

University of Puerto Rico
Medical Sciences Campus

BROAD SCOPE LICENSE

Prepared by: Jossian Javier Pagán Lisboa
Radiation Safety Officer

Reviewed by: Annabell C. Segarra, Ph.D.
Chairperson Institutional Radiation Safety Committee

Approved by: Ilka C Ríos, D.M.D.
Chancellor UPR Medical Sciences Campus

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Item 2: NAME AND MAILING ADDRESS OF APPLICANT

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Item 3: ADDRESSES WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

1. Medical Sciences Campus of the University of Puerto Rico, Dr. Guillermo Arbona Building, Puerto Rico Medical Center, Río Piedras, Puerto Rico 00936
2. Nuclear Medicine Laboratory of the University of Puerto Rico Medical Sciences Campus, 4th Floor, Dr. Isaac González Martínez Hospital, Puerto Rico Medical Center, Río Piedras, Puerto Rico 00936
3. Radiation Safety Office of the University of Puerto Rico Medical Sciences Campus, Basement, Comprehensive Cancer Center, Puerto Rico Medical Center, Río Piedras, Puerto Rico 00936

Item 4: PERSON TO BE CONTACTED ABOUT THIS APPLICATION

1. Mr. Jossian J. Pagán Lisboa, Radiation Safety Officer
University of Puerto Rico, Medical Sciences Campus
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Office direct phone number: (787) 766-3062
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ITEM 5 - RADIOACTIVE MATERIAL AND ITEM 6 - PURPOSE

The maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides and purpose is sated **Appendix A, Table1, "Radioactive Material and Purpose"**. It is also included all the sealed sources under the UPR-MSc material license and the manufacturer's name, model number and the maximum activity per source and the total possession limit is provided in the reference table so that the NRC can verify that they have been evaluated in a SSD registration certificate or specifically approved on a license.

5.2 FINANCIAL ASSURANCE AND RECORDKEEPING FOR DECOMMISSIONING

The possession limits on the Medical Sciences Campus University of Puerto Rico material license 52-01946-07 have been reduced to a level that does not require financial assurance.

1. Letter dated June 11, 2018, University of Puerto Rico Medical Sciences Campus, license amendment, mail control no. 602678. Amendment No. 37 eliminates a number of sealed and unsealed radioisotopes from our license. Due to the reduction in the limits of radioactive material in our possession, we are no longer be required to maintain financial assurance.
2. Letter dated August 21, 2018 University of Puerto Rico Medical Sciences Campus, return of financial assurance (mail control no. 609113). Original financial assurance documents were returned to the UPR-MSc, since they are no longer required.

Item 7: Individuals Responsible for Radiation Safety Program And Their Training and Experience

The Chancellor (executive management, the Radiation Safety Committee (RSC), and the Radiation Safety Officer (RSO) and his or her staff, as necessary, work as a team to oversee the broad scope program. Each plays a critical role within a given area of responsibility. Regardless of the individual's title, the Chancellor appoints a representative who actively participates as a member of the radiation safety committee (RSC) and has the authority to delegate necessary resources to the radiation safety program. Members of the Radiation Safety Committee (RSC) are users of radioactive material, they actively direct and participate in research projects as principal investigators or may have significant administrative or clinical experience involving the safe use, storage and disposal of radioisotopes. Enclosed is an organizational chart that describes the management structure, reporting paths, and the flow of information between executive management, the RSC and the RSO. **Appendix B, "Management Organizational Chart"**

7.1 CHANCELLOR OF UPR - MSC:

The Chancellor delegates sufficient authority to the Radiation Safety Committee to establish and enforce UPR-MSC policies and procedures. The Chancellor or his/her delegate is responsible for oversight of the UPR - MSC radiation safety program and has the ultimate responsibility of the license and the activities associated with the license. Executive management has an important role in implementing and managing the radiation safety program. Executive Management will ensure that the "As Low as Reasonably Achievable" (ALARA) concept is utilized by all employees, staff, students, patients and visitors. **Appendix C, "The Chancellor's Duties"**. This responsibility is carried out by means of:

1. Authority to delegate resources for the program and appropriate funds in a timely manner.
2. Available to facilitate effective and immediate action on behalf of management, the RSC, and the RSO, particularly in the event of an emergency.
3. Authority to make prompt decisions without having to consult with higher management officials, including the authority to take whatever action is necessary to ensure that all radiation safety practices are in accordance with the regulations and conditions of the license.

7.1.1 DUTIES OF THE CHANCELLOR: (Appendix C)

7.2 RADIATION SAFETY COMMITTEE (RSC)

This is a high-level group of scientists and researchers appointed by the Chancellor to establish policies and regulations governing the use of ionizing radiation, implementing, and managing the radiation safety program of the UPR-MSC in compliance with federal and local regulations. The RSC ensures the safety and compliant handling and use of radiation sources and that radiation exposure to employees, staff, patients, and the environment are maintained As Low as Reasonably Achievable (ALARA). **Appendix D, "Duties and Responsibilities of the RSC"**.

7.2.1 DUTIES AND RESPONSIBILITIES OF THE RSC. (Appendix D)

7.2.2 MEMBERSHIP AND ORGANIZATION OF THE RSC. (Appendix D)

7.2.3 REQUIREMENTS OF THE RSC AND THE RSO FOR AUTHORIZING NEW USERS AND NEW USES. (Appendix D)

7.2.4 PROCEDURES FOR AUTHORIZATION OR INSTITUTIONAL LICENSE TO USE AND HANDLE RADIOACTIVE MATERIALS AT THE UPR – MSC. (Appendix D)

7.2.5 SANCTIONS FOR VIOLATIONS OF MSC RADIATION SAFETY POLICY. (Appendix D)

7.2.6 ORDERING RADIOISOTOPES AND OTHER RADIOACTIVE MATERIALS. (Appendix D)

7.3 RADIATION SAFETY OFFICER (RSO):

Name of RSO: Jossian J. Pagán Lisboa

Office phone number: (787) 758-2525, extensions 1687 or 1688

Office direct phone number: (787) 766-3062

Email: jossian.pagan@upr.edu

Previously on License No.: NRC 52-01946-07, Docket No.: 030-13584

Delegation of Authorization, Letter March 12, 2018 (ML18085B076). **Appendix E, "Radiation safety Officer Delegation of Authority"**

The RSO is a professional and a qualified individual by training and experience in radiation protection assigned by the Chancellor of the MSC-UPR to serve as the Radiation Safety Officer (RSO) with responsibility for the overall radiation safety program and compliance with the regulations for the use of byproduct material. The RSO reports to top management, the Administration Representatives, and the RSC. The RSO has access to all levels of the organization and has the authority to terminate any activity in which health and safety appear to be compromised. The RSO has no disciplinary authority which shall reside instead with the Dean of Administration or the Chancellor.

The RSO must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used in a safe manner. Therefore, the RSO manages the day-to-day operations of the Radiation Safety Program and assures compliance with the MSC-UPR policies and procedures and with the NRC rules and regulations to adequately protect public health and safety and maintain exposures ALARA. The RSO typically performs a preliminary review of proposed new uses and users, prior to formally discussing the proposal with the RSC. The RSC grants the formal approval of new users and uses. To accomplish this, the RSO should have access to all activities involving the use of byproduct material.

The RSO is a member of the RSC and works closely with the RSC and executive management in implementing the radiation safety program. In an emergency, a designee of the RSO, or of the Chairperson of the RSC, may act as RSO when necessary to control or prevent an incident involving radioactive materials, including the temporary cessation of laboratory operations, or withholding authority to purchase or use isotopes until the RSC reviews these infractions. The RSO and the RSC shall be provided with sufficient authority, organizational freedom, and management prerogative to accomplish these goals.

7.3.1 DUTIES OF THE RSO. (Appendix E)

7.4 RADIATION SAFETY OFFICE STAFF

The Radiation Safety Office, which is comprised of technicians under the direction of the RSO, is responsible for the UPR-MSC overall compliance with policies and regulations. The Radiation Safety Office also provides a variety of technical services and audits necessary to achieve such compliance. The licensee will provide sufficient professional and administrative staff to assist the RSO in implementing the radiation safety program.

Licensee will evaluate the licensed program and ensure that the RSO has adequate resources to effectively manage the program.

The Radiation Safety Office is also known as the Office of Laboratory Safety in Research (OLSR). This Office has the overall responsibility to oversee the safe use of biological, chemical, and radioactive material in biomedical research laboratories of the MSC-UPR. Currently the RSO also serves as the Director of the Office of Laboratory Safety in Research. The Director of OLSR reports to the Chancellor, the Dean of Administration, and the Chairpersons of the Radiation Safety Committee (RSC) and the Institutional Biosafety Committee (IBC).

7.5 AUTHORIZED USERS (AU's)

Individuals must have adequate training and experience with the types and quantities of licensed material that they propose to use. Their training and experience are reviewed by the RSC and after evaluation approved (or denied) the use of licensed radioactive materials. They directly supervise the use of licensed material in his or her laboratory according to regulatory requirements. The information demonstrating that each AU is qualified by training and experience to use licensed materials is available in the AU's file.

Appendix F "The Authorized Users (AU) Responsibilities"

7.6 RADIATION WORKER

Individuals who use radioactive materials assume certain responsibilities in their work. The individual worker is the "first line of defense" in the protection of students, personnel and the environment against undue risks of radiation exposure and/or contamination. Since the workers themselves, are the direct handlers of the radioactive material, the ultimate responsibility lies with them for safety and compliance with laws and regulations. For this reason, it is critical that they be aware of the risks, safe practices and requirements for use, management, and disposal of radioactive materials. The Workers may be graduate students, technicians, post-doctoral fellows, visitors, or any other individual working under the supervision of an Authorized User who handles radioactive material. **Appendix G, "The Radiation Worker Responsibilities".**

ITEM 8: TRAINING FOR INDIVIDUAL WORKING IN OR FREQUENTING RESTRICTED AREAS

All employees that handle radioactive materials in the course of their employment, are likely to receive in a year an occupational dose greater than 1 mSv (100 mrem). Before starting to work with licensed material they will receive radiation safety training commensurate with their assigned duties and responsibilities specific to the licensee's radiation safety program. The UPR-MSC will not assume that safety instruction has been adequately covered by prior employment or academic training. The person conducting the training is the RSO and the AU's. These are the individuals that meet the qualifications and are familiar with the licensee's program. Records of workers training will be maintained for at least 3 years and will include the date of the instruction or training and the name(s) of the attendee(s) and instructor(s).

The UPR-MSC radioactive material license dictates the training requirements to work with ionizing radiation sources. The extent of training will vary upon the type and frequency of radiation used. For most workers, initial and annual refresher training are required and provided.

Ancillary personnel (e.g., clerical, janitorial and/or housekeeping, technicians, security) whose duties require them to work in the vicinity of radioactive material will be informed by the RSO or designee about radiation hazards and the appropriate precautions (what symbols to look for, which waste containers to empty, or which areas to enter or avoid). Periodic refresher training will also be provided. Retraining will be performed whenever there is a change in the duties or the work environment and at a sufficient frequency ensuring that all staff are adequately trained.

For laboratory workers (e.g., students), who are NOT radiation workers but work for a researcher who is an Authorized User (AU), it is the responsibility of the AU to provide appropriate training to these workers. The employee must successfully complete a "General Radiation Safety Training Course" or equivalent. This can be accomplished by viewing the "Radiation Safety" video. The AU must certify in written that they received this training and present a copy of this certificate to the Radiation Safety Office. The training must be commensurate with the worker's potential exposure to radiation. In some cases, training may not be necessary (e.g., workers not required to work in any of the laboratories where radioactive material is authorized). The AU may also contact Radiation Safety Office for assistance.

Training may be in the form of lectures, demonstrations, videotapes, or self-study, and emphasize practical subjects important to the safe use of licensed material.

8.1 TRAINING PROGRAM FOR INDIVIDUALS USING RADIOACTIVE MATERIALS FOR MEDICAL USE

The UPR-MSC has developed and implemented written procedures for the required training for each group of workers, including topics covered, qualifications of the instructors, method of training, method for assessing the success of the training, initial training, and annual refresher training." We have established and implemented the Model Training Program that was published in Appendix J, NUREG 1556, Vol. 9, Program-Specific Guidance About Medical Use Licenses, Revision 3 (September 2019). **Appendix H, "General Information for Training Program and Frequency"**.

8.1.1 Training for Individuals and staff involved in the Medical Use of Byproduct Material such as: AU's, nuclear medicine physicians, nurses, technologists, will be provided and will extend to persons that are involved in the care of patients during diagnostic or therapeutic procedures

8.1.2 Training for staff directly involved in administration to or care of patients administered byproduct material for which a written directive is required (including greater-than-30 microcuries of I-131); (e.g., technologist, nursing and, AU,)

8.2 TRAINING PROGRAM FOR INDIVIDUALS USING RADIOACTIVE MATERIALS FOR NON-MEDICAL USE

Training for staff working with byproduct material for nonmedical uses or animals containing byproduct material will include, as appropriate, the elements that are listed in **Appendix H, Section I A “General Information for Training Program and Frequency”**.

8.3 TRAINING FOR ANCILLARY STAFF

For the purpose of this section, ancillary staff includes personnel engaged in janitorial and/or housekeeping, laboratory, and security. The training program for ancillary personnel performing duties that are likely to result in a dose more than 1 millisievert (100 millirem) will include instruction commensurate with potential radiological health protection problems present in the workplace. Alternatively, prohibitions on entry into controlled or restricted areas may be applied to ancillary personnel unless escorted by trained personnel. The topics of instruction are listed in **Appendix H, Section II, “General Information for Training Program and Frequency”**.

8.4 TRAINING REQUIREMENTS

8.4.1 The Nuclear Medicine Physicians:

Any medical use of byproduct material must be carried out by or under the supervision of an authorize user as defined in 10 CFR 35.2. Subpart D and E of the NRC 10 CFR Part 35 outlines the training and experience that the NRC has found acceptable for physicians who will use byproduct materials for medical use listed in Sections 35.100, 35.190, 35.200, 35.204, 35.290, 35.300, 35.390, 35.392, 35.394, and 35 396.

- They must present evidence of prior training and experience working with radioactive material.
- They are required to take a ten (10) hour training course from the Radiation Safety Office. This training must be completed before the approval of the Radioactive Material Use Permit.
- A one-hour refresher course will be required annually. Radioactive information concerning any changes to the ALARA Program of the UPR-MSD will be informed.

8.4.2 The Nuclear Medicine Technologist:

1. Shall have formal training in Nuclear Medicine Technology in a recognized institution in the Continental U.S.A. or in Puerto Rico and a candidate to receive the Nuclear Medicine Technologist Certified Board (NMCTB).
2. Shall have a working knowledge of the rules and regulations established by the NRC.
3. Shall comply with all regulations of UPR-MSD.

4. The Technologist is also required to have formal and on-the-job training in radiation safety.
5. May use byproduct material for medical use under an AU's supervision in accordance with 10 CFR 35.27, "Supervision,".
 - The AU must ensure that individuals working under their control are properly supervised and trained to enable safe working habits and prevent exposures to themselves and others and/or contamination of the work areas or environment.
 - They are also required to take a five (5) hour training course from the Radiation Safety Office. This training must be completed before starting to work with an authorized user.
 - After this a one-hour annual refresher course will be required.

8.4.3 Nurse:

1. Shall have formal training as a nurse in a recognized institution in the Continental U.S.A. or in Puerto Rico and be a certified nurse by the Commonwealth of Puerto Rico.
2. Shall have a working knowledge of the rules and regulations established by the NRC.
3. Shall comply with all regulations of UPR-MS.
4. The Nurse will also be required to have formal or on-the-job training in radiation safety.
5. May use byproduct material for medical use under an AU's supervision.
 - The AU must ensure that individuals working under their control are properly supervised and trained to enable safe working habits and prevent exposures to themselves and others and/or contamination of the work areas or environment.
 - They are also required to take a five (5) hour training course from the Radiation Safety Office. This training must be completed before starting to work with an authorized user.
 - After this a one-hour annual refresher course will be required.

8.4.4 The Ancillary Personnel:

The ancillary staff includes personnel engaged in janitorial and/housekeeping duties, clerical, laboratory, and security personnel that are likely to result in exposures of 1 mSv (100 mrem). Their training program will include instruction commensurate with potential radiological health protection problems present in the workplace. Alternatively, prohibitions on entry into controlled or restricted areas may be applied unless escorted by trained personnel. They will be informed by the Nuclear Medicine Physicians, the Technologist or by the RSO about radiation hazards and the appropriate precautions.

- They are also required to take a five (5) hour training course from the Radiation Safety Office. This training must be completed before starting to work in the vicinity of radioactive materials.
- After this, a one-hour annual refresher course will be required.

8.4.5 Principal Investigator or Scientists, Program Directors, and/or Investigators at Staff Positions:

They may be authorized by the Radiation Safety Committee to use radioactive materials in research activities at the UPR-MSC. Candidates should submit evidence of training and experience in accordance with the requirements of 10 CFR 33.15 (b) (2). AU's have adequate training and experience with the types and quantities of licensed material that they propose to use. They are also known as "principal investigator", their training and experience have been reviewed and approved by the RSC of the UPR-MSC for the use of licensed materials. Their names appear on the license after the application is approved by the RSC. They directly supervise the use of licensed material in his or her laboratory. The information regarding the AU qualifications is available in the AU's file.

- They must present evidence of prior training and experience of working with radioactive material.
- They are also required to take a ten (10) hour training course from the Radiation Safety Office. This training must be completed before the approval of the Radioactive Material Use Permit.
- After this, a one-hour refresher course will be required annually. Radioactive information concerning any changes to the ALARA Program of the UPR-MSC will be informed.

8.4.6 Radiation Worker (Lab. Technicians and Graduate Students):

Those workers whose major responsibilities involve working with sources of ionizing radiation or radioactive material.

- The AU must ensure that individuals working under their control are properly supervised and trained to enable safe working habits and prevent exposures to themselves and others and/or contamination of the work areas or environment.
- They are also required to take a five (5) hour training course from the Radiation Safety Office. This training must be completed before starting to work with an authorized user.
- After this, a one-hour annual refresher course will be required.

8.4.7 Groups in the Training Program and Frequency. Appendix H, Section III, "General Information for Training Program and Frequency"

ITEM 9: FACILITIES AND EQUIPMENT

9.1 ANNOTATED DRAWINGS:

The UPR-MSC facilities and specialized equipment provide sufficient engineering controls and barriers to protect the health and safety of the public and their employees, keep exposures to radiation and radioactive materials ALARA, and minimize the danger

to life and property from the types and quantities of radioactive materials to be used. These facilities not only reduce the exposure from the source but may also limit access to the source.

Layout diagrams describe the facilities and adjacent areas where radioactive materials will be used at the UPR - MSC facilities. These include adjacent areas where byproduct material is prepared, used, administered, and stored, at a level of detail that is sufficient to demonstrate that the facilities and equipment are adequate to protect the health and to minimize danger to life or property. It also indicates whether the room is a restricted or unrestricted area as defined in 10 CFR 20.1003. The diagrams are marked as "Security-Related Information – Withhold Under 10 CFR 2.390."

The UPR-MSC research laboratories are classified based on type, toxicity and quantity of byproduct material being requested. Diagrams also include and identify the facilities described above, where it indicates their locations (i.e., buildings, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallways), including areas above, besides, and below the areas where radioactive material is being used. **Appendix I, Annotated Drawings**". The information about the type, thickness, and a description of any portable shields used is included in **Appendix J, "Description of the Facilities and Equipment"**.

Included is the license material amendment No 39, letter dated September 16, 2021, acknowledging the addition of PET facilities in the UPR-MSC material license (mail control No. 626933 and documents ML21159A152.

1. NUCLEAR MEDICINE LABORATORY AND PET DEPARTMENT

- UPR, MSC, 4th Floor, Dr. Isaac Gonzalez Martinez Hospital, Puerto Rico Medical Center, Rio Piedras, Puerto Rico

Note: The UPR-MSC is authorized for any diagnostic study or therapeutic procedure permitted by 10 CFR 35.300, for which the patient can be released under the provisions of 10 CFR 35.75 under the NRC license material. For now, it is not used to hospitalize patients for therapeutic procedures thus there are no facilities identified for this purpose.

There are no changes to the PET installation that is currently on the license.

2. BIOMEDICAL RESEARCH LABORATORIES AT UPR-MEDICAL SCIENCES CAMPUS:

- Medical Sciences Campus of the University of Puerto Rico, Dr. Guillermo Arbona Building, Puerto Rico Medical Center, Rio Piedras, Puerto Rico.

3. RADIOACTIVE WASTE STORAGE FACILITIES AT UPR-MEDICAL SCIENCES CAMPUS:

- Floor 10 RCM Dr. Guillermo Arbona Building
- Floor 1 RCM Library Building

- Bunker (Floor 1) Between Pediatric Hospital and Infant and Maternity Health Center (CEMI) of the UPR-MSU
- Radiation Safety Office # 103, Bunker at Basement at Comprehensive Cancer Center used for storage of sealed sources.

ITEM 10. RADIATION SAFETY PROGRAM

10.1 AUDIT PROGRAM

10.1.1 MANAGEMENT AND RADIATION SAFETY COMMITTEE (RSC) AUDITS:

The Radiation Safety Committee (RSC) is appointed by the Chancellor of UPR MSC and has the responsibility to perform an annual audit to ensure adequate oversight of the licensed program, to identify program weaknesses and to determine early corrective actions. During an audit, we take into consideration not only the requirements of NRC's regulations, but also the licensee's commitments put forth in the application as well as in all correspondence with NRC. It is in the best interest of the UPR-MSU to identify potential violations of regulatory requirements and take the necessary steps to correct them. The audit form is tailored to UPR-MSU needs and includes specific items regarding our licensed program. The auditor also evaluates whether the licensee is maintaining exposures to workers and the public as low as is reasonably achievable (ALARA) and, if not, will oversee the steps to be taken to correct and improve the safety of all students and employees. All areas indicated in the audit may not be applicable to everyone and thus will not be addressed during each audit.

1. **MANAGEMENT OVERSIGHT:** Management will provide all the necessary support to the radiation safety program, to the radiation safety committee, radiation safety officer (RSO), program audits (including annual reviews of program and ALARA reviews), control by authorized users, appropriate follow-up on events, implementation of corrective actions from previous audit/inspection findings, and active communication and interaction with other committees if conducting human and/or animal research.
2. **AMENDMENTS AND PROGRAM CHANGES:** Amendments to the license were properly implemented; if applicable, program and procedural changes were approved and implemented in accordance with license condition.
3. **FACILITIES:** Facilities as described in license (uses, control of access, engineering controls, calibration facilities, shielding, and air flow).
4. **EQUIPMENT AND INSTRUMENTATION:** Operable and calibrated survey and effluent monitoring equipment, and Title 10 of the Code of Federal Regulations (10 CFR) Part 21.21 requirements)
5. **MATERIAL USE, CONTROL, AND TRANSFER:** Materials and users authorized, security and control of licensed materials, and procedures for receipt and transfer of licensed material)

6. **AREA RADIATION SURVEYS AND CONTAMINATION CONTROL:** Radiological surveys, air sampling, leak tests, inventories, handling of radioactive materials, contamination controls, records, and public doses.
7. **TRAINING AND INSTRUCTIONS TO WORKERS:** Training and retraining requirements and documentation, interviews and observations of routine work, staff knowledge of all routine activities, requirements in 10 CFR Part 19 and 10 CFR Part 20, emergency situations, and supervision by authorized users.
8. **RADIATION PROTECTION:** Radiation protection program with ALARA provisions, external and internal dosimetry, exposure evaluations, dose and survey records and reports, annual notifications to workers, and bulletins and other generic communications.
9. **RADIOACTIVE WASTE MANAGEMENT:** Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment; incinerators, hoods, vents, and compactors; and license conditions for special disposal method.
10. **DECOMMISSIONING:** Records relevant to decommissioning; decommissioning plan and schedule, notification requirements, cost estimates, funding methods, financial assurance; "timeliness rule" requirements, and changes in radiological conditions since decommissioning plan was submitted—(NUREG-1757, Volume 3, provides guidance on decommissioning).
11. **TRANSPORTATION:** Quantities and types of licensed material shipped, special form and packaging design requirements and documentation, shipping papers, hazardous materials (HAZMAT) communication procedures, return of sources, procedures for monitoring radiation and contamination levels of packages, HAZMAT training, records and reports.
12. **NOTIFICATIONS AND REPORTS:** Reporting and follow-up of theft, loss, incidents, and overexposures. Notification of change in RSO or authorized user. Radiation exposure reports provided to individuals.
13. **POSTING AND LABELING:** Notices; license documents; regulations; bulletins, and generic information; posting of radiation areas; and labeling of containers of licensed material.
14. **INDEPENDENT AND CONFIRMATORY MEASUREMENTS:** Areas surveyed, both restricted and unrestricted; measurements made; comparison of data with staff's results and regulations.
15. **AUDIT FINDINGS**

10.1.2 THE RADIATION SAFETY OFFICER (RSO) AUDITS:

The audit mechanism implemented by the RSO and her or his staff, is responsible for the day-to-day operation of the licensed program, to determine user compliance with NRC regulations, the terms and conditions of the NRC license, the requirements of the RSC or RSO-approved permits (as appropriate), and ALARA principles. The audit program includes performance based routine unannounced inspections of each user's facility and practices to supplement and audit the routine monitoring performed by the user. It is in the best interest of the RSO to identify potential violations of regulatory requirements and take necessary steps to correct them. Facility inspections include:

1. Review of user inventory and survey records
2. Evaluation of user and technician training through discussion and observation of work practices
3. Performance of independent surveys of user work areas
4. Evaluation of compliance with NRC regulations, the conditions of the license, the RSC/RSO permit and safety manual requirements
5. Evaluation of performance-based instruction for users and technical-level staff.

The Nuclear Medicine Department is audited weekly, and the research laboratories are audited on a monthly basis. The frequency of surveys and audits helps ensure close communications and proper surveillance of individual radioactive material users. It is essential that once problems are identified, comprehensive corrective actions are taken in a timely manner to prevent recurrence. It is in the best interest of the UPR-MSD to identify potential violations of regulatory requirements and take the necessary steps to correct them.

10.1.3 RECORDKEEPING:

Under the requirement of 10 CFR 20.2102 the UPR-MSD maintains records of audits and other reviews of program content and implementation for 3 years from the date of the record. Records of audits include date of audit, name of person(s) who conducted the audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up. They are available for inspection by the NRC.

10. 2 RADIATION MONITORING INSTRUMENTS

The RSC and/or RSO receives, reviews, and acts on all applications to approve radiation monitoring instrumentation and ensures that appropriate radiation monitoring equipment will be used during licensed activities. This will be evaluated according to the radioisotope and amount of activity that is permitted in the research laboratory or clinical areas of the nuclear medicine department. These instruments will be calibrated on an annual basis.

All work involving radioactive material must be conducted under the supervision of an approved AU. Each AU is ultimately responsible for the safety of those who use radioisotopes under his/her supervision and is responsible for the correct functioning and

calibration of monitoring instruments. To become an AU, the principal investigator interested in handling license material, must apply to the RSC for evaluation and approval. These forms can be found on the MSC website for Institutional Compliance Committees (<http://www.committees.rcm.upr.edu/rsc/>). The RSO does an initial perusal of the application and submits it to the RSC for evaluation.

AUs for license material using 1 mCi or more of P-32, S-35, Tc-99m, I-131, F-18, Tl-201, Ga-67 In-111, etc., at any one time are required to always have a working survey instrument with a thin-end window or pancake Geiger-Mueller probe in the laboratory. AUs that might be using 1 mCi or more of I-125 at any one time will be required to always have a working survey instrument with a low energy sodium iodide crystal probe in the laboratory. Survey instruments in use must be returned to the Radiation Safety Office or the manufacturer for recalibration on an annual basis. When a new survey instrument is purchased, a copy of the manufacturer's calibration certificate must be sent to the Radiation Safety Office.

In the case of a survey instrument malfunctioning, the Radiation Safety Office will be notified, will evaluate the instrument and provide instructions to the AU to contact the manufacturer for repair and recalibration. A copy of the manufacturer's calibration certificate must be sent to Radiation Safety Office. A battery and an operational test is required each day an instrument is used and prior to working with radioactive material. If the battery test falls below the battery condition line, the instrument must be taken out of use until the batteries are replaced. An instrument operational check must be performed with a dedicated check source each day an instrument is used. The reading taken must fall within the range limits stated on the side of the instrument. If the reading falls outside the stated range, the instrument must be taken out of use and Radiation Safety Office must be contacted.

Instruments will be calibrated by a vendor who is licensed by NRC or by an Agreement State to perform instrument calibrations when necessary, they will be calibrated annually. We also established and implemented the model procedure for calibrating survey instruments that was published in Appendix H of Consolidated Guidance: About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope (NUREG-1556, Volume 11, Rev 1 February 2017). **Appendix K, "Radiation Monitoring Instrument Specifications".**

Equipment used to measure patient dosages, the Dose Calibrator, will be calibrated in accordance with nationally recognized standards and the manufacturer's instructions. A Biodex Atom Lab 500, dose calibrator will be used to measure and confirm the activity received from each unit dose before administering it to patients. The Dose Calibrator chamber is covered with lead split rings of 1 ¼" (3 cm) thick for full shielding. In addition, the chamber is inside a lead cave built of 6" l x 3" w x 4" h (15 x 8 x 10 cm) lead bricks. This shielding gives maximum radiation protection when working with 511 KeV nuclides and mounted on a table cabinet. Dose calibrator should be tested as follows:

- Constancy, at least once each day prior to assay of patient dosages (+/- 10%)
- Linearity, at installation and at quarterly basis thereafter (+/- 10%)

- Geometry dependence, at installation or after repair (+/- 10%)
- Accuracy, at installation and at least annually thereafter (+/- 10%)

The wipe test counter will be calibrated in accordance with nationally recognized standards and the manufacturer's instructions. The liquid scintillation counter is calibrated on a monthly basis and has an annual maintenance program with the manufacturer. We reserve the right to upgrade our survey instrument as necessary as long as they are adequate to measure the type and level of radiation for which they are used. A description of the current instruments are as follows:

1. Dose rate meter:

- Geiger Mueller, Ludlum Model 14C, Range 0.1-1000 mR/hr, End window or pan probe
- Geiger Mueller, Ludlum Model 3, Range 0.1-100 mR/hr, End window or pan probe

2. Scaler wipe test counter:

- Capintec CRC-55t R Dose Calibrator
- Capintec, Captus 3000 Wipe Test Counter
- Biodex Atomlab 500, Wipe Test Counter

3. A liquid scintillation counting (LSC) system can be used to count samples containing most beta-emitters and gamma-emitters (if efficiency is great enough to achieve the required sensitivity for measurements). The LSC is the most common instrument used for measurement of tritium (H-3) contamination and other low-energy beta-emitters commonly used in laboratory research, such as carbon-14, sulfur-35, and phosphorus-32.

