

**MEDICAL ONCOLOGY  
& HEMATOLOGY**

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Pamela J. Honeycutt, M.D., Ph.D.  
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**RADIATION ONCOLOGY**

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**RADIATION THERAPY**

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**RESEARCH**

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January 27, 2009

Materials Licensing Branch  
U.S. NRC Region III  
2443 Warrenville Rd.  
Suite 210  
Lisle, IL 60532-4352

NRC Representative:

This letter is to request an amendment to U.S. NRC Radioactive Materials License number 24-32604-01, to include byproduct material for medical use under 10 CFR 35.200 for imaging and localization studies (PET) and to add Vijay Sadhu, MD to our current license. Enclosed is a copy of the NRC license of which he is listed. The changes requested are to comply with new NRC regulations in reference to NARM as published in 72 FR 55864. Materials to be added to the license are listed below.

**Radioactive Material**

Material	Chemical/Physical Form	Maximum Amount
Fluorine-18	Liquid glucose, liquid sodium fluoride	1 Ci
Germanium-68	Sealed sources	100 mCi
Any	Any source authorized by 10 CFR 35.65	Per 10 CFR 35.65

**Purposes for which licensed material will be used**

Material	Purpose
Fluorine-18	Diagnostic studies involving imaging and tumor location, calibration, reference, and quality control
Germanium-68	Calibration and transmission scanning
10 CFR 35.65	Calibration, reference, and quality control

**Authorized Users for licensed material**

Authorized User	Materials	Comments
Vijay Sadhu, MD	F-18, Ge/Ga-68	Currently listed as AU on NRC license #24-01565-01
Mark P Bryer, MD	F-18, Ge/Ga-68	Listed as AU on current license 35.400, 35.600
James Allen, MD	F-18, Ge/Ga-68	Listed as AU on current license 35.400, 35.600
Joseph Bean, MD	F-18, Ge/Ga-68	Listed as AU on current license 35.400, 35.600
Steven Westgate, MD	F-18, Ge/Ga-68	Listed as AU on current license 35.400, 35.600
William Decker, MD	F-18, Ge/Ga-68	Listed as AU on current license 35.400, 35.600



**MISSOURI  
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ASSOCIATES, LLC**

■ Medical and Radiation Oncology ■ Hematology ■

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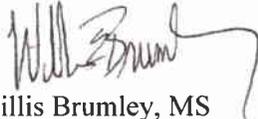
(573) 817-8538

Attached is a *facility diagram* demonstrating the room numbers referenced in ( ) below. The PET area has no occupancy above or below. Radioisotopes are received, stored and secured in the lockable hot lab (1141). The dose drawing and sharps waste storage areas in the hot lab will be shielded by a high-energy L-block/interlocking brick enclosure. ½" thick tungsten syringe shields will be used during all injections to help reduce exposure to facility staff. The dose calibrator chamber will be shielded by a ring shield of 2" thick interlocking lead bricks. PET imaging patients are dosed with the radioactive materials in the prep rooms (1114, 1115, 1118), which are shielded. PET imaging is performed in the PET suite (1145). The hot lab, prep rooms, and PET suite are controlled areas. We would request the PET technologist work area (1144) be considered a non-restricted area. The prep rooms and PET suite are shielded to maintain radiation worker and public radiation exposure well below legal limits. Area dose monitors are in place to monitor public exposure as demonstrated in the *member of public exposure survey policy F-17*, attached. .

Policies and procedures pertaining to the use of radioactive materials have been submitted in previous amendment applications. All existing policies and procedures will apply to the use of the above materials. The *PET policies and procedures* and the *PET quality and Safety Program Audit* have been attached to further answer any questions you may have concerning our PET program.

Please do not hesitate to contact me if you have any questions.

Sincerely,



Willis Brumley, MS  
Medical Physicist, RSO  
Missouri Cancer Associates  
573-441-3710  
[willis.brumley@usoncology.com](mailto:willis.brumley@usoncology.com)

	<b>PET</b>	No: B-2
	CATEGORY:  Equipment	EFFECTIVE DATE:  March 1, 2007
RESPONSIBLE PARTY:	SUBJECT:  QUALITY CONTROL OF MONITORING AND ASSAY EQUIPMENT	REVISED DATE:

## Quality Control of Monitoring and Assay Equipment

### Required Equipment

- Radiation survey meters
- Radiation room monitors
- Dose calibrator
- Well counter
- Lead shielded drawing station
- Titanium syringe shields
- Disposable gloves, syringes, and needles
- Emergency decontamination kit
- Absorbent pads
- Decontamination agents

### **PURPOSE:**

As committed with the initial RAM license application, State and/or NRC rules require each radiopharmaceutical dose to be assayed prior to patient injection. To ensure compliance with these rules, the laboratory equipment responsible must be assessed for optimum performance on a regular basis. This section outlines a Quality Control program for such equipment.

	<b>PET</b>	No: B-2
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RESPONSIBLE PARTY:	SUBJECT: <b>QUALITY CONTROL OF MONITORING AND ASSAY EQUIPMENT</b>	REVISED DATE:

**POLICY:**

- A. Maintenance for electronic and other equipment is performed as needed, or per manufacturer's recommendations, environment, past history, etc.
- B. Laboratory equipment performance is typically assessed on the following schedule:
1. Dose Calibrator – Daily (Constancy), Quarterly (Linearity), Annual (accuracy).
  2. Well Counter – Daily (Calibration), Annually (Well Efficiency).
  3. Survey Meter(s) – Annually (Quantitative Accuracy) unless the meter is deemed a mobile device, in which case the calibration is done semi-annually.
- C. If a piece of equipment is found to be in need of repair, the following options are available:
1. If the repair is of minor nature (e.g. well counter gain adjustment), it can be done immediately on site until appropriate performance is attained.
  2. If the repair cannot be done on site, and the performance error is predictable (e.g. geometrical variation > 5%), a correction factor may be used until an appropriate repair can be made.
  3. If the repair is major and the equipment yields results with an unpredictable error, the item will be removed from service. A temporary alternative method (e.g. reliance on radiopharmacy assay, wipe counting with pancake probe) will be implemented until an appropriate repair can be made.

	<b>PET</b>	No: <b>B-2</b>
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RESPONSIBLE PARTY:	SUBJECT: <b>QUALITY CONTROL OF MONITORING AND ASSAY EQUIPMENT</b>	REVISED DATE:

### **PET Suite Posting Requirements**

Three types of signs are commonly used

1) Caution Radioactive Materials:

An area or room where radioactive material is used or stored

2) Radiation Area:

An area where a major portion of the body may  
receive in excess of 5 mR/hr or 100 mR in 5 consecutive days

3) High Radiation Area:

An area where a major portion of the body may receive in excess of 100 mR/hr

	<b>PET</b>	No: B-2.1
	CATEGORY: <b>Equipment</b>	EFFECTIVE DATE: <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT: <b>QUALITY CONTROL OF MONITORING AND ASSAY EQUIPMENT</b>	REVISED DATE:

## Quality Control of Monitoring and Assay Equipment

### DOSE CALIBRATOR CALIBRATION

1. The dose calibrator will be checked for accuracy.
  - a. A sealed source, Na-22 source is utilized to check the accuracy of the dose calibrator. The accuracy of the assay of these standards will be at least  $\pm 5\%$  and traceable to National Institute of Standards and Technology sources.
  - b. The dose calibrator will be checked for accuracy upon installation, following repair, and at annual intervals using the sealed source listed above. This will be done by assaying the source at the appropriate setting, including a correction for background. Net activity readings will be recorded.
  - c. The activity displayed by the dose calibrator must agree with the stated assay, corrected for decay, to within  $\pm 10\%$ . Variations greater than 10% from the expected or calculated value shall cause the instrument to be repaired and recalibrated prior to use for assay of patient doses.
2. The dose calibrator will be checked for constancy.

	<b>PET</b>	No: <b>B-2.1</b>
	CATEGORY: <b>Equipment</b>	EFFECTIVE DATE: <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT: <b>QUALITY CONTROL OF MONITORING AND ASSAY EQUIPMENT</b>	REVISED DATE:

a. This will be done at the same time the accuracy test is done and subsequently at the beginning of each day of use. The activity of the constancy source will be consistent with applicable regulatory limits. The sealed source will be placed in the chamber and the unit set to measure that nuclide. The activity displayed with background and decay considered, must fall within  $\pm 10\%$  of the predicted activity based on the value obtained at the time of the last accuracy test.

b. The daily constancy check will be extended to include verification of displayed activities using the same standard but with the dose calibrator set to measure each of the different nuclides to be assayed on that day. With background and decay considered, variation in displayed activities must fall within  $\pm 10\%$  of the activity shown at the time of the most recent accuracy check. If variations greater than  $\pm 10\%$  are noted, the dose calibrator will be repaired or replaced.

3. The dose calibrator will be checked for linearity.

a. Activity linearity will be checked upon installation, following repair, and at quarterly intervals. This test will be performed using the maximum activity of F-18 that would typically be administered during a patient study.

	<b>PET</b>	No: B-2.1
	CATEGORY:  <b>Equipment</b>	EFFECTIVE DATE:  <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT:  <b>QUALITY CONTROL OF MONITORING AND ASSAY EQUIPMENT</b>	REVISED DATE:

The linearity test will be continued by repeating the assay of the source several times over 10 half-lives of the isotope. The linearity test shall proceed over the range medical administrations, typically 20 mCi to 30  $\mu$ Ci.

b. The linearity test data will be plotted or calculated as a function of time and compared to the predicted activities at the same time. The acceptable range of error will be  $\pm 10\%$ . If test result error exceeds  $\pm 10\%$ , the unit will be evaluated for the necessity of repair. The unit may be used in the interim utilizing correction factors as appropriate.

c. As an alternative procedure, the linearity test can be performed with the use of the Calicheck Kit or the Lineator. The manufacturer's instructions for use will be followed. The source used shall be the activity of the largest dose measured for a patient study. Limits of acceptability and corrective actions will be as above. Verification of this method against the decay-based method will be performed at intervals not to exceed two years.

4. The dose calibrator will be tested for geometrical variation.

a. Geometry will be tested upon installation and after chamber repair. This test will be performed on commonly used syringes containing approximately 500 uCi of F-18 in each syringe size. The initial geometrical

	<b>PET</b>	No: B-2.1
	CATEGORY:  <b>Equipment</b>	EFFECTIVE DATE:  <b>March 1, 2007</b>
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configuration will approximate that of a point source. The source geometry will then be changed, usually by dilutions of 0.5 ml to 2 ml, with assays performed at each step. The amount of the volume change will depend on the syringe size. Measurements will be made for at least four different volumes and will include the maximum volume measurable by the syringe. Data will be analyzed comparing the various readings to a configuration that represents a common, midpoint, or typical volume that is used for that particular container. The procedure will be repeated using all commonly used syringe sizes (typically this will be 3 ml, 5 ml, and 10 ml). Correction factors will be used with clinical assays when geometry induced errors exceed  $\pm 10\%$ .

