



Title: **University Radiation Safety Manual**

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1. Introduction

The University is authorized to procure and use radioactive materials under a Broad Academic and Medical license issued by the New York State Department of Health (DOH)/ Bureau of Environmental Radiation Protection. This license is contingent upon the existence of a Radiation Committee and a Radiation Safety organization which, among other requirements must:

- 1.1 Ensure that any investigator using radioactive materials is qualified by training and experience, has the facilities to handle the materials safely and proposes a use which is safe to all concerned.
- 1.2. Assure observance of requisite safety standards established by the New York State Department of Health, Nuclear Regulatory Commission (NRC), National Council on Radiation Protection and Measurements (NCRP) and other regulatory or standards setting agencies.
- 1.3. Keep records of the receipt, storage, use, transfer, and ultimate disposal of all radioisotopes used at University.
- 1.4. Keep records of the monitoring of personnel and areas involved in the use of radionuclides and other sources of ionizing radiation.

The University is subject to periodic inspection to insure that all requirements of the license are being met. These inspections are very thorough, including monitoring checks of laboratory areas, inspection of procurement and disposition records, records of the qualifications of individual users, and records of administrations to patients. Violations of license requirements can result in a loss of the license.

2. Authorities and Responsibilities

2.1 Presidential Statement

In accordance with state and federal laws and Stony Brook's broad scope radioactive material license, the President has delegated to the Administrative Vice President the authority to administer the radiation safety program. Routine administration of the program is delegated to the Radiation Protection Services Division, with oversight from the University Radiological Protection Committee (URPC) and the University Hospital Radiation Safety Committee (UHRSC). The Committee shall have the following responsibilities:

- 2.1.1 Review all applications for the use of all radiation sources within the University from the standpoint of radiological health safety and other factors which the Committee may wish to establish for medical use of these materials.
- 2.1.2 Prescribe special conditions which may be necessary, such as physical examinations, additional training, designation of limited area or location of use, waste disposal methods, etc.
- 2.1.3 Review records and receive reports from the Radiation Safety Officer or other individuals responsible for health safety practices.
- 2.1.4 Recommend remedial action when a person fails to observe safety recommendations and rules.
- 2.1.5 Keep a record of actions taken by the Committee.

2.2 Vice President for Administration -

The Office of the Vice President for Administration provides management structure for the establishment of policy, and operational capability to the Radiation Protection Services Division, as outlined below. The President's office appoints the members of the University Radiological Protection Committee (URPC) and the University Hospital Radiation Safety Committee (UHRSC). These bodies establish policy for the use of ionizing radiation on the Stony Brook Campus. The Administrative Vice President is responsible for the operational aspects of the radiation safety program performed under the auspices of the Radiation Protection Services Division.

2.3 Radiation Safety Officer

The Radiation Safety Officer shall have the following responsibilities:

- 2.3.1 Administration of the Radiation Safety Officer for the reception and distribution of all radioactive materials entering the.
- 2.3.2 Recommending operational procedures regarding the safe handling and administration of radioactive materials.
- 2.3.3 Maintenance of an inventory record system to record all radioactive materials entering the University and distribute by the Radiation Safety Office.
- 2.3.4 Administration of personnel monitoring program, including the maintenance of all necessary records.
- 2.3.5 Systematic inspection of all radiation areas within the University to determine the extent to which safety requirements are being met.
- 2.3.6 Maintenance of a radioactive waste disposal system.

- 2.3.7 Report to the Committee annually, and at such other times as may be necessary on findings revealed by inspections.
- 2.3.8 To assist the Committee in the development of such safety programs as may seem desirable.
- 2.3.9 To take immediate charge in the case of all accidents where radioactive materials have been involved and to take such measures as may be required to return the area to a safe operating condition.
- 2.3.10 Report for the Committee as may be required by the Federal, State, and City agencies concerned with community radiation control.

2.4 University Radiological Protection Committee (URPC)

- 2.4.1 The Radiation Safety Committee is required by State regulations. It is responsible for maintaining Stony Brook personnel radiation exposures as low as reasonably achievable (ALARA) and for activities at Stony Brook involving the use of radioactive material and radiation-producing machines. The Committee develops University policy concerning radiation safety.
- 2.4.2 The chairperson of the URPC Committee is selected from faculty who are knowledgeable in radiation safety and the use of radioactive material and radiation-producing machines. The term of membership is one year and is renewable. The Radiation Safety Committee has the authority to evaluate and authorize research, development, or educational use of radioactive material or radioactive material or radiation-producing machines. The Committee may suspend or revoke an authorization for the use of radioactive material or the operation of a radiation-producing machine. The committee meets bi-monthly to carry out the responsibilities outlined in the bylaws.

2.5 University Hospital Radiation Safety Committee (UHRSC)

The University Hospital Radiation Safety Committee is required by regulation and reviews proposed uses involving the administration of radioactive material or external ionizing radiation to human subjects. The chairperson and members are selected from University Hospital faculty who are knowledgeable in radiation safety and the human use of radioactive material and radiation-producing machines. The term of membership is one year and is renewable. The UHRSC has the authority to evaluate and authorize research, development, or educational use of radioactive material or radiation-producing machines. The Committee may suspend or revoke an authorization for the use of radioactive material or the operation of a radiation-producing machine. The committee meets quarterly to carry out the responsibilities outlined in the bylaws.

2.6 Office of Environmental Health & Safety (EH&S)

The Office of Environment, Health & Safety is responsible for assuring that all University facilities are operated in a safe manner and comply with the requirements of governmental agencies and Stony Brook University policies. EH&S provides guidance and services to ensure a safe working environment at Stony Brook University. EH&S activities are carried out by professionals in safety engineering, industrial hygiene, sanitation, biological and chemical safety, emergency planning, fire safety, and radiation safety. The EH&S Director and/or Associate Director serves on various safety committees.

Environmental Health and Safety
110 Suffolk Hall
Zip 6200

Main Office: 632-6410

FAX: 632-9683

2.7 Radiation Protection Services (RPS)

The Radiation Protection Services Division is the operational unit for the radiation safety program and is managed by the Radiation Safety Officer (RSO). The RSO is designated by name and position as a broad scope license condition and is an ex-officio member of the Radiation Safety Committee and the Medical Radiation Safety Committee.

- 2.7.1 Regulatory functions such as the administration of the radioactive material and X-ray machine authorization programs; survey and audit functions; and assuring compliance with state, federal, and local radiation control regulations.
- 2.7.2 Educational functions to support and train radiation users and to provide community outreach activities.
- 2.7.3 Service functions to supply client needs such as radioactive waste disposal, instrument calibration, and emergency response.

2.8 Department Chair

The Department Chair shall be responsible to oversee the Radiation Safety Compliance Program for all the faculty members in his/her department. The Radiation Safety Officer will copy the Department Chair on all RPS lab inspections and radiation safety compliance reports.

2.9 Senior Investigator (SI)

The Senior Investigator (SI) assures that activities under the radiation use authorization are conducted in accordance with radiation safety requirements and good practices, as presented in this manual and in other reference material available from the Radiation Safety Division. In addition, the Senior Investigator must maintain records demonstrating compliance with radiation safety laws, regulations, and University policy concerning personnel training and safety when using radioactive material or radiation-producing machines. The Senior Investigator will be provided with a Radiation Safety logbook during the licensing process.

2.10 Radiation Workers (RW)

Radiation workers are responsible for complying with conditions of the radiation use authorization, radiation safety requirements, and good practices as presented in this manual and in other reference material available from the Radiation Safety Division

Each individual who, at any time, has control over a source of ionizing radiation is responsible for:

- 2.10.1 Keeping personal exposure to radiation as low as reasonably achievable (ALARA), and specifically below the maximum permissible exposure as listed in the following table:

REMS PER CALENDAR QUARTER:

Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads.....	1.25
Hands and forearms; feet and ankles	12.25
Skin of whole body	12.25

To maintain exposure to personnel ALARA, the Radiation Safety Office will examine all exposures exceeding 10% of the above maximum permissible doses. and follow a detailed ALARA management program.

2.10.2 Wearing the prescribed monitoring equipment, such as film badges, finger TLD, and pocket dosimeters in radiation areas. Personnel who work only with pure beta emitters having a maximum energy of less than 0.2 Me V (e.g., H-3, C-14, S-35) will not be required to wear film badges.

2.10.3 Surveying his hands, shoes, and body for radioactivity and removing all loose contamination before leaving a radioisotope laboratory to smoke, etc, etc.

2.10.4 Utilizing all appropriate protective measures such as:

- a) Wearing protective clothing whenever contamination is possible and not wearing such clothing outside of the laboratory area.
- b) Using protective barriers whenever possible (including syringe shields).
- c) Using mechanical devices (forceps) whenever their aid will assist in reducing exposure.
- d) Using pipette filling devices. Never pipette radioactive solutions by mouth.
- e) Performing radioactive work within confines of an approved hood or glove box unless serious consideration has indicated the safety of working in the open.

2.10.5 Dispose of waste only in specially designated receptacles.

2.10.6 Abstaining from smoking, drinking, or eating in isotope laboratories. Refrigerators shall not be used jointly for foods and radioactive materials.

2.10.7 Maintaining good personal hygiene:

- a) Keep fingernails short and clean.
- b) Do not work with radioactive materials if there is a break in skin below the wrist.
- c) Wash hands and arms thoroughly before handling any object which goes to the mouth, nose, or eyes.

- 2.10.8 Checking the immediate areas, e.g., hoods, benches, etc., in which radioactive materials are being used for contamination. It is recommended that such checks be made at least once weekly. A log record should be maintained of these surveys including results which are entirely negative. Any contamination observed should be immediately cleaned and re-checked. (See Section 9 for permissible contamination levels).
- 2.10.9 Keeping the laboratory neat and clean. The work area should be free from equipment and materials not required for the immediate procedure. Keep or transport materials in such a manner as to prevent breakage or spillage (double container), and to insure adequate shielding. Whenever practical, keep work surfaces covered with absorbent material, preferable in a stainless steel tray or pan, to limit and collect spillage in case of accident.
- 2.10.10 Labeling and isolating radioactive waste and equipment such as glassware, used in laboratories for radioactive materials. Once used for radioactive substances, equipment should not be used for other work, sent from the area to central cleaning facilities, or repair shops until demonstrated to be free of contamination.
- 2.10.11 Requesting Radiation Safety Office supervision of any emergency repair of contaminated equipment in the laboratory. At no time shall servicing personnel be permitted to work on equipment in radiation areas without the presence of a member of the laboratory staff to provide specific information.
- 2.10.12 Reporting accidental inhalation, ingestion, or injury involving radioactive materials or radiation source to his supervisor and the Radiation Safety Office, and carrying out their recommended corrective measures. The individual shall cooperate in any and all attempts to evaluate his exposure.
- 2.10.13 Carrying out decontamination procedures when necessary, and for taking the necessary steps to prevent the spread of contamination to other areas.
- 2.10.14 Complying with requests from the Radiation Safety Office for body burden measurements and the submission of urine samples for radioassay. Requests for these tests may be made in the case of workers using significant quantities of both beta and gamma emitters.
- 2.10.15 Promptly reporting any condition which may cause a violation of regulations or unnecessary exposure to radiation or to radioactive materials. (See Section 12, Notification of Incidents).

3. Maintaining Occupational Radiation Exposures at Stony Brook

3.1 ALARA (As Low As Reasonably Achievable)

- 3.1.1. The Administration of SUNY at Stony Brook is committed to the program described in this policy for keeping exposures (individual and collective) As Low As is Reasonably Achievable (ALARA). In accord with this commitment, a description of an administrative organization for radiation safety has been developed, and the necessary written policy, procedures and instructions to foster the ALARA concept within our institution has been established. The organization includes a Presidential safety committee, titled University Radiological Protection Committee (URPC), whose function it is to oversee all research that involves the use of radioisotopes or ionizing radiation producing equipment. The organization also includes the University Radiation Safety Officer (RSO) whose function it is to maintain the University's radioactive materials license and monitor the radiation safety program on a day-to-day basis.
- 3.1.2 It is assured that a formal annual review of the radiation safety program, including ALARA considerations, will be conducted. This shall include reviews of operating procedures, past exposure records, annual state inspections, reports, reported incidents, as well as new projects that are being considered in the new year.
- 3.1.3 Modifications to operating and maintenance procedures and to equipment and facilities will be made to reduce exposures when they are practical. Documentation will be maintained of what improvements have been sought, what modifications have been considered, and which have been implemented. Documentation describing the reasons for not implementing them will also be maintained.
- 3.1.4 In addition to maintaining doses to individuals as far below the limits (see Appendix 3) as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level.

3.2. University Radiological Protection Committee (URPC)

3.2.1 Review of Proposed Users and Uses

- The URPC will thoroughly review the qualifications of each applicant, with respect to the types and quantities of materials and uses for which that person has applied, to assure that the applicant will be able to take appropriate measures to maintain exposure ALARA.
- When considering a new use by-product material, the URPC will review the efforts of the applicant to maintain exposure ALARA. The URPC will ensure that the user will have procedures to attain ALARA, and shall have incorporated special equipment (lab shields, rubber gloves, etc.) in the proposed use.
- The URPC will ensure that all projects justify the procedures and that dose will be ALARA (individual and collective).

3.2.2 Delegation of Authority

- The URPC will delegate authority to the RSO for enforcement of the ALARA concept.
- The RSO will bring instances of deficiencies to the attention of the URPC, and the URPC will record the basis of its action in the Committee minutes.

3.2.3 Review of ALARA Program

- The URPC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
- The URPC will evaluate the institution's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the RSO, authorized users and workers, as well as those of the University.

3.3 Radiation Safety Officer (RSO)

3.3.1 Annual and Quarterly Review

- The RSO will perform an annual review of the Radiation Safety Program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.
- The RSO will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigation Levels [see Table] are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigation Levels are exceeded (see paragraph VI).
- Quarterly records of Radiation Level Surveys: The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

3.3.2 Education Responsibilities for an ALARA Program

- The RSO will inform workers of ALARA program efforts.
- The RSO will assure that authorized users, workers and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that the University, the URPC and the RSO are committed to implementing the ALARA concept.

3.3.3 Cooperative Efforts for Development of ALARA Procedures

- Radiation workers will be given opportunities to participate in formulation of the procedures that they will be required to follow.

- The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
- The RSO will receive and evaluate the suggestions of individual workers for improving health physics practices.

3.3.4. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices; and, if possible, determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

3.4. Authorized Users

3.4.1. New Studies, Research, or Procedures Involving Potential Radiation Exposures

- The authorized user will consult with and receive the approval of the RSO and/or the URPC during the planning stage before using radioactive materials for a new study.
- The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

3.4.2. Responsibility of the Authorized User to Those Supervised

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

3.5. Persons Who Receive Occupational Radiation Exposure (Workers): Workers will be instructed in the ALARA concept and its relationship to their working procedures and work conditions. Workers will be advised of what recourses are available if they feel that ALARA is not being promoted on the job.

3.6. Establishment of Investigation Levels in Order to Monitor Individual Occupational External Radiation Exposures.

3.6.1. SUNY at Stony Brook has established Investigation Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the University Radiological Protection Committee and/or the Radiation Safety Officer. The Investigation Levels that we have adopted are listed in the Table below. The levels apply to the exposure of individual workers.

