

<b>NRC FORM 313M</b> (9-81) 10 CFR 35	<b>U.S. NUCLEAR REGULATORY COMMISSION</b> <b>APPLICATION FOR MATERIALS LICENSE – MEDICAL</b>	Approved by OMB 3150-0041 Expires 9-30-83
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**INSTRUCTIONS** – Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.

<b>1.a. NAME AND MAILING ADDRESS OF APPLICANT</b> (institution, firm, clinic, physician, etc.) INCLUDE ZIP CODE  Steven A. Artz, M.D. Medical Staff Building, Suite 911 3100 MacCorkle Avenue, SE Charleston, West Virginia TELEPHONE NO.: AREA CODE (304) 343 - 7651	<b>1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED</b> (If different from 1.a.) INCLUDE ZIP CODE  Same
<b>2. PERSON TO CONTACT REGARDING THIS APPLICATION</b>  Same as above  TELEPHONE NO.: AREA CODE ( ) _____	<b>3. THIS IS AN APPLICATION FOR:</b> (Check appropriate item) a. <input type="checkbox"/> NEW LICENSE b. <input type="checkbox"/> AMENDMENT TO LICENSE NO. _____ c. <input checked="" type="checkbox"/> RENEWAL OF LICENSE NO. <u>47-16156-01</u>
<b>4. INDIVIDUAL USERS</b> (Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)  Steven A. Artz, M.D. (currently authorized under present license)	<b>5. RADIATION SAFETY OFFICER (RSO)</b> (Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)  Steven A. Artz, M.D.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE			
RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)	ADDITIONAL ITEMS:
10 CFR 31.11 FOR IN VITRO STUDIES	X	3 mCi	IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED	PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED	PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.
10 CFR 35.100, SCHEDULE A, GROUP III	X	2 curies	GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED	IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED	XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.
10 CFR 35.100, SCHEDULE A, GROUP VI			

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. (Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)			
ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
Iodine-131  <b>8508120719 850724</b> <b>REG2 LIC30</b> <b>47-16156-01 PDR</b>	capsules	30 uCi	Transferring a single capsule to designated patients for ingestion at a latter specified time for uptake studies.

June 2, 1985  
 Applicant: Nuclear Medicine Service  
 Check No. 47-24  
 Amount/Fee Category 580 (70)  
 Type of Fee Ren.  
 Date Check Rec'd 6/26/85  
 Received By Jacques

50630

# **INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23**

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. \_\_\_\_\_ Date: \_\_\_\_\_

<b>7. MEDICAL ISOTOPES COMMITTEE</b>		<b>15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL (Check One)</b>	
<input type="checkbox"/>	Names and Specialties Attached; and	<input type="checkbox"/>	Appendix G Rules Followed; or
<input type="checkbox"/>	Duties as in Appendix B; or _____ (Check One)	<input checked="" type="checkbox"/>	Equivalent Rules Attached
<input type="checkbox"/>	Equivalent Duties Attached	<b>16. EMERGENCY PROCEDURES (Check One)</b>	
<b>8. TRAINING AND EXPERIENCE</b>		<input type="checkbox"/>	Appendix H Procedures Followed; or
<input type="checkbox"/>	Supplements A & B Attached for Each Individual User; and	<input checked="" type="checkbox"/>	Equivalent Procedures Attached
<input type="checkbox"/>	Supplement A Attached for RSO.	<b>17. AREA SURVEY PROCEDURES (Check One)</b>	
<b>9. INSTRUMENTATION (Check One)</b>		<input type="checkbox"/>	Appendix I Procedures Followed; or
<input type="checkbox"/>	Appendix C Form Attached; or	<input checked="" type="checkbox"/>	Equivalent Procedures Attached
<input checked="" type="checkbox"/>	List by Name and Model Number	<b>18. WASTE DISPOSAL (Check One)</b>	
<b>10. CALIBRATION OF INSTRUMENTS</b>		<input type="checkbox"/>	Appendix J Form Attached; or
<input type="checkbox"/>	Appendix D Procedures Followed for Survey Instruments; or _____ (Check One)	<input checked="" type="checkbox"/>	Equivalent Information Attached
<input checked="" type="checkbox"/>	Equivalent Procedures Attached; and	<b>19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS (Check One)</b>	
<input type="checkbox"/>	Appendix D Procedures Followed for Dose Calibrator; or _____ (Check One)	<input type="checkbox"/>	Appendix K Procedures Followed; or
<input checked="" type="checkbox"/>	Equivalent Procedures Attached	<input type="checkbox"/>	Equivalent Procedures Attached
<b>11. FACILITIES AND EQUIPMENT</b>		<b>20. THERAPEUTIC USE OF SEALED SOURCES</b>	
<input checked="" type="checkbox"/>	Description and Diagram Attached	<input type="checkbox"/>	Detailed Information Attached; and
<b>12. PERSONNEL TRAINING PROGRAM</b>		<input type="checkbox"/>	Appendix L Procedures Followed; or _____ (Check One)
<input checked="" type="checkbox"/>	Description of Training Attached	<input type="checkbox"/>	Equivalent Procedures Attached
<b>13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL</b>		<b>21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon - 133)</b>	
<input checked="" type="checkbox"/>	Detailed Information Attached	<input type="checkbox"/>	Detailed Information Attached
<b>14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS (Check One)</b>		<b>22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS</b>	
<input type="checkbox"/>	Appendix F Procedures Followed; or	<input type="checkbox"/>	Detailed Information Attached
<input checked="" type="checkbox"/>	Equivalent Procedures Attached	<b>23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b</b>	
<input type="checkbox"/>		<input type="checkbox"/>	Detailed Information Attached

