NRC FORM 313
(1-84)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 5-31-87

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- [X] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip Code)*

Plateau Medical Center
420 Main Street
Oak Hill, WV 25901

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.

Plateau Medical Center
420 Main Street
Oak Hill, WV 25901

47-25469-01
030-35028

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Brian Mooney

TELEPHONE NUMBER

(304) 469-8626

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL. a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.
9. FACILITIES AND EQUIPMENT.	10. RADIATION SAFETY PROGRAM.
11. WASTE MANAGEMENT.	12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)* FEE CATEGORY 7.C. AMOUNT ENCLOSED $ 1800.00

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE—CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
Hank Woodson	Hank Woodson	Administrator	4/23/99

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS

- [ ] <$250K
- [ ] $250K–500K
- [ ] $500K–750K
- [ ] $750K–1M
- [ ] $1M–3.5M
- [ ] $3.5M–7M
- [ ] $7M–10M
- [ ] >$10M

b. NUMBER OF EMPLOYEES *(Total for entire facility excluding outside contractors)*

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION *(dollar and/or staff hours)* ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? *(NRC regulations permit it to protect confidential commercial or financial—proprietary—information furnished to the agency in confidence)*

- [ ] YES
- [ ] NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
AMOUNT RECEIVED	CHECK NUMBER			DATE

PRIVACY ACT STATEMENT ON THE REVERSE

258347

NMSS/RGNI MATERIALS-002

RADIOACTIVE MATERIAL

Byproduct Material	Amount	Purpose
5.a. Material in 35.100	As needed	6.a. Medical Use
5.b. Material in 35.200 except Xenon-133.	As needed	6.a. Medical Use

AUTHORIZED USER / RADIATION SAFETY OFFICER

Radioactive materials will be used by or under the supervision Ali Goodarzi, MD. Dr. Goodarzi will act as both the Authorized User (for both 35.100 and 35.200 material) and as Radiation Safety Officer.

Dr. Ali Goodarzi currently holds certification from the American Board of Radiology in Diagnostic radiology. A copy of his certification is attached as ATT 7.1.1. Also attached as ATT 7.1.2 is a copy of the Meritus PLS, Inc. NRC license (license number 45-25194-01) listing Dr. Goodarzi as an authorized user under their license.

The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association
and the American Society of Therapeutic Radiologists
Hereby certifies that

Ali A. Goudarzi, M.D.

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology
On this seventh day of June, 1980
Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of

~~Diagnostic Radiology~~ RADIOLOGY

E. Richard Levy, President C. Allen Good, Secretary

THIS COPY IS AUTHENTIC
THE ABR

AMERICAN BOARD OF MEDICAL SPECIALTIES

ATT 7.1.1

4-7-98

NRC FORM 374 (7-94) U.S. NUCLEAR REGULATORY COMMISSION PAGE 1 OF 4 PAGES

MATERIALS LICENSE

Amendment No. 9

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

Licensee	
1. Meritus PLS, Inc. (formerly Meritus Health Systems, Inc.)	In accordance with letter dated April 9, 1997 3. License Number 45-25194-01 is amended in its entirety to read as follows:
2. 233 Hershberger Road Suite 200 Roanoke, Virginia 24012	4. Expiration Date July 31, 2002
	5. Docket or Reference No. 030-32701

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200, except xenon 133	B. As needed, except no single patient dose of I-125 or I-131 to exceed 1.11 megabecquerels (30 1Ci)
C. Uranium depleted in uranium 235	C. Metal	C. 999 kilograms

9. Authorized Use:

A. Medical use in uptake, dilution and excretion studies identified in 10 CFR 35.100

B. Medical use in imaging and localization studies identified in 10 CFR 35.200

C. Shielding for molybdenum-99/technetium-99m generators

CONDITIONS

10. A. Licensed material shall be used only at temporary job locations of the licensee in Virginia and West Virginia.

B. Notwithstanding the requirement of 10 CFR 35.80(a), the licensee may transport molybdenum-99/technetium-99m generators to temporary job locations for use only within the mobile nuclear medicine facility.

258347

FORM 374A U.S. NUCLEAR REGULATORY COMMISSION

PAGE 3 OF 4 PAGES
License Number 45-25194-01
Docket or Reference Number 030-32701
Amendment No. 9

MATERIALS LICENSE SUPPLEMENTARY SHEET

(Continued) CONDITIONS

	Authorized users	Material and Use
E.	Michael E. Shahan, M.D.	Medical uses described in 10 CFR 35.100 and 35.200.
F.	Ezad N. Ahmad, M.D.	Technetium 99m radiopharmaceuticals for cardiac imaging studies.
G.	M. R. Ramakrishnan, M.D.	Medical uses described in 10 CFR 35.100 and 35.200.
H.	Je Hyun Kim, M.D.	Medical uses described in 10 CFR 35.100 and 35.200.
I.	Steven A. Artz, M.D.	Medical uses described in 10 CFR 35.100 and 35.200.
J.	Ali Goodarzi, M.D.	Medical uses described in 10 CFR 35.100 and §35.200.
K.	Stephen P. Raskin, M.D.	Medical uses described in 10 CFR 35.100 and 35.200.
L.	Emily Wang Lewis, M.D.	Medical uses described in 10 CFR 35.100 and 35.200.
M.	F. Caryle Stebner, M.D.	Medical uses described in 10 CFR 35.100 and 35.200.
N.	M. S. Kim, M.D.	Medical uses described in 10 CFR 35.100 and 35.200.
O.	J. K. Kim, M.D.	Medical uses described in 10 CFR 35.100 and 35.200.
P.	Yvonne J. Weaver, M.D.	Technetium 99m radiopharmaceuticals for cardiac imaging.
Q.	Vincent J. Mascatello, M.D.	Medical uses described in 10 CFR 35.100 and 35.200.
R.	Scot A. LeBolt, M.D.	Medical uses described in 10 CFR 35.100 and 35.200.
S.	Dennis Joseph McCabe, M.D.	Medical uses described in 10 CFR 35.100 and 35.200.
T.	Mark Cameron Lopiano, M.D.	Medical uses described in 10 CFR 35.100 and 35.200.
U.	Herbert P. Rhodes, M.D.	Medical uses described in 10 CFR 35.100 and 35.200.