TABLE

	Investigation Levels (mrems per calendar quarter)	
	Level I	Level II
1. Whole Body Deep:	125	375
2. Lens of Eye:	375	1,125

3. Whole Body Shallow:	1,250	3,750
4. Extremity:	1,250	3,750
5. Organ:	1,250	3,750

3.6.2. The Radiation Safety Officer will review and record on Form NRC-5, Current Occupational External Radiation Exposures, or an equivalent form (e.g. dosimeter processor's report), results of personnel monitoring, not less than once in any calendar quarter, as is required by 10 CFR 20, 20.401. The following action will be taken at the Investigation Levels shown in the Table.

Quarterly Exposure of Individuals to less than Investigation Level I

- Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than values for Investigation Level I.
- Personnel exposures equal to or greater than Investigation Level I, but less than Investigation Level II
- The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigation Level I. The RSO will report the results of his reviews at the first URPC meeting following the quarter when the exposure was recorded. If the exposure does not equal or exceed Investigation Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, consider each such exposure in comparison to others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

Exposure equal to or greater than Investigation Level II

- The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigation Level II and, if warranted, take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the URPC at its first meeting following completion of the investigation. The details of these reports will be sent to the administration of this institution for review. The minutes, containing details of the investigation, will be made available to Radiological Health Inspectors for review at the time of the next inspection. This provision shall also apply to radioactivity intakes which are greater than those which would result from inhalation for ten hours in any one week at uniform concentrations specified in Appendix B, Table I, column 1 of 10 CFR Part 20.

3.6.3 Re-establishment of an individual occupational worker's Investigation Level II above that listed in the Table

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

- The URPC will review the justification for, and will approve all revisions of, Investigation Level II. In such cases, when the exposure equals or exceeds the newly established Investigation Level II, those actions listed in paragraph B3 above will be followed.

4. Authorization to Use Radioactive Materials

4.1 All Applications

As the recipient of a Type A License of Broad Scope for use of radioactive material, the University is charged with the responsibility of insuring that such materials as are procured under the license be used in a manner that is completely safe and without hazard to personnel or to property. The University Radiological Protection Committee has been delegated this responsibility and has the authority to issue or withdraw authorizations for the use of radioisotopes. Before any radioactive material can be used, an application must be approved by the Committee and an appropriate authorization for such use must be issued in the name of the Committee by the Radiation Safety Officer. Before an application can be approved for an individual user, the Committee must determine that the training and experience of the applicant is adequate to conduct the proposed investigation in a safe manner. Such a determination is critically dependent upon the proposed use, since the kind and quantity of radioactive material coupled with the way the material is to be used specifies the degree of the hazard. Each application for an authorization to use radioactive material must contain a complete statement of the applicant's training and experience. This is, of course, in addition to the statement of the kind, quantity, and proposed use of the material. The Committee in its review of the application determines whether or not the statement of training and experience is consistent with the kind, quantity, and proposed use of radioactive material that the applicant has specified. For additional information be sure to visit our Web site at www.stonybrook.edu/facilities/ehs/radiation.

Training sufficient for the proposed use may be obtained by the applicant from a formal training course, or by collaboration with an experienced person. As a prerequisite for approval, the applicant and his technical staff shall provide satisfactory evidence of his knowledge of:

- A) Principles and practices of radiation safety
- B) Radioactivity measurements, standardization, and monitoring techniques and instruments
- C) Mathematics and calculations basic to the use and measurement of radioactivity
- D) Biological effects of radiation

An acceptable formal training course is available to the University personnel. The Radiation Safety Course offered annually includes subjects essential for approval for an individual to use radioactive materials. In addition to the training requirement, the applicant must show that sufficient experience has been acquired in the safe handling of the material for which application is made or that equivalent experience has been acquired.

If the applicant has had training and experience suitable for a large variety of problems but not enough for the use which is proposed, this investigator should make his application in his own name and in the name of a collaborator (joint application). Such an application will be approved in the name of the experienced person but with the understanding that the work will be performed by the inexperienced person under the supervision of the other. Responsibility for safe use of this material will be vested in the experienced user who will remain responsible throughout the life of the authorization. At such time as the supervising investigator is willing to recommend that the inexperienced person is ready to undertake the work without supervision, a new application may be submitted in the name of the new experienced person with his recently acquired experience listed in Item 12 of the application.

Applications for possession and use of radioactive material are to be made on RSO Forms EHSD0002 Obtaining Authorization to use radioactive Materials. Copies of these forms are available on the WEB: Copies of these forms are available on our WEB site: www.stonybrook.edu/facilities/ehs/radiation/radforms.shtml.

Both forms are to be completed for the initial application of a prospective user. These forms are required if the user wishes to report changes in equipment, facilities, or procedures. Ordinarily, the application from an investigator already authorized to use one or more radioisotopes and who wishes to extend his coverage will require to complete an amendment to his/her existing license permit.

4.2 Application for Human Use

Applications for the administration of radiation (x-rays or radioisotopes) to human subjects in research projects must be made to the RSO for proper committee review. The completed application and a copy of the Research Project Notification should be sent to the Radiation Safety Office. The application is then reviewed by the University Radiological Protection Committee. The following guidelines have been imposed for research projects involving a non-FDA approved radiopharmaceutical:

4.2.1 Radiation Dose to Subjects

- To assure that the radiation dose to research subjects is as low as practicable to perform the study the University Radiological Protection Committee shall require that:
- The investigator provide absorbed dose calculations based on biologic distribution data available from published literature or from other valid studies.
- The investigator provides an acceptable method of radioassay of the radioactive drug prior to its use to assure that the dose calculations actually reflect the administered dose.
- The radioactive drug chosen for the study has that combination of half-life, types of radiation, radiation energy, metabolism, chemical properties, etc., which results in the lowest dose to the whole body or specific organs with which it is possible to obtain the necessary information.
- The investigator utilizes adequate and appropriate instrumentation for the detection and measurements of the specific radionuclides.

4.2.2 Limit on Radiation Dose

The amount of radioactive material to be administered shall be such that the subject receives the smallest radiation dose with which it is practical to perform the study without jeopardizing the benefits to be obtained from the study.

Under no circumstances may the radiation dose to an adult research subject from a single study or cumulatively from a number of studies conducted within one year exceed the following:

Whole body, active blood-forming organs, lens of the eye, and gonads:

	Rems
Single dose	3.0
Annual and total dose commitment	5.0
Other organs:	
Single dose	5.0
Annual and total Commitment.....	15.0

For a research subject under 18 years of age at his last birthday, the radiation dose shall not exceed 10 percent of the above limits.

All radioactive material included in the drug either as essential materials or as a significant contaminant or impurity shall be included when determining the total radiation doses and dose commitments. Radiation doses from x-ray procedures that are part of the research study (i.e., would not have occurred but for the study) shall also be included. The possibility of follow-up studies shall be considered for inclusion of the dose calculations.

Numerical definitions of dose shall be based on an absorbed fraction method of radiation absorbed calculation, such as the system set forth by the Medical Internal Radiation Dose Committee of the Society of Nuclear Medicine, or the System set forth by the International Commission on Radiological Protection.

4.2.3 Limit on Pharmacological Dose

The amount of active ingredients to be administered shall be known not to cause any clinically detectable pharmacological effect in human beings. To determine that the amount of active ingredients to be administered does not exceed the limitation, the committee shall require that the investigator provide pharmacological dose calculations based on data available from published literature or from other valid human studies. If the same active ingredients (exclusive of the radionuclide) are to be administered simultaneously, e.g., under a "Notice of Claimed Investigational Exemption for a New Drug" or for a therapeutic use in accordance with labeling for a drug approved under Part 314 of 21 CFR, the total amount of active ingredients including the radionuclide shall be known no to exceed the dose limitations applicable to the separate administration of the active ingredients excluding the radionuclide.

4.2.4 Quality of Radioactive Drug

The radioactive drug used in the research study shall meet appropriate chemical, pharmaceutical, radiochemical, and radionuclide standards of identity, quality, and purity as needed for safety and be of such uniform and reproducible quality as to give significance to the research study conducted. The University Radiological Protection Committee shall determine that radioactive materials for parenteral use are prepared in sterile and pyrogen-free form.

4.2.5 Qualification of Investigator

Any individual wishing to use radioactive materials in human subjects must be a physician licensed to dispense drugs in the practice of medicine by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. Outlined below are training and experience criteria which the Committee will accept for physicians who use radiopharmaceuticals. Each physician's training and experience are examined on a case-by-case basis. If a physician wishes to use radiopharmaceuticals but does not have the training and experience described, he may submit an application listing his specific qualifications and this will be reviewed by the Committee. Training may be obtained in a residency, formal training course, or collaboration in a program using radioactive material. A physician's background should include the basic radioisotope training in Section 3.1 plus, Clinical Radioisotope Training Consisting of:

1. Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation on dosage to be prescribed.
2. Collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurements, and plotting data;
3. Adequate period of training to enable the physician to manage radioactive patients and to follow patients through diagnosis and/or the course of treatment.
4. Study and discussion with preceptor of case histories to establish most appropriate diagnostic and/or therapeutic procedures, limitations, contraindications, etc.

4.2.6 Human Research Subjects

Each investigator shall select appropriate human subjects and shall obtain the consent of such human being or their representatives. The research subjects shall be at least 18 years of age and legally competent. Exceptions are permitted only in those special situations when it can be demonstrated to the committee that the study presents unique opportunity to gain information not prescribed available and requires the use of research subjects less than 18 years of age and is without significant risk to the subject. Studies involving minors shall be supported with review by qualified pediatric consultants to the University Radiological Protection Committee. Each female research subject of child-bearing potential shall state in writing that she is not pregnant, or, on the basis of a pregnancy test, be confirmed as not pregnant before she may participate in any study.

4.2.7 Research Protocol

No matter how small the amount of radioactivity, no study involving administration of a radioactive drug, to research subjects shall be permitted unless the University Radiological Protection Committee concludes, in its judgment, that scientific knowledge and benefit is likely to result from that study. Therefore, the protocol shall be based upon a sound rationale derived from appropriate animal studies or published literature and shall be of sound design such that information of scientific value may result. The radiation dose shall be both sufficient and no greater than necessary to obtain valid measurement. The projected number of subjects shall be sufficient but no greater than necessary for the purpose of the study. The number of subjects shall also reflect the fact that the study is

intended to obtain basic research information and not intended for immediate therapeutic, diagnostic or similar purposes or to determine the safety and effectiveness of the drug in humans for such purposes, (i.e., to carry out a clinical trial).

4.2.8 Annual Report

Some research projects may require an annual report to be submitted to the Food and Drug Administration. Such reports must be made on Form FD 2915 and submitted to the Committee before January 31. The following information must be presented:

1. Title of the research project.
2. Brief description of the purpose of the research project.
3. Name of the investigator responsible.
4. Pharmacological dose:
 - a) active ingredients
 - b) Maximum amount administered per subject
5. Name of the radionuclide(s) used, including any present, as significant contaminants or impurities.
6. Radiation absorbed dose. Give the methods by which radiation dose commitment was estimated, such as by calculation, by in vivo measurements, by uptake excretion, or by other methods. For each subject, provide:
 - a) Age, sex
 - b) Amount of each radionuclide administered
 - c) Estimated absorbed dose per single administered of radioactive drug, expressed as whole body active blood-forming organs, lens of the eye, gonads, and other organ dose.
 - d) If more than one administration of a radioactive drug per subject, cumulative radiation dose and dose commitment, expressed as whole body, and active blood-forming organs, lens of the eye, gonads, and other organ doses from the administered radionuclides.
7. A claim of confidentiality, if any.

4.2.9 Informed Consent

Research subjects shall be informed in writing that their participation in the study will involve radiation exposure. The magnitude of the radiation exposure and the associated risks should be presented in meaningful terms. Inclusion of a statement such as the

following is suggested:

"The Food and Drug Administration has listed the conditions under which the uses of radioactive drugs for research are considered as safe and effective. The amount of radiation you will receive as a result of the radioactive substance to be injected for this study is no more than that permitted by the FDA for a single study."

4.3 Authorizations

When the submitted application is approved by the Committee, the investigator is notified by receipt of an Authorization Form indicating the response of the Committee to the application. Most commonly, the investigator is authorized to possess and use the radioactive materials in the quantities and forms that he requested. Occasionally, in the interest of radiation safety, the Committee will add certain restrictions on the use of the radioactive material to insure compliance with current Federal and State regulations.

If an investigator has no positive plans for the use of a given authorization, he should consider its retirement in order to save on bookkeeping by the Radiation Safety Office. Such a retired authorization can usually be reactivated in one day should need for it develop. Whenever an authorization is inactivated or terminated, the Radiation Safety Office must insure that:

- A. The area is free of all radioactive materials and contaminants.
- B. All radiation caution signs and labels are removed.
- C. All radioactive material that is still in the possession of the user is stored in the Radiation Control Area or that disposal of such material has been properly carried out.
- D. Personnel monitoring services are discontinued.

4.4 Clinical Use of Radioactive Materials

Exposure to ionizing radiation of all individuals should be limited to an amount considered necessary to accomplish the desired therapeutic results or diagnostic result.

Every person who receives radiation in any amount and form any source shall have this fact recorded in a permanent record of the. This will be included in the patient's medical history record in addition to the permanent records maintained by the department concerned. These notions will be made by the physician responsible for administering the radiation.

If a patient dies or requires emergency surgery within two weeks after receiving a therapeutic dose of any radioisotope, the Radiation Safety Officer shall be called to determine if a radiation hazard exists. Under no circumstances shall an autopsy be performed, nor the body released from the, until certification has been obtained from the Radiation Safety Officer or his designate. For purposes of this section "therapeutic amounts" is defined as ten millicuries or more of any radioisotope with a half-life greater than 1 day.

Patients who receive amounts of radioactive materials which make them a hazard to others, shall be isolated in a designated area or areas of the. Arrangements for radiation isolation shall be made by the responsible physician before such amounts are administered. .

When therapeutic amounts of gamma emitting materials are being used in patient treatment, pregnant personnel shall be transferred from the area of radiation exposure. No visitors are permitted without specific permission from the Radiation Safety Office.

Tissue specimens, blood, ascetic fluid, feces, urine, emesis, etc., from patients undergoing radioisotope therapy shall not be sent to the clinical laboratories without permission of the responsible radiotherapist or the Radiation Safety Office.

5. Registration of Electronic Radiation Devices

5.1 Each electronic device capable of producing ionizing radiation shall be registered with the Committee.

The Committee may incorporate restrictions and conditions upon the use of the registered radiation device. The registrant must notify the Committee in writing before making any changes which would render the information contained in the registration no longer accurate.

5.2 Plans and specifications for the construction of new radiation facilities, or the major modification of existing facilities, shall be approved by the Committee. The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operation conditions indicate the possibility of an individual receiving a dose in excessive of the applicable standards. The plans should show as a minimum, the following:

The normal location of the radiation producing equipment's radiation port; the port's travel and transverse limits; general direction(s) of the radiation beam; location of any windows; the location of the operator's booth; and the location of the equipment's control console.

Structural composition and thickness of all walls, doors, partitions, floor and ceiling of the room(s) concerned.

