APPENDIX I

DEPARTMENTAL QUALITY ASSURANCE PROCEDURES

NUCLEAR MEDICINE DEPARTMENT

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POLICY FOR ADMINISTRATION OF THERAPEUTIC DOSES OF RADIOPHARMACEUTICALS AND DIAGNOSTIC DOSES GREATER THAN 30 MICROCURIES

1. An authorized user must sign and date a written directive for any therapy procedure prior to administration of a radiopharmaceutical. This shall include diagnostic doses of quantities greater than 30 $\frac{\text{Ci}}{}$ of either sodium iodide, I-125, I-131, P-32 and Sr-89. Only in certain circumstances is there any revisions or oral directives permitted. Those are as follows:

If, because of the patient’s medical condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient’s health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient’s record and revised immediately in the patient’s record and revised written directive is dated and signed by the authorized user within 48 hours of the oral revision.

Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage.

If, because of the emergent nature of the patient’s medical condition, a delay in order to provide a written directive would jeopardize the patient’s health, an oral directive will be acceptable, documented immediately in the patient’s record and a written directive is prepared within 24 hours of the oral directive.

2. Before administering a radiopharmaceutical dosage, the licensed user or designee will verify by more than one method the identity of the patient as the individual named in the written directive. The procedure used to identify the patient will be to ask the patient’s name corresponding information in the patient’s record: birthdate, address, social security number, signature, the name on the patient’s ID bracelet or hospital ID card, or the name on the patient’s medical insurance card.

3. The licensed user or designee will verify, before administering the byproduct material, that the specific details of the administration are in accordance with the written directive. The radiopharmaceutical, dosage, and route of administration will be confirmed by the person administering the radiopharmaceutical to verify by agreement with the written directive, that is, the dosage will be measured in the dose calibrator and the results compared with the prescribed dosage in the written directive.

4. The licensed user will encourage all workers to seek guidance if they do not understand how to try out the written directive. That is, workers will ask if they have any questions about what to do or how it should be done rather than continuing a procedure when there is any doubt.
I-131 THERAPY PROCEDURE
FOR IN-HOUSE PATIENTS

Indication: For treatment of residual functioning thyroid cancer. Ablation of thyroid tissue post thyroidectomy.

Patient preparation: The patient must not have taken any thyroid medication for 3 weeks prior to dosing. The patient must not have had any iodinated contrast for at least 6 weeks prior to dosing. Fill out a thyroid questionnaire prior to dosing (this should be done in the nuclear medicine department during workup). An I131 total body scan shall be performed prior to scheduling the therapy and approval through the Nuclear Medicine physician.

1. Obtain approval for scheduling through the Nuclear Medicine physician.
2. Notify Radiation Safety of patient's therapy, patient's name, room and amount of radiation will be required.
3. Verify results of whole body scan to be sure patient will be treated with the Nuclear Physician to assess proper dosage needs.
4. Once dose is determined, notify the nuclear pharmacy of the patient name and date scheduled.

A. Room Preparation:

1. Verify room availability and suitability with bed control. Corner room or room with stairwell adjacent on the side and a vacant patient room on the other is most desirable. (10E has two dedicated rooms for therapy)
2. Radiation Safety will wrap the room prior to patient arrival (if possible):
   a. plastic gloves
   b. heavy mil plastic
   c. wide tape
   d. large heavy mil bags for storage
   e. large absorbent pads
   f. 2 dedicated trash cans

Cover floor and lower walls of bedroom and bathroom completely with plastic. Heavy traffic areas should then be covered with large absorbent pads and taped securely for patient safety. Use large absorbent pads and plastic tape in the bathroom. Cover toilet seat with absorbent pads. Cover all light switches and door handles with gloves and tape them in place. Cover telephone with gloves also. Cover the mattress with heavy plastic or plastic mattress cover. Cover the night stand, chair, food tray and writing stand with plastic. Table tops and sink shelf will be covered with plastic or chucks. Side rail of bed should be covered. Line the trash cans with heavy mil plastic bags and assure proper labeling. Label one for trash, the other for linen. Both should have a radioactive sticker.

3. After the room has been wrapped, a thorough inspection by Radiation Safety will be performed.
4. After approval for use, the patient can then be brought into the room. All the patient’s belongings and street clothes must be bagged and retained for the patient’s discharge. The patient may keep in the room for use any disposable materials they wish (e.g., toothbrush, magazines, personal soaps).

B. **Dosing:**

Notify Nuclear Medicine that patient may be dosed.

1. Nuclear Medicine Physician and Radiation Safety representative will be present at dosing. The nuclear medicine Physician will obtain consent prior to dosing.

2. Radiation safety will educate axillary staff, make sure the room is correctly posted, and the appropriate forms and charts are located in the patient’s medical records jacket.

3. Refer to the Quality Management policy and procedures for documenting the dose, administration, identification and documentation records (see attached). A written directive must accompany the patient’s records.

[Fill out check list for dosing therapy patients (refer to policy on administration of Therapeutic doses)]

C. **Monitoring of Patient:**

1. An authorized Radiation Safety personnel will monitor the patient daily with the Cutie Pie (ionization chamber) immediately after dosing and again once each day. A note will be made daily on the patient’s chart in the progress notes. Once the radiation level is less than 2 mR at 3 feet from the patient, (total body burden <30 mCi) he/she can then be discharged with no precautions. Care should be taken to be consistent when monitoring the patient.

2. All physicians and Radiation Safety personnel present at dosing or monitoring of patients are required to have their necks counted in Nuclear Medicine within 48 hours of dosing and recorded in the neck count book for review by radiation safety.

D. **Clean-Up of Room:**

Equipment Required:

- gloves
- foot covers
- paper towels
- G-M tubes
- Radiac Wash
- scissors

Once patient has been discharged, he/she will leave the room and not return at all. Clean-up of the room can begin. Radiation Safety personnel will perform the clean-up of the room.