4. Capintec, Captus 600, Thyroid Uptake System

10.3 MATERIAL RECEIPT AND ACCOUNTABILITY

10.3.1 ADMINISTRATIVE PROCEDURES TO ASSURE CONTROL OF PROCUREMENT AND USE OF BYPRODUCT MATERIAL.

The UPR-MSO, has developed, implemented, and maintains procedures for always ensuring accountability of licensed materials. The purchase of radioactive material including both licensed and license-exempt quantities is handled through the Radiation Safety Office. An AU is encouraged to establish standing and/or blanket orders for the purchase of radioactive material with the Radiation Safety Office. To establish these orders, each AU must:

1. Complete the appropriate purchase request and deliver it personally to the Radiation Safety Office for approval. Instructions on how to complete the purchase

order is available from the Radiation Safety Office website. All orders for radioactive materials to be purchased through the MSC shall not be proceed until approved by the Radiation Safety Office.

2. Once the standing and/or blanket order has been established, research groups will place their radioactive material orders with the Radiation Safety Office.
3. Only principal investigators with an approved and unsuspended application will be allowed to establish standing and/or blanket orders and place radioactive material orders.
4. All requests should include the following information: Principal Investigator's Name, Isotope, Activity, Vendor, and Chemical Compound. If orders do not have all of the information listed, it will cause a delay upon approval of the radioactive material.
5. Note that orders for radioactive material must be limited to the isotopes, chemical forms, and maximum activity per shipment as shown on the application form.
6. Orders for other materials or activities greater than specified on the application cannot be ordered. Researchers are required to submit an amendment application to the Radiation Safety Office.
7. The Radiation Safety Office will review the order request to determine the following:
 - That the user has been authorized to use the type and quantity of radioactive material being ordered. The name of the AU must be clearly indicated on the order.
 - That the radioactive material being ordered will not cause the AUs inventory limits to be exceeded.
 - That the AU has no unresolved items of safety noncompliance, including responses to survey reports and training notices.
 - That the AUs radionuclide inventory reports are current.

When the above criteria are met, the order will be approved and signed by authorized personnel of the Radiation Safety Office and a package receipt will be handed to the principal investigator and must be included as an inventory record. If the above criteria are not met, the Authorized User will be notified by telephone to expedite acquisition of the necessary information. Authorization is based on prior protocol approval by the RSC as described earlier. Every shipment of radioactive material received must be tracked in the inventory database and added with the campus totals. This is to prevent an individual AU, or the campus, from exceeding individual approval or MSC license possession limits respectively.

10.3.2 ADMINISTRATIVE CONTROLS AND PROVISIONS RELATING TO MATERIALS CONTROL, ACCOUNTING AND SECURITY

The Radiation Safety Office must approve all orders for radioactive material and ensure that the requested material, quantities, manufacturer, and model are authorized by the license and that the possession limits are not exceeded.

1. Receipt of radioactive materials shipments should be between 7:00 AM to 4:00 PM Monday to Friday.
2. Shipments are delivered directly to an AU. A designated, trained individual will

receive it and follow the guidelines for package receipt and opening.

3. The AU or laboratory designee will proceed to document the following information in the inventory logbook: name of the radioisotope, amount (activity received) chemical form and the initials of the individual that received it.
4. The AU will notify the Radiation Safety Office that they received the radioactive material and will be included in the Radiation Safety Office inventory logbook.
5. During normal working hours, immediately upon receipt of any package of licensed material, each package must be visually inspected for any signs of shipping damage, such as crushed or punctured containers or signs of dampness.
6. Any obvious damage must be reported to the RSO immediately. Do not touch any package suspected of leaking. The package should be contained to a restricted area to minimize spread of contamination until it can be safely sealed and removed. Request the person delivering the package to remain until monitored by the RSO.
7. The package must be surveyed at its surface and at one meter with the GM counter and a wipe tested. The results must be documented in units of mRem/hr and dpm respectively. **Appendix L, "Procedure for Safely Receiving and Opening Packages, Monitoring Requirements and Record Maintenance"**
8. Since certain packages of licensed material will have detectable external radiation, they should be sent immediately to a designated storage area, where they will be checked for contamination and external radiation level as soon as practical.
9. During off-duty hours, deliveries usually will be handled by security office personnel or other designated trained personnel. The RSO will instruct them to accept delivery of radioactive packages.
 - Any packages containing radioactive material that arrive during off-duty hours, between (e.g., 4:30 p.m. and 7:00 a.m. or on Saturdays, Sundays or on Holidays) will be signed for by the security guard (or other designated trained individual) on duty and taken immediately to the designated receiving area.
 - Because certain packages of licensed material will have detectable external radiation, they should be sent immediately to a designated storage area, where they will be checked for contamination and external radiation level as soon as practical. They should not be allowed to remain in the receiving area any longer than necessary, as they may be a source of exposure for receiving personnel.
 - Security Office personnel of the UPR-MSC (or other designated trained individual) should unlock the door, place the package in the designated secured storage area, and re-lock the door.
10. The Radiation Safety Office personnel will perform monthly inspections in order to maintain accountability of licensed material at all times.

10.3.3 TRANSFER OF RADIOACTIVE MATERIALS:

Complex governmental regulations control the physical and custodial transfer of radioisotopes. No physical transfer of radioactive materials involving transport over public highways or in any type of vehicle shall be made without the supervision of the Radiation Safety Office personnel. Strict compliance with the following procedures will be needed to avoid violations:

1. Transfer of radioactive material between investigators of different projects must be approved by the RSO and within the limits of the approved quantities. The transfer should not take place until authorized by the RSO or the RSC.
2. No approved user of radioactive material at the MSC shall transfer custody or delegate responsibility without the approval of the Radiation Safety Office.
3. Approval will be granted only if the recipient is an AU.
4. All transfers must be done in a way that minimizes the probability of spillage or breakage.
5. Licensed material shall not be transferred or shipped from one institution to another without the approval of the RSO.
6. Transfer of radioactive material between AUs, should follow Medical Science Campus license conditions and any other applicable regulatory requirements.
7. Transfer of radioactive material to another institution requires a NRC material license to possess that material by the receiving institution.
8. The Radiation Safety Office must be notified in written before any transfers take place, either between MSC Authorized Users or with outside facilities.
9. The Radiation Safety Officer will investigate the license status and qualifications of the intended transfer.
10. If transfer is approved, the Radiation Safety Office will supervise the packaging and shipment to ensure compliance with all packaging and transportation regulations.
11. Users must record any transfers on the Radionuclide Inventory Form. Any material that is either donated or received free-of-charge (e.g., received on a trial basis or free samples, or samples from other research facilities) must be approved prior to receipt by the Radiation Safety Office.

10.3.4 PHYSICAL SECURITY OF RADIOACTIVE MATERIALS

The Rule: All radioactive material received at the MSC must be secured or under constant surveillance at all times. Shipments of radioactive materials which have not been delivered must be secured at the receiving site by personnel trained by Radiation Safety Office until delivery can be made.

1. Delivery personnel are prohibited from delivering a package with radioactive materials unless there is an authorized person (Authorized User, Alternate Authorized User, or Radiation Worker) at the location who will accept it, sign for its receipt, and secure the radioactive materials.
2. Shipments of radioactive materials must not be left unsecured in corridors:
 - If it is necessary to deliver the package to an office, the authorized person receiving the shipment must immediately secure the package in a laboratory or storage room designated for work with radioactive materials.
 - If the delivery person cannot find an authorized person to receive the shipment, the package must be taken to the Radiation Safety Office where it will be secured until delivery can be completed. Radioactive materials are not to be left unsecured at any time.

3. Any radioactive material in use in a laboratory must be attended at ALL TIMES, or secured by locking the laboratory when not attended.
4. Radioactive materials may not be left unsecured even momentarily.
5. Radioactive materials in storage, not being used, must be secured when the room in which it is stored is unoccupied. The required security may be accomplished by locking the room while unoccupied, or alternatively, by locking the radioactive materials within refrigerators, freezers, cabinets, or lock boxes. Wherever possible, lock boxes are recommended for storage of radioactive materials.
6. Only authorized persons may have access to radioactive materials. Radioactive materials that are stored or used in areas common to both authorized and unauthorized personnel must be secured at all times from unauthorized personnel.
7. It is strongly recommended that all laboratories containing radioactive materials be locked when unoccupied during daytime hours and at night.
8. Corridors (hallways, elevator lobbies, and utility chases, etc.) are not secured areas. Therefore, the use and storage of radioactive materials in these areas are prohibited.
9. All radioactive wastes are considered as radioactive materials. Radioactive wastes, including dry waste, liquid waste, medical pathological waste, and mixed waste, must be secured at all times. Radioactive waste may be placed in lockable containers. Recommendations may be obtained from the Radiation Safety Office.
10. Unescorted unauthorized personnel may not enter into a laboratory if an authorized person is not present. Any persons admitted into the laboratory must be accompanied at all times by an authorized person who works in the area.
11. Persons performing work in the area, such as engineering or maintenance personnel, contractors (i.e. janitorial staff, telephone, or computer support personnel) or commercial service representatives must also be accompanied by an authorized person at all times.
12. Persons unknown to the occupants of an area where radioactive materials are used or stored should not be permitted into the area without proper identification and a legitimate reason for entry.

10.4 OCCUPATIONAL DOSE

10.4.1 PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES ALARA

The UPR-MSO will monitor individuals in accordance with the criteria in the section titled, 'Radiation Safety Program—Occupational Dose' in NUREG-1556, Vol. 11, Rev. 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope. The occupational exposure dose will be evaluated according to the annual limits. **Appendix M, "Applicable Annual Limits"**

10.4.2. ESTABLISHMENT OF INVESTIGATIONAL LEVEL IN ORDER TO MONITOR INDIVIDUAL OCCUPATIONAL EXTERNAL RADIATION EXPOSURES.

It is a requirement in the law, meaning all facilities possessing radioactive materials licenses must have a formal ALARA program. It may be defined as a professional standard of excellence, and is practiced by keeping all doses, releases, contamination

and other risks as low as reasonably achievable.

Our ALARA program depends on the cooperation of all users of radionuclides at the MSC. The program includes the use of proper equipment and procedures to lower radiation exposure. The RSO will investigate any whole-body and extremities dose in excess of level I (125 mrem or 1,875 mrem respectively) to any individual in any one quarter. If any worker receives a whole-body and /or extremities dose in excess of level II (375 mrem or 5,625 mrem respectively) to any individual in any one quarter, direct actions will be taken to minimize any future exposures. These actions may require a change in laboratory procedure or an increased application of the principles of personnel protection.

This institution hereby establishes Investigational Levels in order to monitor occupational external radiation exposure to individuals. If these levels are exceeded, an investigation by the Radiation Safety Committee and/or the RSO will be performed. **Appendix N, "Investigational Levels (mrems)"**

10.5 SAFE USE OF RADIONUCLIDES AND EMERGENCY PROCEDURES

The Radiation Safety Office will investigate all accident, spills, fires, or other incidents in which radiological material is involved. In the event of an accident, the Radiation Safety Office will assist by providing technical advice and by monitoring personnel.

The Radiation Safety Office, through the Radiation Safety Officer (RSO), the Radiation Safety Committee, and the Occupational Health Clinic (CASSO), have the responsibility to plan and arrange emergency medical care for victims contaminated with radioactive material or overexposed to radiation at MSC facilities. The Radiation Safety Office will ensure that procedures for emergency care, a list of telephone numbers, and contacts are made available to all Authorized Users.

All AU's of radioactive materials will be familiar with these procedures before any emergency arises. When an accident involving radioactive materials occurs, the greatest hazard will be addressed first. Lifesaving measures always take precedence over decontamination or other concerns. Personnel working nearby will be advised as soon as possible of any hazard or accident and will be prevented from entering the hazardous area. In case of an incident or accident the Office of Laboratory Safety in Research and RSO will be notified immediately.

The UPR-MSC will adopt the procedures for the safe use of radionuclides and emergencies as published in Appendix K of NUREG-1556, Volume 11, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope. **Appendix O, "General Topics for Safe Use of Radionuclides and Model Emergency Procedures"**.

10.5.1 General Topics for Safe Use of Radionuclides

10.5.2 Security of Radioactive Materials

10.5.3 Information of Radioisotopes

10.5.4 General Safety Procedures to Handle Spills

10.5.5 Spill/Contamination Procedure

10.5.6 Procedures for Handling Emergencies

10.5.6.1 Minor Spills of Liquids and Solids

10.5.6.2 Major Spills of Liquids and Solids

10.5.6.3 Incidents Involving Radioactive Dusts, Mists, Fumes, Organic Vapors, and Gases

10.5.6.4 Minor Fires

10.5.6.5 Fires, Explosions, or Major Emergencies

10.5.6.6 Incidents Involving Sealed Sources

10.5.6.7 Procedures for Collecting Bioassay Samples

10.6 Surveys and Leak Tests

Licensees are required, pursuant to the regulations listed above, to make surveys of potential radiological hazards in their workplace. The NRC requires testing to determine whether there is any radioactive leakage from sealed sources. Licensees must retain records of surveys and leak test results in accordance with license conditions and NRC regulations.

Radiation Surveys:

The frequency of surveys depends on the quantity and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect the worker and members of the public from external exposure to radiation.

Surveys should be sufficient to identify areas of contamination that might result in doses to workers or to the public. Combined removable and fixed contamination should be surveyed using appropriate radiation detection equipment. Removable contamination can be detected and measured through a wipe test of the surface, which is counted in an appropriate counting instrument, such as a liquid scintillation counter, a sodium iodide or germanium gamma counter, or a proportional alpha/beta counter.

Contamination surveys should be performed:

- To evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment
- After each experiment, any spill or contamination event
- When procedures or processes have changed
- To evaluate the potential contamination of users and the immediate work area, at the end of the day or prior to leaving the area of use, when licensed material is used
- In unrestricted areas at frequencies consistent with the types and quantities of materials in use but generally not less frequently than quarterly
- In areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment.

Personnel should survey for contamination in locations where individuals are working with an unsealed form of radioactive material. These surveys should be done at a frequency appropriate to the types and quantities of radioactive materials in use. By doing this, the potential for exposures can be evaluated and reduced, if necessary. Records of these surveys must be maintained for review. Nuclear medicine personnel will survey after daily work or when necessary and on weekly basis. **Appendix P, "Survey Diagrams of Restricted and Unrestricted Areas Description"**.

The Radiation Safety Office will make independent surveys of all active radioisotope labs on monthly basis and in nuclear medicine laboratory for medical use weekly. Such things as inventory assessment, contamination control, personnel monitoring, training, and waste disposal practices will be addressed during these surveys. **Appendix Q, "Laboratory Surveillance Frequency"**.

Copies of the results of surveys will be forwarded to the AU, and a recheck may be conducted in the event problems have been detected that need corrective action. The RSC may accompany the Radiation Safety Office on surveys as deemed necessary for problem laboratories or for purposes of auditing the radiation safety program.

When removable radioactivity is found, the area must be decontaminated and then re-surveyed and documented. Detectable levels of removable contamination should be removed, and non-removable contamination should be labeled and shielded whenever possible to maintain ALARA limits. **Appendix R, "Area Survey Contamination Maximum Permissible Limits"**.

It is understood that certain areas may be routinely contaminated, such as internal parts of equipment and the inside areas of glassware, and that it may not be practical to decontaminate these surfaces. If this occurs, signs must be posted, and protective clothing and gloves should be used when in contact with these areas. In some cases, such as ^{32}P contaminated equipment, shielding is required.

Contamination found in unrestricted areas should be immediately decontaminated to background levels. When it is not possible to get to background levels, the AU must ensure that the amounts of contamination on equipment do not exceed the contamination levels.

If the contamination is found on building surfaces, the AU must ensure that the amounts of contamination do not exceed the contamination levels. **Appendix S, "Screening Levels for Unrestricted Release"**. Radioactive contamination found at or above these levels must be decontaminated or shielded and labeled.

The UPR-MSD will survey our facility and maintain contamination levels and perform bioassays of occupationally exposed workers in accordance with the survey frequencies and contamination levels published in Appendix L of NUREG-1556, Volume 11, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope".

Leak Tests

The UPR-MSU will implement the model leak test program published in Appendix M of NUREG-1556, Volume 11, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope". **Appendix T, "Leak Test of Sealed Sources"**.

10.7 WASTE MANAGEMENT

At MSU all disposal of radioactive waste must be authorized by the RSO. All radioactive waste shall be separated from non-radioactive waste and collected for proper disposal. The Radiation Safety Office will be contacted for radioactive waste pickup arrangements.

The issue of radioactive waste disposal is very complex, due not only to the radioactive nature of the waste and its inherent disposal problems, but also the recent concerns with the chemical hazards associated with the same waste. Hence, it is possible to have mixed waste, which contains not only radioactive waste, but RCRA (Resource Conservation and Recovery Act) hazardous chemical waste. Some liquid scintillation fluids are an example because they contain toluene or benzene, which is hazardous under the RCRA laws, due to flammability and toxicity. Consequently, radioactive waste must be properly manifested for the isotope and activity, and any other hazardous constituents, including chemical or biohazardous components. The Radiation Safety Officer will be consulted when planning new research to develop waste minimization strategies and discuss waste disposal procedures. It may not be economically reasonable to do certain experiments due to the associated waste disposal costs.

Radioactive waste is any waste that contains or is contaminated with radioactive material. This includes liquids, solids, animals, used scintillation counting liquids (LSC) etc. Radioactive waste must never be placed in any non-radioactive waste container. The RSO will not approve any disposal of radioactive waste thru the sink. No general (non-radioactive) waste may be disposed of in radioactive waste containers. Radioactive waste must never be placed in the corridor or any public areas.

All radioactive waste must be labeled with the appropriate label (Radioactive Waste Label) stating the radioisotope name, activity, date of disposal, and the AUs full name, telephone number and lab number. Tags must be always filled out after any radioactive waste is placed in the designated decay storage area in the lab and contain the universal symbol of radiation and phrase "Caution, Radioactive Material". All individual plastic containers, scintillation vials, bags and bottles of radioactive waste must be tagged with this label. Bench top waste containers are considered part of the experiment, and must be labeled with the isotope, activity in dpm or μCi , and the date.

Records of radioactive waste disposal must be maintained by the University for NRC review, so this labeling is critical. A Radioactive Waste Disposal Log should be used to compile a list of the radioisotopes disposed of in the waste cans.

It is the responsibility of the AU to supply primary and secondary containers to prevent the waste from leaking or contaminating surfaces. All radioactive waste must be stored in appropriate containers until its disposal, and the integrity of the waste containers must be assured. All radioactive waste must be secured against unauthorized access or removal. Laboratories must supply their own shielding for waste that may cause external exposures to workers in the area. To dispose of waste under the current regulatory constraints, it is necessary to segregate all radioisotopes from each other (except ^3H and ^{14}C), and to segregate chemically hazardous waste from other radioactive waste. It is prudent that workers only place waste which is contaminated with radiation in the radioactive waste containers to control waste disposal cost.

All radioactive waste containers must be located in a secure area within the laboratory. Consult with the Radiation Safety Office to obtain appropriate lockable waste and waste storage containers.

Radioactive waste pickup must be scheduled by calling the Radiation Safety Office or sending an e-mail requesting the service. The following information is needed to schedule a pickup:

1. Name of Radiation Worker and phone number.
2. Location of waste (building and laboratory number).
3. Type of waste (liquid, solid, carcasses, LSC vials, etc.).
4. Radionuclide(s) in waste.
5. Any special handling instructions.

The Radiation Safety Office will assist AUs in obtaining an appropriate radioactive waste storage container for each isotope used in the laboratory. Each waste container will be used for disposal of ONE radioisotope ONLY, except for dual labeled radioisotope experiments. Disposal procedures for these containers will be based on the longest half-life. The radioactive waste cans will be stored in an area within the laboratory where they will not be knocked over, used for other waste, or accidentally mistaken as cans for non-radioactive waste. Authorized Users and Radiation Workers are responsible for securing waste until the Radiation Safety Office removes it.

The UPR-MSU has a few radioactive waste storage facilities for waste decay as follows:
Appendix P, "Survey Diagrams of Restricted and Unrestricted Areas Description"

1. Radiation Waste and Decay Storage # 1 – Floor 10 RCM Main Building
2. Radiation Waste and Decay Storage # 2 – Floor 1 RCM Library Building
3. Radiation Waste and Decay Storage # 3 – Floor 1 Between Pediatric Hospital and Infant and Maternity Health Center (CEMI) of the UPR-MSU
4. Radiation Waste and Decay Storage # 4 (sealed sources)– Radiation Safety Office # 103 Laboratory Basement at Comprehensive Cancer Center Building, Storage Area for Sealed Sources (Bunker)

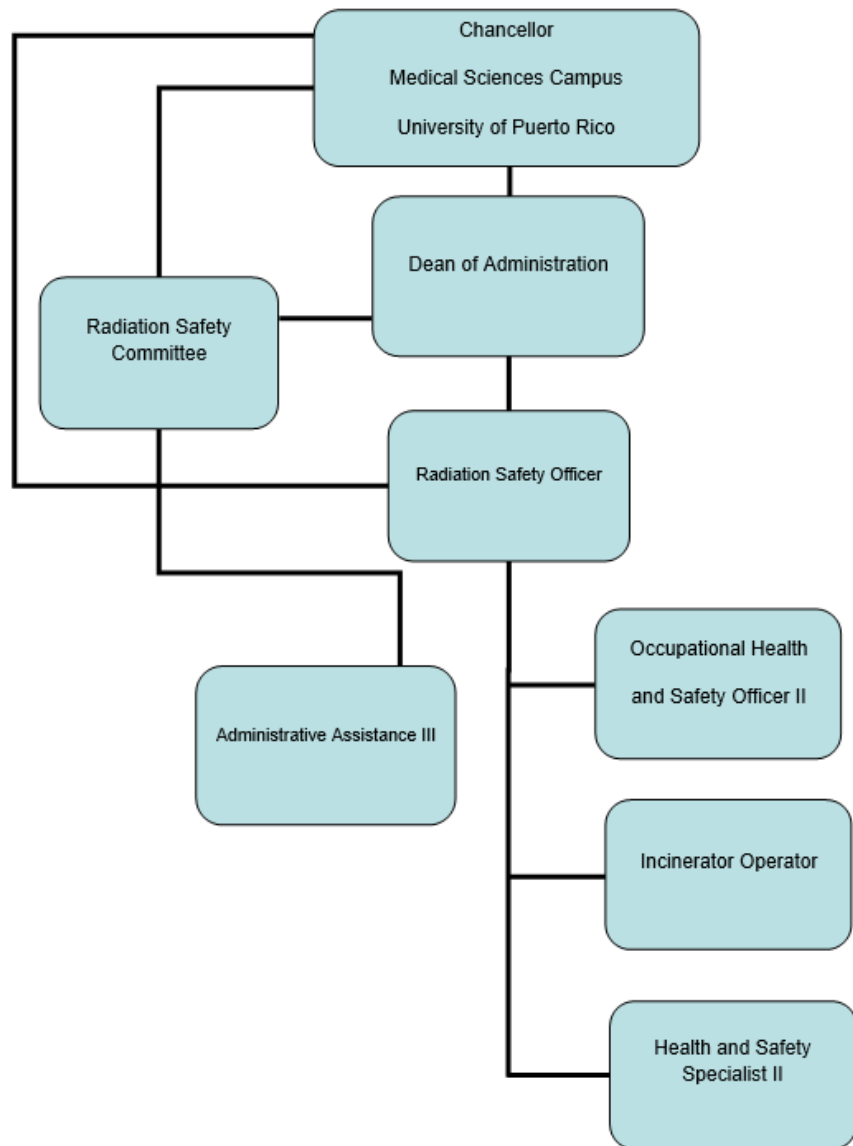
APPENDIX A

RADIOACTIVE MATERIAL AND PURPOSE (Items 5 and 6 on NRC Form 313)

Items 5 and 6 on NRC Form 313: Radioactive Material and Use This response includes security-related sensitive information that is included in Appendix I and P and marked "Security-Related Information—Withhold Under 10 CFR 2.390" <u> X </u> Yes <u> </u> No			
Byproduct Material	Form	Amount	Purpose use
Any byproduct material permitted by in 10 CFR 35.100	Any	As needed.	Any uptake, dilution, and excretion study permitted by 10 CFR 35.100
Any byproduct material permitted by in 10 CFR 35.200	Any	As needed.	Any imaging and localization study permitted by 10 CFR 35.200
Any byproduct material identified in 10 CFR 35.300	Any	44.4 GBq (1200 millicuries)	Any diagnostic study or therapeutic procedure permitted by 10 CFR 35.300, for which the patient can be released under the provisions of 10 CFR 35.75.
Any byproduct material with Atomic Numbers 1 through 83 with half-life less than or equal to 120 days, with exceptions	Any	2.22 GBq (60 millicuries of each radionuclide not to exceed 2 curies)	For the use in medical diagnosis, therapy and research in humans. Research and development as defined in 10 CFR 30.4, including animal studies; instrument calibration; student instructions; and in-vitro studies.
Iodine 125- (I ¹²⁵)	Any	1.85 GBq (50 millicuries)	For the use in medical diagnosis, therapy and research in humans. Research and development as defined in 10 CFR 30.4, including animal studies; instrument calibration; student instructions; and in-vitro studies.
Phosphorus 32- (P ³²)	Any	3.7 GBq (100 millicuries)	For the use in medical diagnosis, therapy and research in humans. Research and development as defined in 10 CFR 30.4, including animal studies; instrument calibration; student instructions; and in-vitro studies.
Sulfur 35 (S ³⁵)	Any	7.4 GBq (200 millicuries)	For the use in medical diagnosis, therapy and research in humans. Research and development as defined in 10 CFR 30.4, including animal studies; instrument calibration; student instructions; and in-vitro studies.
Carbon 14 (C ¹⁴)	Any	1.85 GBq (50 millicuries)	For the use in medical diagnosis, therapy and research in humans. Research and development as defined in 10 CFR 30.4, including animal studies; instrument calibration; student instructions; and in-vitro studies.
Hydrogen 3 (H ³)	Any	1.85 GBq (50 millicuries)	For the use in medical diagnosis, therapy and research in humans. Research and development as defined in 10 CFR 30.4, including animal studies; instrument calibration; student instructions; and in-vitro studies.
Nickel 63 (Ni ⁶³)	Sealed Sources (Isotope Products Laboratory or New England Nuclear, Model NER-004)	0.37 GBq (10 millicuries per source) and 0.74 GBq (20 millicuries) total	To be used for sample analysis in compatible gas chromatography devices that have been registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with a

			Commission or Agreement State specific license authorizing distribution to persons specifically authorized by a Commission or Agreement State license to receive, possess, and use the device.
Cesium 137	Sealed Sources Manufacturer: (AEA Technologies, Model 773)	5.883 GBq (159 millicuries)	For the use in calibration and checking of the licensee's instruments. Teaching and training of students.
Cesium 137	Sealed Sources Manufacturer: Syncor, New England Nuclear , Model: NES 356	196 μ Ci, 10 μ Ci, 256.1 μ Ci and 462.1 μ Ci total	For the use in calibration and checking of the licensee's instruments. Teaching and training of students.
Cobalt 57	Sealed Sources Manufacturer: Isotope Products Eckert& Ziegler Model: SRV-057-5M	5.178 mCi, 5.545 mCi, 10 mCi and 20.723 mCi total	For the use in calibration and checking of the licensee's instruments. Teaching and training of students.
Barium 133	Sealed Sources Manufacturer: Isotope Products Eckert& Ziegler Model: RV-133-250U	251.6 μ Ci, 259.4 μ Ci and 511 μ Ci total	For the use in calibration and checking of the licensee's instruments. Teaching and training of students.
Germanium 68	Sealed Sources Manufacturer: Isotope Products Eckert& Ziegler Model: EG-0320 VQC-068	94.6 μ Ci, 1.49 mCi and 1.585 mCi total	For the use in calibration and checking of the licensee's instruments. Teaching and training of students.

APPENDIX B
MANAGEMENT ORGANIZATIONAL CHART



APPENDIX C
DUTIES OF THE CHANCELLOR

1. Has the authority to make prompt decisions based on the information available without having to consult with higher management officials, including the authority to take whatever action is necessary to ensure that all radiation safety practices are in accordance with the regulations.
2. Authority to appropriate funds in a timely manner for the radiation safety program significant financial needs.
3. Available to facilitate effective and immediate action on behalf of management, the RSC, and the RSO, particularly in the event of an emergency.
4. Selects an executive management representative to the RSC with a science background or an aptitude for radiation safety issues.
5. Appoint a representative who actively participates as a member of the radiation safety committee (RSC) and has the authority to delegate necessary resources to the radiation safety program, as identified by the RSC.
6. Designated representative will be available to the RSO and RSC chairperson to facilitate in an effective and immediate action on behalf of management or the RSO and RSC in the event of radiation safety emergency or potential emergency.
7. Completeness and accuracy of the radiation safety records, and all information provided to NRC. Knowledge about the contents of the license and application.
8. Compliance with current NRC and Department of Transportation (DOT) regulations and the licensee's operating and emergency procedures.
9. Commitment to provide adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that patients, the public and workers are protected from radiation hazards. Therefore, executive management identifies resources for the RSO, and the radiation support staff if indicated, to attend professional meetings.
10. Selection of a qualified individual to serve as the Radiation Safety Officer (RSO) with responsibility for the overall radiation safety program. The RSO shall have independent authority to stop unsafe operations and will be given sufficient time to fulfill radiation safety duties and responsibilities.
11. Commitment to report defects, noncompliance, or reportable events, including medical events in accordance with regulations.
12. Prohibition against discrimination of employees engaged in protected activities.
13. Commitment to provide information to employees regarding the employee protection and deliberate misconduct.
14. Obtaining NRC's prior written consent before transferring control of the license.
15. Notifying appropriate NRC regional administrator in writing, immediately following filing of petition for voluntary or involuntary bankruptcy

APPENDIX D

A. DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY COMMITTEE (RSC)

1. Determine the adequacy of the training and experience of Authorized Users (AU) to possess and use radioactive material and radiation sources under the MSC-UPR material license. Evaluate the training and experience requirements of applicants that request authorization to use radioactive material at the MSC-UPR. Also review each proposal, protocol for using radioactive material, general design of facilities, personal protective equipment, surveys for removable contamination, waste disposal etc., to ensure that all procedures are in accordance with good radiation safety practices and regulations for RSC approval.
2. Evaluate and approve new users and new uses of byproduct material. Thoroughly reviews the overall compliance status for AU.
3. Evaluate and approve modifications to existing uses to an AU's license material.
4. The RSC Chairperson and the RSO must sign all Radioactive Material Licenses and amendments. In their absence, the license may be signed by an alternate, provided the alternate meets applicable regulatory requirements and is approved by the RSC (typically another RSC member).
5. Review and approve of policy or procedural changes to the radiation safety program.
6. To approve a new policy or procedure, a simple majority of a quorum of the Radiation Safety Committee is required prior to authorization. The approved change will be documented and will state the reason for the changes and summarize the radiation safety matters that were considered prior to approval of the change. The RSC will oversee the implementation of the change including training of personnel and audits to ensure compliance.
7. Ensures that the material possessed under the broad scope program may only be used by, or under the direct supervision of individuals approved by the RSC.
8. Receive, review, and take appropriate action on reports from the RSO, (e.g., areas and personnel monitoring; accidents in handling, storage, and use of radioactivity; medical events, items of non-compliance identified in audits, loss, or theft of any amount of radioactivity; records of radionuclide procurement and disposal).
9. Require cessation of any operation involving radiation upon a determination of inadequate safety procedures.

