RUTGERS

Rutgers Environmental Health and Safety

RUTGERS BIOMEDICAL AND HEALTH SCIENCES (RBHS)

NEWARK CAMPUS

REHS-Office of Radiation Safety Services

RADIATION SAFETY POLICY MANUAL

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RBHS Newark Campus Radiation Safety Policy Manual

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Institutional Licenses for Radioactive Materials and Radiation-Producing Machines

Radioactive Materials License:

Issuer: NJDEP (New Jersey is an Agreement State of the US Nuclear Regulatory Commission)
Program Interest (PI) ID # 450669
Expiration Date: August 31, 2024
License Type: Medical Broad Scope

Radiation-Producing Machines Registered with NJDEP-BXC

Facility ID # 109848: UH Machines (Administrator – UH Radiology Director/Designee):

Facility ID # 109848: UH Dental Machines (Administrator – UH Radiology Director/Designee):

Facility ID # 121382: NJMS Machines (Administrator – Senior Associate Dean for Clinical Affairs):

Facility ID # 121383: RSDM Machines (Administrator – Director -RSDM Facilities):

Facility ID # 122356: Rutgers Health Group, Inc.-DOC Machines (Administrator – Program Manager):

Facility ID # 117355: Rutgers – University Dental Center at Somerdale (Administrator – Admin Co-Ordinator):

Facility ID # 117156: Rutgers – University John H Cronin Dental Center at Northfield (Administrator –Admin Co-Ordinator):

Facility ID # 122206: Rutgers Health University Dental Associates, Somerset (Administrator – Team Supervisor):

1. Organization of Responsibilities

RUTGERS RADIATION SAFETY MANAGEMENT TRIANGLE

License Administrator
(Executive Vice President for Academic Affairs)

Administrative Representative

Radiation Safety Committee (RSC) **RBHS Newark Radiation Safety Officer**

1.1 Radiation Safety Committee

1.1 (a) **General Information**: The Radiation Safety Committee reviews and acts on all proposed uses of radioactive material and other ionizing sources including electron microscopes, develops and approves radiation safety programs consistent with the ALARA (As Low As Reasonably Achievable) philosophy, performs routine audits of safety program effectiveness, and reviews and acts on all incidents involving radioactive material and reported items of noncompliance with State, Federal, and Local regulatory requirements. The Radiation Safety Committee may establish subcommittees to expedite the review of license applications, medical use applications, enforcement issues, and policy development.

1.1 (b) **Membership**: The composition of the Radiation Safety Committee shall meet the membership requirements outlined in Title 10, Part 35.24, of the Code of Federal Regulations, and Title 7, Chapter 28, Subchapter 4.8, of the New Jersey Administrative Code. The membership shall include, but not be limited to the following: individuals who represent each type of use of ionizing radiation for which the University has authorization, and who through training or experience possess special competence in the areas of radiation protection and/or risk assessment; the Radiation Safety Officer; a representative of management who is not an authorized user; a pathologist or internist; nuclear medicine physician; and a representative from the Department of Radiology.

The Dean of the New Jersey Medical School will recommend the Chair of the Radiation Safety Committee.

The Chair will appoint members of the Radiation Safety Committee and the Chairs of the various subcommittees. Appointments are to be made in consultation with the Radiation Safety Officer and the Chairs of the subcommittees. The Chair will appoint at least ten (10) members from NJMS, two (2) members from RSDM, four (4) members from UH (these shall include at a minimum, a nursing representative, a representative from Radiology, a UH executive-level administrative representative), and two (2) *ex officio* that are Graduate Medical Education residents.

Other Newark Campus-based facilities, such as the School of Nursing, the School of Health Professions, or Graduate Medical Education, may be included on the Radiation Safety Committee if the need to use radioactive materials or ionizing radiation equipment arises.

The composition of the Radiation Safety Committee will be submitted as requested to the Dean of NJMS and the UH University Hospital Medical Executive Committee. Office of the Executive Vice President for Academic and Clinical Affairs. Committee members will serve three (3) year terms.

1.1 (c) **Human Use Subcommittee Membership**: The composition of the Human Use Subcommittee shall meet the requirements outlined in Title 10, Part 361.1, of the Code of Federal Regulations. Membership shall include but not be limited to the following: individuals whose disciplines are pertinent to the field of nuclear medicine (e.g., diagnostic and/or therapeutic radiologists); clinical pathologists; internists; radio pharmacists or radiochemists; and Radiation Safety Officer. The membership shall be sufficiently diverse to allow for expert review of the technical and scientific aspects of proposals submitted to the Subcommittee.

1.1 (d) **Licensing Subcommittee Membership**: The composition of the Licensing Subcommittee shall include licensees representing the various non-human use procedures authorized by the University's medical broad scope radioactive material license, and who, through training or experience, possess sufficient expertise in radiological safety and regulatory guidelines to permit thorough review of license applications.

1.1 (e) **Education and Training Subcommittee Membership**: The composition of the Education and Training Subcommittee shall include licensees and ionizing radiation users representing the various areas or departments authorized for ionizing radiation activities, and who, through training and experience, possess sufficient expertise in radiological safety to evaluate educational programs designed to instruct all persons (as required in 10 CFR Part 19.12) whose duties may require them to work in or frequent areas where radioactive materials or other radiation sources are used (e.g. nursing, security, physical plant, laboratory staff, housekeeping).

1.1 (f) **Meeting Requirements**: The Radiation Safety Committee shall meet at least quarterly, and:

i. At least one-half of the Committee shall be present, including the Chair (or designee of the Chair), Radiation Safety Officer, and a representative of management, to establish a quorum and conduct business.

ii. Minutes of the proceedings shall be recorded, which include the meeting date, members present and absent, a summary of deliberations and discussions, the numerical results of ballots, and a record of the ALARA program reviews undertaken.

1.1 (g) **Committee Responsibilities**: The Radiation Safety Committee shall review and approve or disapprove all proposed uses of radioactive material on the Newark campus; develop, approve and audit programs required to ensure the radiological health and welfare of RBHS and University Hospital personnel and the general public, and compliance with pertinent State, Federal, and Local regulatory requirements. In fulfilling these responsibilities, the Committee shall:

i. Review on the basis of safety, and with regard to State and Federal standards for training and experience, all applications for a license for radioactive material.

ii. Evaluate the adequacy of facilities and equipment for specific radionuclide applications.

iii. Review quarterly, with the assistance of the Radiation Safety Officer, a summary of the occupational radiation dose records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive.
    a. Notify radiation users and their respective supervisors when users of body/collar dosimeters exceed Weber-calculated monthly doses of 250 mrem.
    b. Notify radiation users and their respective supervisors when users of body/ring dosimeters exceed 25% of the allowable doses for either hand or body. These monthly ALARA trigger limits are 1000 mrem for the hands and 100 mrem for the body.

iv. Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials or other radiation sources are used (e.g., nursing, security, housekeeping, physical plant) are appropriately instructed as required in 19.12 of 10 CFR Part 19.

v. Ensure that the byproduct and Naturally Occurring Radioactive Materials (NORM) licenses and NJDEP registrations are amended if required prior to any changes in facilities, equipment, policies, procedures, and personnel.

vi. Review at least annually the Radiation Safety Officer's summary report of the entire radiation safety program to determine that all activities are being conducted safely, in accordance with the NRC and NJDEP regulations and the conditions of the licenses, and consistent with the ALARA program and philosophy. The review must include an examination of records, reports from the Radiation Safety Officer, results of NRC and NJDEP inspections, written safety procedures, and an assessment of the adequacy of the management control system.

vii. Recommend remedial action to correct any deficiencies identified in the radiation safety program; working with radioactive material; and all incidents involving radioactive material with respect to the cause and the corrective actions taken.

1.1 (h) **Human Use Subcommittee Responsibilities**: The Human Use Subcommittee shall review all phases of the use of radioactive material in or on humans and make recommendations to the Radiation Safety Committee regarding conditions for approval or disapproval of human use license applications and/or research protocols. When the research protocol falls within the provisions of 21 CFR 361.1, the Human Use Subcommittee serves as the Radioactive Drug Research Committee. In fulfilling its responsibilities, the subcommittee shall:

i. Review the qualifications of human use license applicants concerning State and Federal standards for training and experience.

ii. Evaluate the adequacy of facilities and equipment designated for specific human use applications and establish that each individual involved in the proposed use has received the appropriate level of training in radiological health and safety.

iii. Review all human-use research protocols about the suitability of the proposed radionuclide, the radioactive drug formulation, the dosimetry methodology, the absorbed dose to the subject, and the pharmacological dosage.

iv. Ascertain whether the research protocol has received the consent of the RBHS Newark campus Institutional Review Board, and whether the protocol is subject to the provisions contained in 21 CFR 361.1 "Radioactive Drugs for Certain Research Uses".

v. Review and take appropriate action on all reports of medical events and adverse reactions following administration of radioactive material.

1.1 (i) **Licensing Subcommittee Responsibilities**: The Licensing Subcommittee shall review all non-human use license applications and all radiation incidents and reports of safety violations and submit recommendations to the Radiation Safety Committee regarding the appropriate course of action. In fulfilling this responsibility, the Licensing Subcommittee shall:

i. Review the qualifications of each non-human use license applicant concerning State, Federal, and Local standards for training and experience.

ii. Evaluate the adequacy of the facilities and equipment of each applicant concerning the handling procedures described in the application.

iii. Review each incident involving radioactive material, ascertain whether the incident resulted from an infraction of State, Federal, or Local safety regulations, and order corrective measures or initiate enforcement actions where appropriate.

1.1 (j) **Education and Training Subcommittee Responsibilities**: The Education and Training Subcommittee shall review the training and education efforts of the Office of Radiation Safety Services and submit recommendations to the Radiation Safety Committee regarding training needs at the Newark Campus. In fulfilling this responsibility, the Education and Training Subcommittee shall:

i. Review the training programs presented by the Office of Radiation Safety Services.

ii. Determine their adequacy.

iii. Assist the Office of Radiation Safety Services in developing programs for RBHS and University Hospital staff.

iv. Identify target groups that should receive training but are not presently on the list.

1.2 Radiation Safety Officer (RSO)

1.2 (a) **General Information**: The primary function of the Radiation Safety Officer (RSO) is to manage the radiation safety program to preserve the radiological health and welfare of the RBHS and University Hospital personnel and the general public and ensure compliance with State and Federal regulations and Local policies. The RSO is solely responsible for administering the Office of Radiation Safety Services and its staff. As per the **RUTGERS RADIATION SAFETY MANAGEMENT TRIANGLE**, the RSO reports to the Senior Executive Vice President for Academic Affairs and the Radiation Safety Committee. The Radiation Safety Committee develops the specific programs for which the Office of Radiation Safety Services is charged with implementation and management. However, the Office of Radiation Safety Services maintains sufficient authority, organizational freedom, and management prerogative to identify radiation safety problems; initiate, recommend, or provide corrective actions; and to verify that corrective actions have been implemented and assess their effectiveness.

1.2 (b) **RSO Responsibilities**: In addition to the specific programs and procedures developed by the Radiation Safety Committee, the Radiation Safety Officer is responsible for:

i. Ensuring that all radionuclide acquisitions are authorized under the institution's State licenses and the user's license.

ii. Maintaining a centralized program for the receipt and inspection of radioactive shipments and keeping an inventory record of the radioactive materials on hand.

iii. Ensuring that radiation safety survey and testing equipment is calibrated at the required frequency.

iv. Evaluating the effectiveness of the radiation safety program through routine inspections and surveys.

v. Implementing and maintaining a personal monitoring program, including bioanalysis testing, and establishment of action levels which, when exceeded, shall initiate an investigation to determine the cause.

vi. Investigating all incidents involving radioactive materials, including unauthorized removal and/or theft, spills and accidental releases, unauthorized receipt, medical events, and any activities that are not being conducted in full compliance with State, Federal, and Local regulations, and implementation of corrective actions as necessary.

vii. Maintaining records and reports required by State and Federal regulatory agencies, and preparation of reports and program audits for the Radiation Safety Committee.

viii. Preparing and presenting radiation safety training sessions for personnel handling radioactive material or frequenting areas where ionizing radiation is present.

ix. Managing a program for the processing, packaging, and disposal of radioactive waste.

x. Implementing the recommendations of the Radiation Safety Committee.

1.3 Radioactive Material Licensee for Non-Human Use:

1.3 (a) **General Information**: In accepting a license for radioactive material, the licensee acknowledges his/her responsibility to handle radioactivity in accordance with State, Federal and Local regulations and to ensure that sound radiation safety principles are integrated into their laboratory procedures. Furthermore, the licensee shall provide the Office of Radiation Safety Services with access to his/her laboratory facilities, record files, and personnel, the purpose of inspections being to verify that safety requirements are fulfilled.

1.3 (b) **Non-Human Use Licensee Responsibilities**: In addition to any specific license conditions imposed by the Radiation Safety Committee, each licensee is specifically responsible for:

i. Ensuring that he/she and radioisotope users under their supervision have attended the required radiation safety training program.

ii. Providing on-the-job training which addresses the specific hazards associated with the use of radionuclides and handling procedures in the laboratory.

iii. Ensuring that the radiation exposure to himself/herself, individuals under his/her supervision, and to members of the general public, is kept As Low As Reasonably Achievable (ALARA).

iv. Providing appropriate safety devices and equipment to minimize personal radiation exposure, and for ensuring that monitoring and survey instrumentation have a current calibration.

v. Ensuring that they, and individual users under their supervision, have and use personal monitoring devices, and submit for bioanalysis testing at the frequency specified by the Office of Radiation Safety Services.

vi. Performing routine laboratory surveys for contamination and monitoring of radiation levels, following the procedures and frequency specified by the Office of Radiation Safety Services, and whenever contamination or significant changes in the radiation exposure rate are suspected.

vii. Preparing and maintaining records of survey and monitoring results, and acquisition, handling, and final disposition of radioactive material.

viii. Maintaining a file of all correspondence and documents relating to radioactive material use, including copies of their license application, license document, Office of Radiation Safety Services and Radiation Safety Committee memorandums, information notices, and notices of violation.

ix. Implementing emergency actions in the event of a radiation incident, and for immediately reporting all accidents, unauthorized radionuclide removal, unusual radiation exposures, medical events, or known pregnancies to the Office of Radiation Safety Services.

x. Providing back-up supervision when he/she is unable to fulfill their responsibilities as a licensee due to absence.

xi. Instructing the worker in the potential hazards of his/her work as interim training until he/she attends the Radiation Safety Orientation.

2. Radioactive Material Licenses

2.1 General Information:

2.1 (a) Rutgers, The State University of New Jersey, has been issued a Specific Medical License of Broad Scope for use of radioactive materials at the RBHS Newark campus from the New Jersey Department of Environmental Protection (NJDEP). Under the provisions of this license, the issuing agency does not accept applications from researchers for individual licenses but instead requires that individuals apply for authorization from the Radiation Safety Committee to work under the institution's broad scope license. Thus, the Radiation Safety Committee acts as the local responsible agency with RBHS-Newark campus, answerable to NRC and NJDEP.

2.1 (b) In acting on a license application, the Radiation Safety Committee shall adopt the same training, experience, and facilities requirements as is employed by the NRC and NJDEP.

2.2 Application for a Non-Human Use License

2.2 (a) A completed non-human use application must be submitted for acquisition of a new license, renewal of a license about to expire, or for an amendment of an existing license where significant changes in the authorized activities are requested. When an amendment requires only minor changes in the licensed activity, an application may be made in the form of a memorandum detailing the requested changes.

2.2 (b) Application forms for a non-human use license are available from the Office of Radiation Safety Services via download from the website (https://ipo.rutgers.edu/rehs/radioactive-materials-for-nonhuman-use-app), and must be signed by the applicant and submitted to the RSO. During its review, the RSO may request that the applicant provide further information. In this case, all additional statements made by the applicant shall be incorporated as part of the original application.

2.2 (c) Applications submitted to the Office of Radiation Safety Services receive an initial review for clarity and completeness and are then presented to the Licensing Subcommittee for review during its next meeting. Following recommendation for approval by the Licensing Subcommittee, the applicant may begin licensed activities; however, this authorization is contingent upon the application receiving the approval of the Radiation Safety Committee during its next meeting.

2.2 (d) Following its review of a non-human use application, the Licensing Subcommittee will recommend approval provided the following criteria are met:

(i.) The applicant has a faculty appointment to the Rutgers New Jersey Medical School, Rutgers School of Dental Medicine, Rutgers School of Health Professions, or a clinical appointment at University Hospital.

(ii.) The radionuclide(s), possession limit(s), and proposed use(s), contained in the application, are authorized under the institution's State and Federal licenses.

(iii.) The applicant has provided sufficient information to justify the choice of radionuclide(s), possession limit(s), and proposed use(s), described in the application.

(iv.) The applicant possesses adequate training and experience to use the requested radionuclide(s) in such a manner as to protect health and minimize the danger to RBHS or University Hospital property.

(v.) The applicant has attended the required portions of the radiation safety training program presented by the Office of Radiation Safety Services.

(vi.) The Radiation Safety Officer for the radioactive material requested has deemed the applicant's laboratory facilities adequate, and the applicant possesses sufficient safety devices and monitoring equipment to protect health and minimize the danger to RBHS or University Hospital property.

