UNIVERSITY OF SOUTH ALABAMA

RADIATION SAFETY PROCEDURES MANUAL



2023 Edition (Approved by ADPH) Reviewed Annually by RSO Last Review 6-1-2023. All ideas & requests for edits/changes are encouraged and should be directed to <u>mwtaylor@southalabama.edu</u>. Changes must be approved by the USA Radiation Safety Committee and ADPH prior to implementation. The University of South Alabama is granted permission by the Alabama Department of Public Health (ADPH) to use ionization radiation for purposes of medical and non-medical research, and to detect and treat conditions in humans. ADPH issued broad-scope radioactive materials license #584, particle accelerator registration #118 and multiple x-ray registrations that allow us to exercise these tasks.

The radiation safety officer and the University of South Alabama Radiation Safety Committee have developed the following procedures to ensure radiation safety at the University of South Alabama. These procedures have been reviewed and accepted by ADPH's Office of Radiation Control (hereafter called the Agency). Adherence to these procedures is necessary to continue advancing in our x-ray and nuclear science activities.

This manual is a part of the university's radioactive materials license and, as such, may not be changed without the approval of the University of South Alabama Radiation Safety Committee and the Agency. The <u>Alabama Department of Public Health's Rules for Radiation Control</u> govern the use of radioactive material and ionizing radiation in Alabama. This manual establishes specific procedures to be followed by all individuals at the University of South Alabama to assure that our radiation safety program complies with Alabama Radiation Control Rules.

It is important to understand that these rules were established to protect everyone's health and safety. Procedures in this manual shall be followed. Compliance with these procedures is the responsibility of all Authorized Users of radiation and administrators at the University of South Alabama. Procedures described in this manual are made a part of the conditions of our radioactive material license. Procedures cannot be changed without prior written approval of the Agency. Violation of these procedures constitutes a violation of our radioactive material license and established radiation safety procedures of the University of South Alabama.

If you do not understand any requirements outlined in this manual or conditions of our radioactive material license, assistance can be obtained by contacting our radiation safety officer, Michelle Taylor (460-7063) or the Alabama Department of Public Health, Office of Radiation Control, P.O. Box 303017, Montgomery, Alabama 36130-3017. (Phone 334-209-6244 or 800-582-1866).

22, 2023

Jo Bonner President University of South Alabama

PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE AS LOW AS REASONABLY ACHIEVABLE (REQUIRED ALARA STATEMENT).

Management Commitment

- We, the management of the University of South Alabama (USA), are committed to the program described in this manual for keeping individual and collective doses as low as reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and instructions to foster the ALARA concept within USA. The organization does include a radiation safety officer (RSO).
- Radiation Safety staff will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff and/or outside consultants.
- Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.
- In addition to maintaining individual radiation doses as far below the established regulatory limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses of individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

Radiation Safety Officer

Annual and Quarterly Review

<u>Annual review of the radiation safety program.</u> The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.

- <u>Quarterly review of occupational exposures.</u> The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA.
- <u>Quarterly review of records of radiation level surveys.</u> The RSO will review radiation levels in unrestricted and restricted areas to determine if they were at ALARA levels during the previous quarter.

Education Responsibilities for ALARA Program

- The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.
- The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management and the RSO are committed to implementing the ALARA concept.
- <u>Cooperative Efforts for Development of ALARA Procedures.</u> Radiation workers will be given opportunities to participate in formulating 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 establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage use of those procedures.
- <u>Reviewing Instances of Deviation from Good ALARA Practices.</u> The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

Authorized Users

New Methods of Use Involving Potential Radiation Exposures

The authorized user will consult with, and receive the approval of, the RSO during the planning stage before using radiation and radioactive materials for a new method of use.

The authorized user will evaluate all methods of use before using radiation and radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced by using trial runs. Authorized User's Responsibility to Supervised Individuals.

The authorizer user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.

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

Unless continual physical presence (as described in <u>Rule 420-3-26-.07</u>) is required, the authorized user shall be immediately available by telephone (within ten minutes) to communicate with the supervised individual, and can be physically present at the area of use within one hour of notification.

Individuals Who Receive Occupational Radiation Exposure.

Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.

Workers will know what recourse is available if they feel that ALARA is not being promoted on the job.

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

The University of South Alabama hereby establishes investigational levels for occupational external radiation dose which, when exceeded, will initiate review or investigation by the RSO. The investigational levels that we adopted are listed in Table 1. These levels apply to the exposure of monitored radiation workers.

Table 1 Investigation I evals

		Investigation Levels (millirems per quarter)	
		Level I	Level II
1.	Whole body; head and trunk, active Blood-forming organs; lens of eyes, or gonads	125	375
2.	Hands and forearms; feet and ankles	1,875	5,675

The RSO will review results of personnel monitoring not less than once in any calendar quarter. Actions in response to investigational levels as stated in Table 1 are defined on the next page.