10. Participate in an annual review of the Radiation Safety Program, in collaboration with the RSO based on radiation protection principles to achieve doses that are ALARA and provide any necessary recommendations to ensure this.
11. Conducts periodic audits to the Radiation Safety Program with the RSO, that includes the review of all records, visits to the locations where radioactive material is authorize to be use, the reports from the RSO, (e.g., area monitoring; personnel monitoring; accidents in handling, storage, and use of radioactivity; items of non-compliance identified in audits, loss or theft of any amount of radioactivity; records of radionuclide procurement and disposal), the results of NRC inspection, written safety procedures, the adequacy of the institution's management control system. Also, the RSC reviews any consultant's audit findings and documents the acceptance or rejection of the consultant's findings in the RSC minutes.
12. Review the Radiation Safety Program based on radiation protection principles to achieve ALARA doses and analyze possible trends and determines the course of corrective action(s) to be taken.
13. Advise the MSC-UPR Administration regarding matters of radiation protection.
14. Provides technical oversight, advice, and assistance to the Administration and the Radiation Safety Office on matters concerning radiation safety and security.
15. Meets at least quarterly to review radiation safety issues and receive a status report on such issues from the RSO. The Chair of the RSC have the authority to make temporary policy decisions when a formal RSC meeting cannot be scheduled in a timely fashion. Such temporary policy decisions are subject to a full review by the RSC at its next meeting. Written minutes are kept for regulatory audits.
16. The RSC chairperson has direct line of communication with the Chancellor to discuss radiation safety issues that need to be brought to management's attention.
17. Institutional AU license termination will be produced by the RSC when health and safety of employee, property and environment appears to be compromised with repeated violations to radiation safety regulations and/or user's responsibilities.

B. MEMBERSHIP AND ORGANIZATION OF THE RSC:

The RSC and its chairperson are appointed by and are responsible to the Chancellor of MSC-UPR. The regulatory requirements state that the RSC shall be composed of: (1) the Radiation Safety Officer (RSO); (2) the Chairperson of the RSC and (3) a representative of the MSC-UPR executive management and persons trained and experienced in the safe use of radioactive materials representing each type of use (e.g., authorized users, radiation workers such as nurses, nuclear medicine technologist and occupational health employees). The RSC have members with expertise on clinical use of radioactivity as well as members that conduct biomedical research with radionuclides. Members represent the various types of uses of

radioactive materials or radiation sources throughout the MSC-UPR. The Chancellor of MSC-UPR may at her/his discretion, remove or reappoint any member of the RSC at any time. The RSC may recommend to the Chancellor the appointment of additional members to improve the effectiveness of the RSC. Ex-officio members may also be appointed by the Chancellor or the RSC Chairperson, as needed.

The Chairperson will be selected upon several factors including knowledge of radiation safety issues, good leadership abilities, the authority and credibility by virtue of his or her position within the facility, and with time to devote to the position in addition to other responsibilities he or she might have within the facility. The RSC will conduct business at formal meetings held as often as necessary, but at a minimum will meet at intervals not exceeding six (6) months.

The Chairperson calls and presides over all meetings, establishes agendas, maintains close communication with the RSO, the Radiation Safety Office and the Administration. he/she will inform the Chancellor of important matters pertaining to the Radiation Safety Program. The Chairperson also establishes working groups and appoints ex-officio members to the Committee, as the Committee deems necessary. During a leave of absence, a member of the RSC will be nominated to serve as interim Chairperson of the RSC. The Administration shall provide administrative support to the Committee. Meetings are conducted at least four times a year at three-month intervals or as often as needed to ensure the radiation safety program is operating in compliance with the license, established procedures and the regulations. A quorum will be satisfied with half the members plus one, including the chairperson and the RSO or Deputy RSO (his designee) and a representative from each area of use from which specific issues will be discussed, and any other member whose field of expertise is necessary for the discussion.

The RSC Administrative Assistant maintains minutes of its meetings. The minutes includes the date, the members present and absent to demonstrate a quorum was present, a summary of the discussions, recommendations, and the results of votes. The RSC should also document its review of new users, uses, and program changes. The minutes will also include information related to the ALARA program reviews and the annual radiation safety program review.

C. REQUIREMENTS OF THE RSC AND THE RSO FOR AUTHORIZING NEW USERS AND NEW USES:

The RSC evaluate and approve new authorized users (AU) for the use of radioactive material or radiation sealed sources in the promises of the UPR MSC. To become an AU, the investigator must apply for the use of radioactive material and complete one of the following forms: Application Form for Nuclear Medicine or Application Form for Biomedical Research. The RSO does an initial perusal of the application and submits it to the RSC for evaluation.

Approval for the use of radioactive materials is given by the RSC and is reviewed periodically. The evaluation will be based upon minimum criteria developed by the RSC. This is done by applying submitting required information such as: description of the requested material and quantity to be used, the location and general design of facilities, surveys for removable contamination, waste disposal process, individuals who will handle the material, present evidence of training and experience of the applicant working with radioactive material, the

training of workers, the personnel protective equipment to be used, monitoring equipment, a brief description of experimental procedures and protocols with emphasis on potential safety concerns, methods and a description of measures employed to minimize radiation exposure to the experimenter, any human subjects, and equipment are adequate to protect health and minimize danger to life or property and the protection of the environment.

Only physicians who are licensed to practice medicine in Puerto Rico and who fulfill the experience and training requirements will be considered for routine medical use of radioisotopes. The required documents and forms for application will be available at the Radiation Safety Office.

Investigators or directors of research protocols involving uses of radioactive materials "in vitro" or animals will also have to provide the information requested in corresponding application form and fulfill the minimum experience and training. Applicant will submit a complete protocol describing his research plan to include its rationale, background, methods, and a description of measures employed to minimize radiation exposure to the experimenter, any human subjects, and the protection of the environment.

To approve a new User, a simple majority of a quorum of the RSC is required prior to authorization. The RSO and RSC Chairperson must sign all Radioactive Material Licenses and amendments. In their absence, the license may be signed by an alternate, provided the alternate meets applicable regulatory requirements and is approved by the Radiation Safety Committee (typically another RSC member). Complete records and documents of all MSC Institutional Licenses will be filed by the Chairperson of the RSC and the originals of the Licenses will be filed in the Radiation Safety Office.

D. PROCEDURES FOR AUTHORIZATION OR INSTITUTIONAL LICENSE TO USE AND HANDLE RADIOACTIVE MATERIALS AT THE UPR - MSC

The RSC is responsible to approve new uses of ionizing radiation (radioactive material and machine produced radiation) by individual physicians or other scientists in clinical or research activities and any amendment to an authorized user's radioactive material license. The RSC will follow guidelines in each case. Anyone wishing an authorization or Institutional License must arrange an interview with the RSO to review the applicant's experimental procedures and available facilities and discuss any applicable regulations, procedures, and practices. The applicant must provide all information requested on the Application Form and submit it to the RSO for his review and recommendations to the RSC.

AU must apply for new uses of ionizing radiation (radioactive material and machine produced radiation) and submit amendments to their license for any change in experimental procedures which have an impact on safety, and for a change in chemical or physical form of a material previously approved.

1. The RSC will evaluate and approve new uses of ionizing radiation (radioactive material and machine produced radiation) and any modification to existing uses. In case of any significant change in the experiment procedures, the RSC and/or RSO will decide if a new application

is recommended. For their approval, a simple majority of a quorum of the RSC is required prior to authorization and it is valid for the entire duration of the project.

2. The AU shall renew their application form on annually basis. Failure to comply with this requirement, will lead to suspend his institutional license by the RSC.
3. The RSO and RSC Chairperson must sign all Radioactive Material Licenses and amendments. In their absence, the license may be signed by an alternate, provided the alternate meets applicable regulatory requirements and is approved by the Radiation Safety Committee (typically another RSC member)

E. SANCTIONS FOR VIOLATIONS OF MSC 'S RADIATION SAFETY POLICY

Failure to adhere to the rules for proper usage of radioactive materials can result in sanctions against the Authorized User or Radiation Worker. A description of these sanctions follows:

- **Level I Sanction**: This sanction will be for violations that appear to be inadvertent or occasional lapses that are discovered by MSC inspection teams. The Authorized User or Radiation Worker must provide the RSC and RSO a written explanation for the failure and their corrective actions to prevent future failures.
- **Level II Sanction**: This sanction will be invoked for a serious violation or repeated violations that appear to indicate a lack of regard for NRC and MSC radiation safety regulations. This sanction involves a suspension of the Authorized User's or Radiation Worker's access to radioactive material for a minimum of 60 days. All radioactive materials will be confiscated, and the Authorized User/Radiation Worker will be required to retake the radiation safety training course, as well as reapply for permission to use radioactive materials. The RSC may also recommend that the MSC administration take additional disciplinary actions against the Authorized User and/or Radiation Worker.
- **Level III Sanction**: This sanction will be imposed for flagrant violations or those that intentionally set coworkers at risk of injury from radioactive materials. This sanction results in permanent revocation of the use of radioactive materials. The RSC may also recommend that the MSC Administration exert additional disciplinary actions against the Authorized User and/or Radiation Worker.

F. ORDERING RADIOISOTOPES AND OTHER RADIOACTIVE MATERIALS

The purchase of radioactive material including both licensed and license-exempt quantities is handled through the Radiation Safety Office. Authorize users are encouraged to establish standing and/or blanket orders for the purchase of radioactive material with the Radiation Safety Office. To establish these orders, each AU must complete the appropriate purchase request and hand carry it to the Radiation Safety Office for approval. Instructions on how to complete the purchase request may be obtained from the Radiation Safety Office. All orders for radioactive materials to be purchased through the MSC shall not be processed until approved by the Radiation Safety Office.

Once the standing and/or blanket order has been established, the AU should place their radioactive material orders with the Purchase Department. Only AUs with an approved and unsuspended application will be allowed to establish standing and/or blanket orders and place radioactive material orders. All requests should include the following:

Principal Investigator's Name, Nuclide, Maximum Activity, Vendor, and Chemical Form. Additional information is requested to present total amount of nuclides in possession Activity in uCi or mCi) and total amount of each type of radioactive waste stored in the laboratory (vials, solids, or liquids). If orders do not have all the information listed, it will cause a delay upon approval of the radioactive material.

Note that orders for radioactive material must be limited to the isotopes, chemical forms, and maximum activity per shipment as shown on the application form. Orders for other materials or activities greater than specified on the application cannot be ordered. The AUs are required to submit an amendment application to the Radiation Safety Office for the approval of the RSC.

The Radiation Safety Office will review the order request to determine the following:

1. That the user has been authorized to use the type and quantity of radioactive material being ordered. The name of the Authorized User must be clearly indicated on the order.
2. That the radioactive material being ordered will not cause the Authorized User's inventory limits to be exceeded.
3. That the Authorized User has no unresolved items of safety noncompliance, including responses to survey reports and training notices.
4. That the Authorized User's radionuclide inventory reports are current.

When the above criteria are met, the order will be approved and signed by authorized personnel of the Radiation Safety Office. The AU or designee will hand to the Radiation Safety Office a package receipt when radioactive material is received in the laboratory. The amount received must be included as an inventory record. If the above criteria are not met, the AU will be notified by telephone to expedite acquisition of the necessary information. Authorization is based on prior protocol approval by the RSC as described earlier.

Every shipment of radioactive material received must be tracked in the inventory database and added with the campus totals. This is to prevent an individual AU, or the campus, from exceeding individual approval or MSC license possession limits respectively.

Note: The purchase of radioactive material by credit cards is not approved by the Central Administration of the University of Puerto Rico and the Medical Sciences Campus will comply with these criteria.

G. RADIOACTIVE MATERIAL LICENSE STATUS

An AU may request that his/her authorization to use and store radioactive materials be temporarily changed to an Inactive Status. This status allows the AU to perform and document survey/wipe tests and inventories on a less frequent basis (quarterly). This provision is designed for laboratories which are not planning on using radioactive materials for at least six months. The AU may not use radioactive materials with this status (this is a storage only authorization). The AU must submit a request to the RSC to return to active status when so desired.

The "status" of each Authorization (and Authorized User) falls into one of following categories:

1. **Active:** An AU is authorized by the RSC to use, purchase, and possess radioactive material including equipment containing sealed sources, irradiators, or radiation producing machines. This person purchases or performs experiments with radioactive material or radiation sources at least once in a year. A person must remain classified as "active" if they possess any amount of usable encapsulated radioactive material or if they are using equipment containing sealed sources, irradiators, or radiation producing machines.
2. **Inactive:** The AU is authorized to use, purchase, and possess radioactive material including equipment containing sealed sources, irradiators, or radiation producing machines. An inactive user has chosen not to perform experiments utilizing encapsulated radioisotope or use radiation equipment for an extended period exceeding one year. A user who wishes to change to inactive status must notify the RSO and the RSC in writing of this decision. An inactive user shall have no usable encapsulated radioactive material (including radioactive waste) in their possession. Inactive users who have equipment containing sealed sources, irradiators, or radiation producing machines must not use them and must declare this information to the RSO and the RSC, in writing, at the same time as they request "inactive" status. If an inactive user desires to reinstate their "active" status, they must notify the RSO and the RSC in writing and fulfill "Active" status training requirements.
3. **Terminating Employment:** If an AU terminates employment at the UPR-MSC, the RSO and the RSC shall be notified at least one month beforehand. Arrangements must be made to remove or reassign any radioactive materials. Before the termination date, the Radiation Safety Office will conduct a final radiation survey of the radioisotope laboratory to determine the presence of unused radioisotopes and/or the presence of contamination. This person has no radioactive material, equipment containing radioactive material, or radiation producing equipment. A "terminated status" AU shall have completed (either prior to termination or in absentia) a "close-out" procedure, in which the inventory of radioactive material under the Authorization has been disposed or transferred, radioactive waste has been removed, and rooms and facilities have been surveyed and determined to be free of radioactive contamination. Documentation of the "close-out" will be maintained by the Radiation Safety Office.

Radiation workers who terminate their education and/or employment at the university shall notify the Radiation Safety Office and the RSC, and their badges

must be returned. Federal law, implemented on January 1, 1994, mandates that new workers who will use radioactive materials must supply the current year's exposure report to the RSO prior to beginning work with radioactive materials. To meet this requirement at future locations, this information will be supplied to a worker leaving the UPR-MSC after the radiation detection badge has been returned to the Radiation Safety Office.

- 4. Termination of Laboratory Operations (Close – Out):** When an AU ends his/her affiliation with UPR-MSC, or desires to terminate his/her radiation license, any laboratory space controlled by that user must be decommissioned (cleaned out by the AU and checked by the Radiation Safety Office) before the area can be returned to non-radiation use or occupied by another AU. Any AU who anticipates terminating his or her Authorization shall notify the RSO and the RSC of the termination in writing or via electronic mail no less than thirty (30) days prior to the anticipated date of termination.

5. Decommissioning

Permittee Responsibilities:

1. Notify Radiation Safety Office when the Radioactive Materials Permit is no longer needed.
2. Transfer remaining stock materials to radioactive storage area approved by the RSO.
3. Dispose of all unwanted radioactive waste through the Radiation Safety Office.
4. Clean all areas where radioactive materials or waste were used and stored.
5. Perform swipe tests of radioactive use areas.
6. Notify Radiation Safety Office and schedule a decommissioning survey be performed by Environmental Health and Safety office.
7. Transfer the following records to Radiation Safety Office:
 - All actions followed to reduce the contamination of a worker, including name of person surveyed, description of incident with prior work activity, probable cause and steps taken to reduce future incidence of contamination, times, dates, and the surveyor's name and signature
 - Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment or site
 - Records should include any known information or identification of involved nuclides, quantities, forms and concentrations
 - Limit records to instances when contamination remains after cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in porous materials such as concrete

8. Remove all radiation symbols and sign upon decommissioning release of area by RSO and RSC.
9. Ensure that decommissioning procedure is followed by the Permittee (Faculty or permitted employee under Department's supervision).
10. The RSC will approve the decommission process of the research and clinical laboratories and will released these areas for unrestricted use as required.
11. The Code of Federal Regulations (CFR) Title 10: Nuclear Regulatory Commission, Part 70 Section 38 (10 CFR 70.38) and Part 30 Section 36 (10 CFR 30.36) on the subject of "Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas" states that a process of decommissioning will begin in sites where no principal activities have been conducted for a period of 24 months.
12. NRC will be notified and amendment to the UPR-MSR will be requested if necessary. Documents regarding decommission process will be available for NRC inspections.

APPENDIX E

RADIATION SAFETY OFFICER DELEGATION OF AUTHORITY



Universidad de Puerto Rico, Recinto de Ciencias Médicas
University of Puerto Rico, Medical Sciences Campus

February 27, 2018

Oficina del Rector
Chancellor's Office

Jossian Javier Pagán Lisboa, DrPH(c), MS, CNMT
Radiation Safety Officer
Medical Sciences Campus
University Puerto Rico


Segundy Rodríguez Quilichini, MD, FACS, FASCRS
Interim Chancellor
Medical Sciences Campus
University Puerto Rico

DELEGATION OF AUTHORITY

It is my pleasure to appoint you as the Radiation Safety Officer of the University of Puerto Rico, Medical Sciences Campus. You are responsible for ensuring the safe use of radioactive material and managing the Radiation Protection Program together with the Radiation Safety Committee (RSC). Your duties include: identifying radiation protection problems, initiating, recommending, and providing corrective actions, verifying implementation of corrective actions, stopping unsafe activities, and ensuring compliance with regulations.

You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations, when justified, to maintain radiation safety. You are required to notify management if staff does not cooperate and does not address radiation safety issues. The disciplinary authority shall reside within the Chancellor of the UPR, Medical Sciences Campus. In addition, you are free to raise issues with the U.S. Nuclear Regulatory Commission (NRC) at any time.

It is estimated that you will spend 25 hours per week conducting radiation protection activities. You will also have the resources and sufficient commitment from the management to fulfill the duties and responsibilities specified in 10 CFR35.24 to ensure that radioactive materials are used in a safe manner.

I accept the above responsibilities,

Dirección/Address:
P.O. Box 365067
San Juan, PR
00936-5067

Teléfono/Phone:
787-758-2525
Exts. 1708, 1709

Fax: 787-754-0474



Patrono con
Igualdad
de Oportunidad
en el Empleo
M/M/V/H
Equal Employment
Opportunity
Employer M/W/V/H


Radiation Safety Officer


Date

Cc: Arq. Alejandro Argüelles Rodríguez, Interim Dean of Administration
Annabell C. Segarra Marrero, PhD, Chair of RSC
Directors and Authorized Users of Radioactive Materials
Dr. Luis A. Rivera, Consultant of Interim Chancellor

DUTIES OF THE RADIATION SAFETY OFFICER (RSO)

Specific duties and responsibilities of the RSO include but are not limited to:

1. The RSO performs audits of all areas of use and individuals who are authorized to use byproduct material to ensure work is done in accordance with the license, regulations, and user permit conditions.
2. Monitoring and surveys of all areas in which radioactive material is used.
3. Overseeing ordering, receipt, surveys, and delivery of byproduct material.
4. Packaging, labeling, surveys, etc., of all shipments of byproduct material leaving the Institution.
5. Monitoring programs, including determining the need for and evaluating bioassays.
6. Monitoring personnel exposure records, and developing corrective actions for those exposures approaching maximum permissible limits.
7. Developing and implementing an ALARA and training program for all personnel.
8. Overseeing the waste disposal program and any decontamination process.
9. Monitoring inventory and leak tests of sealed sources.
10. Investigating incidents, responding to emergencies, and notifying the appropriate Agencies.
11. Maintaining all required records.

APPENDIX F

RESPONSIBILITIES OF THE AUTHORIZED USERS (AU)

The Authorized Users (AU) is responsible for ensuring that individual responsibilities are discharged by those under their control, and are further responsible for:

1. Adequate planning. Before an experiment is performed, the AU should determine the types and amount of radiation or radioactive material to be used. This will generally give a good indication of the protection required. The procedure must be well outlined. In many cases, before the procedure is performed with radiation, it should be rehearsed to preclude problem areas or unexpected circumstances. In any situation where there is an appreciable radiation hazard, the Radiation Safety Office shall be consulted before proceeding.
2. Instructing supervised employees on safe radiation practices for all personnel working with radioisotopes. Ensure that all laboratory personnel, including guest investigators, complete the UPR MSC Radiation Safety Training before they start working in the laboratory as Radiation Workers. This also includes people who occasionally enter facilities where radioactive material is handled. Ensuring attendance at required radiation safety courses. Technologist and resident students should attend the Basic Seminars sponsored by the RSC and organized by the RSO every year.
3. Provide the Radiation Safety Office with information concerning individuals and activities in their areas, changes in their personnel and authorized room locations.
4. Contacting the Radiation Safety Office whenever major changes in operational procedures, alterations in use locations (e.g., the removal of radiochemical fume hood), or when new operations, which might lead to personnel exposure, are anticipated.
5. Complying with the regulations governing the use of radioactive materials, as established by the RSC. This includes:
 - Utilizing the correct procedure for the procurement of radioactive materials by purchase or transfer. The purchase of license material must be approved by the RSO. Maintaining reasonably accurate inventory records of radioisotopes.
 - Submit the company's name from which radioactive material will be purchased. New suppliers may request a copy of the MSC-NRC license.
 - Posting areas where radionuclides are kept or used, or where radiation areas may exist.
 - Assure that areas beyond his facilities are not affected by radiation or radioactive contamination.

- Providing personal protective equipment and supplies necessary for safe procedures with radioisotopes.
 - Assurance of proper labeling of sources, storage areas, contaminated equipment, etc.
 - Performing and recording laboratory surveys consistent with nuclide use and license requirements. To ensure absence of contamination and appropriateness of shielding and maintaining records for inspection reviews.
 - List instruments available for detecting radiation leak and/or contamination, instruments for analysis such as liquid scintillation counters or gamma counters.
 - Recording the receipt, transfer, and proper disposal of radioactive waste. Also ensuring that radioactive waste requirements are followed.
 - Prevent the transfer of radioactive materials to unauthorized individuals. This includes the proper disposition of radioactive materials possessed by terminating workers and securing radioactive materials against unauthorized removal.
 - Ensuring that all radiation sources are secured when no one is in attendance and keeping laboratory doors closed.
 - Notification to the RSO of the intended transfer of radioisotopes to another authorized user or other institution.
 - Notification of the Radiation Safety Office of any accident or abnormal incident involving or suspected of involving radioisotopes or radiation producing machines.
 - Arranging for transferring of obligations or institutional license termination during extended absences, e.g., sabbaticals or leave without payment.
 - Ensuring that all individuals working in or visiting his radioisotope facilities follow the Radioisotope Laboratory Safety Rules.
6. Keeping stocks of stored radioactive materials to a minimum authorized within laboratory areas. Maintaining radionuclide inventory under proper security to prevent unauthorized use.
 7. Complying with the procedure for termination of employment or termination of any experiment using radioactive materials. The AU is reminded, to proceed with the arrangements for the decommission process. A final termination survey must be performed to all specialized equipment and areas where radioactive material was used and stored. The survey results will be analyzed, and the RSC will approve and release these areas for other uses. The radioactive materials (including waste) assigned under his/her license, personnel monitoring devices and shielding materials are returned to the Radiation Safety Office.

APPENDIX G

THE RADIATION WORKER RESPONSIBILITIES

Everyone at the UPR-MSC who has any contact with radioactive materials is responsible for:

1. Keeping his exposure to radiation as low as reasonably achievable (ALARA), and specifically below the maximum permissible doses as listed in the following table:

ANNUAL OCCUPATIONAL DOSE LIMITS FOR ADULTS	
Whole body – Total Effective Dose Equivalent (TEDE)	5,000 mrem
Lens of the eye (LDE)	15,000 mrem
Extremities – Shallow Dose Equivalent (SDE)	50,000 mrem
Skin – Shallow Dose Equivalent (SDE)	50,000 mrem
Total Organ Dose Equivalent (TODE)	50,000 mrem

2. Applying the principles of time, distance and shielding to reduce exposures.
3. Wearing the monitoring badges or dosimeters in radiation areas. Personnel who work only with pure alpha emitters or only with pure beta emitters having a maximum energy of less than 0.25 MeV will not be required to wear badges. This includes H³, C¹⁴ and S³⁵.
4. Workers are responsible to report the RSO of any loss or contamination of the dosimeter.
5. Performing surveys on their hands, shoes, and body for contamination, and removing all loose contamination at the end of the day and before leaving the laboratory. Minimize the potential for exposures, contamination, or release of radioactive materials.
6. Utilizing appropriate protective measures such as:
 - Wearing protective clothing whenever contamination is possible. Do not wear such clothing outside of the laboratory area if contaminated. Contaminated clothing should be checked by RSO to determine appropriate actions.
 - Wearing disposable gloves or double gloves when necessary.
 - Using protective barriers and other shields whenever practical.
 - Using pipette filling devices. Never pipette radioactive solutions by mouth

7. The use of food, drink, candy, handling of contact lenses, tobacco, and application of cosmetics, lotion, or lip balm is prohibited in areas where radioactive material is used or stored. Refrigerators shall not be used jointly for foods and radioactive materials.
8. Maintaining Laboratory Safety Practices such as:
 - Disposable gloves should be always worn when working with radioactive material.
 - Use laboratory coats at all moments
 - Do not work with radioactive materials if there is a break in the skin below the wrist without first covering it.
 - Wash hands thoroughly after handling radioactive materials.
9. Surveying the immediate areas, (e.g., hoods, benches, etc.), in which radioactive materials are being used. Any contamination observed should be clearly marked and decontaminated. Complete a contamination Report and notify the Radiation Safety Office for guidance and recommendations.
10. Keeping the laboratory organize and clean. DO NOT LEAVE IT FOR ANOTHER PERSON TO CLEAN UP. The work area should be free from equipment and materials not required for the immediate procedure to ensure a safety work environment. Wherever practical, keep work surfaces covered with absorbent material, preferably in a stainless-steel tray or pan, to limit and collect spillage in case of an accident.
11. Labeling and isolating radioactive waste and equipment, such as glassware, used in laboratories for radioactive materials. Once used for radioactive substances, equipment should not be used for other work. An area within the laboratory with a sink should be identified with a label containing the following phrase "Caution, Radioactive Material" for the process of washing the glassware that is contaminated with radioactive material.
12. All radioactive areas and containers with radioactive material should be identified with a label with "Caution, Radioactive Material":
 - Radioactive waste containers
 - Radioactive storage areas such as refrigerators, safety cabinets, etc.
 - Waste or Decay storage area
 - Radioactive material containers such as: radioactive vials, reference sealed sources containers, patient dose containers, flood source for calibration purpose

- Specialized and dedicated instruments or equipment for the use of radioactive material such as: centrifuge, liquid scintillation counters, gamma counters, geiger mueller counters (GM), etc.
13. Workers are responsible for maintaining security of radioactive materials. Follow the recommendations of the Authorized User for those procedures that are specific to their laboratory for the storage, usage, recording, and disposal of radioactive materials.
 14. Requesting Radiation Safety Office supervision of any emergency repair of contaminated equipment in the laboratory by shop personnel or by commercial service contractors. At no time shall service personnel be permitted to work on equipment in radiation areas without the presence of a member of the laboratory staff to provide specific information.
 15. Reporting accidental inhalation, ingestion, or injury involving radioactive materials to the supervisor and the Radiation Safety Office and carrying out their recommended corrective measures immediately. The individual shall cooperate in all attempts to evaluate his exposure. The supervisor shall complete and submit an accident report to the Radiation Safety Office following the next 24 hours.
 16. Radiation work areas must be surveyed and documented at the end of the day. If contamination is found, it must be cleaned up.
 17. Carrying out decontamination procedures when necessary, and for taking the necessary steps to prevent the spread of contamination to other areas. Report any radioactive contamination to the RSO immediately and document it.
 18. Complying with the Radiation Safety Office requirements for thyroid burden measurements, and the submission of urine samples for radioassay when required.
 19. Ensuring training requirements are followed.
 20. Knowledgeable of the MSC Radiation Safety Manual and be responsible for its contents as applicable to their duties in the laboratory.
 21. Complying with the "Safety Rules", "Emergency Procedures", and "Notice to Employees" posted in the laboratory
 22. Call the MSC Security Office at 7-911, immediately report any fire, explosion, or major accident and tell the dispatcher that the accident involves radioactive materials. Next, notify Radiation Safety Office and their immediate supervisor and/or the Authorized User responsible for their laboratory. Emergency numbers must be posted near the telephone and visible to the laboratory personnel.

APPENDIX H

GENERAL INFORMATION FOR TRAINING PROGRAM AND FREQUENCY

SECTION I. TRAINING PROGRAM FOR INDIVIDUALS USING RADIOACTIVE MATERIALS FOR MEDICAL USE AND NON-MEDICAL USE

A. Training for individuals involved in the medical use and non-medical use of byproduct material, staff such as: AU's, nuclear medicine physicians, nurse, technologist, principal investigator, laboratory technicians, students, etc. will include, as appropriate, the following elements:

1. Basic radiation biology (e.g., interaction of ionizing radiation with cells and tissues).
2. Basic radiation protection to include concepts of time, distance, and shielding.
3. Concept of maintaining exposure ALARA.
4. Risk estimates, including comparison with other health risks.
5. Posting requirements.
6. Proper use of personnel dosimetry (when applicable).
7. Access control procedures.
8. Proper use of radiation shielding, if used.
9. Patient release procedures.
10. Instruction in procedures for notification of the RSO and AU, when responding to patient emergencies or death, to ensure that radiation protection issues are identified and addressed in a timely manner. The intent of these procedures should in no way interfere with or be in lieu of appropriate patient care.
11. Occupational dose limits and their significance.
12. Dose limits to the embryo/fetus, including instruction on declaration of pregnancy.
13. Worker's right to be informed of occupational radiation exposure.
14. Everyone's obligation to report unsafe conditions to the RSO.
15. Worker's right to contact the regulatory agency with concerns.
16. Applicable regulations, license conditions, information notices, bulletins, etc.
17. Where copies of the applicable regulations, the NRC license, and its application are posted or made available for examination.
18. Proper recordkeeping required by NRC regulations.
19. Appropriate surveys to be conducted.
20. Proper calibration of required survey instruments.
21. Emergency procedures.
22. Decontamination and release of facilities and equipment.
23. Dose to individual members of the public.
24. Licensee's operating procedures (e.g., survey requirements, instrument calibration, waste management, sealed-source leak testing).
25. Hazardous Materials (HAZMAT) training for preparing shipments of radioactive material.

