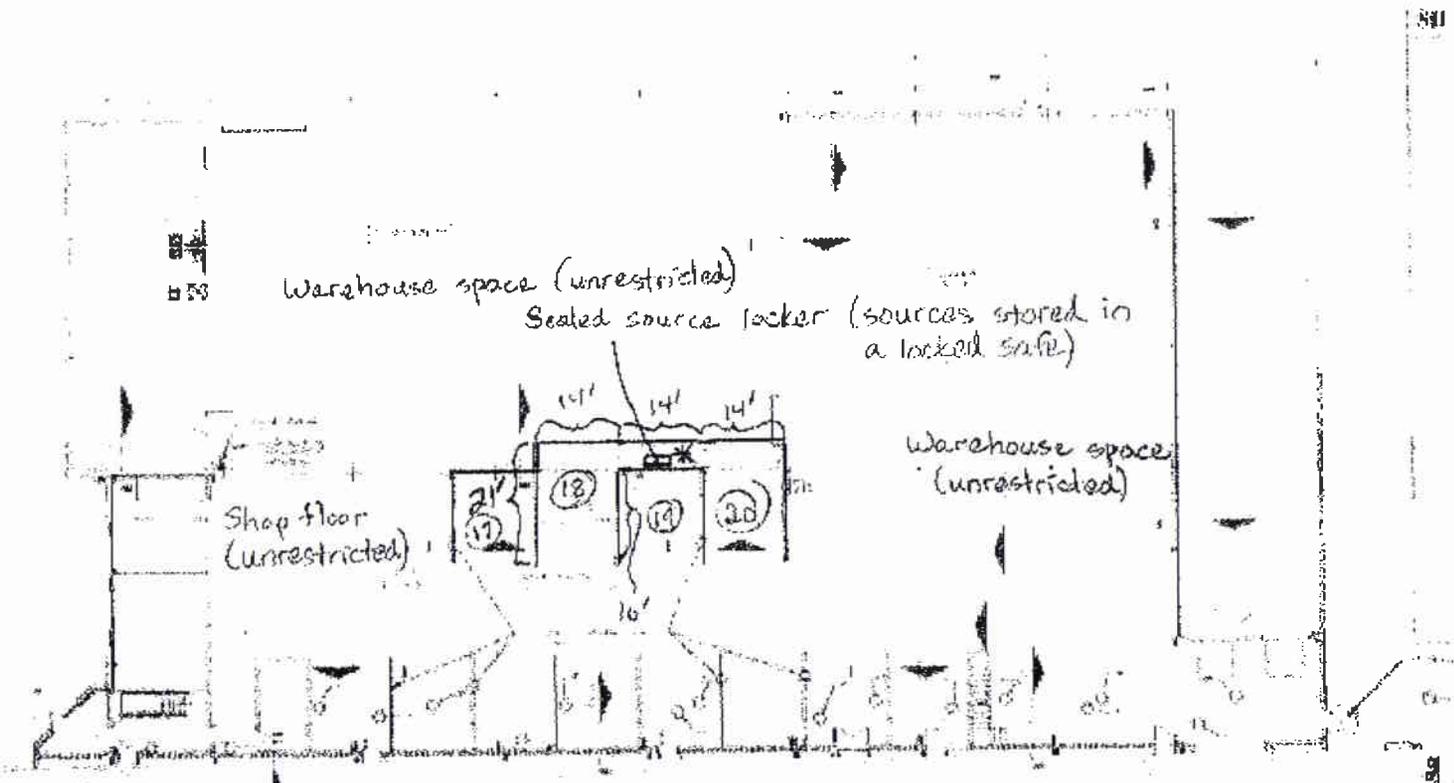
### **Decay in Storage**

1. Only material with a physical half-life of less than 120 days may be decayed in storage at the facility.
2. Each container will be tagged to include:
  - a. the date sealed or set into storage
  - b. the longest-lived isotope in the container
3. Material will be decayed until its radioactivity cannot be distinguished from the background radiation level.
4. Prior to disposal as in-house waste, each container will be monitored as follows:
  - a. Low-range GM survey meter will be checked for proper operation on the most sensitive scale.
  - b. Waste will be monitored in a low level area.
  - c. Any shielding around the container will be removed.
  - d. All surfaces of each individual container will be monitored.
  - e. Only those containers, which cannot be distinguished from background levels will be disposed of after all radioactive labels, have been defaced.

5. Records of decay-in-storage disposal shall be maintained for three (3) years and must contain the following information:
  - a. Date of disposal will be recorded
  - b. Survey instrument used
  - c. Background radiation level
  - d. Radiation level measured at the surface of the container
  - e. The name of the individual that performed the survey

#### **Unit Dose Waste**

If a unit dose pharmacy is used, the materials supplied by them (e.g., syringes, needles, etc.) may be returned to the unit dose pharmacy in the original shipping container.



Warehouse space (unrestricted)

Sealed source locker (sources stored in a locked safe)

Shop floor (unrestricted)

Warehouse space (unrestricted)

⑱, ⑲, ⑳ are room numbers

⑱ and ⑳ are areas used for refurbishing PET scanners

⑲ is an area used for refurbishing CT scanners as is ⑰

F-18 will be stored in the area marked \* and will be used in rooms ⑱ and ⑳



## **RULES FOR THE SAFE USE OF RADIOPHARMACEUTICALS**

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 unsealed radioactive materials.
3. Either after each procedure or before leaving the area, monitor your hands and clothing for contamination in a low background area.
4. Use syringe shields for manipulation of dosages, except in those circumstances in which their use is contraindicated. In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose.
5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is used or stored.
6. Do not store food, drink, or personal effects in areas where radioactive material is used or stored.
7. Wear personnel monitoring devices (as prescribed by the RSO) at all times while in areas where radioactive materials are used or stored. Store personnel monitoring devices at the facility 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. Confine radioactive solutions in shielded containers that are clearly labeled with the isotope, compound name, and the date and time of receipt or preparation.
11. Always keep radioactive materials in shielded locations or containers.

6-15-10

Attention: Teye Simmons  
USNRC, Region III  
Materials Licensing Section

Fax: 630-515-1078

Control #: 319041

From: Patrick Byrne

11 pages to follow