The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, shown distance to the closet existing occupied area(s).

To make and model of the radiation producing equipment including the maximum energy output (for x-ray machines is the kilovolt peak potential).

The type of examination(s) or treatment(s) which will be performed with the equipment (e.g., dental, orthodontal, chest, gastrointestinal, fluoroscopic, computed tomography, podiatry, fixed therapy, rotational therapy, etc.).

Information on the anticipated workload should be provided, if available. Any other information considered pertinent in support of the application.

5.3 Posting and Labeling

Posting and labeling of radiation producing machines of all kinds shall be according to the requirements of the NYS DOH Part 16 regulations.

Rooms that are used for medical diagnosis should have a warning light that indicates "X-Ray On", to alert personnel or other people who may inadvertently enter a room during operation of the machine.

Rooms that are used for radiation therapy also have a warning light indicating that the beam of radiation is "ON". In addition standard signs with magenta radiation symbol on the yellow background "HIGH RADIATION AREA" are placed on the treatment room door.

Other types of devices such as cabinet X-ray equipment, bone scanner or electron microscopes are marked with signs stating "CAUTION--THIS DEVICE PRODUCES IONIZING RADIATION".

These types of devices should be placed in the areas away from main traffic pattern. Certain level of security is required to prevent unauthorized operation.

5.4 Departmental Radiation Safety and QA Requirements

All devices producing ionizing radiations should receive regular preventive maintenance, during which interlocks and safety devices are checked and repaired, if needed.

The NYS DOH Part 16 regulations require each installation using medical X-ray or other types of radiation producing devices to have **Quality Assurance** Programs, the implementation of which will be the basis for ensuring that employees, patients and general public are not subjected to undue radiation exposures. Specifics of each program depend on the type of installation, machine category and application.

5.4.1 QA programs for diagnostic facilities

A quality assurance program is a system of plans, actions, reviews, reports and records whose purpose is to ensure that diagnostic facilities achieve consistent high quality imaging and other diagnostic results, while maintaining radiation output at optimum and personnel exposures within ALARA limits. The Chief Medical Physicist for Radiology and Nuclear Medicine is charged with the responsibility to have in place and to manage the implementation of the QA Program, including at minimum:

5.4.1.1 The adoption of a manual containing written policies and procedures which are consistent with the types of equipment and services provided, including but not limited to, use of gonad and thyroid shielding; personnel monitoring; protection of pregnant workers and patients; holding of patients. The manual must describe the various processing, generator and systems quality control tests appropriate for the types of equipment and services provided in sufficient detail to ensure that they will be properly carried out;

5.4.1.2 The performance of quality control tests and the correction of deficiencies;

5.4.1.3 The maintenance of equipment records for each diagnostic imaging system, containing test results, records of equipment repairs and other pertinent information;

5.4.1.4 The provision for a formalized in-service training program for employees, including, but not limited to, quality assurance and applicable radiation protection procedures;

5.4.1.5 The measurement of radiation output at the point of skin entry for common X-ray examinations;

5.4.1.6 The provision of the information obtained in 5.2.2.5 to be provided to any patient upon request;

5.4.1.7 The conduct of an on-going analysis for of repeated, rejected or misadministered diagnostic studies which are designated to identify and correct

problems and optimize quality;

5.4.1.8 The Departmental QA and Radiation Safety manual may include procedures relating to the use of radioactive materials in Nuclear Medicine or these procedures may be in the form of a separate manual. In either case, the program must include the measurement of the amount of activity of each dose of a radiopharmaceutical administered to a patient and the calculated absorbed dose for each diagnostic procedure involving radioactive materials. Additionally, a provision must be made to properly convey this information to any patient upon request.

5.4.2 QA Programs for the Use of Radiation for Therapy in Humans

A quality assurance program for Radiation Oncology is a system of plans, actions, reviews, reports and records whose purpose is to ensure a consistent and safe fulfillment of the dose prescription to the target volume, with minimal dose to normal tissues. The Chief Medical Physicist for Radiation Oncology is charged with responsibility to have in place and implement a QA Program, including at minimum:

A. The adoption of a manual containing written policies and procedures regarding external beam therapy, designed to assure effective supervision, safety, proper performance of equipment, effective communication and quality control. These policies must specifically assure that:

- (1) Each patient's evaluation and intended treatment is documented in the patient's record;
- (2) A written, signed and dated order for medical use of radiation (and radioactive materials) is made for each patient; No person other than a qualified physician shall direct or order the application of radiation from X-ray therapy equipment (or radioactive materials) to a human being. Nor shall any person other than a qualified physician, or licensed/registered radiation therapy technologist (or a student currently enrolled in an approved program of study in therapeutic radiologic technology working under direct supervision of a qualified physician or technologist): position patients, set techniques or apply radiation therapy to human beings;
- (3) All orders and other treatment records are clear and legible;
- (4) Staff will be instructed to obtain clarification before treating a patient if any element of the order or other record is confusing, ambiguous or suspected to be erroneous;
- (5) Each patient's response to treatment is assessed by a physician knowledgeable in external beam therapy (and brachytherapy) and that unusual responses are evaluated as possible indications of treatment errors;
- (6) Complete treatment records containing data recorded at the time of each treatment are maintained;
- (7) The treatment charts of patients undergoing fractionated treatment are checked for

completeness and accuracy at weekly intervals;

- (8) Final plans of treatment and related calculations are checked for accuracy before 25% of the prescribed dose for external beam therapy (or 50% of the prescribed dose for brachytherapy) is administered. If a treatment plan and related calculations were originally prepared by a radiation therapy physicist possessing qualifications specified in the NYS DOH Part 16 regulations it may be checked by the same person using a different calculational method. Treatment plans and related calculations prepared by other personnel must be checked by a second person using procedures specified in the treatment planning manual - this person must possess qualifications as outlined in Part 16;
- (9) There is quality control for all physical components of radiation therapy such as: equipment function and safety (including treatment planning equipment), treatment planning procedures and computer codes, treatment application procedures, dosimetry, and personnel radiation safety;
- (10) The quality control tests are performed and documented, including: detailed procedures for performing each test, the frequency of each test, acceptable results for each test, corrective actions to be taken and record keeping and reporting procedures for test results.

- B. A radiation therapy physicist possessing the qualifications specified in Part 16 is charged with responsibility to prepare a procedures manual describing how radiation therapy treatment planning is to be performed. This Treatment Planning Manual may be part of the Departmental QA manual as described in 5.2.2.1 or a separate document. In either case, it shall include the calculation methods and formulas to be used at the facility (including the methods for performing the checks of treatment plans and related calculations). This manual shall be reviewed annually by a radiation therapy physicist and shall be included in training given to the facility staff who will be participating in treatment planning.
- C. A radiation therapy physicist responsible for QA program shall assure that all equipment used in planning and administering radiation therapy is properly functioning and designed for intended purpose, is properly calibrated and maintained in accordance with the manufacturer's instructions and the Departmental QA program.
- D. The effectiveness of the radiation therapy QA program is required to be reviewed annually. The reviews may be in the form of either external or internal audit, in accordance with Part 16. Audit findings, record of resulting actions and all appropriate documentation must be maintained.
- E. A radiation therapy physicist responsible for radiopharmaceutical and brachytherapy is charged with responsibility to prepare a procedure manual. This manual may be part of the Departmental QA Manual or a separate document. In either case, this document must include all elements listed in A. Similarly, the requirements listed above in C through D, as they apply to particular modality of treatment, must be met.

5.4.3 QA programs for radiation producing devices utilized in non-human applications.

No person shall operate an ionizing radiation producing equipment unless such equipment has been properly procured and registered, as described in 5.1 and evidenced by a current certificate of registration with the NYSDOH. The Head of the department utilizing such equipment or a responsible P.I., whichever appropriate, is responsible for having in place equipment specific

Departmental QA Program documented in the form of a manual. This program must include the following elements:

- (1) the performance of quality control tests,
- (2) the maintenance of repair records and other pertinent information,
- (3) the provision for a formalized in-service training program for employees, including but not limited to, quality assurance and radiation safety procedures,
- (4) the maintenance of training records
- (5) the maintenance of records of radiation surveys performed by the Radiation Safety Officer.

All Departmental QA programs described above are reviewed by the University Radiological Protection Committee on an annual basis.

6. Policies and Procedure for Using Radioactive Materials

6.1 Proper Posting of Laboratories, Areas, and Equipment

- 6.1.1 A "CAUTION RADIOACTIVE MATERIALS" sign must be conspicuously posted on the doors to laboratory areas where radioactive materials are being used or stored. The name and home telephone numbers of the individual responsible for the posted area shall be shown in order to facilitate contact in case of emergency. The authorized user shall be responsible for seeing that the posted information is current. The signs must not be removed from any room except by Radiation Safety Office personnel following an inspection survey.
- 6.1.2 Storage areas shall be conspicuously marked with "CAUTION RADIOACTIVE MATERIALS" sign. In addition, containers in which materials are transported or stored shall bear a durable, clearly visible label bearing the radiation caution symbol and the words "CAUTION RADIOACTIVE MATERIALS." This label shall also state the quantities and kinds of radioactive materials in the containers and the date of measurement of the quantity.
- 6.1.3 Radiation areas in the laboratory, i.e., areas where radiation levels might expose individuals to 5 millirem in any one hour; or in any five consecutive days, a dose in excess of 100 mrem, shall be posted with sign "CAUTION RADIATION AREA".
- 6.1.4 All equipment contaminated with radioactive material shall be marked with signs, decals, or other conspicuous means. Labeling shall not be required for laboratory containers such as beakers, flasks, and test tubes, used transiently in laboratory procedures during the presence of the user.
- 6.1.5 All signs referred to in this part are available from the Radiation Safety Office.

6.2 Shielding of Sources

The Radiation Safety Office will check during periodic surveys to insure that adequate shielding is used in all radiological operations. The total amount of shielding materials that will be necessary will depend on the amount of activity and the type of radiation involved. In some instances, it may be necessary to construct a "hot cell" or large shielding barrier to meet shielding requirements. The Radiation Safety Office will be available for consultation on all shielding problems encountered.

6.3 Aerosols, Dusts, and Gaseous Products

- 6.3.1 Procedures involving aerosols, dusts, or gaseous products or procedures which might produce airborne contamination in excess of regulatory limits shall be conducted in a hood, dry box, or other suitable closed system.
- 6.3.2 All release from such systems shall not exceed the maximum permissible concentration in air for nuclide in question, when averaged over one year. However, where practical, traps should be incorporated in the experimental set-up to insure that environmental releases are as low as possible.
- 6.3.3 Radioactive gases must be stored in gas-tight containers and must be kept in areas having approved

ventilation.

- 6.3.4 Hoods to be used for radioisotope work must be tested by the Radiation Safety Office to insure that they meet the minimum requirements for air velocity at the face of the hood.

6.4 Work Surfaces

All work areas (bench tops, hood floors, etc.) as well as storage areas and areas adjacent to permanent set-ups and sinks should be covered at all times with stainless steel or plastic trays, uncracked glass plates, or other impervious materials. For some purpose a plastic-baked absorbent paper (e.g., Kimpak) will be satisfactory. However, if such paper is used, it should be discarded frequently to prevent active materials from dusting off the surface.

6.5 Radiation Surveys

Area Surveys

In general, no detectable radioactive contamination shall be tolerated. Exceptions to this will include certain hood trays, stainless steel trays, diaper-lined absorbent paper protecting work surfaces, or other equipment which is used frequently for active work and which will be clearly marked with the standard radiation caution signs or stickers, as described above in Section 6.1.3. Each S.I. is responsible for performing routine surveys for contamination in locations under his/her supervision, where unsealed sources are handled.

- (1) Removable Contamination Survey Procedures (Wipe Testing). These surveys shall be in the form of wipe tests which shall be taken and counted utilizing a procedure that utilizes the following:
 - (a) Wipe tests shall be made of **all** surfaces where radioactive materials are handled, and in other locations which have a risk of becoming contaminated such as sinks, refrigerator, freezer handles, telephone etc;
 - (b) Each wipe test shall cover an area no greater than one 100 cm², and the number of wipe tests taken per survey shall be sufficient to ensure that any contamination within the area is detected;
 - (c) Wipes shall be assayed on a calibrated counting instrument in such a way as to detect contamination levels of below hundred disintegrations per minute /(100 dpm) on a sample;
 - (d) 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 nuclide, counting configuration, and counting cocktail used;
 - (e) Wipe tests for contamination with gamma emitters shall be counted using a well type sodium iodide scintillation counting system for which counting efficiency is known for the radionuclides being sampled and the counting source geometry used;

- (f) The results of wipe test surveys shall be maintained for inspection by Radiation Protection Services. All results above the background shall be recorded in the units of dpm;
- (g) Wipe test samples which give a count rate of greater than 200 dpm indicate the presence of contamination.

(2) Area Surveys

Area surveys of personnel and areas potentially contaminated should be performed using a GM survey meter having a probe with a window sufficiently thin to allow detection of the radionuclide(s) being surveyed. Surfaces should be surveyed at a distance of not more than 1 cm.

(3) Decontamination

Decontamination procedures (Section 7.) shall be initiated whenever a contamination survey or spot check yields positive results (for instance: when a count rate in excess of three times the background rate).

(3) Decontamination (Continued)

- a. More than 200 uCi is used on a daily basis:
 - area survey daily
 - removable contamination survey (Wipe Test) weekly
- b. Less than 200 uCi but more than exempt
 - Removable contamination survey (Wipe Test) weekly
 - Removable contamination survey (Wipe Test) monthly

(4) Frequency of Contamination Surveys

The contamination surveys described above in (1) & (2) shall be performed at the following frequency:

- (a) Daily area surveys shall be performed in areas where more than two hundred microcuries (200 uCi) of radioactive material is used on a daily basis;
- (b) Monthly surveys shall be performed in areas where less than two hundred microcuries (200 uCi) but more than exempt quantity of radioactive material is routinely used on a daily basis;
- (c) Special contamination surveys shall be performed immediately whenever contamination is suspected;
- (d) Spot checks should be performed between routine surveys, at the start of any new procedure involving sources of radiation and whenever significant or unpredictable changes in the exposure rate are possible.
- (e) The University RSO shall be contacted whenever an area survey reveals a radiation

level in which an individual may receive a whole body dose in excess of five (6) millirem in any one hour.

6.5.1.2 Leak Testing of Sealed Sources

Authorized Users who possess sealed sources that contain activity greater than exempt quantity should have these sources leak tested. The following criteria and frequency will apply:

- (1) Each source containing more than one hundred (100) microcuries of beta and/or gamma or twenty five (25) microcuries of alpha emitting radionuclide must be subjected to a wipe-test. This test must be performed in accordance with ANSI N44.2 - 1973 standard procedures, on a semi-annual basis;
- (2) Each leak test sample shall be assayed using counting equipment capable of detecting **0.005** microcuries of removable contamination;
- (3) When removable contamination exceeds **0.005** microcuries the source is considered to be failing leak test. The University Radiation Safety Officer shall be notified. The source yielding positive results of leak test must be immediately removed from service, sealed in a separate container and returned to the supplier for repair, replacement or disposal;
- (4) University Radiation Safety Officer provides leak test services to those University users who are authorized to handle sealed sources containing millicurie level of radioactive materials and to those users who require assistance in this area;

6.5.1.3 Survey of Laboratory Equipment

Some equipment is likely to become contaminated in the laboratories where unsealed radioactive materials are handled. The following procedures shall apply when the equipment requires servicing, transfer or disposal:

(1) Repair or Maintenance of Equipment

Before such equipment can be serviced by shop and maintenance personnel or by commercial service contractors, it shall be demonstrated to be **free of contamination**.