 <b>US Oncology</b>	<b>PET</b>	NO: <b>B-2.2</b>
	CATEGORY:  <b>Equipment</b>	EFFECTIVE DATE:  <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT:  <b>QUALITY CONTROL OF MONITORING AND ASSAY EQUIPMENT</b>	REVISED DATE:

### Quality Control of Monitoring and Assay Equipment

#### **SURVEY INSTRUMENT CALIBRATION**

The area survey instrument will be calibrated as follows:

1. When radioactive material is required to calibrate the radiation detection instrument, the entity performing the calibration must be specifically authorized by the U.S. Nuclear Regulatory Commission or the presiding non-Agreement state, State of Missouri, program to perform such calibrations.
2. The area survey instruments used in this program require calibration by a licensed provider of calibration services. The entity chosen to perform the survey instrument calibrations will do so in accordance with the following:
  - a. The radionuclide sources used for calibration shall approximate point sources.
  - b. The source activities used shall be traceable\* to within +5% accuracy to the NIST calibrations.\*\*
  - c. The frequency of calibration shall be at intervals not to exceed one year and after servicing/repair.

 <b>US Oncology</b>	<b>PET</b>	No: <b>B-2.2</b>
	CATEGORY:  <b>Equipment</b>	EFFECTIVE DATE:  <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT:  <b>QUALITY CONTROL OF MONITORING AND ASSAY EQUIPMENT</b>	REVISED DATE:

- d. Each scale of the radiation detection instrument shall be calibrated at least at two points such that: (a) one point is in each half of the scale; and (b) the two points are separated by 50-60% of full scale. Logarithmic and digital readout radiation detection instruments with only a single readout scale shall be calibrated, at a minimum, at one point near the midpoint of each decade.
- e. The exposure rate measured by the radiation detection instrument should not deviate more than +10% from the calculated or known value for each point checked. Readings within +20% will be considered acceptable if a calibration chart or graph is prepared and attached to the radiation detection instrument. If the radiation detection instrument cannot be adjusted so that each reading falls within the +20% range, it shall be taken out of service and sent to the manufacturer or to a qualified radiation detection instrument laboratory for repair.
- f. If an electronic device is used to calibrate the instrument, the instrument must still be checked for response to a known source of radiation.
3. We reserve the right to upgrade our survey instruments, as necessary, as long as they are adequate to measure the type and level of radiation for which they are used.

	<b>PET</b>	No: B-2.3
	CATEGORY:  Equipment	EFFECTIVE DATE:  March 1, 2007
RESPONSIBLE PARTY:	SUBJECT:  QUALITY CONTROL OF MONITORING AND ASSAY EQUIPMENT	REVISED DATE:

### Quality Control of Monitoring and Assay Equipment

#### **WELL COUNTER CALIBRATION**

The well counter instrument is used to measure wipe samples as part of the package receipt procedures. It will be calibrated as follows:

1. The well counter is required to assess removable contamination levels on wipe samples taken from incoming and outgoing radioactive packages. These measurements must provide contamination levels in units of activity (uCi or dpm). Consequently, the well counter must be calibrated at periodic intervals to ensure use-appropriate accuracy.
2. The well counter instrument will be calibrated at weekly intervals to within 5% accuracy of a NIST traceable standard. The automatic tuning algorithm provided by the well counter manufacturer will be used to perform this calibration with a Cs-137 reference point source. Nominal activity of the standard will be approximately 0.5 uCi.
3. Direct measurement of well efficiency factors for all nuclides for which quantitative results are required will be performed as follows:
  - a. The radionuclide sources used for calibration shall approximate point sources.

 <b>US Oncology</b>	<b>PET</b>	No: <b>B-2.3</b>
	CATEGORY:  <b>Equipment</b>	EFFECTIVE DATE:  <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT:  <b>QUALITY CONTROL OF MONITORING AND ASSAY EQUIPMENT</b>	REVISED DATE:

- b. The source activities used shall be traceable to within +5% accuracy of a NIST standard.
- c. Calibration shall occur upon initial installation and subsequently at intervals not to exceed one year following service or repair.
- d. Well efficiency measurements of short-lived nuclides for which NIST standards are not easily obtainable may be determined by comparison to a long-lived standard, as long as the relative efficiencies of the two nuclides for this well counter are known or can be clearly demonstrated.
- e. If an electronic device is used to calibrate the instrument, the instrument must still be checked for response to a known source of radiation.

	<b>PET</b>	NO: D-13
	CATEGORY:  <b>General Safety</b>	EFFECTIVE DATE:  <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT:  <b>HAZARDOUS MATERIALS PROGRAM</b>	REVISED DATE:

### **Hazardous Materials (HAZMAT) Training Program**

The facility requires all PET Technologists to be in compliance with the training requirements of the Federal Department of Transportation (DOT) in accordance with provisions of 49 CFR 172 Subpart H-Training for HAZMAT employees. The NRC and the State Radiation Control agency will also have a “Memorandum of Understanding” to incorporate DOT regulations into their regulations. The Hazardous Materials Training Program is for any employee who:

- loads, unloads, or handles hazardous materials (e.g., radiopharmaceuticals)
- test, reconditions, repairs, modifies, marks, or otherwise represents packaging as qualified for use in the transportation of hazardous materials
- prepares hazardous materials for transportation
- is responsible for safety of transporting hazardous materials

Each HAZMAT employee must:

- train and test
- certify, and
- develop and retain records of current training (inclusive of preceding three years) for each HAZMAT employee (during the period of employment and 90 days thereafter)

	<b>PET</b>	NO: <b>D-13</b>
	CATEGORY: <b>General Safety</b>	EFFECTIVE DATE: <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT: <b>HAZARDOUS MATERIALS PROGRAM</b>	REVISED DATE:

### **Initial Training**

For initial training for a new employee, or an employee who changes job function, the employee may perform HAZMAT job functions before completing training, provided:

- the employee does so under the direct supervision of a properly trained and knowledgeable HAZMAT employee and
- the HAZMAT training is completed within 90 days of the employment or change of job function

The current HAZMAT Training Program for this facility requires viewing of a CD/reading materials, taking a written test, and being certified by the credentialed HAZMAT Trainer (currently the RSO). Records will be kept for examination and include HAZMAT employee's name, completion date of training, training materials, name and address of HAZMAT trainer, and certification that the HAZMAT employee has been trained and tested.

### **Recurrent Training**

Recurrent training is required at least once every three years. The three year period begins on the actual date of training. Also, relevant training received from a previous employer or source may be used to satisfy the requirements provided a current record of training is obtained from the previous employer or source.

	<b>PET</b>	No: E-1
	CATEGORY:  Clinical	EFFECTIVE DATE:  March 1, 2007
RESPONSIBLE PARTY:	SUBJECT:  APPROVED INDICATIONS FOR CLINICAL PET PROCEDURES	REVISED DATE:

### Approved Indications for Clinical PET Procedures

The following is a list of approved clinical indications for the routine imaging procedures performed at this facility. Confirmation by an approved technologist of the presence of one or more of these indications (see Standing Medical Orders) will allow that technologist to proceed with the corresponding PET examination, even in the absence of an Authorized Physician User. Any deviation from these approved indications or any deviation from the approved dosage range for the respective examination will require prior authorization from an authorized physician user (APU) listed within the Radioactive Material License. If, at any time, there is a question regarding the appropriateness of an indication, the ability of the patient to cooperate sufficiently for adequate images to be obtained, the area of the body being imaged, the dosage to be administered, or the imaging technique to be employed, the technologist will consult with an APU prior to initiating the examination.

#### INDICATIONS FOR ONCOLOGIC WHOLE-BODY, SKULL-BASE TO THIGH, OR LIMITED AREA (INCLUDING BRAIN) PET WITH FDG:

1. Differentiation of benign from malignant lesions
2. Staging of malignant disease
3. Re-staging of malignant disease after completion of a prescribed therapy regimen
4. Grading of malignant brain lesions
5. Differentiation of recurrent or residual malignant disease from therapy-induced changes
6. Monitoring response to therapy
7. Delineation of tumor extent for treatment planning purposes
8. Imaging performed as part of an approved research protocol, as confirmed in writing by the PET Medical Director

ANNUAL CONCURRENCE

\_\_\_\_\_  
Medical Director

\_\_\_\_\_  
Date

	<b>PET</b>	No: <b>E-2</b>
	CATEGORY:  <b>Clinical</b>	EFFECTIVE DATE:  <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT: <b>STANDING MEDICAL ORDERS FOR CLINICAL PET PROCEDURES</b>	REVISED DATE:

### Standing Medical Orders for Clinical PET Procedures

The following document reflects orders, rules, regulations or procedures to be used as a guide in preparation for and carrying out PET procedures for patients who have been examined or evaluated by a Clinical Practitioner prior to the ordering of a scan, to be performed at this PET facility. These orders, rules, regulations or procedures as defined in the facility's Policies and Procedures Manual, constitute authority and direction for certain prescribed acts for patients by authorized persons, as distinguished from specific orders written for a particular patient.

Any technologist who has been hired to perform PET imaging procedures for this facility, who possesses a current General Certificate as a Certified Nuclear Medicine Technologist may review each imaging procedure referral for acceptance, based on the exam-specific, approved clinical exam indications listed below. Once a matching clinical indication has been confirmed, this technologist is hereby delegated the authority, even without the presence of an authorized physician user, to initiate and complete the following procedure:

- Schedule exams and place licensed radiopharmaceutical drug orders in my name, direct any approved and appropriate exam preparations,
- Administer the approved radiopharmaceutical within the stated activity range and via the approved route for any physician-referred patient who lacks all specified contraindications,
- Perform the imaging protocol outlined within the Policies and Procedures Manual, including any additional images that would not require an additional radiopharmaceutical administration.

Any deviation from what is explicitly authorized within the Policies and Procedures Manual will require prior authorization from an authorized physician user (APU) listed within the Radioactive Material License.

\_\_\_\_\_  
Medical Director

\_\_\_\_\_  
Date

ANNUAL CONCURRENCE

	<b>PET</b>	NO: F-1
	CATEGORY: <b>Radiation Safety</b>	EFFECTIVE DATE: <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT: <b>RADIATION PROTECTION AND ALARA PROGRAM</b>	REVISED DATE:

**Radiation Protection and ALARA Program**

**Operating, Safety, and Emergency Procedure:**

1. The Radiation Protection and ALARA program is located in the Health Physics office and is available to the PET/Nuclear Medicine Technologist and other occupationally-exposed employees.

**Personnel Monitoring:**

1. Whole-body badges and extremity monitors will be worn as specified in ***Policy F-10***.
2. Control badge will be stored in a low background area.
3. Personnel monitoring devices will be worn as follows: badges at or near the collar and a ring on the dominant hand with detector on source side.
4. The ALARA program will be followed and will ensure combined occupational total dose (e.g., when agent(s) are exposed at second job) to any employee receiving occupational exposure at our facility and at other facilities does not exceed 5 rem per year
5. No minors will be employed in areas where radioactive material is used
6. Based on documented personnel monitoring records and surveys in all areas of our facility, employees not currently wearing a personnel

	<b>PET</b>	NO: F-1
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RESPONSIBLE PARTY:	SUBJECT:	REVISED DATE:
	<b>RADIATION PROTECTION AND ALARA PROGRAM</b>	

monitoring device are not likely to exceed 10% of the dose limits and are, therefore, not required to wear personnel monitoring.

7. Declared pregnant employees will be allowed to continue their duties as long as an additional personnel monitoring device is worn at the waist to monitor the exposure to the fetus and the exposure do not exceed (10% of 5,000mR). (DECISION WILL BE MADE BY MANAGEMENT, AFTER CONSULTATION WITH A LICENSED MEDICAL PHYSICIST).
8. Documentation of declarations of pregnancy will be maintained in the Health Physics office. Exposure records for the embryo/fetus will be maintained with other personnel monitoring records.