13. Prior to vacating or releasing any field office or storage location authorized by this license, the licensee shall notify the Nuclear Regulatory Commission in accordance with the provisions of 10 CFR 30.36.

14. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

15. The licensee shall maintain records of information important to safe and effective decommissioning at 233 Hershberger Road, Roanoke, Virginia, pursuant to the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

16. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum specified 10 CFR 30.35 for establishing decommissioning financial assurance.

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 and content 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, housekeeping, and security personnel receive proper instruction in the items specified in applicable § 19.12 of 10 CFR Part 10, to include:

A. Areas where radioactive materials are used or stored.

B. Potential hazards associated with radioactive materials.

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:

A. Before assuming duties with or in the vicinity of radioactive materials.

B. During annual refresher training.

C. Whenever there is a significant change in duties, regulations, or the terms of the license.

FACILITIES AND EQUIPMENT

9.1 Annotated Drawing - Appended as ATT 9.1.

9.2 Survey Instrument Calibration Procedures

We have developed a survey instrument calibration procedure for your review that is appended as ATT 9.2.

9.3 Dose Calibrator Calibration Procedures

We have developed a dose calibrator calibration procedure for your review that is appended as ATT 9.3.

9.4 External Monitoring Program

We have developed an external monitoring program for your review that is appended as ATT 9.4.

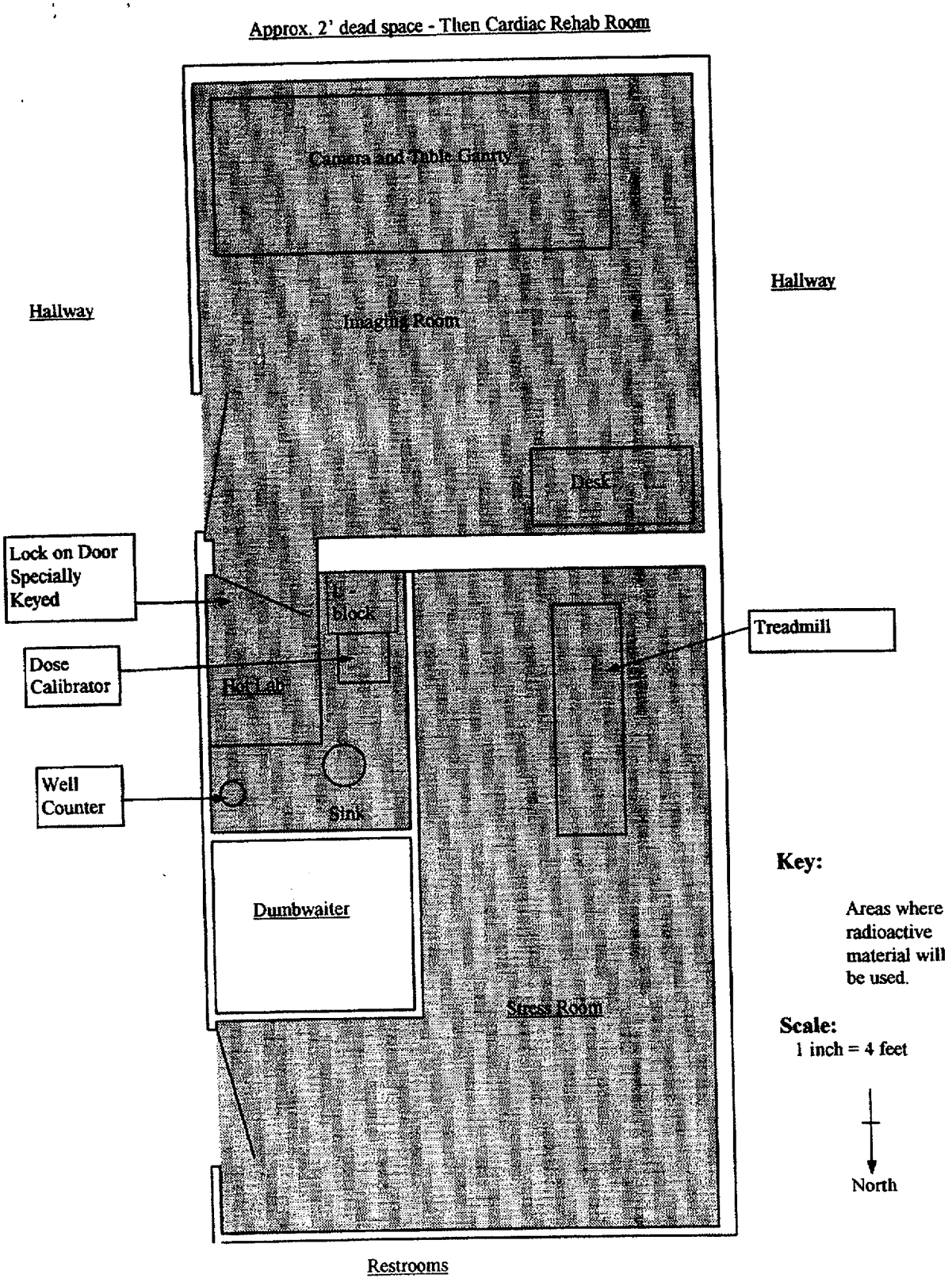
9.5 Imaging Equipment

NA -- We are not transporting imaging equipment as part of a mobile nuclear medicine service, and therefore, are not submitting a procedure for checking the equipment to ensure the unit is not damaged in transit.