If it becomes necessary to make emergency repairs on contaminated equipment, radiation safety aspects of the work will be supervised by a member of Radiation Safety staff to assure that all necessary safeguards are taken. It is the responsibility of the laboratory personnel to contact the University Radiation Safety Officer and request this supervision.

(2) Removal of Equipment from the Laboratory

Once used for radioactive substances, laboratory equipment shall not be used for other work or removed from the area until demonstrated to be free of contamination. Equipment will be permitted to be removed from the area when dose rate is **0.2 mR/hr** or less at one centimeter from all accessible surfaces. The University Radiation Safety

staff will provide assistance in this determination.

6.6 Control of Radioactive Materials

All acquisitions of radioactive materials shall be done in accordance with the procedures described in Section 7. Once received, the sources of radiation become a responsibility of the P.I. who must assure that the following aspects of their handling are properly addressed:

(1) Storage and Shielding

Radiation sources shall be stored in properly posted areas, specifically designated for this purpose. In the laboratories, sources are usually stored in the freezers, refrigerators or special cabinets. Certain sources may be stored in a safe, others in the hood. All radiation sources should be adequately shielded to prevent unnecessary exposures. The type and amount of shielding will depend on the amount of activity and the type of radiation involved. In some instances, it may be necessary to construct a "Hot cell" or a large shielding barrier. The University RSO will be available for consultation on all shielding problems encountered;

(2) Inventory of Radioactive Materials

Authorized users or persons assigned by them shall keep accurate records of inventory of all types of radiation sources in their possession. Areas utilizing unsealed radiation sources should keep "running" inventory. Each time the material is received, used or disposed of, appropriate entry is made in a log book. Sealed source control is handled in a similar fashion: all sources, including those containing exempt quantities coming into or leaving source storage area (usually "Hot Lab") are logged in the inventory control book.

All authorized users are required to perform and document physical inventory of sources on a quarterly basis. Any discrepancy in source record must be reported to the University RSO as soon as it is discovered.

(3) Disposal of Laboratory Radwaste

Laboratory waste must be carefully separated to avoid any amount radioactive material reaching regular waste or medical (red bag) waste. Radwaste materials shall be disposed of in the designated, properly labeled containers. Arrangements for radioactive waste pick-up shall be made by Senior Investigators or persons designated by them. At the time of waste pick-up, each container will have a label containing the following information: isotope identification, approximate amount and date. Disposal record must be placed in the inventory logbook. Low level radioactive waste disposal is coordinated through Radiation Protection Services.

The types of radwaste and specific guidelines on the methods of their disposal are provided in the Departmental Policies and Procedures and in Section 8 of this manual.

6.7 Record Keeping

Authorized Users or persons designated by them shall have the responsibility of keeping

accurate records of all activities pertinent to radiation protection. Specifically, these documents will include:

- (1) Copies of the original license application, renewal and/or amendment applications, and all correspondence submitted in support of the application to the University RSO or the URPC;
- (2) Copies of licenses, permits or work authorization;
- (3) Copies of all correspondence between the S.I. and the URPC or RSO;
- (4) Copies of all survey and inspection reports;
- (5) Copies of all reports of personnel monitoring results;
- (6) Record of radiation safety training;
- (7) The results of routine contamination monitoring and radiation area surveys;
- (8) A current inventory record of radioactive materials utilization;
- (9) An up-to-date radiation safety logbook;

These records will be reviewed by RPS staff during routine laboratory inspections.

6.8 Laboratory Monitors

Each laboratory or area (other than those where ^3H is used exclusively or where only exempt quantities of other radionuclides are handled) shall have available a portable or semi portable monitoring device to be used for personnel and area monitoring.

6.9 Removal of Equipment from the Laboratory

Once used for radioactive substances, equipment shall not be used for other work or sent from the area to cleaning facilities, repair shops, or returned to the source of supply, until demonstrated to be free of contamination.

6.10 Repair or Maintenance of Equipment in the Laboratory

Equipment to be repaired by shop and maintenance personnel, or by commercial service contractors, shall be demonstrated to be free of contamination prior to servicing. If it becomes necessary to make emergency repairs on contaminated equipment, the work will be supervised by a member of the Radiation Safety Office staff, who will assure that the necessary safeguards are taken. It is the responsibility of the laboratory personnel to request this supervision from the Radiation Safety Office.

6.11 Radioactive Contamination of Areas

In general, no radioactive contamination can be tolerated. Exceptions to this will include certain hood trays, stainless steel trays, kimpak covered surfaces, or other equipment which is used frequently for

active work and which will be clearly marked with the standard radiation caution signs or stickers. Any contamination that is not confined to protected surfaces should be reported immediately to the Radiation Safety Office. The Radiation Safety staff will supervise the decontamination of such areas or equipment.

6.12 Animal Facility

The following provisions shall be met in all facilities where radioactive animals are maintained:

6.12.1 Gloves, lab coats, and personnel dosimeters (if warranted) shall be worn while handling such animals or their excreta.

6.12.2 Animals injected with radioactive material shall be kept in a room marked: "CAUTION RADIOACTIVE MATERIAL". Each cage shall be clearly marked with the following information:

- a) Isotope and activity administered to each animal.
- b) Date of injection.
- c) Principal investigator name.
- d) "CAUTION - RADIOACTIVE MATERIALS" tag or tape affixed to each cage.

6.12.3 All excreta from such animals shall be collected and retained separate from the others. In the event that excreta shows no significant activity above background with an appropriate survey instrument for the isotope involved, the excreta may be mixed and disposed of with excreta from other animals. That which is in excess of normal background may be:

Stored for decay or a commercial disposal company in an appropriately marked container (date, isotope and activity).

Discharged to the sanitary system provided a log (date, isotope and activity) is maintained and concentrations are less than those specified in Appendix B, Table II, Column 2 of Part 16.

6.12.4. Cages for animals injected with radioactive materials shall be cleaned separate from the rest. Scrub brushes, mild detergent, and disposable gloves shall be used. Each such cage shall be verified not contaminated before being placed back into service.

6.12.5.1.1 Contaminated carcasses and biological samples will be disposed of as indicated in 10.1.

6.13 Sabbatical

6.13.1 As with other individuals of any large University, sabbaticals and leaves of absence are common occurrences for Senior Investigators. With the absence of the Senior Investigator, communication between the radioactive materials laboratory and Radiation Protection Services is in jeopardy. Minor daily problems involving radiation protection can remain

unattended until they collectively create a situation of major proportion.

At this stage, Radiation Protection Services is left little choice but to suspend radioisotope work in the laboratory. This action interrupts important research, delays academic pursuits, and frustrates everyone involved. Such situations are easily avoided when the Senior Investigator notifies Radiation Protection Services of his/her intended leave and appoints a mutually agreed substitute supervisor to be responsible for his/her laboratory during his/her absence.

6.13.2 Responsibility of Senior Investigators Concerning Sabbatical or Leave of Absence

- i. Senior Investigators will notify the Radiation Safety Division in writing of intended absences from the University of greater than two weeks duration.
- ii. During such absence, the Senior Investigator will appoint a designated supervisor mutually agreeable to himself and Radiation Protection Services.
- iii. In many past instances, knowledge of where the Senior Investigator can be contacted during his/her absence has proven extremely helpful. Therefore, Radiation Protection Services encourages Senior Investigators to voluntarily make such information available.

6.14 Decommissioning

6.14.1 Vacating Radioactive Materials Laboratories

To ensure compliance with existing Federal and State law it is essential that the Radiation Protection Services be notified at least 60 days prior of the Senior Investigator's intention to vacate a radioactive materials laboratory. In addition to the notification, surveys for residual radioactive materials or contamination must be conducted to assure the safety of future occupants of laboratory. Transportation of radioactive materials from one location to another unless conducted in accordance with existing Department of Transportation regulations can result in severe financial penalties to individuals transporting the material. Therefore, arrangement for surveys, packaging, and transportation of such materials should be made by Radiation Protection Services.

6.14.2 Senior Investigator Responsibility

1. Each Senior Investigator shall, before vacating any radioactive materials laboratory, notify Radiation Protection Services in writing of such intent with a 60 day notice.
2. Each Senior Investigator shall ensure that all areas of the laboratory that are contaminated with radioactive material are permanently decontaminated to as low as reasonably achievable.
3. Each Senior Investigator shall ensure that pre-decommissioning surveys are carried out and that arrangement is made for the removal of all radioactive waste and radioactive waste containers. In addition, all storage areas (containers, draws, cabinets, refrigerators, safes, rooms, etc.) are free and clear of all radioactive material product.

6.14.3 Radiation Protection Services Responsibility

1. Upon notification from the Principal Investigator that the radiation control area is ready for decommissioning, Radiation Protection Services will perform a close-out survey on the lab areas and generate a permanent decommission report for the Department Chair.
2. Should contamination or radioactive materials be discovered, the Senior Investigator will be notified of all the details of the radiological survey. After corrective action is taken by the Senior Investigator, step #1 will be repeated until the radiation control area is found to be free and clear of any contamination or radioactive material.

7. Procurement of Radiation Sources

The following procedures for the procurement of radioactive materials are intended to ensure compliance with the terms and conditions of the licenses issued to the University. The Committee requires that all orders for radioactive materials be placed through the University Procurement Office and approved by the RSO or designated RPS staff. In cases other than purchase, the same procedure shall be followed to notify the Radiation Safety Office that the receipt of radioactive materials is contemplated through gifts or transfers from any source.

7.1 Ordering Procedures

Before the purchase request is initiated, the individual shall have the Committee's authorization for the possession and use of the particular radionuclide, activity, and chemical form requested. The Radiation Safety Office will approve the purchase request if the Committee's authorization is verified.

All requests for radioactive materials **ARE REQUIRED** to be processed through the Procurement Office and the Radiation Safety Office. This is true for materials that are purchased, received as gifts, or received directly from other institutions. There are many reasons for this, all relating to radioactive materials safety.

First, in order to provide proper protective measures, an accurate inventory of radioactive be vigilantly maintained. This is also a strict condition of our New York State Department of Health License.

Second, all packages must be inspected for damage and their integrity verified. This ensures that there is no spread of potential radioactive contamination from damaged packages.

Third, in the unlikely event of a vehicular accident involving the transporter of the package, we would need to be notified and provide proper protective advice to any responders.

Ordering radioactive materials through Procurement and the Radiation Safety Office provides these safeguards. The ordering process is simple and here is a summary for you to follow:

1. Prepare a purchase requisition. Be sure to include your in stock inventory and list your entire low level radioactive waste inventory.
2. Submit the completed paperwork to Office of Grants Management (OGM)

When the package arrives on campus, Radiation Protection Services will inspect it and deliver it.

Special arrangements are easily made to accommodate international shipments and other special situations. Just call the Radiation Safety Office, explain your situation, and we will work with you to ensure the shipment arrives safely, quickly and legally.

7.2 Receiving and Distribution

The Radiation Safety Officer or designee will process all order forms for radioactive

material to ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded. Each order form will include isotope, activity and chemical form, as well as the following shipping instructions:

Normal Hours: Direct Delivery

All requests for Group V and VI materials will include a written request by the physician who will perform the procedure.

8. Transfer of Radioactive Materials

8.1 Transfers within the Institution

Transfer of materials between Authorized Users is sometimes permissible, but only with prior approval by the Radiation Safety Officer.

Each container used in transporting radioactive materials shall be marked or tagged with the radiation symbol to warn personnel approaching from all reasonable directions. It should be tagged with all necessary information to provide the reader with knowledge of the hazards such as radiation levels and handling precautions. It should be adequately sealed against leakage, and if fragile protected against breakage. No significant external contamination should be present.

8.2 Transfers from the Institution

When radioactive material is to be sent from the University, the sender must notify the Radiation Safety Officer. The Radiation Safety Office staff will pick up these shipments on telephone request and will assist with the packaging to insure compliance with Department of Transportation regulations.

The recipient of any material to be sent from University must provide evidence of an NRC or NYS DOH license by furnishing a copy of his license to the Radiation Safety Officer before shipment can be made. Noncompliance with this requirement is a violation of the Federal and State regulations and is subject to criminal prosecution, as well as denial to University of further radioisotopes. Check first with Radiation Protection Services by telephone to see if the recipient's license is already on file. If not, then request a copy from the recipient in order to fulfill this requirement.

9. Contamination Limits and Decontamination Procedures

9.1 Maximum Permissible Levels of Radioactive Contamination

The maximum permissible levels of radioactive contamination on hoods, bacteriological cabinets, laboratory benches, other working surfaces, floors and other areas shall not exceed the following limits:

9.1.1 Alpha activity detectable at the surface in excess of 1×10^{-4} microcuries per 100 cm^2 by smear tests.

9.1.2 Removable beta or gamma activity in excess of 1×10^{-3} microcuries per 100 cm^2 by smear tests.

The permissible levels on glassware, tongs, lead bricks, and other laboratory equipment will be the same as those for working surfaces; however, it is expected that, in certain instances in which such equipment is to be used over again in radiological operations, contaminated equipment will be present and is permissible as long as it is appropriately labeled and stored separately from uncontaminated equipment. The glassware will be labeled as being contaminated with radioactivity and not to be removed from the laboratory.

To ensure that these levels are maintained, the Senior Investigator will perform and document routine wipe tests of all areas under his control. Any contamination that is not confined to protected surfaces and can not be decontaminated shall be reported immediately to the Radiation Safety Office. The Radiation Safety staff will supervise the decontamination of such areas of equipment.

9.2 Decontamination of Areas Contaminated with Radioactivity

Preparations for decontamination shall be started promptly. Determine the extent and hazard of contamination. The Radiation Safety Officer will assist in this evaluation. The individual responsible for the contamination will be expected to do most of the cleanup under the supervision of the Radiation Safety staff. After decontamination, the area or equipment shall be considered contaminated until proved otherwise by the Radiation Safety Office.

9.3 Decontamination of Personnel Contaminated with Radioactivity

9.3.1 Notify the Radiation Safety Office immediately after the contamination accident.

9.3.2 Wash body involved thoroughly for 2 or 3 minutes, repeatedly, "soaping" and rinsing. Consideration should be given to the chemistry of the contaminant and an attempt made to find a suitable agent for dissolving it. Any cleansing agent may be used, but synthetic detergents are preferred to soaps. Avoid prolonged use of any one decontamination procedure. Irritation to the skin may impede the success of more suitable procedures. Avoid the use of organic solvents. They make the skin more permeable to radioactive contaminants.