Double gloving and foot covers are worn at all times in the room, and must be removed in order to leave the room (to hallway, etc.):
1. Place any linen, food items or paper items into the appropriate trash cans. Remove all plastic from light switches, telephone, etc. and obtain G-M readings from these areas. Consider all areas contaminated until monitored and wiped. All contaminated areas are to be scrubbed with Radian Wash in towels until they are at background readings or until it is determined that radiation is fixed, i.e., it cannot be removed. Once all wrap is removed, the floor cover can be taken up, folded in on itself and bagged. This often requires another large clear bag and is most often contaminated. Secure it and survey for contamination with a G-M survey meter. Any items above BKG are put into trash cans and removed from the room and stored for decay.

2. With the radiation sources out of the room, more accurate survey readings may be obtained. All areas of the room should be closely checked and surveyed. Any areas above background must be decontaminated. (Areas routinely above acceptable limits are the toilet and the sink.) The goose neck of the sink and drainpipe is considered fixed and is the only area (unless patient bath has a shower with a similar drain) which can remain above the background without attention of the Radiation Safety Officer. Should the toilet seat remain over the limits it shall be removed and replaced by physical plant personnel and then retained for decay.

3. Once G-M ratings are low as reasonably achievable, the Radiation Safety personnel shall take wipe tests of representative areas of the room:

   Label test tubes accordingly: a, b, c,...
   a. Floor of patient room
   b. Floor of bathroom
   c. Top of sink
   d. Side rail of bed
   e. Telephone, if it remains
   f. Toilet seat, if it remains
   g. Wall next to patient bed
   h. Door handle
   i. Television set, if present

   After wipes are performed, they are counted on I-131 window in the well counter.

   Wipe tests are read in well counter at one minute per wipe at proper settings. All wipes shall be less than 100 dpm. Any areas above 100 dpms will require additional decontamination until the wipe is below the trigger level. Once all criteria is met, the Radiation Safety Office will release the room to bed control.

4. Next, the radioactive waste is to be taken to the holding area designated by radiation safety and be transferred to dedicated barrels for decay.
Release of Patients Containing Radiopharmaceuticals or Permanent Implants

The licensee may release any individual who has been administered radiopharmaceuticals or permanent radioactive implants from his/her control if:

a. The total effective dose equivalent to any other individual is not likely to exceed 500 mRem (5 mSv).

b. The total effective dose equivalent to a minor, pregnant female, or a potentially pregnant female is not likely to exceed 100 mRem (1 mSv).

Records of Release

For patients released according to RHA 3.1, column 1 of Table 1, there is no recordkeeping requirement. However, if any other individual is likely to exceed 100 mRem (1 mSv), the license shall provide the released individual with written instructions to ensure compliance with RHA 4.8.12.1. The release records shall include the patient identifier, the radioactive material, activity and date administered.

These records shall be maintained by the licensee for 3 years from the date of release (Example on pages 166-168). If the patient was released based on a dose calculation the following information shall also be included on the release records (Example on pages 164-165):

a. Patient-Specific Calculation (retained activity): the equation, patient-specific factors, basis used to calculate the dose and calculated dose to the person exposed to the patient. (See Regulatory Guide for Patient Release Criteria, Appendix B)

b. Measured Dose Rate (occupancy factor): results of measurement, survey instrument (manufacturer, model, and serial number), and name of individual performing survey.

c. Radioactive Decay Calculation (biological/effective half-life): time of administration, date and time of release, and results of the decay calculation.

d. Measured Dose Rate (shielding by tissue): results of measurement, survey instrument (manufacturer, model, and serial number), and name of individual performing survey.

If a breast-feeding infant or child could receive a radiation dose from no interruption of breast-feeding, the release instructions shall also include:

a. Precautions for interruption or discontinuance of breast-feeding and consequences if breast-feeding continues.

b. Patient identification, adhering to confidentiality policies, radiopharmaceutical, activity and date administered.

c. Instructions provided to patient concerning breast-feeding of an infant or child.
**INSTRUCTIONS**

1. Fill the Green cells. All the others cells will be filled automatically.

2. Select the authorized user from the list at the bottom of the page.

   Current Authorized users in the list are:
   
   - Dr. Leonie Gordon
   - Dr. Ken Spicer
   - Dr. C
   - Dr. D
   - Dr. E
   - Dr. F

3. Verify the calculation results.

4. PrintPreview the document before printing.
   
   Change the % Scaling under File/PageSetUp/Page to adjust the breaks.

5. Print the document.

6. Click "Save Patient File" at the bottom of the 1st page to save the data in the patient calculation folder.
   
   (Alternatively you may select Tools/SavePatient or hit ctrl-e.)

   Patient calculation folder is:

7. Close the file or exit the program.
   
   To continue with calculations for another patient:
   
   Click on "Clear" at the bottom of the 1st page to clear the data from the first patient.
   
   (Alternatively you may select Tools/Clear or hit ctr+h.)
   
   Proceed to step 1 above.

Warning: You will lose the patient data file if you click on "Save Patient Data" AFTER clicking on "Clear."
**INPUT**

<table>
<thead>
<tr>
<th>Patient Identifier:</th>
<th>Jane Doe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex (M / F):</td>
<td>F</td>
</tr>
<tr>
<td>Age:</td>
<td>46 yrs.</td>
</tr>
<tr>
<td>Date:</td>
<td>1/23/01</td>
</tr>
<tr>
<td>Prescribed Dosage:</td>
<td>38.58 mCi</td>
</tr>
<tr>
<td>Date of Administration:</td>
<td>1/23/01</td>
</tr>
<tr>
<td>Measured Thyroid Uptake Fraction (NA if not measured):</td>
<td>NA %</td>
</tr>
<tr>
<td>Treatment type (hyperthyroidism = H / thyroid cancer = C):</td>
<td>C</td>
</tr>
</tbody>
</table>

**Occupancy Factors**

<table>
<thead>
<tr>
<th>Distance from others</th>
<th>0 - 2 hrs after administration: 0.75</th>
<th>2 - 8 hrs after administration: 0.5</th>
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</thead>
<tbody>
<tr>
<td>8 hrs to 3 days:</td>
<td>0.5</td>
<td>100 cm</td>
</tr>
<tr>
<td>3 days to complete decay:</td>
<td>0.5</td>
<td>100 cm</td>
</tr>
</tbody>
</table>