9.6 Other Equipment

We have developed a list of "to be purchased" radiation detection and measuring equipment and other equipment and facilities for the use and storage of material. The list is appended as ATT 9.6

A[illegible]9.1


Approx. 2' dead space - Then Cardiac Rehab Room
Camera and Table Gantry
Hallway
Hallway
Imaging Room
Desk
Lock on Door Specially Keyed
Pb block
Treadmill
Dose Calibrator
Hot Lab
Well Counter
Sink
Dumbwaiter
Stress Room
Key:
Areas where radioactive material will be used.
Scale:
1 inch = 4 feet
North
Restrooms

CALIBRATION OF SURVEY METER INSTRUMENTATION

Survey meter calibrations will be conducted at intervals not to exceed twelve months by an NRC or Agreement State licensed firm such as AM Calibrations, Gaithersburg, Maryland, using a sealed ^{137}Cs source of sufficient activity.

Adequate survey meter instrumentation will be on hand at the facility at all times. This includes those times when survey meter calibrations/repair is necessary.

SURVEY METER CALIBRATION PROCEDURES

Source

Sealed ^{137}Cs source of sufficient activity (not to exceed 400 mCi), authorized under an NRC or Agreement State license for calibration purposes. The exposure rate at discrete distances has been determined with NIST traceable ion chambers by a certified radiological physicist.

Procedure

1. Turn on instrument to be calibrated and check batteries, etc. Replace as necessary.
2. Prepare calibration certificate in duplicate.
3. Unlock calibrator and turn on.
4. Compare instrument at two points on each scale (approximately 30% and 70% of scale) to known exposure levels. If deviation from the true exposure rate exceeds ±20%, make appropriate adjustments in accordance with the instrument manual.
5. After appropriate adjustments, repeat Item 4 above. If deviations still exceed ±20%, forward for appropriate maintenance with customer's consent.
6. Complete a calibration certificate and insure that the true exposure and meter response is listed for two points on each scale. Also give correction factor for each scale.
7. Turn off and lock calibrator, and sign the certificate.
8. Insure that certificate accompanies instrument when returned to customer.
9. Affix calibration sticker with date of calibration on side of meter and pack for shipping.
10. Check the response of the dedicated internal check source and note the reading on the calibration sticker.

DAILY SURVEY METER CHECK

On a daily basis, survey meter response will be checked using the owner supplied or built in check source.

DOSE CALIBRATOR CALIBRATION PROCEDURES

1. The following tests will be performed at the frequency indicated. Repair, replacement, or other corrective actions will be considered if the dose calibrator falls outside the indicated tolerances.

   A. Constancy will be checked at least once each day prior to assay of any patient dose. A corrective action level of ±10% will be used. Constancy will be evaluated per ATT 9.3.1.

   B. Linearity will be checked upon installation, after repair, and at least quarterly thereafter. A corrective action level of ±10% will be used. Linearity will be evaluated per ATT 9.3.2.

   C. Geometric dependency will be evaluated upon installation and following repair or maintenance. A corrective action level of ±10% will be used. Geometric independence will be evaluated per ATT 9.3.3.

   D. Accuracy will be evaluated upon installation, after repair, and at least annually thereafter. A corrective action level of ±10% will be used. Accuracy will be evaluated per ATT 9.3.4.

DOSE CALIBRATOR CONSTANCY

Dose calibrator constancy will be evaluated on each day the dose calibrator is used, prior to patient dose assay. At least one source will be used with a reproducible geometry. The source(s) will have a minimum activity of 10 μCi of ^{226}Ra or 50 μCi of any other photon emitting radionuclide.

PROCEDURE:

1. If applicable, the test voltage will be checked to ensure that the operation of the unit is within ±20% of the battery voltage.

2. The background will be measured to confirm proper operation of either the automatic or manual background subtract circuit.

3. The source will be assayed using the appropriate dose calibrator setting. The result will be recorded.

4. The source used for constancy will be decayed so that the activity of the source on the day of measurement is known. The result will be maintained on a daily basis.

5. The source will then be assayed on all commonly used settings. The results will be recorded. Records must include the model and serial number of the dose calibrator, the identity of the radionuclide contained in the check source, the date of the test, the activity measured, and the initials of the individual performing the test.

6. Action levels will be established and maintained on file for each setting. Values obtained during constancy checks will be evaluated against these action levels.

7. If activities measured exceed ±10% of the predicted activity, either the RSO or Nuclear Medicine Technologist will be notified and will ensure that the dose calibrator is repaired or replaced as required by 10 CFR §35.50.

DOSE CALIBRATOR LINEARITY

Dose calibrator linearity will be evaluated upon installation, after repair, and at least annually. This test will be done using a vial or syringe of ^{99m}Tc whose activity is at least as large as the maximum activity normally assayed in a prepared radiopharmaceutical kit, in a unit dosage syringe, or in a radiopharmaceutical therapy dose, which ever is largest. The linearity test will be performed using either the Decay Method described below or an approved sleeve method per manufacturer's instructions.

Decay Method

1. Assay the ^{99m}Tc syringe or vial in the dose calibrator and subtract the background, if applicable, to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity.

2. Repeat the above assay at least daily until the activity is less than 30 μCi.

3. Either manually or using a computer program:

   a. Convert the time and date information recorded to elapsed time.

   b. Use the decay equation with one of the data points as a reference or linear regression (natural log of activity vs. elapsed time) to determine a predicted activity at each reading time. Calculate the percent deviation from the predicted activity. [% deviation = 100 x ($A_{observed}$ - A_{line}) / A_{line}]

   c. The following will be recorded: the model and serial number of the dose calibrator, the calculated and measured activities, dates of the test, and the identity of the individual(s) performing the test.

4. If the worst deviation is more than ±10%, the RSO or Nuclear Medicine Technologist will be notified and will ensure the unit will either be repaired or mathematically corrected as required by 10 CFR §35.50.

5. The RSO will review and sign all Dose Calibrator Linearity test reports.

DOSE CALIBRATOR GEOMETRY INDEPENDENCE

Dose calibrator geometric independence will be evaluated upon installation and after repair. The test will be performed for 3-cc plastic syringes and 30-cc glass vials, if radiopharmaceutical kits are to be prepared.

