NRC FORM 313
(6-93)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120
EXPIRES 6-30-96

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

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.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

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

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

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

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
61 Forsyth Street, NW, SUITE 23 T 87
ATLANTA, GA 30303-3415

IF YOU ARE LOCATED IN:

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

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, IL 60532-4351

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

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

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

RADIOACTIVE MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1450 MARIA LANE
WALNUT CREEK, CA 94596-5368

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 JURISDICTIONS.

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

X A. NEW LICENSE
___ B. AMENDMENT TO LICENSE NUMBER ___
___ C. RENEWAL OF LICENSE NUMBER ___

2. H. James Stanton, M.D.
3100 MacCorkle Avenue, SE
Suite 606
Charleston, WV 25304

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

Same

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION
Sharon L. Long
National Physics Consultants

TELEPHONE NUMBER 330-878-8057

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2" 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.	INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.	8.	TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.	
9.	FACILITIES AND EQUIPMENT.	10.	RADIATION SAFETY PROGRAM.	
11.	WASTE MANAGEMENT.	12.	LICENSE FEES *(See 10 CFR 170 and Section 170.31)* FEE CATEGORY 7C	AMOUNT ENCLOSED $ 2400.00

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, 36, 39 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.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
H. James Stanton MD	[signature]	7/16/01

FOR NRC USE ONLY

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

UNITED STATES NUCLEAR REGULATORY COMMISSION
APPLICATION FOR LICENSE FOR RADIOACTIVE MATERIALS

Name of Corporation/Individual Applying for License: **H. James Stanton, M.D.**

Item #5 and #6, RADIOACTIVE MATERIAL, AMOUNT AND PURPOSE: Refer to Attachment 5.

Item #7.1, AUTHORIZED USERS: Refer to Attachment 7.1.

Item #7.2, RADIATION SAFETY OFFICER: Refer to Attachment 7.1.

Item #8.1, TRAINING PROGRAM: We will establish and implement the training program that is enclosed as Attachment 8.1.

Item #9.1, FACILITIES AND EQUIPMENT DIAGRAM: Our facilities and equipment diagram is enclosed as Attachment 9.1.

Item #9.2, SURVEY INSTRUMENT CALIBRATION: Survey instruments will be calibrated as described in Attachment 9.2.

Item #9.3, DOSE CALIBRATOR CALIBRATION: We will establish and implement the dose calibrator calibration procedure enclosed as Attachment 9.3.

Item #9.4, PERSONNEL EXTERNAL EXPOSURE MONITORING PROGRAM: We will establish and implement the personnel external exposure monitoring program enclosed as Attachment 9.4.

Item #10.1, RADIATION SAFETY COMMITTEE CHARTER AND RADIATION SAFETY OFFICER DELEGATION OF AUTHORITY: A Radiation Safety Committee Is Not Required For This Facility

Item #10.2, PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE AT MEDICAL INSTITUTIONS ALARA: We will establish and implement the ALARA program enclosed as Attachment 10.2.

Item #10.3, PROCEDURE FOR LEAK TESTING SEALED SOURCES: We will perform leak tests on sealed sources through contractors who are licensed for this service by the, the NRC or an Agreement State as appropriate. As an alternative, sealed sources may be leak tested by personnel who have been instructed in the proper techniques. The leak test samples will then be mailed to an appropriately licensed facility for analysis.

Item #10.4, RULES FOR SAFE USE OF RADIOPHARMACEUTICALS: We will establish and implement the safety rules enclosed as Attachment 10.4.

Item #10.5, SPILL PROCEDURES: We will establish and implement the spill procedures enclosed as Attachment 10.5.

Item #10.6, PROCEDURE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL: We will establish and implement the procedure for ordering and receiving radioactive material that is enclosed as Attachment 10.6.

Item #10.7, PROCEDURE FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL: We will establish and implement the procedure for opening packages enclosed as Attachment 10.7.

Item #10.8, RECORDS OF UNIT DOSAGE USE: We will establish and implement the procedure for unit dosage record system enclosed as Attachment 10.8.

Item #10.9, RECORDS OF MULTIDOSE VIAL USE: We will establish and implement the procedure for a multidose vial record system enclosed as Attachment 10.9.

Item #10.10, MEASURING AND RECORDING MOLYBDENUM CONCENTRATION: We will establish and implement the procedure for measuring and recording molybdenum concentration enclosed as Attachment 10.10.

Item #10.11, INVENTORY OF IMPLANT SOURCES: NA

Item #10.12, PROCEDURE FOR AREA SURVEYS: We will establish and implement the procedure for area surveys enclosed as Attachment 10.12.

Item #10.13.1, WORKER DOSE FROM NOBLE GASES: NA

Item #10.13.2a, WORKER DOSE FROM AEROSOLS: NA

Item #10.13.3, PUBLIC DOSE FROM AIRBORNE EFFLUENT: NA

Item #10.13.4, SPILLED GAS CLEARANCE TIME: NA

Item #10.14, PROCEDURE FOR RADIATION SAFETY FOR PATIENTS NOT RELEASED ACCORDING TO 10 CFR 35.75: NA

Item #10.15, PROCEDURE FOR RADIATION SAFETY DURING IMPLANT THERAPY: NA

Item #11.1, PROCEDURE FOR WASTE DISPOSAL: We will establish and implement the general guidance and procedures for waste disposal enclosed as Attachment 11.1.

UNITED STATES NUCLEAR REGULATORY COMMISSION
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Attachment 5

BYPRODUCT MATERIAL	AMOUNT	PURPOSE
Material in 35.200 (excluding I-125 and I-131 in excess of 30 uCi and Xenon-133)	As needed	Medical use

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Attachment 7.1

AUTHORIZED USERS FOR MEDICAL USE

AUTHORIZED USER		AUTHORIZATION
1.	H. James Stanton, M.D.	10 CFR 35.200 (Limited to Cardiology)
2.	Stephen L. DiBlasi, M.D.	10 CFR 35.200 (Limited to Cardiology)

Radiation Safety Officer: H. James Stanton, M.D.

For above physicians, refer to the application for license #47-15473-01 for evidence of training and experience. A copy of this document , including the current authorized user list, is attached for reference.