**Distance from others**

<table>
<thead>
<tr>
<th>Distance from others</th>
<th>0 - 2 hrs after administration: 0.75</th>
<th>2 - 8 hrs after administration: 0.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 hrs to 3 days:</td>
<td>0.5</td>
<td>100 cm</td>
</tr>
<tr>
<td>3 days to complete decay:</td>
<td>0.5</td>
<td>100 cm</td>
</tr>
</tbody>
</table>

Does the patient sleep alone (Y / N): Y

**Justification:**
The patient is able to fully comply with the above occupancy factors and distances.

**CALCULATIONS**

<table>
<thead>
<tr>
<th>0 - 2 hrs</th>
<th>2 - 8 hrs</th>
<th>8 hrs - 3 d</th>
<th>3 d -decay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-uptake dose (Physical Decay):</td>
<td>10.1</td>
<td>20.0</td>
<td></td>
</tr>
<tr>
<td>Post-uptake dose (X-thyroidal):</td>
<td></td>
<td></td>
<td>43.3</td>
</tr>
<tr>
<td>Post-uptake dose (Thyroidal):</td>
<td></td>
<td></td>
<td>11.7</td>
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**Thyroid Cancer**

<table>
<thead>
<tr>
<th>Days required to sleep alone:</th>
<th>-- days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated TEDE (sleep dose after -- days included):</td>
<td>-- mrem</td>
</tr>
<tr>
<td>Estimated TEDE (without sleep dose included):</td>
<td>125.6 mrem</td>
</tr>
</tbody>
</table>

**Outpatient**

Inpatient treatment criteria: TEDE < 500 mrem (<450 mrem, allowing 10% tolerance for actual vs. prescribed dosage)

Patient may not prepare food for others. Practice safe blood and body fluid precautions. Wear gloves to minimize contamination within the house. Use a dishwasher for dishes or disposable dishes.

**COMMENTS**

Actual Dosage (if different from the prescription): 38.58 mCi

<table>
<thead>
<tr>
<th>Exposure Rate @ 1 meter:</th>
<th>mR/hr</th>
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</thead>
<tbody>
<tr>
<td>Background Exposure</td>
<td>mR/hr</td>
</tr>
<tr>
<td>Survey Instrument:</td>
<td>Victoreen 450P sn:3655</td>
</tr>
</tbody>
</table>

**Radiation Safety Officer**

Authorized User: ___________________________ Signature X
Instructions for I-131 Therapy Patients

You have been given Iodine-131 for the treatment of your thyroid condition. Most of this radioactive iodine will be in your thyroid, but smaller amounts are also present in the urine, saliva, and sweat. Federal regulations require that the radiation exposure to other people with whom you may have contact with (as an outpatient) be limited. Therefore, the following precautions should be observed for the first 3 days after treatment.

1. Do not kiss on the lips, and do not have sexual intercourse.

2. Avoid close physical contact with people, especially children and pregnant women. For your treatment, this has been determined to be no closer than 3 feet. Being in the same house with other people is not a problem if you maintain your distance from members of the household.

3. Drink plenty of liquids.

4. Keep the toilet and bathroom clean (preferably using cleaners without bleach). Flush the toilet 2 to 3 times after use.

5. Wash your hands before preparing food and after going to bathroom.

6. Do not share eating utensils or dishes.

7. We advise you and your spouse not to attempt to have any children for 1 year.

8. Nursing mothers should stop breast feeding for two months. Failure to stop breast feeding could result in potential harm to the child's thyroid.

The above precautions should be observed for 3 days.

Follow the precautions until: 1/22/01

If you have any questions, please contact Department of Radiology, Nuclear Medicine Division at (843) 792-4294, or call your doctor.

I Understand the precautions I must follow and have received a copy of the instructions.

Patient Initials: __________     date: ____________________
**Medical University of South Carolina**

**Department of Radiology, Nuclear Medicine Division**

Patient Identifier: Jane Doe  
Prescribed Dosage: 100.00 mCi  
Date of Administration: 1/19/01  
Total Estimated EDE: 325.6 mrem

### EDE as a function of % Administered Activity*

<table>
<thead>
<tr>
<th>Dosage (mCi)</th>
<th>Percent Administered</th>
<th>0-2 hrs</th>
<th>2-8 hrs</th>
<th>X-T, 8h - 3d</th>
<th>T, 8h - 3d</th>
<th>X-T, 3d - decay</th>
<th>T, 3d - decay</th>
<th>Total</th>
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<tbody>
<tr>
<td>70.0</td>
<td>70%</td>
<td>18.4</td>
<td>36.3</td>
<td>78.5</td>
<td>21.2</td>
<td>0.2</td>
<td>73.4</td>
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<tr>
<td>75.0</td>
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<td>19.7</td>
<td>38.9</td>
<td>84.1</td>
<td>22.7</td>
<td>0.3</td>
<td>78.6</td>
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<tr>
<td>80.0</td>
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<td>21.0</td>
<td>41.5</td>
<td>89.7</td>
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<td>83.8</td>
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<td>44.0</td>
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<td>27.2</td>
<td>0.3</td>
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<td>49.2</td>
<td>106.5</td>
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<td>51.8</td>
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<td>105.0</td>
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<td>54.4</td>
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<td>59.6</td>
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<td>32.9</td>
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<td>37.8</td>
<td>0.4</td>
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<td>130.0</td>
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<td>67.4</td>
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### Dose Rate Calculations*

*Calculations based on differentials of TEDE equations in NRC Regulatory Guide 8.39*

<table>
<thead>
<tr>
<th>Time (d)</th>
<th>Time (hr)</th>
<th>0-2 hrs</th>
<th>2-8 hrs</th>
<th>X-thyroid</th>
<th>thyroid</th>
<th>Total Rate</th>
<th>TEDE</th>
<th>op=1 @ .3 m</th>
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<tbody>
<tr>
<td>0.00</td>
<td>0</td>
<td>13.20</td>
<td>8.67</td>
<td>13.20</td>
<td>0.00</td>
<td>195.56</td>
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<tr>
<td>0.02</td>
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<td>13.18</td>
<td>8.61</td>
<td>13.18</td>
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<td>0.04</td>
<td>1</td>
<td>13.15</td>
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<td>13.15</td>
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<td>0.08</td>
<td>2</td>
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<td>8.55</td>
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</tr>
<tr>
<td>1.50</td>
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<td>0.39</td>
<td>0.46</td>
<td>0.86</td>
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<td>30.89</td>
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</tr>
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*Sleep dose is not included in the above calculations.*
Sleep Dose Calculations