Syringe Method

1. Draw 0.5-cc of ^{99m}Tc solution with activity of approximately 1 - 20 mCi into a 3-cc syringe.
2. Assay the syringe. Record the volume and activity indicated by the dose calibrator.
3. Draw another 0.5-cc of non-radioactive saline into the syringe.
4. Repeat steps #2 and #3 until a volume of 3-cc has been assayed and recorded. The entire process should take less than 5 minutes to negate the effects of radioactive decay.
5. Pick one of the data points as a standard activity. For all other volumes, calculate the percent deviation from the standard activity. [% deviation = $100 \times (A - A_{standard}) / A_{standard}$]

Vial Method

1. Draw 1-cc of ^{99m}Tc solution with activity of approximately 1 - 20 mCi into a 30-cc vial.
2. Assay the vial. Record the volume and activity indicated by the dose calibrator.
3. Continue drawing non-radioactive saline into the vial, assaying the vial, and recording the results until a 20-cc volume has been assayed. (Typically, draw assay volumes of 1, 2, 5, 10, 15, and 20-cc.) The entire process should take less than 5 minutes to negate the effects of radioactive decay.
4. Pick one of the data points as a standard activity. For all other volumes, calculate the percent deviation from the standard activity. [% deviation = $100 \times (A - A_{standard}) / A_{standard}$]

If any of the percent deviations exceed ±10%, a correction factor will need to be determined for the given point. The correction factor will be used to mathematically correct future assayed dosages.
[Correction Factor = $A_{standard} / A$]

Records of the test will include the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and identity of the individual performing the test.

The RSO will review and sign all Dose Calibrator Geometric Independence test reports.

DOSE CALIBRATOR ACCURACY

Dose calibrator accuracy will be evaluated upon installation, after repair, and at least annually. At least two sealed sources containing different radionuclides will be used. The sources will be certified by the manufacturer to be within 5% of the stated activity. One of the sources must have a principal photon energy between 100 keV and 500 keV. Each source must also have an activity of at least 10 μCi for ^{226}Ra or 50 μCi for any other photon-emitting radionuclide.

1. Assay each calibrated reference source at the appropriate setting. Remove the source and measure background. Subtract the background from the indicated activity to obtain the net activity.

2. Calculate the actual source activity based on the activity provided by the manufacturer and correcting for decay.

3. Calculate the percent deviation between the measured activity and the actual decayed activity. [% deviation = $100 \times (A_{measured} - A_{actual}) / A_{actual}$]

4. Record the model and serial number of the dose calibrator, the calculated and measured source activities, the date of the test, and the identity of the individual performing the test.

5. If the percent deviation exceeds ±10% for either source, either the RSO or Nuclear Medicine Technologist will be notified and will ensure that the dose calibrator is repaired or replaced as required by 10 CFR §35.50

6. The RSO will review and sign all Dose Calibrator Accuracy test reports.

PERSONNEL MONITORING PROGRAM

1. The RSO or his/her designee will promptly review all exposures to look for workers or groups of workers whose exposures are unexpectedly high or low. This procedure does not apply to backup monitor records, for example, pocket ionization chambers, when the monitor of record is a film, TLD, or some other NVLAP accredited dosimetry device.
2. Individuals who are occupationally exposed to ionizing radiation where the potential exists for exposure to exceed 10% of the occupational dose limits will wear dosimeters (film, TLD, or some other device) that are processed by a NVLAP accredited contract service (Landauer, ICN, etc.). This will exclude all personnel who are exposed to radiation on an occasional basis, such as security and secretarial personnel from wearing dosimetry devices.
3. Individuals who, on a regular basis, handle radioactive material that emit ionizing radiation where the potential exists for exposure to exceed 10% of the occupational extremity dose limit will wear extremity monitoring devices, such as ring TLDs. The extremity monitoring devices will be provided and processed by a NVLAP accredited contract service (such as Landauer, ICN, etc.).
4. Personnel dosimetry devices will be issued to employees pursuant to 10 CFR § 20.1201.
5. Personnel dosimetry devices will be supplied by a NVLAP accredited contract service such as Landauer, Inc., or ICN Dosimetry.

OTHER EQUIPMENT AND FACILITIES

We are in the process of purchasing the following types of radiation detection and measurement equipment. We will notify the NRC of any deviations from the list of types of equipment below. At a minimum, we will have purchased the following types of equipment prior to using radioactive materials for medical use.

Imaging Equipment

We are in the process of purchasing a Toshiba Nuclear Medicine camera.

Detection Equipment

Survey Meters:

We will be purchasing two surveys meters, prior to beginning use of licensed materials. We will likely be purchasing instruments such as a Ludlum 14C and/or Bicron 2000 meters with pancake and/or end window detectors.

Dose Calibrator:

We will be purchasing a dose calibrator, such as an Atomlab 100 or Capintec dose calibrator. The dose calibrator will be received and calibrated (as per the Dose Calibrator Calibration procedures outlined in this document) prior to the administration of any licensed materials to patients.

Well Counter:

We are purchasing a Ludlum 2200 scaler with well counter, or similar instrument, for counting removable contamination surveys (package wipes, areas wipes, etc.).

Shielding/Handling Equipment

Syringe shields – 3cc and 6 cc sizes,
2 Lead shielded syringe disposal system – One for short half-life materials (^{99m}Tc), one for long half-life materials (^{201}Tl, etc.),
L-block,
Lead bricks,
Leaded waste container(s).

RADIATION SAFETY PROGRAM

10.1 Radiation Safety Committee / Radiation Safety Officer

We have developed a Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority that is appended as ATT 10.1.

10.2 ALARA Program

We have developed an ALARA program for your review that is appended as ATT 10.2.

10.3 Leak Test Procedure

We have developed a lead testing procedure for your review that is appended as ATT 10.3.

10.4 Safe Use of Radiopharmaceuticals

We have developed rules for the safe use of radiopharmaceuticals for your review that are appended as ATT 10.4.

10.5 Spill Procedures

We have developed spill procedures for your review that are appended as ATT 10.5.