UNITED STATES NUCLEAR REGULATORY COMMISSION
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Attachment 8.1

Training Program

The following identifies the groups of workers who will receive training and the method and frequency of training. Records of training will include a list of attendees, dates, and topics and will be retained for three years.

INDIVIDUALS	FREQUENCY	METHOD
Chief Nuclear Medicine Technologist	Per the model program	Review by RSO, authorized user and/or as provided by our visiting consultants.
Nuclear Medicine Technologist	Per the model program	Review by RSO, authorized user, Chief Nuclear Medicine Technologist and/or as provided by our visiting consultants.
Other staff as appropriate	At orientation and annually thereafter	Review by RSO, authorized user, Chief Nuclear Medicine Technologist and/or participation in health physics consultations or review of the consulting reports as provided by our visiting consultants.

It may not be assumed that safety instruction has been adequately covered by prior occupational training, board certification, etc. Site-specific training will be provided for all workers. Ancillary personnel (e.g., nursing, clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions. All training will be tailored to meet the needs of the individuals in attendance.

Personnel will be instructed:

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.

Instruction for individuals in attendance will include the following subjects:

1. Applicable regulations and license conditions.

2. Areas where radioactive material is used or stored.

3. Potential hazards associated with radioactive material in each area where the employees will work.

4. Appropriate radiation safety procedures.

5. Licensee's in-house work rules.

6. Each individual's obligation to report unsafe conditions to the Radiation Safety Officer.

7. Appropriate response to emergencies or unsafe conditions.

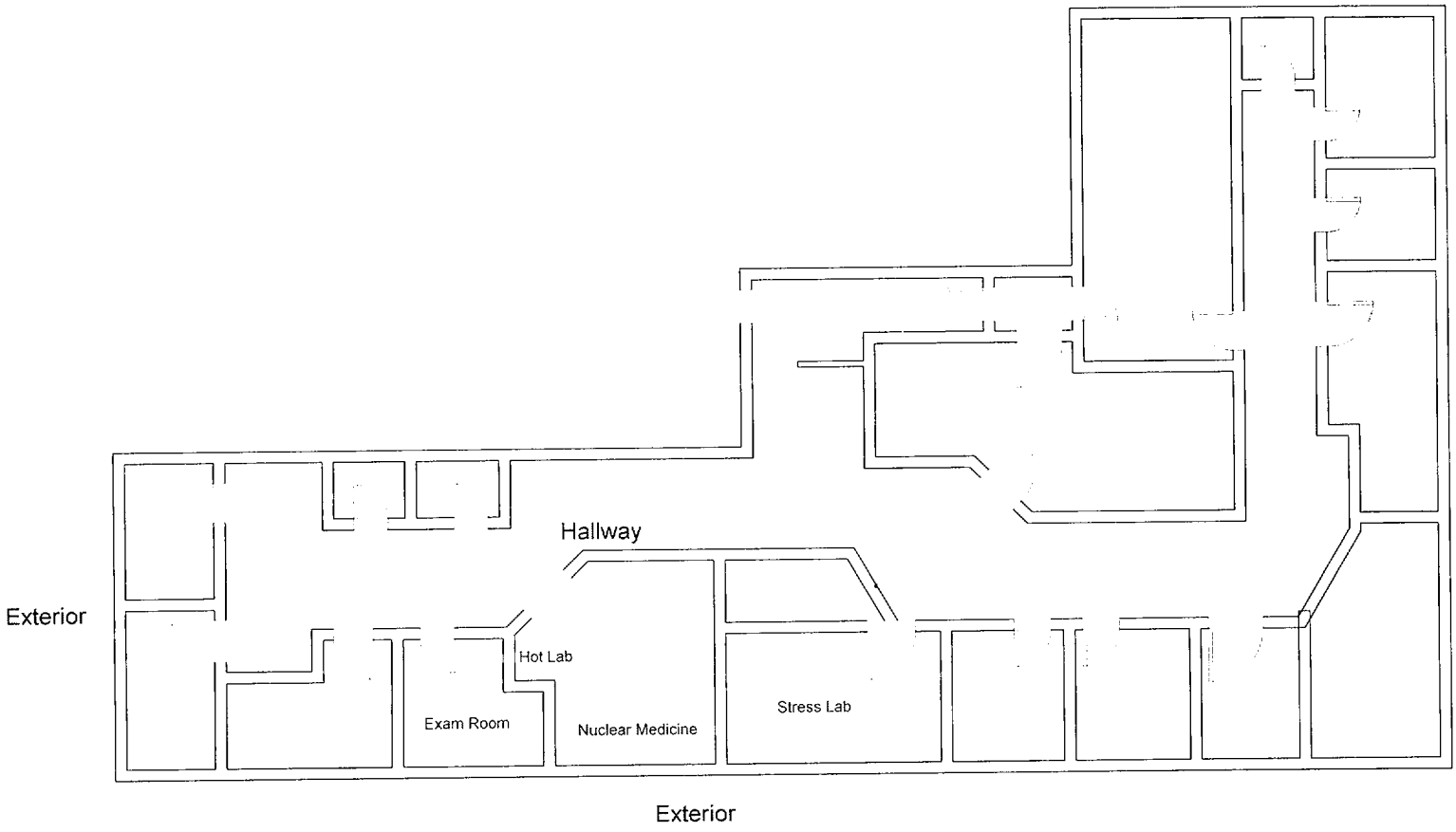
8. Worker's right to be informed of occupational radiation exposure and bioassay results.

9. Locations where the licensee has posted or made available notices, copies or pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.