**Quality Assurance Programs:**

Records of the quality assurance programs utilized when handling and/or using radioactive materials are listed in the license application for equipment used in our PET facility. The license application includes checks that are done, intervals at which they are done, and what actions are taken if discrepancies are noted. The PET Technologist is responsible for conducting quality assurance checks on equipment. The quality assurance program regarding appropriateness and quality of patient care is maintained by the technologist in accordance with guidelines specified by our Policy and Procedures Manual.

	<b>PET</b>	NO: F-1
	CATEGORY: <b>Radiation Safety</b>	EFFECTIVE DATE: <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT: <b>RADIATION PROTECTION AND ALARA PROGRAM</b>	REVISED DATE:

**Training:**

1. Training requirements of technologists are listed in the RAM license application.
2. Continuing education credits, as required by the Technologist's certifying organization, will be obtained in a timely manner by all PET technologists.

**Posting/Labeling:**

1. Signs and postings, as required, are located in the PET facility
2. Areas where postings and signs are required will be monitored by the technologists and annually by a medical physicist to ensure compliance. Likewise, any containers requiring labeling will be maintained the same way.

**Compliance with Dose Limits to the Public:**

1. Calculations for determining radiation exposure to a member of the public are calculated by placing personnel monitoring devices in areas of the facility where the public frequents. These records are maintained along with personnel monitoring records and are available at Agency review.
2. A level of 0.06 mR/hr in areas where a specific member of the public might temporarily be present (defined as less than 8 hours total for the

	<b>PET</b>	NO: F-1
	CATEGORY: <b>Radiation Safety</b>	EFFECTIVE DATE: <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT: <b>RADIATION PROTECTION AND ALARA PROGRAM</b>	REVISED DATE:

year) will be used to determine if the area meets requirements of a total exposure of less than 100 mR/yr to a member of the public. PET patients will be confined to the prep rooms for injections and uptake time (i.e., approximately a 45-60 minute period for radiopharmaceutical distribution throughout the body.) Consideration will be given to the fact that no individual member of the public is likely to be present in an occupationally-exposed area, such as a waiting room or reception area, for a time greater than 8 hours total in a year. Unrestricted areas adjacent to areas where radioactive materials are stored will be surveyed with a GM meter and monitored with film badges to ensure the 100 mR/yr limit is met.

**Surveys/Audits:**

1. Surveys, including intervals and locations, conducted in the PET facility are identified **Policy F-8** in the radioactive materials license application. Audits of the RPP are conducted by a medical physicist. The physicist will audit the department on an annual basis. The RSO will review the RPP at least annually. The RSO will oversee monthly and quarterly tasks as spelled out by the Radiation Protection Program of our RAM license application.
2. The PET Nuclear Medicine Technologists will perform all routine surveys

	<b>PET</b>	NO: F-1
	CATEGORY: <b>Radiation Safety</b>	EFFECTIVE DATE: <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT: <b>RADIATION PROTECTION AND ALARA PROGRAM</b>	REVISED DATE:

3. A low-level GM meter will be used to perform all area surveys with either a side window or pancake probe. All contamination wipes will be performed in accordance with **Policy F-8**.
4. All survey and audit results will be maintained on file in the P.E.T. area.
5. Procedures for ensuring that packages are properly received, shipped and surveyed are specified in **Policy F-3**.
6. Procedures for conducting inventories of radioactive material are specified in **Procedure F-13**.
7. Procedures for conducting leak tests are specified in **Procedure F-13**.

**Recordkeeping:**

1. The RSO is responsible for maintaining all records as required by **Policy F-15**. The RSO may designate these duties to the PET Technologists in regards to records required to be formulated in the PET facility.
2. Records will be maintained in the P.E.T. department.

**Waste:**

1. Procedures for ensuring proper handling, storage, and surveys of waste are specified in **Policy F-9**.
2. Waste disposal will either be in the regular trash, after suitable

	<b>PET</b>	NO: F-1
	CATEGORY: <b>Radiation Safety</b>	EFFECTIVE DATE: <b>March 1, 2007</b>
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decay and survey, or if the waste is bio-hazardous, it will be collected by a licensed vendor.

**Other Engineering Controls:**

1. Controls used to reduce or control exposure to radiation, such as protective gloves, lab coats, lead shielding, and distance will be used conscientiously, as specified in our ALARA program.

**Instrumentation:**

1. The types of radiation detection instrumentation available at our facility include the following:
  - Dose Calibrator
  - GM Survey Meter
  - PET Scanner
  - Scintillation Detector, either well or probe
  - o The dose calibrator is used for assaying radiopharmaceuticals
  - o The survey meters are used for area surveys and package surveys
  - o The well counter is used for contamination analysis.
  - o The scanner is used for clinical studies.
  - o These instruments are always used in accordance with **Policy F.8.**
3. Calibration of the instrumentation, including who performs the calibrations and at what intervals is specified in our Policy and Procedure Manual.

	<b>PET</b>	No: <b>F-1</b>
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	<b>RADIATION PROTECTION AND ALARA PROGRAM</b>	

4. A medical physicist will audit our department annually, including an inspection of instrumentation, to ensure proper maintenance of such instrumentation and proper calibration.

**Other General Requirements:**

1. The Radiation Safety Officer will be responsible for ensuring the Notices to Workers, as required, are appropriately posted.
2. Employees will be provided copies of NRC Regulatory Guides 8.13 and 8.29.
3. The Radiation Safety Officer, with the assistance provided by the Medical Physicist, is responsible for providing such instruction.

	<b>PET</b>	No: F-2
	CATEGORY: <b>Radiation Safety</b>	EFFECTIVE DATE: <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT: <b>GENERAL RULES OF RADIATION SAFETY</b>	REVISED DATE:

**General Rules of Radiation Safety for the PET Department**

1. Wear laboratory coats or other protective clothing while handling dispersible radioactive materials.
2. Wear disposable gloves at all times while handling dispersible radioactive materials.
3. Monitor hands and clothing if contamination is suspected.
4. Always use PET-grade syringe shields, pre-established intra-venous lines, and 5-10 ml saline flush for routine preparation and administration of patient doses.
5. a) Do not eat, drink, smoke, chew, or apply cosmetics in any area where radioactive material is stored or used.  
b) Do not store food, drink, or personal effects with radioactive material.
6. Assay each patient dose in the dose calibrator prior to administration.  
Remember the principles of **time, distance, and shielding** when performing this assay.
7. Instruct patients to remain in their respective injection rooms - with the exception for using the bathroom if needed – during the FDG uptake

	<b>PET</b>	NO: <b>F-2</b>
	CATEGORY: <b>Radiation Safety</b>	EFFECTIVE DATE: <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT: <b>GENERAL RULES OF RADIATION SAFETY</b>	REVISED DATE:

phase between injection and scanning. Immediately prior to imaging, have the patient void.

8. Wear personnel monitoring devices (PMD) – such as film badge or TLD – at all times while in areas where radioactive materials are used and stored. Personnel Monitoring Devices (PMD) must be worn between waist and collar level at all times. Extremity monitors (ring badges) should be worn with the chip facing the palm of the hand. Personnel monitoring devices when not being worn to monitor occupational exposure should be stored in a designated low-background area.
9. Wear TLD finger badge during preparation, assay, and injection of radiopharmaceuticals.
10. Dispose of radioactive waste only in specifically designated sharps that are properly shielded. When transferred to a disposal container, confirm background activity.
11. Survey laboratory work area for contamination after each procedure when contamination is suspected, or at the end of the day and decontaminate as necessary.
12. Contain radioactive solutions in covered containers plainly identified.
13. Always transport radioactive material in shielded containers.

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14. For PET scanning:

- A. Whenever possible, mechanical devices only (e.g. tape, Velcro straps, etc.) shall be utilized to immobilize patients during PET procedures. Unless special circumstances require it, employees, nurses, and patient family members/friends will not be present in the PET scan room during the exam.
- B. Always stand inside the shielded control booth when initiating an exposure.
- C. Annual radiation safety in-service training with documentation of staff attendance is required.
- D. New personnel are oriented to Radiation Safety practices.
- E. Pregnant females and children will be asked to wait outside the uptake room, in one of the waiting areas.

15. Pregnant employees who declare pregnancy will wear an additional PMD below the waist level.

	<b>PET</b>	No: F-3
	CATEGORY:  <b>Radiation Safety</b>	EFFECTIVE DATE:  <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT:  <b>RECEIVING AND OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS</b>	REVISED DATE:

## Receiving and Opening Packages Containing Radioactive Materials

1. Packages containing radioactive materials will be monitored for surface contamination and external radiation levels within three hours of receipt if received during working hours. No radioactive materials will be delivered during off-duty hours. All shipments of liquids greater than exempt quantities will be tested for leakage. The Radiation Safety Officer (RSO) will be notified if removable contamination or external radiation levels exceed the limits specified in NRC regulations 10 CFR 20.1906 (b) and (c). These limits are 0.01  $\mu\text{Ci}$  (370 Bq) per 100  $\text{cm}^2$ , 200mR/hr at the package surface or 10mR/hr @ 1 m.
  
2. For packages received under this license, the following procedure will be observed for opening each package:
  - a. Put on gloves to prevent hand contamination.
  - b. Visually inspect the package for any sign of damage (e.g., wet or crushed), If damage is noted, stop the procedure and notify the RSO.
  - c. Measure exposure at 1 m and at the package surface and record. If the reading is higher than expected as discussed in NRC regulations 10 CFR 20.1906 (b) and (c) see above, stop and notify the RSO.
    - i Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.
    - ii For packages labeled with a White I, Yellow II, or Yellow III label, survey and wipe the surface of the package. If > 6600 dpm measured over 300  $\text{cm}^2$ ,

	<b>PET</b>	No: F-3
	CATEGORY:  <p style="text-align: center;"><b>Radiation Safety</b></p>	EFFECTIVE DATE:  <p style="text-align: center;"><b>March 1, 2007</b></p>
RESPONSIBLE PARTY:	SUBJECT:	REVISED DATE:
	<p><b>RECEIVING AND OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS</b></p>	

stop and notify the RSO. Monitoring for radiation is not necessary if the package contains only radioactive material as a gas or in special form.

- iii The monitoring required shall be performed as soon as practicable after receipt, but not later than 3 hours after the package is received if it is received during working hours and no radioactive materials will be accepted during off-duty hours.
  - d. Open the package with the following precautionary steps:
    - i Open the outer package (following the manufacturer's directions, and remove the packing slip.
    - ii Open inner package and verify that the contents agree with the packing slip.
    - iii Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
    - iv Check also that the shipment does not exceed possession limits.
  - e. If there is evidence of package degradation, wipe external surface of the final source container. Check the wipe in a low background area using a G-M survey meter and take precautions against the spread of contamination, as necessary.
  - f. Check the user request to ensure that the material received is the material that was ordered.
  - g. Monitor the packing material and the empty packages for before discarding.
    - i If contaminated, treat this material as radioactive waste.
    - ii If not contaminated, remove or obliterate the radiation labels before discarding as normal trash.
  - h. Make a record of the receipt including the result of all monitoring.
3. Maintain records of the results of checking each package, using a "Radioactive Shipment Receipt Record", or a similar form containing the appropriate information.