## 24. PERSONNEL MONITORING DEVICES

TYPE <small>(Check appropriate box)</small>		SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	<input checked="" type="checkbox"/> FILM	R.S. Landauer & Co., Glenwood, IL	Monthly
	<input type="checkbox"/> TLD		
	<input type="checkbox"/> OTHER <small>(Specify)</small>		
b. FINGER	<input type="checkbox"/> FILM		
	<input checked="" type="checkbox"/> TLD	Same	Same
	<input type="checkbox"/> OTHER <small>(Specify)</small>		
c. WRIST	<input type="checkbox"/> FILM		
	<input type="checkbox"/> TLD		
	<input type="checkbox"/> OTHER <small>(Specify)</small>		

d. OTHER (Specify)

Refer to the attached ALARA Program

## 25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL			
NAME OF HOSPITAL Charleston Area Medical Center		b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.	
MAILING ADDRESS P.O. Box 1393		c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.	
CITY Charleston	STATE WVA	ZIP CODE 25322	

## 26. CERTIFICATE

*(This item must be completed by applicant)*

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED <small>(See Section 170.31, 10 CFR 170)</small>		b. APPLICANT OR CERTIFYING OFFICIAL <small>(Signature)</small> Steven A. Artz M.D.	
(1) LICENSE FEE CATEGORY: 7c		(1) NAME <small>(Type of Print)</small> President	
(2) LICENSE FEE ENCLOSED: \$ 580.00		(2) TITLE June 18, 1985	
		c. DATE	

## PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).
2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.
3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.
4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.
5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.



## CHARLESTON AREA MEDICAL CENTER

1210 Elmwood Avenue • P. O. Box 1547  
Charleston, West Virginia 25326 • 304/348-7627

June 12, 1985

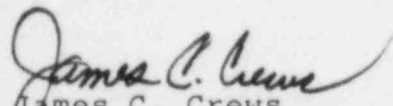
Steven A. Artz, M. D.  
Nuclear Medicine Services, Inc.  
3100 MacCorkle Avenue, S. E.  
Charleston, WV 25304

Dear Doctor Artz:

This is to advise that Steven A. Artz, M. D., is hereby approved to admit patients who have been given parenteral radioactive materials, to The Charleston Area Medical Center.

In addition, be advised that you will also be responsible for radiation safety matters pertaining to patients admitted as described above.

Sincerely,

  
James C. Crews  
President

dhh



## RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER

The specific duties of the Radiation Safety Officer include:

1. Establishing and maintaining operations procedures so that the radiation exposure of each worker is kept as far below the maximum permissible exposure as is practicable.
2. Instructing personnel in safe working practices and in the nature of injuries resulting from overexposure to radiation.
3. Assuring that personnel monitoring devices are used where indicated and that records are kept of the results of such monitoring.
4. Investigating any case of excessive or abnormal exposure to determine the cause and taking steps to prevent its recurrence.
5. Advise radiation workers of any unusual procedures which they must employ in order to reduce unnecessary exposure.
6. See that all license commitments and regulatory requirements have been met. To this end, Health Physics Services, Inc., Potomac, Maryland, will assist the Radiation Safety Officer in managing the overall radiation protection program.
7. Review the radiation survey reports furnished by Health Physics Services, Inc. The surveys will include the following:
  - A. Smears for spreadable contamination
  - B. Survey meter measurements in those areas where radioactive materials are used or stored
  - C. A review of all personnel dosimetry reports
  - D. A review of the records of inventory, isotope receipt, isotope disposal, and other health physics records for completeness and accuracy
  - E. Required dose calibrator instrumentation tests (e.g. accuracy and linearity)
  - F. Sealed source leak testing
  - G. Survey meter calibration results
  - H. Any other health physics records pertinent to license compliance
8. Be available to respond to any radiation emergency.

## INSTRUMENTATION

### 1. Survey Meters

Eberline E-120 with HP-190 probe, 0-50 mR/hr, monitoring

Victoreen CDV-715, 0-500 R/hr, monitoring (2 meters)

### 2. Dose Calibrator

Capintec CRC-6A

### 3. Diagnostic Instrumentation

Ludlum Model 261 spectrometer

Micromedics Model 4-200 automatic gamma counter

Medotopes Model 210 spectrometer

Medotopes Model 240 well counter

Ohio Nuclear Anger Camera Series 100

## CALIBRATION OF SURVEY METER INSTRUMENTATION

Survey meter calibrations will be conducted at intervals not to exceed six (6) months by Health Physics Services, Inc., Potomac, Maryland, using sealed a Cesium-137 source of approximately 500 mCi, authorized by the State of Maryland under License Number MD-31-035-01. The calibration procedures are on file with the NRC, under License No. 19-19791-01.