10. Question and answer period.

H. James Stanton, M.D.
July 2001

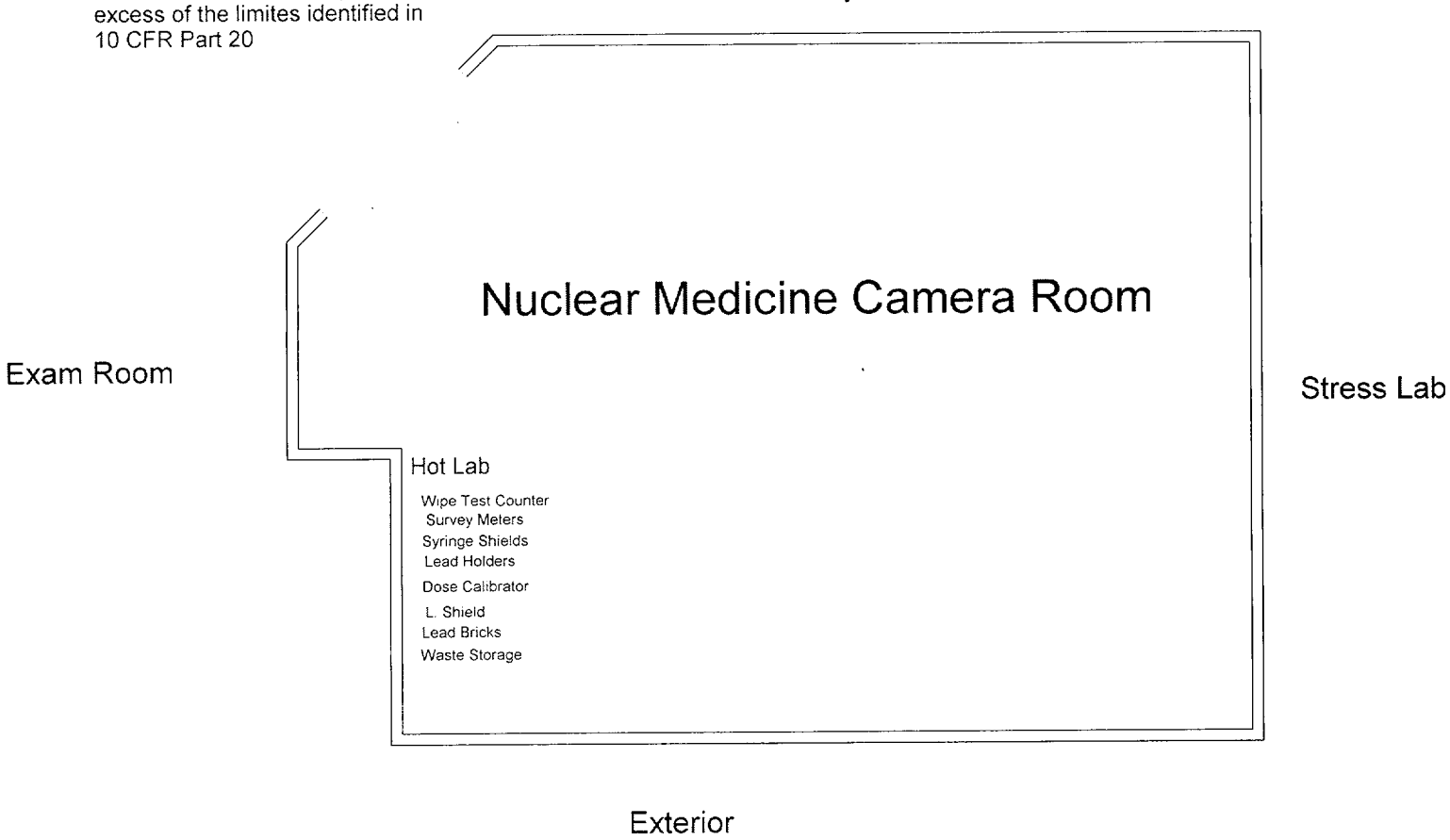
Item 9.1



H. James Stanton, M.D.
July 2001

Item 9.1

Shielding in all areas will be adequate to assure that no individual will receive exposures in excess of the limites identified in 10 CFR Part 20



UNITED STATES NUCLEAR REGULATORY COMMISSION
APPLICATION FOR LICENSE FOR RADIOACTIVE MATERIALS

Name of Corporation/Individual Applying for License:
H. James Stanton, M.D.

Attachment 9.2

Survey Instrument Calibration

Survey instruments will be calibrated after servicing and at intervals not to exceed 12 months by the manufacturer or by a commercial service. The latter will be done using the methods outlined in regulatory guide 10.8 revision 2 Appendix B or in accordance with the commercial service's license application (for example License # MD 31-206-01) . Records of these calibrations will be maintained and recommendations for repair will be followed. A survey meter will not be used beyond twelve months after its last successful calibration.

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Attachment 9.3

Dose Calibrator Calibration

The dose calibrator will be calibrated as follows:

1. At least two sealed sources will be used to establish accuracy. They will consist of Co-57 and/or Ba-133 and Cs-137 with activities in excess of 50 µCi each. The accuracy of the assay of these standards will be at least ±5% and traceable to National Institute of Standards and Technology sources.

   The dose calibrator will be checked for accuracy upon installation, following repair and at intervals identified in 10 CFR Part 35, using the sealed sources listed above. This will be done by assaying the source at the appropriate setting, and then removing the source and measuring background. These net activity readings will be recorded.

   The activity displayed by the dose calibrator must agree with the stated assay, corrected for decay, to within ±10%. If the unit displays readings with an error greater than ±10%, it will be repaired or replaced.

2. The dose calibrator will be checked for constancy. This will be done at the same time the accuracy test is done and subsequently at the beginning of each day of use. A Cs-137 source will be used for this purpose. The sealed source will be placed in the chamber and the unit set to measure that nuclide. The activity displayed with background and decay considered, must fall within ±10% of the predicted activity based on the value obtained at the time of the last accuracy test.

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

3. The dose calibrator will be checked for activity linearity upon installation, following repair, and at intervals identified in 10 CFR Part 35. This test will be performed using the maximum activity measured for administration for patient studies. The linearity test will be continued by repeating the assay of the source several times a day over a two to three day period. The linearity test shall proceed down to the limits specified in 10 CFR Part 35.

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

   As an alternative procedure, the linearity test can be performed with the use of the Calicheck Kit or the Lineator. The manufacturer's instructions for use will be followed. The source used shall be the activity of the largest dose used for patient studies. Limits of acceptability and corrective actions will be as described above.