Quarterly exposure of individuals to less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the Investigational Level I.

Quarterly exposure equal to or greater than Investigational Level I but less than Investigational Level II.

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the RSO. The RSO will, however, consider each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality.

Quarterly exposure equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation and any actions taken will be presented to the Radiation Safety Committee for review. The report containing details of the investigation will be made available to Agency inspectors for review at the time of the next inspection.

<u>Reestablishment of Investigational Level for an individual occupational worker's Level II</u> to a level above that listed in Table 1.

- In cases where a worker's or a group of workers' doses need to exceed Investigational Level II, a new, higher Investigational 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 Investigational Level II will be documented.
- Some individuals' doses, who work exclusively in fluoroscopic environments (Interventional Radiology for example), routinely exceed our ALARA Level II on dosimetry reports. They are known to wear shielded PPE and are subjected to the EDE2 calculations although they aren't identified as such on dosimetry reports. EDE2 subtracts 70% of the incident dosimeter exposure from the reported dose due to PPE use. Investigational levels for these people are three times that identified in Table 1, which assumes no PPE is used.

Signature of Licensee Administrator:

I hereby certify that University of South Alabama has implemented the ALARA Program set forth above.



Jo Bonner President University of South Alabama

TO: All users of ionizing radiation at the University of South Alabama

This manual is the official Radiation Safety Procedures Manual for the use of ionizing radiation at the University of South Alabama.

Utilization of ionizing radiation at the University of South Alabama and in any of its departments and sub-divisions is to be pursuant to the procedures set forth herein.

Sellante MD

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INTRODUCTION

Ionizing radiation is being used effectively at the University of South Alabama in medical and non-medical applications for teaching, research, diagnostic, and therapeutic purposes. We recognize that its use is not without some risk, however small, to the user, patient, other individuals, and the environs. To minimize these risks, radiation exposure of people and the environs should be kept **As Low As Reasonably Achievable (ALARA)**. National and international scientific organizations have proposed guidelines for the use of radionuclides and radiation-producing machines, and the federal and state governments have established regulations controlling the use of radiation.

The Alabama Department of Public Health granted the University of South Alabama a broad scope medical radioactive materials license for using radioactive materials. They also granted several x-ray registrations for radiation-producing machines. Copies of these licenses and registrations are kept in the Radiation Safety Department and are available for inspection. A broad scope medical radioactive materials license is issued to institutions that perform a variety of tasks with many different radionuclides and who have demonstrated the knowledge and capability for performing this work safely. A radiation safety committee composed of individuals knowledgeable in various applications of radiation administers the broad scope medical radioactive materials license. This committee must approve in advance all authorized users of radionuclides. There is a radiation safety officer to advise and assist on radiation safety issues, as required by the regulations. The radiation safety officer is an ex-officio member of the University of South Alabama Radiation Safety Committee.

The University of South Alabama Radiation Safety Committee grants capable individuals a permit for the use of radionuclides. All users of radionuclides shall be permit holders or supervised by a permit holder. The permit holder is responsible to the University of South Alabama Radiation Safety Committee for the safe use of radionuclides.

This manual is provided to define the proper procedures for procuring and using radionuclides at the University of South Alabama. The procedures are based on the Alabama Department of Public Health's regulations and shall be followed. Unless the University of South Alabama Radiation Safety Committee approves other provisions in writing, all university personnel shall use the procedures set forth in this manual.

MANAGEMENT PHILOSOPHY AND ORGANIZATION

The radiation protection responsibility of licensee management^{*} at the University of South Alabama should maintain the code of excellence by keeping radiation exposures **As Low As Reasonably Achievable (ALARA)** for employees, visitors, students, and patients not under medical supervision for the administration of radionuclides for therapeutic or diagnostic purposes.

The University of South Alabama management is responsible for initiating and maintaining radiation protection. Management should provide means to keep radiation exposures **As Low As Reasonably Achievable (ALARA)** for employees, visitors, students, and patients not under medical supervision for the administration of radionuclides.

This responsibility must be carried out through:

- a. information and policy statements to the appropriate university staff and employees,
- b. periodic management audits of operational efforts to maintain exposures ALARA,
- c. continuing management evaluations of radiation safety staffing, program, and budget requirements,
- d. management programs to ensure that all appropriate university staff and employees receive briefings and training in radiation safety, including ALARA concepts,
- e. delegation of sufficient authority to the radiation safety officer § to enforce regulations and administrative policies regarding radiation safety, and
- f. administrative direction to ensure that any new facilities or equipment that may affect radiation protection will be planned or designed in consultation with the radiation safety officer.

^{* &}quot;Management" is defined here as those persons authorized by the University of South Alabama to make its policies and direct its activities.