Calculations based on addition of 8 hrs/day occupancy factor @ 50 cm after n days sleeping separately

Patient Identifier: Jane Doe
Prescribed Dosage: 100.00 mCi
Date of Administration: 1/19/01

Total Estimated EDE (without sleep dose included): 325.6 mrem

Days required to sleep alone: 7 days

TEDE with the sleep dose after -- days sleeping separately included: 492.8 mrem

### TEDE (0-3 days):

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<th>Thyroidal Dose 3 - n days</th>
<th>X-thyroidal Dose n/d - decay</th>
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ORAL THERAPY WITH I-131  
FOR DOSES LESS THAN 30 mCi

INDICATIONS: Treatment of Graves Disease.

PATIENT PREPARATION: 
The patient should remain NPO for at least 2-4 hours prior to administration of I-131. The patient should not be on any anti thyroid medications for 3 weeks prior to administration. The patient should not have had any iodinated contrast for at least 6 weeks prior to administration.

ISOTOPE: 1 - 29.9 mCi of I-131 to be determined by the nuclear physician to be administered orally in liquid or capsule form.

PROCEDURE: 
A thyroid scan and uptake should be performed and reviewed with the Nuclear Medicine physician for determination of dosage. A thyroid profile is required prior to dosing for assistance in determining dosage.

1. The Nuclear Medicine Physician will discuss the procedure with the patient’s physician.

2. Refer to the Quality Management policy and protocol for documentation requirements. (See attached checklist).

3. Explain the entire procedure to the patient. Include precautions for patients receiving I-131 therapy. Provide the patient with the preprinted information booklet and acquire the appropriate consent from the patient.

4. The patient should be dosed in the room adjacent to the Nuclear Pharmacy. Prepare the surface with an absorbent pad. The dose should be vented in the fume hood for at least 5 minutes prior to dosing (pharmacy). Two persons should verify and document reading of I-131 in dose calibrator.

5. The dose will be administered under the direct supervision of the Nuclear physician. The vial will be shielded with the lead pig and should remain within that pig. Water will be available for diluting the residue within the vial for the patient’s consumption to assure as much of the dose as possible is administered. After dosing the patient, contain and return the straw, vial and gloves to the radiopharmacy for disposal.

6. Physician in Nuclear Medicine will give patient instructions regarding personal care and contact with others. Incontinent patients should be catheterized.

NOTES: Patient does not have to be an in-patient

Although there are limited restrictions for patients receiving less than 30 mCi, some precautions should be kept in mind for in-patients. Depending on the size of the dose and the patient’s capabilities, guidelines will be established with the nursing personnel involved in the care of the patient.
Month: _______________________

Nuclear Medicine Department
QM Yearly Review Form For
Therapy and Diagnostic Administrations

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<th>Rx #</th>
<th>Dose Admin. In mCi</th>
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RRx s include P$_{32}$, Sr$_{89}$, I$_{131}$, and I$_{125}$

Health Physicist’s Signature ______________________________________________________

*** Any deviations from the prescribed dose by more than 10% will be ***

*** recorded and cause will be identified. ***

Recommendations:

Copies to: Radiation Safety Office, Chief Nuclear Medicine Physicist,
Director of Nuclear Medicine, Administrator of Radiology.
MEDICAL UNIVERSITY HOSPITAL
CHECKLIST FOR RADIOIODINE THERAPY PATIENTS

Patient: ______________________________________ Room #: _____________________
was administered _______________ mCi of I-131 on ______________________________
at ________________ AM/PM

_____ Room approved for use

_____ Nursing instructions posted in chart

_____ Room posted with radiation signs

_____ Nursing staff instructed in patient care precautions

_____ Check list and documentation of QM program (documentation found in patients X-ray jacket)

DAILY RADIATION SURVEYS:

_____________________________________________________________________________

_____________________________________________________________________________

_____________________________________________________________________________

_____________________________________________________________________________

_____________________________________________________________________________

_____________________________________________________________________________

_____________________________________________________________________________

_____ Patient consultation regarding radiation safety precautions.

_____ Room released for reuse.

By: ________________________________ Date: _____________
MEDICAL UNIVERSITY HOSPITAL
RADIOACTIVITY PRECAUTIONS FOR PATIENTS CONTAINING RADIOIODINE

Patient: _________________________________________ Room #: _____________
was administered ______________ mCi of radioiodine ___________________ in the form
of ________________________________ on ______________________________________
at __________________ AM/PM. By: ___________________________________________

Radiation Survey: By: ______________________________________________________
Date: _______________________ at _________________________ AM/PM

Maximum Exposure Rate: @ 1 foot from patient _____________ mR/hr
@ 3 feet from patient _____________ mR/hr
@ 6 feet from patient _____________ mR/hr
@ door entry _____________ mR/hr
@ adjacent room _____________ mR/hr
(nearest patient)

Time Restrictions: Nursing and hospital staff:

Maximum stay time of ____________ minutes/day at beside.
Maximum stay time of ____________ minutes/day at 3 feet.

Visitors:

Maximum stay time of ____________ minutes/day outside of warning tape line
No visitors permitted ____________

Special Instructions: (applicable if checked)

________ Patient must remain in room
________ Nursing staff must be film badged
________ Nursing staff must wear disposable gloves and shoe covers in room
________ Disposable eating utensils only
________ Collect all urine in special containers for radioassay
________ Collect all stools in special containers for radioassay
________ Patient may not be discharged until approved by Radiation Safety
________ Room may not be released until approved by Radiation Safety

Special Precautions: _____________________________________________________________
_____________________________________________________________________________

Radiation Safety Officer ____________________________ Date __________________
MEDICAL UNIVERSITY HOSPITAL
INSTRUCTIONS FOR FAMILY OF RELEASED RADIATION PATIENTS

Please show this form to every physician consulted concerning this patient until ____________.
Patient: ___________________________________ Phone: _________________________
Address: ______________________________________________________________________
Next of kin: ___________________________________ Phone: _________________________

________________________ was treated on __________________
with ___________ mCi of __________________ in the form of ________________________.