2.2 (e) No non-human use of radioactive materials is permitted until its use and/or uses are approved by the Radiation Safety Committee. Only routine use and/or uses are approved on an interim basis by the Chairperson of the Licensing Subcommittee. The Radiation Safety Committee has established the following criteria for "routine" uses that can be given interim approval:

i Sealed sources - new uses and/or users of self-shielded sources possessed by RBHS can be considered routine.

ii Acquiring new sources in shielded devices requires Radiation Safety Committee approval, both for safety and to consider future disposal problems and costs that may be associated with some sources. Use of unshielded sources (or acquiring the same) requires Radiation Safety Committee approval.

iii Unsealed radioactive materials - new uses of less than ten (10) millicurie quantities can be considered routine if they:

(a.) Do not present radiation safety considerations different than those in "common use", for example: Southern Blots, Northern Blots, Plaque and Colony Lifts, DNA sequencing, Protein Kinase Assays, DNA Typing, Reporter Gene Assays, Translation in vitro Positive control, Cell Proliferation Assays, Cytotoxicity Assays, etc.

(b.) The proposed users have appropriate experience with types and quantities requested.

(c.) If the proposed radioactive materials do not present unusual biohazard (gaseous, aerosol, etc.) or waste problems (mixed waste, very long half-lived isotopes, etc.), or if use would call for an increase in financial assurance requirements.

2.2 (f) Non-human use radioactive material licenses are valid for a period of three (3) years, after which time a new application must be completed and submitted for renewal of the license.

2.2 (g) The Radiation Safety Committee may, at any time after a license has been approved, require statements from the licensee to enable it to determine that deficiencies have been corrected or to decide whether a license should be modified, suspended, or revoked. In this case, all statements and representations made by the licensee shall be incorporated into the original license application.

2.2 (h) Authorization for use of the irradiator shall require submission of an "Application for Authorization to Use Irradiator Unit." The Licensing Subcommittee shall recommend approval of an application, provided the applicant has justified his/her need to have access to the unit and has received the orientation program provided by the Office of Radiation Safety Services covering procedures for safe operation of a sealed source irradiator.

2.2 (i) Non-human use radioactive material licenses are valid for activities performed on the RBHS Newark campus only. This authorization may not be transferred to another institution/license, nor shall a license obtained at another institution be honored at the Newark campus.

2.2 (j) A licensee is required to comply with all pertinent State and Federal regulations and Local policies until such time that their radioactive material license is officially terminated. Termination of a license shall be approved if the following conditions are met:

(i.) The licensee shall provide written communication with the intent of terminating use of radioactive materials to the Radiation Safety Officer.

(ii.) A "Radioactive Material Disposition" form, accounting for all radioactive material received by the licensee, is completed and submitted to the Office of Radiation Safety Services.

(iii.) All radioactive material in the possession of the licensee is surrendered to the Office of Radiation Safety Services, or is physically transferred, with the approval of the Radiation Safety Officer, to an individual licensed to possess the material.

(iv.) The licensee’s laboratory/equipment has been surveyed by the Office of Radiation Safety Services for contamination.

(v.) All contamination shall be removed prior to release as an unrestricted area.

(vi.) The letter of release shall be sent to the licensee and the departmental chairperson.

2.3 Application for a Human Use Radioactive Material License

The Human Use Subcommittee of the RBHS-Newark Radiation Safety Committee undertakes a review of in-house and industry-sponsored human research protocols that involve ionizing radiation. The Human Use Subcommittee does not review Cooperative Group protocols (COG, RTOG, ECOG, NSABP, ACOSOG, and Coalition of National Cancer Cooperative Groups) as these studies have already received an exhaustive peer review by the National Cancer Institute through its Cancer Therapy Evaluation Program (CTEP) Branch. The Human Use Subcommittee defers to the review of cooperative group protocols with respect to patient safety and the definition of standard-of-care for a given clinical indication. Therefore, the Radiation Safety Committee remands such protocols back to the Rutgers-IRB.

2.3 (a) A Human Use License application must be submitted for acquisition of a new license, renewal of an expired license, and for amendment of the authorized procedures contained in an existing license.

2.3 (b) Human use applications are by download from the Office of Radiation Safety Services website (https://ipo.rutgers.edu/rbhs/authorized-users-app). Completed applications, including applicant signature and required addenda, should be emailed to the Radiation Safety Officer.

2.3 (c) The Radiation Safety Officer shall perform an initial review of the application for clarity and completeness and forward the application for review by the Human Use Subcommittee of the Radiation Safety Committee.

2.3 (d) No interim approval shall be issued for human use research protocols.

2.3 (e) The Human Use Subcommittee shall recommend approval of an application by the Radiation Safety Committee, provided the following criteria are met:

i. The applicant is a member of the faculty of Rutgers New Jersey Medical School or Rutgers School of Dental Medicine and satisfies all other requirements for a Human Use License.

ii. The applicant is a physician licensed to practice medicine in the State of New Jersey.

iii. The applicant has a clinical appointment at RBHS or The University Hospital.

iv. The applicant possesses, or has authorized access to, adequate facilities and equipment for the clinical care of patients, protection of health and property, and minimizing radiation exposure.

v. When the application is for authorization to perform uptake, dilution, and/or excretion studies, the applicant has:

1) Obtained certification by The American Board of Nuclear Medicine in nuclear medicine, or The American Board of Radiology in diagnostic radiology or radiology, The American Osteopathic Board of Radiology in radiology or

diagnostic radiology or is certified by a medical specialty board whose certification has been recognized by the US Nuclear Regulatory Commission;

OR

2) Received formal training and experience as follows:

(i.) 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include:

(a.) Laboratory and classroom training that included radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiopharmaceutical chemistry (chemistry of byproduct material for medical use.

AND

(b.) Work experience, under the supervision of a licensed user at a medical institution that included: ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; calibrating instruments used to determine the activity of dosages and performing checks for operation of survey maters; calculating, measuring, and safely preparing patient or human research subject dosages; using administrative controls to prevent medical event; using procedures to contain spilled by product material and using proper decontamination procedures, examination of patients for suitability for radioisotope diagnosis, radiopharmaceutical selection and measurement, radiopharmaceutical administration with appropriate shields, interpretation of test results, and patient follow up;

OR

3) Completed a six-month training program in nuclear medicine which has been approved by the Accreditation Council for Graduate Medical Education and includes the topics listed in 2.3(e) v(2).

vi. When the application is for authorization to perform imaging and/or localization studies, the applicant has:

Met the certification requirements identified in paragraph 2.3(e) v (1) in this section.

OR

(i) Received supervised training and experience in handling prepared radiopharmaceuticals, generators, and reagent kits, and included 700 hours of

training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must be included.

a. Laboratory and classroom training that included radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiopharmaceutical chemistry (chemistry of byproduct material for medical use.

AND

b. Supervised work experience under an authorized licensee at a medical institution that included ordering and inspecting packages of radioactive material, calibration of imaging and survey instrumentation and a dose calibrator, calculating and preparing patient dosages, employing administrative controls to prevent medical events, implementing emergency procedures, generator elution and testing the elute, and preparation of radiopharmaceutical using reagent kits

AND

c. Examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications; Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages; Administering dosages to patients and using syringe radiation shields; Collaborating with the licensee in the interpretation of radioisotope test results; and patient follow-up.

OR

d. Completed a six-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and covers the topics covered in paragraphs 2.3 (e) vi (1) of this section.

vii. When the application is for the therapeutic use of radiopharmaceuticals (written directive required), the applicant has:

(1) Obtained certification by The American Board of Nuclear Medicine, or The American Board of Radiology in radiology or therapeutic radiology or The American Osteopathic Board of Radiology in radiology.

OR

(2) Received supervised training and experience in the techniques applicable to the therapeutic use of radiopharmaceuticals that included 80 hours of classroom and laboratory training covering the items listed in paragraph 2.3(e)v(2) of this section.

AND

(3) Received supervised clinical training under an authorized licensee at a medical institution that included the use of iodine-131 for the diagnosis of thyroid function and treatment of hyperthyroidism or cardiac dysfunction in ten (10) individuals, and treatment of thyroid carcinoma in three (3) individuals.

viii. When the application is for the use of iodine-131 for treatment of hyperthyroidism only, the applicant has:

(1) Obtained special experience in the treatment of thyroid disease and has received supervised training and experience that included 80 hours of classroom and laboratory instruction covering the topics listed in paragraph 2.3(e)v(2) of this section.

(2) Supervised clinical experience under an authorized licensee at a medical institution that includes the use of iodine-131 for the diagnosis of thyroid function and treatment of hyperthyroidism in ten (10) individuals.

ix. When the application is for iodine-131 for the treatment of thyroid carcinoma only, the applicant has:

(1) Obtained special experience in the treatment of thyroid disease and has received supervised training and experience that included 80 hours of classroom and laboratory instruction covering the topics listed in paragraph 2.3(e)v(2) of this section.

AND

(2) Received supervised clinical experience under an authorized licensee at a medical institution that included the use of iodine-131 for the treatment of thyroid carcinoma in three (3) individuals.

x. When the application is for the use of sealed sources for brachytherapy, the applicant has:

(1) Obtained certification from The American Board of Radiology in radiology oncology or therapeutic radiology, or The American Osteopathic Board in radiation oncology, in radiology with specialization in radiotherapy.

OR

(2) Been in the active practice of therapeutic radiology and has received supervised training and experience that included 200 hours of classroom and laboratory training covering the topics identified in paragraph 2.3(e)v(2) of this section.

AND

(3) Received 500 hours of supervised clinical training under an authorized licensee at a medical institution that included:

(i) Ordering and inspecting radioisotope shipments.

(ii) Testing survey meters for proper operation.

(iii) Preparation and implantation, and removal of sealed sources.

(iv) Inventory maintenance of sources.

(v) Use of administrative controls to prevent medical events.

(vi) Implementing emergency procedures; and

(4) Obtained three years of supervised clinical experience that included one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of The American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized licensee at a medical institution that included:

(i) Examination of patients and determination of their suitability for brachytherapy treatment and any limitations or contraindications.

(ii) Selection of brachytherapy sources, dosage, and method of administration.

(iii) Dose calculations.

AND

(iv) Post-administration follow-up and review of case histories in collaboration with the authorized licensee.

xi. When the application is for the use of ophthalmic procedures, the applicant has:

(1) Been active in the practice of therapeutic radiology or ophthalmology and has received supervised training and experience that included 24 hours of classroom and laboratory training covering the topics listed in paragraph 2.3(e)v(2) of this section.

(2) Received supervised clinical training in ophthalmic radiotherapy under an authorized licensee at a medical institution that included examination of patients to determine their suitability for treatment, calculation of dose, patient follow up and interpretation of results.

xii. When the application is for use of sealed sources for diagnosis, the applicant has:

(1) Obtained certification from The American Board of Nuclear Medicine in nuclear medicine, or The American Board of Radiology in radiology, diagnostic radiology, or therapeutic radiology, or The American Osteopathic Board in radiology or diagnostic radiology.

(2) Received 8 hours of classroom and laboratory training covering the topics listed in paragraph 2.3 (e) v (2) of this section in addition to special training in the use of the device for the uses requested.

xiii. (Reserved for teletherapy training requirements)

2.3 (f) The applicant must furnish evidence of having obtained the board certification required for the human use procedure requested or must furnish a preceptor statement completed and signed by the authorized licensee under whom training and clinical experience were gained.

2.3 (g) Human use licenses are active for three (3) years, at which time renewal shall require submission of a renewal license application. New licenses out of cycle will be issued for less than three years, so that they only extend to the upcoming cycle date. NJMS and UH appointments are required for renewal. Licenses are contingent upon maintenance of NJ state medical licenses and specialty board certifications. Licensees must report status changes in NJMS and UH appointments, and specialty board certifications to the RSO immediately.

2.4 Registration to perform In-Vitro Clinical Assays Using Radioactive Material

2.4 (a) A "Registration for In-Vitro Clinical use of Radioisotopes Under NRC General License" must be submitted for acquisition of a new license, or renewal of an expired license, to perform routine in-vitro tests for clinical purposes.

2.4 (b) Registration forms are available from the Office of Radiation Safety Services website (https://ipo.rutgers.edu/rbhs/authorized-users-app). Completed registration forms should be signed by the applicant and emailed to the Radiation Safety Officer.

2.4 (c) The Radiation Safety Officer shall perform an initial review of the registration form for Diagnostic Tests clarity and completeness and forward it to the Human Use Subcommittee. The Human Use Subcommittee must approve the Registration form before it is presented for action by the Radiation Safety Committee.

2.4 (d) The Human Use Subcommittee shall recommend approval of the registration form by the Radiation Safety Committee, provided that the following criteria are met:

i. The applicant is a physician licensed to practice medicine in the State of New Jersey.

ii. The applicant has a clinical appointment at Rutgers New Jersey Medical School and/or University Hospital.

iii. The applicant is Board Certified in clinical pathology and satisfies all other requirements for a Human Use license.

iv. The applicant possesses, or has authorized access to, adequate facilities and equipment to perform the in-vitro procedures listed in the registration form, following instructions provided in the manufacturer's package insert.

2.4 (e) Authorization to perform in-vitro clinical tests are active for three years, at which time renewal shall require submission of a new registration form.

2.5 Training for Authorized Medical Physicist

2.5 (a) The authorized medical physicist shall be an individual who is a certified by the American Board of Radiology in therapeutic radiology physics; Roentgen ray and gamma ray physics; X-ray and radium physics; or radiological physics or is certified by the American Board of Medical Physics in radiation oncology physics; or holds a master's or doctor's degree in physics, biophysics, radiological physics and an additional year of full time work experience under the supervision of a medical physicist at a medical institution.

3. Authorized Uses of Radioactive Material

3.1 Non-Human Use Radioactive Material License

3.1 (a) Radioactive materials obtained under a non-human use license shall only be used for research and development and teaching purposes.

3.1 (b) The licensee shall limit the use of radioactive materials to only those purposes authorized in his/her license and in such a manner as to maintain compliance with the conditions specified in the license.

3.1 (c) Radioactive material shall not be used on humans and shall not be used for in-vitro tests to obtain diagnostic medical information for use in the treatment of human subjects.

3.1 (d) Radioactive material shall only be used by the licensee and those individuals under his/her supervision who are designated authorized users. To qualify as an authorized user, the individual must meet the following conditions:

i. The individual shall be an RBHS or University Hospital employee or student or shall have an official appointment to the RBHS or University Hospital staff.

ii. The individual shall have been designated as an authorized user on the licensee's non-human use license application or an amendment request.

iii. The individual shall have attended the training program provided by the Office of Radiation Safety Services.

iv. The individual shall have received on-the-job training from the licensee covering the specific procedures and attendant hazards associated with the work to be performed.

3.1 (e) An Authorized User who does not possess any radioactive materials or radioactive waste and has not ordered radioactive material within the last 12 months shall be placed on inactive status. The License may be reactivated following the Radiation Safety Committee approval of a written request submitted by the Licensee.

1. If a licensee does not reactivate their license within 24 months, the license is subject to termination. If the license is terminated, the faculty member may reapply by filling out a standard radioactive materials license application and obtaining approval from the Radiation Safety Committee.
2. During the inactive status of the RAM license, ORSS will not conduct regular inspections of that lab, and the licensee need not maintain wipe test records.
3. Before being placed on inactive status, all RAM material must be transferred from the lab to ORSS.

3.2 Human Use of Radioactive Material License

3.2 (a) Radioactive material obtained under a human use license shall only be used for those clinical procedures authorized in the license and in such a manner as to maintain compliance with the conditions specified in the license.

3.2 (b) Only a physician, acting within the limitations of the procedures specified in his/her human use license, is authorized to determine that the administration of radioactive material to a patient is appropriate.

(i) Advance Practice Nurses (APN) are authorized to request diagnostic nuclear medicine radiopharmaceutical procedures within the scope of the Collaborative Practice Agreement (CPA) between each APN and the Collaborating Physician (CP). As per this CPA agreement APN and CP have agreed to work collaboratively to render health care services pursuant to N.J.S.A. 45:11-49 and N.J.A.C. 13:35-6.6 and N.J.A.C. 13:37-6.3. However, only an authorized nuclear medicine physician can prescribe these procedures. There is no such agreement between Physician Assistant (PA) and CP Hence, PAs are not authorized to request studies involving radiopharmaceuticals.

3.2 (c) The licensee shall determine what radiopharmaceutical, dosage level, and mode of administration shall be used for the patient. In addition, the prescribing physician shall receive the images or results of the procedure and make the ultimate interpretation regarding the diagnostic information obtained or the effectiveness of therapy.

3.2 (d) The licensee shall maintain a written directive (WD) to provide high confidence that radioactive material or radiation from radioactive material will be administered as prescribed. The WD forms are available at the Office of Radiation Safety Services.

3.2 (e) For preparations containing iodine-131, the licensee may not prescribe administration of a radiopharmaceutical containing iodine-131 for diagnosis or any therapeutic dosage of unsealed by product material, or any therapeutic dose of radiation from byproduct material without personally examining the patient and the patient's chart, consulting with the referring physician if reasonably available, and preparing a written directive for the material which includes the patient's name, radiopharmaceutical to be administered, dosage, and route of administration.

3.2 (f) Under a license to perform uptake, dilution, and excretion studies, the licensee is authorized to use:

i. Any byproduct material in a radiopharmaceutical for which the FDA has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA) for this purpose.

OR

ii. Any radionuclide which is described for this purpose in a protocol for medical research which has been approved by the Radiation Safety Committee and the Rutgers Institutional Review Board (IRB), and on which the licensee is named as an authorized user.

3.2 (g) Under a license to perform imaging and localization studies, the licensee is:

i. Authorized to use any byproduct material in a diagnostic radiopharmaceutical or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical for which the FDA has accepted an IND or approved NDA.

OR

ii. Authorized to use any radiopharmaceutical listed in NJSL 70033-01 for this purpose.