^{§ &}quot;radiation safety officer" is used to designate the qualified individual who is responsible for directing our radiation safety program and identified as the radiation safety officer on Radioactive Materials License #584.

RADIATION SAFETY COMMITTEE

The radiation safety officer of the University of South Alabama appoints members to serve on the University of South Alabama Radiation Safety Committee. This committee shall meet at intervals not to exceed six months. In accordance with Agency Regulations, the University of South Alabama Radiation Safety Committee must include an authorized user of each type of use permitted by the license, the radiation safety officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a radiation safety officer, and may include other members as the licensee deems appropriate.

Some of our members serve on a three-year rotation while some members serve indefinitely. Presently, our committee is composed of representatives of the following units:

- P Research scientists familiar with non-human use
- Nursing Services P
- Hospital Administration P
- **Radiation Safety Officer** P
- Mitchell Cancer Institute Research Technologist P
- Ŧ Members of the USA Laser Safety Committee
- P M.C.I. Rad. Onc. Services Manager

This list of representative positions is not intended to establish a precedent or rule, but merely represents the committee membership at this writing.

The responsibilities of the University of South Alabama Radiation Safety Committee are:

- a. to establish radiation safety policies to be employed at the University of South Alabama,
- b. to enforce the radiation safety procedures as outlined in this University of South Alabama Radiation Safety Procedures Manual and Agency regulations,
- c. to develop criteria to evaluate qualifications of all individuals working with radionuclides,
- d. to approve or disapprove permit applications to use radionuclides and to review compliance of issued permits,
- e. to comply with federal, state, and local regulations pertinent to radiation safety,
- f. to maintain records of the Committee actions and meetings,
- g. to review plans for all new buildings and modifications of existing buildings where ionizing radiation is to be used,
- h. to maintain a radiation safety training program dedicated to teaching the fundamentals of radiation safety to all individuals involved in the use of radionuclides, and
- to review and approve or disapprove the qualifications of all individuals seeking to work i. with radionuclides.

Radiation safety issues with permit holders are routinely communicated to the permit holder. If the permit holder's response is unsatisfactory, the department chairman is included in the interaction. If the response remains unsatisfactory, cooperation from the appropriate Dean of the College under which the permit holder works is solicited. When routine procedures fail or in the instance of an emergency, the University of South Alabama Radiation Safety Committee shall have direct access to the president of the University of South Alabama (see Appendix I).

- P Nuclear Medicine technologists P Radiology directors
- P E.H. & S. director
- P
- Associate RSO
- P Medical Staff, Radiology

THE RADIATION SAFETY DEPARTMENT / RADIATION SAFETY OFFICER*

The radiation safety officer shall be responsible to the Associate Dean of Research of the University of South Alabama. The radiation safety officer is the director of the Radiation Safety Department and, as such, receives authority from and is responsible to the Associate Dean of Research of the University of South Alabama for the operation of the Radiation Safety Department. The associate radiation safety officer shall be responsible to and report directly to the radiation safety officer. Radiation safety technologists shall be responsible to and report directly to the radiation safety officer.

The radiation safety officer (RSO) shall be knowledgeable in handling alpha, beta, gamma, and neutron emitters. The RSO shall be familiar with the instruments used in the detection of various types of radiation, with radiation safety principles, and with the government regulations.

The radiation safety officer may stop any work that is deemed to be a radiological hazard, and which may be resumed only by written permission from the President of the University of South Alabama, the University of South Alabama Radiation Safety Committee or the radiation safety officer.

The radiation safety officer shall advise and assist in matters concerning the use of ionizing radiation, shall act as a liaison between the users of ionizing radiation and the University of South Alabama Radiation Safety Committee and keep the Committee informed of matters affecting or involving the use of ionizing radiation at the University of South Alabama.

The radiation safety officer is also the University of South Alabama Laser Safety Officer as described in the University of South Alabama Laser Safety Manual.

^{*} "Radiation Safety Officer" is used to designate the qualified individual who is responsible for directing our radiation safety program and the person listed as the radiation safety officer on our Radioactive Materials License. The radiation safety officer communicates with and makes commitments on behalf of the University of South Alabama to the Alabama Department of Public Health's Radiation Control Office and the U.S. Nuclear Regulatory Commission.

