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North Campus
1211 Wilmington Avenue
New Castle, PA 16105-2595
Telephone: 724.658.9001

South Campus
1000 South Mercer Street
New Castle, PA 16101-4673
Telephone: 724.658.3511



*Continuing the Tradition of Leadership
in Community HealthSM*

J-2

10 September 2007

Willie J. Lee, Health Physicist
United States Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

LICENSEE: Jameson Memorial Hospital
LICENSE NUMBER: 37-01146-03
DOCKET NUMBER: 030-02977
CONTROL NUMBER: 140743
DATE: 06 September 2007

Dear Mr. Lee:

Thank you for taking the time to speak with me today. Regarding your e-mail dated 30 August, 2007, this additional information is being sent at your request. After discussions with our Radiologic Health Physicist, and discussion at our quarterly Radiation Safety Committee Meeting last week, it has been determined that if adding 138 additional areas of use is not required. We would then like to amend our NRC license to include the generic safety procedures, precautions, and equipment we discussed whenever it is necessary to use a patient room as an area of use.

1. After each use in an unrestricted area such as a patient room, staff will remove all materials used for injection and survey those materials upon return to the Nuclear Medicine to ensure that no individuals are exposed to radiation levels that might result in radiation doses in excess of any dose limits. (procedure NMS-22A enclosed)

2. 10 CFR 20.1301 requires that the Total Effective Dose Equivalent (TEDE) to an individual member of the public from your licensed operations does not exceed 100 milli-Rem in a year, and that the dose in any unrestricted area from external sources does not exceed 2 milli-Rem in any one hour. Excluding source of radiation

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NMSS/RGN1 MATERIALS-002

from the patient, all sources will be removed from any areas and all radioactive material will be shielded when not in use. (NMS-20 enclosed)

3. All radiation level surveys at our facility are performed with a survey meter sufficiently sensitive to detect 0.1 milliroentgen (mR) per hour. Surveys/measurements are recorded, as required using the electronic Unit Dose Management System. (NMS-22 enclosed)

4. As discussed, no unit doses will be stored in patient rooms and all residual byproduct material and contaminated items will be returned to the Nuclear Medicine Hot Lab area after each use. (NMS-22 enclosed)

Enclosed please find procedures NMS-20, NMS-22, and NMS-22A I have also enclosed procedure NMS-26 the procedure for area surveys and copies of our posted procedures for minor and major spills. We have sent a review of these procedures to circulate with Nursing Unit staff in anticipation of implementing this requested change. Please contact me at (724) 656-4123 for any additional information or rondo@jamesonhealth.org.

Sincerely,



Robert A. Ondo

Radiation Safety Officer

Jameson Health System

C: Radiation Safety Committee

File copy

enclosures

Special consideration for administering radiopharmaceuticals outside of the Nuclear Medicine Department

All the following information can be found in the Nuclear Regulatory Commission's (NRC) NUREG on this issue, NUREG-1556 Vol. 9 Rev. 1, "Consolidated guidance About Material Licenses - Program-Specific Guidance About Medical Use Licenses." (Please also see it on the Web site.)

Appropriate survey requirement: are based on the requirements of 10 CFR 20.1301 (that the Total Effective Dose Equivalent [TEDE] to an individual member of the public from the licensed operation does not exceed 1 mSv [0.1 rem] in a year, and that the dose in any unrestricted area from external sources does not exceed 0.02 mSv [0.002 rem] in any one hour).

1. Before the administration of radiopharmaceutical outside the controlled area of Nuclear Medicine, a disposable absorbent chuck will be placed under the immediate area and patient injection site.
2. After the injection, the absorbent chuck will be gathered up and returned to Nuclear Medicine.
3. To meet the above requirement, a survey of the absorbent material will be performed and the results documented after the Technologist returns to the department.
4. In the event radiation levels are discovered above trigger levels, the technologist will take further steps to determine the presence of removable contamination where the injection was performed including but not limited to an area survey with appropriate meter and/or wipe test.
5. In addition, surveys will be performed (with the patient out of the area) when it is reasonable under the circumstances to evaluate a radiological hazard and when necessary for the licensee to comply with the appropriate regulations regarding injecting outside the department.
6. **No** therapeutic administration of radionuclide is to be performed in any unrestricted area.