OR

iii. Authorized to use any radionuclide described in a protocol for medical research approved by the Radiation Safety Committee and Rutgers-IRB and on which the licensee is named as an authorized user.

iv. Required to obtain approval from the Radiation Safety Committee and Rutgers-IRB for the use of any FDA-approved drug for unapproved application and/or for any departure from the manufacturer's instructions for eluting generators and preparing reagent kits.

3.2 (h) Under a license to use radiopharmaceuticals for therapy, the licensee is authorized to use:

i. Any byproduct material in a radiopharmaceutical for a therapeutic use for which the FDA has accepted an IND or approved NDA.

OR

ii. Any radionuclide for use in therapy as described in a protocol for medical research which has been approved by the Radiation Safety Committee and the Rutgers-IRB, and on which the licensee has been named as an authorized user.

iii. The licensee shall comply with the package insert instructions regarding indications and method of administration.

3.2 (i) Under a license to perform brachytherapy, the licensee is authorized to use any of the following sources for the purpose identified:

i. Cesium-137 as a sealed source in needles or applicator cells for topical, interstitial, and intracavitary treatment of cancer.

ii. Cobalt-60 as a sealed source in needles or applicator cells for topical, intracavitary, and interstitial cancer treatment.

iii. Gold-198 as a sealed source in seeds for interstitial treatment of cancer.

iv. Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer.

v. Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions.

vi. Iodine-125 as a sealed source in seeds for interstitial treatment of cancer.

vii. Palladium-103 as a sealed source in seeds for interstitial treatment of cancer; The department must maintain copies of X-ray images of the patient after seed implantations to ensure proper seed placement.

AND

viii. Use of any other byproduct material or radiation source approved for medical use by the NRC and FDA.

3.2 (j) Radioactive material for diagnostic studies shall only be administered to patients by the licensee or an authorized user under the supervision of the licensee and who is administering the material under an order or prescription issued by the licensee. To qualify as an authorized user in diagnostic procedures, an individual must meet the following criteria:

i. The individual is an employee of, or has an official staff appointment to RBHS or University Hospital; and

ii. The individual is a physician licensed to perform the diagnostic procedure being performed or, is a nuclear medicine technologist possessing a license issued by the State of New Jersey to practice nuclear medicine technology; or

iii. The individual is a physician enrolled in a residency program in radiology, or is a student enrolled in an accredited teaching program in radiologic or nuclear medicine technology, and who is administering the radioactive material under the direct supervision of a physician licensed to perform the procedure or a certified nuclear medicine technologist; or

iv. The individual is a physician who, for clinical reasons, has been requested to assist in the administration, and who is administering the radioactive material under the direct supervision of an individual who is otherwise authorized to perform the procedure.

3.2 (k) Radioactive material for use in a therapy procedure shall only be administered by a physician licensed by the Radiation Safety Committee to perform the procedure. A licensed nuclear medicine technologist may prepare a radiopharmaceutical for therapy under the direction of the licensed physician; however, the physician must personally assay the dosage and administer the material.

3.3 Authorized Use in a Human Use Research Protocol

3.3 (a) Radioactive material for use in a medical research protocol, which has been approved by the Radiation Safety Committee and Rutgers-IRB, shall meet the following specifications:

i. The radiopharmaceutical shall be prepared following the method described in the protocol application and shall have passed all quality control tests contained in the protocol.

OR

ii. Radioactive material shall be received as a radiopharmaceutical that has been manufactured, labeled, and packaged by a supplier having a State or Federal license to manufacture or distribute radiopharmaceuticals.

3.3 (b) Radioactive materials shall be used in such a manner as to maintain compliance with all conditions and limitations either written or explained in the approved protocol application, including labeled material(s) to be administered, selection criteria, absorbed dose, radiopharmaceutical dosage schedule, and mode of administration.

3.3 (c) Radioactive material shall only be administered to or used for humans by those individuals designated on the approved protocol application whose human use license authorizes them to perform the designated procedures.

3.3 (d) Unless specifically exempted, radioactive material shall be used in compliance with the provisions contained in Section 3.2 "Human Use of Radioactive Material License", in this Chapter, and the provisions contained in Chapter 5, "Special Requirements for Medical Use of Radioactive Material".

4. Radiation Safety Requirements

4.1 General Information:

4.1 (a) The local policies outlined in this section have been established to restrict the use of radioactive material in such a manner as to maintain the radiation exposure to RBHS and University Hospital personnel and the general public As Low As Reasonably Achievable (ALARA), to minimize the danger to property and the environment, and to ensure compliance with all applicable State and Federal regulatory codes.

4.1 (b) Each user of ionizing radiation, whether a licensee or an individual working under the authority of a licensee, shall ensure that they shall not possess or handle radioactive materials unless all applicable provisions of this chapter are met.

4.2 Restricted and Unrestricted Areas

4.2 (a) A restricted area is defined as any location in which there is a likelihood of an individual:

i. Receiving a 2 millirem (0.02 mSv) (external) whole body deep dose in one hour of continuous exposure.

OR

ii. Receiving a 100 millirem (1 mSv) (external) whole body deep dose in any seven (7) consecutive days of continuous exposure.

OR

iii. Receiving 500 millirem (5 mSv) in one year from the sum of the (external) deep dose and the (internal) committed effective dose equivalent.

OR

iv. Being exposed to radioactive material in concentrations over the limits given in Appendix B to 20.1001-2402 of 10 CFR Part 20 and columns C and D of Section 6.5 of NJAC Title 7.

4.2 (b) An unrestricted area is any location in which there is no reasonable likelihood of an individual being exposed to the limits identified in paragraph 4.2 (a) of this section.

4.2 (c) Each licensee shall take appropriate steps to limit the access to the restricted area under their supervision so that only authorized individuals, using a personal radiation monitoring device (when required), may enter.

4.2 (d) Areas used for shipping, receiving, or transporting radioactive material packaged in accordance with State and Federal DOT regulations are exempt from the requirements for a restricted area.

4.3 Permissible Limits of Radiation Exposure

4.3 (a) Radioactive material shall be stored and handled in a manner so that no member of the general public receives a total effective dose equivalent (radiation dose) in excess of 0.1 rem

(1mSv) per year resulting from the sum of the (external) whole body dose equivalent and the (internal) committed effective dose equivalent. This limit shall apply if a licensee allows access to a restricted area by a member of the general public.

4.3 (b) Radioactive materials shall be stored and handled in a manner so that no individual occupationally exposed receives a radiation dose above the following rem limits, where rem is defined as the RAD dose multiplied by a quality factor. (The quality factor for beta particles of energies below 0.05 keV is 1.7, the quality factor for all other beta particles, gamma rays, and X-rays is 1.0)

i. The annual dose limit shall be the more limiting of:

(1) The sum of the (external) whole body deep dose equivalent and the (internal) committed effective dose equivalent is equal to 5 rems (0.05 Sv).

OR

(2) The sum of the (external) deep dose equivalent and the (internal) committed dose equivalent is equal to 50 rems (0.5 Sv) to an organ or tissue other than the lens of the eye.

ii. The dose equivalent limit to the lens of the eye, to the skin, and the extremities shall be as follows:

(1) An annual dose equivalent to the lens of the eye of 15 rems (0.15 Sv).

(2) An annual dose equivalent to the skin and each of the extremities of 50 rems (0.5 Sv) (this limit applies to a dose equivalent averaged over an area of 10 square centimeters in the region of highest exposure).

iii. The quarterly whole body external deep dose component of the annual effective dose equivalent limit listed in 4.3 (b) i, above, shall not exceed 2 rem (0.02 Sv).

4.3 (c) If an individual receives an exposure which exceeds the 2 rem (0.02 Sv) quarterly limit, but does not exceed the 5 rem (0.05 Sv) annual limit, then the licensee shall limit further exposure to the individual such that the 5 rem (0.05 Sv) annual limit is not exceeded.

4.3 (d) If an individual receives a dose that exceeds the annual 5 rem (0.05 Sv) dose limit the licensee shall not assign that person to any task in which there is a likelihood of any additional occupational exposure.

4.3 (e) The licensee shall not assign an individual to a task that is expected to result in any of the following situations:

i. Ingestion of radioactive material in excess of 10% of the Allowable Limit of Intake (ALI);

ii. Exposure to airborne concentrations of radioactive material in excess of 10% of the Derived Air Concentration (DAC);

iii. Exposure to concentrations of radioactive material in excess of 10% of the Maximum Permissible Average Concentrations (MPAC) in Air and Water;

iv. Minors and declared pregnant individuals likely to receive, in one (1) year, a committed effective dose equivalent in excess of 0.05 rem (0.5 mSv);

(ALI and DAC limits are established by the NRC, MPAC limits are established by the New Jersey Department of Environmental Protection. MPAC values for occupational exposures are listed Appendix A)

4.3 (f) The following restrictions shall apply to the radiation exposure of declared pregnant employees.

i. The pregnant employee shall notify their supervisor of the pregnancy. The supervisor shall, in turn notify the Radiation Safety Officer.

ii. The absorbed dose to the embryo/fetus shall be limited to no more than 0.5 rem (5 mSv) during the entire gestation period.

iii. The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant employee so as to satisfy the 0.5 rem (5 mSv) limit.

iv. The Radiation Safety Officer shall determine whether there is a likelihood of the embryo/ fetus receiving the 0.5 rem (5 mSv) limit. If this possibility exists, then the individual shall be assigned tasks that require significantly less or no radiation exposure. At their request, the employee may continue to be assigned the same tasks; however, the frequency of TLD badge exchanges shall be increased to twice a month. If the fetus dosimeter (FS) readings indicate that the 0.5 rem limit may be exceeded, the employee shall be removed from their presently assigned tasks and assigned responsibilities that involve significantly less or no radiation exposure.

v. The dose to the embryo/fetus shall be taken as the sum of:

(1) The deep dose equivalent to the declared pregnant individual; and

(2) The dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant individual.

4.3 (g) Radioactive material shall be stored and handled in a manner such that no minor or declared pregnant individual shall be exposed to a radiation dose in excess of 10% of the annual dose limits specified in 4.3 (b) and (e).

4.4 Personal Monitoring Requirements

4.4 (a) Trans-Luminescence-Dosimeter (TLD)[1] for monitoring of whole-body radiation doses, the Office of Radiation Safety Services shall issue them to individuals specified in the following categories:

[1] The dosimeters are "APex™", Optically Stimulated Luminescence of Beryllium Oxide type, but are generally referred to as TLD for simplicity of terminology in this manual. APex™ is a proprietary name for a brand of dosimeters manufactured by Mirion Technologies.

i. Each individual assigned to work in, or frequently, a restricted area where a source of penetrating radiation is present, and who may be exposed under circumstances where they may receive a whole-body radiation dose in excess of 25 millirem in any seven (7) consecutive days, or in excess of 500 millirem in one year.

ii. Everyone enters a high radiation area.

iii. Each minor may enter a restricted area.

iv. Each visitor who enters an area posted with a "Caution Radiation Area" sign.

v. Any RBHS or University Hospital employee who sincerely believes that he/she is being exposed to levels of radiation that are significantly above background.

4.4 (b) Individuals assigned to handle sources of penetrating radiation shall be issued finger (ring) monitors to determine the absorbed dose to the hands.

4.4 (c) The Office of Radiation Safety Services shall provide auxiliary monitoring devices, including direct reading dosimeters, to any individual where the absorbed dose to a body part may not be adequately defined by the readings obtained with a TLD badge or finger monitor.

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

4.4 (e) Other individuals who are exposed to radiation on an occasional basis, such as security personnel who deliver packages, secretarial personnel, and nurses who occasionally care for patients who have received diagnostic nuclear medicine dosages, will not normally be issued exposure monitors.

4.4 (f) Personnel dosimeters and/or finger monitors shall be exchanged on a frequency determined by the RSO in consultation with the Radiation Safety Committee.

4.4 (g) All UH Radiology/Cardiology or any high-call list staff and authorized irradiator personnel will receive monthly/quarterly dosimeters as determined by the RSO. All nursing staff and RSDM personnel will receive quarterly dosimeters. All area monitors are installed quarterly. Residents and outside vendors rotating in must request dosimeters through their home institutions. All previously issued dosimeters must be returned promptly to the Office of Radiation Safety Services upon delivery of new dosimeters.

4.4 (h) Each individual who is issued a personal monitor/dosimeter shall ensure that:

i. A personal monitor intended to measure whole body exposure is worn on the trunk of the body, e.g., on the collar, chest pocket, or belt loop.

ii. A finger monitor is worn on the tip of the finger (under the protective glove) on the hand most frequently used to handle radioactive material.

iii. They only wear the personal monitor(s) assigned to them by the Office of Radiation Safety Services.

iv. They immediately notify the Office of Radiation Safety Service when a personal monitor is lost, or if it is suspected that a monitor has become contaminated or damaged; and

v. They protect monitors against exposure to high heat or humidity, and do not remove the monitors from the Newark campus.

4.4 (i) Personal monitors are issued to determine an individual's occupational exposure only. Monitors shall not be worn by an employee receiving a medical examination or treatment involving ionizing radiation.

4.4 (j) It is the responsibility of each licensee to ensure that individuals under his/her supervision are provided with personal monitors; as a consequence, the licensee shall bear the cost of this service.

4.4 (k) Thyroid Monitoring requirements:

a. Everyone who handles radioiodine in a dispersible (liquid) form shall perform a thyroid bioassay within 24 to 72 hours post iodination or administration, in accordance with the provisions of NRC NUREG-1556, Vol. 9 and NRC Regulatory Guide 8.2. If the 72-hour period falls during a weekend or holiday, the bioassay shall be performed during the individual's next working day. Unless otherwise authorized, thyroid bioassay shall be performed at the University Hospital Nuclear Medicine section or at the Office of Radiation Safety Services.

i. For 1-131 sodium iodide therapy treatments in capsule form, bioassays will only be performed within 72 hours of administration if there is an accident during administration (capsule breaks, patient vomits, etc.). Monthly bioassay uptake measurements for all personnel in the Division of Nuclear Medicine will be used to monitor exposure of personnel conducting capsule treatments, and results will be submitted to the RSC in the form of ALARA reports at quarterly meetings.

ii. Unless otherwise authorized, thyroid bioassay shall be performed at the University Hospital Nuclear Medicine section or at the Office of Radiation Safety Services.

iii. Nuclear Medicine Physicians, Technologists, or Residents who have handled or administered radioiodine within a given calendar month shall receive a thyroid bioassay after the administration and within the same calendar month.

iv. Any individual may request a bioassay anytime.

v. The Radiation Safety Officer or designee may mandate a thyroid bioassay anytime, if deemed necessary.

4.4 (l) When an uptake measurement yields positive results, the Radiation Safety Officer shall immediately calculate the resulting committed radiation dose to the thyroid and initiate an investigation to determine the route of internalization.

4.4 (m) Each individual who is exposed under circumstances that may result in an internalization of radioactive material over 10% of the Allowable Limit of Intake (ALI) listed in Appendix B of 10 CFR Part 20, or who is using respiratory filters to limit their intake of radioactive material, shall submit urine specimens for the purpose of bioanalysis for internalized radionuclides. The frequency for submission of urine specimens is based on the type of radioisotope used and the amount (activity) handled in one day. Any individual who has used:

i. P-32 $\geq$ 200 uCi (0.2 mCi);

OR

ii. C-14 $\geq$ 200 uCi (0.2 mCi).

OR

iii. H-3 $\geq$ 1000 uCi (1.0 mCi).

OR

iv. Cr-51 $\geq$ 1000 uCi (1.0 mCi).

OR

v. any other isotopes other than those listed above $\geq$ 1/3 the Allowable Limit of Intake (ALI); should submit a urine specimen to the Office of Radiation Safety Services within 48 hours after use of the radionuclides listed in this section.

4.4 (n) The individual user shall provide the urine sample in a specimen container issued by the Office of Radiation Safety Services. The container shall be labeled with the user's name and the date the specimen was obtained. Specimens should be submitted within 48 hours of the use of specific radionuclides listed in this part.

4.4 (o) When urinalysis yields positive results, the Office of Radiation Safety Services shall immediately determine the radionuclide(s) present and initiate an investigation to determine the total activity and route of internalization and shall calculate the resulting committed organ doses.

4.5 Acquisition of Radioactive Material

4.5 (a) All acquisitions of radioactive materials, whether through purchase or transfer from another authorized licensee, shall be arranged through the Office of Radiation Safety Services.

4.5 (b) All requisitions for the purchase of radioactive material must be approved by the Office of Radiation Safety Services before the purchasing department issue a purchase order number. The Office of Radiation Safety Services will approve a purchase requisition provided that:

i. The requisitioner has an active license issued by the Radiation Safety Committee, which covers the radionuclide(s) and the chemical and physical forms requisitioned.

ii. Acquisition of the radioactive material will not result in the RBHS exceeding the possession limits specified in its State or Federal license and will not result in the licensee exceeding the possession limit specified in his/her institutional license; and

iii. The requisition contains the following information:

(1) The shipping instructions specifies the licensee's name and the notation "in care of the Office of Radiation Safety Services - Medical Science Building Room A679," and the complete address of the RBHS Newark campus, and the licensees at ICPH must specify the shipping address as “in care of the Office of Radiation Services – ICPH Room W 130 W, “and the complete address of the ICPH.

(2) The radionuclide, chemical form, and activity to be purchased.

(3) The vendor and catalog number.

(4) The requested delivery date.