10.6 Ordering and Receiving

We have developed a procedure for ordering and receiving radioactive material for your review that is appended as ATT 10.6.

10.7 Opening Packages

We have developed a procedure for safely opening packages containing radioactive materials for your review that is appended as ATT 10.7.

10.8 Unit Dose Records

We have developed a procedure for a unit dosage record system for your review that is appended as ATT 10.8.

10.9 Multi-dose Vial Records

We have developed a procedure for a multi-dosage vial record system for your review that is appended as ATT 10.9.

10.10 Molybdenum Concentration Records

We have developed a procedure for molybdenum concentration record-keeping system for your review that is appended as ATT 10.10.

10.11 Implant Source Use Record

NA – We will not be involved in implanting radioactive sources within patients.

10.12 Area Survey Procedures

We have developed survey procedures for your review that are appended as ATT 10.12.

10.13 Air Concentration Control

1. NA – We will not be using radioactive gasses.
2. We will collect spent aerosol in shielded single use trap devices.
3. We will not directly vent spent aerosols to the atmosphere and therefore no effluent estimations is necessary.
4. NA – We will not be using any radioactive gasses.

10.14 Radiopharmaceutical Therapy

NA -- We will not be administering radioactive iodine in quantities exceeding 30 mCi at this facility.

10.15 Implant Therapy

NA -- We will not be performing brachytherapy implant therapy procedures under this license.

10.16 Quality Management Rule

NA -- We will not be performing studies (such as radiopharmaceutical therapy and administration of I-131 sodium iodide in quantities exceeding 30 μCi) for which a radiopharmaceutical Quality Management Program is required.

Radiation Safety Committee Charter

Plateau Medical Center, Inc.

Charge: The Committee shall:

1. Ensure that licensed materials will be used safely. This includes review as necessary of training programs, equipment, facilities, supplies, and procedures;
2. Ensure that licensed material is used in compliance with NRC regulations and the institutional license;
3. Ensure that the use of licensed material is consistent with the ALARA philosophy and program;
4. Establish a table of investigational levels for individual occupational radiation exposures; and
5. Identify program problems and solutions.

Responsibilities: The Committee shall:

1. Be familiar with all pertinent NRC regulations, the license application, the license, and amendments;
2. Review the training and experience of the proposed authorized users and the Radiation Safety Officer (RSO) to determine that their qualifications are sufficient to enable the individuals to perform their duties safely and are in accordance with the regulations and the license;
3. Review on the basis of safety and approve or deny, consistent with the limitations of the regulations, the license, and the ALARA philosophy, all requests for authorization to use radioactive material within the institution;
4. Prescribe special conditions that will be required during a proposed method of use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures;
5. Review quarterly the RSO's summary report of the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive;
6. Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials are used (e.g., nursing, security, housekeeping, physical plant) are appropriately instructed as required in §19.12 of 10 CFR Part 19;
7. Review at least annually the RSO's summary report of the entire radiation safety program to determine that all activities are being conducted safely, in accordance with NRC regulations and the conditions of the license, and consistent with the ALARA program and philosophy. The review must include an examination of records, reports from the RSO, results of NRC inspections, written safety procedures, and the adequacy of the management control system;
8. Recommend remedial action to correct any deficiencies identified in the radiation safety program;
9. Maintain written minutes of all committee meetings, including members in attendance and members absent, discussions, actions, recommendations, decisions, and numerical results of all votes taken; and
10. Ensure that the byproduct material license is amended if required prior to any changes in facilities, equipment, policies, procedures, and personnel.

Administrative Information:

1. The committee shall meet as often as necessary to conduct its business, but not less than once in each calendar quarter.
2. Membership must include at least one authorized user for each type of use authorized under the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor the RSO. Management may appoint alternate members to participate in meetings in the case of absence of principal members.
3. To establish a quorum, one half of the committee's membership, including the RSO and the management representative, must be present.
4. To the extent that they do not interfere with the mission of the Committee, management may assign other responsibilities such as x-ray radiation safety, quality assurance oversight, etc. to the Committee.

c. Personnel dose 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, will take action. A report of the investigation and any actions taken will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be included in the RSC minutes.

d. Re-establishment of investigational levels to levels above those listed in Table 1.

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

Table 1

Investigational Levels

	Investigational Levels (mrem per calendar quarter)	
	Level I	Level II
1. Total Effective Dose Equivalent	125	375
2. Lens of the Eye	375	1125
3. Skin / Extremities	1250	3750
4. Total Organ Dose (Maximally Exposed Organ)	1250	3750

7. Signature of Certifying Official

I hereby Certify that this facility has implemented the ALARA Program set forth above.

Signature Hank Woodson

Name Hank Woodson, Administrator

Date 4/23/99

'lateau Medical
Center, Inc.

430 Main Street

Oak Hill, WV 25901

Phone (304) 469-8600

Fax (304) 469-8605

TO: All Employees

FROM: Hank Woodson, Administrator

DATE: April 23, 1999

RE: Delegation of Radiation Safety Officer

Ali A. Goodarzi, MD, has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of radiation. The Radiation Officer is responsible for managing the radiation safety program, identifying radiation safety problems, initiating, recommending or providing corrective actions, verifying implementation of corrective actions and ensuring compliance with regulations. The Radiation Safety Officer is hereby delegated the authority necessary to meet those requirements.

BM:HW:spj

An Affiliate of
Heritage Health
System, Inc.

258347

ALARA PROGRAM

Plateau Medical Center

DATE: _____

1. Management Commitment

   a. The management of Plateau Medical Center are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accordance with this commitment, we hereby describe administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).

   b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the staff and/or outside health physics consultants.

   c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if 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 when reasonable. If 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.

2. Radiation Safety Committee

   a. Review of Proposed Users and Uses

      (1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposures ALARA.

      (2) When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposures ALARA.

      (3) The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

   b. Delegation of Authority

      (1) The RSC will delegate authority to the RSO for enforcement of the ALARA concept.