10. Radioactive Waste Management

- 10.1. All persons using radioactive materials must comply with Part 16 of the State Sanitary Code and with other applicable State and University regulations for the disposal of all radioactive wastes. The University Radiation Protection Program and a Licensed Contractor provide services for the collection and ultimate disposal of radioactive wastes.
- 10.2 The types of radioactive waste most commonly accumulated are:
- a. Combustible solid waste, including paper
 - b. Non-combustible solid waste, such as glassware and metal laboratory equipment
 - c. Liquid organic solvent waste, such as benzene, alcohol and toluene
 - d. Aqueous waste
 - e. Animal carcasses
 - f. Gaseous waste
- 10.2.1 Special metal containers, which are painted yellow and are appropriately labeled, are available.
- 10.2.2. Persons who have been approved by the University to possess and use radioactive materials must obtain appropriate waste containers for the work anticipated. Contact the Radiation Safety Officer, who will order these containers at no cost to the Senior Investigator.
- 10.2.3 The following general information concerns the collections, transportation, and final disposal of radioactive wastes. More detailed procedures on each type of radioactive waste are listed under the section for the specific type of waste.
- a. Records must be maintained by the approved user of the type and quantity of radioactive materials contained in each radioactive waste container. The Project Director must be responsible for the proper handling and storage of the radioactive waste in the laboratory.
 - b. Radioactive waste containers should be stored as close to the work area as possible to allow for convenient disposal of radioactive waste and to minimize the possibility of spillage in transfer of waste to the containers. Containers must be stored in the laboratory, not in halls, corridors, stairwells or other uncontrolled areas.
 - c. The containers must remain covered at all times when not in use. When handling or transferring radioactive waste, the individual should wear a laboratory coat and disposable gloves.
 - d. Radioactive wastes emitting penetrating radiation must not be placed in these containers if the radiation level outside the container could exceed 5mRem/hour at the surface. Contact the Radiation Safety Officer about disposal of penetrating radiation sources.
 - e. When the waste containers are almost full, the Radiation Safety Officer should be notified. The Department of Environmental Health and Safety will pick up the waste as soon as possible, usually within three or four days.

When a laboratory requests radioactive waste pick-up, the approved radioisotope user must provide the Radiation Safety Officer with an estimate of the amount of each

radioisotope in each container. Radioactive waste cannot be picked up until this information has been recorded. Inform the Radiation Safety Officer if contaminated materials are too large to fit into the waste container. Such materials will be collected separately.

- f. Radioactive wastes that contain carcinogenic, biological or special chemical hazards must be inactivated and packaged in such a way that they present no hazard to those who collect and dispose of these wastes.

10.2.4 If there are questions about any radioactive waste handling procedure, contact the Radiation Safety Officer (632-6410).

10.3 Solid Radioactive Waste

10.3.1 Radioactive solid waste must be collected in a 55, 30 or 5 gallon can that is painted yellow and labeled with appropriate radiation caution signs.

10.3.2 No liquid, even in a bottle or other sealed containers, may be disposed of in the solid waste containers. The liquid must be poured into an approved liquid radioactive waste container. The empty bottle may then be placed in the solid waste container for non-combustible waste. All liquid radioactive waste transfers, especially the transfer of organic solvents, which present chemical toxicity and flammability hazards, must be done in a well ventilated area.

10.3.3 Liquid scintillation vials will be put into a standard solid waste container which is lined with a 4 mil polyethylene bag and has 6" of vermiculite on the bottom. The vials will be placed into the drum by stratifying the vials and vermiculite in alternating layers. (When properly stratified, approximately 2500 standard 20 ml scintillation vials can be put into the can.

10.4 Liquid Radioactive Waste

10.4.1 Liquid radioactive waste must be properly stored in the laboratory to prevent spills. Two types of approved liquid radioactive waste containers to avoid spillage around the outside of the containers are available, one called a 55 gallon solid pack (s/p), the other a 1 gallon polyvinyl jug filled with diatomaceous earth.

10.4.2 Solid materials should not be placed in liquid waste containers.

10.4.3 Care should be taken when pouring liquids into the liquid waste container to avoid spillage around the outside of the can and overloading of the S/P. The liquid waste container must not be filled with more than 15 gallons of liquid.

10.4.4 Under no circumstances should organic solvent be released to the sewage system.

10.4.5 There are many special problems involving chemical reactions between mixtures of liquid wastes. The disposal of cyanides into acidic liquid waste will result in the production of hydrogen cyanide, a very toxic gas. Special care should also be taken in the disposal of tissue being digested in nitric acid, as oxides of nitrogen may be formed that could cause an explosion in the container, particularly if the cover has been put on tightly. The Laboratory Director must ensure that chemical reactions will not occur in liquids collected for disposal. Contact the Department of Environmental

Health and Safety for further instructions (632-6410)

10.5 **Radioactive Gaseous Waste**

10.5.1 When airborne radioactive materials in the form of radioactive gases or airborne radioactive particulates will be released, the project must be conducted in a properly ventilated hood. Before the start of such a project, the Radiation Safety Officer must be contacted to evaluate the air flow in the hood and to assess possible methods for removal of the airborne contaminant. The concentration of radioisotopes released in the air effluent must be within the levels specified by Part 380 of NYS Department of Environmental Conservation.

10.6 **Non-Acceptable Methods for the Disposal of Radioactive Waste**

10.6.1 Disposal in Wastebaskets

- a. Under no circumstances, regardless of the quantity or type of radioisotope, shall radioactive wastes be disposed of in non-approved containers.

10.6.2 Disposal by Burial in the Soil

- a. Under no circumstances shall any quantity of radioactive waste be buried in the soil by personnel using radioisotopes.

10.6.3 Disposal into the Sewage System

- a. Personnel using radioisotopes must not allow radioactive wastes to be introduced into the sewage system, except for the residual contamination that remains on the glassware after the first rinse. The radioactive material, along with the first rinse, must be emptied into the waste container.

10.7 **Mixed Waste**

Mixed waste is composed of radioactive waste as defined under the Atomic Energy Act (AEA) and hazardous waste as defined under the Resource Conservation and Recovery Act (RCRA). In New York State, mixed waste is regulated by the Department of Health through the issuance of Radioactive Materials Licenses and corresponding regulations at 27 Department of Labor Regulations Part 38, and by the Department of Environmental Conservation through the Prevention and Control of Environmental Pollution by Radioactive Materials regulations in 6 NYCRR Part 380 and the hazardous waste regulations in 6 NYCRR Parts 370 – 376. Because of its dual regulation, mixed waste management can be a complex issue.

This document establishes procedures for managing mixed waste in compliance with the applicable regulations. There are limited disposal options for mixed waste and the costs are very high. Therefore, waste minimization strategies are encouraged wherever possible.

10.7.1 Management Responsibility

Responsibility for managing mixed waste generated at Stony Brook lies with the Radiation Protection Services (RPS) group within the Environmental Health & Safety Department. This group advises and works with the mixed waste generators in the laboratories, and removes the waste from the labs when notified to do

so. Mixed waste is temporarily stored in the Hazardous Materials Management Facility (HMMF) prior to being sent off-site for disposal. Some examples of commonly generated mixed waste streams are solvent-based scintillation fluids, some tritiated organic compounds, and uranyl acetate/nitrate.

10.7.2 What is a Mixed Waste?

A mixed waste is a waste that contains both radioisotopes and either regulated hazardous chemicals or regulated medical waste. This policy addresses mixed radioactive and hazardous wastes only. Therefore, any references to mixed waste in this document refer only to mixed hazardous and radioactive waste. Any radiation activity above background typically constitutes a radioactive waste. In general, for a waste to be considered hazardous, it must either; 1) exhibit one of the following characteristics – ignitability, corrosivity, reactivity, or toxicity, or 2) contain a chemical specifically listed in 6 NYCRR § 371.4. See Stony Brook's Hazardous Waste Management Policy, No. 8-1 for more details on characterizing hazardous waste.

10.7.3 Mixed Waste Minimization

It is Stony Brook's policy to minimize generation of all types of waste. This is an environmentally responsible course of action, it promotes a safer work environment, and reduces costs. Whenever possible, combining hazardous and radioactive materials should be avoided. Examples of measures that can help minimize the amount of mixed waste generated are: substitute a non-ignitable, biodegradable scintillation fluid for an ignitable solvent-based fluid; use shorter-lived isotopes; and never add aqueous waste to mixed waste.

10.7.4 Mixed Waste Management

Due to the type of research and teaching that occurs at Stony Brook, some amount of mixed waste will be generated. This chapter describes proper mixed waste management procedures, designed to comply with both the ionizing radiation and hazardous waste regulations.

10.7.5 Mixed Waste Management in the Laboratory

Prior to procuring materials for a process that will generate a new type of mixed waste, Principal Investigators must contact RPS to ensure a means of disposal is available for the waste. Whenever possible, hazardous chemical waste and radioactive waste should be collected in separate containers.

10.7.6 Mixed Waste Management Procedures

When a mixed waste is generated in a lab, it must be managed as follows:

1. The mixed waste must be collected at or near the point of waste generation in a location that is under the control of the operator (i.e., in the lab in which it is generated).
2. Use separate containers to collect mixed waste from short-lived (<90 days) and long lived isotopes (> 90 days).
3. No more than 55 gallons of mixed waste may be accumulated in a single satellite accumulation area (SAA). If this amount is exceeded, the container must be dated and removed from the lab (to a 90-day storage area) by RPS within 72 hours.
4. Each mixed waste collection container must be labeled with a "Caution Radioactive Materials" sticker and a label that includes the words "Hazardous Waste" and further indicates the chemical contents of the container.

5. Waste collection containers must be in good condition and not in danger of leaking. Containers should be stored in secondary containment. Containers must be compatible with their contents.
6. Mixed waste containers must be closed at all times except when necessary to add waste.
7. Containers should not be handled or managed in a way that may cause them to leak.

10.7.7 Removal of Mixed Waste from the Laboratory

When mixed waste is ready to be removed from the laboratory (i.e., when a container is nearly full), take the following steps:

1. Do not fill containers completely – leave some head space.
2. Measure then record the isotope activity of the container contents, and secure it to the outside of the container.
3. Completely fill out the Radioactive Waste Tracking Form and place it with the container.
4. If the mixed waste is being accumulated in a drum (i.e. scintillation vials) wipe test the outside of the drum and record the results on the back of the Radioactive Waste Tracking Form.
5. Call RPS (2-9680) to arrange for the waste's transfer to the HMMF.

10.7.8 Mixed Waste Management in the Storage Area

When mixed waste is removed from the generating laboratory, it is transferred to the Hazardous Materials Management Facility (HMMF) prior to being sent off-site for appropriate disposal. The waste is transported from the labs to the HMMF by trained RPS personnel. Prior to removing the waste from the lab, RPS staff ensures that the container is properly labeled with the isotope activity and the chemical contents.

10.7.9 Mixed Waste Identification

Some potential mixed wastes may not be clearly identified as such, so RPS evaluates all potentially radioactive materials generated. For example, if RPS received a lead pig for disposal that had radioactive contamination, it would likely also be a hazardous waste due to the lead. As another example, uranyl acetate and uranyl nitrate can potentially contain heavy metals above the RCRA-regulated concentrations. Therefore, solutions of these materials, as well as the unused chemicals being disposed, will be characterized to determine whether they would be considered both radioactive waste and hazardous waste.

10.7.10 Mixed Waste Exception

Liquid scintillation fluids containing less than or equal to 0.05 uCi/gm of H-3 or C-14 (only these two isotopes) need not be managed as radioactive waste. If the scintillation fluid is an ignitable solvent based fluid, these wastes may be considered hazardous waste only. 6 NYCRR § 380-4.3(a)(1)

10.7.11 Other Wastes Managed by RPS

In addition to mixed waste, RPS also manages radioactive waste and hazardous waste at the HMMF. The radioactive waste is primarily dry waste that is being held for decay-in-storage. The hazardous wastes are scintillation fluid vials and bulked scintillation fluids whose radiation level is not above background levels, and are therefore not considered mixed waste.

10.7.12 Mixed Waste Container Management

Containers holding mixed waste in the HMMF must be managed as follows:

1. Each mixed waste collection container must be labeled with a "Caution Radioactive Materials" sticker and a "Hazardous Waste" label. The "Hazardous Waste" label must also indicate the chemical contents of the container.
2. Each "Hazardous Waste" label must indicate the date the container arrived at the HMMF. Containers must be sent for disposal within 90 days.
3. Waste collection containers must be in good condition and not in danger of leaking.
4. Containers must be compatible with their contents and containers of incompatible wastes must be segregated.
5. Mixed waste containers must be closed at all times except when necessary to add or remove waste.
6. Containers must not be opened, handled, or managed in a way that may cause them to leak.
7. Mixed waste containers must be stored on a specifically-designated shelf, separate from other radioactive or hazardous wastes.
8. Weekly inspections must be conducted and documented to ensure compliance with container management rules. (See weekly inspection form in Appendix 10.)

10.7.13 Decaying/Treating Mixed Waste in the HMMF

RPS does not typically decay or treat mixed waste in the HMMF. However, if the mixed waste can be decayed to background radiation levels, it can be managed as only a hazardous waste. Alternately, if the hazardous component can be treated and eliminated, the waste can be managed as only radioactive waste. There are restrictions on both of these options that Stony Brook must be aware of. Regarding decay in storage, because the mixed waste has been removed from the point of generation and is now in the hazardous waste storage area, it must be removed from the HMMF and sent for disposal within 90 days. Therefore, the mixed waste has less than 90 days to decay once it is moved to the HMMF. If the mixed waste cannot complete the decay-in-storage minimum of ten half lives in this time period, the waste must still be considered radioactive. Whenever possible, mixed waste should be allowed to decay in the generating laboratory prior to moving it to the HMMF.

Generators in New York are only allowed to perform a few specific types of hazardous waste treatment without obtaining a permit. These treatment exemptions are only available to generators who comply with specifically delineated requirements. For example, if Stony Brook had a mixed waste that was hazardous only because it was corrosive, it could potentially neutralize the waste and dispose of it as only radioactive waste. However, prior to doing so, Stony Brook must ensure it is in compliance with the elementary neutralization exemption requirements, which include logging the waste that is treated and recording it in the annual DEC Hazardous Waste Report, ensuring the neutralization is performed by trained personnel, and describing the treatment process in the University's Hazardous Waste Contingency Plan.

10.8 Transportation of Radioactive Waste

10.8.1 The Department of Environmental Health and Safety and licensed contractor will provide the service of radioactive waste transport and will follow the procedures outlined by the Radiation Safety Officer for handling and transport. The following packaging and labeling procedures must be followed:

- a. All radioactive waste must be contained in Department of Transportation approved containers. Specifications for appropriate Department of Transportation containers may be

obtained from the Radiation Safety Officer.

- b. Each container must be labeled with radiation caution tags listing each radioisotope and the activity (in millicuries) in the container.
- c. The appropriate Department of Transportation shipping label must be affixed to the sides of the shipping container. The label to be used is determined by measuring radiation exposure levels at the external surface and at three feet from the external surface of the shipping container with an appropriately calibrated instrument:
 - i. White I - 0.5 mRem/hour at external surface
 - ii. Yellow II-50 mRem/hour at external surface and 1.0 mRem/hour at 3 feet from external surface
 - iii. Yellow III - 200 mRem/hour at external surface and 10 mRem/hour at 3 feet from external surface

All drums must be smear tested before removal. See Radioactive Waste Disposal Handout for additional information.