(5) Requisitions for standing orders of radioactive material will be approved by the Office of Radiation Safety Services provided that the requisition indicates an anticipated delivery schedule and number of shipments for each radionuclide, and the licensee confirms that prior shipments are depleted (i.e., have been disposed of) before a new shipment is received. Standing orders will not be approved for low dose-rate (LDR) brachytherapy seeds. Blanket approvals to order RAM for Nuclear Medicine, PET/CT and Radiation Oncology (HDR source only) are permitted, as they are tracked by the Office of Radiation Safety staff immediately upon arrival.

4.5 (c) Acquisition of radioactive material through transfer from another licensee, either inside or outside the institution, will be approved by the Office of Radiation Safety Services, provided that the conditions identified in 4.5 (b) i and 4.5 (b) ii are met. If the radioactive material is to be received from a licensee outside the institution, then the shipping instruction provided to the sender shall conform to those described in 4.5 (b) iii (1), above.

4.5 (d) Licensees may not directly receive a shipment of radioactive material unless written authorization is received from the Office of Radiation Safety Services. Incoming shipments of radioactive material shall be routed directly to the Office of Radiation Safety Services, where they will be logged into a master inventory record and inspected for integrity, radiation levels, and proper labeling before being released to the licensee. When the licensee has written authorization to directly receive packages, then he/she shall be required to inspect the shipment following the procedures provided by the Office of Radiation Safety Services, and to notify the Office of Radiation Safety Services that the shipment has been received.

4.5 (e) Once under the control of the licensee, radioactive material shall be secured in such a manner as to prevent unauthorized access or accidental exposure to the radioactive material, shall be locked in a cabinet, refrigerator, or freezer, or locked box which is attached to the refrigerator or freezer to which only the licensee, and individuals authorized to handle the material, possess a key. Laboratories containing radioactive material shall be locked when the licensee or a designated user is not present. It is the statutory responsibility of the authorized users to guarantee that radioactive material under their license is secured at all times.

4.6 Disposal of Radioactive Material

4.6 (a) Disposal of radioactive material shall be arranged through the Office of Radiation Safety Services. Unless authorization is obtained to do otherwise, licensees shall transfer all of their radioactive waste to the radioactive waste room located in Room A 665 of the Medical Science

Building, or Room EB40T at International Center for Public Health where long lived wastes will be processed and packaged in accordance with the requirements of the licensed low level radioactive waste (burial) site, the transport broker, and State and Federal DOT regulations. Short-lived waste shall be held for decay following the procedure described in 4.6 (c), below.

4.6 (b) The Office of Radiation Safety Services will continue to be the point of receipt for all types of radioactive waste for disposal or interim storage, provided the following conditions are met:

i. Radioactive waste shall be pre-segregated into the following categories:

(1) Dry Solid Material (DSM) - which contains no pourable liquids or biological tissues or fluids of any kind.

(2) Large Volume Aqueous Liquids - which consist of containers having a volume in excess of 50 milliliters of aqueous, non-corrosive fluid.

(3) Small Volume Aqueous Liquids - which consist of containers having a volume of less than 50 milliliters of aqueous fluid.

(4) Scintillation Vials Exempt - which consists of vials containing liquid scintillation fluid with tritium and/or carbon-14 in concentrations exceeding 0.005 microcuries (μCi) per milliliter (ml) but less than regulated threshold levels.

(5) Scintillation Vials Regulated - which consists of vials containing liquid scintillation fluid concentrations exceeding with tritium and/or carbon-14 in 0.05 microcuries per milliliter, or any other radionuclide in concentrations of 0.002 microcuries per milliliter (4,440 dpm/ml).

AND

(6) Biological Materials - which consist of animal carcasses, tissue, and fluids.

ii. Each category of waste is marked with radionuclide, activity content, date, and licensee's name.

iii. The radiation exposure rate on the surface of the waste package does not exceed 200 mR/hr.

iv. The radioactive waste is accompanied by a signed requisition indicating to which account the disposal cost should be charged.

v. The radioactive waste is brought for processing and packaging during the specified hours of operation of the radioactive waste room.

4.6 (c) Storage of radioactive materials for decay shall only be performed at the radioactive waste room under the control of the Office of Radiation Safety Services. Short-lived radioactive waste shall be stored for a minimum of ten half-lives and be free of detectable radioactivity when monitored using a thin window GM survey meter before it is released as normal trash.

4.6 (d) The Office of Radiation Safety Services shall accept waste for storage for decay, provided that the following conditions are met:

i. The radionuclide(s) have a half-life of less than 120 days.

ii. Each package of radioactive material contains only one radionuclide.

iii. The radiation exposure rate on the surface of the package does not exceed 5 mR/hr.

iv. The radioactive material is double bagged and has a permanent label indicating the radionuclide contained, activity, date, and licensee's name.

v. All radioactive warning labels must be defaced or removed prior to disposal for decay. (no radioactive labels inside the bag).

vi. Radioactive waste is brought to the radioactive waste room for storage during the specified hours of operation.

4.6 (e) Short-lived radioactive waste may not be held for decay in the user's laboratories.

4.6 (f) No licensee shall dispose, or allow to be disposed, any radioactive material through release with normal trash.

4.6 (g) All disposable items used during radioactive procedures shall be monitored for contamination before disposal as normal trash: Be especially careful to monitor items such as animal bedding, pipette tips, and reaction vials.

a) Radioactive warning labels must be removed or defaced prior to disposal as normal trash.

4.6 (h) Radioactive waste storage containers in laboratories shall be conspicuously posted with a radioactive materials warning sign and a worded warning to housekeeping personnel not to remove the waste.

4.6 (i) Disposal of radioactive material into the sanitary sewer system shall not be performed; however, the licensee may wash labware (glass, plasticware, etc.). The Office of Radiation Safety Services shall provide containers to collect liquid waste.

4.6 (j) Liquid radioactive waste shall be picked up by the Office of Radiation Safety Services provided the following criteria are met:

i. The radioactive compound is readily soluble (or is readily dispersible biological material) in water.

ii. The liquid waste is non-toxic.

iii. Each radionuclide is maintained in a separate container and separated as short-lived and long-lived liquid waste; and

iv. All liquid waste containers are labeled with tags provided by the Office of Radiation Safety Services. The tag must list the following information:

(1) Name of licensee.

(2) Isotope.

(3) Amount (microcuries).

(4) Chemical form (on reverse side of tag); and

(5) Date of pick-up.

4.7 Licensee Facility Requirements

4.7 (a) Radioactive material shall only be used and stored in those areas designated in the licensee's approved radioactive material application.

4.7 (b) The Radiation Safety Committee shall not approve a radioactive material license application until the Radiation Safety Officer has inspected the applicant's laboratory facilities and determined that the following minimum requirements are met:

i. All work surfaces shall be constructed of smooth, non-porous material (such as stainless steel or alberene stone) which is resistant to absorption of, or reactions with radioactive compounds.

ii. Sinks used for decontamination or disposal of radioactive material shall be lined with a smooth, non-porous material.

iii. When required at the discretion of the Radiation Safety Officer, a fume hood shall be present, which is located away from windows, doors, and ventilation outlets. All airflow lines shall be directed into the hood with a minimum velocity of 100 linear feet per minute at the face with the sash fully open. The walls of the hood shall be smooth and non-porous, and resistant to absorption of, or reaction with, radioactive materials. The floor of the hood shall be sufficiently strong to support lead shielding when required.

iv. There shall be means of securing access to the room whenever no authorized users are present.

v. Refrigerators, freezers, and cabinets used for storage of radioactive material shall be lockable to prevent unauthorized access.

vi. The radiation exposure rate in unrestricted areas adjacent to the laboratory facility shall be less than 0.5 mR per hour with the proposed radionuclide(s) and activity(s) fully unshielded at the proposed work locations within the lab.

vii. Appropriate shielding to use radioactive materials (lucite for beta emitters, lead for gamma emitters) shall be available.

viii. The laboratory shall be equipped with remote handling devices such as pipettes, tongs, etc.,

AND

ix. If storing radioactive material in a locked box, the locked box must be fitted to the inside of a refrigerator, freezer, or cabinet.

4.7 (c) In addition to the laboratory specifications identified in paragraph 4.7 (b) above, the Radiation Safety Committee may impose other requirements, before or after a licensee's application is approved, to ensure that health and environmental safety are maintained.

4.8 Resources and Equipment Requirements

4.8 (a) The Radiation Safety Committee shall not approve an application for a radioactive material license until the Radiation Safety Officer determines that the applicant, as a minimum, possesses the appropriate safety resources and equipment to satisfy the following requirements:

i. Each licensee shall maintain a supply of disposable protective gloves and shall provide protective laboratory coats.

ii. Each licensee possesses mechanical pipettors for transferring radioactive solutions.

iii. Each licensee shall maintain a supply of waterproof-backed absorbent paper to protect large surfaces against contamination, and splash trays of adequate size to protect against spills when large volumes of radioactive solutions are handled.

iv. Each licensee authorized to use sources of penetrating photon or high-energy beta radiation shall possess remote handling devices of appropriate design and of such diversity as to preclude the necessity of handling unshielded sources with the hands.

v. Each licensee authorized to use phosphorus-32, strontium-90/yttrium-90, or other sources of high-energy beta radiation shall possess a plexiglass (or lucite, etc.) shield with a minimum thickness of 0.5 inches or 1.25 centimeters, and of a size sufficient to protect the body and head of the worker.

vi. Each licensee authorized to use sources of penetrating photon radiation shall possess lead shields of appropriate design and of such diversity to individually shield each source greater than 10 microcuries or shall possess lead blocks and/or sheets to construct a "cave" or similar concept to shield sources. Licensees who routinely use millicurie amounts of photon emitters shall possess an "L-block" shield with a lead glass view window to protect the body and head of the worker.

vii. Each licensee authorized to use millicurie quantities of penetrating radiation shall possess a GM survey meter having a probe with a window sufficiently thin to allow detection of the radiation emitted by the source(s).

viii. Each licensee shall have access to a liquid scintillation counter for analysis of contamination surveys for beta-emitting radionuclides and/or a sodium iodide scintillation counter for analysis of contamination surveys for gamma-emitting radionuclides.

   a. All defunct liquid scintillation counters shall be pooled at a single secure location and the Office of Radiation Safety Services shall be notified of additions.

ix. Each licensee authorized to use a volatile form of radioactive material shall possess breathing masks having a filter designed to protect against inhalation of the radioactive compound.

x. Each licensee possesses appropriate containers for the temporary storage of radioactive waste.

4.8 (b) The Radiation Safety Committee may at any time require a licensee to obtain any further resources and equipment which it deems necessary to ensure safe laboratory practices, the protection of health or the environment.

4.9 Posting Requirements

4.9 (a) All signs and labels used to caution individuals of the presence of radiation or radioactive materials shall have a standard three-bladed radiation symbol in black or purple on a yellow background.

4.9 (b) Each room where non-exempt quantities of radioactive materials are used or stored shall be posted with a conspicuous sign bearing a radiation symbol and the words "Caution, Radioactive Materials."

4.9 (c) Each room in which there is a location where an individual may receive a whole body dose equivalent of 5 millirem (0.05 mSv) in one hour at a distance of 30 centimeters from a source or a surface through which the radiation penetrates shall be posted with a conspicuous sign bearing a radiation symbol and the words "Caution, Radiation Area".

4.9 (d) Each room in which there is a location where an individual may receive a whole body dose equivalent of in excess of 100 millirem (1 mSv) in one hour at a distance of 30 centimeters from a source or a surface through which radiation penetrates shall be posted with a conspicuous sign bearing a radiation symbol and the words "Caution, High Radiation Area" or "Danger, High Radiation Area."

4.9 (e) Each room in which there is a location where an individual may receive a whole body dose equivalent of in excess of 500 rads (5 grays) in one hour at a distance of 100 centimeters from a source or a surface through which radiation penetrates shall be posted with a conspicuous sign bearing a radiation symbol and the words "Grave Danger, Very High Radiation Area."

4.9 (f) Each room in which radioactive material is dispersed in the air in the form of dust, fumes, particulates, mists, vapors, or gases shall be posted with a conspicuous sign bearing a radiation symbol and the words "Caution, Airborne Radioactive Material".

4.9 (g) Each room in which airborne radioactivity exists in concentrations listed below shall be posted with a conspicuous sign bearing a radiation symbol and the words "Caution, Airborne Radioactivity Area" or Danger, Airborne Radioactivity Area."

i. Over the derived air concentrations (DACs) specified in Appendix B to 10 CFR 20;

OR

ii. To such a degree that an individual present in an area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6% of the annual limit of intake (ALI) or 12 DAC hours.

4.9 (h) Each refrigerator, freezer, cabinet or other device or appliance that contains radioactive material shall have a conspicuous sign bearing a radiation symbol and the words "Caution, Radioactive Materials."

4.9 (i) Each container of radioactive material shall have a durable label bearing a radiation symbol and the words "Caution, Radioactive Material" or "Danger, Radioactive Material." In addition, the label will also specify the radionuclide present, the date, and the activity present on that date.

4.9 (j) Each container used for temporary storage of radioactive waste shall be conspicuously posted with a label bearing a radiation symbol.

4.9 (k) Each laboratory bench area routinely used for handling radioactive material shall have a border made of yellow tape having radiation symbols or be posted with a conspicuous sign having a label bearing a radiation symbol and which reads "Caution Radiation Work Area."

4.9 (l) Each sink used for decontamination shall be posted with a sign bearing a radiation symbol and the words "Caution, Radioactive Material."

4.9 (m) In addition to posting signs and labels to caution individuals of the presence of radiation and/or radioactive materials, each licensee shall post the following documents and ensure that each individual under his/her supervision knows their presence.

i. Copies of forms NRC-3 "Notice to Employees", and/or NJDEP "Notice to Employees: Standards for Protection Against Radiation." NRC-3 shall contain a statement notifying workers that copies of 10 CFR 19 and 10 CFR 20 are available at the Office of Radiation Safety Services. NJDEP shall have a statement notifying workers that copies of relevant sections of the NJAC Title 7, Chapter 28, are available at the Office of Radiation Safety Services.

ii. Copies of the emergency procedures listed in section 4.12 of this Chapter and a list of individuals, with telephone numbers, who should be contacted in the event of a radiation incident.

iii. Each licensee shall, before removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive material.

4.10 Radiation Safety Surveys:

4.10 (a) Each licensee is responsible for performing routine surveys for contamination in locations under his/her supervision, where unsealed sources of radioactive material are handled. These surveys shall be in the form of wipe tests, which shall be taken and counted utilizing a procedure that incorporates the following:

i. Wipe tests shall be made of all surfaces where radioactive materials are handled, and in other locations which have a risk of becoming contaminated (e.g. sinks, refrigerator or freezer handles, telephones, etc.).

ii. Each wipe test shall cover an area no greater than one square foot, and the number of wipe tests taken per survey shall be sufficient to ensure that any contamination within the work area is detected.

iii. Wipe tests shall be assayed on a calibrated counting instrument in such a way as to detect contamination levels of 200 disintegrations per minute on each sample.

iv. Wipe tests for contamination with alpha or beta emitters shall be counted using a liquid scintillation counter for which the counting efficiency (cpm to dpm conversion factor) is known for the radionuclide, counting configuration, and counting cocktail used.

v. Wipe tests for contamination with gamma emitters shall be counted using a well type sodium iodide scintillation counting system for which the counting efficiency is known for radionuclide being sampled and the counting source geometry used.

vi. The results of wipe test surveys shall be entered on the form provided by the Office of Radiation Safety Services. Positive results shall be recorded in units of disintegrations per minute.

vii. Wipe test samples that give a count rate in excess of three times the background level shall indicate the presence of contamination.

4.10 (b) Contamination surveys described in 4.10 (a) above, shall be performed at the following frequency:

i. Weekly contamination surveys shall be performed in areas where a total of $\geq$ 200 microcuries of radioactive material is used in a week.

ii. Monthly surveys shall be performed in areas where less than 200 microcuries, but more than exempt quantities, of radioactive material are routinely used.

iii. Special contamination surveys shall be performed immediately whenever contamination is suspected.

4.10 (c) Spot checks for personal and area contamination should be performed between routine contamination surveys. Spot checks may be performed using a GM survey meter having a probe with a window sufficiently thin to allow detection of the radionuclide(s) being surveyed.

4.10 (d) Decontamination procedures shall be initiated immediately whenever a contamination survey or spot check yields positive results. The trigger levels for removable contamination surveys in research laboratories are 200 dpm per 100 cm^2 for all radionuclides with the exception of alpha-emitting radionuclides, such as Po-210, which has a trigger level of 20 dpm per 100 cm^2 above background levels.

4.10 (e) Each licensee who "uses" at any one time, quantities $\geq$ 200 microcuries of unsealed sources of gamma or energetic beta-emitting radiation shall perform area surveys of radiation levels in his/her work area and document the results. These surveys shall incorporate the following procedures:

i. Area surveys shall be performed using an energy-dependent portable ionization chamber or a GM survey meter that reads in exposure units of mR/hr and which has been calibrated against an NBS traceable source.

ii. The locations surveyed shall include shield surfaces, storage units, worker locations with source(s) unshielded, the unshielded source surfaces, and adjacent unrestricted areas.

iii. The results of the ambient radiation level survey shall be entered in units of mR/hr onto the form provided by the Office of Radiation Safety Services.

4.10 (f) Spot checks of radiation levels should be made at the start of new procedures involving sources of penetrating radiation and whenever significant or unpredictable changes in the radiation exposure rate are possible.

4.10 (g) The Office of Radiation Safety Services shall be contacted whenever an area survey reveals a radiation level in which an individual may receive a whole-body dose in excess of 5 millirems in one hour.

