

(10-94)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

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 (T-6 F33), 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.

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.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

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
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

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

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

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-6064

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.

<p>1. THIS IS AN APPLICATION FOR (Check appropriate item)</p> <p><input type="checkbox"/> A. NEW LICENSE</p> <p><input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____</p> <p><input checked="" type="checkbox"/> C. RENEWAL OF LICENSE NUMBER <u>29-20876-01</u></p>	<p>2. NAME AND MAILING ADDRESS OF APPLICANT (include Zip code)</p> <p>University of Medicine and Dentistry of New Jersey - School of Osteopathic Medicine Science Center 2 Medical Center Drive Stratford, New Jersey 08084</p>
--	---

<p>3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED</p> <p>same as in #2</p>	<p>4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION</p> <p>Lloyd J. Forman, Ph.D.</p> <p>TELEPHONE NUMBER (609) 566-6117</p>
--	--

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.

<p>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.</p>	<p>6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.</p>
<p>7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.</p>	<p>8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS</p>
<p>9. FACILITIES AND EQUIPMENT.</p>	<p>10. RADIATION SAFETY PROGRAM.</p>
<p>11. WASTE MANAGEMENT.</p>	<p>12. LICENSEE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY <u>exempt</u> AMOUNT ENCLOSED \$</p>

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.

<p>CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE</p> <p>Lloyd J. Forman, Ph.D., RSO</p>	<p>SIGNATURE</p> <p><i>Lloyd J. Forman</i></p>	<p>DATE</p> <p>10/12/95</p>
---	--	-----------------------------

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED \$	CHECK NUMBER	COMMENTS
APPROVED BY				DATE	<p>NMSS/RGNI MATERIALS-002</p>

TABLE OF CONTENTS

ITEM 5: Radioactive Material.....	2
ITEM 6: Purposes for Which Licensed Material Will be Used.....	3
ITEM 7: Individuals Responsible for Radiation Safety Program and their Training and Experience.....	4
ITEM 8: Training for Individuals Working in or Frequenting Restricted Areas	6
A. Training for Users of Radioactive Material.....	6
B. Training for Housekeeping Personnel.....	7
C. Training for Security Personnel.....	8
ITEM 9: Description of Facilities and Equipment for Radionuclide Use in Research Laboratories.....	9
ITEM 10: Radiation Safety Program.....	12
A. Purchase and Acquisition of Radionuclides.....	12
B. Receipt of Radioactive Materials.....	12
C. Package Inspection.....	12
D. Area Survey Procedures and Personnel Protection.....	13
E. Procedures and Precautions with Laboratory Animals.....	15
F. Radiation Detection Instruments.....	16
G. Personal Monitoring Devices.....	17
H. Grant Applications.....	17
I. UMDNJ-SOM Radiation Safety Policy Manual.....	18
ITEM 11: Waste Management.....	19

ITEM 5: Radioactive Materials

A) Element - Mass No.	B) Chemical/Physical Form	C) Possession Limits (mCi)
Hydrogen - 3	conjugates of: estradiol progesterone nucleosides and nucleotides amino acids organic substrates (alcohols, fatty acids, etc.)	Total Activity = 500
Carbon -14	conjugates of : glucose amino acids organic substrates nucleosides and nucleotides	Total Activity = 20
Phosphorus - 32	nucleotide triphosphate	Total Activity = 200
Phosphorus - 33	nucleotide triphosphate	Total Activity = 200
Sulfur - 35	methionine sodium sulfate	Total Activity = 120
Calcium - 45	calcium chloride	Total Activity = 2
Chromium - 51	sodium chromate	Total Activity = 50
Iron-59	ferrous chloride	Total Activity = 1
Copper - 64	copper acetate	Total Activity = 10
Iodine - 125	sodium iodine radioimmunoassay kits	Total Activity = 50
Iodine - 131	sodium iodine	Total Activity = 10

ITEM 6: Purposes for Which Licensed Material Will Be Used

- Hydrogen - 3**
- radioimmunoassay procedures
 - in vivo and in vitro metabolic studies
 - cell labeling/incorporation for determination of cell growth, protein synthesis and synthesis of DNA
 - enzyme assays
 - incorporation into hemoglobin
- Carbon - 14**
- in vitro metabolic studies
 - protein synthesis rates
 - collagenase assays
 - in vivo and in vitro metabolic tracer studies
 - in vitro enzyme assays
- Iodine - 125**
- radioimmunoassay procedures
 - radioiodination of organic compounds for radioimmunoassay (RIA) procedures
 - antibody labeling
- Iodine - 131**
- radioiodination of organic compounds for RIA
- Phosphorus - 32**
- in vitro metabolic tracer studies for protein phosphorylation and DNA and RNA probe generation
- Phosphorous- 33**
- DNA sequencing
- Sulfur - 35**
- in vitro uptake studies
 - radiolabeling of cellular protein
 - sulfate labeling of cartilage
- Chromium - 51**
- labeling of red blood cells
- Iron - 59**
- incorporation into hemoglobin
- Copper - 64**
- in vivo and in vitro metabolic tracer studies
- Calcium - 45**
- in vitro radiolabeling and analysis of contractile proteins

ITEM 7: Individual Responsible for Radiation Safety Program and Their Training and Experience.