RADIATION SAFETY OFFICER (Continued)

Responsibilities of the Radiation Safety Officer are to:

- a. review all applications for the use of radiation ensuring that the applicant has adequate facilities and/or equipment for storing and using radionuclides,
- b. provide adequate dosimetry for persons working in radiation areas or with radionuclides, maintain radiation dosimetry records of all monitored personnel,
- c. perform periodic surveys of radiation areas where radionuclides are used,
- d. perform leak tests of all radioactive sealed sources as required by Agency regulations,
- e. maintain records of all radiation surveys and leak tests,
- f. make routine inventories of all radionuclides,
- g. ensure that proper records are maintained for all radionuclide orders, receipts, disposal, surveys,
- h. ascertain that all orders for radionuclides are in accordance with the individual's permit,
- i. inform the individual and the University of South Alabama Radiation Safety Committee when a 'higher-than-expected' exposure occurs,
- j. make certain that all radiation areas and containers of radionuclides are properly labeled and posted,
- k. ensure that air concentrations do not exceed the allowable limit,
- 1. investigate and report to the University of South Alabama Radiation Safety Committee any accident or loss involving radionuclides,
- m. be responsible for the collection, storage, and disposal of all radionuclides,
- n. ensure that all shipments of radionuclides from the University of South Alabama conform to Agency regulations,
- o. calibrate all portable survey instruments on a routine basis,
- p. maintain records of all instrument calibrations,
- q. assist in the radiation safety training programs,
- r. formulate emergency procedures and administrative controls as necessary,
- s. accompany each radiation safety technologist prior to allowing them to work independently and annually thereafter to assure predetermined competence level is maintained,
- t. maintain accuracy of the university's x-ray machine equipment registrations and solicit registration amendments to the Agency on behalf of the University of South Alabama,
- u. maintain accuracy of the university's radioactive materials license and solicit license amendments to the Agency on behalf of the University of South Alabama, and
- v. conduct the routine operations of the Radiation Safety Department.

RESPONSIBILITY OF THE PERMIT HOLDERS AND SUB-PERMIT HOLDERS

The success of the radiation safety program at the University of South Alabama depends on the individuals handling radionuclides or using a device that produces ionizing radiation. Users of radioactive materials are grouped into the two categories of medical and non-medical. Since regulatory language refers to medical permit holders as "authorized users", we refer to physician permit holders as authorized user permit holders or simply authorized users.

Sub-permit holders are individuals handling radionuclides or using a device that produces ionizing radiation under the supervision of permit holders. Permit holders are responsible for the actions of sub-permit holders that work under their permit.

Permit Holders

A non-medical permit to use radioactive materials is issued after consideration by the University of South Alabama Radiation Safety Committee to qualified primary investigators allowing them to use radioactive materials in research and/or medical research. A permit holder is most commonly a primary investigator and permanent employee of University of South Alabama who submits an application to the University of South Alabama Radiation Safety Committee. Applicants for such a permit must furnish documentation of training and experience in the use of radioactive materials. They must furnish a written explanation of why they want the permit and protocols for use. If training documentation is not available, the USA Radiation Safety Department is authorized to provide basic training.

Permit holders are responsible for acquiring all required safety equipment including suitable survey instruments. Permit holders are directly responsible for actions of those individuals working under them as sub-permit holders.

Authorized User Permit Holders

A permit to use radioactive materials in medicine is issued after consideration by the University of South Alabama Radiation Safety Committee to a qualified physician with a current Alabama medical license allowing them to use radioactive materials or radiation from radioactive materials in medical diagnosis and/or treatment as well as medical research. An authorized user permit holder must be employed by the University of South Alabama at least on a locum tenens basis and must submit an application to the University of South Alabama Radiation Safety Committee. Applicants for such a permit must furnish documentation of required training and experience consistent with their requested use. Requirements for physician authorized user permits are too lengthy to reproduce in this manual and may be found in <u>Rule 420-3-26-.07</u> of Agency regulations.

Authorized Medical Physicists

A permit to use radioactive materials in therapeutic medical physics is issued after consideration by the University of South Alabama Radiation Safety Committee to a qualified medical physicist. An authorized medical physicist permit holder must be employed by the University of South Alabama at least on a locum tenens or contract basis who submits an application to the University of South Alabama Radiation Safety Committee. Applicants for such a permit must furnish documentation of required training and experience consistent with their requested use. Requirements for authorized medical physicist permits are too lengthy to reproduce in this manual and may be found in Rule 420-3-26-.07.

Sub-Permit Holders

A sub-permit is issued after consideration by the radiation safety officer allowing the individual to perform hands-on work with radioactive materials under the permit and supervision of a permit holder. The permit holder must be in the building while their new sub-permit holder works for the first six months during an initial probationary period. After six months, the permit holder may write a letter notifying the RSO that the sub-permit holder is competent to work independently at which time the probationary period is lifted.