4. The dose calibrator will be tested for geometrical variation upon installation and after chamber repair. This test will be performed on a commonly used syringe containing approximately 1-10 mCi of Tc-99m. The initial geometrical configuration will approximate that of a point source. The source geometry will then be changed, usually by dilutions of 0.5 ml to 2 ml, with assays performed at each step. The amount of the volume change will depend on the syringe size. Measurements will be made for at least four different volumes and will include the maximum volume measurable by the syringe. Data will be analyzed comparing the various readings to a configuration that represents a common, midpoint, or typical volume that is used for that particular container. The procedure will be repeated using all commonly used syringe sizes and, if a generator is used or if radiopharmaceutical kits are prepared, vial sizes. Correction factors will be used in clinical assays when geometry induced errors exceed ±10%.

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Attachment 9.4

Personnel External Exposure Monitoring Program

1. The RSO will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records, for example, pocket ionization chambers, when the monitor or record is a film or thermoluminescence dosimeter (TLD).

2. All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a film, TLD or whole body monitor that will be processed by a contract service on a at least a quarterly basis. Only thermoluminescent or optical luminescent monitors may be exchanges quarterly. If film badges are used, a monthly exchange frequency will be required.

3. All individuals who, on a regular basis, handle radioactive material that emits ionizing photons will be issued a film or TLD finger monitor that will be processed by a contract service on a at least a quarterly basis. Only thermoluminescent or optical luminescent monitors may be exchanges quarterly. If film badges are used, a monthly exchange frequency will be required.

4. All individuals who are occupationally exposed to radiation on an occasional basis, such as nurses caring for radiopharmaceutical therapy or implant patients, will be issued a whole body monitor when caring for such patients.

5. Other individuals who are exposed to radiation on an occasional basis such as security personnel who deliver packages, secretarial personnel who work in the nuclear medicine clinic but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages will not normally be issued exposure monitors.

UNITED STATES NUCLEAR REGULATORY COMMISSION
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Attachment 10.2

Program for Maintaining Occupational Radiation Exposure
ALARA

1. Management Commitment

   a. We, the management of this medical facility, are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an 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 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 radiation safety staff or outside 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 Officer

a. Review of Proposed Users and Uses

(1) The RSO 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 exposure ALARA.

(2) When considering a new use of radioactive material, the RSO will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA, and shall have incorporated the use of special equipment (such as syringe shields, disposable gloves, etc.) in his proposed use.

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

b. Delegation of Authority

(The judicious delegation of RSO authority is essential to the enforcement of an ALARA program.)

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

(2) The facility management will support the RSO when it is necessary for the RSO to assert authority.

c. Review of ALARA Program

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

(2) The RSO will perform a quarterly review of occupational radiation exposure with particular attention to instances where investigational levels in Table 1 are exceeded. The principle 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. The ALARA levels noted in table 1 may be changed ministerially if the management and the RSO determine that the change is warranted, however at no time will the levels exceed the maximum permissible dose identified by the regulations.

TABLE 1: Investigational Levels (millirem per calendar quarter)		
	ALARA LEVEL I	**ALARA LEVEL II**
Whole Body	125 mrem	375 mrem
Extremities or Skin	1250 mrem	3750 mrem
Lens of Eyes	375 mrem	1125 mrem

(3) The RSO 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 (continued)

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 methods of use may be conducted on a more frequent basis.

(2) Quarterly review of occupational exposures. The RSO 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 .

(3) Quarterly review of records of radiation surveys. The RSO 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.

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, 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 will investigate all known instances of deviation from good 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 during the planning stage before using radioactive materials for 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 Responsibility 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 prompted on the job.

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

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

The RSO will review and record on Form NRC-5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than annually . 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. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriately . The RSO will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality .

c. Personnel dose equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, any actions taken, and a copy of the individual's Form NRC-5 or its equivalent will be presented to facility management.

d. Establishment of investigational levels to levels above those listed in Table 1.

In cases where a worker's or a group of workers' doses need to exceed an investigational level, a new, higher investigational level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigational levels will be documented.

UNITED STATES NUCLEAR REGULATORY COMMISSION
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Attachment 10.4

Rules for Safe Use of Radiopharmaceuticals

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. Either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area with a low-level G-M detector or a scintillation detector.

4. Use syringe shields for routine preparation of multi-dose vials and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins, infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).

5. Do not eat, drink, smoke, or apply cosmetics in any area identified as a restricted area.

6. Do not store food, drink, or personal effects in any area identified as a restricted area.

7. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer. 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 monitor 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 designated, labeled, and properly shielded receptacles.

10. Wipe test byproduct material storage, preparation, and administration areas for contamination at intervals identified in 10 CFR Part 35. If necessary, decontaminate or secure the area for decay.

11. With a radiation detection survey meter, survey the generator storage, kit preparation, and injection areas for contamination at intervals identified in 10 CFR Part 35. If necessary, decontaminate or secure the area for decay as appropriate.

12. Confine radioactive solutions in shielded containers that are clearly labeled. Radiopharmaceutical multi-dose diagnostic vials and therapy vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation. A record must be kept identifying the preceding information and total prepared activity, specific activity as mCi/cc at a specified time, total volume prepared, total volume remaining, the 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.

13. Assay each photon-emitting patient dosage in accordance with 10 CFR Part 35 before administration. Do not use the dosage if it varies from the prescribed dose more than the allowed variance identified in 10 CFR Part 35 , except for prescribed dosages whose activity is less than that specified in 10 CFR 35. When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle. Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administration.

14. Flood sources, syringes, waste, and other radioactive material should be kept in shielded containers if warranted by the exposure rate.

15. Because even sources with small amounts of radioactivity exhibit a high dose rate on contact, use of a cart or wheelchair to move flood sources, waste, and other radioactive material should be considered.

UNITED STATES NUCLEAR REGULATORY COMMISSION
APPLICATION FOR LICENSE FOR RADIOACTIVE MATERIALS

Name of Corporation/Individual Applying for License: **H. James Stanton, M.D.**

Attachment 10.5

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 other contaminated disposable material in the bag.

4. Survey the area with a low-range radiation detector 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 and a Radioactive Spill Contamination Survey.

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 will supervise the clean-up of the spill and will complete a Radioactive Spill Report and a Radioactive Spill Contamination Survey.

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.

Table 1 will be used as general guidance to determine whether a major spill procedure or a minor spill procedure should be implemented.