For instruments used to monitor lower energy radionuclides such as Tc-99m, etc., a correction factor is determined. After calibration with Cesium-137, a Tc-99m factor is determined by measuring the response of the instrument to a calibrated source of Cobalt-57. The exposure rate at an arbitrary distance for the Cobalt-57 source is determined using the inverse square law and verified with a calibrated dose rate meter.

### DOSE CALIBRATOR CALIBRATION AND LINEARITY PROCEDURES

1. On a daily basis, the constancy of the dose calibrator will be determined with two sources: 200uCi of Cesium-137, and greater than one millicurie of Cobalt-57. These sources are NBS traceable with an accuracy of  $\pm 5\%$ . Should the error of the constancy measurement be greater than  $\pm 5\%$ , appropriate adjustment or instrument repair will be affected.
2. At intervals not to exceed six (6) months, Health Physics Services, Inc., Potomac, Maryland, will conduct the dose calibrator accuracy test under Maryland License No. MD-31-035-01. A Cobalt-57 source of approximately 10 millicuries will be used to insure the dose calibrator accuracy. Should the calibration deviate by greater than  $\pm 5\%$ , appropriate adjustment or instrument repair will be conducted. This semi-annual procedure will be repeated using a Cesium-137 and a Barium-133 source of approximately 0.2 millicuries each. The three calibration sources are NBS traceable with an accuracy of  $\pm 5\%$ .
3. The linearity of the dose calibrator will be determined quarterly, by Health Physics Services, Inc., in accordance with the NRC Medical Licensing Guide, Appendix D, Section 2.E., over the full range of activities of Technetium used. Should the linearity (measured versus calculated) vary by greater than  $\pm 5\%$ , appropriate corrective action will be conducted.
4. Test for geometrical variation will be conducted in accordance with Appendix D, Section 2, Item F., of the NRC Medical Licensing Guide, unless certified data is supplied by the dose calibrator manufacturer.

### CALIBRATION OF DIAGNOSTIC INSTRUMENTATION

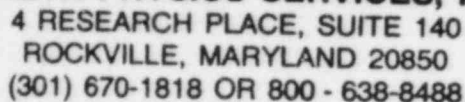
Calibrations of diagnostic instrumentation, to include gamma cameras and associated instrumentation will be conducted in accordance with the manufacturers' instructions.

Daily floods will be conducted to insure integrity of the camera.

### LEAK TESTING OF SEALED SOURCES

At intervals not to exceed six (6) months, all sealed sources of radioactive material will be leak tested by Health Physics Services, Inc., in accordance with their Maryland license, No. MD-31-035-01.





Health Physics Technician

## FACILITIES AND EQUIPMENT

### Radiation Handling Equipment

To enable personnel to work safely with unsealed radioactive materials, the Nuclear Medicine laboratory will have the proper radiation handling equipment. The following is a list of basic radiation handling equipment which is available in the Nuclear Medicine Departments.

### Shielding/Handling Equipment

Lead bricks (e.g., 2" x 4" x 8")

Lead syringe holders for transporting syringes containing radioactivity

Lead syringe shields for reducing exposure during injection of radiopharmaceuticals

Lead vial and container shields (pigs) for reducing exposure during transport and storage of vials, etc., that contain radioactive material

Remote handling devices (tongs)

If applicable, generators will be maintained in the manufacturer's lead shielding or addition lead shielding, e.g. bricks, will be utilized

### Contamination Control

Laboratory coats or uniforms

Absorbent pads (absorbent layer backed by non-absorbent plastic material) for covering work surfaces

Disposal gloves

Decontaminating agents for decontaminating hands, utensils, work areas, etc.

Signs and labels indicating the presence of radioactive materials in areas or rooms where they are being used or stored. Labels on containers indicating radionuclide, activity, and date.

### Monitoring

Appropriate survey instrumentation relative to the types and quantities of radioactive materials requested. Refer to the equipment/instrumentation listing.