B. Training for Staff Directly Involved in Administration to or Care of Patients Administered Byproduct Material for which a Written Directive Is Required (Including Greater-than-30 microcuries of I-131); (e.g., technologist, nursing and, AU,):

In addition to the topics identified in Section A, the following topics may be included in instruction for staff involved in the therapy treatment of patients (e.g., nursing, RSO, AMP, AU, and technologist), *commensurate with their duties*:

1. Leak testing of sealed sources, as applicable.
2. Emergency procedures (including emergency response drills, as applicable.
3. Operating instructions, as applicable.
4. Computerized treatment planning system, as applicable.
5. Dosimetry protocol, as applicable.
6. Detailed pretreatment quality assurance checks, as applicable.
7. Safe handling (when applicable) of the patient's dishes, linens, excretions (saliva, urine, feces), and surgical dressings that are potentially contaminated or that may contain radioactive sources, as applicable patient control procedures, as applicable.
8. Visitor control procedures, such as visitors' stay times and safe lines in radiation control areas (patient's room), as applicable.
9. Licensee's written directive (WD) Procedures, to ensure that each administration is in accordance with the WD, patient identity is verified, and where applicable, attention is paid to correct positioning of sources, applicators, and collimators to ensure that treatment is to the correct site, as applicable.
10. Proper use of safety devices and shielding to include safe handling and shielding of dislodged sources, as applicable.
11. Size and appearance of different types of sources and applicators, as applicable
12. Licensee operational safety training (to new staff and annually to all individuals operating the unit) that is device model-specific and includes, as applicable.
 - Vendor training (prior to first use of a new unit or after manufacturer upgrades that affect operation and safety of the unit).
 - Design, use, and function of the device, including safety systems and interpretation of various error codes and conditions, displays, indicators, and alarms.
 - Hands-on training in actual operation of the device under the direct supervision of an experienced user, including "dry runs" (using dummy sources) of routine patient set-up and treatment and implementation of the licensee's emergency procedures.
 - A method, such as practical examinations, to determine each trainee's competency to use the device for each type of proposed use.

SECTION II. TRAINING FOR ANCILLARY STAFF

For the purposes of this section, ancillary staff includes personnel engaged in janitorial and/or housekeeping, laboratory, and security. The training program for ancillary staff performing duties that are likely to result in a dose more than 1 millisievert (100 millirem) will include instruction commensurate with potential radiological health protection problems present in the workplace. Alternatively, prohibitions on entry into controlled or restricted areas may be applied to ancillary personnel unless escorted by trained personnel. Instructions include:

1. Maintain informed of the storage, transfer, or use of radiation and/or radioactive material
2. Instruct of potential biological effects associated with exposure to radiation and/or radioactive material, precautions, or procedures to minimize exposure, and the purposes and functions of protective devices (e.g., ALARA concepts of time, distance, and shielding)
3. The applicable provisions of NRC regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material (e.g., posting and labeling of radioactive material)
4. Their responsibility to report promptly to the licensee any condition that may lead to or cause a violation of NRC regulations and licenses or unnecessary exposure to radiation and/or radioactive material (e.g., notification of the RSO regarding safety issues)
5. Appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material
6. Advise as to the radiation exposure reports that workers must be furnished pursuant to regulations.

SECTION III GROUPS IN THE TRAINING PROGRAM AND FREQUENCY

Group	Frequency
1. The Nuclear Medicine Physicians	<ul style="list-style-type: none">• 10 hours before assuming duties• 1-hour annual refresher course
2. Technologists, Nurses and Graduate students	<ul style="list-style-type: none">• 5 hours before assuming duties• 1-hour annual refresher course
3. Housekeeping, janitors, security, and clerical personnel	<ul style="list-style-type: none">• 1 hour before assuming duties• 1-hour annual refresher course
4. Principal Investigators (AU's)	<ul style="list-style-type: none">• 10 hours before assuming duties• 1-hour annual refresher course
5. Undergraduate students (usually short period of time):For laboratory workers (e.g., students), who are NOT radiation workers but work for a researcher who is an AU, it is his/her responsibility to provide appropriate training. The training should be commensurate to their potential exposure to radiation. In some cases, training may not be necessary (e.g., workers not required to work in any of the laboratories where radioactive material is authorized). The AU may also contact Radiation Safety Office for assistance and the students may participate in the RSO Annual Refresher Training.	<ul style="list-style-type: none">• 1-hour before assuming duties• 1-hour annual refresher course
6. Newly appointed researchers without previous acceptable training	<ul style="list-style-type: none">• 10 hours before assuming duties• 1-hour annual refresher seminar
7. Newly appointed research technicians without previous acceptable training	<ul style="list-style-type: none">• 5 hours before assuming duties• 1-hour annual refresher seminar
8. Radiation Safety Committee	<ul style="list-style-type: none">• 2 hours seminar about ALARA program

APPENDIX I

ANNOTATED DRAWINGS

SECURITY – RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390

NUCLEAR MEDICINE FACILITIES:

4. UPR- Nuclear Medicine Laboratory, Dr. Isaac González Hospital

BIOMEDICAL RESEARCH LABORATORIES AT UPR-MEDICAL SCIENCES CAMPUS:

1. Laboratory A-643

RADIOACTIVE WASTE STORAGE FACILITIES AT UPR-MEDICAL SCIENCES CAMPUS:

1. Radiation Waste and Decay Storage # 1 – Floor 10 RCM Main Building
2. Radiation Waste and Decay Storage # 2 – Floor 1 RCM Library Building
3. Radiation Waste and Decay Storage # 3 – Floor 1 Between Pediatric Hospital and Infant and Maternity Health Center (CEMI) of the UPR-MS
4. Radiation Waste and Decay Storage # 4 – Radiation Safety Office # 103 Laboratory Basement at Comprehensive Cancer Center Building, Storage Area for Sealed Sources (Bunker)

F. Outside Building

C. Outside Building

D. Outside Building, Limit of Remodeling Works

E. Outside Building, No Construction in this area of the 4th floor

Area's Adjacent to Nuclear Medicine Laboratory

A. Lobby

B. Social Workers Office

C. Patient Rehabilitation Facilities

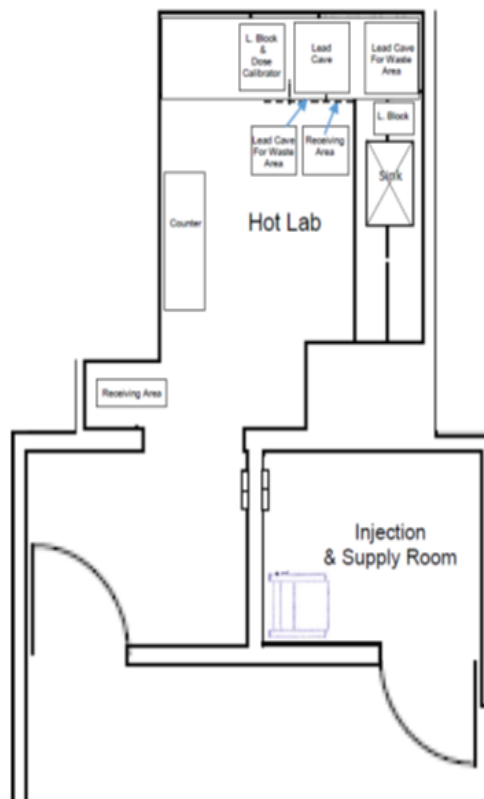
D. Outside Building, Limit of Remodeling Works

E. Outside Building, No Construction in this area of the 4th floor

A. Lobby
B. Social Workers Office
C. Patient Rehabilitation Facilities
D. Outside Building, Limit of Remodeling Works
E. Outside Building, No Construction in this area of the 4 th floor
F. Outside Building, No Construction in this area of the 4 th floor
13. Waiting Area
14. Receptionist Area
15. Nuclear Medicine Director's Office
Note: On top of the Nuclear Medicine Department facilities is the roof of Dr. Issac González Martínez Hospital.

**SECURITY - RELATED INFORMATION -
WITHHOLD UNDER 10 CFR 2.390**

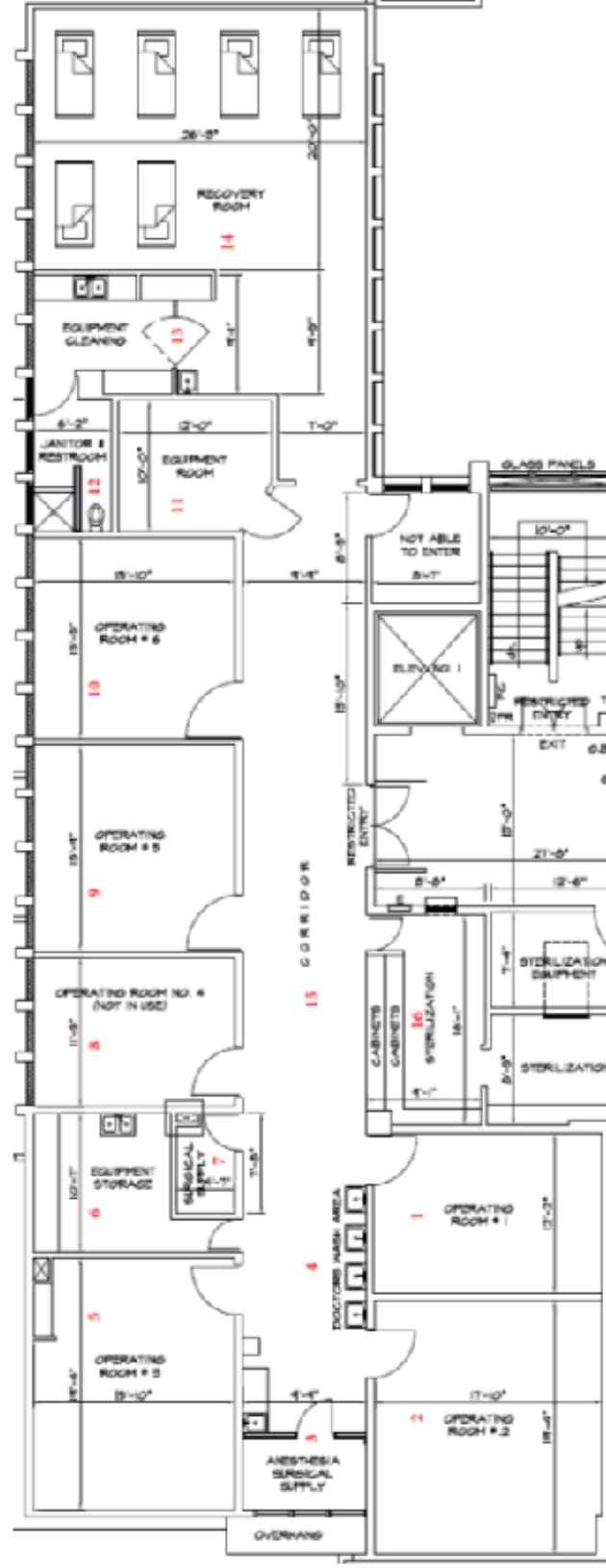
Medical Sciences Campus of the University of Puerto Rico
Diagram of Hot Lab in the Nuclear Medicine Department
on the Fourth Floor of Oncology Hospital, Dr. Isaac González Martínez



SECURITY – RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390

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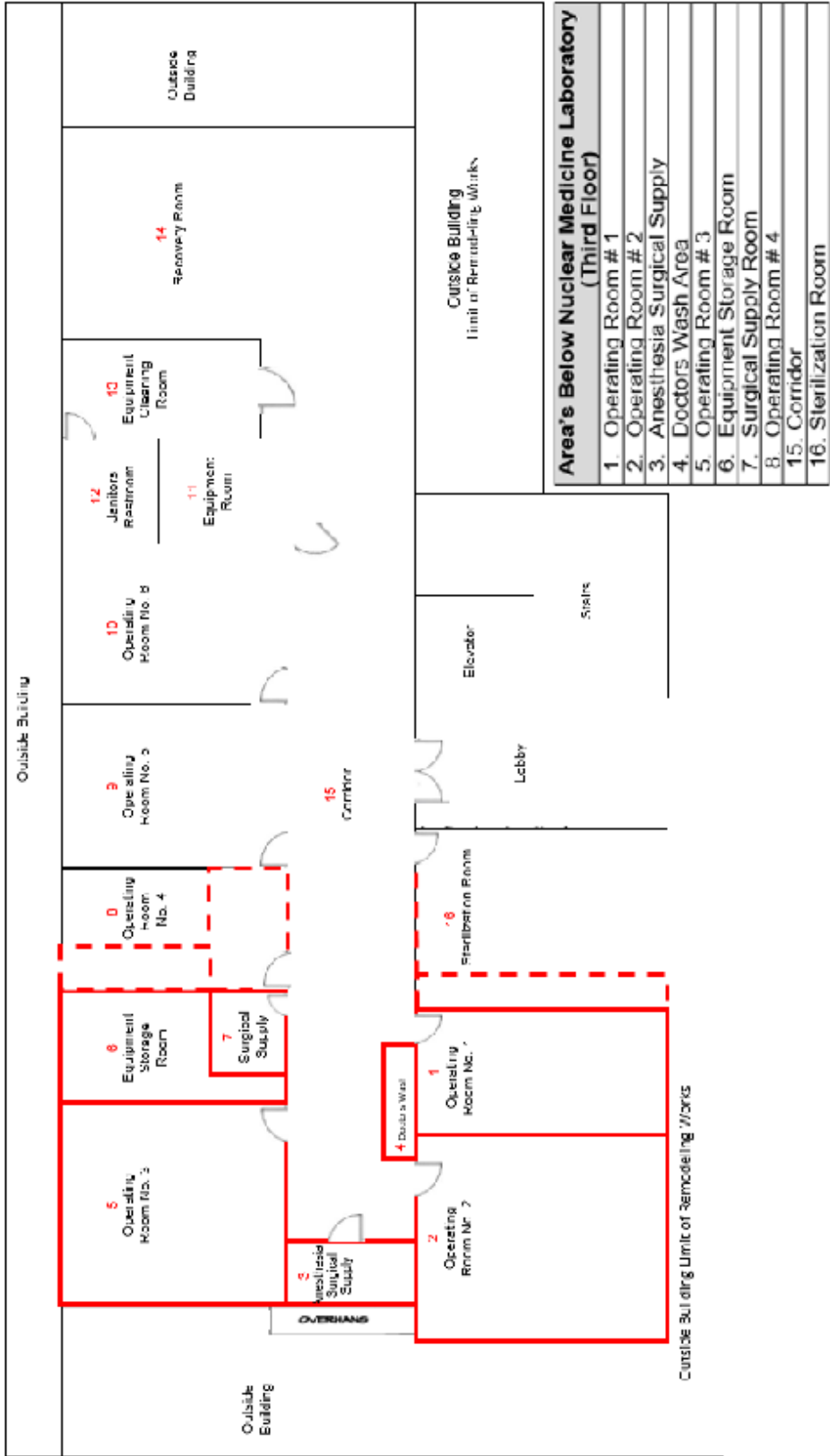
Medical Sciences Campus of the University of Puerto Rico
 Facility Diagram Below Nuclear Medicine Department
 on the Third Floor of Oncology Hospital, Dr. Isaac González Martínez



Area's on the Third Floor	
1. Operating Room # 1	9. Operating Room # 5
2. Operating Room # 2	10. Operating Room # 6
3. Anesthesia Surgical Supply	11. Equipment Room
4. Doctors Wash Area	12. Janitors Restroom
5. Operating Room # 3	13. Equipment Cleaning Room
6. Equipment Storage Room	14. Recovery Room
7. Surgical Supply Room	15. Corridor
8. Operating Room # 4	16. Sterilization Room

Medical Sciences Campus of the University of Puerto Rico
Diagram Areas Below Nuclear Medicine Laboratory
on the Third Floor of Oncology Hospital, Dr. Isaac González Martínez

SECURITY – RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390



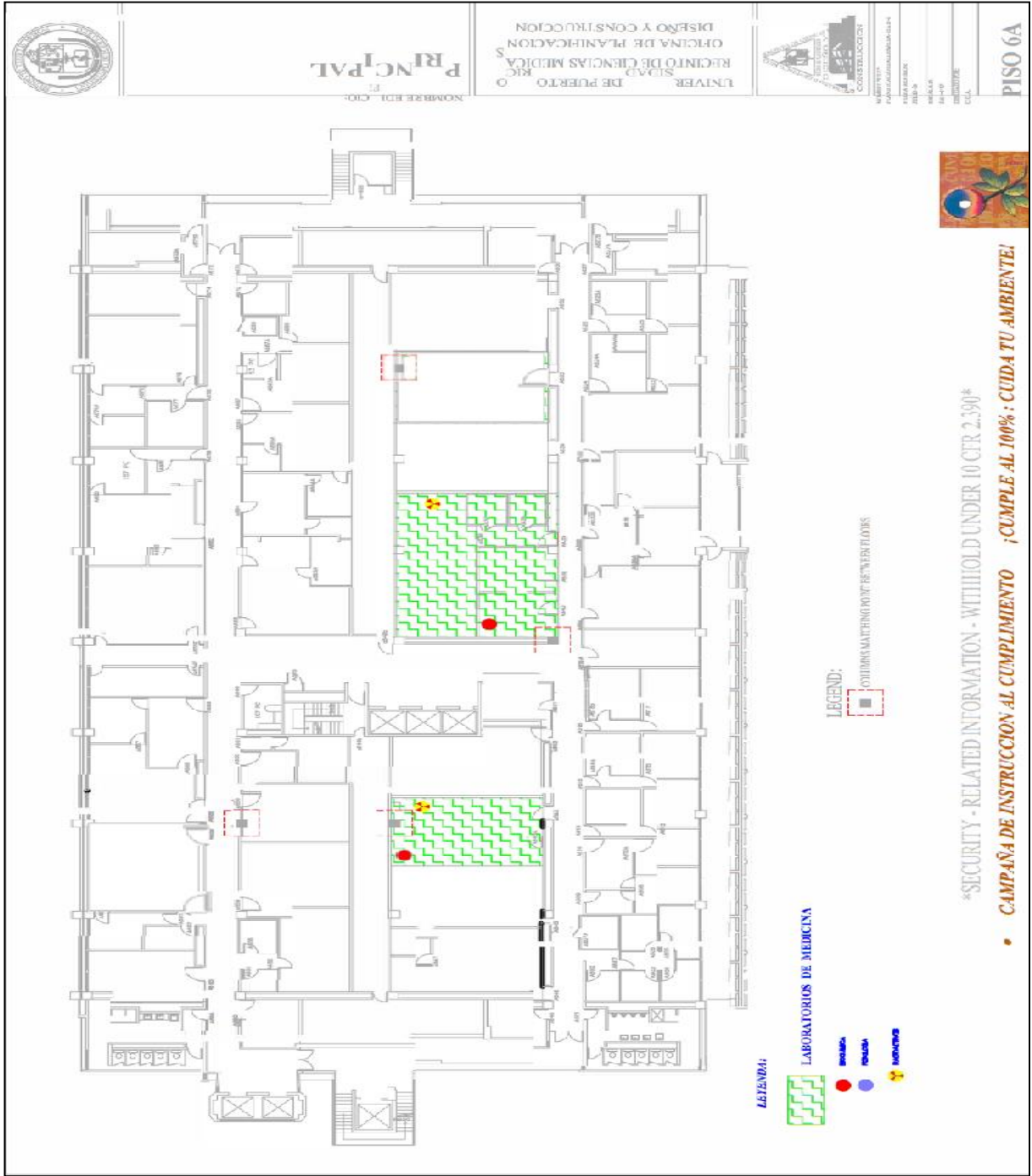
SECURITY – RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390

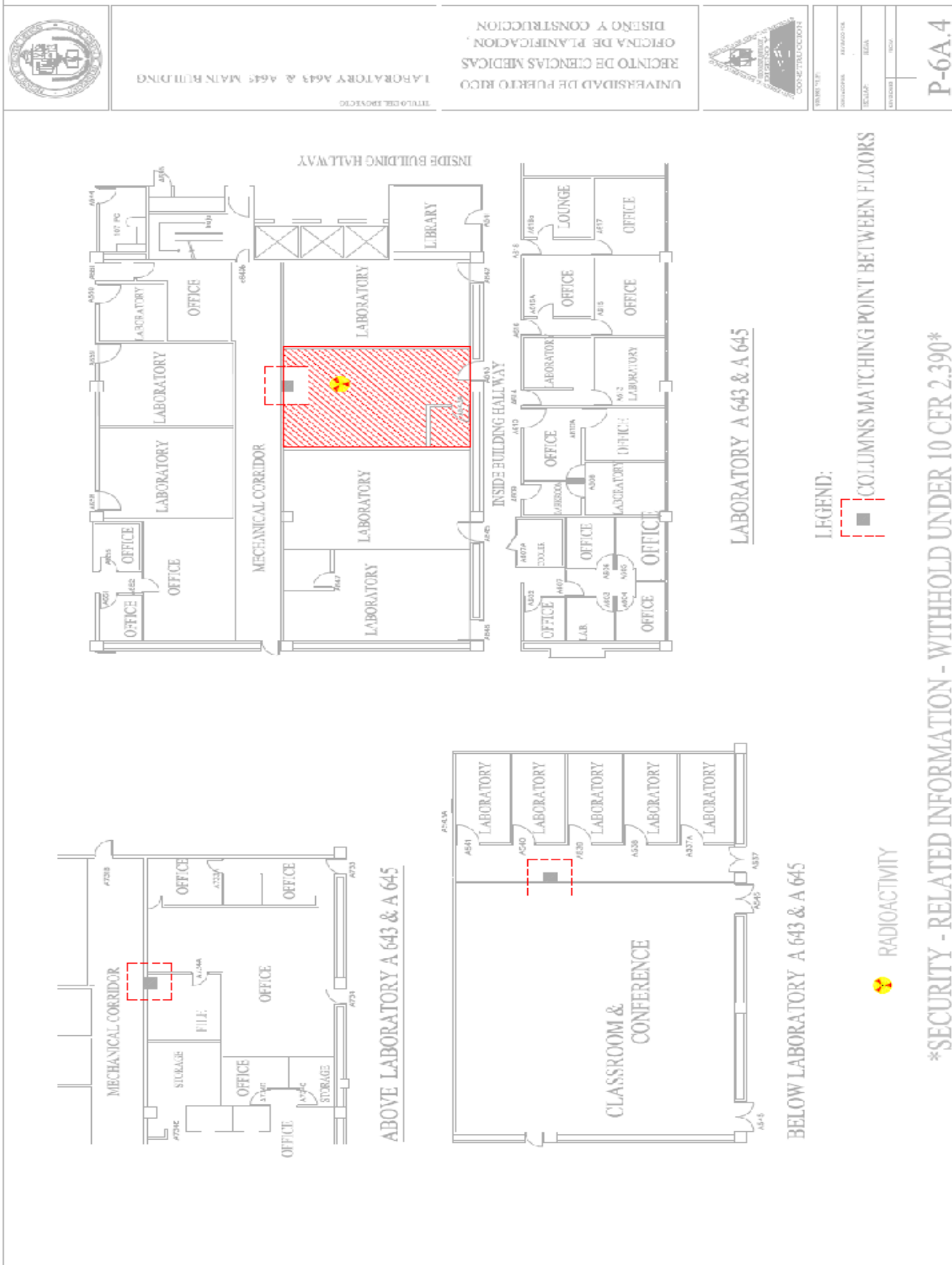
APPENDIX D

**BIOMEDICAL RESEARCH LABORATORIES
UPR- MEDICAL SCIENCES CAMPUS
SECURITY – RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390**

**BIOMEDICAL RESEARCH LABORATORIES
UPR- MEDICAL SCIENCES CAMPUS
SECURITY – RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390**