A permit or sub-permit is required of every individual who independently works with radioactive material. Permit holders and sub-permit holders shall be responsible for:

- a. safe use of the radionuclides or machines with which they are working,
- b. reporting any defective equipment or radiation survey instrument to his supervisor or to the Radiation Safety Department,
- c. being familiar with this University of South Alabama Radiation Safety Procedures Manual and any administrative control that may apply to their work,
- d. proper labeling of all vials containing radionuclides,
- e. proper storage of all radionuclides in locked facilities,
- f. immediate notification to the Radiation Safety Department of an emergency or situation that may be a radiation safety hazard,
- g. wearing (where necessary) an applicable dosimeter on the collar,
- h. reporting immediately to the permit holder and RSO any lost or stolen radionuclides,
- i. wearing adequate protective clothing (if they are not aware of what protective clothing is needed, they should consult the Radiation Safety Department),
- j. restricting radiation areas from unauthorized entrance,
- k. continuing to review the University of South Alabama Radiation Safety Procedures Manual improving educational standards regarding work and radiation safety,
- 1. performing surveys and wipe tests of radionuclide work areas, as designated by an area sketch, at the completion of each usage (at least daily) and documenting results, and
- m. notifying the Radiation Safety Department if radionuclides are to be transferred to areas other than those stated on the permit application.
- During an inspection of your lab, each Permit Holder shall afford to the radiation safety personnel at all reasonable times, upon request, an opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these rules.
- This Radiation Safety Procedures Manual is a condition of our Broad Scope Medical Radioactive Materials License. It is imperative that we audit ourselves to find and issue internal citations for breaking our own rules. This may prevent Agency Inspectors from citing us for the same violations during an Agency inspection.

METHODS USED TO REDUCE RADIATION EXPOSURE

The radiation protection responsibility of licensee management at the University of South Alabama should maintain the code of excellence by keeping exposures as low as reasonably achievable (ALARA) for employees, visitors, students, and patients not under medical supervision for the administration of radionuclides for therapeutic or diagnostic purposes.

While working with radiation or when around patients containing radionuclides, one should try to keep occupational exposure to a minimum. There are three methods of reducing exposures from external sources.

- a. **TIME.** The less time spent near a source, the less radiation exposure is received. If the time spent near a radiation source is reduced by one-half, then the exposure is reduced by one-half. In fluoroscopic procedures, time may be exploited by using a pulsed mode when activating the beam. Some fluoroscopic units (such as in Special Procedures) do not allow the end user to utilize a continuous beam, even when requested. It is always a pulsed beam.
- b. **DISTANCE.** Radiation intensity decreases as distance from the source increases. As the distance is doubled, the intensity is inversely squared. For example, a dose rate at one foot from a source may be 0.100 rem/hour; but at two feet, it would be reduced by 1/4th to 0.025 rem/hour; and at three feet, it would be 0.011 rem/hour (1/9th). The mathematical equations for

these examples are:
$$\left(\frac{1 \text{ foot}}{2 \text{ feet}}\right)^2 \times 0.100 \text{ rem=} 0.025 \text{ rem} \text{ and } \left(\frac{1 \text{ foot}}{3 \text{ feet}}\right)^2 \times 0.100 \text{ rem=} 0.011 \text{ rem}.$$

The inverse square law absolutely works and should be employed to lower exposures whenever a source is exposed nearby.

c. SHIELDING. Material placed between the worker and the radiation source will absorb or

scatter some of the radiation, thus reducing exposure. Materials commonly used for shielding are lead, iron, and concrete for gamma emitters and wood or plastic for beta emitters. All persons inside the four walls of a room utilizing fluoroscopic equipment where the primary beam exceeds 100 mR/hr shall wear a leaded apron. There is no compromise on this rule.

Although external exposures are more likely to occur, internal exposures are more difficult to evaluate and may be more serious. **Extreme care must be taken to prevent entry by ingestion, inhalation, and absorption.** Hospital use of Na¹³¹I is absorbed readily through skin and other radionuclides may absorb through an open wound or puncture. Good housekeeping and personal grooming are essential in preventing internal exposure. Strict adherence to the radiation safety procedure regarding protective clothing, removal of material from a patient's room, and radiation surveys is a necessity. (See pages 10 & 11 for more on internal monitoring.)

PROCEDURE TO MEET PERSONNEL MONITORING REQUIREMENTS

The University of South Alabama established personnel monitoring procedures to comply with the Agency's annual regulatory limits, which are:

- a. 0.050 Sv (5 Rem^{*}) total effective dose equivalent to adults,
- b. $0.150 \text{ Sv} (15 \text{ Rem}^*)$ to the eyes,
- c. 0.500 Sv (50 Rem^{*}) to the skin or any extremity,
- d. 0.005 Sv (0.5 Rem^{*}) to an embryo/fetus during the entire pregnancy, due to occupational exposure of a "declared pregnant woman"[§] (A second individual monitoring device is required for a declared pregnant woman.), and
- e. 0.001 Sv (0.1 Rem^{*}) total effective dose equivalent per year to individual members of the public from a licensed or registered operation.

The maximum whole body exposure of individuals under age 18 must be 10% of the annual occupational dose limits specified above. Personnel monitors shall be provided to each individual who enters a restricted area under such circumstances that they receive, or may receive, more than 10 percent of these limits.