Lloyd J. Forman, Ph.D. serves as the Radiation Safety Officer. He holds the academic rank of Associate Professor and has served as the Radiation Safety Officer for UMDNJ-SOM since 1985. He has experience working with both soft and hard beta-emitters and gamma radiation. His research has involved the use of radionuclides since 1975. As a graduate student he took a course in Radiation Biology and received extensive training in the use of radioactive iodine and radiation safety as a post-doctoral fellow in the Department of Physiology at Michigan State University. Since joining the faculty, Dr. Forman has participated in numerous Continuing Professional Education Short Courses dealing with radiation safety as well as with issues of state and federal guidelines for the use of radioactive materials and their disposal. These courses were offered by Cook College, part of the Rutgers University system. He is also a member of the New Jersey Radioactive Materials Waste Management Group and has been an advocate of the development of a radioactive materials storage facility in New Jersey.

To assist in the continuous duties of the Radiation Safety Officer and to perform an oversight function to insure radiation safety standards, a committee composed of two principal investigators in the Science Center and a representative of the Office of Research Administration has been established. The committee includes; Kai Mon Lee, Ph.D., Robert Nagele, Ph.D. and James Kleven, Director of the Office of Research Administration. The Radiation Safety Committee meets quarterly, or at any time needed, to survey all records and procedures carried out in the radiation safety program and to assess the strengths and weaknesses of the program.

The duties of the Radiation Safety Officer are as follows:

1. The implementation of safety programs necessary to insure compliance with the provisions of Title 10, Code of Federal Regulations, and to maintain exposures ALARA.
2. Administration of radiation safety training programs to all individuals utilizing radioactive materials or working in a laboratory utilizing radioactive materials in the Science Center.
3. Working with the individual investigators, coordinates the ordering/acquisition, receipt and delivery of radioactive materials to the laboratories in the Science Center. Upon delivery, he works with receiving and the investigator for the purpose of insuring the integrity of the package and assessment of potential contamination levels of the materials received.
4. Administration of a personal monitoring program, including distribution and collection of badge TLDs, and acquisition of bioassay samples when required.

5. Reviews the monthly or quarterly records of radiation contamination surveys performed by the authorized users including routine surveys for radiation in unrestricted areas.
6. Coordination of radioactive waste collection, packaging, removal and the maintenance of all documentation associated with this process.
7. Investigates all incidents involving radioactive material and reports his findings of the cause, the extent of personnel exposure and/or property damage, and the immediate actions taken to the Department Chairman, the Office of the Dean for Research and the appropriate regulatory agencies.

As Radiation Safety Officer Dr. Forman has the authority to halt any use of radioactive material which is not in accordance with NRC guidelines, or which may result in personal exposure inconsistent with ALARA concept, or which may result in release of radioactive material to unrestricted areas. The Radiation Safety Officer is given this authority by the Assistant Dean for Research through the office of the Dean for the School of Osteopathic Medicine.

The RSO will verify , on a yearly basis, that the licensed activities are being conducted in compliance with the NRC's regulations and the terms and conditions of the license. This will be documented in order to demonstrate regulatory compliance. It will also be the responsibility of the RSO to verify, by way of meeting with, and reporting to, the Assistant Dean of Research on an annual basis, that the program for radiation safety is being conducted in full compliance with the regulations of the NRC. The RSO shall present documentation indicating that the program is being conducted in accordance with the NRC guidelines and the license. The minutes of this meeting will be taken by the Director of the Office of Research Administration and maintained on file in that office.

ITEM 8: Training for Individuals Working In or Frequently Restricted Areas

The Radiation Safety Officer shall arrange for training in radiation safety for all individuals who work or frequent the Science Center in areas where the use of radioactive material is occurring. These programs are commensurate with the extent to which the individual will be involved with radioactive materials and previous education, training and experience.

A. Training for Users of Radioactive Material

The following individuals are principal investigators who will be running the individual laboratories in the Science Center. Each has participated in a training course under the direction of Dr. Forman. In addition, each authorized user (laboratory head) has provided a signed statement to the Radiation Safety Officer indicating their (prior) training and experience in the safe use and handling of radioactive materials. This signed statement will also be indicative of their willingness to assume the responsibility of overseeing the safe use and handling of radioactive materials by the members of their laboratory including provided specific hands-on training for the use of the radionuclides specifically used in that laboratory as required.

G. Bailin, Ph.D.

K. Battaglia, Ph.D.

S. Caradonna, Ph.D.

R. Carsia, Ph.D.

K. Foster, Ph.D.

P.-S. Lai, Ph.D.