      (2) The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.

c. Review of ALARA Program

(1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

(2) The RSC will perform a quarterly review of occupational radiation exposures with particular attention to instance in which the investigational levels in Table I are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded (see section 6 below for a discussion of investigational levels).

(3) The RSC will evaluate our institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. Radiation Safety Officer (RSO), and Consultant Staff

a. Annual and Quarterly Review

(1) Annual review of the Radiation Safety Program. The RSO with the assistance of the health physics consultant 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 with the assistance of the health physics consultant will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 6 of this program and will prepare a summary report for the RSC.

(3) Quarterly review of records of radiation surveys. The RSO with the assistance of the health physics consultant will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter and will prepare a summary report for the RSC.

b. Education Responsibilities for ALARA Program

(1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

(2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the 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 formulating 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 RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO with the assistance of the health physics consultant will investigate all known instances of deviation from hood ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

4. Authorized Users

a. New Methods of Use Involving Potential Radiation Doses

(1) The authorized user will consult with the RSO and/or RSC during the planning stage before using radioactive materials for the new uses.

(2) The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.

b. Authorized User's Responsibilities to Supervised Individuals

(1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.

(2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Individuals Who Receive Occupational Radiation Doses

a. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.

b. Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.

6. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Doses

This insitiution hereby establishes investigational levels for occupational radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the doses of individual workers.

The RSO will review the results of personnel monitoring not less than once in any calendar quarter. The following actions will be taken at the investigational levels as stated in Table 1:

a. Personnel dose 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 dose is less than Table 1 values for the Investigational Level I.

b. Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II.

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the committee minutes.

Procedure for Leak Testing Sealed Sources

At intervals not to exceed six month, leak testing will be performed on all sealed sources of radioactive materials required by § 35.59 to be leak tested. (A health physics consultant, such as the Charleston Area Medical Center's health physicist, will typically perform testing on site following the procedure listed below.)

1. A list of all sources to be tested will be made. The list will include at least the isotope, the activity on a specified date, and the physical form.
2. A separate wipe sample shall be prepared for each source. An injection prep pad, filter paper, tissue paper, or cotton tip applicator will be used. Each wipe will be labeled/numbered against the inventory list. As all sealed sources used are small in size, the entire accessible surface area shall be wiped. Particular attention will be made to seams and joints.
3. Samples will be analyzed as follows:
    a. An instrument that is sufficiently sensitive to detect 0.005 microcuries shall be used. At a minimum, a crystal with a ratemeter or scaler will be used.
    b. The detection efficiency of the counting system used to assay the wipe samples will be calculated using a check source whose activity is certified by the supplier. The isotope within the check source will either be the same as the sealed source or of similar energy. Calculations shall demonstrate that the instrument will be sufficiently sensitive to detect 0.005 microcuries.
    c. The wipe will be assayed. It will be measured with the same geometry relative to the detector as the check source.
    d. The wipe sample assay shall be recorded in counts per minute and microcuries (or some other multiple curie unit).
    e. The same analysis procedure shall be performed for all leak test samples.
    f. If the lead test activity is 0.005 microcuries or greater, the RSO shall be notified. The source must be withdrawn from use to be repaired or discarded. If it is a source distributed under a NRC or Agreement State license, the NRC must be notified. (See § 21.21(b) of 10 CFR Part 21 and §35.59(e)(2) of 10 CFR Part 35.)
    g. Sign and date the list of sources, data, and calculations.
4. The RSO will review and sign the inventory and leak testing reports.

RULES FOR THE SAFE USE OF RADIOACTIVE MATERIALS

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
2. Wear disposable gloves at all times while handling radioactive materials.
3. Hands and clothing will be monitored for contamination with a survey meter in a low-background area before leaving areas where radioactive materials are used and at the end of each working day.
4. Use syringe shields for routine administrations of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated and would compromise the patient's well being.
5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
6. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.
7. Wear personnel monitoring devices, if recommended by the RSO, at all times while in areas where radioactive materials are used or stored. When not being worn to monitor occupational exposures, personnel monitoring devices should be stored in the work place in a designated low background area.
8. Wear a finger exposure monitoring devices, if recommended by the RSO, during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals; and when holding patients during procedures.
9. Dispose of radioactive waste only in specifically designated, labeled receptacles.
10. Never pipette by mouth.
11. Radiopharmaceutical preparation and injection areas will be surveyed for contamination with a survey meter at the end of each day. If necessary, decontaminate or secure the area for decay as appropriate.
12. Preparation, injection, and storage areas will be wipe tested weekly for removable contamination. If necessary, decontaminate or secure the area for decay.
13. Confine radioactive solutions in shielded containers that are clearly labeled. Radiopharmaceutical multi-dose vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation. A log, either electronic (computer) or manual (log book), will be used to record the preceding information and the total prepared activity, specific activity at a specified time, total volume prepared, total volume remaining, and measured activity of each patient dosage, and any other appropriate information. Syringes and unit dosages should be labeled with the radiopharmaceutical name or abbreviation, type of study, or the patient's name and identification number.
14. Assay each gamma emitting patient dosage in the dose calibrator before administering it. Do not administer the dosage if it does not meet the criteria outlined in the RSC approved "Radiopharmaceutical Dose List" or without the consent of an Authorized User. When measuring dosages, this facility will not consider the radioactivity that adheres to the syringe wall or remains in the needle as significant. The patient's name and identification number and the prescribed radionuclide, chemical form, and dosage will be checked prior to administration.
15. Always keep flood sources, syringes, waste, and other radioactive materials in shielded containers.
16. Because sources with small amounts of radioactivity exhibit a high dose rate on contact, the staff will endeavor not to hold items (such as flood sources, and waste) in their arms or next to their bodies so as to maintain the ALARA principal. These items will be moved by wheelchair or cart.

EMERGENCY SPILL PROCEDURES

Minor Spills of Liquids and Solids

1. Notify persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill with absorbent paper.
3. Clean up the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
4. Survey the area with a low-range radiation detection survey meter. Check the area around the spill. Also check your hands, clothing, and shoes for contamination.
5. Report the incident to the Radiation Safety Officer (RSO).
6. The RSO will follow up on the cleanup of the spill and will complete a Radioactive Spill Report.