	<b>PET</b>	NO: F-4
	CATEGORY: <b>Radiation Safety</b>	EFFECTIVE DATE: <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT: <b>RADIOPHARMACEUTICAL ORDERING AND SUPERVISION OF USE</b>	REVISED DATE:

### **Radiopharmaceutical Ordering and Supervision of Use**

1. Any Nuclear Medicine Technologist licensed as such in this state, trained appropriately in the use of PET radiopharmaceuticals, and engaged in performing diagnostic PET imaging studies at this facility under the supervision of an authorized physician user (APU) has the authority to order, receive, and administer diagnostic radiopharmaceuticals under the guidelines set forth in this manual.
2. The Nuclear Medicine Technologist will place all orders for radioactive materials and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.
3. Supervision of PET procedures by an APU will consist of:
  - a. For indications considered standard, accepted, and routine, APU delegates the authority to initiate and perform diagnostic PET procedures to the Nuclear Medicine Technologist employed by the facility. A list of accepted indications for a routine PET procedure is provided to the technologist. Appropriate sources for confirmation of such indications include:
    - i information provided by the referring physician or his/her staff at the time of scheduling or at the time of the study, or
    - ii information provided by the patient, provided he/she is deemed a reasonable historian; information contained in the patient's written record (inpatient or outpatient chart), or
    - iii information provided by the patient's nursing staff; or
    - iv information provided by a staff radiologist involved in the patient's diagnosis or treatment.
  - b. If a requested study does not clearly fit one of these accepted indications or if there is any question regarding whether a study should be modified in any way, the responsible authorized user must be consulted prior to initiating the study
  - c. Responsible APU will be immediately accessible by telephone at all times while studies are being performed.
  - d. Responsible APU will be close enough to permit an on-site response within 1 hour of being notified of a medical event.

	<b>PET</b>	NO: F-4
	CATEGORY: <b>Radiation Safety</b>	EFFECTIVE DATE: <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT: <b>RADIOPHARMACEUTICAL ORDERING AND SUPERVISION OF USE</b>	REVISED DATE:

**Radiopharmaceutical Ordering and Supervision of Use**  
**(Continued)**

2. A system for ordering and receiving radioactive materials will be established and maintained. The order, receipt and utilization records will consist of:
  - a. Printed requisition/receipt record attached to each dose by our commercial radiopharmaceutical supplier. This receipt is peeled off and affixed to the day's operating log to document both the receipt of the material and the drug order and utilization records. In total, the record will include:
    - i patient name
    - ii authorized user
    - iii drug
    - iv quantity ordered
    - v quantity dispensed
    - vi lot number
    - vii quantity administered
    - viii wipe and survey results from the shipment
  
4. During normal working hours, and when the technologist is available to receive the shipment, carriers will be instructed to deliver radioactive packages directly to the hot lab receipt area under the control of the receiving technologist. When the technologist is not present, carriers will be instructed to deliver radioactive packages to a designated storage area and will be entrusted to secure the packages against unauthorized removal.
  
5. No delivery of radioactive packages will occur during off-duty hours.

	<b>PET</b>	No: <b>F-7</b>
	CATEGORY: <p style="text-align: center;"><b>Radiation Safety</b></p>	EFFECTIVE DATE: <p style="text-align: center;"><b>March 1, 2007</b></p>
RESPONSIBLE PARTY:	SUBJECT: <p style="text-align: center;"><b>EMERGENCY PROCEDURES</b></p>	REVISED DATE:

### **Emergency Procedures**

**PURPOSE:**

To outline procedures to be followed for fires and other major emergencies involving the PET suite.

**POLICY:**

An accident is an event compromising the interior or exterior portions of the PET scanner or the Hot lab facility. Failure of the robotic transmission source manipulator in which one of the sources fails to return to the shielded position after scanning or calibration is not considered an accident, but the procedure for managing the situation will be the same, with the exception of the notification and reporting steps.

The locations of the radioactive material in this P.E.T. facility are:

- a. There are three (3) line sources in the P.E.T. scanner gantry. The isotope is Ge/Ga-68, and the nominal activity of the source is 1.5 mCi.
- b. In the hot lab: reference sources. The isotopes are Na-22 (x2), Ge-68, and Cs-137. The nominal activities are 182uCi, 97uCi, 0.3971uCi, and 0.5uCi. (2) Ge/Ga-68 phantom sources, and one (1) Ge/Ga-68 line source.
- c. An emergency decontamination kit is located in the radiopharmacy.

	<b>PET</b>		No: <b>F-7</b>
	CATEGORY: <p style="text-align: center;"><b>Radiation Safety</b></p>		EFFECTIVE DATE: <p style="text-align: center;"><b>March 1, 2007</b></p>
RESPONSIBLE PARTY:	SUBJECT:		REVISED DATE:
	<b>EMERGENCY PROCEDURES</b>		

**In the case of an accident, the general guidelines are:**

- **Notification:** the 24-hour emergency contact telephone number is listed below for our Radiation Safety Officer (RSO). The emergency contact number for the NRC is: 800-522-3025. **Secure the area:** Restrict access to the facility until radiation surveys have been made to determine if any radiological hazards exist.
- **Locate:** Determine the location of the sealed Ge-68/Ga-68 sources. If any of these sources was affected by the accident, demarcate their location with Caution Radiation signs and/or radiation tape.
- **Signage:** Use the tape having the “Caution Radiation” sign to secure the area.
- **Survey:** Using the portable radiation survey meter to locate the radioactive source. Radiation surveys should be performed only by individuals properly trained in the use of radiation survey equipment.
- **Retrieve** and secure any radioactive source that may become detached and/or dislodged to the extent that a radiological hazard is created. The procedure for this is as follows:

If the radioactive source was found detached and/or dislodged to the extent that it can be picked up by a pair of tongs, pick up the source using a pair of tongs and put the radioactive source into the emergency shielded source container. Apply the principle of time, distance and shielding to minimize exposure.

**Decontamination:** Under almost any conceivable circumstances, the special form material (sealed sources) will not cause dispersible contamination. In the event this does occur, and for normal form material (F-18), refer to the decontamination procedures described earlier in this manual.

- **Final Survey:** Perform a complete survey of the area and permit no person to resume work in the area without the approval of the RSO or the alternative RSO.
- **Report:** Prepare a complete history of the incident and subsequent remedial or protective measurements and submit to the NRC.

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	<b>CATEGORY:</b> <p style="text-align: center;"><b>Radiation Safety</b></p>	<b>EFFECTIVE DATE:</b> <b>March 1, 2007</b>
<b>RESPONSIBLE PARTY:</b>	<b>SUBJECT:</b> <p style="text-align: center;"><b>EMERGENCY PROCEDURES</b></p>	<b>REVISED DATE:</b>

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**Radiation Safety Officer:** Willis Brumley: 573- 441-3710,  
ext. 2165 (work)  
573-673-9114 (cell)

**Alternation RSO:** Mark Bryer, M.D. 573-874-7899 (work)

**P.E.T. Technologist:** Dona Severson 573-214-0688

	<b>PET</b>	No: F-8
	CATEGORY: <b>Radiation Safety</b>	EFFECTIVE DATE: <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT: <b>AREA SURVEY PROCEDURES</b>	REVISED DATE:

### Area Survey Procedures

Area survey procedures are the responsibility of the Nuclear Medicine Technologist. The following procedures are normally conducted by the technologist in the areas where radiopharmaceuticals are used:

- End-of-day survey procedures will include measurements of the patient restroom(s), and a minimum of 4 other selected areas in the work areas, hot lab, injection rooms, receipt/storage area. Readings will be recorded<sup>†</sup>.
  - Weekly surveys will include a measurement of any removable contamination wiped from a minimum of 5 selected areas among those listed above, plus scanner room. The weekly surveys will consist of:
    - A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.05 mR/hr.
    - A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 1000 dpm/100 cm<sup>2</sup> for the contaminant involved. Wipes of elution and preparation areas or other “high background” areas will be removed to a low background area for measurement.
1. A permanent record will be kept of all survey results, including negative results. The record will include:

<sup>†</sup> For daily surveys where no abnormal exposures are found, the date, the identification of the person performing the survey, the identification of survey instrumentation used, and the survey results recorded.

	<b>PET</b>		NO: F-8
	CATEGORY: <p style="text-align: center;"><b>Radiation Safety</b></p>		EFFECTIVE DATE: <p style="text-align: center;"><b>March 1, 2007</b></p>
RESPONSIBLE PARTY:	SUBJECT:		REVISED DATE:
	<b>AREA SURVEY PROCEDURES</b>		

- A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.05 mR/hr.
  - Clearly identifiable name or initials of person conducting the survey.
  - Drawing of the area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.
  - Measured exposure rates, keyed to locations on drawing. Identification of survey meter(s) used by serial number, including probes, and date of most recent calibration.
  - Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective actions, and any appropriate comments.
2. Areas will be decontaminated if the wipe test indicates a contamination level exceeding 1000 dpm/100 cm<sup>2</sup>.

 <b>US Oncology</b>	<b>PET</b>		NO: F-9
	CATEGORY:	<b>Radiation Safety</b>	EFFECTIVE DATE: <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT:	REVISED DATE:	
	<b>RADIOACTIVE WASTE DISPOSAL</b>		

### **Radioactive Waste Disposal**

**POLICY:**

All disposal of radioactive wastes from the PET Department will adhere to the following guideline: all radioactive waste material will be disposed of in compliance with state or NRC rules.

The methods for the radioactive waste disposal are:

- to the sewage system
- to the normal trash
- to waste storage for later disposal

**Radioactive Waste Disposal to the Sewage System**

- This method is to be used only when instrumentation must be washed for reuse or when storage for decay is impractical.
- The material must be readily soluble or dispersible in water.
- State rules require that a detailed record must be kept of the amount of radioactive material released to the sewage system.
- Excreta from individuals undergoing medical diagnosis or therapy with radioactive material shall be exempt from any limitations on dispersal by release into the sewage system.

 <b>US Oncology</b>	<b>PET</b>	No: <b>F-9</b>
	CATEGORY:  <b>Radiation Safety</b>	EFFECTIVE DATE:  <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT:  <b>RADIOACTIVE WASTE DISPOSAL</b>	REVISED DATE:

### **To Decay in Storage for Later Disposal**

Radioactive waste may be placed in storage for decay and then final disposal to the normal trash, sewage system, or shipped away for burial. Since (F-18) fluoro-deoxyglucose (FDG) is primarily used in the PET Department, the decay will be rapid. This allows for waste to be emptied from the auxiliary lead shield container in the Hot Lab on the following morning, if necessary. Each time a container is removed to storage, it should be labeled with the type of radioactive material (F-18) and the date placed in storage. This date should also be logged in the "To Storage for Decay" logbook. At the time of permanent disposal, the container/containers will be surveyed and the reading/readings recorded in the appropriate logbook. Each survey reading should be matched to the appropriate container date in the logbook.

Should you have any questions regarding the disposal of radioactive material, contact the Radiation Safety Officer.