C. Ng, Ph.D.

J. Grandoni, Ph.D.

R. Schimmel, Ph.D.

R. Safaei, Ph.D.

S. Biswas, Ph.D.

P. Wong, Ph.D.

R. Sharma, Ph.D.

L. Forman, Ph.D.

C.E. Hock, Ph.D.

K. Yin, Ph.D.

T. Duda, Ph.D.

Z. Zhang, Ph.D.

R. Nagele, Ph.D.

P. Stein, Ph.D.

K.-M. Lee, Ph.D.

All individuals who will be working in the research facility (principal investigators, staff, temporary employees) must complete training in radiation safety arranged for by the Radiation Safety Officer. The following is a general overview of this training and may be modified according to education and professional training and experience.

1. The nature of radionuclides and radioactivity

- a. atomic structure
- b. radioactive decay and emissions
- c. radioactive half-life
- d. units of measurement

II. Interactions of ionizing radiation with matter

- a. interactions of alpha and beta particles, gamma and x-rays with matter
- b. range of emissions vs. matter
- c. units of exposure and dose
- d. external radiation hazards
- e. internal radiation hazards

III. Detection and measurement of radioactivity

- a. types and operation of portable survey equipment
- b. personal radiation monitoring devices
- c. interpretation of readings and measurement

IV. Principles of radiation safety

- a. minimizing personal exposure
- b. radioisotope handling techniques and safety procedures for transporting radioisotopes between laboratories
- c. avoidance and control of personal and area contamination
- d. accident procedures
- e. radioactive material storage
- f. radioactive material disposal
- g. labeling and posting requirements

V. Federal and State regulation and local policies

- a. responsibilities of authorized users
- b. responsibilities of the institution
- c. federal and state regulatory guides
- d. inspections

B. Training for Housekeeping Personnel

Housekeeping and other support services are only performed during normal working hours when authorized users are present in their laboratories. To ensure that support personnel are not accidentally exposed to radioactive materials is the responsibility of the laboratory director (principal investigator). Housekeeping personnel are educated concerning warning labels and are instructed by the investigator as to the location of radioactive materials and waste. The Radiation Safety Officer shall work with the director of Environmental Support Services to ensure that

newly hired support staff employees receive proper orientation in radiation safety prior to the start of work in areas near radioisotope laboratories.

C. Training for Security Personnel

Training for security personnel will be provided on an "as needed" basis. The Radiation Safety Officer will provide training to security supervisors in those areas of radiation safety which might relate to their job responsibilities and responsibilities of personnel under their supervision. Topics covered would be:

- I. elementary discussion of radioactive emissions
- II. presentation of the various types of warning labels and their meaning
- III. procedures for handling radioactive packages during non-working hours
- IV. emergency procedures
- V. identification of safety violations
- VI. federal and state regulatory guides and responsibilities of the institution

D. Refresher Training - Investigators and their Staff

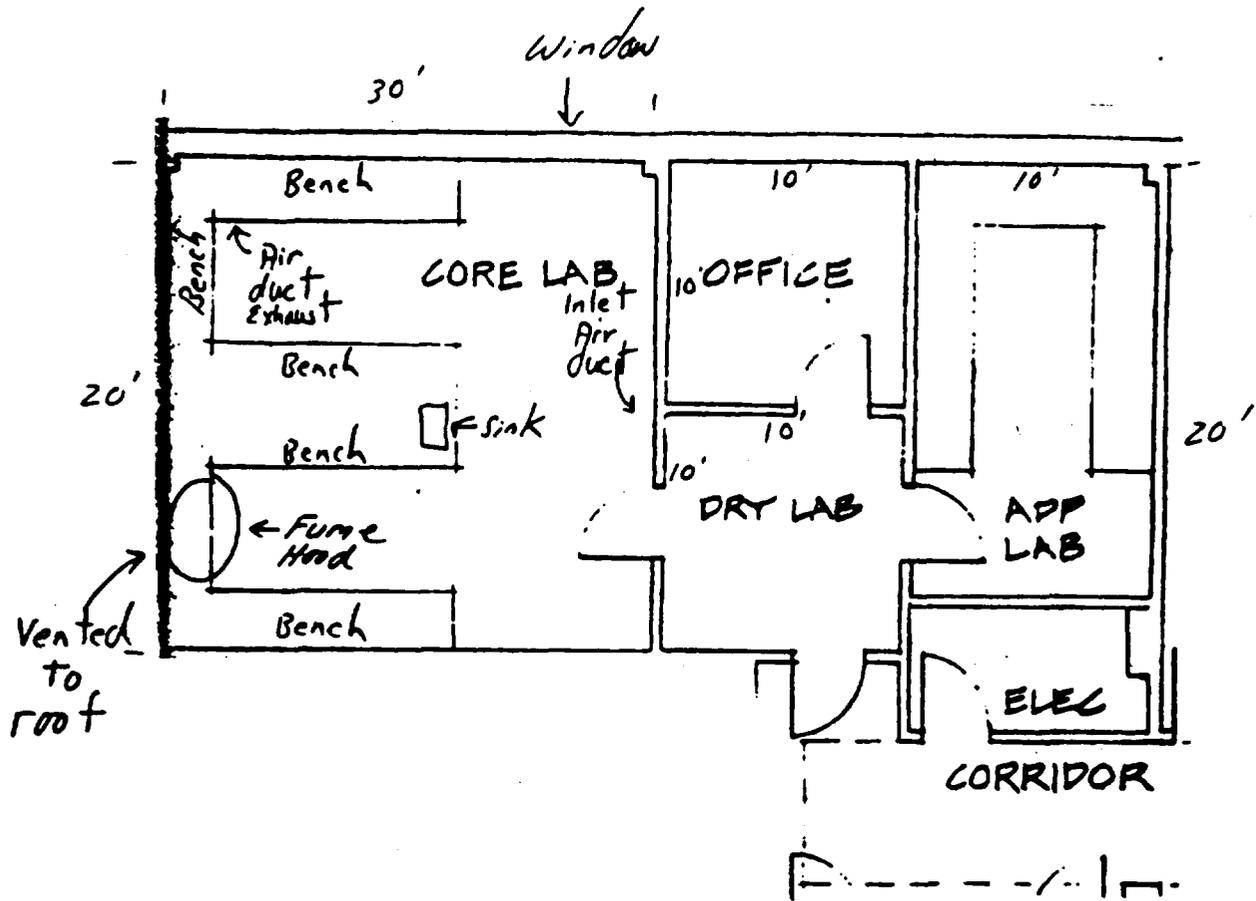
All investigators and their staff involved in the use of radioactive materials will be required to attend a refresher training session once each year. This session will be given by the RSO and will cover general procedures for safe handling of radioactive materials and their proper disposal. At this time current procedures for the handling of radioactive waste will be reviewed as well as any topic deemed necessary by the RSO. Records of the date of this training, the length of the session, those attending the session and the topics discussed, will be recorded. If the presenter is other than the RSO, this shall be indicated.