NO SPECIAL RADIATION SAFETY PRECAUTIONS ARE NECESSARY AFTER:

Until that time:

Persons under 45 years of age should not remain closer than the following distances from the
patient, for the time period indicated below:

A. ______ to ______: Permissible distance: _______ feet or more, for _______ hours per
week. At other times remain farther than 6 feet.

B. ______ to ______: Permissible distance: _______ feet or more, for _______ hours per
week. At other times remain farther than 6 feet.

Note: During the above times, brief periods of closer contact (for example, shaking hands or
kissing the patient) are permissible.

SPECIAL PRECAUTIONS:
A. Spouse or other person taking care of patient: __________________________________
   _______________________________________________________________________
   _______________________________________________________________________

B. Children or pregnant women:_______________________________________________
   _______________________________________________________________________
   _______________________________________________________________________

C. Sleeping arrangements: ____________________________________________________
   _______________________________________________________________________
   _______________________________________________________________________.

If the patient is to be hospitalized, or if death should occur, notify the following individuals
immediately:

__________________________________________ Phone: _______________________
__________________________________________ Phone: _______________________
**THERAPY WITH P-32**

I. Intravenous therapy with Sodium Phosphate P-32. Treatment for Polycythemia Vera.

   A. The Nuclear Medicine physician will discuss procedure with the patient's physician. Physician requesting therapy will fill out special Request Form for Radioisotope Therapy.

   B. Nuclear Medicine physician will give patient instructions regarding personal care.

   C. This patient does not need to be isolated.

   D. Nuclear Physician will inject dose.
**P-32 ABDOMINAL CAVITY THERAPY**

**PURPOSE:** To ablate and/or palliate widespread intraperitoneal metastases with P-32 Chromate irradiation.

**DOSE:**
- 2 mCi of 99mTc Sulfur Colloid followed by 500 cc ½ N Saline
- 15 mCi of P-32 Chromate in 500 cc ½ N Saline

**INSTRUMENTATION:**
- Energy of Radionuclide: 140 KeV for Tc-99m SC imaging
- Single Head LFOV Camera
- Low Energy General Purpose Collimator
- Images obtained for 500K Counts

**PROCEDURE:**

1. When a requisition for cavity P-32 therapy, with 1) appropriate clinical history, 2) diagnosis, and 3) physician s signature, is submitted to nuclear medicine, a nuclear medicine attending physician will evaluate it and review the inpatient chart to assure appropriateness of the request for therapy.

2. Once the requisition is approved, the chief technologist will coordinate scheduling with the patient and the referring physician to a time slop when a nuclear medicine attending physician will be in the clinic.

3. The nuclear medicine physician will prescribe P-32 dose and the chief technologist will arrange for delivery to the nuclear medicine clinic at the appropriate time.

4. At the scheduled time, the nuclear medicine physician will conduct the therapy according to the following protocol:
   
   **A.** An informed consent agreement will be obtained prior to administration of radionuclide.
   **B.** Either the referring physician at time of pre-therapy surgery or nuclear medicine physician in the nuclear medicine scan room will obtain catheter access to the patient's peritoneal cavity.
   **C.** The patient will be placed on a stretcher that can be tilted in Trendelenburg and reverse Trendelenburg positions.
   **D.** Warm normal saline in body temperature water before opening storage bag.
   **E.** 2 mCi Tc-99m Sulfur Colloid will be injected through the catheter along with 500 cc ½ normal saline. The patient will be rolled gently from side (90°) to side to allow for circulation of fluid.
   **F.** Attending nuclear medicine physician shall observe anterior and both lateral images on gamma camera computer monitor. These images of the abdomen will be filmed for later review by nuclear medicine attending.
   **G.** If the radioactivity appears loculated, it may be necessary to repeat and/or alter catheter placement.
   **H.** Once the best conduit for the injection of therapeutic radioactivity has been established, the patient will be kept motionless until P-32 Chromate infusion is completed.
I. 15 mCi of P-32 Chromic Phosphate shall be administered by nuclear medicine attending physician, by first introducing the dose into 500cc of ½ normal saline and then instilling this solution into the peritoneal cavity.

J. Catheter will be removed and the patient rotated slowly 360° twice (20 minutes), and the patient’s head raised and/or lowered, to evenly and universally distribute the P-32 dose throughout the peritoneum. Once the dose is evenly distributed, as demonstrated by a final anterior and lateral image (Tc-99m window) the patient will be returned to ward where nursing will continue rotating patient to insure complete intraperitoneal distribution. Call referring physician if sutured catheter in place to assure proper removal procedure while in Nuclear Medicine area.

K. Dispose of contaminated material and monitor room for contamination.

L. The next morning, the patient will return to nuclear medicine for repeat anterior and lateral images. (Anterior and Lateral view using Bremstrallung window, P-32 emissions) if possible. If not, Tc-99m window images will be made for review by the nuclear medicine attending physician.

M. Following interpretation of these 16 to 24 hour images, the nuclear medicine attending physician will dictate a summary report which describes the therapeutic effort and result and the patient’s reaction.

Materials Required:

2 each, 500ml bag NaCl Sterile Gloves (6 ½, 7, 7 ½, or 8)
2 each, IV Infusion Sets Sterile Drape
Betadine Solution 10-20 ea sterile 4 x 4 gauze
1 each, disposable sterile scissors Collodion Flexible
1 each, disposable needle driver 2 each, 5 ml ampules 1% Lidocaine
IV Pressure Infusor Chux
Steri strips Sterile sutures 3-0 silk, x-1 cutting
3 cc syringe 2 each, 20 guage needles
2 each, 25 gauge needles 1 each, 10 cc syringe
k-53 Infusion Set P-32 Consent Form
**P-32 EYE TUMOR LOCALIZATION**

**PURPOSE:** To differentiate benign tumors from those that are malignant. The most common intraocular tumor is the malignant melanoma which has a high rate of metastasis.