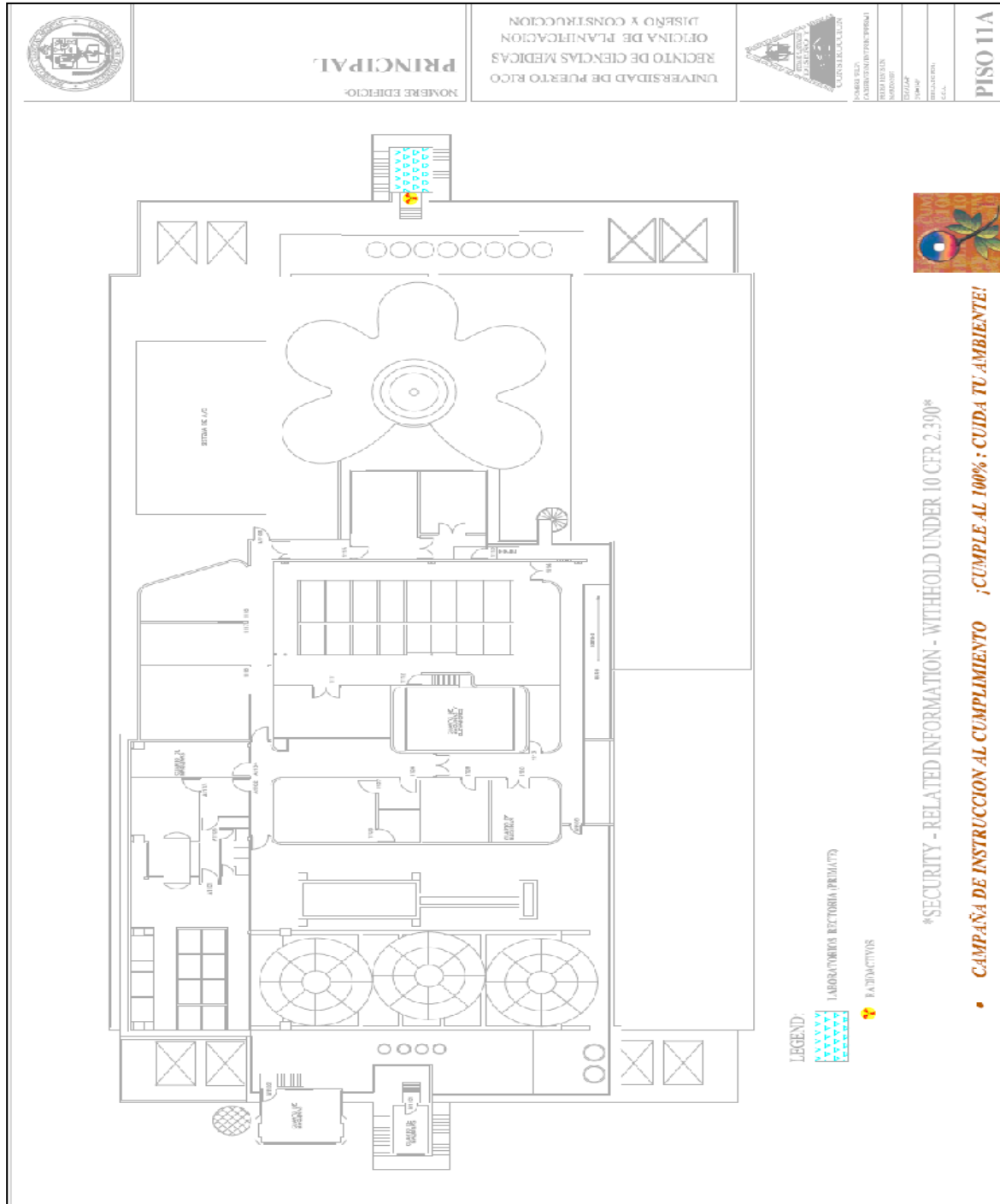
Laboratory A-643

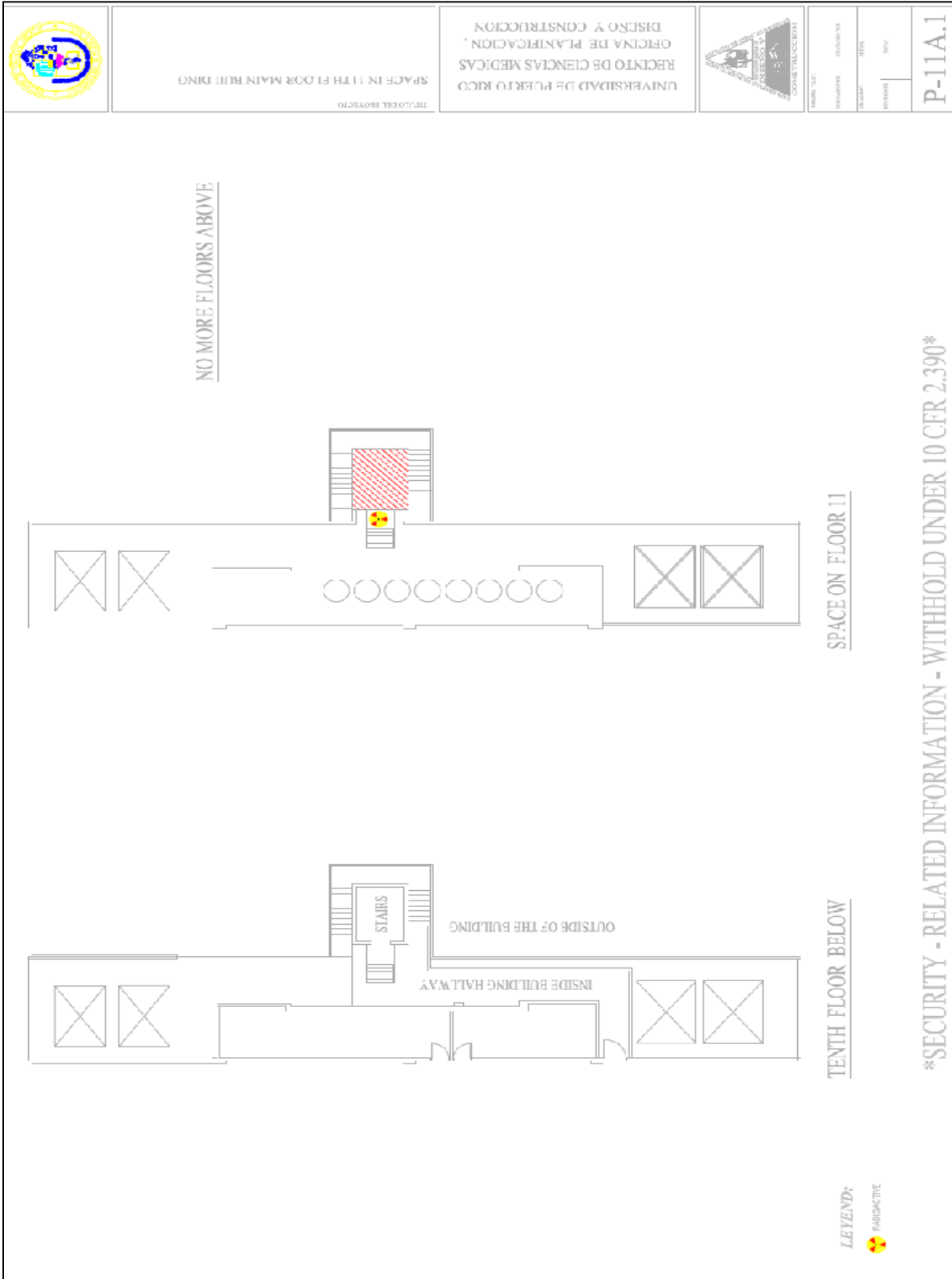




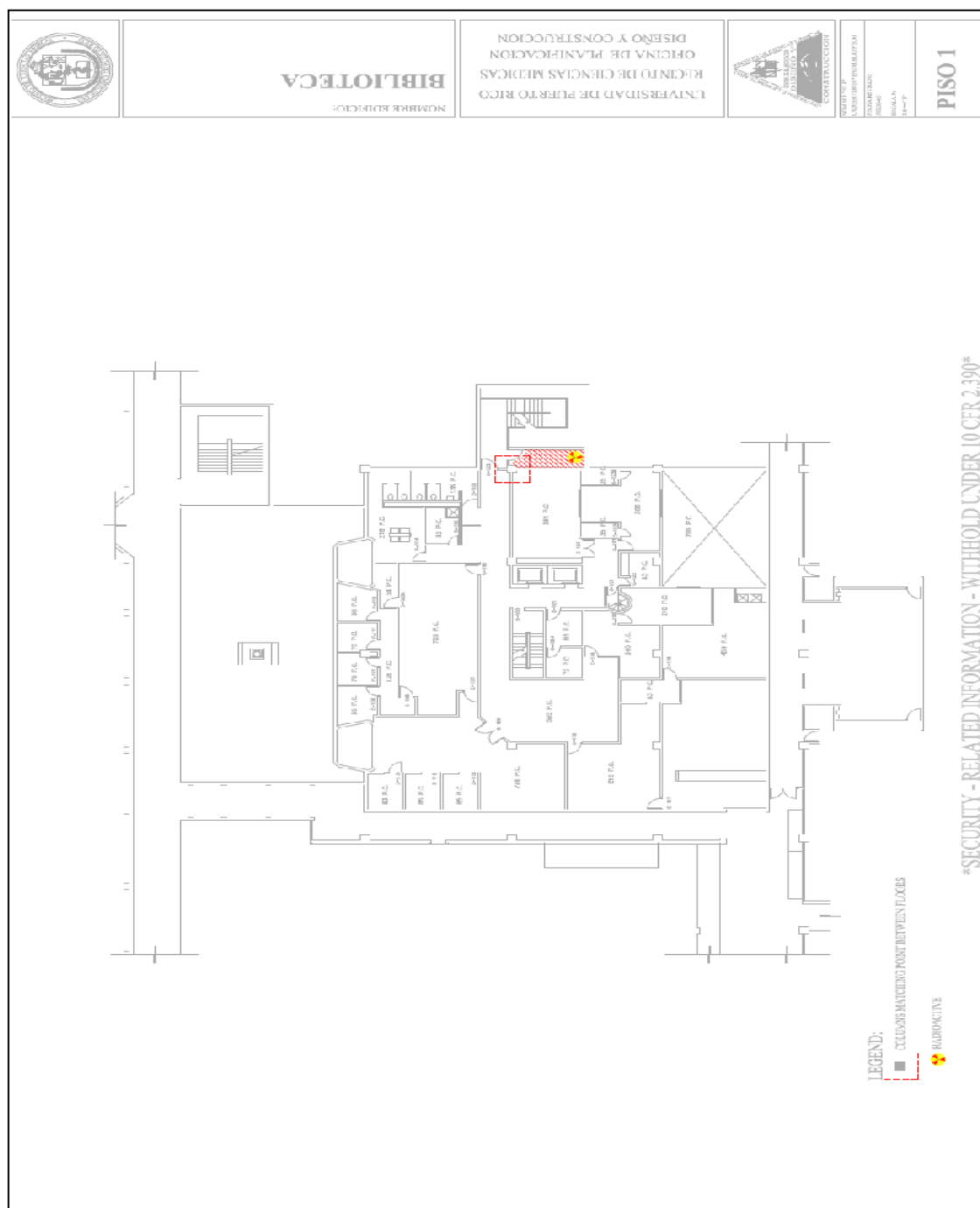
**UNIVERSITY OF PUERTO RICO – MEDICAL SCIENCES CAMPUS
RADIOACTIVE WASTE STORAGE AREAS
SECURITY – RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390**

1. Radiation Waste and Decay Storage # 1 – Floor 10 RCM Main Building



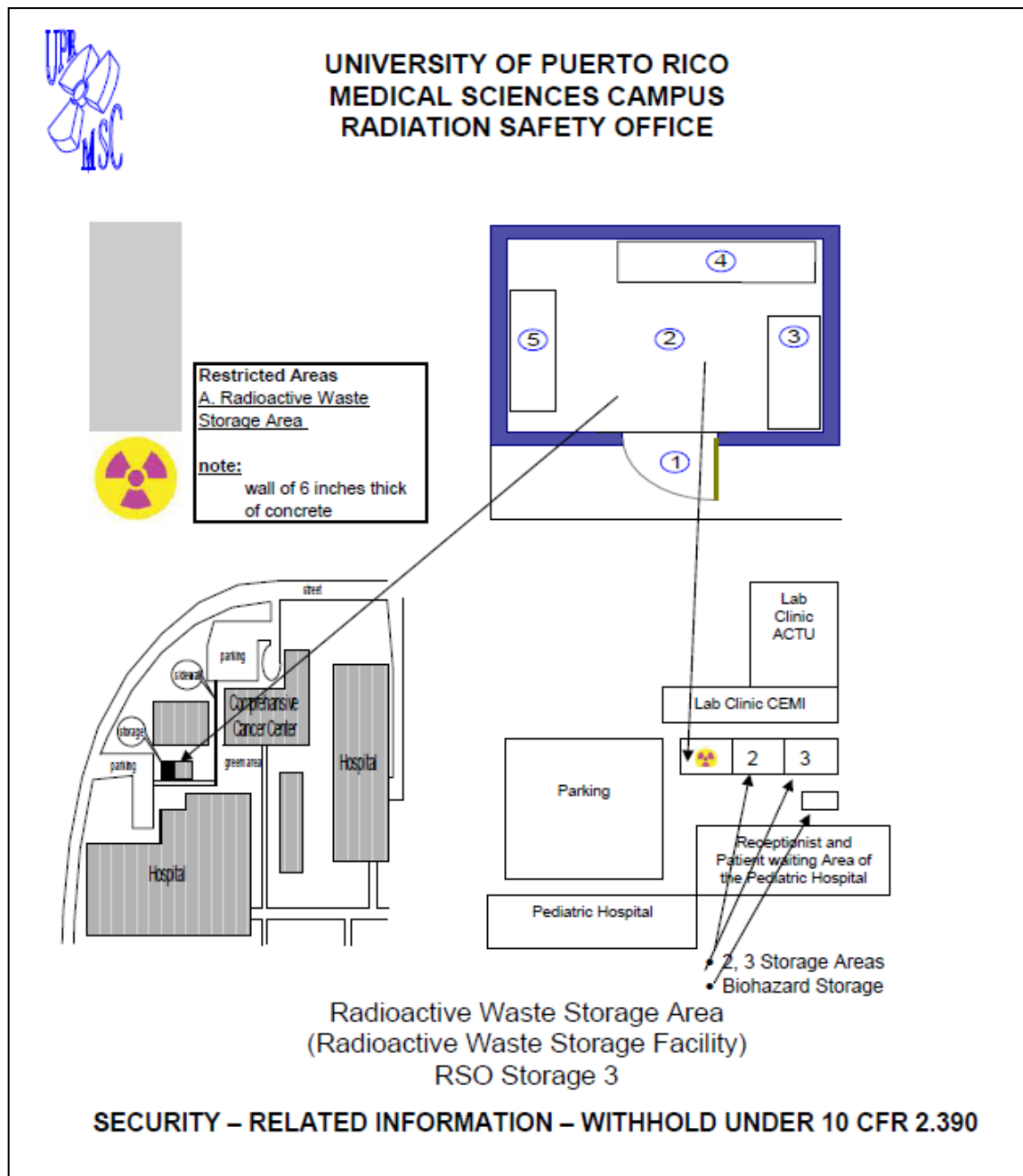


9. RADIATION WASTE AND DECAY STORAGE # 2 – FLOOR 1 RCM LIBRARY BUILDING



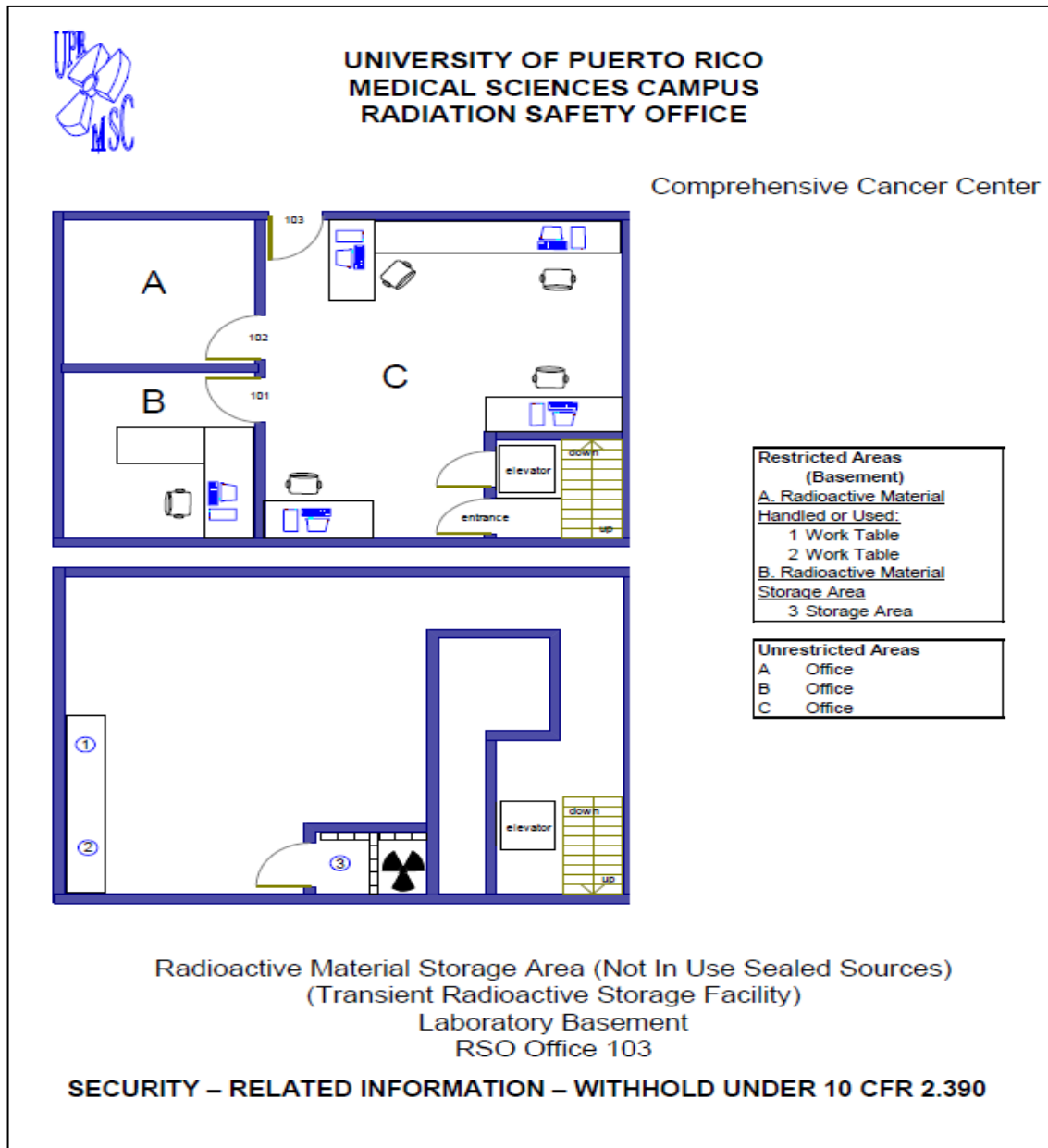
**UNIVERSITY OF PUERTO RICO – MEDICAL SCIENCES CAMPUS
RADIOACTIVE WASTE STORAGE AREAS
SECURITY – RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390**

10. RADIATION WASTE AND DECAY STORAGE # 3 – FLOOR 1 BETWEEN
PEDIATRIC HOSPITAL AND INFANT AND MATERNITY HEALTH CENTER (CEMI)
OF THE UPR-MSC



**UNIVERSITY OF PUERTO RICO – MEDICAL SCIENCES CAMPUS
RADIOACTIVE WASTE STORAGE AREAS
SECURITY – RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390**

11. RADIATION WASTE AND DECAY STORAGE # 4 – RADIATION SAFETY
OFFICE # 103 LABORATORY BASEMENT AT COMPREHENSIVE CANCER
CENTER BUILDING, STORAGE AREA FOR SEALED SOURCES
(BUNKER)



APPENDIX J

LIST OF TOPICS USED FOR DEVELOPING A DESCRIPTION OF THE FACILITIES AND EQUIPMENT:

1. Restricted areas are defined as areas to which access is limited by the licensee to protect individuals against undue risks from exposure to radiation and radioactive materials. Diagrams of the laboratories and facilities approved by the RSC are included. The information about the shielding is according to the radioisotope to be use. Drawings and sketches will be submitted showing the relationship between restricted areas and unrestricted areas and the location of all pertinent safety-related equipment.
2. Bench top or open work areas may be used for sealed sources, for small quantities of solid materials in a form not likely to become airborne or dispersed, and for small quantities of liquids of such low volatility as not to cause airborne contamination or toxicity problems. Trays and/or absorbent surface covers to catch and retain spilled liquids will be used on these open work surfaces and inside closed systems. Surfaces are smooth and non-porous, to facilitate decontamination.
3. Radioactive materials that are handled or used in unsealed forms are confined to control the release of material and to prevent the spread of contamination. Gaseous, volatile, and fine particulate solid materials will be handled in closed or isolated systems such as fume hoods or glove boxes with controlled, and possibly filtered, exhaust systems when required.
4. Chemical-type fume hoods provide a working area with controlled inward airflow from the room to the hood exhaust system. Hoods are used for gases, for unsealed volatile licensed materials, and for processes such as evaporation that may release gases and vapors. Fume hoods provide emergency ventilation and exhaust for unplanned releases, such as accidental spills and ruptures, as well as routine exhaust of effluents.
5. Sink will be used for skin contamination has occurred, by decontaminating it by gently washing with warm water and mild soap, washing downwards towards extremities, not upwards for five to ten minutes. No disposal of liquid radioactive waste to the sanitary sewerage system is allowed. It will also be used for glassware cleanup that has been used with a minimum amount of radioactive material.
6. Shielding consisting of lead or other high-density material in the form of bricks, panels, L-shields, storage containers, or other shapes are used on bench tops, in fume hoods or in glove boxes to reduce radiation exposure from gamma-emitting radioactive materials. Similarly, shielding of low atomic number material, such as high-density plastic, are used to reduce the exposure from high-energy beta-emitting materials. Shielded shipping containers are frequently used for continued storage after receipt of materials.

7. Labeled waste containers are used. These containers are shielded as necessary, placed near the waste-generating areas and away from areas frequently occupied by personnel.
8. Remote handling tools, such as forceps or extension handles, are used to provide distance in the handling of radioactive materials (ALARA). In addition, shielded handling devices, such as shielded syringes, are used to protect workers from materials that cannot be handled remotely. Pipetting is done using appropriate devices. Pipetting by mouth is strictly forbidden.
9. Designated areas are provided for coats and personal belongings, to avoid contamination.
10. Areas with the lowest possible background radiation levels are designated for personnel dosimetry storage when not in use.
11. Areas of use are well-lighted to avoid spills and other accidents that could result in contamination build-up.
12. The combination of containment, shielding, and handling devices proposed for any use of radioactive materials is appropriate to the type and quantity of materials to be used and to the type and duration of operations to be conducted. The research laboratories that handle radioactive materials such as P^{32} and S^{35} utilize shielded (e.g., leaded glass) windows, through transparent plastic beta shields for the protection of occupational exposures.
 - **Shielding:** If the radiation source is a high energy beta or gamma emitter, shielding will reduce the dose rate. For beta emitters, it will be using a low atomic number material such as plastic, Lucite, Plexiglas, and glass. For gamma emitters, high atomic number materials such as steel or lead are preferred (lead is also a toxic material, so gloves will be use when handling it). For low energy beta emitters: (3H , ^{14}C , ^{33}P , and ^{35}S) shielding is not necessary. For high energy beta emitters (^{32}P), 3/8" acrylic is the shielding material of choice. Lead shield will not be use with high energy beta radiation (e.g., ^{32}P) because it will cause secondary radiation of a more penetrating X-ray type radiation. For gamma or x-ray emitters (^{99m}Tc , ^{68}Ga , ^{201}Tl , ^{111}In , ^{131}I and ^{18}F) lead is used when exposure rates are significant.

Shielding will be used wherever it is necessary to reduce or eliminate exposure. By placing an appropriate shield between the radioactive source and the worker, radiation is attenuated, and exposure may be eliminated or reduced to an acceptable level. The type and amount of shielding needed to achieve a safe working level varies with the type and quantity of radioactive material used.

Observation of activities conducted behind shielding will be accomplished by leaded glass on the doors and by remote video patient monitoring system.

**UNIVERSITY OF PUERTO RICO, MEDICAL SCIENCES CAMPUS
FACILITIES AND EQUIPMENT
NUCLEAR MEDICINE LABORATORY,
DR. ISAAC GONZÁLEZ HOSPITAL**

SHIELDING DESCRIPTION:

The floor above and below the Nuclear Medicine Laboratory, specially from the areas of the PET/CT Camera Room, Patient Suite and Injection Room and Hot Room are 8 feet between the Nuclear Medicine Laboratory. Above the Nuclear Medicine Department is the Dr. Isaac González Martínez Hospital (Oncology Hospital) roof. The roof is an open and empty space and there is no construction on it. The roof is made of approximately 5 inches of concrete that serves as shield.

The description of the shielding in the areas where radioactive material is use and stored in the UPR Nuclear Medicine Laboratory at Dr. Isaac González Hospital is as follows:

1. **PET/CT CAMERA ROOM:** A restricted area and it is posted with a “*Caution, Radioactive Area*” Sign. The lateral walls are 7 inches (17.8 cm) thick that serves as concrete shielding.

- The wall from the PET /CT Room to the PET/CT Control Station is 8.75 inches (22.2 cm) thick of concrete block and contains two 1/8 lead panels (1/4 inches of lead) up to the acoustical ceiling.
- The wall from the PET /CT Room to the Patient Suite and Injection Room is 8.75 inches (22.2 cm) thick of concrete block and contains two 1/8 lead panels (1/4 inches of lead) up to the acoustical ceiling.
- The wall from the PET /CT Room to the Hot Room is 6 inches (15.2 cm) thick of concrete blocks and a gypsum board panel with 1/16 inches of lead integrated up to the acoustical ceiling.

2. PATIENT SUITE AND INJECTION ROOM:

- The wall from Patient Suite and Injection Room to the PET/CT Control Station has 6 inches (15.24 cm) of concrete blocks and a gypsum board panel with 1/16 inches of lead integrated up to the acoustical ceiling.
- The wall from Patient Suite and Injection Room to the Gamma Camera Room is 8 inches (20.32 cm) thick of concrete.
- The Patient Suite and Injection Room will be used for:
 - injection of PET patients and
 - waiting room for PET patients prior to proceeding to the imaging room.
- This is the only quiet room for PET patients in the Department of Nuclear Medicine. It will also be used for the administration of technetium to patients for diagnostic procedures when necessary.

3. PET/CT CONTROL STATION:

- The wall from Patient Suite and Injection Room to the PET/CT Control Station has 6 inches (15.24 cm) of concrete blocks and a gypsum board panel with 1/16 inches of lead integrated up to the acoustical ceiling.
- The wall from the PET /CT Room to the PET/CT Control Station is 8.75 inches (22.2 cm) thick of concrete block and contains two 1/8 lead panels (1/4 inches of lead) up to the acoustical ceiling.

4. GAMMA CAMERA ROOM:

- The wall from the Gamma Camera Room toward the Patient Suite and Injection Room is 8 inches (20.32 cm) thick of concrete.
- The rest of the walls inside the Gamma Camera Room is 7 inches (17.8 cm) thick of concrete.

5. TECHNOLOGIST PROCESSING STATION:

- Has three lateral walls with 7 inches (17.8 cm) thick of concrete and one 5 inches thick of concrete

6. STORAGE ROOM:

- It has three lateral walls of concrete, two is 6 inches (15.24 cm) and the other one is 5 inches (12.7 cm) thick.
- The wall adjacent to the PET/CT Control Station has two gypsum board panels with 6 inches (15.24 cm) separated from each other.

7. STRESS, UPTAKE AND PATIENT ROOM:

- The wall toward the outside of the building is 7 inches (18 cm) thick of concrete.
- The wall adjacent to the nuclear medicine hallway 2 has two gypsum board panels with 6 inches (15.24 cm) separated from each other. The wall toward the Social Workers Offices is 6 inches (15.24 cm) thick of concrete.

8. HOT ROOM:

This area is identified as a restricted area and it is posted with a “*Caution, Radioactive Material*” Sign. In this area radioactive material shipping containers will be received from the Radiopharmacy, Lantheus Medical Imaging or Cardinal Health and stored for daily use. This area is prepared for the safety use, management and storage of radioactive material and waste. The access to this area is controlled by the use of a key to avoid entrance of unauthorized individuals. Eventually it will be change by a code security lock system. Only authorize

personnel will have the key to this area. It has all the necessary equipment to work with radioactive material in a safety way.

- It has a two lateral walls of concrete, one is 7 inches (17.8 cm) (toward outside building) and the wall toward the Nuclear Medicine Director's Office is 5 inches (12.7 cm) thick.
- The wall from the PET /CT Room is 6 inches (15.2 cm) thick of concrete blocks and a gypsum board panel with 1/16 inches of lead integrated up to the acoustical ceiling.

The hot room contains the following:

- Two lead caves, one to store radioactive sealed sources and radioactive single doses and the other one to store radioactive waste for decay. They are built with rectangular lead bricks with dimensions: 6" l x 2" w x 4" h (15 x 5 x 10 cm). They are designed to place radioactive waste and are adequate to shield PET radiopharmaceuticals.
- Two areas to received shipping containers with radioactive material, one for FDG lead containers and the other for the radioactive single doses received from the Radiopharmacy. Nonetheless, PET radiopharmaceuticals will remain inside the shielded containers in which they are received from the radiopharmacy. The containers that are not used will be returned to radiopharmacy. There are appropriate containers to dispose of the sharp wastes generated in the handling of PET material. However, the syringes used will remain inside the shielded containers in which they arrived and returned to the radiopharmacy the next morning.
- A Dose Calibrator to measure and confirm the activity received from each unit dose before administrating it to patients. Dose Calibrator chamber is covered with lead split rings of 1 ¼" (3 cm) thick for full shielding. In addition, the chamber is inside a lead cave built of 6" l x 3" w x 4" h (15 x 8 x 10 cm) lead bricks. This shielding gives maximum radiation protection when working with 511 KeV nuclides and mounted on a table cabinet.
- A Wipe Test Counter: Dimensions: 6" dia x 11" h (15.24 x 27.9 cm), Detector: 2" x 2" NaI (TI) integral line scintillation detector with a 0.75" dia x 1.44" depth well (1.9 x 3.7 cm), Style: Remote Detector, Channels: 64, MCA: Integral to Well Counter, Spectral Resolution: FWHM 10%, Count Rate: (Maximum) 30,000 cps, Lead Shielding: 0.5" thick (1.2 cm) integral lead shield
- The Nuclear Medicine Department has the appropriate syringe shields and forceps designed to handle PET radiopharmaceuticals.
- Has two L-Blocks:

- One L-Block shielded and designed for managing large quantities of high-energy radionuclides.

The shield is constructed of 2.4" thick lead encased in steel, and features a large 8" x 8" x 4" lead glass window. A convenient lever allows quick adjustment of window to optimal angle for any user and procedures. A lead brick cave was installed into the sides of the vertical section to provide lateral shielding around the full perimeter of the L-Block's base.

- A small L-Block to be use when necessary to manage Technetium 99M unit doses.

- A sink to be use for cleanup and hand wash protocol
- A radioiodine fume hood will be installed in the Injection and Medical Supply Room to handle liquid Iodine -131 for therapy treatments when required.

9. INJECTION & MEDICAL SUPPLIES ROOM:

- A restricted area and it is posted with a "*Caution, Radioactive Material*" Sign.
- All the walls are 6 inches (15.24 cm) thick of gypsum board panels.
- A radioiodine fume hood will be installed in this area for temporally storage and handling of liquid Iodine -131 for therapy treatments when required.
- It is going to be use for the administration of radioisotopes (Tc^{99M} , Ga^{67} , Tl^{201} , In^{111} and $I-^{131}$ (capsules) to patients.

10. NURSE WORK STATION:

- Open area near the Hot Lab for patient interview

11. PATIENT BATH ROOM:

- All the walls are of gypsum board panels, two are 6 inches (15.24 cm) thick and the other two are 5 inches (13 cm) thick.
- This bathroom is designated only for the use of patient's administered with radioisotopes.

12. NUCLEAR MEDICINE HALLWAY 2:

- The Nuclear Medicine Laboratory will have an access control system to this area.
- Directly below PET/CT Imaging Room is the Operating Room No 3 and part of the Equipment Storage Room.

- Directly below Hot Lab is the Equipment Storage Room, Surgical Supply and part of the Operating Room No 4.
- Directly below the Injection & Medical Supply Room is the Operating Room No 4.
- Directly below Patient Suite and Injection Room is the Anesthesia Surgical Supply and above
 - To ensure that the radiation emitted by the PET radiopharmaceutical does not exceed the public dose limit listed in 10 CFR 20.1301(a)(2) (2 mrem in any one hour) radiation surveys were conducted in the floors below and above the Patient Suite and Injection Room i.e.: at the Anesthesia Surgical Supply Room on the third floor and at the roof respectively. The radiation counts obtained comply with the regulatory requirement in 10 CFR 20.1301(a)(2). The public dose rates are less than 2 mrem/hr in any one hour at the Anesthesia Surgical Supply Room as well as on the roof of the Oncology Hospital. These measurements were certified by the Medical Health Physicist/Consultant of the Oncology Hospital.
- Directly below the Gamma Imaging Room is the Operating Room No 2
- Directly below the Stress, Uptake and in Patient Room is the Operating Room No 1 and part of the Sterilization Room
- Directly below the PET/CT control station and Nurse Work Station is the Doctor's Wash Area and Corridor.

APPENDIX K

RADIATION MONITORING INSTRUMENT SPECIFICATIONS

A. Instrument Specifications and Model Survey Instrument Radiation Monitoring

Table H.1 Typical Survey Instruments¹ (instruments used to measure radiological conditions at licensed facilities). The following table will help choose the proper radiation detection equipment for monitoring the radiological conditions.

Portable Instruments Used for Contamination and Ambient Radiation Surveys			
Detectors	Radiation	Energy Range	Efficiency
Count Rate Meters			
Exposure Rate Meters	Gamma, X-ray	μR-R	N/A
GM	Alpha	All energies (dependent on window thickness)	Moderate
	Beta	All energies (dependent on window thickness)	Moderate
	Gamma	All energies	< 1%
NaI Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
Plastic Scintillator	Beta	C-14 or higher (dependent on window thickness)	Moderate
BF3 Proportional Tube*	Neutron	Thermal neutron	High
Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples			
Detectors	Radiation	Energy Range	Efficiency
LSC*	Alpha	All energies	High
	Beta	All energies	High
	Gamma		Moderate
Gamma Counter (NaI)*	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	< 1%
*Table from "The Health Physics and Radiological Health Handbook, Revised Edition," edited by Bernard Shleien, 1992 (except for * items)			

B. Facilities and Equipment for Calibration of Dose Rate Measuring Instruments

1. To reduce doses received by individuals not calibrating instruments, calibrations will be conducted in an isolated area of the facility or at times when no one else is present.
2. The calibration source will be well-collimated, and the calibration area will be designed to minimize scatter of radiation, which could affect the calibration process.
3. The calibration area will be appropriately controlled so that persons entering the area will be aware if a radiation source is in use.
4. Posting of the calibration area is with appropriate radiation warning signs, as required by Subpart J of 10 CFR 20.

5. Individuals conducting calibrations of radiation survey instruments will wear assigned dosimetry.
6. Individuals conducting calibrations will use a calibrated and operable radiation survey instrument to ensure that unexpected changes in exposure rates are identified and corrected.

C. Model Procedure for Calibration Sources for Dose and Dose Rate Measuring Instruments

A radioactive sealed source(s) will be used for calibrating dose and dose rate measuring radiation survey instruments, and this source will have the following characteristics: Approximate a point source

1. Approximate the same energy and type of radiation as the environment in which the calibrated device will be employed
2. Calibration fields from gamma sources should be known with an accuracy when compared to secondary or primary national standards of 5 percent for dose rates greater than or equal to 1.0 microgray/hour ($\mu\text{Gy/h}$) [0.1 millirad/hour (mrad/h)] and 10 percent for dose rates less than 1.0 $\mu\text{Gy/h}$ [0.1 mrad/h].
3. The source should contain a radionuclide that emits radiation of identical or similar type and energy as the environment in which the calibrated device will be used.
4. The source should be strong enough to give an exposure rate of at least 7.7 microcoulomb per kilogram per hour [30 milliroentgen per hour] at 100 centimeters {e.g., 3.1 gigabecquerels [(85 mCi (millicuries))] of cesium-137 or 780 megabecquerels [21 mCi] of cobalt-60}.