When radioactive waste shipping containers require a Yellow III Department of Transportation label, all four sides of the shipping vehicle must be labeled with Department of Transportation approved signs that indicate RADIOACTIVE. Information concerning these signs and labels is available from the Radiation Safety Officer.

- 10.8.2 Special procedures will be specified by the Radiation Safety Officer for collection and transport of radioactive waste from other University campuses and research facilities. These procedures will be based on the specific use conditions of radioactive materials at the particular campus or facility. In instances in which there is extensive use of radioactive materials (i.e., East Campus, South campus), the campus or facility must provide a central radioactive waste collection facility and must appoint a custodian for the collection facility to ensure proper handling and packaging of radioactive waste.

11. Emergency Preparedness and Response

11.1 Preventive Measures

Many accidents involving radioactive materials can be avoided if the recommended procedures for safe handling are followed by all laboratory personnel. New techniques and procedures should be approved by the Radiation Safety Officer and, when necessary, tested by dummy runs. Where danger of contamination to the person exists, suitable protective clothing and rubber gloves shall be mandatory. Workers shall be thoroughly familiar with the location of telephone, exits, and all available safety devices.

11.1.1. Spills

When danger of spills of radioactive solution exists plastic backed absorbent paper (e.g., Kimpak™) or trays shall always be used. Containers should be kept covered whenever possible, and only those amounts of radioactive solutions that are immediately necessary should be drawn from stock.

11.1.2 Dusts, Mists, Fumes, Organic Vapors, and Gases

Adequate forced ventilation is always a first precaution to be considered in laboratories working with radioactive dusts, mists, fumes, organic vapors, or gases. The use of glove boxes and hoods, provided with adequate exhaust fans, is mandatory. Floors of hoods and glove boxes should be covered with disposable papers to catch dust, spray, or condensate. Radioactive gases and volatile materials, whether in the laboratory or in storage areas, should always be kept in gasketed, gas tight containers.

11.1.3 Fires and Other Major Emergencies

If possible, all radioactive materials in the laboratory not immediately in use should be sorted in a manner that will safeguard against possible accidental spread of radioactive contamination in the event of a major disaster.

11.2 Emergency Procedures

11.2.1 Minor Spills Involving No Radiation Hazard to Personnel

- 1) Notify all other persons in the room at once.
- 2) Permit only the minimum number of persons necessary to deal with the spill into the area.
- 3) Confine the spill immediately.

Liquid Spills:

Don protective gloves
Drop absorbent paper on spill

Dry Spills:

Don protective gloves

Dampen thoroughly, taking care not to spread contamination (unless mixing with water causes volatilization).

- 4) Notify the Radiation Safety office as soon as possible. The Radiation Safety staff will be responsible for the remaining steps.
- 5) Decontaminate
- 6) Monitor all persons involved in the spill and cleaning.
- 7) Permit no person to resume work in the area until a survey is made.
- 8) Prepare a complete history of the accident and subsequent activity related thereto for the necessary records.

11.2.2 Major Spills Involving Radiation Hazard to Personnel

- 1) Notify all persons not involved in the spill to vacate the room at once.
- 2) If the spill is liquid, and the hands are protected, right the container.
- 3) If the spill is on the skin, flush thoroughly.
- 4) If the spill is on clothing, discard outer or protective clothing at once.
- 5) Switch off all fans.
- 6) Vacate the room.
- 7) Notify the Radiation Safety office as soon as possible. The Radiation Safety staff will be responsible for the remaining steps.
- 8) Take immediate steps to decontaminate personnel involved, as necessary.
- 9) Decontaminate the area. (Personnel involved in decontamination must be adequately protected).
- 10) Monitor all persons involved in the spill and cleaning to determine adequacy of decontamination.
- 11) Permit no person to resume work in the area until a survey is made.
- 12) Prepare a complete history of the accident and subsequent activity related thereto for the necessary records.

11.2.3 Accidents Involving Radioactive Dusts, Mists, Fumes, Organic Vapors and Gases

- 1) Notify all other persons to vacate the room immediately.
- 2) Hold breath and close escape valves, switch off air circulating devices, etc., if time permits.
- 3) Vacate the room.
- 4) Notify the Radiation Safety Office at once.
- 5) Ascertain that all doors giving access to the room are closed and post conspicuous warning or guards to prevent accidental opening of doors.
- 6) Report at once all known or suspected inhalations of radioactive materials. The Radiation Safety staff will be responsible for the remaining steps.
- 7) Evaluate the hazard and the necessary safety devices for safe reentry.
- 8) Determine the cause of contamination and rectify the condition.
- 9) Decontaminate the area.
- 10) Perform air survey of the area before permitting work to be resumed.
- 11) Monitor all persons suspected of contamination.
- 12) Prepare a complete history of the accident and subsequent activity related thereto for the necessary records.

11.2.4 Injuries to Personnel Involving Radiation Hazard

- 1) Wash minor wounds immediately, under running water while spreading the edges of the gash.
- 2) Report all radiation accidents to personnel (wounds, over-exposure, ingestion, inhalation) to the Radiation Safety Officer, as soon as possible.
- 3) Call a physician qualified to treat radiation injuries at once.
- 4) Permit no person involved in a radiation injury to return to work without the approval of the Radiation Safety Officer and the attendant physician.
- 5) Prepare a complete history of the accident and subsequent activity related thereto for the necessary records.

11.2.5 Fires or Other Major Emergencies

- 1) Alert all personnel in immediate danger.

- 2) Report the fire immediately regardless of size.
- 3) Try to put out manageable fires. If fire is not manageable, leave the area immediately, close the door, and wait for assistance.
- 4) Notify the Radiation Safety Office.
- 5) Govern fire-fighting or other emergency activities by the restrictions of the Radiation Safety Officer. The Radiation Safety staff will be responsible for the remaining steps.
- 6) Following the emergency, monitor the area and determine the protective devices necessary for safe decontamination.
- 7) Decontaminate.
- 8) Permit no person to resume work until conditions allow.
- 9) Monitor all persons involved in combating the emergency.
- 10) Prepare a complete history of the emergency and subsequent activity related thereto for the necessary records.

12. Notification of Incidents

- 12.1 Each authorized user shall report to the Radiation Safety Office the **theft** or **loss** of any source of radiation immediately after such occurrence becomes known.
- 12.2 Each authorized user shall immediately notify the Radiation Safety Office of any incident involving any source of radiation which may have caused or threatens to cause:
- a) **A radiation exposure in excess of applicable limits to any individual, or**
 - b) **The release of radioactive materials which will cause excessive levels and concentrations of radionuclides in air or water; or**
 - c) **A loss of one day or more of the operation of any facilities affected; or**
 - d) **Damage to property in excess of \$100.**
 - e) **Misadministration.**

13. Radiation Guidelines and Glossary

ALPHA PARTICLES

Alpha particle emitting radioisotopes (^{226}Ra , ^{241}Am , ^{210}Po) are highly radiotoxic because alpha radiation presents a significant internal hazard.

Most alpha particles present no external radiation hazard because they cannot penetrate the protective layer of skin covering the body surface. An alpha particle of at least 7.5 MeV is required to penetrate a tissue thickness of 0.07 mm, which is the thickness of the dead layer of skin.

BETA PARTICLES

A beta particle of at least 0.07 MeV is required to penetrate the protective layer of skin (0.07 mm).

The range of a beta particle in air is approximately 12 feet/MeV. The range of the maximum energy beta from ^{32}P would be:

$$1.71 \text{ MeV} \times 12 \text{ feet/MeV} = 20 \text{ feet}$$

The range of beta particles in gm/cm^2 (density thickness = thickness in cm \times density of gm/cm^3) is approximately equal to the maximum beta energy (MeV) divided by 2 ($R-E/2$).

The average energy of a beta particle spectrum for a particular radioisotope is approximately 1/3 the maximum beta energy.

The dose rate in rads per hour in a solution of a beta emitting radioisotope is $1.12 EC/p$, where E is average beta energy per disintegration (MeV), C is concentration (Ci/cm^3), and p is the density of the solution.

The surface dose rate through the protective layer of skin (7 mg/cm^2) from a uniform thin deposition of 1 uCi/cm^2 is about 9 rads/hour for beta energies of about 0.6 MeV. In a thin layer the beta dose rate exceeds the gamma dose rate for equal energies released by about a factor of 100. For a point source of beta radiation (neglecting air and self absorption), the dose rate at 1 cm is approximately equal to $200 \times$ number of mCi's = rads/hour. This varies only slightly with beta energy. Dose rate at 1 cm for 1 mCi of ^{32}P is about 200 rads/hour.

Bremsstrahlung (braking radiation) or x-rays produced as a result of beta particles being slowed down increases approximately with the square of the maximum beta energy, and about as the square of the atomic number of the absorbing material. For this reason, low Z materials are recommended for shielding beta emitters.

When beta particles of 1 to 2 MeV pass through low Z materials such as water, aluminum, Lucite, or glass, less than 1% of the energy is converted to Bremsstrahlung.

GAMMA RAYS

The exposure rate (mRem/hour) at 1 foot from a point source gamma radiation emitter between 0.07 and 4 MeV is approximately equal to $6 \times \text{mCi} \times E \times n$, where mCi-millicuries, E-energy in MeV, n = number of gammas per disintegration.

The dose rate in rads/hour in an infinite medium contaminated with a gamma emitter is $2.12/EC/p$, where E =average gamma energy per disintegration in MeV, C =number of Ci/cm^3 , and p =density of gm/cm^3 . Surface dose rate is about 1/2 this dose rate.

X-RAYS

The exposure rate at 2 feet from a diagnostic x-ray tube operated at 100 kVp and 100 mA is about 2.3 R/second in the primary beam.

The exposure rate in the primary beam of a fluoroscopic x-ray unit operated at 80 kVp and 1mA should not exceed 2.1 R/minute.

The exposure rate in the primary beam of a fluoroscopic x-ray unit operated at 100 kVp and 100 mA is about 2.3 R/second. In the primary beam.

X-ray diffraction units can have primary beam intensities as high as 400,000 R/minute. Scattered radiation at approximately 1 foot from the point of scatter can be on the order of 150 R/hour.

The threshold dose for skin erythema from x-rays is about 300 to 400 R. The minimum single dose for cataract production is 200 rads, and a dose of 750 rads results in a high incidence of cataracts.

RULES of THUMB

The activity of any radioisotope is reduced to less than 1% after 7 half lives ($2^{-7}=0.8\%$).

For radioisotopes with half life greater than 6 days, the change in activity in 24 hours will be less than 10%.

A GM instrument, even when equipped with a thin window probe, should not be used to monitor for low energy beta radiation emitter contamination (^3H -0.018 MeV will not penetrate the end window).

The relationship between activity and mass of a radioisotope (specific activity) may be determined as follows:

$$\text{Curies/gm} = 1.308 \times 10^8 A T_{1/2}$$

A =atomic weight and $T_{1/2}$ = half life in days.

Neither diagnostic x-rays nor radiation emitted by radioisotopes (gamma or beta radiation) results in activation of body tissue. There is no residual radioactivity: persons or materials do not become radioactive as a result of exposure to these radiations. **XIV.**

13. GLOSSARY

ABSORBED DOSE. When ionizing radiation passes through matter, some of its energy is imparted to the matter. The amount per unit mass of irradiated material is called the absorbed dose and is measured in rems or rads.

ACCELERATOR. A device for increasing the velocity and energy of charged elementary particles (such as electrons or protons) through application of electrical or magnetic forces. Accelerators have made particles move at velocities approaching the speed of light. Types of accelerators include betatrons, Cockcroft-Walton accelerators, cyclotrons, linear accelerators, synchrocyclotrons, and Van de Graaff generators.

ACTIVITY. The spontaneous decay or disintegration of an unstable atomic nucleus, usually accompanied by the emission of ionizing radiation.

AEC. U.S. Atomic Energy Commission, which is now abolished and has been replaced by the Nuclear Regulatory Commission (NRC), and the Energy Research and Development Administration (ERDA).

ALPHA PARTICLE. Symbol α (alpha). Positively charged particle emitted by certain radioactive materials. It is composed of two neutrons and two protons bound together, hence it is identical with the nucleus of a helium atom. It is the least penetrating of the three common types of radiation (alpha, beta, gamma) emitted by radioactive material. Alpha particles can be stopped by a sheet of paper. Alpha particles are not dangerous to plants, animals or man unless the alpha-emitting substance entered the body.

APPROVED USER. An individual who has obtained from the appropriate radioisotope license committee, or directly from the Nuclear Regulatory commission, a signed permit for possession and use of radioactive materials.

BETA PARTICLES. Electron or positron, symbol β (beta). An elementary particle emitted from a nucleus during radioactive decay, with a single electrical charge and a mass equal to $1/1837$ that of a proton. A negatively charged beta particle is identical to an electron. A positively charged beta particle is called a positron. Beta radiation may cause skin burns, and beta-emitters are harmful if they enter the body. Most beta particles are easily stopped by a thin sheet of metal.

BIOASSAY. Assay and measurement procedures used to determine the amount of radioactive material in a biological system.

BREMSSTRAHLUNG. Electromagnetic (x-ray) radiation associated with the deceleration of charged particles passing through matter. Usually associated with energetic beta-emitters, such as phosphorus-32.

COLLIMATOR. A device for focusing or confining a beam of particles or radiation, such as an x-ray.

CONTAMINATION. The presence of radioactive material on material or places where it's undesirable.

CURIE. Quantity of any radioactive material in which the number of disintegrations is 3.700×10^{10} per second. Abbreviated Ci. Millicurie: One-thousandth of a curie (3.7×10^7 disintegration per second). Abbreviated mCi. Microcurie: One-millionth of a curie (3.7×10^4 disintegration per second). Abbreviated μ Ci. Picocurie curie: One-millionth of a microcurie (3.7×10^{-2} disintegration per second or 2.22 disintegrations per minute). Abbreviated pCi.

DOSE. Quantity of radiation or energy absorbed in a specified mass. For special purposes, it must be appropriately qualified, e.g., absorbed dose.

DOSE EQUIVALENT. (DE) Quantity used in radiation protection expressing all radiation on a common scale for calculating the effective absorbed dose. The unit of dose equivalent is the rem, which is numerically equal to the absorbed dose in rads multiplied by certain modifying factor such as the quality factor and the distribution factor.

DOSE RATE. Radiation dose delivered per unit time and measured, for instance, in rems per hour.

ELECTROMAGNETIC RADIATION. Radiation consisting of associated and interacting electric and magnetic waves that travel at the speed of light. Examples: light, radio waves, gamma rays, x-ray. All can be transmitted through a vacuum.

ELECTRON. Negatively charged elementary particle, which is a constituent of every neutral atom. Its unit of negative electricity equal 4.8×10^{-10} electrostatic units or 1.6×10^{-10} coulombs. Its mass is 0.00549 atomic mass units.

EXTERNAL RADIATION HAZARD. Exposure to ionizing radiation emitted from a radiation source (radioactive material, x-ray machine, etc.) located outside the body. The ionizing radiation must penetrate through the skin to deeper body tissue to cause biological effects.