4.10 (h) Surveys for airborne radioactivity shall be undertaken whenever a licensee performs a procedure that may result in the release of radioactive fumes, vapors, or aerosols. Air surveys shall be conducted under the supervision of the Office of Radiation Safety Services, which shall provide the sampling device and the appropriate filters, and shall select the locations from which air samples are taken. The calculations of airborne concentrations, based on air sampling results, shall be made by the Radiation Safety Officer.

4.10 (i) Licensees authorized to possess sealed sources of beta (β-) radioactivity in amounts greater than 50 microcuries per source shall perform leak tests on these sources at six (6) month intervals; (ii)The sealed sources of containing alpha (α-) radioactivity in amounts greater than 50 microcuries shall perform leak tests at three (3) month intervals; (iii) All sealed source inventory will be conducted every quarter; (iv) Each leak test sample shall be assayed on a counting system capable of detecting 0.005 microcuries of removable radioactivity. The Office of Radiation Safety Services shall be contacted whenever a leak test yields positive results.

4.11 General Rules of Safety

4.11 (a) Each individual who handles radioactive material is responsible for minimizing the radiation exposure to themselves and other individuals within the work area, and to take appropriate steps to prevent personal contamination and contamination of the environment. To satisfy this requirement, each licensee and authorized user shall ensure that, as a minimum, the following rules are observed in rooms or areas where unsealed sources of radioactive material are handled:

i. Eating and drinking, or the presence of food, fruits or beverages, is forbidden. It is advised strictly to store food and drink outside of the laboratory.

ii. The presence of reusable cups or eating implements in open laboratory areas is forbidden.

iii. Smoking, or the presence of tobacco products and smoking paraphernalia, shall be forbidden.

iv. Pipetting by mouth shall be forbidden.

v. Radioactive materials shall not be handled by individuals with exposed cuts or abrasions.

vi. No individual shall handle unsealed radioactivity unless he/she is wearing protective gloves and a lab coat. Protective gloves and lab coats shall be removed immediately when contamination is suspected.

vii. Handling of radioactive materials shall be limited to the smallest area possible. To the extent practical, radioactive work areas shall be delineated using warning tape or warning signs. Each worker is responsible for informing others in the laboratory of the locations where he/she is using radioactive material.

viii. All items such as glassware, pipettes, forceps, pens, etc., used during procedures involving unsealed radioactivity shall be labeled with radioactive material warning tape.

ix. All surfaces on which work with unsealed radioactivity is conducted shall be covered with waterproof, backed absorbent paper. This covering shall be changed when contaminated. Work involving large volumes of radioactive liquid shall be carried out in a splash tray capable of containing the volume being handled.

x. Vials containing sources of penetrating radiation shall be maintained in a suitable shield to a practical extent.

xi. Unshielded sources of radioactivity shall only be handled using forceps or other devices to maintain an adequate distance from the fingers.

xii. When personal or area contamination is suspected, work with unsealed radioactivity shall be stopped as soon as possible so that decontamination procedures may be undertaken.

4.11 (b) Immediate notification of the Office of Radiation Safety Services is required in the event of any of the following incidents:

i. A known or suspected whole body radiation exposure which may result in an absorbed dose equivalent of 25 millirem in one hour.

ii. A spill of radioactive material in excess of 5 microcuries.

iii. Any known or suspected internalization of radioactive material by an individual.

iv. Any known or suspected presence of airborne radioactivity.

v. Any known or suspected unauthorized release of radioactive material to an unrestricted area, or exposure of a member of the general public.

vi. Any theft or otherwise unauthorized removal of radioactive material.

vii. Minor incidents not falling into the categories identified in paragraph 4.11 (b) above shall be reported to the Office of Radiation Safety Services during its next routine inspection.

4.12 Emergency Procedures

4.12 (a) The procedures to be undertaken in the event of a spill or other release of radioactivity are provided in Appendix B of this manual. Each licensee shall conspicuously post a copy of the emergency procedures which relate to activities authorized under his/her license and ensure that personnel working under his/her supervision are aware of the location of the posting. In addition, the licensee shall ensure that emergency telephone numbers are listed on the space provided on the posting.

4.13 Special Requirements with Research Animals

Principal Investigators (PI) must obtain IACUC approval for protocols that involve the administration of radioactive materials or radiation-producing machines. PIs must have an active radioactive materials license (RAM) and receive appropriate training to apply for such an IACUC protocol.

4.13 (a) Any procedure in which radioactive research animals will be housed in the Research Animal Facility shall require prior authorization by the Facility's director or his/her designee.

4.13 (b) Whenever possible, radioactive research animals should be isolated from other research animals in a separate room assigned by the Research Animal Facility.

4.13 (c) Rooms containing radioactive animals shall be posted and surveyed by the licensee, under the supervision of the Office of Radiation Safety Services, in accordance with the requirements contained in Sections 4.9 and 4.10 of this chapter. Special radioactive labeled stickers should be affixed to cage cards.

4.13 (d) The licensee shall be responsible for all aspects of animal care during the period that animals are “hot”. Facility personnel shall not care for radioactive animals when animals exceed 2 mR/h and/or the cage-bottom wipe test exceeds a dpm/100 cm^2 specified by the RSO for the specific radionuclide.

4.13 (e) After radioactive animals have been sacrificed, or after all radioactive material has been excreted from live animals, the licensee shall be required to perform a close-out survey of the room used. All decontamination of cages shall be performed by the licensee using the designated cage washers. Once cage-washing in designated cage washers has been proven (3 times) to remove all removable contamination, the authorized user does not have to continue to provide cage-bottom wipe tests. The licensee shall contact the Office of Radiation Safety Services to confirm his/her survey results and certify that decontamination is complete.

4.13 (f) The Radiation Safety Officer shall provide the Research Animal Facility with written confirmation that a radioactive animal room is cleared as a general-purpose room before RAM signage is removed.

4.13 (g) Animal carcasses, tissues, and bedding containing long lived radioactive material shall be disposed of as radioactive waste and shall not be transferred to the Research Animal Facility for disposal. Carcasses, tissues, and bedding containing radionuclides with a half-life of 120 days or less may be stored for decay under the supervision of the Office of Radiation Safety Services. Radioactive animal carcasses and tissues shall be stored for a minimum of ten half-lives and be monitored by the Office of Radiation Safety Services for residual activity prior to being transferred

to the Research Animal Facility for disposal. It is the Licensee's responsibility to return all types of waste to the Office of Radiation Safety Services.

4.13 (h) When radioactive tissues are used in histology, FACS (flow cytometry) and other core facilities, the respective instruments shall be wipe tested and cleaned until removable contamination is reduced below limits specified for the radionuclide used. Wipe test and survey results shall be presented to the Radiation Safety Officer and the manager of the core facility.

4.14 Required Record Keeping

4.14 (a) Each licensee shall permanently maintain a file containing the following documents:

i. Copies of their original radioactive material license application, renewal, and/or amendment applications, all correspondence submitted by the licensee in support of an application, and all correspondence from the Radiation Safety Committee regarding a license application.

ii. Copies of their license and amendment documents.

iii. Copies of all correspondence issued by the Office of Radiation Safety Services and Radiation Safety Committee.

iv. Copies of all inspection reports and Notices of Violation.

v. Copies of all reports of personal monitoring results.

4.14 (b) Each licensee shall complete and permanently maintain the following records pertaining to the use of radioactive material. The required information shall be entered on the forms provided by the Office of Radiation Safety Services.

i. A current inventory record of radioactive material utilization shall be maintained. This information shall be entered onto the "Radioisotope Inventory and Disposition" form and shall include the date, amount, and chemical form of each shipment received, the date(s) on which the shipment was used and the amount used on each date, and the date(s), amount(s), and the method of disposal.

ii. The results of routine contamination monitoring, weekly contamination monitoring if applicable, and area radiation surveys shall be maintained. The results shall be entered in the required units on the laboratory layout forms provided by the Office of Radiation Safety Services.

5. Special Requirements for Medical Use of Radioactive Material

5.1 Authorized Use

5.1 (a) Only a physician licensed pursuant to Chapter 2 of this policy manual, or individuals who qualify as authorized users pursuant to Chapter 3 and are acting on the orders of a licensee, may use radioactive materials in or on patients.

5.1 (b) Only physicians, so licensed by the Radiation Safety Committee, may administer therapeutic doses of radionuclides or radiopharmaceuticals in any form to patients.

5.1 (c) All diagnostic and therapeutic procedures involving radioactive material shall be used in accordance with the provisions contained in the Department of Radiology, Division of Nuclear Medicine Policy and Procedures Manual[2] and the Department of Radiology, Division of Radiation Oncology Policy and Procedures Manual[3].

5.2 Administration of Radioactive Material

5.2 (a) Except as specifically authorized in an approved experimental protocol, radiopharmaceuticals shall only be administered to patients in the form received and in accordance with the purpose(s), dosage schedule, and route of administration specified in the manufacturer's product insert; or, shall have been prepared using, a reagent kit and/or generator following the manufacturers preparation procedures and in accordance with the purpose(s), dosage schedule, and route of administration specified in the product insert.

5.2 (b) Radioactive material shall not be administered to a patient unless a "Request for a Nuclear Medicine Examination" form has been completed and signed by the referring physician and has been reviewed and approved by a physician licensed to perform the procedure.

In addition, the reviewing licensee shall have issued orders or a prescription indicating the radiopharmaceutical, dosage, and route of administration to be used, any special procedures or precautions to be followed, and the date the procedure is to be performed.

5.2 (c) The following procedures shall be completed prior to administration of a diagnostic dose of a radiopharmaceutical to a patient:

i. The authorized user shall verify that the radiopharmaceutical in hand agrees with the chemical form and activity ordered.

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[2] A copy of the Department of Radiology, Division of Nuclear Medicine Policy and Procedures Manual may be obtained from the Division of Nuclear Medicine, Room H-141, University Hospital or from the Office of Radiation Safety Services.

[3] A copy of Division of Radiation Oncology Policy and Procedures Manual may be obtained from the Division of Radiation Oncology, Room A-1020, University Hospital or from the Office of Radiation Safety Services.

ii. The authorized user shall assay the activity using a dose calibrator that has passed the calibration testing specified in Section 5.10 (b) of this Chapter.

iii. The authorized user shall prepare and sign a record of the administration which indicates the patient's name, the radiopharmaceutical, activity, and route of administration used, and the date performed; and

iv. The authorized user has verified through observation and inspection of identification that the patient is the individual named in the orders.

v. a) No appointments for SPECT, PET, SPECT/CT, or PET/CT scans will be scheduled without a signed order from the referring physician.

b) Nuclear medicine physicians will prescribe the 18F-FDG dose on the day before it is due to be performed, having reviewed the paperwork in person or by facsimile copy.

c) No request without a signature from the referring physician will be entertained.

d) Technologists will inject the radiopharmaceutical only if signatures of both the referring physician and authorized user are present on the appropriate forms.

5.2 (d) The following procedures shall be completed before administration of a therapeutic dose of a radiopharmaceutical to a patient:

i. The physician prescribing the therapeutic procedure shall personally examine the patient and the patient's chart and consult with the referring physician, and prepare a prescription in writing, indicating the radiopharmaceutical, the body part to be treated, and the radiation dose required.

ii. To determine the amount of radiopharmaceutical to be administered, uptake and clearance studies, and dosimetry calculations, based on the results of the uptake and clearance studies, shall be completed and reviewed by a qualified individual who did not perform the calculations.

iii. The Office of Radiation Safety Services shall be notified that a radiopharmaceutical therapy procedure is planned.

iv. If hospitalization of the patient is required, the prescribing physician shall arrange for admission to a room that meets the requirements specified in this Chapter and shall apprise the hospital floor of the name of the patient, the date of the procedure, and the fact that the Office of Radiation Safety Services will be implementing safety precautions.

v. The physician administering the radiopharmaceutical shall verify that the radionuclide, chemical form, and dosage in hand agree with the written prescription and shall request clarification from the prescribing physician if any element of the prescription or other record is unclear, ambiguous, or erroneous.

vi. The physician administering the radiopharmaceutical shall verify that the activity present agrees with the prescription by measuring the dosage using a dose calibrator that has passed the calibration testing specified in this Chapter.

vii. The administering physician has verified through observation and inspection of identification that the patient present is the individual named in the prescription.

viii. If hospitalization of the patient is required, the administering physician performing the procedure shall require that such a patient wear a wrist band until the patient is released from radiation restrictions. The wrist band shall bear the radiation symbol, the quantity and type of radioactive material administered, and the date on which such quantity was measured.

ix. The physician shall comply with the Quality Management Program specified in section 5.11.

5.2 (e) A radiopharmaceutical shall not be administered for a diagnostic or therapeutic procedure if there is any discrepancy, ambiguity, or apparent error in the prescription or other records, or in a physical measurement, which may result in a misadministration or an unnecessary radiation dose to the patient, or if there is a significant and unanticipated change in the patient's health status.

5.2 (f) A radiopharmaceutical for therapy shall not be administered without the presence of the Radiation Safety Officer or a designee.

5.3 Safety Requirements During Routine Preparation and Administration of Diagnostic Dosages

5.3 (a) Preparation of a radiopharmaceutical kit and unpacking of a prepared radiopharmaceutical shall be performed using a lead "L block" shield with a lead glass view window between the source and the operator.

5.3 (b) Elution from a radiopharmaceutical generator shall be made directly into a shielded vial. Except during assay, the eluant shall remain shielded at all times.

5.3 (c) Preparation of radiopharmaceutical reagent kits and elution of radionuclide generators shall be performed in accordance with the instructions specified in the product insert. An assay of the molybdenum-99 concentration in each elution of technetium-99m from a generator shall be performed in accordance with the procedure provided by the dose calibrator manufacturer. Elutions containing molybdenum-99 concentrations in excess of 0.15 microcuries per millicurie of technetium-99m shall not be used on patients.

5.3 (d) All vials, syringes, and other containers of radiopharmaceuticals shall be stored and transported in an approved shield that bears an outer radioactive material warning label indicating the radionuclide and chemical form, the activity, time, and date, and, when assigned, the patient's name.

5.3 (e) Packages containing the liquid form of radioiodine shall be stored and opened in a fume hood.

5.3 (f) Injections of radiopharmaceuticals shall be performed using an approved syringe shield or an approved shield covering the delivery reservoir.

5.3 (g) When the radiopharmaceutical is in the form of a capsule, the authorized user/licensee shall directly supervise as the patient unshields and swallows the capsules.

5.3 (h) All items that may have become contaminated during radiopharmaceutical administration shall be placed in a properly posted and shielded receptacle.

5.3 (i) Radioactive gases and aerosols shall not be administered unless the authorized user verifies that:

i. The auxiliary exhaust system is activated and properly working.

ii. The room being used is under negative pressure.

iii. The calculated evacuation time following a spill is posted.

iv. The material is delivered using the procedures and shielding devices supplied or recommended by the manufacturer.

v. Volatile radiopharmaceuticals must be stored and opened in a fume hood.

5.3 (j) Each administration of a radiopharmaceutical shall be entered into a permanent log and the patient's chart. These entries shall include the radiopharmaceutical administered, the dosage, date, and time, and any additional instructions regarding future procedures.

5.3 (k) When a patient is administered a radiopharmaceutical on an outpatient basis, he/she shall be given written instructions indicating any requirements associated with the procedure (e.g., that they should not eat before the procedure, etc.) and at what time and date they should return for imaging, or counting, and/or sample collections.

5.4 Safety Requirements for Administration of Therapeutic Amounts of Radiopharmaceuticals

5.4 (a) If a patient is hospitalized, no patient containing more than thirty (30) millicuries of any radiopharmaceutical, and whose external radiation exposure rate is in excess of 5 millirems per hour at a distance of one (1) meter shall be released from, or otherwise allowed to leave, the RBHS or University Hospital building.

5.4 (b) If a patient is hospitalized, no therapy patient given more than seven (7) but less than thirty (30) millicuries of radioactivity shall be allowed to leave the treatment location until:

i. The Radiation Safety Officer, or his/her designee, has made a measurement of the radiation levels produced around the patient.

ii. The patient has been given written instructions covering the radiation precautions to be followed and when these may be discontinued.

iii. The Radiation Safety Officer, or his/her designee, confirms that the patient understands the extent of hazard associated with the radioactivity he/she contains and has the capability to comply with the restrictions contained in the written precautions.

5.4 (c) Patients requiring hospitalization shall only be admitted to a room that meets the following specifications:

i. The room shall be private, having private sanitary facilities.

ii. The room should be as far as possible from the nursing station and heavily trafficked areas and, when possible, shall be a corner room with adjacent rooms that are empty.

iii. The nursing staff assigned to the room shall have received radiation safety training covering patients given unsealed sources of radioactive material and shall have been issued personal monitoring devices.

5.4 (d) A therapeutic dosage of unsealed radioactive material shall not be administered to a hospitalized patient until the following procedures have been completed:

i. The Radiation Safety Officer, or his/her designee, shall have prepared the room by covering the lavatory floor and large areas around the bed and sink with protective paper and other areas, having a high risk for contamination, with plastic bags or sheets.

ii. The room has been provided with labeled radioactive waste containers and a receptacle for contaminated linen.

iii. Portable lead shields have been made immediately available by the Office of Radiation Safety Services.

iv. The room has been posted with a "Caution, Radiation Area" sign and written instructions for attending medical staff.

v. The dietary department has been notified to follow isolation procedures regarding the patient and to supply meals using disposable table service only.

vi. The patient has been given written radiation safety instructions that cover minimizing contamination and exposure of other individuals, collection of excretory samples, and restrictions to be observed by visitors; and

vii. The charge nurse on the floor has been notified that therapy procedures are about to commence.

5.4 (e) When administration of a therapeutic dosage is via injection, the solution shall be kept shielded during the entire procedure.