TABLE 1

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
P-32	10	Tc-99m	100
Fe-59	10	In-111	10
Co-57	100	I-123	10
Co-58	10	I-125	1
F-18	100	I-131	1
Co-60	1	Yb-169	10
Ga-67	100	Hg-197	100
Sr-85	10	Tl-201	100

UNITED STATES NUCLEAR REGULATORY COMMISSION
APPLICATION FOR LICENSE FOR RADIOACTIVE MATERIALS

Name of Corporation/Individual Applying for License: **H. James Stanton, M.D.**

Attachment 10.6

Procedure for Ordering and Receiving Radioactive Material

1. The Radiation Safety Officer (RSO) or a designee must authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that possession limits are not exceeded.

2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:

   a. For routinely used materials

      (1) Written records that identify the authorized user or department, isotope, chemical form, activity, and supplier will be made.

      (2) The above records will be checked to confirm that material received was ordered through proper channels.

   b. For occasionally used materials (e.g., therapeutic dosages)

      (1) The authorized user who will perform the procedure will make a written request that indicates the isotope, radiopharmaceutical, activity, and supplier.

      (2) The person who receives the material will check the physician's written request to confirm that the material received is what was ordered.

3. For deliveries during normal working hours, the RSO will tell carriers to deliver radioactive packages directly to a specified area.

4. For deliveries during off-duty hours, the RSO will tell security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the memorandum enclosed.

MEMO TO: Chief of Security

FROM: Radiation Safety Officer

SUBJECT: Receipt of Packages Containing Radioactive Material

a) *[If couriers or common carriers attempt delivery of packages containing radioactive materials, the supervisor on duty will be contacted. The supervisor will have the carrier escorted to nuclear medicine by personnel who have been assigned this duty. The carrier will place the package in the indicated receipt location. Personnel not trained in the proper handling of radioactive materials are not to personally accept packages containing radioactive materials. The packages will be secured against unauthorized removal. When delivered packages are wet or appear to be damaged, the RSO is to be immediately contacted. The carrier should be requested to remain until it can be determined that neither the carrier nor the delivery vehicle is contaminated.]*

b) *[For deliveries of radioactive materials from a nuclear pharmacy, the delivery personnel may be provided with a key to the nuclear medicine department. The courier will be instructed to place the package in the indicated receipt location. The courier will be instructed to ensure the security of the department after delivery. When delivered packages appear wet or damaged, the RSO is to be immediately contacted.]*

If you have any questions concerning this memorandum, please call the Radiation Safety Officer, _____, at extension _____.

	Name	Home Telephone
Radiation Safety Officer:		
Chief of Nuclear Medicine:		
Chief Nuclear Medicine Technologist:		
Nuclear Medicine Technologist on call (call page operator at extension ____)		
Nuclear Medicine Physician on call (call page operator at extension ____)		

UNITED STATES NUCLEAR REGULATORY COMMISSION
APPLICATION FOR LICENSE FOR RADIOACTIVE MATERIALS

Name of Corporation/Individual Applying for License: **H. James Stanton, M.D.**

Attachment 10.7

Procedure for Safely Opening Packages Containing Radioactive Material

For packages received under the specific license, the following procedure for opening each package will be followed:

1. Put on gloves to prevent hand contamination.

2. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).

3. Measure the exposure rate from the package at 1 meter and at the package surface. If it is higher than expected, stop and notify the Radiation Safety Officer (RSO).

4. For packages labeled with a White I, Yellow II, or Yellow III label, monitor the surface of the package for contamination. If > 22 dpm/cm^2 measured over 300 cm^2, stop and notify the RSO. Monitoring for contamination is not necessary if the package contains only radioactive material as a gas or in special form.

5. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

6. The monitoring required in (4) and (5) above shall be performed as soon as practicable after receipt , but not later than 3 hours after the package is received if it is received during normal working hours or not later than 3 hours from the beginning of the next working day if it is received after working hours.

7. Open the package with the following precautionary steps:

   a. Remove the packing slip.

   b. Open the outer package following the supplier's instructions, if provided.

   c. Open the inner package and verify that the contents agree with the packing slip.

   d. Check the integrity of the final source container. Look for broken seals or vials,

loss of liquid, condensation, or discoloration of the packing material.

e. If anything is other than expected, stop, and notify the RSO.

8. Check the user request to ensure that the material received is the material that was ordered.

9. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding.

   a. If contaminated, treat this material as radioactive waste.

   b. If not contaminated, remove or obliterate the radiation labels before discarding in-house trash.

10. If there is evidence of degradation of package integrity, wipe the external surface of the final source container. Check the wipe for contamination in a low background area using a G-M survey meter and take the necessary precautions against the spread of contamination.

11. Make a record of the receipt including the result of all monitoring.

For packages received under the general license in §31.11, the following procedure for opening each package will be followed:

1. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO.

2. Check to ensure that the material received is the material that was ordered.

UNITED STATES NUCLEAR REGULATORY COMMISSION
APPLICATION FOR LICENSE FOR RADIOACTIVE MATERIALS

Name of Corporation/Individual Applying for License: **H. James Stanton, M.D.**

Attachment 10.8

Records of Byproduct Material Use
Records of Unit Dosage 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 clinical procedure manual),
   b. Measured activity in millicuries or microcuries and date and time of measurement,
   c. Patient name and identification 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.