**PREPARATION OF PATIENT:** No preparation prior to injection.

**DOSE:** 10 Ci/kg (maximum 700 Ci) Sodium Phosphate P-32. This radionuclide is a beta emitter with a 695 KeV energy.

**PROCEDURE:**

1. The radiopharmaceutical is injected intravenously by one of the Nuclear Medicine Physicians.
2. There is at least a 48 hour delay between the injection and the counting procedure.
3. The counting procedure is completed in the office of surgical suite by the physician who has ordered the study. The following is the protocol used:
   
   **A.** A beta particle detector is very carefully placed over the lesion and sufficient counts obtained.
   
   **B.** Counts are also obtained over at least one control area.
   
   **C.** The uptake of the P-32 is calibrated in the following way:

   \[
   \% \text{ uptake} = \left(\frac{C - C_c}{C}ight) \times 100
   \]

   \(C\) = counts over lesion
   \(C_c\) = counts over control area

   **D.** 100% uptake is considered a positive test at the Medical University Hospital.

The benefit of this procedure is the decrease in the number of eyes nucleated for benign lesions.
THERAPY FOR OSSEOUS METASTASES

INDICATIONS: Palliation therapy of painful multiple osseous metastases.

PREPARATION OF PATIENT: The candidate for Sr89 therapy will undergo a careful screening process prior to dosing to assure qualification for the therapy. The Radiation Therapy department will do the initial workup of the patient. Screening criteria will include:

1. Proven metastatic bone disease by
   a. Positive bone scan within 6 wks of therapy
   b. Positive radiograph
   c. Positive CT or MRI
2. WBC counts greater than 24,000/cubic mm.
3. Platelet counts greater than 60,000/cubic mm.
4. Life expectancy greater than 3 months.
5. Normal urine output.

Because of the nature of the Radiopharmaceutical and the expense incurred by the patient, there should be strict adherence to the qualifications and workup.

DOSE: 4 mCi Sr89 (Sr89 is a beta emitter and shielding should be appropriate for such.

APPROVAL FOR INJECTION: The radiation therapy department (Todd Williams) will screen the patient and discuss the case with the Nuclear Medicine Physician prior to scheduling.

PROCEDURE:
1. The Nuclear Medicine physician will discuss the procedure and the expected results with the patient and obtain consent. (See consent form for Sr89) A complete history will be taken on the patient including reviewing the most recent bone scan. An information sheet will be made available to the patient and questions will be entertained prior to consent. (A package of information, including the consent form, is prepared and available for the patient.)

2. Prepare the patient with 22g. butterfly and stopcock with 10cc saline flush attached. Assure free flowing line by drawing blood and injecting saline.

3. The Nuclear Medicine physician performs the injection with a slow IV push over 2 minutes.

4. Give the patient a copy of Precautions for patient s treated with Strontium-89'. The patient is then released for follow-up care with his primary physician.

5. A copy of the patient s nuclear medicine records will be forwarded to Radiation Therapy. Record the information on the log sheet for therapy retained within the department for QM purposes. The original forms will be retained for review and inspection in the patient s Radiology jacket.
Therapy for Osseous Metastases cont...

NOTES:

** Sr89 is not indicated for use in patients with cancer not involving bone. Therefore a recent bone scan should be performed and made available for interpretation prior to the candidate being accepted for therapy.

** Patients may be treated a second time if required. A minimum of 3 months should elapse before scheduling.

Approved ___________________________________ Sr89, the Therapy
Radiation Precautions for patients treated with Strontium-89

___________________________________ was treated with _________ mCi of Strontium 89 on
___________________________________ at _________________ AM/PM. Your attending physician is
___________________________________, M.D. Pager No. 792-0590 ___________.

In the event of a medical emergency, contact the Division of Nuclear Medicine at 792-4294 and ask to speak to the attending physician.

The treating physicians will discuss the precautions and provide the patient with a hard copy of the discussed precautions. Please follow these precautions for one week after the injection.

a. Where a normal toilet is available, it should be used in preference to a urinal. The toilet should be flushed at least 3 (three) time.

b. Wipe up any spilled urine with a tissue paper and flush it away.

c. Ensure that you always wash your hands after using the toilet.

d. Immediately wash any linen or clothes which become stained with urine or blood. Wash them separately from other clothes, and rinse thoroughly.

e. If you should cut yourself, wash away any spilled blood, or wipe up with a tissue paper and flush it away.
METASTRON®
(STRONTIUM-89 CHLORIDE INJECTION)

Information for Patients

What is Metastron?

For many years doctors have used certain types of radiation to relieve pain experienced by people like yourself. Metastron is a new development in this type of treatment. Metastron (Strontium-89 Chloride Injection contains small amounts of a specially selected form of radioactive strontium, chosen because almost all of its radiation is given to the area where it is absorbed. This allows it to deliver therapy precisely where it is needed.

Why has Metastron been prescribed for me?

For many people, Metastron is more appropriate than other types of therapy. It has been prescribed for you as it seems likely that it will be the most suitable treatment in your case.

What effect will Metastron have?

At first you will feel no effect at all. You may even feel a slight increase in pain for two or three days beginning two or three days after injection. This is quite normal, and your doctor may suggest that you temporarily increase your dose of painkillers until the pain is under control.

After about one to two weeks, sometimes a little longer, you should begin to feel the pain diminish. This reduction in pain should continue and the effect should then last for several months.

Are there any side effects?

None that you will normally notice. You can eat and drink normally and there is no need to avoid alcohol or caffeine unless you have already been advised to do so. There may be a slight fall in the number of cells in your blood and your doctor will want to carry out periodic, routine blood tests. If you have any concerns you should of course talk with your doctor.

Should I stop taking pain killing drugs?

Your doctor may advise you to continue taking your pain killing medicine until Metastron begins to become effective. You may then be advised to reduce the dose of your pain medications gradually. Your doctor may want to continue reducing the dose and eventually you may not need pain killers at all. If you have any doubts, consult your doctor.

What about other treatments?