	<b>PET</b>	No: F-10
	CATEGORY: <b>Radiation Safety</b>	EFFECTIVE DATE: <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT: <b>PERSONNEL RADIATION MONITORING</b>	REVISED DATE:

### Personnel Radiation Monitoring

1. A personnel monitoring device (PMD) will be furnished by the PET facility to all persons working in areas where ionizing radiation is in use, in accordance with the judgment of the Radiation Safety Officer.
2. An individual's film badge will be processed immediately when it is suspected that he/she might have received a single exposure greater than 100 mRem or an accumulated exposure greater than 300 mrem in one week.
3. A record of the individual's radiation exposure status will be kept by the Radiation Safety Officer. The Personnel exposure readings will be available for inspection by each employee being monitored. Yearly totals of an individual's exposure are available from the Radiation Safety Officer and are kept in the Health Physics office.
4. At no time will a PMD be exposed to radiation unless worn by the individual to whom it is issued. Any infraction of this rule may result in the loss of that person's privilege to work with radioactive material and/or ionizing radiation at the clinic.
5. Collection and distribution of the PMD's for routine processing will be the

	<b>PET</b>	No: F-10
	CATEGORY: <b>Radiation Safety</b>	EFFECTIVE DATE: <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT: <b>PERSONNEL RADIATION MONITORING</b>	REVISED DATE:

responsibility of the Radiation Safety Officer, however, it is the responsibility of the authorized user, physician, or department manager to insure the cooperation of personnel under his/her supervision.

6. At the discretion of the Radiation Safety Officer, a finger TLD badge will be assigned in addition to whole body PMD's by persons performing implant therapy, preparing radionuclides or injecting radionuclides for imaging or therapeutic purposes.
7. Pregnant workers are urged to declare their pregnancy to the Radiation Safety Officer so that a separate waist-level badge can be provided to estimate the fetal exposure.

	<b>PET</b>	No: F-10
	CATEGORY: <b>Radiation Safety</b>	EFFECTIVE DATE: <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT: <b>PERSONNEL RADIATION MONITORING</b>	REVISED DATE:

**Personnel Radiation Monitoring (Continued)**

8. The estimate of radiation exposure made from the monitoring devices will only be correct if these rules regarding the wearing of the badges are observed:
- A. The PMD shall be worn at all times while working at the clinic.
  - B. Pregnant workers should request an additional badge to be worn at waist level.
  - C. Leave the PMD in a safe place in your work area when not on duty. Do not remove it from the clinic.
  - D. Never wear a PMD issued to another person.
  - E. The PMD issued to you is your responsibility. Turn it in at the right time, exchange for a like one, and take care of it.
  - F. Do not tamper with the PMD.
  - G. Report loss of PMD immediately to your supervisor or the Radiation Safety Officer.
  - H. Report any other incident relative to the wearing of the PMD (such as possible accidental exposure when badge is not worn) to your supervisor or the Radiation Safety Officer.
  - I. The clinic's PMD is not to be worn while on duty at another facility. The badge is the property of the clinic and meant to indicate the efficiency of the clinic's radiation safety program.
  - J. It is the responsibility of the supervisory personnel to see that the above rules are observed and to report radiation protection problems to the Radiation Safety Officer.
  - K. Flagrant violations of this policy may result in reprimand, suspension, or termination.

	<b>PET</b>	NO: F-12
	CATEGORY: <b>Radiation Safety</b>	EFFECTIVE DATE: <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT: <b>RADIATION SAFETY OF PREGNANT PERSONNEL</b>	REVISED DATE:

### **Radiation Safety of Pregnant PET Personnel**

State and NRC rules require that the fetus of a PET and radiation worker not receive a dose equivalent in excess of 0.5 rem (500 mrem or 5 mSv) during the entire pregnancy. Additionally, these regulatory bodies have urged that the monthly fetal dose equivalent not exceed 0.05 rem (50 mrem) over the course of the pregnancy.

To assure that fetal doses do not exceed this 50 mrem/month limit, pregnant PET workers are urged to declare their pregnancy to the Radiation Safety Officer as soon after conception as practical. At that time, an additional personnel monitoring device will be issued to be worn at waist level. This badge will monitor dose to the fetus. The regularly issued PMD should continue to be worn at collar level to estimate the worker's head dose.

PET workers must strictly observe principles of time, distance and shielding to ensure their exposure levels remain below the 50 mrem/month. Duties such as patient injection and patient positioning will likely need to be replaced with clerical or other duties that do not involve close contact with injected patients.

1. Maintain as much distance as practical between yourself and any injected patient.

	<b>PET</b>	NO: F-12
	CATEGORY: <b>Radiation Safety</b>	EFFECTIVE DATE: <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT: <b>RADIATION SAFETY OF PREGNANT PERSONNEL</b>	REVISED DATE:

2. Relinquish injection duties to fellow technologists. Failing this, position yourself behind a portable torso shield. Recruit the assistance of a coworker.
  3. Allow ancillary personnel to perform patient setup and positioning.
- Adherence to these rules will enable the pregnant radiation worker to continue some normal duties with the assurance that the fetus will be protected from radiation effects. Questions or concerns about this policy should be directed to the Radiation Safety Officer.

	<b>PET</b>	NO: F-13
	CATEGORY:  <b>Radiation Safety</b>	EFFECTIVE DATE:  <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT:  <b>SEALED SOURCE HANDLING AND LEAK TESTING</b>	REVISED DATE:

### Sealed Source Handling and Leak Test Program

The following guidelines must be observed to ensure safe handling of sealed source Ge-68/Ga-68 rods used in the **SIEMENS ECAT PET system**:

1. The scanner is shipped with dummy rods installed. Three (3) new rods are installed at the time the scanner is commissioned and initially calibrated. Each source activity is nominally 3.0 – 3.5 mCi.
2. Replacement rods are installed on an **annual** rotation. Two (2) expired rods are returned to the manufacturer. The third rod is retained for use in the bucket setup procedure.
3. Initial leak testing provided by the manufacturer assures the absence of removable contamination on the rod source at the time of shipping. Wipe testing performed as part of the receiving process confirms the absence of removable contamination on the package as shipped from the manufacturer.
4. Ongoing leak testing of all sealed sources covered by this license is required at intervals not to exceed 6 months. Leak testing will be performed by a Medical Physicist or commercial testing service licensed in accordance with the state of Missouri. Rods are housed in lead containers provided by the manufacturer up until the moment when they are inserted into the rod source holder inside the scanner.
5. The source is withdrawn from the lead pig using tongs, and without touching the surface of the stainless steel rod. The rod is inserted into the designated “clam-shell” holder, accessed via removable panel at the back of the gantry, and secured in its shielded holder with screws. Subsequent manipulations during scanning are accomplished by an automated robotic arm.
6. The Radiation Safety Officer is responsible for all such activities by facility personnel.

	<b>PET</b>	No: <b>F-13</b>
	CATEGORY: <b>Radiation Safety</b>	EFFECTIVE DATE: <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT: <b>SEALED SOURCE HANDLING AND LEAK TESTING</b>	REVISED DATE:

If you have any questions about sealed source handling or leak testing, please call the Radiation Safety Officer:

**Radiation Safety Officer (Effective 6-18-08):**

**Willis Brumley: 573- 441-3710, ext. 2165 (work); 573-673-9114 (cell)**

**Alternate RSO: Mark Bryer, M.D.**

**Authorized Physician User: Vijay Sadhu, M.D.**

**PET Director: Mark Bryer, M.D.**

**Field Service Engineer: Marquis Medical**

**Lead PET Technologist: Dona Severson**

	<b>PET</b>	No: F-14
	CATEGORY: <b>Radiation Safety</b>	EFFECTIVE DATE: <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT: <b>GE-68/GA-68 ROD SOURCE REPLACEMENT</b>	REVISED DATE:

### **Ge-68/Ga-68 Rod Source Replacement**

The PET scanner requires Ge-68/Ga-68 rod sources to perform transmission scanning and periodic calibration. These sources produce 511 keV gamma radiation in the vicinity of the PET imaging aperture.

1. Replace the sources at least **annually** or according to the manufacturer's replacement schedule. Schedule the replacement at a convenient time so as to minimize disruption of the patient schedule. Replacement within a few weeks before or after the anniversary of the initial source calibration will maintain optimum system performance.
2. The source is kept in a shielded enclosure and is exposed only during certain maintenance and calibration procedures. To prevent a harmful, cumulative dose to the operator and facility personnel:
  - a. Follow the handling and leak testing guidelines described in ***Policy F-13***.
  - b. Monitor the source exposure warning indicators, located on both sides of the gantry control panels and at the operator's workstation. As much as possible, minimize personnel time in the scan room whenever the rod source is exposed.
  - c. Maintain adequate distance from an exposed source.
  - d. During certain system failures, the robot arm may not retract the rod source all the way into the shield. If this happens, an alarm message appears on the monitor. If a system warning indicates the rod source did not fully retract, take precautionary measures to prevent unnecessary personnel exposure, then call the service engineer to remedy the problem.
  - e. Keep radiation sources in the shielded enclosure whenever exposure is unnecessary.

	<b>PET</b>	No: F-15
	CATEGORY:  <b>Radiation Safety</b>	EFFECTIVE DATE:  <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT:  <b>RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER</b>	REVISED DATE:

### **Responsibilities and Authority of the Radiation Safety Officer**

It is the responsibility of the Radiation Safety Officer to ensure the policies and procedures are followed by all of those at the Center whose work involves the use of radioactive material and/or ionizing radiation. The Radiation Safety Officer is available for consultation to all persons using ionizing radiation. The Radiation Safety Officer will supervise decontamination procedures and advise investigators of the necessity for decontamination in an area.

In brief, the duties of the Radiation Safety Officer include:

1. S/he shall be directly responsible to the Director of the PET Department on matters pertaining to radiation safety.
2. S/he will approve all procedures that could involve radiation exposure and changes in such procedures; except irradiation of a patient for medical diagnosis or therapy.
3. S/he will act in a supervisory capacity in all aspects of the Center's radiation measurement and protection activities, including personnel monitoring, maintenance of exposure records, survey methods, waste disposal, and radiological safety practices.
4. S/he will consult with any potential radiation user and advise her/him on radiological safety procedures.
5. S/he will suspend any operation causing an excessive radiation hazard as rapidly and safely as possible. S/he will maintain

	<b>PET</b>	No: <b>F-15</b>
	<b>CATEGORY:</b> <b>Radiation Safety</b>	<b>EFFECTIVE DATE:</b> <b>March 1, 2007</b>
<b>RESPONSIBLE PARTY:</b>	<b>SUBJECT:</b> <b>RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER</b>	<b>REVISED DATE:</b>

radiation exposures within the PET Department as low as reasonably achievable.

6. S/he will be responsible for keeping all Medical Physics records for the center.
7. S/he will schedule all routine Medical Physics measurements and surveys.
8. S/he will maintain and update the Radiation Safety Manual.
9. S/he will verify document of dose to patient per procedure.

	<b>PET</b>	No: F-16
	CATEGORY: <b>Radiation Safety</b>	EFFECTIVE DATE: <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT: <b>RADIATION SAFETY AUDIT PROGRAM</b>	REVISED DATE:

### **Radiation Safety Audit Program**

Radiation safety is the responsibility Radiation Safety Officer. The following procedures are normally conducted by the RSO. The RSO, at his/her discretion, may delegate the quarterly and semi-annual tasks to a contract-employed medical physicist:

1. Monthly, the RSO should ensure:
  - a. Adherence to Operating and Safety Procedures.
  - b. Completeness of daily survey, dose calibrator constancy records.
  - c. Personnel monitoring results are within established thresholds.
2. Quarterly, the RSO or his delegate should ensure:
  - a. Completeness of weekly survey records. Evaluation for trends.
  - b. Completeness of package receipt, monitoring and daily utilization records.
  - c. Evaluation of dose calibrator linearity, well counter sensitivity.
  - d. Adherence to approved waste disposal methods and completeness of records.
  - e. Up-to-date sealed source inventory (make, model, activity).
3. Bi-Annually, the RSO or his delegate should perform:
  - a. Sealed source leak testing.
4. Annually, the RSO should review:
  - a. Survey meter calibration.