Note: Inverse square and radioactive decay laws should be used to correct changes in exposure rate due to changes in distance or source decay.

D. Calibration of Dose or Dose Rate Measuring Instruments

There are three kinds of scales frequently used on dose and dose-rate survey meters. These are calibrated as follows:

1. **Linear readout instruments** with a single calibration control for all scales should be adjusted at the point recommended by the manufacturer or at a point within the normal range of use. Instruments with calibration controls for each scale should be adjusted on each scale. After adjustment, check the response of the instrument at approximately 20 percent and 80 percent of full scale. Instrument readings should be within $\pm x$ of the conventionally true value for the following ranges:
 - Background to 10 $\mu\text{Gy/h}$ [1.0 mrad/h]; $\pm x = \pm 30\%$
 - 10 $\mu\text{Gy/h}$ [1.0 mrad/h] to 1.0 mGy/h [100 mrad/h]; $\pm x = \pm 20\%$

- mGy/h [100 mrad/h] to 10 Gy/h [1,000 Rad/h]; $\pm x = \pm 10\%$

2. Logarithmic readout instruments, which commonly have a single readout scale spanning several decades, normally have two or more adjustments. Adjust the instrument for each scale according to site specifications or the manufacturer's specifications. After adjustment, check the calibration at a minimum of one point on each decade. Instrument readings should have a maximum deviation from the conventionally true value as described for linear readout instruments.

3. Digital readout instruments should be calibrated the same as linear readout instruments.

Note: Readings above 2.58×10^{-4} coulomb/kilogram/hour [1 roentgen/h] need not be calibrated, unless the licensee expects to make measurements at higher dose rates; regardless, such scales should be checked for operation and response to radiation.

E. Calibration of Surface Contamination Measurement Instruments

Instruments used to detect surface contamination usually consist of a count-rate meter and a detector that is appropriate for the type of radiation(s) being measured. The efficiency of radiation survey meters must be determined by using radiation sources with similar energies and types of radiation that users of the radiation survey instrument intend to measure.

If each scale has a calibration potentiometer, the reading should be adjusted to respond to the calibration source at approximately 80 percent of full scale, and the response at approximately 20 percent of full scale should be observed. If only one calibration potentiometer is available, the response should be adjusted at mid-scale on one of the scales, and response on the other scales should be observed. The instrument efficiency factor (e.g., cpm/dpm) thus obtained should have a signal-to-noise ratio, including the compilation of source and instrument uncertainties, of $\pm x$ for the following ranges:

- alpha measurement:

0.01 Bq/cm² to 2.0 Bq/cm² [60 to 12,000 dpm/100 cm²]; $\pm x = \pm 20\%$

2.0 Bq/cm² to 200 Bq/cm² [12,000 to 1,200,000 dpm/100 cm²]; $\pm x = \pm 10\%$

- beta measurement:

0.05 Bq/cm² to 2.0 Bq/cm² [300 to 12,000 dpm/100 cm²]; $\pm x = \pm 20\%$

2.0 Bq/cm² to 200 Bq/cm² [12,000 to 1,200,000 dpm/100 cm²]; $\pm x = \pm 10\%$

F. Calibration of Analytical Instruments such as Liquid Scintillation Counters, Gamma Counters, Gas Flow Proportional Counters, and Multichannel Analyzers

Analytical instruments used to determine radioactivity in a sample may be specialized equipment according to the type of samples to be analyzed and the types and quantities of radioactivity to be measured. Typically, the sample sizes and activities are very small, and can be difficult to measure. Sample collection and preparation may differ for the various analytical instruments, so manufacturer procedures and industry standard practices should be followed. Such analytical instruments should be calibrated in accordance with the manufacturer's instructions. Analytical instruments typically require routine maintenance and verification procedures to ensure that they are operating properly when used.

As with calibration of other radiation measurement instruments, calibration of analytical instruments uses a radioactive sealed source(s). These should be suitable for the geometry of the sample(s) to be analyzed. The calibration source(s) should have a known activity(ies) and be of similar type and energy as the radioactive materials to be analyzed. The analysis should be sensitive enough to detect the lowest levels of radioactivity desired. Correction of results for quenching, self-absorption, and other factors may be required, depending on the analytical instrument, the samples type, and other environmental conditions.

G. Calibration Records

Calibration records for all radiation survey instruments should indicate the procedure used and the results of the calibration. The records should include the following:

1. The owner or user name of the radiation survey instrument
2. A description of the radiation survey instrument that includes the manufacturer's name, model number, serial number, and type of detector
3. A description of the calibration source, including the exposure rate at a specified distance or activity on a specified date
4. For each calibration point, the calculated exposure rate or count rate, the indicated exposure rate or count rate, the deduced correction factor (the calculated exposure rate or count rate divided by the indicated exposure rate or count rate), and the scale selected on the radiation survey instrument
5. The exposure reading indicated with the radiation survey instrument in the "battery check" mode (if available on the instrument)
6. For radiation survey instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular)
7. For radiation survey instruments with internal detectors, the angle between the radiation flux field and a specified surface of the instrument
8. For radiation detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure
9. The exposure rate or count rate from a check source, if used

10. The name and signature of the individual who performed the calibration and the date on which the calibration was performed

The following information will be attached to the radiation survey instrument as a calibration sticker or tag:

1. For dose and dose rate measuring instruments, the source radionuclide used to calibrate the radiation survey instrument (with correction factors) for each scale
2. For surface contamination measurement instruments, the efficiency of the radiation survey instrument, for each radionuclide the instrument will be used to measure (if efficiency is not calculated before each use)
3. For each scale or decade not calibrated, an indication that the scale or decade was checked only for function but not calibrated
4. The date of calibration and the next calibration due date
5. The apparent exposure rate or count rate from the check source, if used

APPENDIX L

PROCEDURE FOR SAFELY RECEIVING AND OPENING PACKAGES, MONITORING REQUIREMENTS AND RECORD MAINTENANCE

PROCEDURE FOR SAFELY OPENING PACKAGES CONTAINING LICENSED MATERIALS

For packages received under the specific license, authorized individuals must implement procedures for opening each package, as follows:

1. Wear gloves to prevent hand contamination.
2. Approach the package with a radiation survey meter to ensure that no unusual or unexpected radiation levels are present.
3. Visually inspect the package for any sign of damage (e.g., crushed, punctured). If damage is noted, stop and notify the RSO.
4. Check U.S. Department of Transportation (DOT) White I, Yellow II, or Yellow III label or packing slip for activity of contents so shipment does not exceed license possession limits.
5. Monitor the external surfaces of a labeled package in accordance with 10 CFR 20.1906.
6. Open the outer package (following supplier's directions, if provided) and remove packing slip.
7. Open inner package to verify contents (compare requisition, packing slip, and label on the bottle or other container).
8. Check integrity of the final source container (e.g., inspect for breakage of seals or vials, loss of liquid, discoloration of packaging material, high count rate on smear).
9. Check again that the shipment does not exceed license possession limits. If an authorized individual finds anything other than expected, they should stop and notify the RSO.
10. Survey the packing material and packages for contamination before discarding. If contamination is found, treat as radioactive waste. If no contamination is found, obliterate the radiation labels prior to discarding in the regular trash.
11. Maintain records of receipt, package survey, and wipe test results.

12. Notify the final delivery carrier and the NRC Operations Center, 301-816-5100, by telephone when removable radioactive surface contamination exceeds the limits of 10 CFR 71.87(i) or the external radiation levels exceed the limits of 10 CFR 71.47.

PACKAGE MONITORING REQUIREMENTS (10 CFR 20.1906)

Package Monitoring Requirements (10 CFR 20.1906)			
Package	Package Contents	Survey Type	Survey Time*
Damaged	Licensed Material	Radiation Level and Radioactive Contamination	As soon as practicable, but not later than 3 hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Not Gas nor Special Form Greater Than Type A†	Radiation Level and Radioactive Contamination	As soon as practicable, but not later than 3 hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Gas or Special Form Greater Than Type A†	Radiation Level	As soon as practicable, but not later than 3 hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Not Gas nor Special Form Less Than or Equal to Type A†	Radioactive Contamination	As soon as practicable, but not later than 3 hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Gas or Special Form Less Than or Equal to Type A†	None	None
Not Labeled	Licensed Material	None	None‡
<p>*Assumes packages are received during normal working hours. If packages are received outside of normal working hours, the licensee has 3 hours after the beginning of the next work day to perform the required surveys [§20.1906(c)].</p> <p>†Type A Quantity means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A1 for special form radioactive material, or A2, for normal form radioactive material, where A1 and A2 are given in Table A-1 of 10 CFR Part 71, or may be determined by procedures described in Appendix A of 10 CFR Part 71.</p> <p>‡Excepted Packages and limited quantity packages received by many laboratories are required to have the appropriate identification number from the Hazardous Materials Table in 49 CFR 172.101 (i.e., the "UN number") on the outside of the box, identifying it as containing radioactive materials. It is good health physics practices</p>			

TYPE AND RECORD MAINTENANCE

RECORD MAINTENANCE	
Type of Record	How Long Record Must be Maintained
Receipt	For as long as the material is possessed and for 3 years
Transfer	For 3 years after each transfer unless a specific requirement
Disposal	Until the NRC terminates the license
Important to decommissioning*	Until the site is released for unrestricted use
*Information about locations where licensed material is used or stored are among the records important to decommissioning and required by 10 CFR 30.35(g), 10 CFR 40.36(f), and/or 10 CFR 70.25(g). See also the section on “Financial Assurance and Recordkeeping for Decommissioning.”	

APPENDIX M

APPLICABLE ANNUAL LIMITS

The use of individual monitoring devices for external dose is required, pursuant to 10 CFR 20.1502(a), if an adult is likely to receive in 1 year a dose greater than 10% of any applicable limit, for:

- Adults who are likely to receive an annual dose in excess of any of the following (each evaluated separately):
 - 5 mSv (0.5 rem) deep-dose equivalent.
 - 15 mSv (1.5 rems) eye dose equivalent.
 - 50 mSv (5 rems) shallow-dose equivalent to the skin.
 - 50 mSv (5 rems) shallow-dose equivalent to any extremity.
- Minors who are likely to receive an annual dose in excess of any of the following (each evaluated separately):
 - 1.0 mSv (0.1 rem) deep-dose equivalent.
 - 1.5 mSv (0.15 rem) eye dose equivalent.
 - 5 mSv (0.5 rem) shallow-dose equivalent to the skin.
 - 5 mSv (0.5 rem) shallow-dose equivalent to any extremity.
- Declared pregnant women who are likely to receive an annual dose from occupational exposures in excess of 1.0 mSv (0.1 rem) deep-dose equivalent, although the dose limit applies to the entire gestation period.
- Individuals entering a high or very high radiation area.

Internal exposure monitoring is required, pursuant to 10 CFR 20.1502(b), for:

- Adults likely to receive in 1 year an intake in excess of 10% of the applicable Annual Limit of Intake (ALI) for ingestion and inhalation.
- Minors and declared pregnant women likely to receive in 1 year a committed effective dose equivalent in excess of 1.0 mSv (0.1 rem).

APPENDIX N

INVESTIGATIONAL LEVELS (MREMS)

This institution hereby establishes Investigational Levels in order to monitor occupational external radiation exposure to individuals. If these levels are exceeded, an investigation by the Radiation Safety Committee and/or the RSO will be performed. These levels apply to the exposure of individual workers.

ORGANS	For a given quarter		Cumulative for the year	
	LEVEL I mRem	LEVEL II mRem	LEVEL I mRem	LEVEL II mRem
Whole body deep (total effective dose equivalent)	125	375	500	1,500
Individual organs - except lens (sum of deep dose equivalent and committed dose equivalent) Whole body shallow	1,250	3,750	5,000	15,000
Lens eyes	375	1,125	1,500	4,500
Skin or extremity	1,250	3,750	5,000	15,000
Hands and forearms; feet and ankles	1,875	5,625	7,500	22,500
Skin of whole body	750	2,250	3,000	9,000
Organs	1,250	3,750	5,000	15,000

*Note: Investigational levels I and II are one tenth and three tenths respectively, of the applicable regulatory limits.

The Radiation Safety Officer will review on NRC-5 form, "Occupational Exposure Record for a Monitoring Period," or on an equivalent form (e.g., dosimeter processor's report), results of personnel monitoring at least once in any calendar quarter as required by section 20.2102 of 10 CFR Part 20. If personnel are found that have exceeded this limit, the following actions will be taken:

1. Personal dose to less than Investigational Level I:
 - No action will be taken in cases where an individual's exposure is less than Table 1 values for the Investigational Level I.
2. Personal dose equal to or greater than Investigational Level I, but less than Investigational Level II:
 - The RSO will review the exposure of each individual whose quarterly exposures equal or exceeds Investigational Level I and will report the results of the reviews at the first Radiation Safety Committee meeting following the quarter when the exposure was recorded. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.
3. Personal dose equal to or greater than Investigational Level II:
 - The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, will take action. A report

of the investigation, actions taken, if any, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the Radiation Safety Committee at the first Radiation Safety Committee meeting following completion of the investigation. The details of these reports will be recorded in the Radiation Safety Committee minutes. Committee minutes will be sent to the management of this institution for review. The minutes, containing details of the investigation, will be made available to NRC/State inspectors for review at the time of the next inspection.

4. Reestablishment of an individual occupational worker's Investigational Level to a level above that listed in Table 1:
 - In cases where a worker's or a group of workers' exposure need to exceed an Investigational Level, a new, higher Investigational Level may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for new Investigational Levels will be documented. The Radiation Safety Committee will review the justification, and must approve or disapprove, all revisions of Investigational Levels.

A. External Radiation Exposure and Protection

The body may be irradiated in two general ways: externally from radioactive material or radiation sources, or internally from radioactive material deposited in the body. External doses can be the result of exposure to gamma, X-ray, or high energy beta emitters. Low energy beta and alpha emitters lack the energy needed to penetrate the outer layer of skin and subsequently present less of an external hazard; they are of more concern when ingested. The external dose an individual receives depends on the following factors: exposure, time, distance, and shielding.

Radiation dose rate is the radiation dose delivered per unit of time. The unit of radiation dose rate is usually rem/hour, mrem/hour, or μ rem/hour. To eliminate or reduce radiation exposure, one must reduce the dose rate, or the time spent near a source of radiation. Three primary means of eliminating or reducing radiation exposures exist. They include:

- **Exposure:** The "strength" (activity, mR/hr, etc.) of the radiation source. By reducing the amount of radioactive material used (lowering the current settings on a radiation producing machine) dose can be reduced.
- **Maximize the distance from the source:** The dose rate for most gamma and x-radiation varies with the inverse square of the distance from a "point" source. Therefore, the farther you position yourself for the source of radiation, the smaller the dose you receive. Mathematically, $I_2/I_1 = r_1^2/r_2^2$. This is called the inverse square law. For example, if the dose rate is 100 mrem/hour at 5 cm from a point source, you can calculate the dose rate at 20 cm from the source:

$$I_{20\text{cm}}/I_{5\text{cm}} = (5\text{cm})^2/(20\text{cm})^2$$

$$I_{20\text{cm}} = (100 \text{ mrem/hr}) \times (5\text{cm})^2/(20\text{cm})^2$$

$$I_{20\text{cm}} = 6.25 \text{ mrem/hr}$$

For example, doubling the distance from a radiation source will result in 1/4 the exposure in the same amount of time. One practical implementation of this principle is using remote handling devices such as forceps, tongs, and tube racks, etc. to minimize direct contact with sources and containers. Even a small increase in distance can result in a dramatic decrease in dose rate.

- **Minimize time of exposure:** The less time you remain in a radiation field, the smaller the dose you receive. Perform the experiment or the procedure as quickly and as efficiently as possible without increasing the probability of a spill or other accident.
- **Shield the radiation source:** If the radiation source is a high energy beta or gamma emitter, shielding will reduce the dose rate. For beta emitters, use a low atomic number material such as plastic, Lucite, Plexiglas, and glass. For gamma emitters, high atomic number materials such as steel or lead are preferred (lead is also a toxic material, so use gloves when handling it, and wash your hands when you finish).

Place shielding between yourself and a source of penetrating radiation to decrease your dose. For low energy beta emitters: (^3H , ^{14}C , ^{33}P , and ^{35}S) shielding is not necessary. For high energy beta emitters (^{32}P), 3/8" acrylic is the shielding material of choice. Does not use lead with high energy beta radiation (e.g., ^{32}P) because it will cause secondary radiation of a more penetrating X-ray type radiation. For gamma or x-ray emitters (^{51}Cr and ^{125}I) lead is used when exposure rates are significant. Use shielding wherever it is necessary to reduce or eliminate exposure. By placing an appropriate shield between the radioactive source and the worker, radiation is attenuated, and exposure may be eliminated or reduced to an acceptable level. The type and amount of shielding needed to achieve a safe working level varies with the type and quantity of radioactive material used.

B. Internal Exposure Protection:

Internal exposure results from the absorption, ingestion or inhalation of radioactive material. This material can be incorporated in the body in several ways: (1) by breathing radioactive gases, vapors or dust; (2) by consuming radioactive material transferred from contaminated hands, tobacco products, food or drink; (3) by entering through a wound; and (4) by absorption through the skin. The fundamental objectives of radiation protection measures are: (1) to limit entry of radionuclides into the human body (via ingestion, inhalation, absorption, or through open wounds) to quantities as low as reasonably achievable and always within the established limits; and (2) to limit exposure to external radiation to levels that the established dose limits are below and as low as reasonably achievable.

1. **Inhalation:** A chemical fume hood certified for radioactive material work is highly recommended when using potentially volatile compounds. Certain equipment, such as centrifuges, vortex mixers, and shakers can generate radioactive aerosols. Use in such a way that production of and exposure to radioactive aerosols is minimized.
2. **Puncture:** Dispose of syringes and pipettes promptly and in appropriate containers. Guard against glass breakage and puncture injury during use and disposal. Do not attempt to recap needles before disposal.

3. **Ingestion:** NEVER introduce any food or drink into a posted restricted area, even for temporary storage. DO NOT eat or drink in any area where radionuclides are used, never pipette by mouth, and never store food and drinks in a cold room or refrigerator that is designated for radioactive material storage.
4. **Absorption:** Use measures that prevent the contamination of skin and eyes. If there is any possibility that the clothes have been contaminated, remove this clothing before leaving the lab. Eye protection, (e.g., goggles, face shield) is encouraged to prevent contamination of the eyes. This is particularly important for individuals wearing contact lenses since some lenses will absorb and concentrate radiochemicals. Always wear protective gloves when working with radioactive materials. Change gloves frequently during the work, disposing of the used gloves as radioactive waste. Wash hands after using radioactive materials and monitor the hands for contamination, especially before eating or smoking, and prior to leaving the laboratory.

APPENDIX O

General Topics for Safe Use of Radionuclides and Model Emergency Procedures

I. General Topics for Safe Use of Radionuclides

Each laboratory or area where radioactive material is used or stored should have general rules so that workers know what is required. Typical instructions should include:

1. Use authorize quantity to handle radioactive materials allowed per experiment, etc.
2. Always wear a laboratory coat or other protective clothing in areas where licensed materials are used.
3. Wear disposable gloves always when handling licensed materials.
4. Discuss procedures with the RSO to establish limitations and conditions relative to handling unsealed licensed material and what laboratory equipment to use when working with such material. This will include, which licensed materials and what procedures should be confined to radiochemical fume hoods and what shielding is to be used when beta and/or gamma emitting licensed materials are handled.
5. Coordinate with the RSO a dry run prior to the performance of unfamiliar procedures to preclude unexpected complications.
6. that the radiation safety officer (RSO) be present during new procedures.
7. After each procedure or before leaving the area, monitor hands, shoes, and clothing for contamination in a low-background area and document.
8. Follow routine survey and monitoring procedures for contamination control.
9. Do not eat, drink, smoke, or apply cosmetics in any area where licensed material is stored or used.
10. Do not store food, drink, or personal effects in areas where licensed material is stored or used.
11. Wear personnel monitoring devices, if required, always while in areas where licensed materials are used or stored.
12. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles. Follow waste disposal procedures, limitations for disposal of liquid or solid wastes, and procedures to use for waste storage.
13. Prohibition of pipetting by mouth in areas where licensed materials are used.
14. Store radioactive solutions in clearly labeled containers.
15. All radioactive containers should be affixed with a "Caution, Radioactive Material" label and areas where licensed materials are used should be identified.
16. Safely handle sealed sources.
17. Secure all licensed material when it is not under the constant surveillance and immediate control of the user(s).
18. Emergency procedures concerning spills, fires, release of material, and/or accidental contamination of personnel are available.
19. Decontamination procedures to use and whom to contact in case of an emergency.
20. Records to be maintained on use and disposal of licensed materials.

II. Security of Radioactive Materials

1. Licensed materials in use in controlled or unrestricted areas must be under constant surveillance
2. Licensed materials will be secured by one or more of the following methods:
 - storing and using licensed materials only in restricted areas
 - limiting access to an entire facility or building or portion of the building to radiation workers
 - providing storage areas that can be locked to prevent access to the licensed material
 - implementing procedures that require a radiation worker to be within "line of sight" of the materials whenever licensed materials are in use.

III. Information of Radioisotopes

TRITIUM H^3	
Radioactive half-life T 1/2:	12.4 years
Principal emission:	18.6 keV beta (maximum)
Monitoring for contamination:	Swipes counted by liquid scintillation
Biological Monitoring:	Urine samples
Annual Limit on Intake, ingestion or inhalation:	1×10^9 Bq (27 mCi) (tritiated water)
Maximum range in air:	6 mm
Shielding required:	none
Special Considerations for Open Sources:	
<ul style="list-style-type: none">• Tritium, because of its low beta-energy, cannot be monitored directly and therefore special care is needed to keep the working environment clean and tidy. Regular monitoring by counting swipes is advisable in areas where this nuclide is used.• Tritium can be absorbed through the skin. Volatile compounds containing tritium, tritiated water and tritium gas should be handled in a fume hood.• External contamination, although not causing a radiation dose itself, should be kept as low as possible as it can lead to internal and hence hazardous contamination; it can also interfere in experimental results.• DNA precursors (eg <i>tritiated thymidine</i>) are regarded as more toxic than tritiated water partly because activity is concentrated into cell nuclei. This is reflected by lower ALI's for the material in this form.• Bioassays may be required for handling high amounts. Consult permit.	

SULPHUR-35 S^{35}	
Radioactive half-life T 1/2:	87.4 days
Principal emission:	0.167 MeV beta (maximum)
Monitoring for contamination:	Swipes counted by liquid scintillation
Thin end-window Geiger-Müller detector	
Biological Monitoring:	Urine samples
Annual Limit on Intake (ALI) by inhalation or ingestion:	2×10^8 Bq (5 mCi)
Maximum range in air:	26 cm
Shielding:	
<ul style="list-style-type: none">• 1 cm Perspex/Plexiglas, Thinner Perspex/Plexiglas down to 3 mm, although adequate to reduce doses, does not have good mechanical properties. Glass containers, although not generally recommended for shielding of beta radiation, are effective for small quantities of S^{35}.	
Special Considerations for Open Sources:	
<ul style="list-style-type: none">• Note that organic compounds are often strongly retained, and no limits of exposure have been set for them.• Be careful not to generate sulphur dioxide or hydrogen sulphide which could be inhaled.• Radiolysis of S^{35}-amino acids during storage and use may lead to the release of S^{35}-labelled volatile impurities. Handle such material in fume hood. Although the level of these impurities is small (typically less than 0.05%), contamination of the internal surfaces of storage and reaction vessels may occur. Vials should be opened and used in fume hoods.	

CARBON 14 C¹⁴

Radioactive half-life T_{1/2}:5730 years
Principal emission:0.156 MeV beta (maximum)
Monitoring for contamination:swipes counted by liquid scintillation
Thin end - window Geiger-Müller detector
Biological Monitoring:Urine samples, breath measurements (CO₂)
Annual Limit on Intake:4 x 10⁷ Bq (1.1 mCi)
 • by inhalation or ingestion
Maximum range in air:24 cm

Shielding:

- 1 cm Perspex/Plexiglas. Thinner Perspex/Plexiglas down to 3 mm, although adequate to reduce doses, does not have good mechanical properties. Glass containers, although not generally recommended for shielding of beta radiation, are effective for small quantities of ¹⁴C.

Special Considerations for Open Sources:

- There is a possibility that some organic compounds can be absorbed through gloves.
- Care needs to be taken not to generate carbon dioxide which could be inhaled.
- Work with volatile compounds or those likely to generate carbon monoxide or carbon dioxide in fume hood.
- A mandatory wipe test for radioactive contamination after each use is required.
- A dry run prior to the performance of unfamiliar procedures to preclude unexpected complications. In addition, the U.S. Nuclear Regulatory Commission (NRC) recommends that the radiation safety officer (RSO) be present during new procedures.

PHOSPHORUS 32 P^{32}

Radioactive half-life $T_{1/2}$: 14.3 days
Principal emission: 1.709 MeV beta (maximum)
Monitoring for contamination: swipes counted by liquid scintillation
Geiger-Müller detector
Biological Monitoring: Urine samples
Annual Limit on Intake (ALI) by ingestion or inhalation: 1×10^7 Bq (0.27 mCi)
Maximum range in air: 790 cm
Dose rate from 1 MBq (27 mCi) in 1 ml:
 • 210 mSv/h (21 rem/h) at surface
 • 2.5 μ Sv/h (0.25 mrem/h) at 1 m
Shielding required: Plexiglas or similar plastic (at least one cm)

Special Considerations for Open Sources:

- Phosphorus-32 is the highest energy beta emitting radionuclide commonly encountered in research laboratories and as such requires special care. Avoid exposure as much as possible (e.g. do not hold tubes containing even small quantities of ^{32}P any longer than necessary - use a stand or holder).
- If quantities greater than a few tens of MBq (1 mCi) are used, wrist or ring dosimeters must be worn. Remember wrist dosimeters alone may fail to indicate high dose to the fingertips. The use of lead-impregnated rubber gloves is also recommended.
- Even with low-density materials (for example, Perspex/Plexiglas) the absorption of the beta-particles gives rise to relatively high energy Bremsstrahlung which may require some lead shielding when quantities greater than a few hundred MBq (or tens of millicuries) are being handled.

Specific Precautions for the Handling of Phosphorus-32:

- Solutions containing more than 1 mCi (37 MBq) of ^{32}P or carrier-free solutions of ^{32}P require specific handling precautions. Carrier-free material is readily absorbed by the skin and will contribute significant doses to the bone where it is preferentially deposited. Careful handling can avoid high radiation doses to the hands while working with this material.
- Follow all general radioisotope safety precautions
- Double glove (disposable), changing the outer pair frequently during the procedure
- Plexiglas shielding should be used as shielding for all ^{32}P handling and must be used with quantities more than 1 mCi (37 MBq). The half-value layer (HVL) thickness for ^{32}P is 1 cm of plexiglas. Lead or other high-density material may be used as secondary shielding
- Safety glasses or goggles should be used when handling ^{32}P . This will reduce the external irradiation of the eye and skin as well as prevent the high radiation doses which accompany accidental contamination by splashing
- Wrist or ring radiation dosimeters as well as whole body dosimeters must be worn if handling quantities of 1 mCi (37 MBq) or larger
- More than one person should be present during handling involving more than 1 mCi (37 MBq)
- Due to the high dose rates encountered, work should never be carried out above an open container of ^{32}P or other high energy beta emitter
- A solution of phosphate buffer is most effective in removing ^{32}P contaminations from surfaces.

IODINE-125 I^{125}

Radioactive half-life $T_{1/2}$:59.6 days
Principal Emissions:.....35 keV gamma (7% emitted, 93% internally converted)
27-32 keV X-rays (140% Te K X-rays)
Monitoring for contamination:swipes counted by liquid scintillation
Thin end-window Geiger-Müller detector
Biological Monitoring:Thyroid scans (scintillation detector NaI)
Annual Limit on Intake (ALI) by inhalation: 2×10^8 Bq (0.055 m Ci)
Dose rate from 1 GBq point 41 mSv/h (4.1 mrem/h) source at 1 m: First half value layer: 0.02 mm lead

Special Considerations for Open Sources:

- Volatilization of iodine is the most significant problem with this isotope. Simply opening a vial of sodium (I^{125}) iodide at high radioactive concentration can cause minute droplets of up to 100 Bq to become airborne. Solutions containing iodide ions should not be made acidic or stored frozen: both lead to formation of volatile elemental iodine.
- As some iodo-compounds can penetrate surgical rubber gloves, it is advisable to wear two pairs, or polythene (polyethylene) gloves over rubber.
- In the event of suspected or actual significant contamination of personnel the thyroid should be blocked by administration of stable iodine as tablets of potassium iodate (170 mg) or potassium iodide (130 mg) which are available at hospitals.
- To render any spilled Iodine-125 chemically stable the area of the spill should be treated with alkaline sodium thiosulphate solution prior to commencing decontamination. Note, however, that the quantity of radioiodine in normal RIA kits (usually <3.7 MBq or 100 m Ci) is such that these can be handled safely with reasonable care on the open bench.

Specific Precautions for the Handling of Radioiodine:

- Follow all general radioisotope safety practices
- Users of radioiodine must participate in the thyroid bioassay program
- Background bioassay must be conducted prior to beginning use of radioiodine
- Bioassays of the thyroid must be performed within four days after radioiodine use
- Double glove (disposable), changing the outer pair frequently during the radioiodine procedure
- Ensure that the radioiodine container has been properly checked for leakage upon receipt
- Vials containing radioiodine should be opened only in a fume hood, and containers of radioiodine should be kept closed when not required
- Carry out all work involving volatile forms of radioiodine in a fume hood
- A properly functioning Vent Alert alarm system will warn users if the fume hood does not have a proper air exhaust in the range of 100-200 linear feet per minute. Contact the RPS if there is any doubt as to the proper operation of the fume hood
- Charcoal filtration of the exhaust may be required for large quantities of radioiodine
- Direct contact with unshielded containers of radioiodine should be avoided
- Shielding material of sheet lead will reduce doses received from external gamma radiation
- Minimizing the time near radioiodine sources will reduce doses from external radiation
- Radioactive waste contaminated with volatile radioiodine should be kept in the fume hood
- Shielding may be necessary to reduce radiation fields near the waste
- Radioiodine solutions with a pH of 8 or more are less likely to produce vapors
- During the experiment and afterwards, monitor the area with appropriate detection equipment.
- A solution consisting of 0.1 M sodium iodide, 0.1 M sodium hydroxide and 0.1 M sodium thiosulphate is effective in cleaning radioiodine spills.
- Wash hands immediately following a radioiodine procedure.