Major Spills of Liquids and Solids

1. Clear the area. Notify all persons not involved in the spill to vacate the room.
2. Prevent the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.
3. Shield the source if possible. This should be done only if it can be done without further contamination or a significant increase in radiation exposure.
4. Close the room and lock or otherwise secure the area to prevent entry.
5. Notify the RSO immediately.
6. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.
7. The RSO or appropriate designee will supervise the cleanup of the spill and will complete an Radioactive Spill Report.

Major Spills and Minor Spills

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident specific variables such as the number of individuals affected, other hazards present, likelihood of spread of contamination, and types of surfaces contaminated as well as the radiotoxicity of the spilled material. For some spills of short-lived radionuclides, the best spill procedure may be restricted access pending complete decay.

Relative Hazards of Common Radionuclides

Estimate the amount of radioactivity spilled. Initiate a major or minor spill procedure based on the following dividing line. Spills above these millicurie amounts are considered major, below are considered minor.

Radionuclide	Millicuries	Radionuclide	Millicuries
Cr-51	100	In-111	10
Co-57	100	I-123	10
Co-58	10	I-125	1
Ga-67	100	I-131	1
Tc-99m	100	Tl-201	100

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIALS

1. The Radiation Safety Officer or a designee must authorize each order for radioactive materials. (For routine orders, the RSO will have an approved "Standard Dose List" from which the technologist may order radiopharmaceuticals, etc. All non-routine orders or significant deviations from the "Standard Dose List" will require approval of the RSO or his designee.)
2. 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 for use by the requesting authorized user and the possession limits are not exceeded.
3. The RSO or designee will establish and maintain a system for ordering and receiving radioactive material. The system will contain the following information:
    a. Written records that identify the isotope, compound, activity, supplier, etc., will be made.
    b. The written records will be referenced when opening or storing radioactive shipments.
4. During normal working hours, carriers will be instructed to deliver packages containing radioactive material directly to the Nuclear Medicine Hot Lab.
5. For deliveries during off-duty hours, the RSO will instruct security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum shown on the following page.

Plateau Medical Center, Inc.

430 Main Street

Oak Hill, WV 25901

Phone (304) 469-8600

Fax (304) 469-8605

An Affiliate of
Heritage Health
System, Inc.

TO: Harold Shrewsbury, Security Supervisor

FROM: A.A. Goodarzi, MD, Radiation Safety Officer

DATE: April 23, 1999

RE: Receipt of Packages Containing Radioactive Material

The security guard on duty shall accept delivery of packages containing radioactive materials that arrive during hours other than normal working hours. Packages should be placed on a cart or wheelchair and taken immediately to the Nuclear Medicine Department, Hot Lab room. Unlock the door, place the package on the countertop and relock the door.

If the package appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the hospital until it can be determined that neither the driver nor the delivery vehicle is contaminated.

If you have any questions concerning this memorandum, please contact me at ext. 626.

Contacts: Pending

Chief Nuclear Medicine Technologist: Pending

Radiation Safety Officer: Ali A. Goodarzi, MD ext. 626 (work)

[ ]

PROCEDURES FOR OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS

For safely opening packages containing radioactive materials, 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 RSO notified.
3. Measure the exposure rate at the surface and at 1 meter from the package and the results. The RSO should be notified if levels exceed the following:

(*) Package Label	1 Meter Exposure Reading	Surface Reading
White I	Background	0.5 mR/hr
Yellow II	1.0 mR/hr	50 mR/hr
Yellow III	10.0 mR/hr	200 mR/hr

4. Wipe the external surface of the labeled (*) package for contamination unless the package contains only radioactive material in the form of a gas or in special form as defined in 10 CFR 71.4.
5. Open the package with the following precautionary steps:
    a. Open the outer package following manufacturer's instructions, if supplied, and remove the packing slip.
    b. Open inner package and verify that contents agree with those on the packing slip. Compare requisition, packing slip, and label on the final container.
    c. Check the integrity of the final source container, (i.e., inspect for breakage of seals or vials, loss of liquid, and discoloration of the packing material).
    d. Also, check that the shipment does not exceed license possession limits.
6. 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 or returning to the vendor.
7. The above monitoring will be performed as soon as practicable after receipt of the package, but not later than three hours after the package is received at the facility if it is received during normal working hours, or within three hours of the start of the working day if the package was received after normal working hours.
8. Records of all receipts will be maintained by the facility for regulatory review.

PROCEDURES FOR MAINTAINING RECORDS OF UNIT DOSE USE

For each unit dosage received from a supplier, make a record of the:

1. Radionuclide;
2. Generic name or its abbreviation or trade name;
3. Date of receipt;
4. Supplier;
5. Lot number or control number, if assigned;
6. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time;
7. Date of administration or disposal;
8. If administered,
    a. Prescribed dosage (unless already recorded in the clinical procedure manual),
    b. Measured activity in millicuries or microcuries and date and time of measurement,
    c. Patient name and medical record number if one has been assigned;
9. If discarded, the date and method of disposal; and
10. Initials of the individual who made the record.

The records will be maintained either electronically (with a redundant back-up of the data to ensure availability of the data), or manually (paper records).

PROCEDURES FOR MAINTAINING RECORDS OF MULTI-DOSE VIAL USE

For each multi-dose vial received from a supplier or prepared in-house, make a record of the:

1. Radionuclide;
2. Generic name or its abbreviation or trade name;
3. Date of receipt;
4. Supplier;
5. Lot number or control number, if assigned;
6. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time;
7. Date of administration or disposal;
8. If administered,
    a. Prescribed dosage (unless already recorded in the clinical procedure manual),
    b. Measured activity in millicuries or microcuries and date and time of measurement,
    c. Patient name and medical record number if one has been assigned;

11. If discarded, the date and method of disposal; and
12. Initials of the individual who made the record.

The records will be maintained either electronically (with a redundant back-up of the data to ensure availability of the data), or manually (paper records).