All the above has the caveat that we as the licensee must follow all other federal, state, and local requirements, requirements listed as conditions in our existing license, and any commitments made in our license application.

USE OF UNIT DOSE RADIOPHARMACEUTICALS

1. The Hot-Lab (Hospital and Cardiac Center) area is to be kept locked at all times. The unused (fresh) needles, butterflies, syringes, etc, are to be kept in a locked cabinet with access only by the person working with the items.
2. The radiopharmacy delivery personnel have been instructed to obtain access to the radiopharmaceutical drop-off area either by security or Medical Imaging staff.
3. Upon receipt, the Nuclear Medicine staff will survey each package for contamination by two (2) methods: 1) a GM Survey meter at surface and one (1) meter; and 2) a Wipe test. The results of each survey are to be recorded in the unit dose management system.
4. Each package is checked for the proper address and the contents checked for proper identification and shipment quantity.
5. A package is considered contaminated if the level of radiation exceeds 0.5 mR/hr at the surface and/or a wipe test indicates contamination of >300 dpm/100 cm² for all isotopes except therapeutic doses of 131-I.
6. If a package has been determined to be contaminated, it will not be opened, the Radiopharmacy will be notified and the unopened package will be allowed to decay until the decontamination can be removed or the radioisotope decays to an acceptable level.
7. Uncontaminated packages may be opened by breaking the protective seal on the handle/strap assembly with scissors or sharp box opening knife provided. If the seal has been removed or otherwise tampered with, notify the Radiopharmacy immediately.
8. The unit dose management system inventories all radiopharmaceuticals.
9. When dosing patients, enter the patient's full name in the unit dose management system and on the request if it does not already appear there in its entirety.
10. Measure the dose in the dose calibrator prior to administration. Record the initial activity on the patient's request.

USE OF UNIT DOSE RADIOPHARMACEUTICALS

Page 2

11. The measured amount of activity must not differ by more than 10% from the prescribed dose for the exam to be performed. Refer to the Imaging section of this procedure manual for the exact prescribed dosages for each exam.
12. Unit doses of radiopharmaceuticals may be used prior to their calibrated time. These doses may need to be adjusted for activity, by gently letting a few drops of the dose fall into a container already established for short-term radioactive decay. Be careful not to let too much out at a time so as not to short the dose either.
13. Positively identify the patient before beginning the procedure consistent with hospitalwide patient identification procedure (2 forms of ID). Also verify the procedure to be performed. Administer the radiopharmaceutical according to procedure.
 - A. Inject the radiopharmaceutical into the patient using safe and sterile technique as described in the section entitled "Injection Safety".
 - B. Keep all doses and radioactive material shielded when not in use.
 - C. If injecting in the patient's room.
 1. The Nuclear Medicine staff will report to the Nursing station.
 2. The Nuclear Medicine staff will identify themselves and their intent.
 3. Verify the request for study in the patient chart.
 4. Report to the patient's room and verify patient identification by approved method.
 5. Administer the patient dose per protocol and provide all applicable instructions. Use chuck pads under all areas of administration.
 6. Secure all syringes and radioactive material and remove from the patient room returning to the Nuclear Medicine department. In the event of suspected contamination, secure the area and perform appropriate area surveys and/or wipe tests. All staff should be familiar with procedures for minor and major spills.
 7. Document appropriately in the patient's chart.
14. **DO NOT MANUALLY RECAP THE NEEDLE.** After withdrawing the needle from the patient, carefully pull back on the plunger to draw the residual dose back into the barrel of the syringe. The used syringe is now considered to be contaminated and biohazardous. Carefully pull the syringe out of the syringe shield and place it in the appropriate receptacle for radioactive waste.
15. Return the lead pig to a suitcase to be returned to the radiopharmacy and close the suitcase when it is full. Place it on the counter to be monitored for return to the radiopharmacy.
16. Be sure to record all the results of patient dose administration in the unit dose management system.