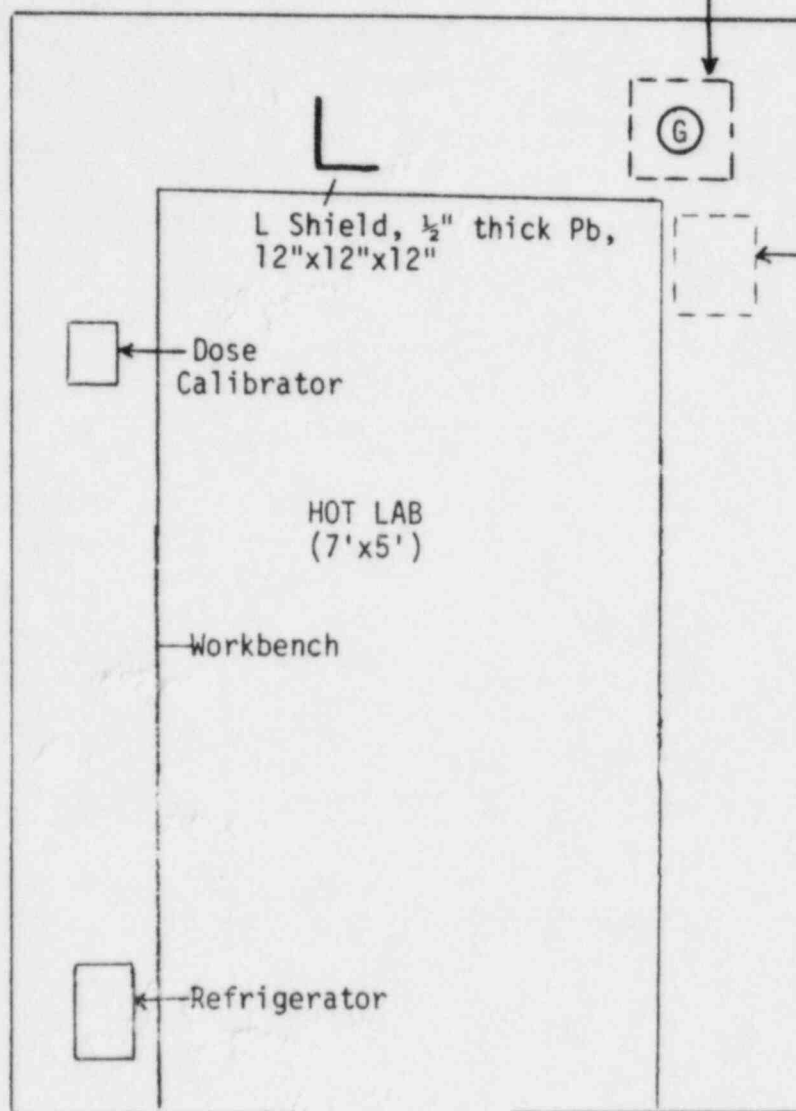
Nuclear Medicine Services, Inc.

Medical Staff Building  
Suite 911  
3100 MacCorkle Ave, S.E.  
Charleston, WV 25304

(OUTSIDE)

Generator surrounded by 2" thick  
Pb bricks, 16"x18"x10"

(SCAN ROOM)



Under counter short  
and long lived  
radioactive waste  
storage, 1/8" thick  
lead, 12"x14"x12"

(OFFICE)

(CORRIDOR)

NOTE: Hot Lab walls and door to be lead lined  
Ninth floor occupancy

## PERSONNEL TRAINING PROGRAM

The personnel training program will be given to all personnel who work with or in the vicinity of radioactive materials. The training will be in the form of lectures and the duration of each session will depend on the extent of applicability to the employees involved. The training program will be of sufficient scope to ensure that all personnel, including technical, clerical, nursing, housekeeping, and security personnel receive proper instruction in the items specified in 19.12 of 10 CFR Part 19, to include:

- A. Areas where radioactive materials are used or stored.
- B. Potential hazards associated with radioactive material
- C. Radiological safety procedures appropriate to their respective duties.
- D. Pertinent NRC regulations.
- E. Rules and regulations of the licensee.
- F. Pertinent terms of the license.
- G. Their obligation to report unsafe conditions.
- H. Appropriate response to emergencies or unsafe conditions.
- I. Their right to be informed of their radiation exposure and bioassay results.
- J. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.

Personnel will be properly instructed as follows:

- 1. Before assuming duties with or in the vicinity of radioactive materials.
- 2. During annual refresher training.
- 3. Whenever there is a significant change in duties, regulations, or the terms of the license.

#### PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. The supervising nuclear medicine technologist or his designee will place all orders for radioactive material, and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.
2. During normal working hours, carriers will be instructed to deliver packages containing radioactive material directly to the nuclear medicine laboratory.
3. There will be no radioactive material packages accepted after normal working hours.
4. A system for ordering and receiving radioactive materials will be established and maintained. The system will consist minimally of the following:
  - a. Written records that identify the isotope, compound, activity levels, supplier, etc., will be used.
  - b. The written records will be referenced when opening or storing radioactive shipments.