PROCEDURES FOR MEASURING & RECORDING MOLYBDENUM CONCENTRATION

Each time the generator is eluted, a record will be made which will include:

1. Either the date the generator was received or the generator lot number;
2. The date and time of elution;
3. Measured ^{99}Mo activity in microcuries;
4. Product of the measured ^{99}Mo activity and the correction factor noted by the molybdenum breakthrough pig manufacturer (if the breakthrough pig method is used);
5. Measured ^{99m}Tc activity in millicuries;
6. Ratio of the ^{99}Mo microcuries per millicurie of ^{99m}Tc and a notation that the ratio is less than 0.07. (If the ratio exceeds 0.07, stop and notify the RSO. In conformance with paragraph 21.21(b) of 10 CFR Part 21, the licensee must notify the NRC if a leaking generator is detected.); and
7. Initials of the individual making the measurements and record.

Note: These records may be in paper format or stored on electronic media that is backed up to prevent loss of data.

AREA SURVEY PROCEDURES

The following area survey procedures will be conducted by the Nuclear Medicine Technologist 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 GM survey meter and decontaminated if radiation levels measured are in excess of established trigger levels. Trigger levels will not exceed 0.2 mR/hr in unrestricted areas and 2 mR/hr in restricted areas.
2. Radiopharmaceutical storage and waste areas will be surveyed weekly.
3. All laboratory areas will be surveyed weekly.
4. The weekly survey will consist of:
    a. Measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.
    b. A series of wipe tests to measure contamination levels. The method of performing wipe tests will be sufficiently sensitive to detect 200 dpm per 100 cm^2 for the contamination involved.
5. 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 to conduct the survey or analyze the results.
    b. Name/initials 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 (mR/hr), keyed to location of the drawing (point out rates that require corrective action).
    e. Detected contamination levels (dpm/100 cm^2), keyed to locations on drawing.
    f. Trigger levels established for each area and decontamination results when necessary.
6. The area will be cleaned or secured for decay if the contamination levels exceed 200 dpm / 100 cm^2 in an unrestricted area or 2000 dpm / 100 cm^2 in a restricted area.
7. The Radiation Safety Officer will be notified if survey results exceed the trigger levels.

WASTE MANAGEMENT

WASTE DISPOSAL PROCEDURES

Solid radioactive waste held for decay will be divided into two groups:

A. Short-lived -- Waste material with a half-life less than 1 day (24 hours) (i.e., ^{99m}Tc).

B. Long-lived -- Waste material with a half-life greater than 1 day (i.e., ^{201}Tl).

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.

Radioactive waste will be stored on site or returned to the vendor/radiopharmacy. Solid radioactive waste not returned to the vendor/radiopharmacy will be held for decay for a minimum of 10 half lives and 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 visible radiation labels will be removed or obliterated, and the waste will be disposed of in normal trash. (Example: Used syringes not returned to the vendor/radiopharmacy will be held for storage in a sealed syringe waste storage box. Following decay in storage and survey, all "radioactive materials" labels visible from the outside of the container will be removed/obliterated. The sealed containers may be transferred to a medical waste processing for incineration, thereby obliterating the labels within the waste container. The medical waste processing company will be instructed not to open the containers and ensure that the containers are incinerated, thereby obliterating the internal "non-visible" radiation labels. See NRC Information Notice 97-03: Defacing of Labels to Comply with 10 CFR 20.1904(b).) Appropriate documentation will be maintained.

Packages containing radioactive materials that are returned to the vendor/radiopharmacy will be transported in accordance with the regulations set forth in 49 CFR and applicable DOT regulations as well as in accordance with the vendor/nuclear pharmacy's procedures.

Liquid radioactive waste will be disposed of in the sanitary sewage system in accordance with 10 CFR § 20.2003.

Records are maintained for each of the described disposal methods. Such records include the date of storage, amount of radioactivity, background radiation levels, description of survey instrument, radionuclide, date of disposal, disposition of materials, and initials of the disposing individual.

ATT 10.1 _____

Plateau Medical Center, Inc.

Memo

DATE: _____

TO: All Employees

FROM: Hank Woodson. Chief Operating Officer

RE: Delegation of Radiation Safety Officer

Ali Goodarzi. MD has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of radiation. The Radiation Safety Officer is responsible for managing the radiation safety program. identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities.

Hank Woodson
Chief Operating Officer
Plateau Medical Center

U.S. Nuclear Regulatory Commission
Region II, Materials Licensing Branch
Atlanta, Federal Center
61 Forsyth St., SW. (Suite 23T85)
Atlanta, GA 30303

RE: Application for Byproduct Materials License – Medical Use
Plateau Medical Center, inc.

Gentlemen:

Please find enclosed two copies of our application for radioactive material licensure.

Enclosed please find a check in the amount of $1800.00 to cover administrative licensing fees.

If you have any questions, or require additional information, please do not hesitate to contact the undersigned.

Sincerely,

Hank Woodson
Chief Operating Officer
Plateau Medical Center

258347

ATT 10.6

Plateau Medical Center, Inc.

Memo

DATE: _____

TO: Chief of Security

FROM: Ali Goodarzi, MD, Radiation Safety Officer

RE: Receipt of Packages Containing Radioactive Material

The security guard on duty shall accept delivery of packages containing radioactive materials that arrive during hours other than normal working hours. Packages should be placed on a cart or wheelchair and taken immediately to the Nuclear Medicine Department, Hot Lab room. Unlock the door, place the package on the countertop and relock the door.

If the package appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the hospital until it can be determined that neither the driver nor the delivery vehicle is contaminated.

If you have any questions concerning this memorandum, please call our hospital Radiation Safety Officer, Ali Goodarzi, at extension 626.

Contacts: (Name, Home phone, and Pager)

Chief Nuclear Medicine Technologist: _____

Radiation Safety Officer: Ali Goodarzi, MD

258347