UNITED STATES NUCLEAR REGULATORY COMMISSION
APPLICATION FOR LICENSE FOR RADIOACTIVE MATERIALS

Name of Corporation/Individual Applying for License: **H. James Stanton, M.D.**

Attachment 10.9

Records of Byproduct Material Use
Records of Multidose Vial Use

For each multidose vial that you receive from a supplier or that you prepare, make a record of the:

1. Radionuclide;

2. Generic name or its abbreviation or trade name;

3. Date of receipt or preparation;

4. Date and time of initial assay and amount in both millicuries and cubic centimeters (cc) or milliliters (ml);

5. Supplier or kit manufacturer;

6. If administered,

   a. Prescribed dosage (unless already recorded in clinical procedure manual),
   b. Date and time dosage was drawn and measured,
   c. Calculated volume that is needed for the prescribed dosage,
   d. Measured activity in millicuries or microcuries,
   e. Patient name and identification number if one has been assigned;

7. If discarded, the method of disposal and date; and

8. Initials of the individual who made the record.

UNITED STATES NUCLEAR REGULATORY COMMISSION
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Attachment 10.10

Records of Byproduct Material Use
Measuring and Recording Molybdenum Concentration

Each time a generator is eluted, make a record of the:

1. Date the generator was received;

2. Date and time of elution;

3. Measured Mo-99 activity in microcuries;

4. Product of the measured Mo-99 activity and the correction factor noted by the molybdenum breakthrough pig manufacturer;

5. Measured Tc-99m activity in millicuries;

6. Ratio of the total Mo-99 microcuries per millicurie of Tc-99m and checkmark that the ratio is less than 0.07 microcuries of Mo-99 per millicurie of Tc-99m. (If it isn't, 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). [The 0.07 action level allows for the quicker decay of the Tc through the day of use. It is assumed that the material will be used within 6 hours, at which time the concentration of Mo-99 to Tc-99m would have doubled.]

7. Initials of the person who made the record.

UNITED STATES NUCLEAR REGULATORY COMMISSION
APPLICATION FOR LICENSE FOR RADIOACTIVE MATERIALS

Name of Corporation/Individual Applying for License: **H. James Stanton, M.D.**

Attachment 10.12
Procedure for Area Surveys

Ambient Dose Rate Surveys

1. Survey Areas

   a. In radiopharmaceutical elution, preparation, and administration areas, survey with a radiation detection survey meter at frequencies identified in 10 CFR Part 35. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

   b. In laboratory areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly with a radiation detection survey meter.

   c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey with a radiation detection survey meter at frequencies identified in 10 CFR Part 35.

   d. In sealed source and brachytherapy storage areas, survey quarterly with a radiation measurement survey meter.

2. Immediately notify the RSO if you find unexpectedly high or low levels.

Removable Contamination Surveys

1. Survey Areas

   a. In radiopharmaceutical elution, preparation, and administration areas, survey for removable contamination at frequencies identified in 10 CFR Part 35. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

   b. In laboratory areas where only small quantities of photon-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly for removable contamination.

c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey for removable contamination at frequencies identified in 10 CFR Part 35.

2. The wipe sample assay procedure should be suffiently sensitive to detect the presence of 2000 dpm/100 cm^2 of removable contamination (200 dpm/100 cm^2 for isotopes of iodine). You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute or cpm) to disintegrations per minute or dpm.

3. Immediately notify the RSO if you find unexpectedly high levels.

Records

1. Keep a record of dose rate and contamination survey results. It must include the following information:

   a. The date, area surveyed, and equipment used.

   b. The name or initials of the person who made the survey.

   c. A drawing of the areas surveyed with contamination and dose rate action levels as established by the RSO. (Recommended removable surface contamination action levels are published in Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions". See Regulatory Guide 8.23 or Table 1 below for guidance in establishing your action levels.)

   d. Measured dose rates in mR/hr or contamination levels in dpm/100 cm^2, as appropriate.

   e. Actions taken in the case of excessive dose rates or contamination and follow-up survey information.

2. The RSO will review and initial the record promptly in those cases in which action levels were exceeded.

Table 1

Recommended Action Levels in dpm/100 cm^2 for Surface Contamination by Radiopharmaceuticals

		P-32, Co-58, Fe-59 Co-60, Se-75, Sr-85 In-111, I-123, I-125 I-131, Yb-169, Au-198	F-18 Cr-51, Co-57 Ga-67, Tc-99m, Hg-197, Tl-201
1.	Unrestricted areas, personal clothing	200	2,000
2.	Restricted areas, protective clothing used only in restricted areas, skin	2,000	20,000

UNITED STATES NUCLEAR REGULATORY COMMISSION
APPLICATION FOR LICENSE FOR RADIOACTIVE MATERIALS

Name of Corporation/Individual Applying for License: **H. James Stanton, M.D.**

Attachment 11.1
Procedure for Waste Disposal

Overview

There are four commonly used methods of waste disposal: release to the environment through the sanitary sewer or by evaporative release; decay-in-storage (DIS); transfer to a burial site or back to the manufacturer; and release to in-house waste. With the exception of the patient excreta (see paragraph 20.2003(b)) and generally licensed in vitro kit exemptions (see paragraph 31.11(f)), nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material. (See paragraphs 30.51(a) and 20.2108.)

General Guidance

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal to in-house waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.

2. Remind employees that nonradioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste.

3. Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.

4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and expense.

PROCEDURE FOR DISPOSAL OF LIQUIDS AND GASES

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere. This dose not relieve licensees from complying with other regulations regarding toxic or hazardous properties of these materials.

1. Regulations for disposal in the sanitary sewer appear in 20.2003. Material must be readily soluble (or readily dispersible biological material) in water. There are monthly limits based on the total sanitary sewerage release of your facility. (Excreta from patients undergoing medical diagnosis or therapy is exempt from all the above limitations; see paragraph 20.2003(b).) Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries), and of the sink or toilet at which the material was released.

2. Limits on permissible concentrations in effluents to unrestricted areas are enumerated in Table 2 of Appendix B to 10 CFR Part 20. These limits apply at the boundary of the restricted area. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries) and estimated concentration, and of the vent site at which the material was released.

3. Liquid scintillation-counting media containing 0.05 microcurie per gram of H-3 or C-14 may be disposed of without regard to its radioactivity (§ 20.2005). Make a record of the date, radionuclide, estimated activity (in millicuries or microcuries), calculated concentration in microcuries per gram, and how the material was disposed of.

PROCEDURE FOR TRANSFER FOR BURIAL

Except for material suitable for DIS and some animal carcasses, solids must be transferred to a burial site. Follow the packaging instructions received from the transfer agent and the burial site operator. For the record of disposal, keep the consignment sheet that the transfer agent provided.

PROCEDURE FOR RELEASE TO IN-HOUSE WASTE

Waste from in vitro kits that are generally licensed pursuant to § 31.11 is exempt from waste disposal regulations. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.

PROCEDURE FOR RETURNING GENERATORS TO THE MANUFACTURER

Used Mo-99/Tc-99m generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with 10 CFR Part 71 and Department of Transportation (DOT) regulations.

1. Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container (see DOT regulations, paragraph 173.415(a) of 49 CFR Part 173).

2. Assemble the package in accordance with the manufacturer's instructions.

3. Perform the dose rate and removable contamination measurements required by paragraph 173.475(I) of 49 CFR Part 173.

4. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.

PROCEDURE FOR DISPOSAL BY DECAY-IN-STORAGE (DIS)

Short-lived material as identified in 10 CFR Part 35 may be disposed of by DIS.

1. Consider using separate containers for different types of waste, e.g., capped needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container. Smaller departments may find it easier to use just one container for all DIS waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for the material.

2. When the container is full, seal it with string or tape and attach an identification tag that includes the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container may then be transferred to the DIS area.

3. Decay the material in accordance with the regulations identified in 10 CFR Part 35.

4. Prior to disposal as in-house waste, monitor each container as follows:

   a. Check your radiation detection survey meter for proper operation;

   b. Plan to monitor in a low-level (less than 0.05 millirem per hour) area;

   c. Remove any shielding from around the container;

   d. Monitor all surfaces of each individual container;

   e. Discard as in-house waste only those containers that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and type of material (e.g., paraphernalia, unused dosages). Check to be sure no radiation labels are visible.

   f. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.

5. If possible, Mo-99/Tc-99m generators should be held 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a radiation detection survey meter at the work area. Dismantle the oldest generator first, then work forward chronologically. Hold each individual column in contact with the radiation detection survey meter in a low-background (less than 0.05 mR/hr) area. Log the generator date and disposal date in the waste disposal records. Remove or deface the radiation labels on the generator shield.

CAMC Nuclear Medicine Privileges Update
(As of December 13, 2000)

Medical Imaging and Radioisotope Therapy Procedures:
The individuals below are Board Certified in Nuclear Medicine or have presented evidence of training commensurate with NRC licensure for 35.100, 35.200, 35.300, 35.400, and 35.500.

Steven A. Artz, M.D.
Timothy Corner, M.D.
Kenneth Dwyer, M.D.
Johnsey Leef, M.D.
Joseph Skeens, M.D. (*)
Robert Smith, M.D.
Mark Younis, M.D. (*)

(*) Approved for ^{131}I & ^{89}Sr therapy and all imaging procedures (not approved for ^{32}P therapy procedures).

Medical Imaging Only:
The individuals below have credentials, which include certification in Radiology. (35.100 & 35.200 procedures only)

John J. Anton, M.D.
Ronald Cordell, M.D.
Stephen M. Elksnis, M.D.
Mary McJunkin, M.D.
Michael J. Maroney M. D.
John F. Mega, M.D.
Pamela M. Phillips, M.D.
John Reifsteck, M.D.
Christopher Schlarb, M.D.
James Smith, M.D.
David Sparks, M.D.
John Willis, M.D.

Radioactive Iodine for Hyperthyroidism and Thyroid Carcinoma:
The individuals below are credentialed on the basis of either evidence of clinical training or presentation of a former NRC license.

Nicholas Cassis, M.D.
Glenn Crotty, M.D.
Steven Grubb, M.D.

Cardiology Section Members:
The individuals below have presented evidence of attendance of a Radiation Safety Course and Nuclear Medicine Cardiology course and/or residency training.

Dilip K. Basu, M.D.
Joseph Devono III, D.O.
Stephen L. DiBlasi
Maria Georgiev, M.D.
John Goad, M.D.
Mohammad Haffar, M.D.
Ramakrishnan Iyer, M.D.
Donald Lilly, M.D.
Steven McCormick, M.D.
Muhammand S. Mian, M.D.
Scott Miller, M.D.
Bassam Moushmoush, M.D.
Dilip C. Patel, M.D.
Gary Roberts, D.O.
Ahmed Sakkal, M.D.
James Stanton, M.D.
Jashvantlal Thakkar, M.D.
M. Babar Yousef, M.D.

Authorized Nuclear Pharmacist:
David Kelly, Pharm. D.

RIA Use Only:
Tamer Yalcinkaya, M.D.

Radiation Oncology (brachytherapy):
Michael B. Harmon, M.D.
Ksharna Jawalekar, M.D.
Lewis A. Whaley, D.O.

Authorized Medical Physicist
Warren Bryant, M.S.

Documentation of the above mentioned individuals is available at the medical staff office in their application files for clinical privileges and credentialing. In addition, copies of Board certifications/NRC licensure/ training from other facilities are available in the Radiation Safety Office.

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MATERIALS LICENSE

Amendment No. 32

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. Charleston Area Medical Center	In accordance with the letter dated April 25, 1997
2. P.O. Box 1547 Charleston, West Virginia 25326	3. License Number 47-15473-01 is amended in its entirety to read as follows:
	4. Expiration Date August 31, 2005 (extended)
	5. Docket or Reference No. 030-09164

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	B. As needed
C. Iodine 131	C. Any unsealed form for preparation and administration as specified in §35.300	C. 55.5 gigabecquerels (1.5 curies)
D. Any byproduct material with a half-life less than 120 days except iodine 131	D. Any form for uses described in §35.300 initially distributed in accordance with a specific license issued pursuant to 10 CFR 32.72 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations.	D. As needed, not to exceed 3.7 gigabecquerels (100 millicuries) per container
E. Any byproduct material identified in 10 CFR 35.400	E. Any brachytherapy source identified in 10 CFR 35.400	E. As needed
F. Any byproduct material identified in 10 CFR 31.11	F. Prepackaged kits	F As needed
G. Gadolinium 153	G. Sealed sources registered pursuant to 10 CFR 32.210 and contained in compatible devices specified in 10 CFR 35.500.	G. 3 sources not to exceed 1000 mCi (37 GBq) each