External Monitoring:

Each individual working in a restricted area where exposures might exceed 2 $^{mR}/_{hr}$ shall wear a personnel dosimeter. Each individual working in a restricted area where an unshielded field of 100 $^{mR}/_{hr}$ exists anywhere inside the four walls of the room shall wear a personnel dosimeter. The device shall be worn on the collar in nuclear medicine and research labs. If in x-ray, wear it on the collar outside any protective apron or thyroid shield. All personnel who are issued a personnel dosimeter are charged with the responsibility of accounting for and wearing it at the appropriate times.

The Radiation Safety Department shall be responsible for the distribution and collection of dosimeters on a routine basis. The Radiation Safety Department shall maintain a supply of dosimeters to replace those lost and those needed for visitors, new users, and temporary users.

<u>In addition to wearing the dosimeter device described above</u>, any person who prepares radiopharmaceutical doses, administers radiopharmaceuticals (other than surgeons administering sentinel node injections), prepares sealed source applicators, inserts sealed sources, removes sealed sources, and cleans sealed sources shall wear either a ring or wrist dosimeter. The device shall be worn on the hand or finger most likely to receive the greatest radiation dose.

Upon receipt of the exposure reports from the dosimetry vendor (currently Landauer), the radiation safety officer shall review the reports. Appropriate actions will be taken if exposures exceed the levels specified in Table 1 on page iv of this manual. Additional emphasis should be placed on all overexposures and trends toward higher exposures. Reporting requirements are specified in Rule 420-3-26-.03 and Rule 420-3-26-.10. Any ALARA Level exposures shall be reviewed by the

^{*} The S.I. unit of biological dose is the seivert (Sv). The traditional unit in the United States is the rem. 1 Sv = 100 rem. 1 rem comes from 1 rad of whole-body exposure multiplied by a Quality Factor assigned to the type of radiation. The Quality Factor for x-ray, gamma ray, beta and fast electron radiation is 1. For example, 1 rad of whole body exposure from x-rays delivers 1 rem (0.01 Sv) of effective dose equivalent. Dosimetry reports are reported in millirem (mrem).

[§] "Declared pregnant woman" is defined as a woman who has voluntarily informed the Radiation Safety Department, in writing, of her pregnancy.

Radiation Safety Committee at each meeting. Copies of each exposure report should be posted in the appropriate department so that each individual can observe his/her exposure record.

NOTE!! <u>No individual will be allowed to work with radiation unless all appropriately required</u> personnel monitoring devices are utilized. If a dosimeter is lost or misplaced, a replacement must be obtained prior to continuing work.

Fetal Monitoring:

Any pregnant employee may declare her pregnancy. Declarations must be in writing and directed to the USA Radiation Safety Department. A declared pregnant woman working in radiology, surgery, GI Lab, Bronch Lab or Cardiology Department must wear an additional dosimeter under the protective apron when working in a situation requiring her to don a protective apron. The second dosimeter must be worn at the umbilicus and must be the designated fetal dosimeter. DO NOT SWITCH THE LOCATION OF THE FETAL AND NORMAL COLLAR DOSIMETER. Dosimeters have a human outline illustrated on the front. Fetal dosimeters have a dot on the umbilicus area while collar dosimeters have the dot on the outline's collar. Declared pregnant employees are not prohibited from working in any radiation area. Managers may make special arrangements to assign declared pregnant employees to 'low-dose' assignments if it is agreeable. Once the fetal dosimeter indicates 375 mrem during the 9-month period, the declared pregnant employee may be removed from radiation areas.

Normally, external radiation exposure shall be determined from a dosimeter worn by the individual. Exposure from internal emitters shall be determined from measurement of biological samples and/or external counting. The required method of monitoring of an individual may be reviewed and changed at any time by the radiation safety officer.

Internal Monitoring:

The normal method of determining exposure to alpha or weak beta emitters shall be through measurements of biological samples from the exposed individual. Such samples (i.e., urine, feces, or blood) shall be submitted to the Radiation Safety Office for analysis.

Individuals involved in operations which utilize, at any one time, more than **100 millicuries of Hydrogen-3** (tritium is the accepted name) in a non-contained form other than metallic foil, shall have urine bioassays performed within one week following a single operation and at weekly intervals for continuing operations. Tritium shall not be used in such a manner as to cause any individual to receive a radiation exposure such that urinary excretion rates exceed 28 μ Ci of tritium per liter when averaged over a calendar quarter.

Urinalysis shall be performed at weekly intervals on all individuals who work in the restricted areas of facilities where more than **100 millicuries (mCi) of tritium** is handled. If the average concentration during a calendar quarter is less than 10 μ Ci per liter, then urinalysis may be performed on that individual at monthly intervals for the following calendar quarter and may continue at monthly intervals so long as the average concentration per quarter remains below 10 μ Ci per liter. The urine specimen shall be collected on the same day of the week if possible.