Contact the Radiation Safety Office immediately in case of any emergency situation involving radioiodine or other radioactive material.

131

Radioactive half-life $T_{1/2}$: 8.04 days

Principal Emissions: 0.365 MeV gamma

0.638 MeV gamma

0.606 MeV beta (maximum)

0.334 MeV beta (maximum)

Monitoring for contamination:swipes counted by liquid scintillation detector (NaI)

Biological Monitoring:Thyroid scans (NaI scintillation detector)

Annual Limit on Intake (ALI) by inhalation: 1×10^6 Bq (0.027 mCi)

Dose rate from 1 GBq point 76.5 mSv/h (7.65 mrem/h) source at 1 m: First half value layer: 0.50 cm lead

Special Considerations for Open Sources:

- Volatilization of iodine is the most significant problem with this isotope. Simply opening a vial of sodium (I^{131}) iodide at high radioactive concentration can cause minute droplets to become airborne. Solutions containing iodide ions should not be made acidic or stored frozen: both lead to formation of volatile elemental iodine.
- As some iodine-compounds can penetrate surgical rubber gloves, it is advisable to wear two pairs or polythene (polyethylene) gloves over rubber.
- In the event of suspected or actual significant contamination of personnel, the thyroid may be blocked by administration of stable iodine as tablets of potassium iodate (170 mg) or potassium iodide (130 mg) which are available at hospitals.
- To render any spilled iodine-131 chemically stable the area of the spill should be treated with alkaline sodium thiosulphate solution before commencing decontamination.

Specific Precautions for the Handling of Radioiodine:

- Follow all general radioisotope safety practices
- Users of radioiodine must participate in the thyroid bioassay program
- Background bioassay must be conducted prior to beginning use of radioiodine
- Bioassays of the thyroid must be performed within four days after radioiodine use
- Contact the *Radiation Safety Office* for information on this service
- Double glove (disposable), changing the outer pair frequently during the radioiodine procedure
- Ensure that the radioiodine container has been properly checked for leakage upon receipt
- Vials containing radioiodine should be opened only in a fume hood, and containers of radioiodine should be kept closed when not required
- Carry out all work involving volatile forms of radioiodine in a fume hood
- A properly functioning Vent Alert alarm system will warn users if the fume hood does not have a proper air exhaust in the range of 100-200 linear feet per minute.
- Charcoal filtration of the exhaust may be required for large quantities of radioiodine
- Direct contact with unshielded containers of radioiodine should be avoided
- Shielding material of sheet lead will reduce doses received from external gamma radiation
- Minimizing the time near radioiodine sources will reduce doses from external radiation
- Radioactive waste contaminated with volatile radioiodine should be kept in the fume hood
- Shielding may be necessary to reduce radiation fields near the waste
- Radioiodine solutions with a pH of 8 or more are less likely to produce vapors
- During the experiment and afterwards, monitor the area with appropriate detection equipment.
- A solution consisting of 0.1 M sodium iodide, 0.1 M sodium hydroxide and 0.1 M sodium thiosulphate is effective in cleaning radioiodine spills.
- Wash hands immediately following a radioiodine procedure.

Contact the Radiation Safety Office immediately in case of any emergency situation involving radioiodine or other radioactive material.

FLUORODEOXYGLUCOSE-F18

Radioactive half-life T_{1/2}: 109.7 minutes.
Principal Emissions: 511.0 keV gamma
..... 249.8 keV positron
Monitoring for contamination:swipes counted by wipe test counter

External Radiation

The specific gamma ray constant for fluorine F 18 is 6.0 R/hr/mCi (0.3 Gy/hr/kB) at 1cm. The half-value layer (HVL) for the 511 keV photons is 4.1 mm lead (Pb). A range of values for the attenuation of radiation results from the interposition of various thickness of Pb. The range of attenuation coefficients for this radionuclide is shown in Table 2. For example, the interposition of an 8.3 mm thickness of Pb, with a coefficient of attenuation of 0.25, will decrease the external radiation by 75%.

Special Considerations for Open Sources:

- Handling time should be kept to a minimum and appropriate
- Shielding should be used such as syringe shields and tongs.
- It is advisable to wear two pairs of polythene (polyethylene) gloves over rubber.
- Store at room temperature.
- Storage and disposal of products should be controlled in a manner, which is in compliance with appropriate regulations of federal or state government agency authorized to license the use of this radionuclide.
- Contain and collect spillage and place in container for disposal according to local regulations. Handle waste materials, including gloves, protective clothing, contaminated spill cleanup material, etc. as appropriate for chemically and pharmacologically similar materials.

Specific Precautions for the Handling of Radioiodine:

- Follow all general radioisotope safety practices
- Contact the *Radiation Safety Office* for information on this service
- Double glove (disposable), changing the outer pair frequently during the dosage preparation and administration.
- A laboratory coat must be worn when handling this product.
- Not expected to require personal respirator usage.
- Glasses or goggles are recommended if eye contact is possible.
- Ensure that the radioisotope container has been properly checked for leakage upon receipt
- Direct contact with unshielded containers should be avoided
- Shielding material of sheet lead will reduce doses received from external gamma radiation
- Minimizing the time near F-18 sources will reduce doses from external radiation
- Radioactive waste contaminated with F-18 should be kept in lead waste container for decay
- Shielding may be necessary to reduce radiation fields near the waste
- Monitor the area with appropriate detection equipment before leaving the laboratory on daily basis or when necessary.
- Wash hands immediately following a F-18 procedure before breaks and immediately after handling the product.
- If skin contact occurs, wash the affected area thoroughly with soap and water until no more radioactivity can be removed. Always blot dry. Do not abrade skin. Notify the Radiation Safety Officer
- Prevent release to drains and waterways. Prevent release to the environment.
- Properly sealed containers are not expected to require and special ventilation.

Contact the Radiation Safety Office immediately in case of any emergency situation involving radioiodine or other radioactive material.

IV. General Safety Procedures to Handle Spills

Emergency contact number of RSO or an alternate person(s) is posted conspicuously in areas of use so that they are readily available to workers in case of emergencies. Also emergency equipment is available for handling spills. Spill kits will include the following:

- disposable gloves
- housekeeping gloves
- disposable lab coats
- disposable head coverings
- disposable shoe covers
- roll of absorbent paper with plastic backing
- masking tape
- plastic trash bags with twist ties
- “radioactive material” labeling tape
- marking pen
- pre-strung “radioactive material” labeling tags
- box of wipes
- instructions for “emergency procedures”
- clipboard with copy of the radioactive spill report form for the facility
- pencil
- appropriate survey instruments, including batteries (for radiation survey meters)

V. Spill/Contamination Procedure

As general guidance to determine whether a major spill/contamination procedure or a minor spill/contamination procedure will be implemented. Spills above these millicurie (mCi) amounts should be considered major, and spills below these levels should be considered minor.

RELATIVE HAZARDS OF COMMON RADIONUCLIDES

Radionuclide	mCi	MBq	Radionuclide	mCi	MBq
nitrogen-13	100	3700	technetium-99m	100	3700
carbon-14	10	370	indium-111	10	370
oxygen-15	100	3700	iodine-123	10	370
fluorine-18	100	3700	iodine-125	1	37
phosphorus-32	1	37	iodine-131	1	37
gallium-67	10	370	samarium-153	10	370
rubidium-82	10	370	yttrium-169	10	370
strontium-82	1	37	mercury-197	10	370
strontium-85	10	370	gold-198	10	370
strontium-89	1	37	thallium-201	100	3700
yttrium-90	1	37	Alpha emitters	*	*

*For radiopharmaceuticals where the primary emission is alpha, consider implementing major spill precautions.

VI. Procedures for Handling Emergencies

A. Minor Spills of Liquids and Solids

Instructions to Workers

- Notify persons in the area that a spill has occurred.
- Prevent the spread of contamination by covering the spill with absorbent paper.
- Wear gloves and protective clothing, such as a lab coat and booties, and clean up the spill using absorbent paper. Clean up the spill by wiping from the perimeter of the spill to the center of the spill.
- Carefully fold the absorbent paper with the clean side out and place in a bag labeled “caution radioactive material” for transfer to a radioactive waste container. Also, put contaminated gloves and any other contaminated disposable material in the bag.
- Survey the area with an appropriate low-range radiation detection instrument sufficiently sensitive to detect the radionuclide. Survey for removable contamination to ensure contamination levels are below trigger levels. Survey the area around the spill for contamination.
- Continue to clean up the spill and re-survey until radiation levels and removable contamination are below trigger levels.
- Survey hands, clothing, and shoes for contamination prior to leaving the area.
- Report the incident to the RSO promptly.
- Allow no one to return to work in the area unless approved by the RSO.
- Cooperate and follow the instructions of the RSO and the RSO staff (e.g., criteria for returning to the work area, investigation of root cause, provision of requested bioassay samples, decontamination techniques, surveys, requested documentation).

Reminders to RSO

- Follow up on the decontamination activities and document the results.
- As appropriate, determine cause and corrective actions needed; consider bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin.
- If necessary, notify the NRC.

B. Major Spills of Liquids and Solids

Instructions to Workers

- Clear the area. Notify all persons not involved in the spill to vacate the room.
- Prevent the spread of contamination by covering the spill with absorbent paper labeled “caution radioactive material,” but do not attempt to clean it up. Paper should be

dampened, if solids are spilled. To prevent further spread of contamination, clearly indicate the boundaries of the spill and limit the movement of all personnel who may be contaminated.

- Shield the source only if it can be done without further contamination or a significant increase in radiation exposure.
- Close the room and lock or otherwise secure the area to prevent entry. Post the room with a sign to warn anyone trying to enter that a spill of radioactive material has occurred.
- Notify the RSO immediately.
- Survey all personnel who could possibly have been contaminated. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with mild soap. Document personnel decontamination efforts.
- Allow no one to return to work in the area unless approved by the RSO.
- Cooperate and follow the instructions of the RSO and the RSO's staff (e.g., criteria for returning to the work area, investigation of root cause, provision of requested bioassay samples, decontamination techniques, surveys, requested documentation).

Reminders to RSO

- Supervise and confirm decontamination of personnel. If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic.
- Then wash the affected area again to remove any contamination that was released by the perspiration.
- Document decontamination results, including all surveys, location of surveys, and decontamination results.
- Determine cause and needed corrective actions; consider need for bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin.
- If necessary, notify the NRC.

C. Incidents Involving Radioactive Dusts, Mists, Fumes, Organic Vapors, and Gases

Instructions to Workers

- Notify all personnel to vacate the room immediately.
- Shut down ventilation system, if possible, unless it is determined that the room ventilation system needs to be used to clear the air for access purposes.
- Vacate the room. Seal the area, if possible.
- Notify the RSO immediately.
- Ensure that all access doors to the area are closed and posted with appropriate warning signs, or post guards (trained) at all access doors to prevent accidental opening of the doors or entry to the area.

- Survey all persons who could possibly have been contaminated. Decontaminate as directed by the RSO.
- Promptly report suspected inhalations and ingestions of licensed material to the RSO.
- Decontaminate the area only when advised and/or supervised by the RSO.
- Allow no one to return to work in the area unless approved by the RSO.
- Cooperate with the RSO and/or the RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).
- Follow the instructions of the RSO and the RSO's staff (e.g., decontamination techniques, surveys, provision, and collection of bioassay samples, requested documentation).

Reminders to RSO

- Supervise decontamination activities.
- Perform air sample surveys in the area before permitting resumption of work with licensed materials.
- Provide written directions to potentially contaminated individuals about providing and collecting urine, breath, blood, or fecal samples, etc.
- Consider need for medical exam and/or whole body count before permitting involved individuals to return to work with licensed material.
- Determine cause and corrective actions needed; consider need for bioassays if licensed material is suspected to have been ingested, inhaled, or absorbed through or injected under the skin. Document incident.
- If necessary, notify the NRC.

D. Minor Fires

Instructions to Workers

- Immediately attempt to put out the fire by approved methods (e.g., fire extinguisher) if other fire hazards or radiation hazards are not present.
- Notify all persons present to vacate the area and have one individual immediately call the RSO and fire department (as instructed by RSO).
- Once the fire is out, isolate the area to prevent the spread of possible contamination.
- Survey all persons involved in combating the fire for possible contamination.
- Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with a mild soap.
- In consultation with the RSO, determine a plan of decontamination and the types of protective devices and survey equipment necessary to decontaminate the area.
- Allow no one to return to work in the area unless approved by the RSO.

- Cooperate with the RSO and/or the RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).
- Follow the instructions of the RSO and/or the RSO's staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

Reminders to RSO

- Supervise decontamination activities.
- If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash affected area again to remove any contamination that was released by the perspiration.
- Consult with fire safety officials to ensure that there are no other possibilities of another fire starting.
- Determine cause and needed corrective actions; consider need for bioassays if licensed material is suspected to have been ingested, inhaled, or absorbed through or injected under the skin. Document incident.
- If necessary, notify the NRC.

E. Fires, Explosions, or Major Emergencies

Instructions to Workers

- Notify all persons in the area to leave immediately.
- Notify the Security Office dialing 7911.
- Notify the RSO and other facility safety personnel.
- Upon arrival of firefighters, inform them where radioactive materials are stored or where radionuclides were being used; inform them of the present location of the licensed material and the best possible entrance route to the radiation area, as well as any precautions to avoid exposure or risk of creating radioactive contamination by use of high-pressure water, etc.
- Cooperate with the RSO and/or the RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).
- Allow no one to return to work in the area unless approved by the RSO.
- Follow the instructions of the RSO and/or the RSO's staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

Reminders to RSO

- Coordinate activities with facility's industrial hygienist or environmental health and safety office and with local fire department.

- Consult with the firefighting personnel and set up a controlled area where the firefighters can be surveyed for contamination of their protective clothing and equipment after the fire is extinguished.
- Once the fire is extinguished, advise firefighters not to enter potentially contaminated areas where radioactive sources may be present or radiation areas until a thorough evaluation and survey are performed to determine the extent of the damage to the licensed material use and storage areas.
- Perform thorough contamination surveys of the firefighters and their equipment before they leave the controlled area and decontaminate, if necessary.
- Supervise decontamination activities.
- Consider bioassays if licensed material is suspected to have been ingested, inhaled, or absorbed through or injected under the skin. Document incident.
- If necessary, notify the NRC.

F. Incidents Involving Sealed Sources

For an emergency situation that may occur concerning a sealed source that has been exposed unintentionally, is unshielded or compromised, the following safety instructions should be considered:

- Immediately secure and post the restricted area; maintain continuous surveillance and restrict access to the restricted area.
- Notify the RSO, RSO designee, and management personnel immediately.
- Retrieval operations should be supervised by the RSO.
- No source or suspected source should be handled directly with bare hands.
- Determine if additional dosimetry will be required during source retrieval.
- Appropriate survey instruments should be used for the response activity.
- Expedient methods of reducing unintended exposure to staff and the public, such as lead shot bags, sandbags, steel plates, and remote handling devices.
- The RSO should make required notifications to the NRC.

G. Procedures for Collecting Bioassay Samples

In the event of an emergency in which an individual may become contaminated and radioactive material was taken into the body through skin absorption or other means or is suspected of having ingested or inhaled radioactive material, an estimate of the amount of material taken into the body may be required. The following items should be considered in developing procedures for collecting bioassay samples:

- the type of bioassay that must be performed (direct or indirect)

- the number of samples or data points to be collected
- the frequency of sampling (e.g., hourly, daily, weekly, once)
- the size of the sample to be collected (e.g., 24-hour urine collection)
- the ease or difficulty of sample collection
- the need for written instructions to be provided to the sample collector, who may be the contaminated individual

Tritium -- Individuals involved in operations that use tritium (^3H) in any form other than metallic foil (as in gas chromatography detectors) that are in quantities greater than those listed in Table below must have bioassays performed. Authorized Users must inform the Radiation Safety Office about any workers whose exposure requires periodic bioassay based on these guidelines.

Bioassays for tritium are obtained by urine samples. An employee working with quantities exceeding those shown in the table during a single operation shall provide a urine sample within one week after the exposure. An employee who, in one month, works with quantities exceeding those shown in the table shall provide urine samples weekly during the exposure and once after the exposure ends. The Radiation Safety Office may also require urine samples at other times.

Bioassay Levels for Tritium			
Processing Done	Tritiated Water or Tritiated Compounds (Ci)	Tritium Gas in Sealed Vessels (Ci)	Tritiated Water Mixed with More Than 10 kg of Inert Water or Other Substances (Ci/kg)
In open room with possible escape of tritium	0.01 (10 milliCuries)	10	0.001
Within fume hood of adequate design	0.10 (100 milliCuries)	100	0.010
Within glove boxes	1.00 (1000 milliCuries)	1000	0.100

Iodine-125 and Iodine 131 -- Employees must undergo thyroid monitoring if in one operation or over a 3-month period, they handle open forms of ^{125}I or ^{131}I in quantities which exceed those given in Table below. For a single operation, monitoring should be done 6 to 72 hours after the exposure; for ongoing exposure to radioiodine, quarterly monitoring is required.

Thyroid monitoring shall also be done when an employee's work with the quantities of radioiodine listed below is completed. Persons whose only radioiodine exposure is using commercial RIA kits should refer to the second column in Table to determine if they need monitoring.

Radioactivity levels in unsealed form above which bioassay is necessary

1. Quantities should consider the cumulative amount of the radioactivity in the process handled by a worker during a 3-month period. When the cumulative amount of radioactivity of iodine in unsealed forms during any 3-month period exceeds the specified quantities in Column 2 and Column 3 above, then bioassay is necessary.
2. The quantities in Column 3 may be used when it can be shown that the radioactive materials in the process are always chemically bound and processed in such a manner that all iodine compounds will remain in a nonvolatile form and will be diluted to a concentration of less than 100 mCi/g (3.7 GBq/g) of nonvolatile agent.
3. Capsules (such as gelatin capsules given to patients for diagnostic tests) may be considered to contain the iodine in sealed form, and bioassay would not be necessary unless a capsule were inadvertently opened (e.g., dropped and crushed).
4. If there is a breach in normal procedures during the administration of ¹³¹I, for example, spillage from the vial that exceeds the capacity of the absorbent pad, a bioassay would be necessary.
5. Certain compounds where radioiodine is normally bound are known to release radioiodine when the material is processed, and in this scenario Column 2 may be applicable.
6. For laboratories that only work with ¹²⁵I in radioimmunoassay (RIA) kits, the quantities of ¹²⁵I are very small and in less volatile forms; thus, Column 3 may be used for bioassay requirements.
7. In field operations, where reagent containers are opened outdoors for simple operations such as pouring liquid solutions, the above table does not apply; however, bioassay should be performed whenever an individual employee handles an unsealed source (e.g., an open bottle or container) of more than 50 millicurie (mCi) (1.8 gigabecquerel (GBq)) at any one time.

Bioassay Levels for ¹²⁵ I and ¹³¹ I		
	Forms	
Processing Done	Volatile or Dispersible (millicurie)	Bound to a Nonvolatile Agent (millicurie)
Column 1	Column 2	Column 3
In open room or bench with possible escape from process vessels	0.1	1.0
Within fume hood of adequate design, but with possible escape of iodine	1.0	10.0
Within glove boxes, but with possible leakage or box contamination	10.0	100.0

Bioassay requirements for other nuclides (e.g. ³²P) will be determined on a case-by-case basis for those individuals who are likely to receive an intake in excess of 10 percent of the applicable annual limit on intake.

H. Emergency Surgery of Patients Who Have Received Therapeutic Amounts of Radionuclides

For emergency surgery or autopsy of patients administered byproduct material, National Council on Radiation Protection and Measurements (NCRP) Report No. 111, "Developing Radiation Emergency Plans for Academic, Medical, or Industrial Facilities," 1991, may contain helpful information.

If emergency surgery is performed within the first 24 hours following the administration of iodine-131 sodium iodide, fluids (e.g., blood, urine) will be carefully removed and contained in a closed system.

Protective eyewear will be worn by the surgeon and any personnel involved in the surgical procedure for protection of the eyes from possible splashing of radioactive material and exposure from beta radiation (if applicable). The radiation safety staff will direct personnel in methods to keep doses as low as reasonably achievable (ALARA) during surgical procedures.

If an injury occurs during surgery that results in a cut or tear in the glove used, the individual involved will be monitored to determine if radioactive material was introduced into the wound.

The RSO will be informed of any possible radiation hazard.

1. Autopsy of Patients Who Have Received Therapeutic Amounts of Radionuclides

- Immediately notify the authorized user (AU) in charge of the patient and the RSO upon death of a therapy patient.
- An autopsy will be performed only after consultation and permission from the RSO. Radiation safety staff should evaluate the radiation hazard(s), direct personnel in safety and protection, and suggest suitable procedures to keep doses ALARA during the autopsy.
- Protective eyewear should be worn by the pathologist and assisting staff for protection from possible splashing of radioactive material. Consider the need for protection against exposure from high-energy beta rays in cases involving therapy with phosphorus-32 and yttrium-90.
- Remove tissues containing large activities early to help reduce exposure of autopsy personnel. Shield and dispose of contaminated tissues in accordance with license conditions. In some cases, exposure reduction may be accomplished by removing tissues for dissection to a location where the exposure rate is lower.
- If an injury occurs during the autopsy that results in a cut or tear in the glove, monitor the wound and decontaminate as appropriate to the situation; inform radiation safety staff.

APPENDIX P

UPR- MEDICAL SCIENCES CAMPUS SURVEY DIAGRAMS OF RESTRICTED AND UNRESTRICTED AREAS DESCRIPTION SECURITY – RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390

NUCLEAR MEDICINE FACILITIES:

- UPR- Nuclear Medicine Laboratory, Dr. Isaac González Hospital

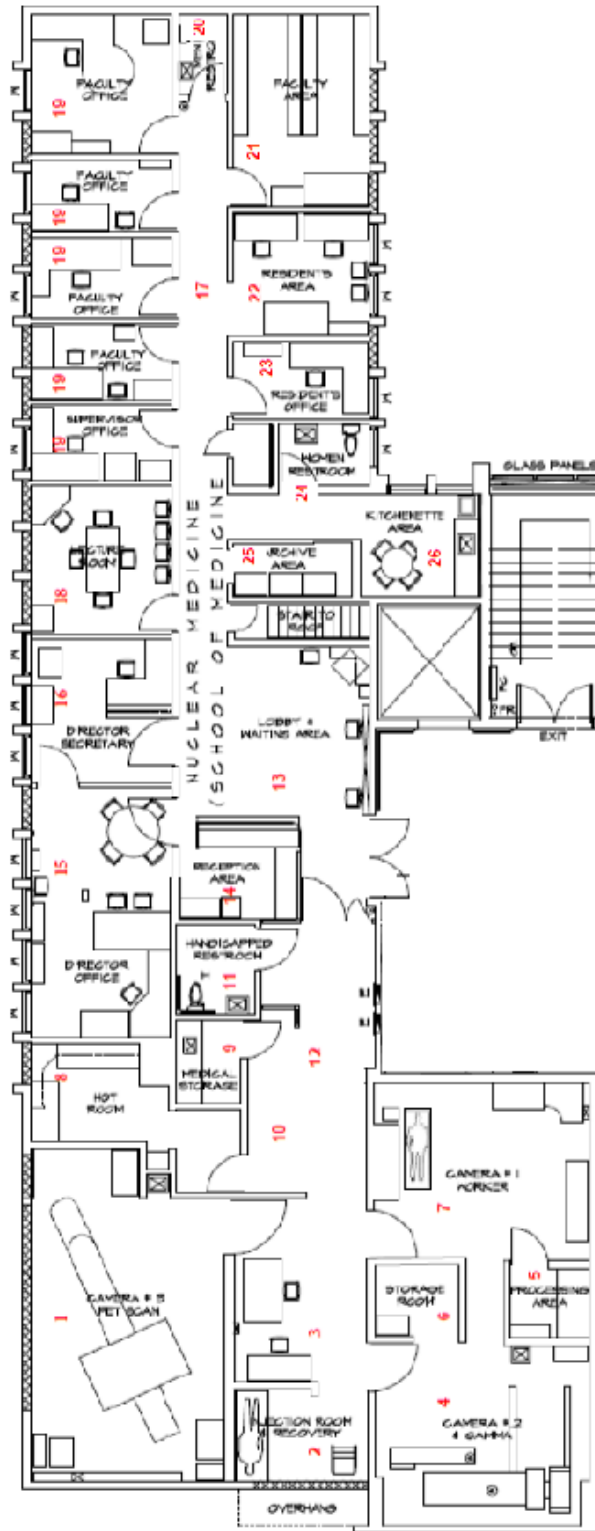
BIOMEDICAL RESEARCH LABORATORIES AT UPR-MEDICAL SCIENCES CAMPUS:

- Laboratory A-643

RADIOACTIVE WASTE STORAGE FACILITIES AT UPR-MEDICAL SCIENCES CAMPUS:

5. Radiation Waste and Decay Storage # 1 – Floor 10 RCM Main Building
6. Radiation Waste and Decay Storage # 2 – Floor 1 RCM Library Building
7. Radiation Waste and Decay Storage # 3 – Floor 1 Between Pediatric Hospital and Infant and Maternity Health Center (CEMI) of the UPR-MS
8. Radiation Waste and Decay Storage # 4 – Radiation Safety Office # 103 Laboratory Basement at Comprehensive Cancer Center Building, Storage Area for Sealed Sources (Bunker)

Medical Sciences Campus of the University of Puerto Rico
Diagram of the Nuclear Medicine Department
On the Fourth Floor of Oncology Hospital, Dr. Isaac González Martínez

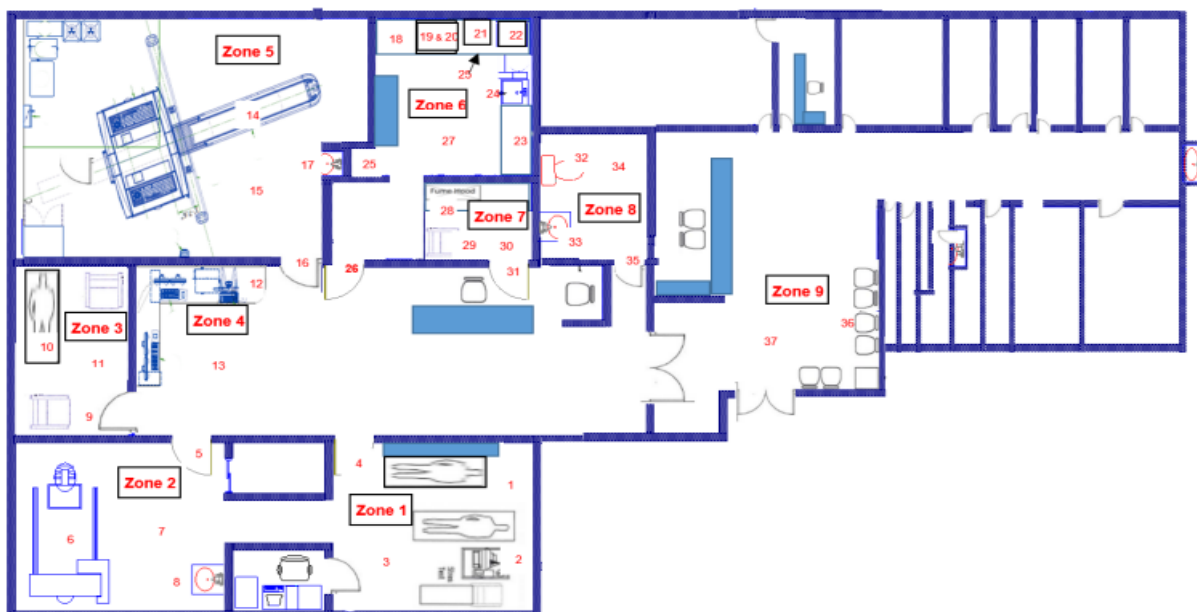


Restricted Areas	Un Restricted Areas
1. PET/CT Camera Room	13. Waiting Area
2. Patient Suite and Injection Room	14. Receptionist Area
3. PET/CT Control Station	15. Nuclear Medicine Director's Office
4. Gamma Camera Room	16. Secretary Office
5. Technologist Work Station	17. Nuclear Medicine Hall Way 2
6. Collimators Storage Room	18. Lecture Room
7. Stress, Uptake and In Patient Room	19. Faculty Offices
8. Hot Room	20. Men Bathroom
9. Injection & Medical Supply Room	21. Patient's Record Room
10. Nurse Work Station	22. Resident's Area
11. Patient Bathroom	23. Resident's Office
12. Nuclear Medicine Hall Way 1	24. Women Bathroom
	25. Archive Area
	26. Kitchenette Area

SECURITY – RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390

APPENDIX K

University of Puerto Rico, Medical Sciences Campus
Nuclear Medicine Laboratory Survey Diagram
Oncology Hospital, Dr. Isaac González Martínez



Daily and Weekly Survey Report

Month: _____ Year: _____

Locations Hot Lab. & Pl. Bathroom Trigger = 2.0 mR/hr, Everything else is 2.0 *Bkg (mR/hr) Bkg = 0.03 mR/hr											Zones in Nuclear Medicine	
Daily	Zone 1	Zone 2	Zone 3	Zone 4	Zone 5	Zone 6	Zone 7	Zone 8	Zone 9	Initials		
1											Zone 1: Pt Assistance and Uptake Room 1=Pt table 2=Uptake System 3=Floor 4=Door Handle	
2											Zone 2: Gamma Imaging Room 1 5= Door Handle 7= Floor 6= Gamma Table 8= Sink	
3											Zone 3: Patient PET Suite & Injection Area 9= Injection Seat 10= Patient Table 11= Floor	
4											Zone 4: PET/CT Work Station 12= Control Table 13= Floor	
5											Zone 5: PET/CT Imaging Room 14= PET/CT Table 15= Floor 16= Door Handle 17= Sink	
6											Zone 6: Hot Room 18= Counter Top 1 23= Counter Top 19= L Block 24= Sink 20= Dose Calibrator 25= Receipt Area 21= Lead Cave 1 (Rad Waste) 26= Door Handle 22= Lead Cave 2 (Sealed Sources) 27= Floor	
7											Zone 7: Injection Room 28= Fume Hood 29= Patient Injection Seat 30= Floor 31= Door Handle	
8											Zone 8: Patient Bathroom 32= Toilet 33= Sink 34= Floor 35= Door Handle	
9											Zone 9: Waiting Area 36= Seats 37= Floor	
10												
11												
12												
13												
14												
15												
16												
17												
18												
19												
20												
21												
22												
23												
24												
25												
26												
27												
28												
29												
30												
31												
Weekly Wipes Locations Hot Lab. & Bathroom Trigger = 2,000 dpm Bkg = 0.03 mR/hr Everything else is 300 - 600 dpm Bkg = 0.03 mR/hr												
Week	Zone 1	Zone 2	Zone 3	Zone 4	Zone 5	Zone 6	Zone 7	Zone 8	Zone 9	Initials	Instrument GM: 1. _____ 14C, S/N: _____	
1												
2											2. _____ 14C, S/N: _____	
3											Wipe test Counter: _____	
4											Model: _____, S/N: _____	
5												