 <b>US Oncology</b>	<b>PET</b>	No: F-16
	<b>CATEGORY:</b> <b>Radiation Safety</b>	<b>EFFECTIVE DATE:</b> <b>March 1, 2007</b>
<b>RESPONSIBLE PARTY:</b>	<b>SUBJECT:</b> <b>RADIATION SAFETY AUDIT PROGRAM</b>	<b>REVISED DATE:</b>

- b. Quarterly audit results and agency inspections.
- c. Radiation safety events, abnormal occurrences, medical events. Evaluate for trends.
- d. Appropriateness of documented radiation protection program.

	<b>PET</b>	No: F-17
	CATEGORY:  <b>Radiation Safety</b>	EFFECTIVE DATE:  <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT:  <b>MEMBER OF PUBLIC EXPOSURE SURVEY</b>	REVISED DATE:  <b>August 31, 2007</b>

### Member of Public Exposure Survey

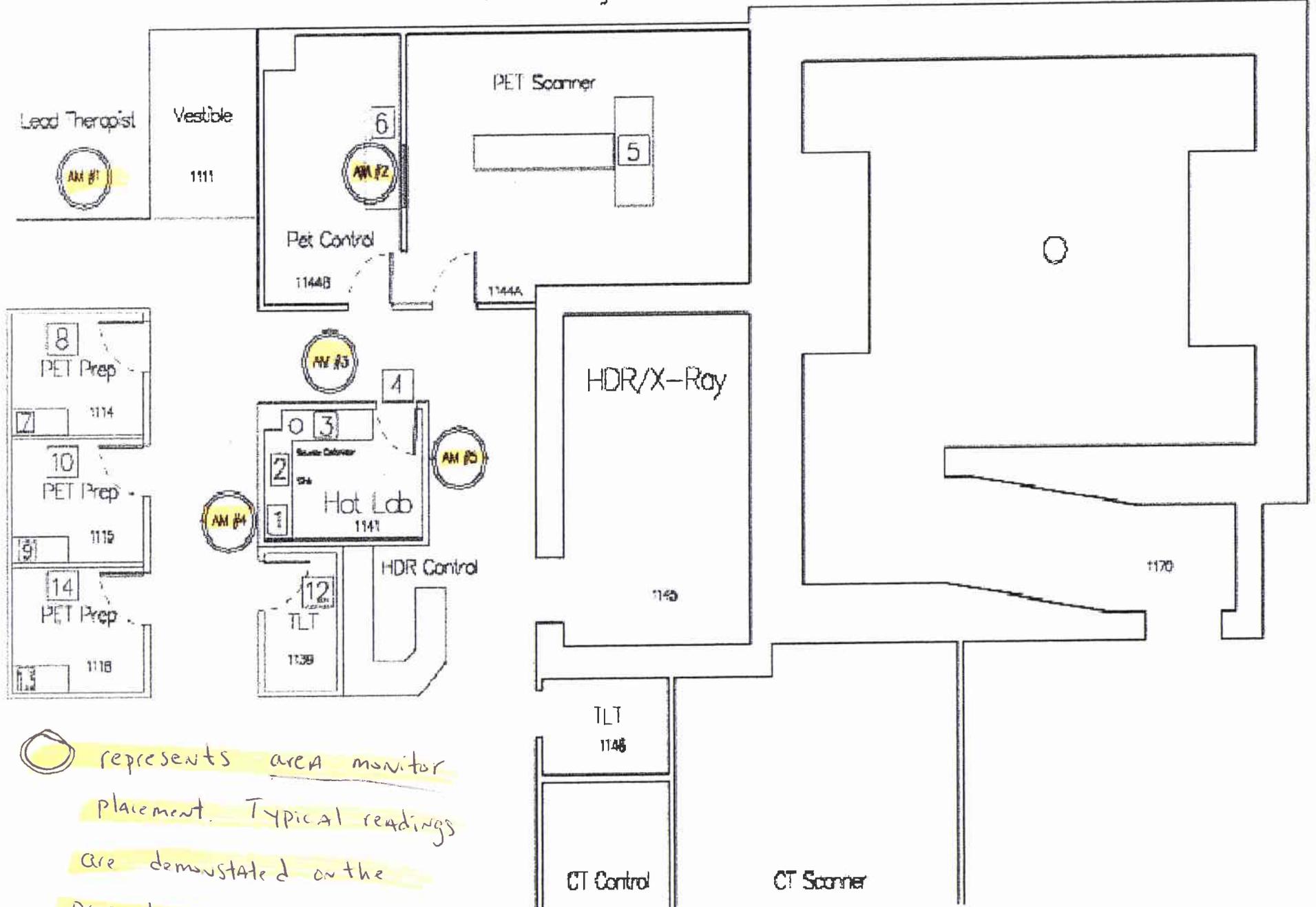
**Overview:** A radiation survey was performed to verify that the areas near and adjacent to the PET suite are safe for members of the general public and radiation workers. Area monitors were placed in five (5) locations, as of September 20, 2007, and will be monitored bimonthly to verify that the design and construction of the facility is adequate. The locations where the area monitors measured annual exposures will be reviewed by the physicist.

**Regulatory Requirements:** 10 CFR 20 requires that operations be conducted so that the total effective dose equivalent to individuals of the general public not exceed 0.1-rem (1 mSv) in one year or receive more than 2 mrem (0.02 mSv) in any one hour. This survey was performed to monitor the areas under actual use conditions. Regulatory compliance was verified.

**Methods and Materials:** Survey readings will be converted to estimate annual exposure (full occupancy) by calculating the average daily workload for injection rooms and scanner room from the number of patients handled in each area during a 250-day work year. Once the total of 250 days of scans is achieved, the survey readings will be converted to estimated annual exposure. The uptake procedure in the injection room lasts 45 minutes, meaning one injection room averages 3.7 patients/day, and is occupied 3.0 hours/day. The scanning procedure lasts 53 minutes, so the scanner currently handles an average 3.7 of patients/day, and is occupied an average 4 hours/day.

**Units:** The units used were millirems. One hundred millirems is equal to one millisievert.

External Building



○ represents area monitor placement. Typical readings are demonstrated on the preceding pages

WJ 11/9/29

	<b>PET</b>	No: F-17
	CATEGORY: <b>Radiation Safety</b>	EFFECTIVE DATE: <b>March 1, 2007</b>
RESPONSIBLE PARTY:	SUBJECT: <b>MEMBER OF PUBLIC EXPOSURE SURVEY</b>	REVISED DATE:

**Member of Public Exposure Survey, Cont.**

**Results:** Five (5) areas were monitored in the survey. All comply with MOP limits. There are no areas where exposure to any individual member of the public would receive more than 2 mrem/hour or 100 mrem/year. The results of these surveys are kept on file at Missouri Cancer Associates.

**Comments:** The regulatory limit of 100 millirems (1 mSv) per year for members of the general public applies to areas occupied full time by the same individual for all procedures, that is, an occupancy of 100%. Occupancy factors are used from NCRP-49.

These occupancy factors significantly overestimate the occupancy by any single individual, so any significant increase in patient volume (e.g. 2-fold) would still not impact the safety of these areas.

**Conclusion:** All exposure values corrected for occupancy are below the instantaneous and annual regulatory limits of 2 mrem/hr and 100 mrem/year. The radiation exposure from this facility does not constitute a hazard to the general public or to its radiation workers.

This survey was reviewed by Smerou

Reviewed on: 12-19-07

Monitoring period: Sept. 20, 2007 through November 19, 2007

MISSOURI CANCER ASSOCS  
 ATTN WILLIS BRUMLEY  
 SUITE 100  
 105 KEEN ST  
 COLUMBIA MO 65201

# LANDAUER®

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 Glenwood, Illinois 60425-1586  
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## RADIATION DOSIMETRY REPORT

ACCOUNT NO. 155323	SERIES CODE COL	ANALYTICAL WORK ORDER 0734050057	REPORT DATE 12/12/07	DOSIMETER RECEIVED 12/06/07	REPORT TIME IN WORK DAYS 4	PAGE NO. 2
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PARTICIPANT NUMBER	NAME			DOSIMETER	USE	RADIATION QUALITY	DOSE EQUIVALENT (MREM) FOR PERIODS SHOWN BELOW			YEAR TO DATE DOSE EQUIVALENT (MREM)			LIFETIME DOSE EQUIVALENT (MREM)			RECORDS FOR YEAR	INCEPTION DATE (MM/YY)
	ID NUMBER	BIRTH DATE	SEX				DEEP DDE	EYE LDE	SHALLOW SDE	DEEP DDE	EYE LDE	SHALLOW SDE	DEEP DDE	EYE LDE	SHALLOW SDE		
FOR MONITORING PERIOD:							09/20/07 - 11/19/07			2007							
00046	[REDACTED]	[REDACTED]	[REDACTED]	Pa	WHBODY	P	M	M	1	11	16	31	100	118	167	5	05/03
00053	[REDACTED]	[REDACTED]	[REDACTED]	Pa U	WHBODY RFINGR		M	M	M	43	43	41	53	54	53	4	09/04
00057	[REDACTED]	[REDACTED]	[REDACTED]	Pa U	WHBODY RFINGR		M	M	M	M	M	M	11	16	32	5	07/05
00059	[REDACTED]	[REDACTED]	[REDACTED]	Pa F	CHEST ASSIGN		M	M	M	M	M	M	94	M	106	10	11/05
00061	[REDACTED]	[REDACTED]	[REDACTED]	Pa	WHBODY	P	13	18	20	82	107	124	126	161	182	5	05/06
00062	[REDACTED]	[REDACTED]	[REDACTED]	Pa	WHBODY		M	M	M	36	36	41	36	39	50	5	07/06
00063	[REDACTED]	[REDACTED]	[REDACTED]	Pa	WHBODY	P	1	1	3	10	11	16	79	81	90	5	07/06
00066	[REDACTED]	[REDACTED]	[REDACTED]	Pa	WHBODY		M	M	M	15	16	18	104	105	103	5	07/06
00067	[REDACTED]	[REDACTED]	[REDACTED]	Pa	WHBODY		M	M	M	2	3	8	2	3	8	5	09/06
00072	[REDACTED]	[REDACTED]	[REDACTED]	Pa U	WHBODY RFINGR	PH	168	177	211	844	856	899	1073	1085	1128	5	11/06
00077	AREA 1	[REDACTED]	[REDACTED]	Pa	AREA	P	21	21	22	40	40	40	40	40	40	3	05/07
00078	AREA 2	[REDACTED]	[REDACTED]	Pa	AREA		M	M	M	4	5	7	4	5	7	3	05/07

M: MINIMAL REPORTING SERVICE OF 1 MREM

*Room 1144*

QUALITY CONTROL RELEASE: DRB

1 - PR 8893 - RPT1318- N1

- 42605



*Guilford Guilford 12-19-07*  
 NVLAP®

NVLAP LAB CODE 100518-0\*\*

OURI-CANCER ASSOCS  
 ATTN WILLIS BRUMLEY  
 SUITE 100  
 105 KEEN ST  
 COLUMBIA MO 65201

# LANLAUER®

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## RADIATION DOSIMETRY REPORT