E. Refresher Training - Housekeeping and Security

These individuals will also be given a refresher training by the RSO, once each year. Records of the date of this training, the length of the session, those attending the session and the topics discussed, will be recorded.

ITEM 9: Description of Facilities and Equipment for Radionuclide Use in Research Laboratories

This UMDNJ-SOM Science Center (2 Medical Center Drive) currently houses 19 laboratories which utilize radioactive material either routinely or periodically. The following design criteria are characteristic of these labs:



1. Fume Hood - Each lab is equipped with a fume hood located away from windows doors and ventilation openings. All air flow lines are directed into the hood with a minimum velocity of 100 linear feet per minute with the sash fully open. The floor of the hood is capable of supporting the weight of any lead shielding required. These hoods are inspected and certified on a yearly basis.

2. Lab Benches and Sinks - The surface of laboratory benches is a smooth non-porous alberene stone. Sinks used for decontamination of reusable items will be designated and properly labeled as being radioactive.

3. Storage Units - Refrigerators and freezers used for storage of radioactive materials are available in each laboratory. No material of a radioactive nature will be stored in walk-in refrigerators (including waste). Storage of radiolabeled compounds which would produce

an exposure rate of 2 mRem per hour at 3 feet will be in a lead lined refrigerator or specially constructed cave which shall be of sufficient thickness on all sides to reduce the exposure rate to 0.5 mRem per hour at 3 feet.

4. Postings - All entrances into "hot labs" shall have proper signage indicating to anyone entering the room that radioactive materials are present. This will be part of the risk communication signage displayed on the entrance of each laboratory in the building.

The format of this sign will include the standard radiation symbol in black or magenta on a yellow background and shall state "Caution Radioactive Materials". In accordance with revised 10 CFR 20.1902e, such signage will be displayed in areas or rooms in which the storage or use of radioactive materials exceeds 10 times the quantity of this material as specified in appendix C to part 20.1001 - 20.2401. This determination will be made by the RSO.

Authorized users shall also post the following documents in a conspicuous location within the "hot lab".

- 1) A copy of NRC Form 3 "Notice to Employees", on which it is stated where employees can obtain a copy of revised 10 CFR20 and 10 CFR19 (In the office of the Radiation Safety Officer). A copy of this posting will also be displayed in the area of the entrance to the Science Center, available to all employees.
- 2) A copy of "General Safety Requirements for All Individuals Handling Radioactive Materials", issued by the Radiation Safety Officer.

The materials listed below are a requirement for all laboratories in the research facility:

5. Protective Clothing - All users of radioactive material shall insure that there are lab coats and an adequate supply of disposable rubber or plastic gloves available for all individuals under their supervision. Lab coats shall be monitored after each use for contamination and used gloves shall be disposed of as radioactive waste.

6. Remote Pipettors - All authorized users shall maintain devices for remote pipetting of radioactive solutions, mouth pipetting is forbidden.