PROCEDURES FOR SAFELY OPENING PACKAGES  
CONTAINING RADIOACTIVE MATERIAL

For safely opening packages containing radioactive material, the technologist will:

1. Put on gloves to prevent hand contamination.
2. Visually inspect packages for any sign of damage (wetness, crushed, etc.). If damage is noted, the procedure will be stopped and the radiation safety officer notified.
3. Measure exposure rate at 3 feet from package surface and record. If greater than 10 mR per hour, the procedure will be stopped and the radiation safety officer notified.
4. Measure surface exposure rate and record. If greater than 200 mR per hour, the procedure will be stopped and the radiation safety officer notified.
5. Wipe external surface of shipping container and remove wipe to low background area. Assay the wipe and record amount of removable radioactivity (e.g., dpm/100 sq. cm., etc.). Check wipes with a thin end window GM survey meter. The procedure will be stopped if removable contamination is greater than 22,000 dpm/100 sq. cm. above background. The radiation safety officer and health physics consultant shall be notified to determine the "exempt" status of the package with respect to wipe testing. If the package is not exempt, then appropriate notification of regulatory offices will be made.
6. Open the package with the following precautionary steps:
  - A. Open the outer package following manufacturer's instructions, if supplied, and remove packing slip.
  - B. Open inner package and verify that contents agree with those on packing slip. Compare requisition, packing slip, and label on bottle.
  - C. Check integrity of final source container (i.e., inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material).
  - D. Check also that shipment does not exceed possession limits.
7. Wipe external surface of final source container and remove wipe to low background area. Assay the wipe and record amount of removable radioactivity (e.g., dpm/100 cu. cm., etc.). Check wipes with a well counter/scintillation detector or thin end window GM survey meter, and take precautions against the spread of contamination as necessary. The acceptable level of removable contamination will be 200 dpm/ 100 sq. cm. above background. The procedure will be stopped and the radiation safety officer notified if this level is exceeded.
8. Monitor the packing material and packages for contamination before discarding. If contaminated, treat as radioactive waste. If not contaminated, radiation labels will be obliterated before discarding in regular trash.

Records will be maintained of the results of checking each package (see following sample).

# RADIOACTIVE SHIPMENT RECEIPT REPORT

1. P. O. # \_\_\_\_\_ Survey Date \_\_\_\_\_ Time \_\_\_\_\_  
 (if applicable) Surveyor \_\_\_\_\_

2. CONDITION OF PACKAGE:  
 \_\_\_\_\_ O. K. \_\_\_\_\_ Punctured \_\_\_\_\_ Status \_\_\_\_\_ Wet  
 \_\_\_\_\_ Crushed \_\_\_\_\_ Other \_\_\_\_\_

## RADIOACTIVE MATERIAL PACKAGES LABEL CRITERIA (173.399) DOSE RATE LIMITS

LABEL	AT ANY POINT ON ACCESSIBLE SURFACE OF PACKAGE	AT THREE FEET FROM EXTERNAL SURFACE OF PACKAGE (TRANSPORT INDEX)
"RADIOACTIVE-WHITE I"	0.5mR/hr	0
"RADIOACTIVE-YELLOW II"	50 mR/hr	1.0 mR/hr
"RADIOACTIVE-YELLOW III"	200 mR/hr	10 mR/hr

3. Radiation Label number \_\_\_\_\_

4. MEASURED RADIATION LEVELS:

- a) Bkg = \_\_\_\_\_ mRem/hr.
- b) Package surface \_\_\_\_\_ mRem/hr.
- c) 3 feet or 1 meter from surface \_\_\_\_\_ mRem/hr.

5. Notification to the NRC or Agreement state is voluntary if mR/hr levels exceed those indicated for applicable Labels I & II. Notification of the RSO, health physics consultant, carrier, and NRC/Agreement state is mandatory if levels of exposure exceed either 10mR/hr at three feet or 200mR at the surface of the package.

6. DO PACKING SLIP AND VIAL CONTENTS AGREE?

- a. Radionuclide \_\_\_\_\_ yes \_\_\_\_\_ no, difference \_\_\_\_\_
- b. Amount \_\_\_\_\_ yes \_\_\_\_\_ no, difference \_\_\_\_\_
- c. Chem form \_\_\_\_\_ yes \_\_\_\_\_ no, difference \_\_\_\_\_

## 7. WIPE RESULTS

a. Bkg \_\_\_\_\_ CPM (Eff.= \_\_\_\_\_%) ->  $\text{CPM} \times \frac{100}{\text{eff.}} = \text{_____ bkg. DPM}$

b. Outer \_\_\_\_\_ CPM (Eff.= \_\_\_\_\_%) ->  $\text{CPM} \times \frac{100}{\text{eff.}} = \text{_____ DPM}$

c. Final source container \_\_\_\_\_ CPM (Eff.= \_\_\_\_\_%)

->  $\text{CPM} \times \frac{100}{\text{eff.}} = \text{_____ DPM}$

8. SURVEY RESULTS OF PACKING MATERIAL AND CARTONS \_\_\_\_\_ mRem/hr, CPM

9. DISPOSITION OF PACKAGE AFTER INSPECTION \_\_\_\_\_

10. IF NRC/CARRIER NOTIFICATION REQUIRED, GIVE TIME, DATE, AND PERSONS NOTIFIED.

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## GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL

1. Laboratory coats and other protective clothing will be worn at all times in areas where radioactive materials are used.
2. Disposable gloves will be worn at all times while handling radioactive materials.
3. Hands and clothing will be monitored for contamination at the end of each working day.
4. Syringe shields for preparation of patient doses and administration to patients will be used except in circumstances such as pediatric cases when their use would compromise the patient's well-being.
5. There will be no eating, drinking, smoking, or application of cosmetics in any area where radioactive material is stored or used.
6. Each patient dose will be assayed in the dose calibrator just prior to administration. Any doses that differ from the prescribed dose by more than 10% will not be used.
7. Personnel monitoring devices (film badge or TLD) will be worn at all times while in areas where radioactive materials are used or stored.\*
8. TLD finger badges will be worn during elution of generator and preparation, assay, and injection of radiopharmaceuticals.
9. Radioactive waste will be disposed of only in specially designated receptacles.
10. There will be no pipetting by mouth.
11. Kit preparation, and injection areas will be surveyed for contamination after each procedure or at the end of the day and will be decontaminated if necessary.
12. Radioactive solutions will be confined in covered containers, plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.
13. Radioactive material will always be transported and maintained in shielded containers.

\* Personnel monitoring devices will be stored in a designated low background area when not being worn.

GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL (cont'd)

14. The laboratory will be locked when personnel are not present.
15. Emergency notification home telephone numbers will be posted on the door.
16. There will be no storage of food, drink, or personal effects with radioactive material.
17. If therapeutic doses are authorized, the following will be verified with the order written by the physician who will perform the procedure:
  - A. Patient's name
  - B. Radionuclide
  - C. Chemical form
  - D. Activity



## EMERGENCY PROCEDURES

### Minor Spills

1. All persons in the area will be notified when a spill has occurred.
2. The spill will be covered with absorbent paper to prevent its spread.
3. Disposable gloves and remote handling tongs will be used to clean up the spill. The absorbent paper and pad will be carefully folded, inserted into a plastic bag and disposed of in the radioactive waste container. All other contaminated materials such as disposable gloves will also be inserted into the plastic bag.
4. The survey will be conducted using a low-range, G-M survey meter. The area around the spill, hands, and clothing will be checked for contamination.
5. The incident will be reported to the radiation safety officer.

### Major Spills

1. All persons not involved in the spill will be notified to vacate the room.
2. The spill will be covered with absorbent pads, but no attempt to clean it up will be made. The movement of all personnel potentially contaminated will be confined to prevent the spread.
3. If possible, the spill will be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.
4. The room will be vacated, and the door(s) locked to prevent entry.
5. The radiation safety officer will be notified immediately.
6. Contaminated clothing will be removed and stored for further evaluation by the radiation safety officer. If the spill is on the skin, the area will be flushed thoroughly and washed with mild soap and lukewarm water.

RADIATION SAFETY OFFICER: Steven A. Artz, M.D.

OFFICE PHONE: (304) 343-7651

HOME PHONE: (304) 344-3297

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER: \_\_\_\_\_

## AREA SURVEY PROCEDURES

The following area survey procedures will be conducted by the Chief Technologist of the department or his designee, in each area where radioactive material is used or stored:

1. Preparation and injection areas will be surveyed on a daily basis with an appropriately low range G-M survey meter and decontaminated if necessary.
2. All other laboratory areas will be surveyed weekly.
3. The weekly survey will consist of:
  - A. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mRem per hour.
  - B. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 200 dpm per 100 sq. cm. for the contamination involved.
4. A permanent record will be kept of all survey results, including negative results. The record will include:
  - A. Location, date, and type of equipment used.
  - B. Name of person conducting the survey.
  - C. A drawing of the area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.
  - D. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action).
  - E. Detected contamination levels, keyed to locations on drawing.
  - F. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.
5. The area will be cleaned if the contamination level exceeds 200 dpm per 100 sq. cm.

NOTE: For daily surveys where no abnormal exposures are found, only the date, identification of the person performing the survey and the survey results will be recorded.

DAY	DAILY CONSTANCY MEASUREMENTS*		DAILY LABORATORY SURVEY**						WEEKLY WIPE TEST SURVEY***						M	N**
	Co-57 / Cs-137		A	B	C	D	E	F	G	H	I	J	K	L		
1																
2																
3																
4																
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- A. Eye level in front of isotope prep. area  
 B. Waist level in front of storage area  
 C. Injection area  
 D. Non-radioactive waste container  
 E. Background mR/hr  
 F. Surveyor's initials

- G. Hot lab middle of floor  
 H. Scanning Area I, floor  
 I. Scanning Area II, floor  
 J. Scanning Area III, floor  
 K. Bench top, storage area  
 L. Background dpm  
 M. Surveyor's initials

N. Xenon-133 Gas Trap

\*Units in mCi  
 \*\*Units in mR/hr.  
 \*\*\*Units in dpm

(Revised 4/84)

MONTH OF \_\_\_\_\_

## WASTE DISPOSAL PROCEDURES

Solid radioactive waste will be divided into three groups: short-lived, medium-lived, and long-lived.