ACCOUNT NO. 155323	SERIES CODE COL	ANALYTICAL WORK ORDER 0734050057	REPORT DATE 12/12/07	DOSIMETER RECEIVED 12/06/07	REPORT TIME IN WORK DAYS 4	PAGE NO. 3
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\*\* LAST PAGE \*\*

PARTICIPANT NUMBER	NAME			DOSIMETER	USE	RADIATION QUALITY	DOSE EQUIVALENT (MREM) FOR PERIODS SHOWN BELOW			YEAR TO DATE DOSE EQUIVALENT (MREM)			LIFETIME DOSE EQUIVALENT (MREM)			RECORDS FOR YEAR	INCEPTION DATE (MM/YY)
	ID NUMBER	BIRTH DATE	SEX				DEEP DDE	EYE LDE	SHALLOW SDE	DEEP DDE	EYE LDE	SHALLOW SDE	DEEP DDE	EYE LDE	SHALLOW SDE		
FOR MONITORING PERIOD:							09/20/07 - 11/19/07			2007							
00079	AREA 3	<i>N wall not 100</i>		Pa	AREA	P	34	34	34	48	48	51	48	48	51	3	05/07
00080	AREA 4	<i>10</i>		Pa	AREA	P	25	25	25	35	35	35	35	35	35	3	05/07
00081	AREA 5	<i>E " " "</i>		Pa	AREA	P	23	23	22	138	138	134	138	138	134	3	05/07
00082	AREA 6	<i>N wall not 100</i>		Pa	AREA	P	M	M	M	13	13	12	13	13	12	3	05/07
				Pa	WHBODY		M	M	M	40	42	42	40	42	42	3	05/07
				Pa	WHBODY	P	3	3	3	31	31	31	31	31	31	3	05/07
				M	U	REINGR			M			M			M	3	05/07

M: MINIMAL REPORTING SERVICE OF 1 MREM

QUALITY CONTROL RELEASE: DRB

1 - PR 8893 - RPT1318- N1

- 42605

*Imcroud  
12/19/07*



NVLAP LAB CODE 100518-0\*\*

	<b>PET</b>	No: F-18
	<b>CATEGORY:</b> <b>Radiation Safety</b>	<b>EFFECTIVE DATE:</b> <b>March 1, 2007</b>
<b>RESPONSIBLE PARTY:</b>	<b>SUBJECT:</b> <b>HANDLING AND RELEASE OF RADIOACTIVE PATIENTS</b>	<b>REVISED DATE:</b>

### **Handling and Release of Radioactive Patients**

In order to minimize radiation exposure to the public, it is the policy of Missouri Cancer Associates to retain each patient at least thirty minutes after radiopharmaceutical injection and have the patient void prior to scanning or departure if scanner is inoperable.

This policy will be followed in cases of the PET scanner becoming inoperable after patients have been injected.

This policy does not apply to patients who must be transported urgently (e.g., to a physician's office or the Emergency Room) for clinical management.

Missouri Cancer Associates  
Suite 100, Plaza 4  
1705 East Broadway  
Columbia MO 65201

## **Pet Quality Control and Safety Program Audit**

### **A) Summary**

The Quality Control (QC) and safety program of the Missouri Cancer Associates for PET imaging was audited and reviewed. The registration number of the facility was 700, which was issued on March 7<sup>th</sup>, 2006. The Radiation Safety Officer for this facility is Willis Brumley MS.

### **B) Authorized Materials**

<b>Isotope</b>	<b>Activity Limit</b>	<b>Physical Form</b>	<b>RAM Usage</b>	<b>Normal Dose</b>
<sup>18</sup> F Fluorine 18	1 Ci	Liquid Glucose	Diagnostic PET Imaging	15mCi
<sup>18</sup> F Fluorine 18	100mCi	Liquid, Sodium Fluoride	Calibration	NA
<sup>68</sup> Ge Germanium 68	100mCi total	Sealed Source	Calibration, Transmission Scanning	NA
<sup>22</sup> Na Sodium 22	1mCi	Sealed Source	Calibration	NA

### **C) Missouri State Regulations**

The regulations for the state of Missouri concerning radioactive materials are available to all workers.

### **D) Federal NRC Documentation**

The most recent (5-2005) NRC Form 3 is posted in the hot lab (Room 1141)

### **E) Signs and Labels**

The Magenta on yellow signs are present.

A sign reading "Caution Radioactive Materials" is posted on the PET scanner door, and on the door of the hot lab.

### **F) Radiation Safety Polices and Procedures**

The Policy and Procedure Manual was last updated march 1<sup>st</sup>, 2007. These were reviewed and found to be adequate.

**G) Records of Previous Inspections**

Currently Radioactive materials for PET are licensed by the State of Missouri. No State inspection has been carried out.

**H) Disposal of Radioactive Waste**

Records of the receipt use and disposal of radioactive material are kept in the Hot Lab Room 1141. These are in good order.

**I) Inventory of Radioactive Material and leak Tests**

The inventory of materials present at the MCA facility are displayed in table I.1

Source Inventory							
Source	Activity	Calibration	Maker	Serial #	Form	Location	Leakage
<sup>137</sup> Cs	0.5µCi	05/01/2004	IPL ✓	1034-15-52	Rod	Hot Lab	Pass
<sup>22</sup> Na	226.4µCi	05/15/2004	IPL ✓	1004-89-1	Evia	Hot lab	Pass
<sup>22</sup> Na	0.187 mCi	10/3/2007	Benchmark ✓	BM 06322-04-2	Reference	HotLab	Pass
<sup>68</sup> Ge/Ga	3.2mCi	07/20/2007	Sanders Med ✓	9089	Phantom	Scanner	Pass
<sup>68</sup> Ge/Ga	3.3mCi	07/20/2007	Sanders Med ✓	9082	Line	Scanner	Pass
<sup>68</sup> Ge/Ga	3.3mCi	07/20/2007	Sanders Med ✓	9083	Line	Scanner	Pass
<sup>68</sup> Ge/Ga	3.3mCi	07/2/2007	Sanders Med ✓	9084	Line	Scanner	Pass
<sup>68</sup> Ge/Ga	3.0mCi	06/01/2006	CTI ✓	D4-305	Phantom	Scanner	Pass
<sup>68</sup> Ge/Ga	3.279mCi	06/01/2006	IPL ✓	1114-82-1	Phantom	Scanner	Pass
<sup>68</sup> Ge/Ga	0.3971µCi	06/01/2006	IPL ✓	1114-82-3	Reference	Hot Lab	Pass

**Table I.1 Inventory of PET isotopes present during the Audit**

The inspected materials were all accounted for. All inspected wipe counts were equal to the background, and below the established limits. The most recent inventory leakage tests were conducted on 5-8-08.

**J) Personnel Radiation Monitoring Records**

Personal monitoring is maintained using badges from Landauer, Landauer, 2 Science Road, Gustav, Illinois 60425. All results were reviewed and found to be acceptable.

**K) Authorized Users**

Records of the authorized users of radioactive material, credentials and training are on record at the Missouri Cancer Associates offices. The Latest amendment of the NRC license is kept by the HDR machine treatment console.

**L) PET Operating Technologist Training and Credentials**

The PET Technologist is Donna Severson. Relevant credentials are on record at the Human resource office at the Missouri Cancer Associates offices.

**M) Continuing Education and Maintenance of Certification**

Adequate continuing education reports are on file.

**N) Survey Instruments**

The standard PET survey meter is a Ludlum 14C, Serial Number 204379 with a GM Pancake probe Serial Number 212150. The meter was functional and last calibrated on 2-11-08.

In addition there is another Ludlum 14C meter, and a Victoreen 450p, both within calibration as backup measuring devices.

**O) Radiation Survey**

Using the Ludlum 14C meter Serial Number 204379, and the Victoreen 450p Serial Number 3740, a survey of the PET area was carried out to ensure that the radiation dose was below the 0.2mR/hr limit.

**P) Dose Calibrator Quality Assurance**

The Dose Calibrator used for this PET Center is a Capintec Model CRC-15W, Serial Number 170924.

The annual accuracy and geometry tests were carried out on: 8-9-2007

The Well Counter calibration was carried out on: 8-9-2007

The last linearity test was done on: 5-6-2008

**Q) PET Imaging Quality Assurance**

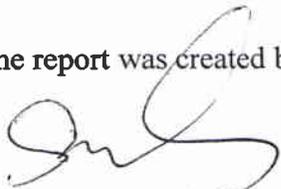
The PET imaging system is a SIEMENS PET model number ECAT EXACT 47, serial number 088-001046. The computer is running on software version V7.2.2. The ACR PET

Phantom Quality assurance was completed on: ACR Accreditation of the unit was obtained on: June 17<sup>th</sup> 2008

**R) PET Preventative Maintenance**

Preventative maintenance is conducted by marquis Medical.

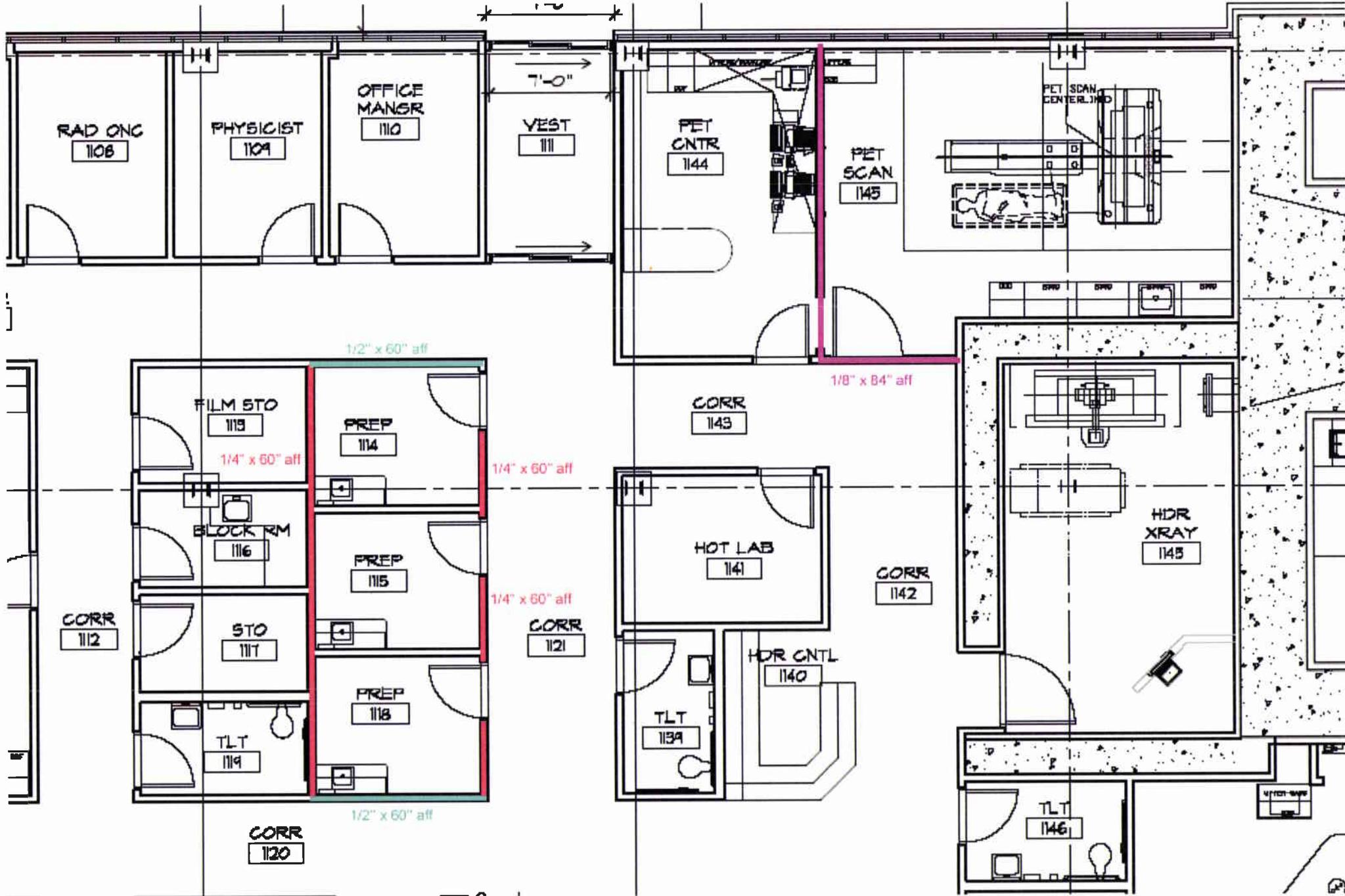
The report was created by:



7-14-08

Steven Crooks PhD DABR

OUTSIDE



Facility diagram and shielding.