Jameson Health System Inc.
Department of Nuclear Medicine

NUCLEAR MEDICINE SAFETY PROCEDURES

CONTROLLED AREAS: The Nuclear Medicine areas of the Hospital and Center for Cardiac Health are considered controlled areas as designated by location and map submitted to the United States Nuclear Regulatory Commission and Pennsylvania Department of Environmental Protection , Bureau of Radiation Protection. An administrative change has been requested from the regulatory agencies to provide the flexibility for radiopharmaceuticals to be administered in patient rooms for certain procedures.

1. All radioactive materials are to be delivered to and secured in the Nuclear Medicine Hot Lab area to ensure control when not in use.
2. Administration of radiopharmaceuticals is to be performed in designated areas of the Hospital Medical Imaging department and Center for Cardiac Health. For some studies, the patient can be injected on the nursing unit saving patient transport time and providing improved patient comfort and a continuum of Nursing care.
3. Non- Nuclear Medicine personnel are **not** permitted to handle radioactive material.
4. Unauthorized persons are not permitted in the Hot Lab or in areas where radiopharmaceuticals are in use.
5. Persons not directly involved with patient care are to have minimum access to the controlled areas of the Nuclear Medicine area. Designated waiting areas are provided within the department.
6. Never allow eating, drinking, smoking or applying of cosmetics in the Nuclear Medicine department. (unless, of course, ingestion is part of a Nuclear Medicine procedure.)
7. Unnecessary materials, items, and equipment should be kept out of Nuclear Medicine rooms to prevent contamination.
8. Personal items should not be kept in any of these areas for the same reason.
9. No doses and/or supplies for Nuclear Medicine will be stored in any patient room. All residual byproduct material and contaminated items will be returned to the hot lab area after each use.

Monitoring of Radiation Exposure:

1. Monitoring of the Nuclear Medicine department, work areas, and clinical areas as designated by location and map submitted to the United States Nuclear Regulatory Commission and Pennsylvania Department of Environmental Protection , Bureau of Radiation Protection is done consistent with model procedures for these area surveys as specified in Appendix R of NUREG-1556, Vol. 9, Rev.2. If suspected contamination exists , the areas in question are monitored to confirm or disprove the presence of radionuclide contamination.
2. Persons working with radionuclides are monitored with replaceable film badges for whole body monitoring and ring badges for monitoring the extremities. This includes all persons working with radioisotopes. Visitor badges are available for persons who may spend an extended amount of time in the Nuclear Medicine areas of the Hospital and Center for Cardiac Health.
3. Trigger or action levels have been established for contamination and are listed in the procedures for area surveys and wipe tests. Any confirmed contamination is to be reported to the individuals involved and the Radiation Safety Officer. Procedures for decontamination and or spill procedures will be initiated.
4. All instruments used by the Nuclear Medicine personnel are calibrated annually and sensitive to ambient radiation levels of less than 0.1 mR/hr.

Jameson Health System Inc.
Department of Nuclear Medicine

PROCEDURE FOR AREA SURVEYS

1. Area surveys will be performed in the event of suspected contamination or at the conclusion of any working day in which a therapeutic dose of radiopharmaceutical has been administered.
2. One of the appropriate meters will be used with the window open. A dedicated operational check source is provided with each instrument and will be checked and the result recorded prior to use.
3. The probe is to be held with the window open facing the area being surveyed at a distance of one inch unless otherwise indicated.
4. A Nuclear Medicine Department survey map is provided to indicate what areas are typically to be surveyed.
5. Record the results of the survey. Be sure to include the model and serial number of the instrument used.
6. In addition to the area survey, the injection or dose administration area will be surveyed using the wipe test method and any areas where radiopharmaceutical kits were prepared.
7. Areas are considered contaminated if the area survey exceeds 0.1 mR/hr in an uncontrolled area or wipe test exceeds 300 dpm/ 100cm².(for 99mTc)
8. For controlled areas, the threshold, action, or trigger levels elevate to 5.0 mR/hr and/or 2200 dpm/100 cm². (for 99mTc)
9. If an area has been determined to be contaminated, the procedure for decontamination will be considered if there is the possibility that the area could be cleaned and resurveyed until an acceptable level has been maintained and demonstrated with three (3) consecutive wipe tests below action level.