- A. Short-lived - Waste material with a half-life less than 1 day (24 hours) (i.e., Tc-99, I-123)
- B. Medium-lived - Waste material with a half-life between 1 - 15 days (i.e., Ga-67, Tl-201, Xe-133, I-131, P-32)
- C. Long-lived - Material with a half-life greater than 15 days

Adequate lead or other suitable shielding will be provided as necessary to reduce the radiation exposure levels to the lowest reasonable level while radioactive waste is in temporary storage.

All solid radioactive waste will be held for decay until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. Once this has been achieved, all radiation labels will be removed or obliterated, and the waste will be disposed of in normal trash. Appropriate documentation will be maintained.

Liquid radioactive waste will be disposed of in the sanitary sewage system in accordance with 10 CFR, Part 20.303, Code of Federal Regulations.

If generators are authorized, they will be disposed of by either of the following methods:

- 1. Returned to the manufacturer in accordance with applicable DOT, NRC, and/or State regulations governing the transport of radioactive materials.
- 2. Generators will be disassembled after a minimum of 10 half-lives from the original assay date. The core will be placed in the medium-lived waste container for subsequent storage and monitoring as described above. The lead will be surveyed as above and disposed of accordingly.

NOTE: The radioactive waste area is located within the hot lab/scan room, which is locked when staff personnel are not present. Radiation surveys are conducted at least weekly.

Records are maintained for each of the described disposal methods. Such records include the date of storage, amount of radioactivity, radionuclides, date of disposal, disposition of materials, and initials of the disposing individual.

# Dose Log - I-131 Capsules

Patient Name: \_\_\_\_\_

Name of individual accepting I-131 capsule: \_\_\_\_\_

Instructions reviewed with individual accepting the capsule: ☐yes ☐no

If no, explain why:

Name of individual dispensing dose and preparing form: \_\_\_\_\_  
(Must be an approved individual)

Assayed dose: \_\_\_\_\_ uCi Time: \_\_\_\_\_ AM/PM (Circle one)

Time to be administered: \_\_\_\_\_ AM/PM (Circle one)

Activity at time of  
administration: (assayed dose) x (decay factor) = \_\_\_\_\_ uCi

Date and time patient to return: Date \_\_\_\_\_ Time: \_\_\_\_\_ AM/PM

Package preparation:

Absorbent material: ☐yes ☐no

Removable contamination: lead pig: \_\_\_\_\_ dpm  
outer package: \_\_\_\_\_ dpm  
background: \_\_\_\_\_ dpm

Radiation levels (external package): \_\_\_\_\_ mR/hr (must be less than  
0.5 mRem/hr)  
background: \_\_\_\_\_

Followup:

Patient returned for evaluation: ☐yes ☐no

Comments:

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## INSTRUCTIONS TO PATIENT

Patient Name: \_\_\_\_\_

You will be given a capsule containing radioactive material in order to evaluate the function of your thyroid. The following precautions should be observed in handling the capsule:

1. The capsule should remain in the package until it is time for you to take it. It should be placed in a safe location, away from children. Please note the capsule is not a radiation hazard provided it is left in the package.
2. You are scheduled to return to this office on \_\_\_\_\_ (date) at \_\_\_\_\_ (time) \_\_\_\_\_. Once you have taken the capsule, it is very important that you keep this appointment. If you know you will be unable to keep this appointment, please do not take the capsule. Please call the office to reschedule the appointment. The capsule must be returned.
3. The capsule should be taken at \_\_\_\_\_ AM/PM on \_\_\_\_\_ (date) \_\_\_\_\_. It is very important that you take the pill at this time.
  - a. The package should be taken with a clear liquid such as water. It should not be taken with dairy products and it should not be opened.
  - b. The capsule should be opened carefully. Inside the box you will find absorbent material. If this material appears to be wet, close the box, wash your hands, and notify Dr. Artz immediately.
  - c. The capsule is inside the inner container. This container should be opened. If the capsule appears damaged or the inside of this container appears to be wet, close the container, wash your hands, and notify Dr. Artz immediately.

I understand these instructions and have no questions at this time. I will contact Dr. Artz at (304) 343-7651 if I have any problems or questions.

\_\_\_\_\_  
Patient's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of person explaining instructions

NUCLEAR MEDICINE SERVICES, INC.

STEVEN A. ARTZ, M.D.

3100 MacCorkle Ave., S.E.

Suite 911

Charleston, West Virginia 25304

Telephone (304) 343-7651

FOREWORD

Ionizing radiation is among the most versatile and useful tools of modern medicine and biomedical research. Like many other instrumentations of medicine, ionizing radiation is potentially hazardous unless used with strict adherence to safety rules and procedures. Thus, the safety rules which govern the use of radiation are concerned with preventing genetic damage as well as with protecting the health of the exposed individual.

The rules and procedures set forth here have one single, straightforward purpose: to protect the employees and visitors from unnecessary and potentially harmful radiation.

The existing radiation safety program has many facets designed to keep the levels of exposure to personnel at a minimum. This program has three main phases:

PHASE I

Achieve the objective of maintaining radiation exposures to "As Low As Reasonably Achievable" (ALARA) to employees and visitors.