7. Bench Top Covering - All individual users of non-sealed sources of radioactive materials will have an adequate supply of absorbent top/non-absorbent bottom paper with which to cover bench tops where radioactive materials are handled. This covering shall be changed subsequent to its use and not remain on the bench-top for extended periods of time.

8. Shielding - All users who possess sources of gamma radiation are required to have shielding of sufficient thickness to maintain the exposure rate below 2 mRem per hour at 3 feet from the surface of the shield. Shielding requirements are determined on an individual basis at which time all phases of the proposed procedure are considered to insure that shielding materials are of appropriate design to afford protection during the entire procedure. Investigators using sources of hard beta radiation shall have lucite or plexiglas shielding of sufficient thickness to absorb all the radiation.

All individuals using radioactive material shall have immediate access to radiation detection and counting equipment for use in evaluating contamination levels. The type of equipment will be appropriate for the type of radionuclide being surveyed, (i.e. liquid scintillation counters will be used for soft beta emitters, solid crystal scintillation counters for gamma emitters). Investigators routinely using millicurie quantities of gamma or hard beta sources are required to maintain their own G.M. - type survey meters for monitoring the activities in their laboratory.

9. Radiation Hood/Glove Box - All procedures presenting a potential release of airborne radioactivity (i.e. radioiodination reactions, work with radioactive gases) will be carried out in a dedicated hood of glove box design, available from the Radiation Safety Officer. This hood has a negative air flow (with arm ports open) of 80 cubic feet per minute and an in-line activated charcoal filter capable of absorbing 99% of airborne radionuclides which discharges independently into the atmosphere.

10. Personal Monitoring - All individuals who handle sources of penetrating radiation, or who frequent rooms in which these sources are used, shall be issued whole body personal monitoring devices ("TLD" dosimeters). These monitors will be supplied by R.S. Landauer Inc. Personal monitors shall be distributed under the direction of the Radiation Safety Officer on a quarterly basis. The Radiation Safety Officer shall also review all monitoring results, as received, to ensure that dose levels are within the limits specified in the revised 10 CFR 20.1001 to 20.2401, in particular section 20.1201 (effective 1/1/94), and are consistent with the ALARA principle.

11. Storage Facility

Radioactive waste is stored in a room fully dedicated for this purpose. This room, which is located on the first floor of the Science Center, is a single access facility which remains locked. This room is away from the normal personnel traffic pattern in the Science Center. It has a concrete floor, cinder block walls, a ventilation system that exhausts air to the outside, a sprinkler system and overhead lights. The key shall be kept by the Radiation Safety Officer only. To dispose of radioactive waste, arrangements must be made with the Radiation Safety Officer (RSO) to gain entry into the storage room.

ITEM 10: Radiation Safety Program

A. Purchase and Acquisition of Radionuclides

All means of procuring radionuclides (i.e. purchase, loan, transfer or gift) are regulated by the Radiation Safety Officer. An authorized user wishing to acquire radionuclides through transfer, loan, or by donation from an outside licensed source must make Radiation Safety Officer aware of the materials since they will not be accompanied by a purchase order.

B. Receipt of Radioactive Materials

All packages containing radioactive materials are delivered to the Department of Materials Management (Receiving). They in turn notify the Radiation Safety Officer and a record is made of the receipt of the radionuclide, the type of radionuclide received and the investigator to whom the package is to be delivered to. The package is inspected for any signs of leakage and delivered to the authorized user. All users are instructed to contact the Radiation Safety Officer immediately if they inadvertently receive a package directly from the vendor. Only deliveries made during normal working hours will be received. Investigators have been informed that no orders shall be made for delivery on weekends or holidays. Materials delivered at these times will not be accepted.

C. Package Inspection

1. The unopened package is inspected for superficial indications of damage or leakage (i.e. puncture marks, evidence of crushing, wet spots). If this inspection reveals that the package is damaged, the Radiation Safety Officer will be notified and a full investigation will be initiated to determine if radioisotope has been lost and the extent of exposure and/or contamination to any individual coming in contact with the package. The vendor, carrier and NRC will be contacted immediately.
2. The package is delivered to the authorized user who will be responsible for wipe testing the outer box, the inner wrapper and the vial containing the radionuclide. The operator will don gloves before inspecting the contents of the package. If the radionuclide or its labeled form is a gas or has a high tendency for becoming air-borne, this procedure will be conducted in the glove box. The radionuclide, chemical/physical form, activity and calibration date will be compared to the information provided with the packing slip and requisition order.
3. Wipe test measurements will be made using a liquid scintillation counter for shipments of beta sources and well-type NaI crystal for shipments of gamma sources. If wipe tests indicate contamination levels equal to or greater than 0.006 microcuries the vendor, carrier and NRC will be notified pursuant to revised 10 CFR 20.1001 to 20.2401, with particular

reference to the material contained in section 20.1906. Packages and/or packing material found to be contaminated will be discarded as radioactive waste and placed in the appropriate containers.