Your doctor will advise you about other treatments that are required. You may have been receiving hormone injections or tablets and your doctor may wish you to continue with these.

What activities can I undertake?

The injection will not prevent you from doing anything that you were already doing. As Metastron begins to relieve the pain, you may find that you can tackle activities that were previously too difficult or too painful. Usually there is no problem with this, but be careful not to overdo it! If you are in any doubt, see your doctor’s advice.

Who should I tell that I have received Metastron?

You should tell any health practitioner who is giving you medical treatment that you have received Metastron, and show them this leaflet.

(continued on back)
NURSING CARE FOR PATIENTS RECEIVING INTRAPERITONEAL CHROMIC PHOSPHATE

The patient is turned every 10 minutes to the following positions to ensure adequate distribution and prevent over exposure in any one area. These positions are repeated twice (for a total of 160 minutes) following chromic phosphate suspension infusion:

**In Trendelenburg:**
- Supine
- Right side
- Prone
- Left side

**In reverse Trendelenburg:**
- Supine
- Right side
- Prone
- Left side
The purpose of the Bioassay Program is to ensure safe working conditions for persons who handle radioactive isotopes of iodine. Persons who handle amounts of radioiodine greater than those in the attached table must participate in the Bioassay Program unless specific approval not to participate is granted by the Radioactive Materials Committee. The amounts in the table are cumulative 3 month activities.

**Types of Bioassays**

**Baseline** - any worker who will be handling amounts of iodine larger than those on page 45 of the Radiation Safety Manual must have a baseline bioassay before beginning work.

**Routine** - regular bioassays to monitor the employee for contamination.

**Emergency** - any employee whether they are a participate in routine bioassays or not must notify the Radiation Safety Officer if they are involved in an incident that might cause internal contamination with radioiodine. The Radiation Safety Officer will determine whether a bioassay is necessary and appropriate timing for that bioassay.

**Ending** - a bioassay must be performed within 2 weeks of working with radioisotopes of iodine. If an employee is transferred to duties that do not require the handling of radioiodine, a bioassay is necessary. Also, any employee who is leaving the employment of the hospital should have a final bioassay if they are on the routine monitoring program.

**Routine Bioassays**

Routine bioassays are normally obtained every 3 months. If the average thyroid burden for an individual exceeds 0.12 Ci of Iodine-125 or 0.04 Ci of Iodine-131, bioassays shall be obtained every two weeks. The Radiation Safety Office may require more frequent bioassays when conditions suggest they are necessary.

**Action Levels**

Action Level I is 0.12 Ci of Iodine-125 and 0.04 Ci of Iodine-131. Whenever the thyroid burden of an individual exceeds these limits, the Radiation Safety Officer shall investigate. The purpose of this investigation is to determine the causes of the exposure, and to evaluate the potential for further exposures. If the potential for further exposures is high, the Radiation Safety Officer may restrict a particular worker or all workers in that area if required. The Radiation Safety Officer may order any corrective actions that will eliminate or lower the potential for further exposures. A repeat bioassay should be taken within two weeks, and at 2 week intervals thereafter in order to determine the dose commitment from the radioiodine.

Action Level II is 0.05 Ci thyroid burden of Iodine-125 and 0.14 Ci thyroid burden of Iodine-131. If the Action Level II of thyroid burden is succeeded, the Radiation Safety Officer shall see that all steps required for Action Level I are carried out, and seek appropriate medical consultation for the contaminated individual. Bioassays shall be done at weekly intervals to determine the dose commitment.

**Methods**
The bioassay shall be done in Nuclear Medicine using the Canberra Series 20. Specific protocol details are attached.

**Summation**

If summation of external and internal doses are required. The following procedures will be followed:

a. **Intake by inhalation:** The total effective dose equivalent limit is not exceeded if the sum of the deep-dose equivalent divided by the total effective dose equivalent limit and the sum of the calculated committed effective dose equivalents from bioassay data does not exceed unity. (Refer to RHA 3.6.1.1 and 3.6.1.1.3)

b. **Intake by oral ingestion:** If the individual ingests greater than 10 percent of the oral intake (ALI) value (See Table 1 of Appendix B, RHA 3.53), the licensee shall account for this intake.

c. **Intake through wounds or absorption through skin:** The licensee shall evaluate and account for intakes through wounds or skin. (Refer to RHA 3.6.1.3)

**Records**

The records of bioassays shall be kept by Nuclear Medicine. The Radiation Safety Officer shall be responsible for notifying any employee whose thyroid burden exceeds the maximum permissible body burden.
Air Concentration Compliance

Airborne radioactive material is measured to ensure minimal inhalation by personnel. (Refer to RHA 3.6.1.1 and 3.6.1.1.3) Air sampling is performed biannually in Scan Room 308 to ensure that the confinement of Xe-133 is effective. The procedures carried out for Nuclear Pharmacy and Nuclear Medicine are outlined on pages 12-21.
AIR CONCENTRATION COMPLIANCE CALCULATION WORKSHEET

FACILITY: MUSC

DATE: 11/20/2000

ROOM: Scan Room 308

DATA

Nuclide: Xe-133

DAC(air, unrestricted): 5.00E-07 uCi/ml

DAC(air, restricted): 1.00E-04 uCi/ml

Flow rates: (CFM):

<table>
<thead>
<tr>
<th>Vent#1</th>
<th>Vent#2</th>
<th>Vent#3</th>
<th>Vent#4</th>
<th>Vent#5</th>
<th>Vent#6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supply=&gt;</td>
<td>450.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exhaust=&gt;</td>
<td>750.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Total Exhaust: 750
* Net Exhaust: 300 <= (Should not be negative number)

Nuclide Usage or Storage in this area, mCi/wk => 205.700

Leakage fraction assumed (0-1): 0.10

Room Dimensions (for evacuation calculations) in feet:

Area 1: Height=> 8.00 Width=> 19.00 Length=> 16.00
Area 2: Height=> 0.00 Width=> 0.00 Length=> 1.00
Area 3: Height=> 0.00 Width=> 0.00 Length=> 0.00