5.4 (f) During administration of a therapeutic dosage, all non-essential personnel shall be evacuated from the room, and visitors shall not be allowed to remain except when a parent or guardian is required for a pediatric patient. In this case, the Radiation Safety Officer shall make a determination of the resulting absorbed dose to the parent or guardian.

5.4 (g) The authorized physician performing the administration shall be on hand for the entire procedure and for sufficient time afterward to respond to any immediate effects that might result from the therapy.

5.4 (h) The authorized physician performing the therapy administration shall make an entry into a permanent log and into the patient's medical chart that indicates the radionuclide, chemical form, and activity administered, the time and date of the procedure, instructions to commence radiation safety orders, and any pertinent information related to the procedure.

5.4 (i) At the close of a therapeutic administration of unsealed radioactive material, the Radiation Safety Officer, or his designee, shall complete the following requirements:

i. A radiation survey shall be performed in the room and adjacent unrestricted areas with the results posted on door to the room where the therapy administration has taken place.

ii. A red tape line shall be placed on the floor at the location where the exposure rate reaches 2 mR per hour.

iii. The radiation safety instructions posted on the door shall be completed to include the radiation levels and restrictions for visitors.

iv. Rolling shields shall be positioned to lower ambient radiation levels where practical.

v. The charge nurse shall be notified to evacuate patients in adjacent rooms who may receive an absorbed dose above 100 millirems, or any patient who is pregnant, and to place 'off-limits' all adjacent locations with a radiation level over 5 mR per hour; and

vi. The charge nurse shall be apprised of any special requirements or restrictions associated with the therapy procedure.

5.5 Safety Requirements for Patients Given a Therapeutic Amount of Unsealed or Liquid Radioactivity

5.5 (a) All hospital personnel crossing the red tape "safety line" to perform routine patient care shall limit the exposure duration to the minimum time necessary to properly complete the required procedure, and shall:

i. Wear a personal monitoring device, which has been issued to them by the Office of Radiation Safety Services, to measure their radiation dose.

ii. Don protective gloves and a laboratory coat before entering the patient's room.

5.5 (b) No hospital personnel, known or believed to be pregnant, shall be assigned to a patient given a therapeutic amount of radioactive material.

5.5 (c) The therapy patient shall not be permitted to leave his/her room until the Radiation Safety Officer, or his/her designee has determined through measurement that the radiation level at 3 feet is less than 5 mR per hour and has entered written clearance in the patient's chart.

5.5 (d) The nursing staff shall ensure that visitors comply with the following restrictions:

i. Visitors shall remain beyond the red tape "safety line" and shall not remain longer than the time limit specified in the written instructions on the door.

ii. Visitors shall be beyond 18 years of age and shall not be pregnant.

iii. Visitors shall avoid contact with the patient's items and shall not use the patient's lavatory facilities.

iv. Visitors shall not remove any items from the patient's room until these have been surveyed and cleared by the Office of Radiation Safety Services.

5.5 (e) Routine housekeeping shall be suspended until the therapy patient has been discharged and the room surveyed, decontaminated, and cleared by the Office of Radiation Safety Services.

5.5(f) No items, except for disposable food trays and plates only, shall be removed from the patient's room until these have been surveyed and cleared by the Office of Radiation Safety Services. Disposable trays and plates may be placed in the trash container placed outside the patient's room for this purpose; however, housekeeping shall not be permitted to empty these containers until they have been surveyed and cleared, and posted with a dated removal authorization label by the Office of Radiation Safety Services.

5.5 (g) Biological specimens for routine medical tests shall not be taken or released to the medical laboratories. When medical tests are required as part of patient care, or have been authorized as part of a research protocol, samples may be sent to the appropriate laboratories provided:

i. The sample is labeled with a "Caution Radioactive Materials" sticker indicating the patient's name and the radionuclide administered.

ii. The laboratory supervisor is contacted and informed that a radioactive specimen is being sent and is given the patient's name.

5.5 (h) Any items suspected of having become contaminated shall be placed in the labeled radioactive waste container placed in the patient's room for this purpose. All linen and gowns shall be placed in the container labeled for this purpose.

5.5 (i) Patients given therapeutic amounts of radioactive material shall not be discharged from the hospital until:

i. The Radiation Safety Officer, or his/her designee, has determined that the exposure rate at three (3) feet (1 meter) from the patient is less than 5 mR per hour and the patient contains less than 30 millicuries of radioactive material.

ii. The Office of Radiation Safety Services has provided the patient with written radiation precautions if he/she contains more than seven (7) millicuries of radioactive material or if the integrated dose at 3 feet from the patient will exceed 500 millirem in one year; and

iii. The Radiation Safety Officer, or his/her designee, has entered a written authorization for discharge in the patient's chart.

OR

iv. The licensee may be authorized to release from his/her control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose to any other individuals from exposure to the released individual is not likely to exceed 0.5 rems (5 mSv).

v. The Office of Radiation Safety Services shall provide the released the patient with written radiation precautions on actions recommended to maintain dose to other individuals as low as reasonably achievable if the total effective dose to any other individual is likely to exceed 1 mSv (0.1 rem).

vi. The licensee must maintain a record of the basis for authorizing the release of an individual, for three (3) years after the date of release, if the total effective dose is calculated by :

1. Using the retained activity rather than the activity measured.
2. Using an occupancy factor less than 0.25 at 1 meter; and
3. Using the biological or effective half-life.

5.5 (j) If a patient is hospitalized, following discharge of a patient given a therapeutic amount of unsealed radioactivity, the room shall not be released to housekeeping services or the admissions office until the following monitoring procedures have been completed:

i. The Office of Radiation Safety Services has removed all radioactive waste from the room.

ii. The Office of Radiation Safety Services has surveyed the room for contamination and has cleaned all contaminated areas to the point where there is no longer any removable contamination; and

iii. The Office of Radiation Safety Services has posted the room with a green sign indicating that all radiation restrictions have been lifted and has provided the charge nurse with written confirmation that the room is clear.

5.6 Administration of Sealed Source for Therapy

5.6 (a) Before beginning treatment with sealed sources of radioactive material, the physician licensed to perform the procedure shall ensure that:

i. If there is a primary care physician, s/he referred the patient for a therapeutic clinical procedure.

ii. A written, dated, and signed prescription has been made in the patient's chart indicating the body part to be treated, the sources of radiation, and the total tumor dose. The appropriate prescription form in section 5.11 of this Chapter shall be completed.

iii. The patient wears a wristband until the patient is released from radiation restrictions. The wrist band shall bear the radiation symbol, the quantity and type of radioactive material inserted or implanted, and the date on which such quantity was inserted or implanted.

5.6 (b) Therapy involving sealed sources shall not be performed if any element of the prescription is unclear, ambiguous, or erroneous.

5.6 (c) Dosimetry calculations for sealed source therapy shall be reviewed before 50 percent of the prescribed dose has been administered to ensure that the final treatment plan will deliver the dose prescribed in the prescription. Manual and computer-generated dose calculations shall be reviewed by a qualified individual who did not perform the calculations or enter patient data into the computer.

5.6 (d) Patients receiving temporary implants shall remain hospitalized until the sources are removed.

5.6 (e) Patients receiving permanent implants shall be provided with written radiation precautions which shall remain in effect until the total effective dose equivalent to an individual from exposure to the released patient is not likely to exceed 500 millirems (5 mSv) in one year.

5.6 (f) Interstitial implantation of permanent or temporary sealed sources shall only be performed by a physician licensed for sealed source therapy. Use of an operating room facility to perform surgical implantation of sealed sources shall require that the following provisions be met:

i. The operating room shall be posted with a "Caution, Radiation Area" sign.

ii. A radiological physicist or the Radiation Safety Officer/designee shall be present to monitor the radiation dose to the operating room staff.

iii. A survey shall be performed at the end of surgery to ensure that no sources remain in the operating room, linen, dressings, or suction devices.

5.6 (g) A brachytherapy procedure in which a pre-determined number of sealed sources of specified strength are afterloaded into a surgically implanted tube or device shall be performed by a physician licensed for this procedure, or by an individual who is qualified by training and experience and who is acting under the orders of the physician.

5.6 (h) The Radiation Safety Officer shall be notified of all sealed source therapy procedures.

5.6 (i) Patients who are to be hospitalized for sealed source therapy shall only be admitted to rooms that meet the following specifications:

i. The room is private and has private sanitary facilities.

ii. The room is away from the nursing station and heavy traffic hallways and, when possible, is a corner room or is adjacent to unoccupied areas.

iii. The nursing staff assigned to the room have received radiation safety training regarding patients administered sealed sources of radioactive material.

5.6 (j) The following procedures shall be performed after a radioactive patient has been transferred to his/her room or afterloading has been completed:

i. The door to the room shall be posted with a "Caution, Radiation Area" sign along with a set of written safety instructions to nursing personnel.

ii. The radiological physicist or the Radiation Safety Officer shall perform a survey of the patient's room and adjacent unrestricted areas and post the results on the door to the room.

iii. A red tape "safety line" shall be placed on the floor at the location where the radiation exposure rate exceeds 2 mR per hour.

iv. Portable lead shields shall be placed next to the patient's bed to reduce the exposure rate to any individual entering the room.

v. The charge nurse shall be notified to evacuate any patients in adjacent rooms who are pregnant, or who may receive an absorbed dose in excess of 100 millirem due to the

therapy procedure, and to place "off-limits" all other adjacent areas where the exposure rate exceeds 2 mR per hour.

vi. Radiation orders shall be placed in the chart, and a "Caution - Radioactive Patient" label placed on the cover of the chart.

vii. A shielded container shall be left in the room for emergency shielding of dislodged sources,

AND

viii. The patient shall be given instructions on the need for confinement to bed and exercising visitor control.

5.7 Safety Requirements for Patients Containing Sealed Sources of Radioactive Material

5.7 (a) Each individual crossing the red tape "safety line" shall wear a personal monitoring device issued by the Office of Radiation Safety Services.

5.7 (b) The time spent in the patient's room shall be limited to the minimum amount necessary to provide the required medical care. Whenever possible, the individual attending to the patient shall keep the portable shield between him/herself and the patient.

5.7 (c) Hospital personnel who are known, or likely, to be pregnant shall not be assigned to a sealed source therapy patient.

5.7 (d) The nursing staff shall ensure that the visitors observe the following restrictions:

i. Visitors shall remain beyond the red tape "safety line" and shall limit the duration of the visit to the time specified in the written instructions posted on the door to the patient's room.

ii. Visitors shall be beyond 18 years of age and shall not be known to be pregnant; and

iii. If the patient contains iodine-125 or palladium-103 seeds, then visitors shall not remove from the room any clothing worn by the patient following implantation.

5.7 (e) The nursing staff shall ensure that patients containing temporary implants remain in bed.

5.7 (f) Temporary implants shall only be removed by a physician licensed to perform sealed source therapy, or by an individual who is qualified by training and experience and is acting under the orders of the licensed physician.

5.7 (g) After the temporary implants have been removed from the patient and shielded, a survey of the patient and room shall be performed to verify that no dislodged sources remain. At this time, the radiation warning sign and safety instructions shall be removed from the patient's door.

5.7 (h) Patients shall not be discharged from the hospital until an entry has been made, dated, and signed in their chart that the sources have been removed and all accounted for.

5.7 (i) Sealed sources shall be immediately returned to the approved storage area. The sources shall be counted before being placed in storage to verify that the number returned agrees with the number removed.

5.8 Leak Test and Inventory Requirements for Sealed Radiotherapy Sources

5.8 (a) Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six (6) months or at such intervals as are specified by the certificate of registration referred to in CFR 32.210, not to exceed three (3) years.

5.8 (b) A physical inventory shall be maintained of all reusable sealed sources. This record shall include:

i. The names of individuals authorized to handle the sources.

ii. The number of sources of each strength and any identifying marks or serial numbers.

iii. The time and date each source was removed, by whom, and the patient's name and room number; and

iv. The time and date each source was returned, by whom, and a signed confirmation that the number of sources agrees with the inventory listing.

5.9 Routine Surveys for Contamination and Radiation Levels in Nuclear Medicine

5.9 (a) Each individual who has handled millicurie quantities of radioactive materials shall monitor him/herself for contamination before leaving the nuclear medicine area or whenever contamination is suspected. Monitoring shall be performed using a Geiger counter and shall include measurements of the hands, clothing, and shoes. Individual monitoring results shall be entered into a permanent log.

5.9 (b) Wipe tests for contamination levels shall be performed on a weekly basis in all nuclear medicine areas where radioactivity in excess of 200 microcuries has been handled. The wipe tests shall be counted using a well-type NaI detector; a Geiger counter shall not be used for weekly contamination surveys. In the event that a wipe sample gives positive results, the relative activity detected, in counts per minute, shall be converted to actual activity units of microcuries or disintegrations per minute. The results of weekly contamination surveys shall be entered into a permanent record form provided/approved by the Office of Radiation Safety Services.

5.9 (c) Spot checks for contamination shall be performed after each generator elution or preparation of a reagent kit. The spot check shall include the work area and the individual performing the elution or kit preparation. The survey may be performed using a counter with the beta shield open and the meter readout set on the most sensitive scale. The results of spot checks shall be entered in a permanent log.

5.9 (d) Surveys of radiation levels in the nuclear medicine area shall be performed daily using an energy-dependent ionization chamber or a counter specifically calibrated to give accurate exposure readings. The areas surveyed shall include, but not be limited to, the surface of the technetium-99m generator, the surfaces of radioactive waste containers, the radiopharmaceutical prep station, and several locations in the imaging rooms. The results of the daily radiation level surveys shall be entered in exposure units of mR per hour on the record forms provided/approved by the Office of Radiation Safety Services.

5.9 (e) A spot check for contamination shall be performed in the stress test laboratory following each stress test in which radioactive material was injected as part of the procedure. The locations spot checked shall include the injection area and the individual performing the injection.

5.9 (f) Incoming shipments of radioactive material that have been delivered directly to the nuclear medicine section shall be inspected for package integrity. The inspection shall include:

i. Verification that the package is posted with the proper DOT labels.

ii. Measurements of the radiation level at the package surface and at a distance of 3 feet (1 meter).

iii. Contamination surveys of the package surface, packing material, and radionuclide container.

iv. Verification that the contents agree with the radionuclide, chemical form, and activity ordered and that are indicated on the package label and shipping manifest.

5.10 Calibration Procedures for Nuclear Medicine Instrumentation

5.10 (a) All portable survey instruments used for radiation safety surveys shall be calibrated annually by the Office of Radiation Safety Services.

5.10 (b) The dose calibrator used for assay of radiopharmaceutical dosages shall consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances, until current results of the following tests are obtained:

i. A daily constancy check, using a dedicated calibration source approved by the Office of Radiation Safety Services, indicates that the precision of measurement does not vary by more than 5%.

ii. A daily accuracy check, using a minimum of three calibration sources approved by the Office of Radiation Safety Services, indicates that the accuracy of measurement is within 5%.

iii. A quarterly linearity test, using a range of activities from 30 microcuries to the highest level of activity administered to a patient, indicates that the accuracy is within 5% over the entire range of activities.

iv. A test for geometric variation, completed at the time of installation, provides correction factors for sample readings that vary by more than 5% from the true activity due to geometric variations related to sample volume and configuration.

5.10 (c) The dose calibrator used for assay of radiopharmaceutical dosages shall not be used if the accuracy, constancy, linearity, or geometric errors exceed 10%.

5.10 (d) Devices used for imaging and localization of radioactive material in patients shall not be used until the current results of the following tests are obtained:

i. A daily test of field uniformity, using a flood source and counting procedure approved by the Office of Radiation Safety Services, reveals no observable 'hot' or 'cold' spots or other artifacts.

ii. A weekly test of intrinsic resolution, using a flood source, bar phantom, and counting procedure approved by the Office of Radiation Safety Services, demonstrates that each field quadrant on each unit can resolve the smallest diameter bar on the phantom.

5.10 (e) The scintillation detector and counting system used to measure uptake and clearance of radioiodine shall not be used until current results from the following tests have been obtained:

i. The set counting window agrees with the principal photons emitted by the radionuclide being counted, and there is no significant change from the counting window settings previously being used.

ii. The counting efficiency for the standard being used in the procedure does not vary significantly from the counting efficiency recorded during previous measurements of standards of the same radionuclide.

5.11 Quality Management Program (QMP) Policies and Procedures

5.11 (a) Before beginning treatment with sealed sources of radioactive material, the physician licensed to perform the procedure shall ensure that he/she shall implement the following QMP procedures to provide high confidence in administering sealed sources:

i. Prior to loading radioactive materials in either a conventional temporary or permanent brachytherapy procedure, the prescription sheet(s) shown in Appendix-D, must be signed by the authorized physician, who has been approved by the RBHS Radiation Safety Committee for the procedure.

ii. Before administering radioactive materials in a brachytherapy procedure, verification of the patient's identity must be made by at least two means. This can be accomplished by first asking the patient his or her name and then confirming at least one of the following by consulting the patient's record: date of birth, address, social security number, patient's unit number, name on bracelet/ID card, and name on insurance card.