Ambient Dose Rate Trigger Levels

Type of Survey	Area Surveyed	Trigger Level
Ambient Dose Rate	Unrestricted	0.1 mR/hr
Ambient Dose Rate	Restricted	5.0 mR/hr

10/99, 8/05, 11/06, 2/07, 6/07, 9/07

**JAMESON MEMORIAL HOSPITAL
DEPARTMENT OF NUCLEAR MEDICINE**

**PROCEDURE FOR DECONTAMINATION OF MINOR RADIOACTIVE SPILLS
(Greater than 5.0 mR/hr but less than 50.0 mR/hr)**

1. **Notify** the persons in the immediate area that a spill has occurred.
2. **Prevent the spread** of contamination by covering the area with absorbent material.
3. **Clean up** the spill by using waterproof disposable gloves and absorbent material. Carefully fold the absorbent material with the clean side out and place in a plastic bag for transfer to a radioactive waste storage container. Also, put contaminated gloves and any other contaminated disposables in the bag.
4. **Survey** the area with a GM meter or ionization chamber suitable for detection of the radioisotope. Check the area around the spill. Also check hands, clothing and shoes for contamination.
5. **Report** the incident to the Radiation Safety Officer (RSO). Fill out the "Minor Spill of Radio pharmaceutical" form located in the Nuclear Medicine Department for report at the Radiation Safety Committee meeting.
6. **Follow-up** on the cleanup of the spill will be done by the Radiation Safety Officer. If the level of Radiation exceeds the "Action" or "Trigger" levels, the area will be secured and further activity in the area will be ceased until the radiation levels are within acceptable limits.
7. **Materials** contaminated by radioisotope will be stored in the Nuclear Medicine Department until radiation levels do not exceed 0.5 mR/hr.
8. **Documentation:** To be kept on form(s) provided and reported quarterly at Radiation Safety Committee.

*This procedure is based on Nuclear Regulatory Commission - model spill procedures.
Regulatory guide NUREG-1556, Volume 9

Contact Hospital Operator (724) 658-9001 for Radiation Safety Officer or Radiologist on call
The commercial telephone number of the NRC Operations Center is (301) 951-0550.

PADEP

**In Case of an Environmental Emergency Please
Call (412)442-4000 24 hours a day.**

Approved by: _____
Robert A. Ondo B.S., C.N.M.T..
Radiation Safety Officer

**JAMESON MEMMORIAL HOSPITAL
DEPARTMENT OF NULEAR MEDICINE**

**PROCEDURE FOR MAJOR SPILLS OF RADIOACTIVE MATERIALS
(Greater than 50.0 mR/hr)**

1. **Clear the area.** Notify all persons not involved in the spill to vacate the room or area.
2. **Prevent the spread** of contamination by covering the area (if possible) with absorbent material.
3. **Do not attempt to clean up the spill.** To prevent the spread of contamination, limit the movement of persons who may be contaminated.
4. **Shield the source of contamination** if possible. Do this only if it can be done without further contamination or significant increase in radiation exposure.
5. **Close the room,** lock or otherwise secure the area to prevent entry.
6. **Notify the Radiation Safety Officer (RSO)** immediately.
7. **Decontaminate personnel** by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with a mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then, wash the affected area again to remove any contamination that was released by the perspiration.
8. **Clean up** will be supervised by the Radiation Safety Officer as well as the reporting process. All available Nuclear Medicine personnel will assist the RSO with contamination surveys and the necessary paperwork.
9. **Materials** contamination by the spill must be kept in the Nuclear Medicine decay lab until radiation levels decay to an acceptable level. (Less than 0.5 mR/hr)
10. **Documentation:** To be kept on form(s) provided and reported quarterly at Radiation Safety Committee.
*Procedure based on model spill procedures NUREG-1556, Vol. 9

Approved by: _____
Robert A. Ondo B.S., C.N.M.T.
Radiation Safety Officer

Contact Hospital Operator (724) 658-9001 for Radiation Safety Officer or Radiologist on call
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