ATTN: Kim Kite - 2 pages



# Missouri Radiation Control Program



## Registration of Radiology Services

PO Box 570 1617 Southridge Jefferson City MO 65102

Phone: 573 / 751-6083 Fax: 573 / 751-6158

MRCP Registration Number: 700

Radiology Service Type: CLINIC

Facility Name: MISSOURI CANCER ASSOCIATES

Address 1705 EAST BROADWAY  
COLUMBIA MO 65201

County BOONE

Phone: (573) 442-5525 FAX: (573) 442-2124

Parent Facility: U S Oncology, 712 N Washington Ste 101, Dallas TX 75246

Authorized Users: RADIOLOGY / RAD ONCOLOGY / NUCLEAR MED Kimberly Kite, RT, Chief Therapist

Facility Last Registration Date of Most Recent Registered X-ray  
Registered: 05/30/2007 Expires: 05/30/2009 On Site inspection: 05/16/2001 Machines Listed Below

Machine Usage	Location	Manufacturer	MODEL	Serial Number	Tubes
CT	Rm R1148	General Elec	Lightspeed RT	108780HM8	1
HDR Therapy	Rad R1145	Nucletron	Nucletron V2	105.002	0
Linear Accelerator	Rm R1170	Varian	IX	3615	0
Linear Accelerator	Rm ?	Varian	Clinac IX Radiothera	3615	0
PET/CT	Rm R1144A	CTI	LS-Exact	4629	1
Rad Therapy/Fixed	CT SIM	General Elcc	2377708-43	374577CNS	1
Radiographic/Fixed	Rm R1145	General Elec	Silhouette VR	573817USO Rad	1

Machine Usage	Location	Manufacturer	MODEL	Serial Number	Tubes
---------------	----------	--------------	-------	---------------	-------

Summary for 'REGIST\_NO' = 700 (7 X-ray machines registered)

4

**X-ray Operators for Facility # 700**

Name of Operator	% of all facility X-rays performed by this person	TYPE OF TRAINING "DR"-Licensed doctor, "RT"-Registered X-ray Tech, "CD"-Certified Dental Assistant or Hygienist, "NT"-On-The-Job Training	Years of Experience
Mark Gehlert, RT	48	RT	13
Patricia Stingley, RT	1	RT	9
Kimberly Kite, RT	1	RT	13
Sonja Crozier, RT	1	RT	22
Keith Hickey, Physicist			
Joe Love, Physicist			
Steven Crooks, Physicist			
Willia Brumley, CMD, Physicist			17
Donna Severson, RT		RT	20
Mark Collins, RT		RT	20
Ernie Chapman, RT		RT	30
Paula Diglins, RT		RT	20
David Moe, RT		RT	12
Laura Neal, RT		RT	14

**Workload, Film and Equipment Service Information for Facility # 700**

Avg Xrays/Month	Patients X-rayed/Month	Avg Xrays/Pt	Most Common Exam	% of All Exams	2nd most common exam	Exam2 %
400			CT	75	General X-ray	25
Processing Methods	Processor Brand/Model	Film Brand Type	Cassette Screen Type	Dosimeters/badges, etc?		
Auto Processing Only	Konica Minolta TSY-212	Kodak ECL, TMG-RA, T	X-Omatic 400	Film Badges		
X-ray Machine Maintn.	X-ray Service Company	Processor Maintenance	Processor Service Comp.	Medical Physicist (if any)		
Formal Maintenance Sc	GE, Varian, MES. Nucler	Formal Maintenance Sc	Source One	Steven Crooks		



**Official Use Only – Security-Related Information**

NRC FORM 374

PAGE 1 OF 5 PAGES  
Amendment No. 76

U.S. NUCLEAR REGULATORY COMMISSION

**MATERIALS LICENSE**

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p align="center">Licensee</p> <p>1. Boone Hospital Center     2. 1600 East Broadway   Columbia, MO 65201</p>	<p>In accordance with the letter dated May 1, 2008,   3. License number 24-01565-01 is amended in its entirety to read as follows:   4. Expiration date April 30, 2015   5. Docket No. 030-02304   Reference No.  </p>
---	--

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As needed
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As needed
C. Any byproduct material permitted by 10 CFR 35.300	C. Any	C. As needed (not to exceed 1 curie of iodine-131)
D. Any byproduct material permitted by 10 CFR 35.400	D. Sealed sources (Oncurs (Medi-Physics) Model No. 6711, Theragenics Model No. 200, Best Industries Model No. 81-01 Series, Bard Model STM-1251, 3M Model No. 6500 Series, Tracer Lab, Model No. RA-1)	D. 4560 millicuries
E. Cesium-137 permitted by 10 CFR 35.400	E. Sealed sources (Nuclear Associates, Model Nos. 67-800 and 67-601)	E. 484 millicuries for Model No. 67-800 and 258 millicuries for Model No. 67-601)
F. Cesium-137	F. Sealed source (Tech. Ops. Model No. 77032)	F. 165 millicuries
G. Any byproduct material permitted by 10 CFR 31.11	H. Prepackaged kit	H. 50 millicuries
H. Depleted uranium	I. Metal	I. 999 kilograms

**Official Use Only – Security-Related Information**

Official Use Only – Security-Related Information

NRC FORM 374A

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**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number

24-01565-01

Docket or Reference Number

030-02304

Amendment No. 76

9. Authorized use:

- A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.
- B. Any imaging and localization study permitted by 10 CFR 35.200.
- C. Any diagnostic study or therapy procedure permitted by 10 CFR 35.300.
- D. Any manual brachytherapy procedure permitted by 10 CFR 35.400.
- E. and F. For storage only incident to disposal.
- G. In vitro studies.
- H. For use as shielding material.

CONDITIONS

- 10. Licensed material may be used at the licensee's facilities located at Boone Hospital Center, 1600 East Broadway, Columbia, Missouri.
- 11. Radiation Safety Officer for this license is Liesje Myers, CNMT.
- 12. Licensed material is only authorized for use by, or under the supervision of:
  - A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
  - B. The following individuals are authorized users for medical use as indicated:

Authorized Users

Material and Use

John Baird, M.D.

10 CFR 35.100, 35.200, iodine-131 diagnostic procedures permitted by 35.300 and 31.11.

Vijay Sachu, M.D.

10 CFR 35.100, 35.200, iodine-131 diagnostic procedures permitted by and 31.11.

Barbara Tellerman, M.D.

10 CFR 35.100, 35.200, iodine-131 diagnostic procedures permitted by and 31.11.

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Charles M. Swaney, M.D.

10 CFR 35.100, 35.200, 31.11, and Iodine-131 for diagnostic procedures and the treatment of hyperthyroidism permitted by 35.300.

Mark Bryer, M.D.

10 CFR 35.300 and 35.400.

Steven Westgate, M.D.

10 CFR 35.300 and 35.400.

Joseph M. Bean, M.D.

10 CFR 35.300 and 35.400.

Terry J. Elwing, M.D.

10 CFR 35.100, 35.200, Iodine-131 diagnostic procedures permitted by 35.300 and 31.11.

Laura J. Sievert, M.D.

10 CFR 35.100, 35.200, Iodine-131 diagnostic procedures and for treatment of hyperthyroidism permitted by 35.300 and 31.11.

James Allen, M.D.

10 CFR 35.300 and 35.400.

Maxwell Lazinger, M.D.

10 CFR 35.100, 35.200, Iodine-131 diagnostic procedures permitted by 35.300 and 31.11.

David Perry Brummett, M.D.

10 CFR 35.100, 35.200, Iodine-131 for diagnostic procedures and the treatment of hyperthyroidism permitted by 35.300 and 31.11.

William E. Decker, M.D.

10 CFR 35.300 and 35.400.

Hun Tai Lee, M.D.

10 CFR 35.100, 35.200, Iodine-131 diagnostic procedures permitted by 35.300 and 31.11.

14.

For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:

- A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State.
- B. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.

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- C. Sealed sources need not be tested if they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material.
- D. Sealed sources need not be tested if they are in storage and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- E. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.
- F. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
- G. Records of leak test results shall be kept in units of microcuries and shall be maintained for 3 years.
15. The licensee shall conduct a physical inventory every 3 months to account for all sources and/or devices received and possessed pursuant to 10 CFR 35.59, 10 CFR 35.400 and every 6 months for all other sources and/or devices. Records of inventories shall be maintained for 5 years from the date of each inventory, and shall include the information required in 10 CFR 35.59(g).
16. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee.
17. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.
18. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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19. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated March 8, 2005;
- B. Letters dated September 10, 1990, October 18, 2006, November 14, 2006, January 15, 2007, August 1, 2007 and October 3, 2007 ;
- C. Facsimile dated April 20, 2005, transmitting letter dated October 29, 2004; and,
- D. Facsimile letter dated April 2, 2007, October 29, 2007 and November 6, 2007.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date AUG 04 2008

By Colleen Carol Casey  
Colleen Carol Casey  
Materials Licensing Branch  
Region III

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 Missouri Cancer Associates  
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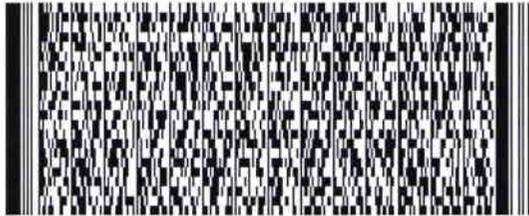


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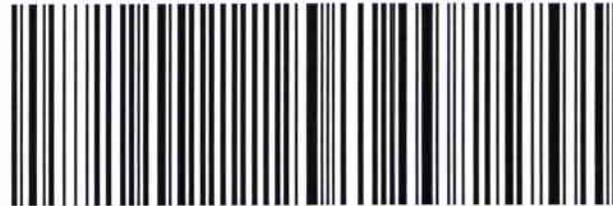
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