Notes:

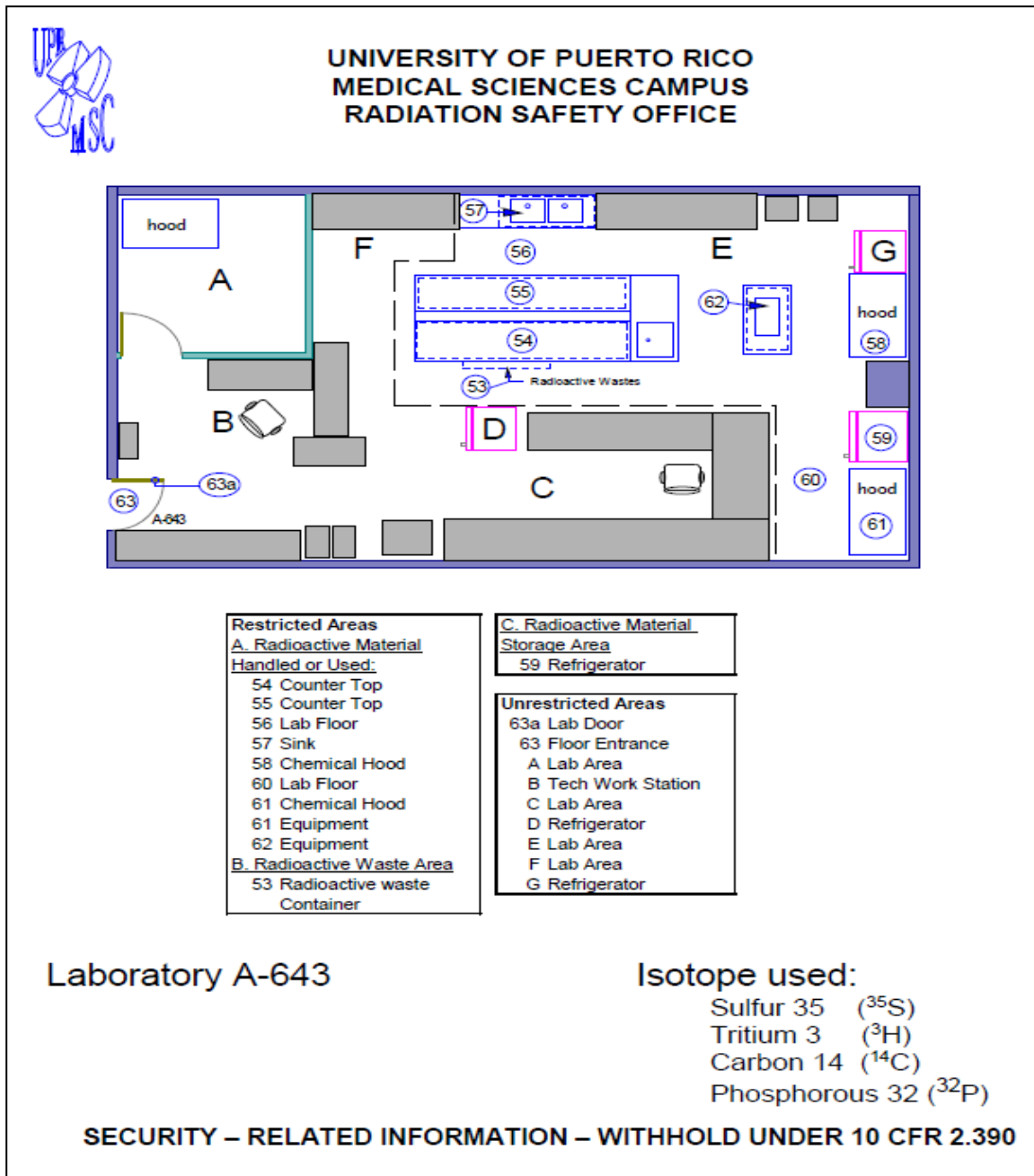
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		Date: _____

**BIOMEDICAL RESEARCH LABORATORIES
UPR- MEDICAL SCIENCES CAMPUS**

SECURITY – RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390

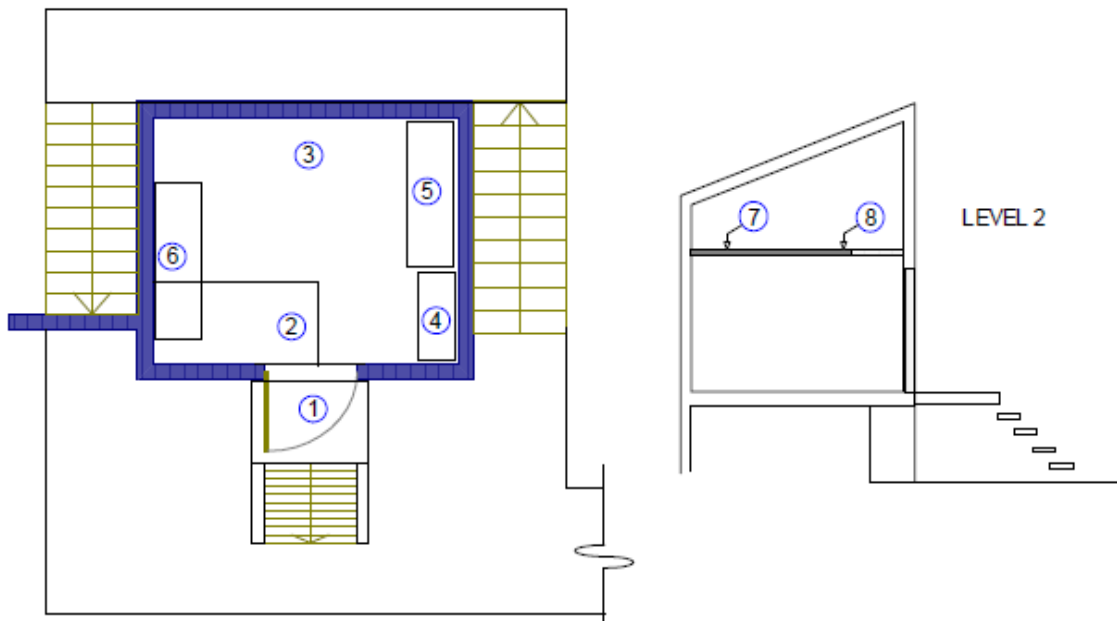
BIOMEDICAL RESEARCH LABORATORIES AT UPR-MEDICAL SCIENCES CAMPUS:

- Laboratory A-643





UNIVERSITY OF PUERTO RICO
MEDICAL SCIENCES CAMPUS
RADIATION SAFETY OFFICE



Restricted Areas
A. Radioactive Waste Area
Storage Area
Level 1
Level 2

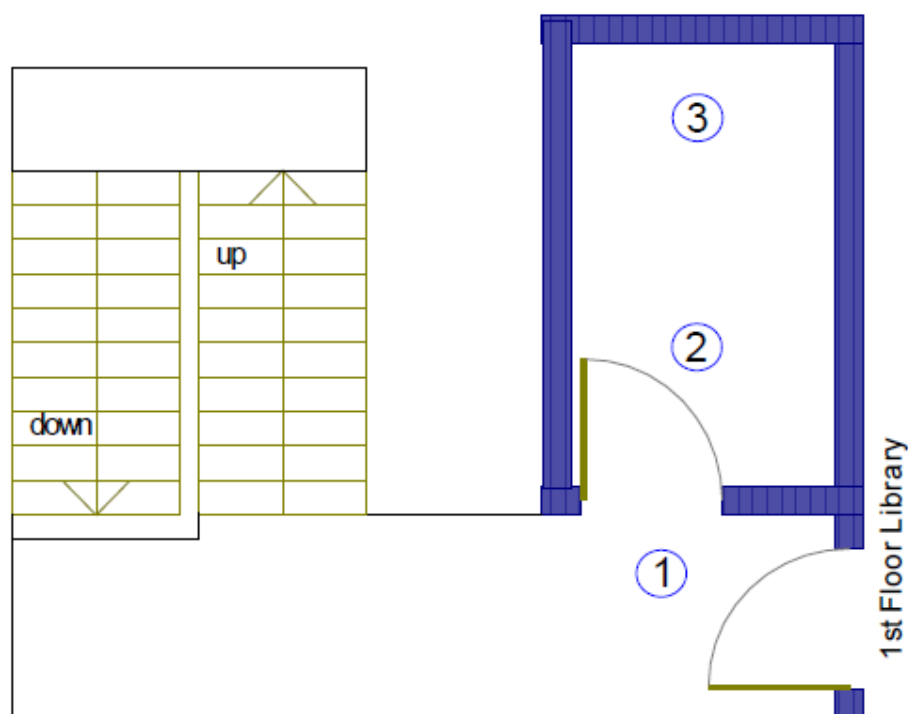
note:
wall of 8 inches thick
of concrete.

Radioactive Waste Storage Area
(Transient Radioactive Waste Storage Facility)
RSO Storage 1 – Floor 10 RCM

SECURITY – RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390



UNIVERSITY OF PUERTO RICO
MEDICAL SCIENCES CAMPUS
RADIATION SAFETY OFFICE



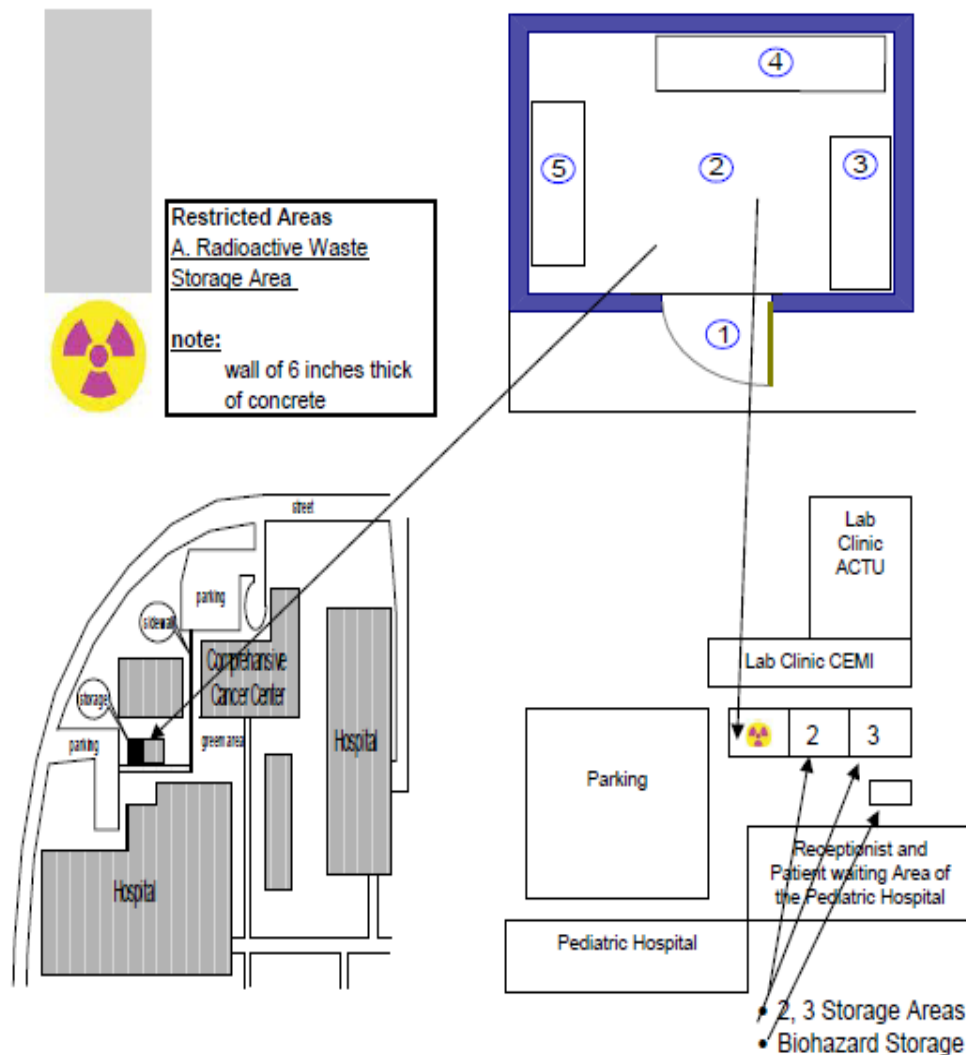
Restricted Areas
A. Radioactive Waste
Storage Area
note:
wall of 8 inches thick
of concrete

Radioactive Waste Storage Area
(Transient Radioactive Waste Storage Facility)
RSO Storage 2 – Floor 1 Library RCM

SECURITY – RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390



UNIVERSITY OF PUERTO RICO
MEDICAL SCIENCES CAMPUS
RADIATION SAFETY OFFICE



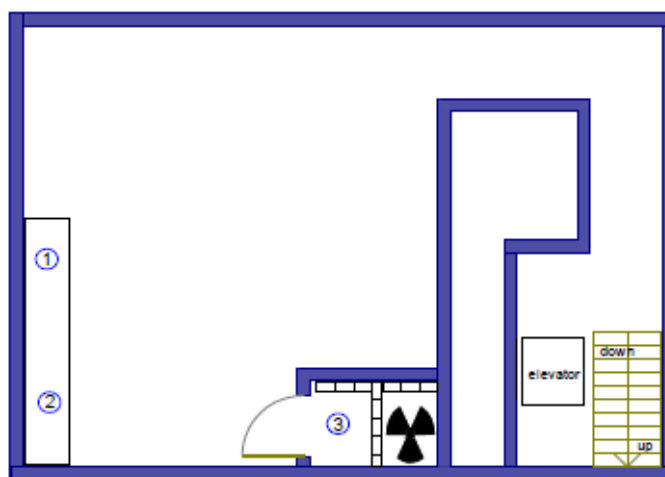
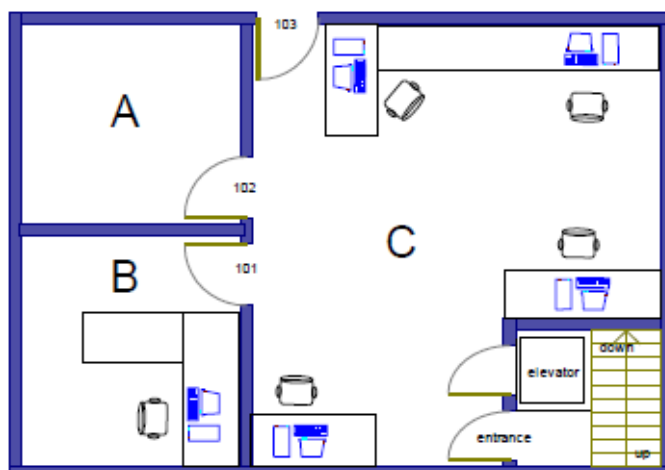
Radioactive Waste Storage Area
(Radioactive Waste Storage Facility)
RSO Storage 3

SECURITY – RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390



UNIVERSITY OF PUERTO RICO
MEDICAL SCIENCES CAMPUS
RADIATION SAFETY OFFICE

Comprehensive Cancer Center



**Restricted Areas
(Basement)**
A. Radioactive Material
Handled or Used:
1 Work Table
2 Work Table
B. Radioactive Material
Storage Area
3 Storage Area

Unrestricted Areas
A Office
B Office
C Office

Radioactive Material Storage Area (Not In Use Sealed Sources)
(Transient Radioactive Storage Facility)
Laboratory Basement
RSO Office 103

SECURITY – RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390

APPENDIX Q

LABORATORY SURVEILLANCE FREQUENCY

Personnel should survey for contamination in locations where individuals are working with an unsealed form of radioactive material in an amount greater than or equal to 10% of the smallest annual limit on intake (ALI) (either the inhalation or ingestion ALI) listed for that Radionuclides in 10 CFR Part 20. These surveys should be done at a frequency appropriate to the types and quantities of radioactive materials in use, but at a minimum quarterly. If amounts are used that are greater than or equal to the smallest ALI listed for that Radionuclides in 10 CFR Part 20, detailed, documented surveys should be performed at least monthly.

LABORATORY SURVEILLANCE FREQUENCY CATEGORY AND MODIFIERS

Survey Category	Activity Range	Survey Frequency
Very Low Level	<0.01 mCi	Once a month
Low Level	0.01 mCi to 1 mCi	Every 2 weeks (Or more frequently at the discretion of the Authorized User)
Medium Level	>1 mCi to 10 mCi	After each operation
High Level	> 10 mCi	After each operation
Modifying Factors		Factors
Simple storage		x 0.01
Very simple wet operations (e.g., dilutions of stock solutions, RIA's done with kits)		x 0.1
Normal chemical operations (e.g., in vitro viral, bacterial, or cell labeling and simple analysis, such as by gel electrophoresis or counting in gamma - or beta counters)		x 1
Complex wet operations (e.g., radiolabeling of nucleic acids, proteins, etc. in vitro viral, bacterial, or cell labeling and complex analysis, such as zonal centrifugation or extractions)		x 10
Simple dry operations (e.g., manipulation of powders) and work with volatile radioactive compounds (e.g., I-125)		x 10
Exposure of non-occupational persons		x 10

The object is to determine how often to survey the laboratory. To do this, multiply the activity range under VERY, LOW, LOW, MEDIUM, and HIGH survey frequency by the appropriate Modifying Factor to construct a new set of mCi ranges for VERY, LOW, LOW, MEDIUM, and HIGH survey frequency.

APPENDIX R

A. AREA SURVEY CONTAMINATION MAXIMUM PERMISSIBLE LIMITS AND ACTIONS LEVELS FOR DECONTAMINATION

Restricted areas:	
<ul style="list-style-type: none"> Alpha emitters Beta or X-Ray emitters Low-Risk Beta or X-Ray emitters 	<ul style="list-style-type: none"> 220 dpm/100 cm² 2,200 dpm/100 cm² 22,000 dpm/100 cm²
Protective clothing worn only in restricted areas:	
<ul style="list-style-type: none"> Alpha emitters Beta or X-Ray emitters Low-Risk Beta or X-Ray emitters 	<ul style="list-style-type: none"> 220 dpm/100 cm² 2,200 dpm/100 cm² 22,000 dpm/100 cm²
Unrestricted area:	
<ul style="list-style-type: none"> Alpha emitters Beta or X-Ray emitters Low-Risk Beta or X-Ray emitters 	<ul style="list-style-type: none"> 22 dpm/100 cm² 220 dpm/100 cm² 2,200 dpm/100 cm²
Personal clothing worn outside restricted area:	
<ul style="list-style-type: none"> Alpha emitters Beta or X-Ray emitters Low-Risk Beta or X-Ray emitters 	<ul style="list-style-type: none"> 22 dpm/100 cm² 220 dpm/100 cm² 2,200 dpm/100 cm²
Skin:	
<ul style="list-style-type: none"> Alpha emitters Beta or X-Ray emitters Low-Risk Beta or X-Ray emitters 	<ul style="list-style-type: none"> 220 dpm/100 cm² 220 dpm/100 cm² 2,200 dpm/100 cm²

B. ACTIONS LEVELS FOR DECONTAMINATION BETA AND GAMMA EMITTERS

Smear Results	Action
Under 220 dpm/100cm ²	No action required by RSO. Left to discretion of Authorized User.
220-350 dpm/100 cm ²	Area or surfaces should be cleaned as soon as possible by the Authorized User or laboratory personnel. Shoe covers and step-off pads shall be used if contamination is on floor.
350-2,200 dpm/100 cm ²	Contamination should be cleaned immediately under supervision of the Radiation Safety Office. Shoe covers and step-off pads are required for entry into area. Only essential personnel will have access.
2,200 dpm/100 cm ²	Air flow should be shut off. Entry of personnel into area should be prevented until a representative of RSO arrives. Cleanup should begin immediately by Authorized user under supervision of RSO. Shoe covers and step-off pads are required.
cm ² = square centimeters (100 cm ² = 4"x 4")	

APPENDIX S

SURFACE CONTAMINATION LEVELS SCREENING LEVELS FOR UNRESTRICTED RELEASE

1. ACCEPTABLE SURFACE CONTAMINATION LEVELS FOR EQUIPMENT

Nuclide	Average	Maximum	Removable
U-nat,	5,000 dpm/100 cm ²	15,000 dpm /100 cm ²	1,000 dpm/100 cm ²
I-125	100 dpm/100 cm ²	300 dpm/100 cm ²	20 dpm/100 cm ²
I-126, I-131, I-133, Sr-90	1,000 dpm/100 cm ²	3,000 dpm/100 cm ²	200 dpm/100 cm ²
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	5,000 dpm/100 cm ²	15,000 dpm/100 cm ²	1,000 dpm/100 cm ²

2. SCREENING LEVELS FOR UNRESTRICTED RELEASE

Radionuclide	Symbol	Screening levels for unrestricted release (dpm/100 cm ²)
Hydrogen-3 (Tritium)	H-3	1.2×10^8
Carbon-14	C-14	3.7×10^6
Sodium-22	Na-22	9.5×10^3
Sulfur-35	S-35	1.3×10^7
Chlorine-36	Cl-36	5.0×10^5
Cobalt-60	Co-60	7.1×10^3
Nickel-63	Ni-63	1.8×10^6
Technetium-99	Tc-99	1.3×10^6
Iodine-129	I-129	3.5×10^4
Cesium-137	Cs-137	2.8×10^4
Iridium-192	Ir-192	7.4×10^4

APPENDIX T

LEAK TEST OF SEALED SOURCES

The RSO shall ensure that leak tests and physical inventories are performed on sealed sources and at the intervals specified in the applicable radioactive material license condition.

The responsible Authorized User shall ensure that:

1. The RSO is notified prior to the acquisition, transfer, relocation, loss, destruction, or disposal of any sealed source.
2. All sealed sources under the AUs control are secured against unauthorized access or removal.
3. A complete inventory of all sealed sources under the Authorized User's control is maintained and kept available for inspection by RRO.

This program is as follows:

- For each source to be tested, list identifying information such as manufacturer, model number, serial number, radionuclides, and activity.
- If available, use a survey meter to monitor exposure.
- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate with identifying information for each source.
- Wipe the most accessible area (but not directly from the surface of a source) where contamination would accumulate if the sealed source were leaking.
- Select an instrument that is sensitive enough to detect 185 becquerels (0.005 microcurie) of the radionuclides and ensure that its calibration is current.
- Using the selected instrument, count, and record background count rate. Calculate efficiency.
- Count each wipe sample; determine net count rate.
- For each sample, calculate and record estimated activity in becquerels (or microcuries).
- Sign and date the list of sources, data and calculations. Retain records for 3 years.
- If the wipe test activity is 185 Bq (0.005 μ Ci) or greater, notify the RSO, so that the source can be withdrawn from use and disposed of properly.

The sealed source(s) shall be tested for leakage and/or contamination at intervals not to exceed 6 months and inventoried on quarterly basis. 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. Any licensed sealed source is exempt from such leak tests when the source contains only hydrogen-3 (tritium), byproduct material with a half-life of less than 30 days, a radioactive gas or contain 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material. Any source in storage which has not been used needs to be tested every ten years. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.

The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material. 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 NRC regulations. A report shall be filed and 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 NRC.

APPENDIX U

RADIOACTIVE WASTE DISPOSAL

Disposal of Radioactive Waste Procedure:

Due to the problems in radioactive waste management and legal requirements, no radioactive waste may be removed from the laboratory without the complete information on the tag. Chronic failure to thoroughly manifest radioactive waste may result in suspension of permission to use radioactive materials. MSC currently manages radioactive waste by one or more of the following methods as directed by the Radiation Safety Office:

1. Decay-in-storage (DIS)
 2. Transfer to an authorized recipient
1. Procedure for disposal by Decay-In-Storage (DIS):
 - Only short-lived waste (physical half-life of less than or equal to 120 days) may be disposed of by DIS.
 - Short-lived waste should be segregated from long-lived waste (half-life greater than 90 days) at the source.
 - Waste should be stored in suitable well-marked containers, and the containers should provide adequate shielding.
 - Liquid and solid wastes must be stored separately.
 - When the container is full, it should be sealed. The sealed container should be identified with a label affixed or attached to it.
 - The identification label should include the date when the container was sealed, the longest-lived radionuclide in the container, total activity, and the name of the individual who sealed the container. The container may be transferred to the DIS area. When large quantities are held for DIS, sufficient quantities may be present even after many half-lives and persons performing surveys should be aware of the potential for measurable radiation.
 - Contact the Radiation Safety Office for waste pickup.
 - The contents of the container should be allowed to decay for a period of time after which it is expected that the radiation levels would not be distinguishable from background. The period of time depends on both the half-life of the radionuclide(s) and the original amount present.

- Prior to disposal as ordinary trash, each container should be monitored with an appropriate radiation detection instrument, on the lowest setting, as follows:
 - Check the radiation detection survey meter for proper operation.
 - Survey the contents of each container in a low background area.
 - Remove any shielding from around the container.
 - Monitor all surfaces of the container.
 - Discard the contents as ordinary trash only if the surveys of the contents indicate no residual radioactivity, (i.e., surface readings are indistinguishable from background).
 - All radioactivity labels must be defaced or removed from containers and packages prior to disposal in ordinary (non-radioactive) waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
 - If the surveys indicate residual radioactivity, return the container to DIS area and contact the RSO for further instructions.
 - If the surveys indicate no residual radioactivity, record the date when the container was sealed, the disposal date, type of waste (e.g., used, or unused material, gloves, etc.), survey instrument used, and the initials of the individual performing surveys and disposing of the waste.

In accordance with 10 CFR 20.1904(b), all radiation labels must be defaced or removed from containers and packages prior to disposal as ordinary trash. Syringes/needles placed into sealed waste containers for decay do not need the labels removed, provided that the following is done: waste barrels are sealed prior to delivery to the waste disposal firm and delivered directly from the licensee's facility.

2. Procedure for disposal by transfer to an authorized recipient:

- The Radiation Safety Office is responsible for finding an appropriate company for waste disposal.

Quantifying Levels of Radioactivity in Waste:

Radioactive and other hazardous materials must be completely manifested in the waste. To accurately list levels of radioactivity on the tags, it is necessary to assess the levels which are disposed in both liquid and solid waste. Suggestions on methods to quantify the waste follow.

1. During a given experiment it is known that a certain quantity of radionuclide is used. At the end of each of several similar experiments, take a sample of liquid waste and count it with the appropriate counting equipment (LSC). The activity in the sample per unit volume is then multiplied by the total volume of the liquid waste generated. For the solid waste, the quantity of radioactivity in the liquid is subtracted from the total quantity used in the experiment, and the remainder is then the quantity in the solid waste.

Example:

Total Used in Experiment (corrected for age): 500 μCi

Liquid Sample Volume: 1 ml

Total Liquid Waste Volume: 4000 ml

Activity in Liquid Waste Sample: $8 \text{ E-}2 \mu\text{Ci/ml}$

Liquid Waste Total Activity: $8 \text{ E-}2 \mu\text{Ci/ml} \times 4000 \text{ ml} = 320 \mu\text{Ci}$ in liquid waste

Solid Waste Total Activity: $500 \mu\text{Ci} - 320 \mu\text{Ci} = 180 \mu\text{Ci}$ in solid waste

2. After the first few experiments, or when the waste carboy is full, take a sample of the pooled liquid waste, and count it as above. Multiply the activity of the sample per unit volume by the total volume in the carboy to obtain the total activity in the carboy. Quantify the solid waste as above by subtracting the liquid waste activity.

Multi-hazard Waste --This is waste contains any combination of radioactive, biohazardous, and chemically hazardous materials known as mixed waste. Avoid creating such materials, if possible! Disposal of multi-hazard-waste is extremely costly and difficult.

Solid Waste -- This includes test tubes, beakers, absorbent paper, gloves, pipettes, and other dry items contaminated with radioactive material but not containing liquid radioactive waste. This material must be placed in plastic bags, sealed with tape. Hypodermic needles, capillary pipettes, and other sharp objects must be placed in puncture-proof containers before being put into the large waste cans.

Containers bearing a radioactive label, but no longer containing radioactive material must be disposed of as ordinary waste only after the radioactive label is defaced or removed and after being decontaminated.

Before any radioactive material contaminated with a microbiological organism (virus, fungus, or bacteria) is disposed, it must be chemically treated in a manner that destroys all living organisms (e.g., with fresh 10 percent bleach solution). Autoclaving or Gamma cell irradiation should be used only when necessary. Care should be taken to protect autoclaves from any radioactive contamination, particularly, tritium, and radioiodine.

Before animal experiments with radioisotopes can begin, animal protocols must be approved by the Animal Use Committee (IACUC) and the RSC must be consulted so that proper arrangements can be made for disposal of radiologically contaminated or infectious carcasses.

- Animal carcasses or animal tissue that contain less than 0.05 microcurie of ^3H or ^{14}C per gram averaged over the weight of the entire animal can be disposed of as biological waste. At concentrations higher than this or for other radioisotopes, the animal or tissues must be disposed of as radioactive waste.

Procedures must be available to ensure that the above limits are not exceeded and that the disposal of animal tissue or carcasses containing licensed material is in a manner that will not permit their use either as food for humans or as animal feed. Accurate records of these disposals must be maintained.

Organic Liquid Waste:

- Vials of liquid scintillation medium that contain less than 0.05 microcurie of ^3H or ^{14}C per gram of scintillation medium should be disposed of as non-radioactive waste pursuant to 10 CFR 20.2005, "Disposal of specific wastes".
- All scintillation vials containing radioactivity above these levels must be labeled as radioactive waste. Scintillation fluid and radioactive waste must be left in the original vials for disposal. These vials should be placed upright in shipping trays rather than in the large waste cans or plastic bags.
- Organic solvents that are insoluble, flammable, or toxic must be collected in inert, airtight plastic bottles and must never be disposed thru the sink. The RSO shall oversee the disposal of any aqueous liquid waste that will be picked up from radiation laboratories by Radiation Safety Staff or their representative.

Aqueous Liquid Waste -- No liquid radioactive waste shall be disposed of by the sewage system. The sink must always be a point of survey when performing decontamination lab surveys. Liquid radioactive waste must be stored in appropriate containers. RIA kits containing ^{125}I should be treated as radioactive waste and will be disposed of by the Radiation Safety Office.