Any iodination procedure (except Na¹³¹I human use procedures) that involves quantities greater than 8 mCi of ¹³¹Iodine shall be conducted within an operating chemical fume hood unless the permit holder provides proof of chemical stability within the solution or compound. Within 72 hours after all non-human-use procedures involving the handling of greater than 8 mCi, personnel

involved shall have a thyroid uptake performed.^{*} The radiation safety officer shall follow any positive thyroid uptake until iodine removal from the thyroid appears complete. New personnel who will be working with ¹³¹I sodium iodide should have a thyroid bioassay performed to set a baseline. If there is a suspected accidental inhalation, ingestion, or skin puncture involving radionuclides, the Radiation Safety Office must be notified immediately.

Liquid ¹³¹I waste shall be buffered by the permit holder to 7.0 pH or higher (reduces the release of free iodine) during storage and/or prior to disposal through the Radiation Safety Office.

Twenty-four to seventy-two hours after the administration of oral $Na^{131}I$ (>8 mCi liquid or >15 mCi in capsule form), all personnel involved with the administration shall perform a thyroid bioassay.

Currently, thyroid bioassays are performed using an Atomlab 960 Medical Spectrometer. This system requires the user to obtain a background count and a count of their thyroid. The system calculates the minimum detectable activity and provides a net cpm reading and a net activity amount for the user. The minimum detectable activity for the system is based on the isotope efficiency which is tested yearly per manufacturer's recommended procedure. The trigger limit is set at 0.04uCi per manufacturer recommendation. The unit produces a pass or fail response based on the data collected.

Sodium ¹³¹Iodide Thyroid Burden Review Level

If the thyroid burden exceeds 2% of the annual limit of intake (ALI) as found in ADPH Regulations (Currently Appendix B of 420-3-26-.03), a program review will be performed to determine the cause(s) of the uptake and evaluate actions to minimize the chance of recurrence. A repeat bioassay will be performed one week later to help determine the effective half-life for use in estimating dose commitment. At this writing, the ALI for ¹³¹I (all compounds) uptake in the thyroid gland is 9 μ Ci, so 2% is 0.18 μ Ci or 180 nCi.

Sodium ¹³¹Iodide Thyroid Burden Investigational Level

If the thyroid burden exceeds 10% of the ALI, an investigation will be performed. All steps from the Review Level will be performed. An appropriate medical consultant will be asked for recommendations regarding procedures that can be followed to accelerate the removal of radioactive iodine from the body. Continue weekly bioassays until the thyroid burden has dropped to less than 2% of the ALI. The RSO will perform an investigation of the causes of any uptakes which exceed the Investigational Level. The RSO and the Radiation Safety Committee shall determine what corrective actions are to be taken to minimize a recurrence. Documentation of investigations and corrective actions shall be maintained.

At this writing, the ALI for ¹³¹I uptake in the thyroid gland is 9 μ Ci. Ten percent is 0.90 μ Ci. Records of all thyroid bioassays shall be maintained including the date of the bioassay, the name of the individual, the thyroid burden measurement and the MDA.

^{*} We recommend a 24-hour delay after working with radioactive iodine to perform bioassay measurements.

Review Of All Occupational Doses

The Radiation Safety Committee will review monthly occupational exposure results that exceed the ALARA Level II limit[£]. The only exception is in interventional radiology where the workload is high and the numbers of staff are few. They are known to wear leaded aprons and thyroid shields with protective eyewear.

The committee will also review radiation contamination exposures or levels that exceed the applicable regulations. Any personnel doses greater than the Occupational Dose Limit shall be reported to the appropriate governmental agency and to the exposed person, as required by the regulation.

Radiation dosimetry results are always available for staff review. If you don't know where to look, ask someone in your department or call the Radiation Safety Department at 460-7063.

The Radiation Safety Office shall maintain a permanent record of all personnel exposures.

^f This "investigational limit" is presently 375 mrem in a quarter based on the values published in the first paragraph of this section. Remember, some monitored individuals (such as staff in the hospital Interventional Radiology Department) will certainly exceed 375 mrem on collar dosimeters, even on a monthly basis. Those exposed employees that are known to be wearing x-ray PPE may not be investigated even when dosimetry reports exceed the ALARA II limit. If, after application of EDE2 calculations at USA, they exceed the ALARA II level, an investigation will proceed.

PROCEDURE FOR OBTAINING PERMITS TO USE RADIATION

No one may use radionuclides, regardless of the quantity, until the University of South Alabama Radiation Safety Committee approves them for such use.^{*} Ordinarily, a permit will be issued to those who have formal training in radionuclide techniques and theory. The individual shall document formal training in the safe use of radionuclides. These individuals are also responsible for the safe use of radiation by those for whom they have administrative responsibility.