In case the patient cannot hear or speak, the patient's name must be confirmed by more than one of the following methods in the patient's record: birth date, address, patient's ID bracelet or hospital ID card, social security number, or name on the medical insurance card.

iii. Prior to administering the brachytherapy sources, the specific details of the procedure must be rechecked with the written directive (prescription sheet) by the authorized physician. The following items must be checked: radionuclide, source activity, source number and arrangement of sources, treatment time, and total dose.

iv. The authorized physician shall confirm that all involved personnel understand the procedures necessary to carry out the written brachytherapy directive.

v. Prior to administering the brachytherapy sources, a second qualified person must verify that the radionuclide is correct, and the source activities, number, and spatial distribution or loading sequence are all correct and properly set. Cesium-137 tubes are color-coded and are stored in drawers segregated by activity. Within each drawer, each source has a separate position. Iridium-192 ribbons are supplied in color-coded

ribbons, with the color corresponding to specified arrangements of activity, spacing, and number of sources.

vi. All temporary brachytherapy implants are to be performed using afterloading techniques. Except in special fixed-geometry situations (e.g., a Delclos vaginal application), orthogonal radiographs or another equivalent means of determining source geometry shall be used to determine the proper positioning of sources. Dummy sources must be used when needed to verify source positions.

vii. For all permanent brachytherapy implants, radiographs (either stereo-shift or orthogonal) or a CT scan shall be made after the implant to determine final source position and radiation dose.

viii. A second trained person, other than the person making the initial dosimetry calculations, shall review all dosimetry calculations before the dose has been administered. All manual calculations shall be reviewed for arithmetic errors and proper transfer of data appearing in the calculation. Computer calculations should be checked for proper specification of source types, strengths, and positions, as presented in the patient's prescription. When possible, manual calculations should be compared to the computer isodose plan. The dosimetry checks listed above should be performed before the brachytherapy insertion has been completed. If the authorized physician determines that delaying checks of dose calculations would jeopardize the patient's health, the checks of calculations should be performed within two working days of the completion of treatment.

ix. As soon as the brachytherapy sources were placed in the patient, the authorized user for a brachytherapy implant should place the following information in the patient's hospital chart: radioisotope, anatomical treatment site, individual strengths and number of sources, geometrical source configuration, total source strength, total duration of implant, total dose delivered during the procedure. The information above must be permanently recorded in the patient's chart, dated, and signed by the authorized user.

x. The prescribed radioisotope, number of sources, source strengths, treatment site, loading sequence, and total dose shall be confirmed by the person administering the brachytherapy treatment to verify agreement with the written directive and treatment plan.

xi. If, because of patient's medical condition, a delay to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to written directive is acceptable, provided that an oral revision is documented immediately in the patient's record and a revised written directive is dated and signed by the authorized physician within 48 hours of the oral revision.

xii. If, because of the emergent nature of the patient's condition, a delay to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable provided that the information provided in the oral directive is documented immediately

in the patient's record and a written directive is prepared within 24 hours of the oral directive.

xiii. Revisions to written directives for brachytherapy may be made, provided that the revision is dated and signed by an authorized user before the administration of the brachytherapy dose or the next brachytherapy fractional dose.

xiv. No computer program or treatment planning system shall be placed in use for patient calculations and isodose distribution until it has passed acceptance testing procedures, as designed and evaluated by a clinical radiation therapy physicist. The acceptance procedure should evaluate the algorithms used to calculate dose and isodose distributions and also compare the results of calculations to published data and manual calculations.

xv. Each brachytherapy administration is performed in accordance with the written directive as required by 10 CFR 35.40.

xvi. Each written directive and a record of each administered radiation dose are retained for three years after the date of administration as required in 10 CFR 35.40 (d).

xvii. As per 10 CFR 35.633, HDR machine calibrations are required to be performed minimum on a quarterly basis.

xviii. A certified medical physicist must perform interlock and security checks on the day of the treatment and monthly.

5.11 (b) Before beginning treatment with NaI I-125 and/or I-131 > 30 uCi, the physician licensed to perform the procedure shall ensure that he/she shall implement the following QMP procedures, to provide high confidence in administering sealed sources:

i. Prior to administering any dosage of quantities greater than 30 uCi of either I-125 and/or I-131, the prescription sheet(s) shown in Appendix-D, must be signed by the authorized physician, who has been approved by the RBHS Radiation Safety Committee for the procedure.

ii. Before administering I-125 and/or I-131 > 30 uCi, verification of the patient's identity must be made by at least two means. This can be accomplished by first asking the patient his or her name and then confirming at least one of the following by consulting the patient's record: date of birth, address, social security number, patient's unit number, name on bracelet/ID card, and name on insurance card.

iii. In case the patient cannot hear or speak, the patient name must be confirmed by more than one of the following methods in the patient's record: birth date, address, name on the patient's ID bracelet or hospital ID card, social security number, and name on the patient's medical insurance card.

iv. Prior to administering the I-125 and/or I-131 > 30 uCi, the specific details of the procedure must be rechecked with the written directive (prescription sheet) by the authorized physician. The following items must be checked: radionuclide, source activity, source number and arrangement of sources, treatment time and total dose.

v. The authorized physician shall confirm that all involved personnel understand the procedures necessary to carry out the written directive.

vi. Prior to administering I-125 and/or I-131 > 30 uCi, a second qualified person must verify that the radionuclide and the activity is correct.

vii. The prescribed radioisotope, total activity, and route of administration shall be confirmed by the person administering I-125 and/or I-131 radiopharmaceutical to verify agreement with the written directive and treatment plan.

viii. If, because of patient's medical condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to written directive is acceptable, provided that a oral revision is documented immediately in the patient's record and a revised written directive is dated and signed by the authorized physician within 48 hours of the oral revision.

ix. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable provided that the information provided in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

x. Revisions to written directives for any diagnostic or therapeutic procedures may be made, provided that the revision is dated and signed by an authorized user prior to the administration of the brachytherapy dose or the next brachytherapy fractional dose.

xi. Each I-125 and/or I-131 > 30 uCi administration is performed in accordance with the written directive as required by 10 CFR 35.40.

xii. Each written directive and a record of each administered radiation dose are retained for three years after the date of administration as required in 10 CFR 35.40 (d).

xiii. The Radiation Safety Officer or designee shall calculate the maximum dose to an individual from a patient administered I-131 for thyroid treatment. This information is useful at the time of release after the administration of therapy doses to counsel the patient about potential exposure of family members and/or caretakers. In addition, the UH contact information cards given to the I-131 therapy patients after the therapy treatments.

5.12 Routine Safety Procedures During In-Vitro Clinical Assays

5.12 (a) Storage and handling of radioactive material shall be limited to University Hospital laboratories.

5.12 (b) Radioactive material shall be used in accordance with safety requirements contained in Chapter 4, Sections 4.1 through 4.12 inclusive, and Section 4.14.

5.12 (c) Radioactive material shall only be used in the form(s) supplied by the manufacturer and for the type of assays specified in the package insert.

5.12 (d) Clinical assays shall only be performed following the methodology outlined in the instructions contained in the manufacturer's package insert and shall be in accordance with the handling procedures described in the Department of Pathology Clinical Chemistry Section Policies and Procedures Manual.

A copy of the Department of Pathology Division of Clinical Chemistry Policy and Procedures Manual may be obtained from the Division of Clinical Chemistry, University Hospital, or from the Office of Radiation Safety Services.

5.13 Administration of I-125 Iotrex™ Liquid Brachytherapy Source for Therapy

5.13 (a) The Radiation Safety Officer shall be notified 48 hours in advance of all I-125 Iotrex™ liquid brachytherapy procedures.

5.13 (b) Patients who are to be hospitalized for I-125 liquid brachytherapy source shall only be admitted to rooms which meet the following specifications:

i. The room is private and has private sanitary facilities.

ii. The room is away from the nursing station and heavy traffic hallways and, when possible, is a corner room or is adjacent to unoccupied areas.

iii. The nursing staff assigned to the room have received radiation safety training regarding patients administered sealed sources of radioactive material.

5.13 (c) Before beginning treatment with I-125 Iotrex™ liquid brachytherapy source of radioactive material, the physician licensed to perform the procedure shall ensure that:

i. The patient has been referred to for a therapeutic clinical procedure by his/her primary care physician/neurosurgeon.

ii. A written directive including the treatment site, the radionuclide (including the chemical/physical form (Iotrex™)), and the dose has been entered in the patient record.

iii. Dosimetry calculations for I-125 Iotrex™ liquid brachytherapy source therapy have been reviewed by a qualified individual as defined in 10 CFR Part 35.940 who did not perform the calculations.

5.13 (d) Therapy involving I-125 Iotrex™ liquid brachytherapy source shall not be performed if any element of the prescription is unclear, ambiguous, or apparently erroneous.

5.13 (e) After implantation but prior to completion of the procedure: the radionuclide (including the chemical /physical form (Iotrex™)), treatment site, and the total dose administered are entered in the patient record. (For brachytherapy using I-125 Iotrex™ liquid brachytherapy source, “prescribed dose” means the total dose documented in the written directive).

5.13 (f) I-125 Iotrex™ liquid brachytherapy procedure shall only be performed by a physician licensed for sealed source therapy. Use of an operating room facility to perform surgical implantation of sealed sources shall require that the following provisions be met:

i. The operating room shall be posted with a "Caution, Radiation Area" sign.

ii. A Medical Physicist or the Radiation Safety Officer shall be present to monitor the

radiation dose to the operating room staff.

iii. A survey shall be performed at the end of surgery to ensure that no radioactive contamination remains in the operating room, linen, dressings, or suction devices.

5.13 (g) The following procedures shall be performed after a radioactive patient has been transferred to his/her room or afterloading has been completed:

i. The door to the room shall be posted with a "Caution, Radiation Area" sign along with a set of written safety instructions to nursing personnel.

ii. The Radiological Physicist or the Radiation Safety Officer shall perform a survey of the patient's room and adjacent unrestricted areas and post the results on the door to the room.

iii. A red tape "safety line" shall be placed on the floor at the location where the radiation exposure rate exceeds 2 mR per hour.

iv. Portable lead shields shall be placed next to the patient's bed to reduce the exposure rate to any individual entering the room.

v. The charge nurse shall be notified to evacuate any patients in adjacent rooms who are pregnant, or who may receive an absorbed dose in excess of 100 millirem due to the therapy procedure, and to place "off-limits" all other adjacent areas where the exposure rate exceeds 2 mR per hour.

vi. Radiation orders shall be placed in the chart, and a "Caution - Radioactive Patient" label placed on the cover of the chart.

vii. A shielded container shall be left in the room for emergency shielding of dislodged sources.

viii. The patient shall be given instructions on the need for confinement to bed and exercising visitor control.

ix. The patient wears a wrist band until s/he is released from radiation restrictions. The wrist band shall bear the radiation symbol, the quantity and type of radioactive material inserted or implanted, and the date on which such quantity was inserted or implanted.

5.13 (h) Patients receiving I-125 Iotrex™ liquid brachytherapy source implants shall remain hospitalized until the I-125 Iotrex™ liquid brachytherapy source is removed.

5.14 Safety Requirements for Patients Containing Gliasite® Sealed Sources of Radioactive Material

5.14(a) Each individual crossing the red tape "safety line" shall wear a personal monitoring device issued by the Office of Radiation Safety Services.

5.14(b) The time spent in the patient's room shall be limited to the minimum amount necessary to provide the required medical care. Whenever possible, the individual attending to the patient shall keep the portable shield between him/herself and the patient.

5.14(c) Hospital personnel who are known, or likely, to be pregnant shall not be assigned to a

sealed source therapy patient.

5.14(d) The nursing staff shall ensure that the visitors observe the following restrictions:

i. Visitors shall remain beyond the red tape "safety line" and shall limit the duration of the visit to the time specified in the written instructions posted on the door to the patient's room.

ii. Visitors shall be beyond 18 years of age and shall not be known to be pregnant.

iii. If the patient contains Iodine-125, then visitors shall not remove from the room any clothing worn by the patient following implantation.

5.14(e) The nursing staff shall ensure that patient containing temporary implants remain in bed.

5.14(f) Temporary implants shall only be removed by a physician licensed to perform sealed source therapy, or by an individual who is qualified by training and experience and is acting under the orders of the licensed physician.

5.14(g) After the temporary implants have been removed from the patient and shielded, a survey of the patient and room shall be performed to verify that no contamination is remaining. At this time, the radiation warning sign, and safety instructions shall be removed from the patient's door.

5.14(h) Prior to removal of the Gliasite® catheter from the resection cavity, the Neurosurgeon must inform the Office of Radiation Safety Services. The Radiation Safety Officer/designee will perform surveys of the instruments used in the procedure, patient table, linen, floor, etc., and personnel involved in the removal procedure. If contamination is detected, the Radiation Safety Officer/designee decontaminates and ensures that there is no residual contamination present in the operating room. The waste generated in the operating room will be stored for decay in storage room.

5.14(i) Patients shall not be discharged from the hospital until an entry has been made, dated, and signed in their chart that the source has been removed.

5.14(j) A Gliasite® catheter must not be removed until the Radiation Safety Officer/designee is present in the operating room.

5.15 Therapy Related Computer Systems:

5.15(a) The licensee shall perform acceptance testing on the treatment planning system of the therapy-related computer system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

i. The source-specific input parameters required by the dose calculation algorithm.

ii. The accuracy of dose, dwell time, and treatment time calculations at representative points.

iii. The accuracy of isodose plots and graphic displays.

iv. The accuracy of the software used to determine sealed source positions from radiographic images; and

v. The accuracy of electronic transfer of the treatment delivery unit from the treatment planning system.

5.16 TheraSphere™ for Treatment of Unresectable Hepatocellular Carcinoma (35.1000 procedures)

i The authorized medical physicist and the licensee must be approved by the Radiation Safety Committee.

ii Patient consultation and recruitment is confirmed by the licensee. This therapy procedure is categorized under 35.1000.

iii Pre-treatment mapping with 99Tc-MAA is performed by the licensee under 35.200 category. The licensee must be approved for 35.200 procedures also in addition to 35.1000 licensing conditions. If the licensee is approved for 35.1000 only, then Nuclear Medicine physician will complete the required administrations for mapping.

iv After the mapping, the dosimetry sheet is completed by the licensee in consultation with the authorized medical physicist.

v The licensee must generate the written directive and the treatment window.

vi The authorized medical physicist cross-checked all the calculations.

vii As per the written directive, the Chief Technologist of Nuclear Medicine will place the order with the company as per the schedule.

viii The package is shipped directly to the Office of Radiation Safety Services lab for package integrity and inventory tests by radiation safety. The RAM vial dosage details are cross-checked by the health physicist against the assigned patient treatment schedule and written directives. The package is labeled with the initials of the patient or MR number against the respective stock vial.

ix The health physicist will schedule a time slot with the medical physicist for dose calibrator measurements at the Division of Nuclear Medicine. The health physicist will transport the dose vial to UH-Nuclear Medicine. The medical physicist, with the presence of a health physicist, will complete assaying the dose with the dose calibrator and complete pre-treatment template measurements.

x The dose vial, 90Y waste container, and the kit utilized for the therapy treatment is arranged to be ready by the Nuclear Medicine or Interventional Radiology (IR) staff and Radiation Safety. The treatment room is prepared by the IR staff by placing absorbing towels and pads on the table, floor, and the cart. The injection table was prepared with the tubing assembly, waste container, absorbent pads, rad pager attached to the injection box and floor protection.

xi The licensee must ensure proper patient identifiers as per the UH policy and verify the dose vial(s) for the correct patient treatment.

xii The interventional radiology physician starts the catheter placement guided by the fluoroscopy machine.

xiii The health physicist will start reading instructions given by the manufacturer. All clinical, nursing, licensee and residents must wear their dosimeters during the therapy treatment.

xiv The authorized RAM licensee is only allowed to administer microspheres from the vial to the intended location and flush the same tubing thrice, ensuring all the activity was delivered by measuring vial activity (pre) and the residual activity (post-) with the radio's pager. All the steps were followed systematically as given by the manufacturer.

xv After the procedure, all the waste, including the catheter tubing, swath, gloves, etc., were collected inside a plastic container shielded by a plexiglass box and taken to the Office of Radiation Safety Services waste room for decay.

xvi All the personnel involved with the procedure, and the floor areas, were surveyed by Radiation Safety. No one is allowed to step outside without being cleared by the Radiation Safety survey.

xvii The template measurement at the beginning and the waste container readings after the injection were logged by the medical physicist as per the written directives. After the injection, the patient is transported to Nuclear Medicine for SPECT imaging.

xviii The patient was also given a patient release form informing them of precautions to be taken while keeping the original copy to inform law enforcement agencies that they received radioactive material treatment at UH.

xix All entries and signatures as per the written directives were completed by the medical physicist and the licensed physician. It is the responsibility of the licensee that the treatment was conducted safely, and the time was also managed effectively. If any adverse effects are noticed, the licensee must bring to the notice of the Radiation Safety officer immediately.

6. X-ray Producing Machines

6.1 Notification to the Office of Radiation Safety Services

6.1 (a) The Office of Radiation Safety Services shall be notified before purchasing any X-ray producing machine (diagnostic and therapeutic units, cabinet X-ray units, X-ray diffraction units, electron microscopes, etc.) with the following information:

i. Date Acquired.
ii. Manufacturer.
iii. Model Name.
iv. Generator Model Number.
v. Generator Serial Number.
vi. Tube Insert Serial Number.
vii. Date Manufactured.
viii. Location.
ix. Maximum kVp and mA
x. Type of Image Receptor.

6.1 (b) The acquisition of an X-ray machine shall have the prior approval of the Office of Radiation Safety Services to ensure proper shielding for the machine and that adequate facilities are available for its use.

6.1 (c) After completion of the X-ray machine installation, the appropriate individual shall notify the Office of Radiation Safety Services to register the X-ray machine with the New Jersey Department of Environmental Protection.

6.1 (d) No modification of any type shall be made on any existing radiation-producing machine without first notifying the Office of Radiation Safety Services.

6.1 (e) Surveys shall be performed by the Office of Radiation Safety Services when the X-ray machine is operable.