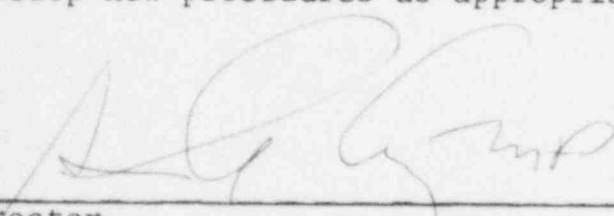
PHASE II

Control operational procedures by the user of radiation sources.

PHASE III

Evaluate the radiation safety program performed by the Radiation Safety Officer, health physics consultant, and the Radiation Safety Committee.

We, the management are committed to the program procedures and develop new procedures as appropriate to implement the ALARA concept.

  
\_\_\_\_\_  
Director

June 18, 1985  
\_\_\_\_\_  
Date

## RADIATION SAFETY PROGRAM (ALARA)

### I. INTRODUCTION

#### A. Purpose

This program sets forth the philosophy and general management policies that are established by this facility to achieve the objective of maintaining radiation exposures to "as low as reasonably achievable" (ALARA), for employees and visitors.

#### B. Policy

In addition to complying with the limits set forth in pertinent regulations, guides, and standards, users and supervisors of radiation sources shall make every reasonable effort to maintain radiation exposures as low as reasonably achievable.

### II. MANAGEMENT COMMITMENT

- A. The management and the entire staff of this facility are committed to the program described herein for keeping radiation exposures, individual and collective, to as low as reasonably achievable.
- B. We will perform a formal annual review of the radiation safety program including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.
- C. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.
- D. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

- E. The services of Health Physics Services, Inc., have been contracted to assist in the program management to insure that all pertinent employees receive appropriate briefings and training in radiation safety including ALARA concepts.

III. RADIATION SAFETY OFFICER, AND HIS CONSULTANT STAFF ARE RESPONSIBLE FOR THE FOLLOWING:

A. Annual and Quarterly Review

1. Annual review of the Radiation Safety Program. The RSO will perform an annual review of the Radiation Safety Program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.
2. Quarterly review of Occupational Exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of paragraph VII of this program.
3. Quarterly review of records of Radiation Level Surveys. The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

B. Education Responsibilities for an ALARA Program

1. The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.
2. The RSO will assure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in ALARA philosophy and informed that management, the RSC and the RSO are committed to implementing the ALARA concept.

C. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in the formulation of the procedures that they will be required to follow.

1. The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
2. The KSO will establish procedures for receiving and evaluating the suggestion of individual workers for improving health physics practices and encourage the use of those procedures.

D. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

IV. PERSONS WHO RECEIVE OCCUPATIONAL RADIATION EXPOSURE

- A. The worker will be instructed in the ALARA concept and its relationship to his working procedures and work conditions.
- B. The worker will know what recourses are available if he feels that ALARA is not being promoted on the job.

V. ESTABLISHMENT OF INVESTIGATIONAL LEVELS IN ORDER TO MONITOR INDIVIDUAL OCCUPATIONAL EXTERNAL RADIATION EXPOSURES

This institution hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the Radiation Safety Officer or consultant staff. The Investigational Levels that we have adopted are listed in Table 1 below. These levels apply to the exposure of individual workers.

TABLE 1

	Investigational Levels - (mrems per calendar quarter)	
	<u>LEVEL I</u>	<u>LEVEL II</u>
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2. Hands and forearms; feet and ankles	1875	5625
3. Skin of whole body*	750	2250

\* Not normally applicable to medical facilities except those using significant quantities of beta emitting isotopes.

The Radiation Safety Officer will review the results of personnel monitoring, film badge report, not less than once in any calendar quarter, as is required by 10 CFR 20, 20.401. The following actions will be taken at the Investigational Levels as stated in Table 1:

- A. Quarterly exposure of individuals to less than Investigational Level I.



Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table 1 values for the Investigational Level I.

- B. Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.

The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required.

- C. Exposure equal to or greater than Investigational Level II.

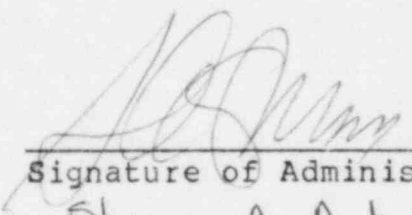
The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, take action. The investigation will be documented and made available to NRC inspectors for review at the time of the next inspection.

- D. Re-establishment of an individual occupational worker's Investigational Level II above that listed in Table 1.

In cases where a worker's or a group of workers' exposure needs to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

#### VI. SIGNATURE OF CERTIFYING OFFICIAL

I hereby certify that this institution has implemented the ALARA Program set forth above.

  
\_\_\_\_\_  
Signature of Administrator

Steven A. Artz, M.D.

\_\_\_\_\_  
Name (type or print)

President

\_\_\_\_\_  
Title