4. The results of the wipe test procedure will be recored on a special form obtained from the Radiation Safety Officer. *A copy of the form used to record package inspection is attached at the end of this application (pg 20).*

5. The results of this inspection will be entered into the permanent record. The activity and chemical form will be entered into the inventory log. The total activity will be compared to the possession limits specified on the institutional license.

6. The authorized user will wipe test the material, record their results and send this information to the Radiation Safety Officer within 24 hours of receipt. The investigator will also retain a copy of the wipe test. If this is not done, no further deliveries of radioactive materials will be delivered to the investigator until the appropriate paper work is received. If this happens routinely, they will forfeit their ability to obtain radioactive materials. In addition, the Departmental Chairperson and the Dean of Research will be notified. A suitable length of forfeiture will be determined by the Radiation Safety Officer, the Chairperson and the Dean of Research.

D. Area Survey Procedures and Personnel Protection

All authorized users are required to perform surveys for contamination and to monitor radiation levels. These surveys will be sent to the Radiation Safety Officer for his review and will be maintained on record in his office. A copy will be retained by the investigator.

1. Radiation Monitoring

All laboratories where sources of gamma or hard beta radiation are used or stored shall be monitored for radiation levels. Monitoring shall be performed during contamination surveys or whenever an increase in the radiation level is suspected.

Radiation levels shall be measured whenever a new procedure involving gamma or hard beta sources is being performed for the first time.

Monitoring procedures shall be performed with a portable survey meter calibrated to read in mRem/hr. If the instrument is energy dependent in its response, the operator will employ a correction factor or refer to a curve to obtain the correct exposure rate.

When area monitoring reveals levels of radiation sufficient to produce whole body dose of two mRem in one hour, the authorized user shall ensure that the room is properly posted with a "caution radiation" sign. If monitoring reveals exposure levels sufficient to

produce a whole body exposure of one hundred mRem in one hour, the area shall be evacuated and the Radiation Safety Officer contacted immediately.

The authorized user is required to keep records of all surveys for contamination and area survey results. The Radiation Safety Officer provides the necessary form for recording the results which indicate the location of the survey on a floor plan and spaces for measurements and background levels. Records of survey results shall be maintained by the authorized user for a period of two years.

2. Wipe Tests

Laboratories where activities up to one millicurie are handled shall be surveyed on a monthly, rather than quarterly basis. Laboratories handling more than one and up to ten millicuries shall be surveyed at weekly intervals. Laboratories where in excess of ten millicuries are routinely handled shall perform daily surveys with a GM survey meter and wipe tested on a weekly basis.

Wipe tests shall be made using a piece of filter paper wetted with a small amount of ethanol to facilitate removal of contamination. Each wipe sample will represent an area of approximately 100 cm² in the location where radionuclides are handled. In addition to these samples, wipe tests shall be made at other locations which could indicate a contamination problem (i.e. doorknobs, refrigerator/freezer handles, floors near doorways, instrument consoles, faucet handles, etc.). Authorized users are instructed to obtain samples from drain traps with a pipet for detection of radioactivity.

All wipe samples for detection of beta emitting radionuclides shall be counted in a liquid scintillation counter. Each authorized user shall be capable of calibrating the counter so measurements in CPM can be converted to DPM. Wipe tests for gamma ray emitting radionuclides will be counted with a NaI detector for which authorized users know the efficiency of detection for the photon energies being measured.

Samples reading 100 DPM for a 100 cm² wipe area will be interpreted as indicating contamination, thus necessitating clean up procedures. Wipe tests shall be made periodically during clean up to evaluate the effectiveness of the procedure. The area will be considered decontaminated when the net count rate is at background levels.

3. Glove Box Requirements

All authorized users handling unsealed sources of volatile radionuclides (i.e. inorganic radioiodine) or radioactive gases are required to handle this material in a glove box located in the radiation safety laboratory. This unit is completely sealed and exhausts through an activated charcoal filter capable of removing greater than 99% of the radionuclides present and discharges independently into the atmosphere.

The presence of radioactivity in the air in the room will be monitored by an air meter equipped with a charcoal filter. The filter will be monitored after every procedure in the glove box. At the first sign of detectable radiation in the air (as indicated by detectable radiation on the filter), the charcoal filter in the glove box will be replaced.

4. Bioassay

Where appropriate, authorized individuals using millicurie quantities of unsealed sources of radionuclides are required to submit urine specimens for analysis of possible ingested radioactive material. The frequency of monitoring will conform with the recommendations contained in NRC Division of Fuel Cycle and Material Safety - publication dated October 19, 1979. "Guidelines for Bioassay Requirements for Tritium", and regulatory Guide 8.20, "Applications of Bioassay for Iodine-125 and Iodine-131".

E. Procedures and Precautions with Laboratory Animals

Authorized users intending to maintain radioactive animals for a period of time are required to make arrangements with the director of research animal facilities and the Radiation Safety Officer prior to the start of the study to ensure a separate room is available to house the animals.