6.1 (f) No changes in location shall be made without notifying the Office of Radiation Safety Services.

6.1 (g) Disposal of an X-ray machine or any part thereof or transferred to another person or company, must have prior approval of the Office of Radiation Safety Services.

6.1 (h) The Radiation Safety Officer must be notified by the administrators of each facility in the case of relocation of radiation-producing machines, purchase of new/used machines, disposal of machines or junked machines.

6.1 (i) Whenever any department, division, or individual clinician/researcher at UH or RBHS Newark is contemplating the purchase of new radiation-producing equipment, or relocation or

disposal or missing of existing radiation-producing equipment, the Radiation Safety Officer must be contacted well in advance to obtain approval for such action.

6.2 Operation of radiation-producing machines:

6.2 (a) No person shall operate or permit the operation of medical radiographic and fluoroscopic equipment or therapy simulation systems unless the following conditions are met:

i. Only individuals required for the medical procedure, for training, or for equipment maintenance shall be in the radiographic or fluoroscopic or therapy simulator room during an exposure.

ii. Any person operating x-ray equipment on humans must be either a New Jersey licensed practitioner, licensed technologist, or a registered dental hygienist. "Licensed practitioner" (cf: 26:2D-26 (g)) means a person licensed or otherwise authorized by law to practice medicine, dentistry, dental hygiene, podiatry, chiropody, osteopathy, or chiropractic.

iii. PA's and/or APN's are not authorized to use radiation-producing machines on humans in the state of NJ unless they meet the criteria found in 6.2 (a) ii.

iv. Individuals who are present in a radiographic or fluoroscopic or therapy simulator room during any exposure shall wear protective aprons of at least 0.25 mm lead equivalent during every exposure.

v. Protective gloves of at least 0.25 mm lead equivalent shall be worn by the fluoroscopist and assistant(s) during every examination when it is required that their hands be placed in the useful beam.

vi. When a patient must be provided with auxiliary support during a radiation exposure and mechanical holding devices are insufficient, the following procedures shall be followed:

(1) The person holding the patient shall be protected with a lead apron of at least 0.25 mm lead equivalent.

(2) The person holding the patient shall be protected with lead gloves of at least 0.25 mm lead equivalent if the hands must be placed in the useful beam.

(3) No licensed practitioner shall order or otherwise cause an individual who is licensed pursuant to N.J.S.A. 26:2D to hold a patient during radiation exposure, except in a life-threatening situation.

(4) No person shall be employed, routinely assigned, or required to hold a patient during radiographic and fluoroscopic procedures.

(5) If a patient must be held during X-ray exposure, non-radiation workers such as aides, orderlies, nurses, or members of the patient's family may be asked to perform this duty; and

(6) No person other than the patient shall hold the film during the exposure.

vii. Gonadal shielding of not less than 0.5 mm lead equivalent shall be used on a patient during radiographic and fluoroscopic procedures, except for cases in which this would interfere with the diagnostic procedure. If the patient is sterile, the use of gonadal shielding may be omitted.

viii. The operator shall collimate X-ray units that do not have positive beam limitations to ensure that the X-ray field does not extend beyond the image receptor.

ix. The radiographic field shall be restricted to the area of clinical interest as far as practical.

x. A method to observe the patient during the X-ray exposure shall be provided for all units. Observation for the patient shall be made from the shielded area.

xi. During radiographic exposures, the operator shall stand behind the protective barrier.

xii. No person shall permit or arrange for the intentional irradiation of a human being except for medical diagnosis or treatment.

xiii. No person shall deliberately expose an individual to the useful beam for the sole purpose of training or demonstration; and

xiv. No person shall operate an ionizing-radiation-producing machine unless that person understands and uses the principles of radiation safety to keep radiation exposure as low as possible.

xv. Routine diagnostic CT procedures shall not be conducted with PET-CT and SPECT-CT machines. These machines can only be used for stand-alone CTs on an emergency basis. This policy prevents incidents and violations involving radiopharmaceutical injections.

6.3 Quality Assurance Programs for Medical Diagnostic X-Ray N.J.A.C. 7:28-22

a) All registrants of medical diagnostic X-ray imaging equipment and computed tomography equipment, which are used for performing diagnostic radiography, fluoroscopy, X-ray bone densitometry, or computed tomography in the healing arts, are required to develop and continually implement quality assurance programs. Such equipment includes, but is not limited to, equipment used in performing diagnostic radiology procedures in hospitals, medical, podiatric, chiropractic, industrial, school, and government facilities.

b) No person shall perform or permit the performance of a diagnostic X-ray procedure in the healing arts using radiographic, fluoroscopic, X-ray bone densitometry, or computed tomography (CT) equipment unless the registrant has developed and continues to implement a quality assurance program in accordance with the compliance schedule in N.J.A.C. 7:28-22.14 and that satisfies the requirements of the subchapter.

c) The quality assurance program shall contain the following elements:

i. A quality assurance program manual as specified in N.J.A.C. 7:28-22.4;

ii. Quality control tests as specified in N.J.A.C. 7:28-22.5, 22.6 or 22.7 (as

appropriate for the diagnostic X-ray equipment).

iii. An initial and annual (not to exceed 14 months) Medical Physicist's QC Survey as specified in N.J.A.C. 7:28-22.8, 22.9, or 22.10.

d) A corrective action plan as required by N.J.A.C. 7:28-22.4(a)4. Registrants of X-ray bone densitometer equipment are required only to implement and continue to carry out the quality assurance programs for such equipment, which are required by N.J.A.C. 7:28-22.11.

e) No person shall engage in the use or employment of dishonesty, fraud, deception, misrepresentation, or false promise.

f) No person shall falsify or make misleading statements on any record.

g) No person shall make misleading or false statements to a representative of the Department or Commission.

h) No person shall falsify any records, nor destroy nor steal any property or records, relating to quality assurance as required by this Subchapter.

i) Quality Control (QC) measures, which shall include:

i. QC Tests to be performed and the frequency of each test.

ii. List of equipment to be tested.

iii. Acceptability limits for each test performed.

iv. Description of each QC test procedure.

v. Sample forms for each QC test performed.

vi. Processor and solutions maintenance; and

vii. Annual Medical Physicist's QC Survey.

j) Policies and Procedures which shall include:

i. Policy for holding patients and for the presence of individuals in the room during radiation exposure.

ii. Policy for pregnant patients and employees.

iii. Policy for gonadal shielding.

iv. A description of the orientation program for operators of radiographic, fluoroscopic, and CT equipment, including the duration and content of that program.

v. Procedures for proper use and maintenance of equipment.

vi. Policies and employee responsibilities concerning personnel radiation monitoring.

vii. Policy for releasing films.

viii. Policy for labeling films (i.e., patients' statistics, facility information).

ix. A commitment to perform a Radiation Safety Survey of the Environs in accordance with N.J.A.C. 7:28-15.10 on newly installed X-ray equipment within 60 days of installation and an initial Medical Physicist's QC Survey as required by N.J.A.C. 7:28-22.8(a), 22.9(a), or 22.10(a) as appropriate for the type of X-ray equipment.

x. Policy for using technique charts; and

xi. Policy and rules on Radiation Safety as required by N.J.A.C. 7:28-15.9(a)8.

k) A plan for taking corrective actions, which shall include:

i. Measures to be taken when the X-ray equipment is determined to need repair, service, or calibration, and

ii. Measures to be taken when the processor is determined to need repair or service.

l) Record keeping, which shall include:

i. Records for the most recent year of the QC tests performed by the registrant.

ii. Records of the initial Medical Physicist's QC Survey plus the two most recent QC Surveys.

iii. Records of corrective actions for the most recent two years; and

iv. Personnel monitoring records.

7. Inspection and Enforcement

7.1 Inspection by the Office of Radiation Safety Services

7.1 (a) The Office of Radiation Safety Services, or any State or Federal agency charged with the regulation of radioactive material, may at any time inspect the facilities and licensed activities of a radioactive material licensee.

7.1 (b) The Office of Radiation Safety Services shall perform routine monthly inspections of the activities of each licensee actively using radioactive material. This inspection shall include, but not be limited to, the following activities:

i. An inspection of the records and files identified in 4.13 (a) and 4.13 (b) shall be made to confirm that all documents are accurate and current.

ii. An inspection of the results of routine contamination and area monitoring shall be made to ensure that these surveys are being performed at the required frequency, and the results do not indicate unsatisfactory conditions.

iii. Random wipe tests and area monitoring shall be performed to confirm the results obtained by the licensee.

iv. The inspector shall attempt to confirm through observation and personnel interviews that all relevant regulations contained in Chapter 4 "Radiation Safety Requirements" are being observed by the licensee and individuals under his/her supervision.

7.1 (c) During an inspection by the Office of Radiation Safety Services, the licensee shall make available all required records and documents and shall assist the inspector, when required, during his/her review of the licensee's activities using licensed material.

7.1 (d) The undertaking of contamination and area surveys, and the review of licensed activities for safety and regulatory compliance, by the Office of Radiation Safety Services shall not relieve the licensee of his/her obligation to perform these functions.

7.1 (e) Two (2) weeks before vacating any laboratory facility or shipping equipment used in controlled areas and potentially contaminated, licensees will submit a Vacate Survey to the Office of Radiation Safety Services. The Office of Radiation Safety Services will review the survey and conduct independent measurements before approving the release of laboratory equipment.

7.2 Inspections by State and Federal Regulatory Agencies

7.2 (a) During the course of inspection by the Nuclear Regulatory Commission, New Jersey Department of Environmental Protection, or other regulatory body, each licensee, so requested, shall cooperate completely with the inspector and shall make available all records pertaining to radioactive material use, shall provide any information requested by the inspector, shall perform any licensed procedures which the inspector wishes to review, and shall have individuals under their supervision available for a closed door interview with the inspector, when this has been requested by either the inspector or the worker.

7.3 Enforcement Procedures

7.3 (a) Each individual shall report to the Office of Radiation Safety Services any conditions or activities that he/she feels may present a risk to human health or the environment, or which may not be in full compliance with State, Federal, or Local regulations.

7.3 (b) The Radiation Safety Officer shall immediately initiate an investigation in response to any complaint or report of the misuse of radioactive material, of an unanticipated radiation exposure or, of an activity which is not in full regulatory compliance.

7.3 (c) The Office of Radiation Safety Services shall prepare a written "Notice of Violation" when an inspection or investigation determines that a licensee's activities violate Governmental and/or local regulatory policies. A copy of this Notice shall be forwarded to the Licensee and the Chairperson of the Licensing Subcommittee of the Radiation Safety Committee.

7.3 (d) The enforcement actions taken by the Radiation Safety Committee shall be based on the Severity Categories established by the NRC. Appendix C contains a listing of these categories.

i. Any violation falling into NRC Severity Category I, II, III, or IV shall result in immediate suspension of the user's license. Consideration for reinstating the license shall not be undertaken until a full investigation by the Radiation Safety Committee is complete and all required corrective measures are in place.

ii. Any violation falling into Severity Category IV (1, 2, 4), or V, shall result in written notification to the licensee by the Radiation Safety Officer, and notification of the Radiation Safety Committee of this action. A subsequent occurrence of the violation shall result in the issuance of a written order by the Radiation Safety Officer requiring that remedial actions be in place within two (2) weeks. A licensee must respond in writing to a written order. The response shall detail the corrective actions undertaken and shall be countersigned by the licensee's department chairman. Failure to respond to a written order or the occurrence of a subsequent violation shall result in the Radiation Safety Committee taking action to suspend, modify, or revoke the licensee's authorization to use radioactive material. Licensees who are cited for numerous violations, which are not repeat violations, shall be subject to the same notification/suspension process described in this paragraph.

iii. In addition to the enforcement policies described in 6.3 (d) i, ii, above, the Radiation Safety Committee maintains the authority to suspend, modify, or revoke any license when the actions of the authorized user(s) present an unacceptable health risk to personal health or property, or jeopardizes the University's State or Federal radioactive material licenses.

iv. The accumulation of three (3) Notice of Violations within twelve (12) consecutive calendar months will result in automatic probation for the licensee. An Additional Notice of Violation will result in suspension of licensure action by the Radiation Safety Committee.

Appendix - A

Tables of Allowable Limit of Intake (ALI), Derived Air Concentrations (DAC), and Maximum Permissible Average Concentrations (MPAC), may be accessed from the following web address:

http://www.nrc.gov/reading-rm/doc-collections/cfr/part020/part020-appb.html

OR

Copies are available at the Office of Radiation Safety Services.

Appendix - B

Emergency Procedures for Radioactive Contamination

I Small Spills of Non-Volatile Radioactive Liquids

1. Contact the Office of Radiation Safety Services to obtain protective shoe covers. Don two pairs of protective gloves.
2. Avoid personal contamination and spreading of the spill. Use a Geiger counter or make wipe tests to determine the extent of the affected area. Mark the perimeter of the spill and cover with absorbent paper.
3. Place saturated paper in double plastic trash bags. Continue covering the spill with absorbent paper until all free liquid has been absorbed.
4. Remove residual radioactivity with detergent and water (use commercial decontaminant when available). Clean a small area at a time using a minimum amount of liquid. Work your way toward the center of the spill. Use a Geiger counter or a liquid scintillation counter to check the paper towels used. Place contaminated towels directly into the plastic waste bags.
5. The spill is considered clean when radioactivity can no longer be detected in the affected area and when the measurements made of the paper towels reveal that there is no longer any removable activity.
6. When decontamination is finished, place the shoe covers and gloves into the plastic waste bag, seal it, and label it with a radioactive material warning sticker.
7. The Radiation Safety Officer or a designee shall confirm that decontamination is complete, monitor individuals for personal contamination, and arrange for bioassay monitoring.

II Large spills of non-volatile radioactive liquids

1. Alert the nearest person to contact the Office of Radiation Safety Services.
2. Don two pairs of protective gloves. While avoiding personal contamination, prolonged exposure, or spreading of the spill, cover the effective area and a two-foot perimeter with absorbent paper and move away.
3. From a safe distance, stand guard to prevent anyone from entering the affected area. Do not leave until the Radiation Safety Officer or a designee arrives to check you for personal contamination.
4. Do not attempt to clean the spill until a member of the Office of Radiation Safety Services arrives to monitor radiation levels, supervise decontamination procedures, and arrange for bioassay monitoring of individuals involved in the procedure.

III Skin Contamination

1. Alert the nearest person to contact the Office of Radiation Safety Services.

2. Immediately, decontamination begins. Use mild soap and water - wash the affected area two or three times, but no more. Be careful not to spread localized contamination. Strenuous scrubbing will abrade the skin, leading to increased penetration of the contaminant. Do not use strong alkaline detergents or organic solvents. Simple washing should be adequate to remove most of the contamination. If residual radioactivity remains on the hands, donning protective gloves to induce sweating will help flush out skin pores; however, the gloves must be removed and the hands washed immediately after profuse sweating begins or else contamination will penetrate the dilated pores. More severe decontamination procedures should only be undertaken under the supervision of the Radiation Safety Officer.
3. If hair becomes contaminated, immediately begin washing with soap and water. Avoid spreading contamination to other parts of the head.
4. If contamination of the eyes occurs, flush with copious amounts of isotonic solution (if available), otherwise, use water. Be sure to roll back the eyelid as far as possible. If residual contamination remains, further decontamination shall require medical supervision.
5. If contamination of the nose or mouth occurs, immediately flush with copious amounts of water; be careful not to ingest the rinse.
6. If contamination of a small wound occurs, stimulate bleeding and flush with sterile water, then follow standard first aid procedures. If contamination of a large wound occurs, control the bleeding and seek medical attention. Decontamination may be undertaken when the situation is medically under control.

IV Contamination of Clothing

1. Contact the Office of Radiation Safety Services to obtain disposable paper surgical scrubs. When these arrive, change out of affected clothing, being careful not to contaminate your skin. Place affected clothing in a plastic bag, label with a radioactive material warning sticker, and transfer to the Office of Radiation Safety Services for decontamination.
2. If the soles of the shoes become contaminated, contact the Office of Radiation Safety Services to obtain a pair of surgical booties. Do not cause the spread of contamination by moving around in contaminated shoes. Shoe soles are typically decontaminated easily using soap and water. Perform this procedure over a sink normally used for radioactive materials. Use a Geiger counter or make wipe tests to determine when decontamination is complete. Initiate a survey of your work area to determine the source of the contamination.

V Release of Airborne or Volatile Radioactivity

1. Alert everyone in the area of the situation and advise them to evacuate the room and to remain in the area outside the room. Have someone contact the Office of Radiation Safety Services.
2. If possible, stop the release of airborne radioactivity from the source, but do not inhale while doing so.

3. Evacuate the room, closing the door behind you. Stand guard to prevent further entry until the Radiation Safety Officer arrives.
4. Personnel who were present in the room should not leave the area until checked for contamination by the Radiation Safety Officer. If contamination is obvious, do not wait for the arrival of the Radiation Safety Officer or a designee, but immediately commence personal decontamination at the nearest sink. Be sure to remove shoes and a lab coat before doing this so that the spread of contamination is limited.
5. Make a list of everyone present in the area during the incident. These individuals must receive bioassay testing for internalized radioactivity.
6. Re-entry and decontamination of the affected room shall only be undertaken under the supervision of the Radiation Safety Officer.

Appendix - C

Listing of NRC Severity Categories

The NRC severity categories may be accessed using the following web address:

http://www.nrc.gov/reading-rm/doc-collections/cfr/part002/full-text.html#part002-0201

or

Copies are available at the Office of Radiation safety Services.

Appendix - D

The Written Directives are available from the supervisors of the clinical divisions. A copy of the same is available at the Office of Radiation Safety Services.