FILM BADGE. Packet of photographic film worn by personnel, which provides an approximate measure of radiation exposure for personal monitoring purposes. The badge may contain two or more films of differing sensitivity, and it may contain filters that shield parts of the film from certain types of radiation.

FILTER, PRIMARY. A sheet of material, usually metal, placed in a beam of radiation to remove, as far as possible, the less penetrating components of the beam.

FILTER, SECONDARY. A sheet of material of lower atomic number, relative to that of the primary filter, placed in the filtered beam of radiation to remove characteristic radiation produced by the primary filter.

FLUOROSCOPE. An instrument with a fluorescent screen suitably mounted with respect to an x-ray tube, used for immediate indirect viewing of internal organs of the body, internal structures in apparatus, or masses of metals, by means of x-rays. A fluorescent image, a kind of x-ray shadow picture, is produced.

GAMMA RAY. Symbol (γ). High energy, short-wavelength electromagnetic radiation. Gamma radiation frequently accompanies alpha and beta emissions and always accompanies fission. Gamma rays are very penetrating and are best stopped or shielded against by dense materials such as lead or depleted uranium. Gamma rays are essentially similar to x-rays but are usually more energetic and are nuclear in origin.

G-M COUNTER (Geiger-Muller). A radiation detection and measuring instrument. It consists of a gas-filled (Geiger-Muller) tube containing electrodes, between which there is an electrical voltage but no current flowing. When ionizing radiation passes through the tube, a short, intense pulse of current passes from the negative electrode to the positive electrode and is measured or counted. The number of pulses per second measures the intensity of radiation. It is also often known as a Geiger counter. It was named for Hans Geiger and W. Muller who invented it in the 1920's.

GENETIC EFFECTS. Radiation effects that can be transferred from parent to offspring. Any radiation-caused changes in the genetic material of sex cells.

HALF-LIFE, BIOLOGICAL (T_b). Time required for the body to eliminate one-half of an administered dose of

any substance by the regular processes of elimination. This time is approximately the same for both stable and radioactive isotopes of a particular element.

HALF-LIFE, EFFECTIVE (T_{eff}). Time required for a radioactive nuclide in a system to be diminished 50 percent as a result of the combined action of radioactive decay and biological elimination.

HALF-LIFE, PHYSICAL (T_r). Time required for a radioactive substance to lose 50 percent of its activity by decay. Each radionuclide has a unique half-life.

HALF-VALUE LAYER. The thickness of any specified material necessary to reduce the intensity of an x-ray or gamma ray beam to one-half its original value.

HEALTH PHYSICS. Branch of radiological science dealing with the protection of personnel from harmful effects of ionizing radiation.

HIGH RADIATION AREA. Any area accessible to personnel, in which there exists ionizing radiation at such levels that a major portion of the body could receive, in one hour, a dose in excess of 100 mRem.

INTERLOCK. Device (usually electronic) for precluding access to high radiation area by automatically terminating or reducing radiation exposure rate upon entry by personnel.

INTERNAL RADIATION HAZARD. Exposure to ionizing radiation emitted from a radioisotope source located or incorporated within the body as a result of deposition of radioisotopes in body tissues (i.e., I131 in the thyroid).

INVERSE SQUARE LAW. The intensity of radiation at any distance from a point source varies inversely as the square of that distance. For example, if the radiation exposure is 100 R/hr at 1 inch from a source, the exposure will be 0.01 R/hr at 100 inches.

IONIZATION. Process of adding one or more electrons to, or removing one or more electrons from, atoms or molecules, thereby creating ions. High temperatures, electrical discharges, or nuclear radiation can cause ionization.

IONIZATION CHAMBER. An instrument designed to measure the quantity of ionizing radiation in terms of the charge of electricity associated with ions produced within a defined volume.

IONIZATION RADIATION. Any electromagnetic or particulate radiation capable of producing ions, directly or indirectly, by interaction with matter.

KEV (keV). Energy acquired by a particle of one electronic charge in passing through a potential difference of one thousand volts (kV).

LINEAR ACCELERATOR. A long straight tube (or series of tubes) in which charged particles (ordinarily electrons or protons) gain in energy by the action of oscillating electromagnetic fields.

LINEAR ENERGY TRANSFER (LET). Measure of the ability of biological material to absorb ionizing radiation. Radiation energy lost per unit length of path through a biological material. In general, the higher the LET value, the greater is the relative biological effectiveness of the radiation in that material.

MAXIMUM PERMISSIBLE DOSE EQUIVALENT (MPD). The maximum dose equivalent that a person, or specified parts of a person's body, shall be allowed to receive in a specified period of time (quarter or year, for example). Also referred to as Radiation Protection Guide (RPG).

MAXIMUM PERMISSIBLE CONCENTRATION (MPC). That amount of a particular radioactive material in the air, water, or food that might be expected to result in the MPD to the person consuming them at the standard rate of intake (based on standard person). Also referred to as Radioactivity Concentration Guide (RCG).

MEV (MeV). Energy acquired by a particle of one electronic charge in passing through a potential difference of one million volts (MV).

NEUTRON. (symbol n) An uncharged elementary particle, with a mass slightly greater than that of the proton, that is found in the nucleus of every atom heavier than hydrogen. A free neutron is unstable and decays with a half-life of about 13 minutes into an electron, proton, and neutrino. Neutrons sustain the fission chain reaction in a nuclear reactor.

PERSONNEL MONITORING. Determination by either physical or biological measurements of the amount of ionizing radiation to which an individual has been exposed. Monitoring methods include measuring the darkening of a film badge or performing a radon breath analysis.

QUALITY FACTOR (QF). The factor by which absorbed dose is to be multiplied to obtain a quantity that expresses on a common scale, for all ionizing radiations, the irradiation incurred by exposed persons.

RAD. The unit of absorbed radiation dose equal to 100 ergs per gram of absorbing material.

RADIATION AREA. Any area accessible to personnel, in which there exists ionizing radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of 5 mRem, or in any five consecutive days a dose in excess of 100 mRem.

RADIATION DETECTION INSTRUMENT. Device that detects and records the characteristics of ionizing radiation.

RADIATION SAFETY OFFICER (RSO). A person trained in radiological science who is responsible for the protection of persons from the harmful effects of ionizing radiation. Also referred to as health physicist or radiation safety officer.

RADIATION PROTECTION SURVEY. Evaluation of the radiation hazards incident to the production, use, or existence of radioactive materials or other sources of ionizing radiation. Such evaluation customarily includes a physical survey of the disposition of materials and equipment, measurements or estimates of the levels of radiation that may be involved, and a sufficient knowledge of processes using or affecting these materials. With this information, it is possible to predict hazards resulting from expected or possible changes in materials or equipment.

RADIOACTIVE DECAY (Disintegration). The spontaneous transformation of one nuclide into a different nuclide or into a different energy state of the same nuclide. The process results in a decrease with time, of the number of the original radioactive atoms in a sample. It involves the emission from the nucleus of alpha particles, beta particles (or electrons), or gamma rays; or the nuclear capture or ejection of orbital electrons; or fission. Also called radioactive disintegration.

RADIOACTIVITY. The spontaneous decay or disintegration of an unstable atomic nucleus, usually

accompanied by the emission of ionizing radiation. Often shortened to "activity".

RADIOISOTOPE (Radioactive Material). A radioactive isotope. An unstable isotope of an element that decays or disintegrates spontaneously, emitting radiation. More than 1300 natural and artificial radioisotopes have been identified.

RADIOTOXICITY. Term referring to the potential of an isotope to cause damage to living tissue by absorption of energy from the disintegration of the radioactive material introduced into the body.

REM. The special unit of dose equivalence ($\text{rem} = \text{rad} \times \text{QF}$). Also, one millirem (mRem) is equal to 1/1000 rem.

RESTRICTED AREA (Controlled Area). Any area to which access is controlled for the purpose of protection of individuals from exposure to sources of ionizing radiation.

ROENTGEN. Abbreviated R. A unit of exposure to ionizing radiation. It is that amount of gamma or x-rays required to produce ions carrying one electrostatic unit of electrical charge (either positive or negative) in one cubic centimeter of dry air under standard conditions. Named after Wilhelm Roentgen, German scientist who discovered x-rays in 1895. Also, one milliroentgen (mR) is equal to 1/1000 R.

SMEAR SURVEY. A procedure in which a swab, such as a circle of filter paper, is rubbed on a surface and its radioactivity measured to determine if the surface is contaminated with removable radioactive material.

THERMOLUMINESCENT DOSIMETER (TLD). A dosimeter made of a certain crystalline material capable of storing a fraction of absorbed ionizing radiation and releasing this energy in the form of visible photons when heated. The amount of light released can be used as a measure of radiation exposure to these crystals.

UNRESTRICTED AREA (Non-controlled Area). Any area to which access is not controlled for the purpose of protection of individuals from exposure to source of ionizing radiation.

VAN DE GRAAFF ACCELERATOR. An electrostatic machine in which electrically charge particles are sprayed on a moving belt and carried by it to build up a high potential on an insulated terminal. Charged particles are then accelerated along a discharge path through a vacuum tube by the potential difference between the insulated terminal and the opposite end of the machine. A Van de Graaff accelerator is often used to inject particles into larger accelerators. Named after R.S. Van de Graaff, who invented the device in 1931.

WASTE, RADIOACTIVE. Equipment and materials (from nuclear operations) that are radioactive and that are no longer being used. Wastes are generally classified as high-level (having radioactivity concentrations of hundreds to thousands of curies per gallon or cubic foot), low-level (in the range of one microcurie per gallon or cubic foot), or intermediate (between these extremes).

X-RAYS. Penetrating electromagnetic radiations having wave lengths shorter than those of visible light. X-rays are usually produced by bombarding a metallic target with fast electrons in a high vacuum. In nuclear reactions, it is customary to refer to photons originating in the nucleus as gamma rays, and those originating in the extra-nuclear part of the atom as x-rays. Sometimes called roentgen rays, after their discoverer, W.C. Roentgen.

14. Appendix Section (1-11)**APPENDIX 1. Guidelines for Safe Use of Radioisotopes**

1. Observe good housekeeping at all times to prevent contamination and to facilitate cleaning.
2. When pipetting radioactive materials, use syringes, remote pipetters, rubber bulbs, or other mechanical devices. Do not pipette by mouth.
3. Do not eat, drink or smoke in the laboratory. Do not store food of any kind in the laboratory or in a refrigerator where radioactive materials are stored.
4. Wear laboratory coats and rubber gloves when working with radioactive material. Wash hands thoroughly after removing gloves.
5. Wear film badges when the radiation hazard warrants such use. The Radiation Safety Officer will evaluate the need for film badges in areas where potential external radiation hazard exist.
6. Post proper radiation caution signs on the doors of laboratories in which radioisotopes are used and to indicate use and storage areas within the laboratory. Contact the Radiation Safety Officer for caution signs.
7. Use a radiation survey instrument to monitor clothing, hands, shoes and the general laboratory area. For ^3H and ^{14}C smears should be taken on laboratory surfaces, including the floor, using a piece of one inch diameter absorbent filter paper. This paper may then be placed in the counting vial and counted in a liquid scintillation counter. It is important that weekly radiation surveys be made to reduce the hazard from radioactive contamination. The authorized user must keep records of these surveys. Contact the Radiation Safety Officer for more details on instrumentation.
8. When working with radioisotopes, use stainless steel trays lined with absorbent paper. Contact the Radiation Safety Officer for information about these trays.
9. If there is any possibility of an airborne hazard, do all work with radioisotopes in a hood.
10. Transport and store all radioisotopes in a manner that will prevent breakage and spills. When radioactive liquids are in a glass container, keep the container in a second nonbreakable container that would hold the radioactive contents if the glass container were to break.
11. If there is any possibility of airborne hazard, open radioisotope shipments in a hood. This is especially important with shipments of particulate matter or materials with high radiotoxicity.
12. When opening a shipment, examine the contents to determine if there has been damage or leakage. Report damaged or leaking shipments immediately to the Radiation Safety Officer.
13. Provide for proper storage of radioisotopes in the laboratory, with sufficient shielding to maintain a safe radiation level.
14. Handle sealed radiation sources, regardless of activity, with tongs. Determine the dose rate at the hand and body location before sealed radiation sources are used or moved. Alpha sources must be leak tested by the Radiation Safety Officer every 3 months, Beta and Gamma sources every 6

months. Report damaged or lost sources immediately to the Radiation Safety Officer.

15. Remove radiation labels before discarding used shipping boxes. All boxes should be discarded because they could be a possible radiation hazard. Do not reuse shipping boxes.
16. Do not remove contaminated tools, glassware, and equipment from the laboratory. Store away from non-contaminated equipment. Glassware used with radioisotopes may not be brought to the glassblower without prior approval by the Radiation Safety Officer.
17. Dispose of radioactive wastes in appropriately marked containers. Do not mix acids and organic solvents as waste. Contact the Radiation Safety Officer for waste disposal services.

For further information on any aspect of radiation safety, contact the Radiation Safety Officer, Department of Environmental Health and Safety, 632-6410.

APPENDIX 2. Some Commonly Used Radioisotopes and Their Relative Radiotoxicities

I. Low Hazard Radioisotopes

The level of intermediate activity for laboratory use in this group is 1 to 30 mCi.

Radioisotope	Half-Life	Type of Ionizing Radiation Emitted	Energy of Radiation
H-3 (tritium)	12 Years	beta	0.014 Mev
C-14	5730 Years	beta	0.15 Mev

II. Medium Hazard Radioisotopes

The level of intermediate activity for laboratory use in the group is 100 Ci - 3mCi.

Radioisotope	Half-Life	Type of Ionizing Radiation Emitted	Energy of Radiation
Na-24	15 hours	beta gamma	1.39 Mev 2.75 Mev
K-42	12.4 hours	beta gamma	3.5 Mev 1.5 Mev
Hg-197	64 hours	gamma	0.19 Mev
P-32	14.3 days	beta	1.7 Mev
S-35	87 days	beta	0.167 MeV
Cl-36	3×10^5 Years	beta	0.714 Mev
Fe-59	45 days	beta gamma	0.46 Mev 1.10 Mev
Rb-86	18.6 days	beta gamma	1.78 Mev 1.08 Mev
Sr-89	50 days	beta	1.46 MeV
Au-198	2.7 days	beta gamma	0.96 MeV 0.41 MeV
Hg-203	46 days	beta gamma	0.21 MeV 0.28 MeV
Cr-51	27.8 days	gamma	0.32 MeV
P-33	25.2 days	beta	0.248 MeV

III. High Hazard Radioisotopes

The level of intermediate activity for laboratory use in this group is 10 uc - 300 uc.

Radioisotope	Half-Life	Type of Ionizing Radiation Emitted	Energy of Radiation
Na-22	2.6 years	positron gamma	0.54 MeV 1.27 MeV
Ca-45	164 days	beta	0.254 MeV
Co-60	5.24 years	beta gamma	0.312 MeV 1.17, 1.33 MeV
Sr-90	28.4 years	beta	0.545 MeV
I-131	8 days	beta gamma	0.6 MeV 0.364 MeV
I-125	60 days	gamma	0.035 MeV
Cs-137	30 years	beta gamma	0.514 MeV 0.667 MeV

IV. Very High Hazard Radioisotopes

Intermediate laboratory level is 1 to 10 uc.