The authorized user will make arrangements to have metabolic cages to collect radioactive urine and feces.

The room will be posted with a "caution radioactive materials" sign on the entrance.

The room will remain locked whenever unoccupied.

The authorized user will be responsible for attending to the animals. Animal facility personnel will be instructed not to care for the animals and to avoid entering the room.

Welfare oversight of these animals will be conducted by the supervisor of the animal facility on a daily basis.

Arrangements will be made to have the Radiation Safety Officer monitor the radiation levels within the room and in adjacent rooms and corridors.

If an airborne hazard is possible, the Radiation Safety Officer will perform air monitoring measurements within the room and in the adjacent corridor.

Authorized users will be responsible for decontamination of the room at the conclusion of the study. The Radiation Safety Officer will perform a back-up survey to substantiate the thoroughness of the clean-up procedures.

Radioactive animal carcasses will be stored as hot waste in commercial disposal drums. If the radioactive material is short-lived, the carcass will be incinerated when the activity has decayed to undetectable levels. If the radionuclide is long-lived the carcass will remain in the drum for burial.

F. Radiation Detection Instruments

Description of Radiation Survey Equipment

Type	Manufacturer Model no.	Window Thickness	Radiation Detected	Sensitivity	Use
<i>Ionization chamber</i>	Ludlum model 9	7 mg/cm ² (cover open)	gamma beta	0.25 mR/hr	area survey
<i>G.M. detector</i>	Ludlum 44-1	0.9 mg/cm ²	beta	10 cpm	area survey
<i>Portable NaI detector</i>	Ludlum 44-2	25 mg/cm ²	gamma	10 cpm	area survey
<i>NaI well detector</i>	Abbott ANSA	0.2 mm A1	gamma	20 cpm	wipe test
<i>Liquid Scint. counter</i>	Beckman LS6000IC	—	beta	20 cpm	wipe test

Portable survey instruments will be calibrated by:

Applied Health Physics Inc.
2986 Industrial Blvd
Bethel Park, PA 15102
(412) 835-9555

They are licensed under NRC license No. 37-09135-01 and have filed with the commission procedures for detector calibration. Calibrations will be performed at yearly intervals or when obvious repair and recalibration is necessary. The Abbott ANSA and Beckman LS6000IC contain internal standardization mechanisms.

G. Personal Radiation Monitoring Devices

All individuals who handle sources of penetrating radiation or who frequent rooms in which these sources are used, shall be issued whole body personal monitoring devices. These monitors shall be supplied by Landauer Inc.

Penetrating radiation is that form and/or energy of radiation which can be detected by a personal monitor (film or TLD badge) used in evaluating external exposure. Any individual authorized to handle sources of gamma and/or x-radiation or sources of beta radiation with maximum energy above three hundred keV shall be issued whole body monitors and required to participate in the bioanalysis program for ingested radionuclides. This category of worker shall include authorized users, students and staff, receiving personnel who handle incoming radionuclide shipments, and operations personnel who may have to effect systems repairs in restricted areas.

Individuals handling sources of soft beta radiation which do not present an external hazard (i.e. tritium, C-14) shall not be issued external personal dosimeters, but shall be required to participate in the bioanalysis program.

H. Grant Applications

The completion of a brief form is required before the submission of any grant application. The original of this form is to be submitted to the Radiation Safety Officer for his signature. A copy of the signed form is to be sent to the Office of Research Administration for their records. This form will indicate the radionuclides intended for use and the amounts to be used on a yearly basis. The purpose of this form necessary to ensure that the needs and requirements for the use of radioactive materials are within the boundaries established in our license.

I. UMDNJ-SOM Radiation Safety Policy Manual

All individuals who will be working in the research facility (principal investigator, staff, students, other employees) will be provided with a copy of the UMDNJ-SOM Radiation Safety Policy Manual (which contains the pertinent material contained in this application).

ITEM 11: Radioactive Waste Management

Radioactive waste material will be stored in a room within the Science Center as described in Item 9, number 11. Radioactive waste containing radionuclides with a half life of greater than 75 days shall be transferred to a licensed broker for delivery to Barnwell S.C. The broker contracted for this service is:

Radiac Research Corp.
261 Kent Avenue
Brooklyn, New York 11211
(718) 963-2233

If Barnwell were to close, there is sufficient additional space available in the Science Center and sufficient possession limits (at the current time) in our license to hold this material until a long term storage facility is established in New Jersey or in one of the member states of our compact.

Prior to transfer to Radiac, Inc., radioactive waste is packaged under the direction of the Radiation Safety Officer to ensure compliance with Federal regulations and the requirements of the licensed burial site. All manifests for the shipping and burial of solid waste will be prepared by the Radiation Safety Officer. It will also be the responsibility of the Radiation Safety Officer to prepare and track shipment of radioactive materials contained in scintillation fluid and considered as radioactive waste and hazardous waste. This will include tracking the receipt of manifests within thirty days of shipping to the treatment site in Florida and the notification of the states of Florida and New Jersey of the tracking and disposal of this mixed waste.