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 47-15473-01

Docket or Reference Number: 030-09164

Amendment No. 32

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum quantity of materia that may be possessed at ny one time under this license
H. Cesium 137	H. Sealed source registered pursuant to 10 CFR 32.210 and contained in a compatible device specified in Item 9.H.	H. 1 source not to exceed 100 millicuries (3.7 GBq)
I. Cesium 137	I. Sealed sources registered pursuant to 10 CFR 32.210 and contained in a compatible device specified in Item 9.I.	I. 3 sources not to exceed 1000 Ci (37 TBq) each
J. Hydrogen 3	J. Any	J. 185 megabecquerels (MBq) (5 millicuries (mCi))
K. Carbon 14	K. Any	K. 185 MBq (5mCi)
L. Phosphorus 32	L. Any	L. 185 MBq (5 mCi)
M. Iodine 125	M. Any	M. 18.5 MBq (0.5 mCi)

9. Authorized Use:

A. Medical use described in 10 CFR 35.100; Use of Iodine 131, Idomethyl-19-norcholestrol (NP-59) shall be in accordance with IND 17,095

B. Medical use described in 10 CFR 35.200

C. and D. Medical use described in 10 CFR 35.300

E. Medical use described in 10 CFR 35.400

F. Clinical in vitro studies

G. Medical use described in 10 CFR 35.500

H. For storage only in a J.L. Shepherd 78 series calibrator

I. For use in an AECL Gammacell 1000 Elite self-contained irradiator for the irradiation of blood and blood samples.

J. *in-vitro* laboratory use

K. *in-vitro* laboratory use

L. *in-vitro* laboratory use

M. *in-vitro* laboratory use

CONDITIONS

10. Location(s) of use:

A. Memorial Division
3200 MacCorkle Avenue
Charleston, West Virginia

B. General Division
501 Morris Street
Charleston, West Virginia

C. Women & Children's Division
800 Pennsylvania Avenue
Charleston, West Virginia

D. Center for Reproductive Medicine
830 Pennsylvania Avenue
Suite 304
Charleston, West Virginia

E. Braxton County Memorial Hospital
100 Hoylman Drive
Gassaway, WV 26624

F. J.L. Shepherd instrument calibrator in Sub-Item 6,7,8,9 H above shall be stored only in the Memorial Division radioactive waste storage area

G. The Gammacell 1000 Elite shall be used only in the Blood Bank at the Memorial Division

H. Material in Sub-Item 6.E shall only be used at the Memorial Division

11. Radiation Safety Officer: Steven Artz, M.D.

12. Authorized user(s):

A. The use of licensed material in or on humans shall be by a physician, dentist, or podiatrist as defined in 10 CFR 35.2.

B. Physicians, dentists, or podiatrists designated to use licensed material in or on humans shall meet the training criteria established in 10 CFR 35, Subpart J and shall be designated by the licensee's Radiation Safety Committee. The licensee shall maintain records of individuals designated as users for three years after the individual's last use of licensed material.

C. Licensed material for other than human use shall be used by or under the supervision of individuals designated by the Radiation Safety Committee. The licensee shall maintain records of individuals designated as users for three years after the individual's last use of licensed material.

Continued -

CONDITIONS

13. A.(1) The source(s) in Item 7. H and I, shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

B. Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.

C. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U. S. Nuclear Regulatory Commission, Region II, Division of Nuclear Materials Safety, 61 Forsyth Street, S.W., Suite 23T85, Atlanta, Georgia 30323-3415. The report shall specify the source involved, the test results; and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

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

15. Sealed sources containing licensed material shall not be opened by the licensee.

16. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal, replacement, and disposal or sealed sources in the irradiator shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.

17. The device manufacturer's Instruction Manual for the Gammacell 1000 devices shall be followed and the licensee shall make copies available to each person using or having responsibility for use of licensed material.

18. The licensee shall maintain records of information important to safe and effective decommissioning at 3200 MacCorkle Avenue, S.E., Charleston, West Virginia in accordance with the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 47-15473-01

Docket or Reference Number: 030-09164

Amendment No. 32

Continued -

CONDITIONS

19. Pursuant to 10 CFR 20.1301(c) and in reliance on statements, procedures and representations made by the licensee in his application dated May 18, 1995, the following maximum radiation levels are hereby authorized, until one year from the renewal date of this license, in the following unrestricted areas:

Maximum Radiation Level	Unrestricted Area
Up to 3 mR/hr	At distances of up to 3 feet from the boundaries of Room 474, 489, 574 and 589.

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

21. Except as specifically provided otherwise in this license and in 10 CFR 35.31, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated May 18, 1995 [renewal]

B. Letters dated:
(1) September 20, 1990 [blood cell irradiator procedures]
(2) June 14, 1991 [training tests for level of comprehension]
(3) April 29, 1993 [procedure for designating authorized users]
(4) December 26, 1995 [Additional storage rooms, add use room at General; change Gd-153 total auth; replace dose calibrator tests; add use room at Memorial]
(5) April 25, 1997 [add place of use]

C. NRC letter dated March 1, 1996 (extends expiration date in accordance with 10 CFR 30.36)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION
HECTOR BERMUDEZ

DATE MAY 16 1997

BY [signature]

N:\MLICENSE\47-15473.A32

Region II, Division of Nuclear Materials Safety
61 Forsyth Street, S.W., Suite 23T85
Atlanta, Georgia 30323-3415

THE CERTIFICATION BOARD OF NUCLEAR CARDIOLOGY

Incorporated 1996

CERTIFIES THAT

H. James Stanton, M.D., F.A.C.C.

HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS BOARD FOR PHYSICIANS RESIDING IN THE UNITED STATES AND HAVING SATISFACTORILY PASSED THE REQUIRED EXAMINATION, IS HEREBY DESIGNATED

A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF

NUCLEAR CARDIOLOGY

FOR THE PERIOD 2000 THROUGH 2010

PRESIDENT

SECRETARY

CERTIFICATE # *1885*

CBNC

OCTOBER 29, 2000

University of Louisville

Department of Medicine

Division of Cardiology
Division of Radionuclide Studies

This is to certify that HOWARD JAMES STANTON, M.D. *has satisfactorily completed the training and experience criteria for diagnostic studies limited to Nuclear Cardiology, above the minimum as set by the Nuclear Regulatory Commission standards. This training involves 250 hours in basic radioisotope handling techniques, 500 hours of experience with the use of byproduct material, and 200 hours of supervised clinical training in the Nuclear Cardiology Program.*

1983-1984
Academic Year

[illegible] B. Syed, Ph.D.
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