* Volume: 2432.00 cu.ft. * Air turnover, air changes per hour: 18.50

Max amount spilled in any incident (mCi): 16.00

RESULTS

Concentration, unrestricted: 9.61E-08 uCi/ml Fraction DAC: 1.92E-01
Concentration, restricted: 4.04E-07 uCi/ml Fraction DAC: 4.04E-03

Min. exhaust air needed (CFM), unrestricted: 144
Min. exhaust air needed (CFM), restricted: 3

Evacuation time, minutes: 2.73 (DAC method)
32.43 (10 air changes)
MEDICAL UNIVERSITY OF SOUTH CAROLINA  
Nuclear Medicine and Nuclear Pharmacy Department  
Radioactive Material Inspection

Inspection Date: ______________  Previous Inspection Date: ______________

I. License Review

A. Copies of MUSC Radiation Safety Manuals, Titles A and B, Title 10CFR and MUSC licensed user authorizations on hand.

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Comments:

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B. Are radioactive materials being used only by authorized personnel and according to approved protocol for diagnosis and therapy?

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Comments:

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C. Are personnel being adequately monitored for exposure and the exposures reviewed by management?

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Comments:

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D. Are personnel credentialed and/or have received proper on the job training as required?

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Comments:

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E. Unusual occurrences, incidents or misadministrations since last inspection.

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Comments:

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F. Comments or Recommendations:
II. Records Review

A. Current Inventory.
B. Receipt and disposal records.
C. Shipment documentation.
D. Records of surveys and receipt transfers.
E. Facility Surveys.
F. Adequate monitoring instruction.
G. Instrumentation calibrated and functioning properly.
H. Required leak tests performed and recorded.
I. Are treatment facilities adequate. (Ventilation rates, security, isolation, shielding, etc.)?
J. Posting of required warning signs, NTE and list of authorized users.
K. Are facilities properly secured and public access restricted where radioactive materials are prepared and used?
L. Comments and Recommendations:

III. Operating Procedures

A. Quality Management Program
   1. Supervised individual(s) instructed in Quality Management Program applicable to the modality of use (RHA 4.16.1)?
   2. Are written directives prepared for each patient (RHA 4.16.1.1)?
   3. Written directives contain required dosage information per RHA 4.2.27?
   4. Exceptions to written directives are documented (footnote to RHA 4.16.1.1)?
   5. Licensee uses more than one method to verify patient’s identity (RHA 4.16.1.2)?
   6. Record of administration maintained in auditable form (RHA 4.16.4)?
   7. Review conducted of the Quality Management Program at intervals no greater than 12 months per RHA 4.16.2.1.3?

B. Disposal of Materials
   1. Are disposal methods adequate for:
      a. Generator
      b. Solid Waste
      c. Liquid Waste
      d. Xenon
      e. Sealed Sources
2. Disposal of waste in accordance with regulatory requirements per RHA 3.27, 3.29, and 4.8.15?

3. Are appropriate surveys made before disposal of decay-in storage waste per RHA 4.8.15.1.2?

4. Records maintained per RHA 4.8.15.2?

5. Transfer of material records maintained.

C. Bioassays

1. Is monitoring program adequate for measuring exposures to potential airborne RAM, ingested RAM, or skin contamination?

2. Do exposure records reflect all pertinent information necessary to calculate personnel exposure (SSN, DOB, Unused permissible dos)?

3. Radioactive Gases
   a. Clearance time and safety procedures are posted per RHA 4.10.3.5.
   b. Are reusable collection systems checked monthly per RHA 4.10.3.6?
   c. Are ventilation rates checked each six months for negative pressure per RHA 4.10.3.6?

D. Radiopharmaceutical Therapy

1. Does license provide safety instructions (RHA 4.11.2) and implements safety precautions (RHA 4.11.3) or equivalents?

2. Are patient room contamination surveys performed (RHA 4.11.3.1.7)?

3. Does release of patients containing radiopharmaceuticals meet requirements in RHA 4.8.12?

4. Thyroid burden measured on individuals involved in dose administrations (RHA 4.11.3.1.8)?

E. Area Surveys

1. Daily Surveys (RHA 4.8.11.1)
   a. All areas where radiopharmaceuticals are routinely prepared for use or administered.

2. Weekly surveys RHA 4.8.11.2 and 4.8.11.5?

3. Records maintained per RHA 4.8.11.8?

4. Instrument used to analyze smear samples?

F. Facilities and Equipment

1. Map of Pharmacy and Nuclear Medicine current (as described in license)

2. Was the following equipment available?
   a. Syringe shields
   b. Remote handling tools
   c. Disposable gloves
   d. Disposable absorbent paper
e. List any special equipment

3. Areas for storage and use of radioactive material
   a. Adequate method used to prevent an unauthorized individual from entering restricted area?
   b. RAM is secured to prevent unauthorized removal from an unrestricted area per RHA 3.20?

4. Dose Calibrator:
   a. Licensee possess and uses calibrator(s) per RHA 4.8.2.1?
   b. Daily constancy checked per RHA 4.8.2.2.1?
   c. Quarterly linearity tested per RHA 4.8.2.2.3?
   d. Accuracy tested per RHA 4.8.2.2.2?
   e. Geometry dependence tested per RHA 4.8.2.2.4?
   f. Readings mathematically corrected if linearity error is greater than 10% per RHA 4.8.2.4?
   g. Records maintained per RHA 4.8.2.5?
   h. RSO signs linearity, accuracy, and geometry dependence tests per RHA 4.8.2.5?

H. Misadministrations

1. Have any misadministrations occurred since the last inspection?
   a. Diagnostic? _______  b. Therapeutic? _______

2. Licensee in compliance with reporting diagnostic misadministration, if required, per RHA 4.7.9.3?

3. Licensee in compliance with reporting therapeutic misadministrations per RHA 4.7.9.1?

4. Appropriate action taken to prevent recurrence?

5. Records maintained per RHA 4.7.9.4?

IV. A. Items of Noncompliance:

B. Management Discussion:
C. Comments: 


Inspector: ___________________________ Date: ___________________________
Inspector Name/Title: ___________________________ Date: ___________________________
Inspection Reviewed by: ___________________________ Date: ___________________________