Radioactive waste is stored in a room fully dedicated for this purpose. This room, which is located on the lower level of the facility, is a single access facility which shall remain locked. The key shall be kept by the Radiation Safety Officer only. To dispose of radioactive waste, arrangements must be made with the Radiation Safety Officer (RSO) to gain entry into the storage room.

ITEM 11: Radioactive Waste Management

1. Storage Site - Radioactive waste material will be stored in a room within the Science Center as described in Item 9, number 11. Radioactive waste is stored in a room fully dedicated for this purpose. This room, which is located on the lower level of the facility, is a single access facility which shall remain locked. The key shall be kept by the Radiation Safety Officer only. To dispose of radioactive waste, arrangements must be made with the Radiation Safety Officer (RSO) to gain entry into the storage room.

2. Management of Radioactive Waste Derived from Radionuclides with a Half-life of Greater than 75 Days

Radioactive waste containing radionuclides with a half-life of greater than 75 days shall be transferred to a licensed broker for delivery to Barnwell S.C. The broker contracted for this service is:

Radiac Research Corp.
261 Kent Avenue
Brooklyn, New York 11211
(718) 963-2233

If Barnwell were to close, there is sufficient additional space available in the Science Center and sufficient possession limits (at the current time) in our license to hold this material until a long term storage facility is established in New Jersey or in one of the member states of our compact.

Prior to transfer to Radiac, Inc., radioactive waste is packaged under the direction of the Radiation Safety Officer to ensure compliance with Federal regulations and the requirements of the licensed burial site. All manifests for the shipping and burial of solid waste will be prepared by the Radiation Safety Officer. It will also be the responsibility of the Radiation Safety Officer to prepare and track shipment of radioactive materials contained in scintillation fluid and considered as radioactive waste and hazardous waste. This will include tracking the receipt of manifests within thirty days of shipping to the treatment site in Florida and the notification of the states of Florida and New Jersey of the tracking and disposal of this mixed waste.

3. Management of Radioactive Solid Waste Derived from Radionuclides with a Half-life of Less than 75 Days

Solid waste material with a half-life of less than 75 days will be stored apart from the radioactive waste which will be removed by our broker. The waste will be stored for 10 half-lives from the date of deposit into the storage facility. Materials will be labeled upon arrival as to the radionuclide, an estimate of the amount of radioactivity (μCi - mCi), the date

of deposit and the date at which the material will have been stored in the storage area for 10 half-lives. At the prescribed time, the material will be moved to an area of low background. It will be monitored with an ionization chamber and with a Geiger counter equipped with a probe commensurate with the detection of the type of isotope comprising the waste (gamma or beta). After 10 half-lives and when emission levels are found to be below detectable limits, all markings indicating radioactive material will be removed and the material will be disposed of as regulated medical waste. Disposal will be accomplished by the broker under contract to UMDNJ-SOM for the removal and disposal of regulated medical waste.

Liquid waste containing radionuclides with a half-life of greater than 75 days is accumulated and solidified with the use of Delaware Custom Material Waste-Packs and then disposed of as solid waste.

4. Management of Radioactive Liquid Waste Derived from Radionuclides with a Half-life of Less than 75 Days

This material will be handled similarly to the handling of solid radioactive waste with certain exceptions. First, when delivered to the storage area, an aliquot will be counted with either a gamma or beta counter and a calculation will be made of the amount of the radioisotope contained in the volume being stored. The investigators are under instruction from the RSO not to mix isotopes, but rather to collect each one in a separated container dedicated to that isotope. After ten half-lives an aliquot will be counted. When background levels have been reached, the material will be disposed of according to the composition of the fluid (ie, chemical waste will be stored for removal by our chemical waste broker and soluble neutral buffers, or tissue culture medium, will be disposed of via the sewer system.).

The RSO will maintain, in his office, records of all material stored for decay. This will include the type of radionuclide, the estimated amount, the date the material was deposited and the date on which it was found acceptable for disposal.

RADIOISOTOPE RECEIPT FORM

DATE: _____

TIME RECEIVED: _____

INVESTIGATOR: _____

PO #: _____

RADIONUCLIDE: _____ ACTIVITY: _____

PHYSICAL (i.e. LIQUID) _____ CHEMICAL FORM: _____

VENDOR: _____

PACKAGE INTEGRITY

VISUAL INSPECTION (i.e. damaged box): _____

PACKAGE CONTAMINATION: _____ CPM

SEALED BAG CONTAMINATION: _____ CPM

VIAL CONTAMINATION: _____ CPM

BACKGROUND CONTAMINATION: _____ CPM

INSPECTED BY: _____

Please retain this form for your records and send a copy to the RSO (Dr. Forman) within 24 hours.