Radioisotope	Half-Life	Type of Ionizing Radiation Emitted	Energy of Radiation
Pb-210	22 years	beta gamma	0.017 MeV 0.0465 MeV
Po-210	138 days	alpha	5.3 MeV
Ra-226	1620 years	alpha	4.7 MeV

APPENDIX 3. Exposure Limits**Exposure of Individuals to Radiation in Radiation Control Areas****Maximum Permissible Dose per Calendar Year**

	Area of Body Exposed	Rems/year
1	Whole body; head and trunk; active blood-forming organs; or gonads	5
2	Hands and forearms; feet and ankles	50
3	Skin of whole body	50
4	Lens of the eye	15

APPENDIX 4. Assessing Spills: Hazards of Radioactive Materials

Group 1. Low Hazard. Above 1 mCi, treat as a major spill.

^3H , ^7Be , ^{14}C , ^{18}F , ^{59}Ni , ^{69}Zn , ^{71}Ge , ^{238}U , Natural Thorium, Natural Uranium, Noble Gases.

Group 2. Medium Hazard. Above 100 uCi, treat as a major spill.

^{14}C , ^{24}Na , ^{31}Si , ^{32}P , ^{35}S , ^{36}Cl , ^{42}K , ^{48}V , ^{51}Cr , ^{54}Mn , ^{56}Mn , ^{55}Fe , ^{59}Fe , ^{64}Cu , ^{65}Zn , ^{72}Ga , ^{76}As , ^{86}Pb , ^{89}Sr , ^{90}Y , ^{91}Y , ^{95}Zr , ^{95}Nb , ^{99}Mo , ^{103}Ru , ^{105}Rh , ^{103}Pb , ^{105}Ag , ^{111}Ag , ^{109}Cd , ^{113}Sn , ^{127}Te , ^{129}mTe , ^{140}Ba , ^{140}La , ^{143}Pr , ^{147}Pm , ^{151}Sm , ^{166}Ho , ^{170}Tm , ^{177}Lu , ^{183}Re , ^{190}Ir , ^{191}Pt , ^{193}Pt , ^{196}Au , ^{198}Au , ^{199}Au , ^{200}Tl , ^{201}Tl , ^{202}Tl , ^{204}Tl , ^{203}Pb , ^{220}Rn , ^{222}Rn , ^{235}U .

Group 3. High Hazard. Above 10 uCi, treat as a major spill.

^{22}Na , ^{45}Ca , ^{46}Sc , ^{60}Co , ^{90}Sr , ^{106}Ru , ^{129}I , ^{131}I , ^{137}Cs , ^{144}Ce , ^{154}Eu , ^{182}Ta , ^{210}Bi , ^{211}At , ^{224}Ra , ^{233}U .

Group 4. Very High Hazard. Above 10 uCi, treat as a major spill.

^{210}Pb , ^{210}Po , ^{226}Ra , ^{228}Ra , ^{227}Ac , ^{228}Th , ^{230}Th , ^{237}Np , ^{238}Pu , ^{239}Pu , ^{240}Pu , ^{241}Pu , ^{242}Pu , ^{241}Am , ^{242}Cm .

APPENDIX 5. Ionizing Radiation Producing Machine Registration Form

This form must be completed in duplicate, typed, and forwarded to the Radiation Safety Officer, Department of Environmental Health and Safety, Suffolk Hall, South Campus, State University at Stony Brook, z=6200.

Name of Applicant:

Title:

Department:

Phone Number:

1. Name, training and experience of individuals who will operate the radiation producing machines (attach additional sheets if needed):

Name	Type of Training and/or Experience	Type of Radiation Producing

2. Description of radiation producing machines (attach additional sheet if needed).

Type of Machine	Manufacture	Model#	Maximum	Location	Purpose for which

3. Radiation Protection Precautions followed in the use of radiation producing machines (give sufficient information on the methods and/or control devices used to prevent accidental or unnecessary radiation exposure of personnel, general public, and patients (if applicable)).

Date:

Applicant's Signature:

The Radiation Safety Officer of the DEHS has made a radiation protection survey of the above listed radiation producing machines, and has discussed with the applicant the radiation protection requirements necessary for use of the machines. If there are any special conditions on the use of the machines, they will be attached.

Health Physicist:

Date:

You have been authorized for use of the radiation producing machines listed above under registration number _____ . This registration expires on _____

The applicant is responsible for re-registration of the machines prior the expiration date.

APPENDIX 6. Information and Procedures for Use of H-3 and C-14

1. Both H-3 and C-14 emit low energy beta radiation (H-3 0.18 MeV and C-14 0.156 MeV), and therefore present no appreciable external radiation exposure hazard. Personnel working with H-3 or C-14 do not require a film badge monitor.
2. Shipments of H-3 or C-14 should be opened in a working hood and inspected for damage and contamination before transfer to a storage area. Most shipments can be stored safely in a laboratory refrigerator or freezer. If the material labeled with H-3 or C-14 is volatile, it should be stored and used in a hood.
3. Because of their low beta energy, H-3 and C-14 cannot readily be detected with a portable GM survey instrument. Therefore, in order to evaluate possible contamination of the laboratory, it is necessary to perform contamination smears surveys on a routine basis of about once each week, using dry filter paper (Whatman No. 1 filter paper). The smears should be counted in a liquid scintillation counting system and the results of each survey recorded in the laboratory radiation safety logbook. Areas showing removable contamination greater than 2 times the background count rate should be decontaminated and resurveyed.
4. Individuals who use H-3 water or gas in quantities of 100 millicuries or more per experiment, or H-3 labeled organic compounds in quantities of 50 millicuries or more per experiment must have a urine analysis performed within two days of single uses, and on a periodic basis of once per week for routine uses of these quantities. Before using the quantities listed above, contact the Radiation Safety Officer, 632-6410, for instructions on collection and analysis of urine samples. Collection vials and procedures are available from the Radiation Safety Officer.
5. If any major spills or other emergency conditions arise, notify the Radiation Safety Officer immediately, 632-6410.

APPENDIX 7. Information and Procedures for Use of P-32

1. All P-32 shipments should be opened in a radioisotope hood and inspected before transfer to a storage area.
2. Because of the high radiation exposure rate*, the P-32 stock solution vial should not be handled with the hands. Use remote handling tools.
3. The stock solution vial must be stored in a shield which provides adequate protection to personnel. Quantities of P-32 greater than 0.5 millicuries should be placed in a Lucite and lead beta radiation shield. Lucite-lead stock solution shields are made by Scientific Apparatus Shop (cylinder with 1/2" Lucite and 1/16" Pb wall and cover and 1 1/2" diameter opening). This shield and other Lucite shields should be ordered through the Radiation Safety Officer, 632-6410.
4. Personnel radiation monitors must be worn by individuals who handle stock solutions of 0.5 millicuries or more on a routine basis. Contact the Radiation Safety Officer to obtain a body badge and finger ring. The finger ring should be worn with the TLD chip turned toward the palm of the hand.
5. Routine contamination smear surveys should be made of all use areas in the laboratory on a weekly basis (No. 1 Whatman filter paper can be used on dry surfaces). The smears should be counted in a liquid scintillation counting system, and any areas indicating removable activity greater than two times the background count rate should be decontaminated and resurveyed. Results of all surveys are to be recorded in the quarterly radioisotope laboratory report.
6. The Radiation Safety Officer should be contacted immediately in the event of any major spills or other emergencies. Prior to initiating new experiments involving large quantities of P-32, contact the Radiation Safety Officer to arrange for radiation exposure monitoring during the initial experiment.
7. Safety glasses, which must be worn in the laboratory, provide protection of the eyes from P-32 beta radiation. Therefore, persons handling P-32 should wear their safety glasses.

* Exposure rates from 1 mCi of P-32 over 1 cm² of skin:

2000 rad/hr at surface
200 rad/hr at 1 cm
22 rad/hr at 10cm

In 1 ml of water the surface dose rate for 1 mCi of P-32 = 780 rad/hr or 13 rads/min. Because of these very high exposure rates, the handling of uncovered vessels (open unshielded top) present a serious potential for excessive and unnecessary radiation dose to the hands and face. Never place hands or any other part of the body over an open unshielded vessel containing large quantities of P-32 in relatively small volumes of liquid.

APPENDIX 8. Information and Procedures for Use of I-125 and I-131

1. I-131 and/or I-125 can present a significant external and internal radiation exposure hazard to personnel working with the material, and to other individuals in the laboratory.
2. All shipments of I-131 or I-125 should be opened in a working hood, and inspected prior to placement in a storage area. Sodium iodide and some other iodinated compounds are volatile and can present a significant inhalation problem and consequently, use must be restricted to a well ventilated hood.
3. Stock solutions of I-131 or I-125 must be used in a properly designed, adequately ventilated hood. Airflow measurements should be made of the laboratory hood before using the radioisotope. This service can be obtained through the Radiation Safety Officer.
4. If iodination procedures are to be done in the laboratory, all aspects of the procedure should be restricted to the hood area. Personnel must wear protective disposable gloves which are to be changed frequently to prevent absorption of I-131 or I-125 through the gloves. Hands should be washed thoroughly upon completion. It is important to locate the column and fraction collector in a hood or some other properly ventilated cabinet because iodine in a volatile form is given off from the fraction tubes. Also, the liquid radioactive waste container for I-131 and I-125 solutions must be stored in the hood, and all liquid waste transfers must be made in the hood.
5. All personnel who handle I-131 and/or I-125 in quantities of 1 millicurie or more during iodination procedures must be assigned a film badge monitor, and must be routinely monitored for thyroid uptake of radioactive iodine. Appropriate monitoring is available through, and will be provided by, the Radiation Safety Officer, Department of Environmental Health and Safety, 632-6410.
6. Those individuals who routinely work with 100 microcuries or more of I-131 or 500 microcuries or more of I-125 must be assigned a personnel radiation monitor.
7. Appropriate radiation shielding must be purchased and used as shielding for I-131 and/or I-125. A thickness of 1/16" lead is adequate for providing shielding from I-125 gamma radiation. Stock solution containers and fraction columns and collectors must be contained in 1/16" or greater thickness of lead shielding. This thickness sheet lead is available from General Storehouse and is stocked under plumbing supplies. A greater thickness of lead will be required to shield the higher energy gamma radiation from I-131. Two-inch thick lead bricks are available and can be purchased through most laboratory supply houses or through General Storehouse. Consult the Radiation Safety Officer for information on the amount of shielding required in the case of I-131. After shielding has been installed the Radiation Safety Officer must be contacted to provide a survey of the shielded area to assure that personnel are adequately protected.
8. Contamination smear surveys must be made of I-131 and I-125 use areas on a weekly basis and upon completion of any iodination procedure. Results of these surveys shall be kept in a laboratory record, and a copy forwarded to the Radiation Safety Officer once every month.
9. Notify the Radiation Safety Officer immediately if any emergency should arise (spills, accidental volatilization in room air, hand punctures, etc.).
10. During work with I-131 and I-125, it is important that a laboratory coat be worn to protect the skin of the arms from contact with these radioisotopes.
11. Rubber gloves should be worn at all times when contamination of hands might occur. When the gloves are removed the hands should be surveyed with a thin end window GM survey instrument. If contamination is found the hands should be scrubbed and resurveyed. Contact the Radiation Safety Office at 632-6410.

APPENDIX 9. Shipment Survey Requirement

All packages must be checked within 3 hours of receipt during normal working hours, and within 18 hours if received after normal working hours. Contact the Radiation Safety Officer, Department of Environmental Health and Safety, at 632-6410, if you have any questions.

Table of Radioisotope Shipment Activities Requiring Contamination and Exposure Rate Evaluation

Radioisotope	Contamination Liquid Form	Shipment Activity Requiring	
		Evaluation Other Form	Exposure Rate Evaluation
1. H-3	10 mCi	20,000 mCi	20,000m Ci
2. C-14	10 mCi	20,000 mCi	20,000m Ci
3. S-35	10 mCi	20,000 mCi	20,000m Ci
4. I-125	10 mCi	3000 mCi	3000 mCi
5. Radioisotopes with half-life less than 30 days			
I-131	100 mCi	3000 mCi	3000 mCi
K-42	100 mCi	20,000 mCi	20,000 mCi
P-32	100 mCi	20,000 mCi	20,000 mCi
Na-24	100 mCi	20,000 mCi	20,000 mCi
Rb-86	100 mCi	20,000 mCi	20,000 mCi
Cr-51	100 mCi	20,000 mCi	20,000 mCi
other	100 mCi	(refer to transport group)	(refer to transport group in 6 blow)
6. Other radioisotopes grouped according to transport group:			
a) Group I: Am-241, Ra- 226, Pu-239, Cf-252	.01 mCi	1 mCi	1 mCi
b) Group II: Sr-90, Pb-210, Th- 234	0.1 mCi	50 mCi	50 mCi
c) Group III: Cs-137, Cl-36, Co-60, Ir-192, Na-22 Sr-89	1 mCi	3000 mCi	3000 mCi
d) Group IV-45 Ca and nearly all other radioisotopes (see transport group table)	1 mCi	20,000 mCi	20,000 mCi
e) Group V	1 mCi	20,000 mCi	20,000 mCi
f) Group VI		mCi	10 ⁶ mCi
g) Group VII	25,000 mCi	10 ⁶ mCi	10 ⁶ mCi
h) Special form	1 mCi	20,000 mCi	20,000 mCi same as 6 (refer to group #)
7. Any radioisotope in gaseous form	not required	not required	

APPENDIX 10. Mixed/Hazardous Waste Weekly Inspection Sheet

Radiation Protection Services

	Yes	No	NA
General			
HMMF is maintained secure, door is locked when unattended.			
No smoking in area is permitted.			
“Danger-Hazardous Waste-Unauthorized Personnel Keep Out” sign is posted.			
Emergency Equipment			
Fire extinguisher is present and fully charged.			
Date of last fire extinguisher inspection.			
Spill control equipment (neutralizers, absorbent pads).			
Safety shower working and not blocked.			
Date of last safety shower inspection.			
Sufficient aisle space is maintained to allow unobstructed movement of emergency equipment.			
Communication Systems			
Phone accessible.			
Emergency phone numbers posted next to phone (Dial 333) or (631) 632-3333.			
Protective Equipment			
Chemical splash goggles are available and in use.			
Proper gloves are available and in use.			
Waste Management			
Hazardous and mixed waste container's contents are identified and container is labeled as “Hazardous Waste”.			
Mixed waste containers are labeled with “Caution Radioactive Materials” sticker.			
Mixed wastes are located only on designated shelf.			
Waste containers are labeled with the date accumulation began.			
No accumulation date exceeds 90 days.			
Waste containers are kept closed.			
Waste containers are stored within secondary containment.			
Incompatible wastes are segregated in secondary containment.			
Containers are not leaking, rusted, bulging or damaged.			
Containers are stored in a manner to prevent damage or leakage.			
The base under containers is in good condition. (free of cracks, gaps and impervious to leaks)			
All persons managing hazardous waste have received proper training.			

APPENDIX 11. Chapter 1 State Sanitary Code 16 – Ionizing Radiation

Part 16 is available on the NYSDOH/BERP WEB site: www.health.state.ny.us/nysdoh/phforum/nycrr16.htm