Applications for use of radionuclides and amendment requests may be obtained from the Radiation Safety Office. The completed application or amendment request should be returned to the Radiation Safety Office. The radiation safety officer shall review the application or the amendment request and inspect the applicant's facilities and equipment to ensure adequacy for the use specified in the application or in the amendment request.

Copies of the application shall be forwarded to committee members for consideration of approval. Any reasons for disapproval shall be made in writing and returned to the chairman of the University of South Alabama Radiation Safety Committee. The chairman may ask for more information from the applicant or the radiation safety officer. The chairman may hold the application for discussion at the next University of South Alabama Radiation Safety Committee meeting.

If the application is denied, it shall be returned to the applicant together with reasons for disapproval. If the application request is approved, a permit shall be granted. Permit holders shall not possess greater than 10 times the exempt quantity amount listed in <u>Appendix II</u> to continue enjoying the relaxed "Exempt Quantity" status.

Permit holders are responsible for compliance with their permit provisions or conditions. Changes in permit provisions or conditions may be requested in writing to the RSO as a permit amendment. The RSO may approve amendments in writing or may seek Committee input.

The University of South Alabama Radiation Safety Committee may revoke an active permit if an individual habitually creates radiation hazards or habitually refuses to abide by the procedures and regulations. The chart below clearly outlines consequences of habitual noncompliance discovered during institutional or Agency radiation safety inspections.

1 st non-compliance:	Notification memo is sent to permit holder, Explanation of this policy, and Warning of permit revocation if the same violation is found a 3 rd time.
2 nd non-compliance of the same nature:	Notification memo sent to permit holder and department chairman alerting that a violation of the same nature for a second consecutive time, Explanation of this policy, and Three months' probation or until the next quarterly inspection, whichever is longer.
3 rd non-compliance of the same nature:	Revocation of permit with a cease and desist order until the permit holder reapplies to the Radiation Safety Committee <i>in person</i> . All radionuclides will be removed from the lab during the re-application process.

^{*} Generally Licensed Devices are the only exception.

PROCEDURE FOR OBTAINING PERMITS TO USE RADIATION (Continued)

The University of South Alabama Radiation Safety Officer shall review each permit every two years. Permit holders shall be responsible for:

- a. safely using radionuclides in their possession,
- b. training personnel working with radionuclides or radiation producing equipment in accordance with items listed in Responsibility of The Permit Holders & Technologists on page 6 of this manual. (The University of South Alabama Radiation Safety course shall be available periodically). Every individual working with radionuclides shall be familiar with these procedures. The permit holder shall be familiar with the applicable regulations,
- c. availability of properly operating radiation detection instruments,
- d. procurement of all material and equipment needed for the safe use and storage of radionuclides or radiation producing equipment,
- e. maintaining records showing the receipt, use, disposal and transfer of all radionuclides (Radionuclide record forms and radionuclide transfer forms are available in the Radiation Safety Office),
- f. ensuring that all personnel working in radiation areas or with radionuclides wear the dosimeters specified by the radiation safety officer,
- g. submitting specimens for required bioassays,
- h. notifying the Radiation Safety Office of transfers of radionuclides to areas other than those stated on permit application,
- i. the use of radionuclides in humans shall be confined to those for which the United States Food and Drug Administration has assigned Investigative New Drug (IND) or New Drug Application (NDA) numbers, unless approval has been obtained from the University of South Alabama Radioactive Drug Research Committee or Institutional Review Board,
- j. notifying the Radiation Safety Department of any change in personnel,
- k. providing the Quality Control Assurance for all equipment and procedures,
- 1. notifying the radiation safety officer of a change in building and/or room number, and
- m. making available at all reasonable times, upon request, an opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these rules.

This Radiation Safety Procedures Manual is a condition of our Broad Scope Medical Radioactive Materials License. When we find a violation of these rules, it is imperative that we issue an internal citation. This may possibly prevent Agency Inspectors from citing us for these same violations.

PROCEDURE FOR PROCUREMENT OF RADIONUCLIDES

Only those persons holding permits issued by the University of South Alabama Radiation Safety Committee may receive radionuclides. In order to receive radionuclides, each non-clinical permit holder shall submit a purchase order to the Radiation Safety Office stating the full description of the material needed, the activity, the catalog number, and the vendor. The permit holder shall sign the purchase order. Any special details regarding the shipment shall be worked out between the permit holders and the vendor and stated on the purchase order.

The radiation safety officer is the official purchasing agent for radionuclides and is tasked with the payment of all purchases. Any permit holder whose account is not up to date shall be denied the right to purchase any radionuclides and all vendors shall be notified of this situation.

The Radiation Safety Office shall not assume any responsibility for materials until delivery is complete. Tracing the material and correcting the order shall be the responsibility of the permit holder. The Radiation Safety Office personnel shall be available for assistance in ordering material or equipment.

The nuclear medicine, nuclear cardiology, PET/CT & MCI infusion clinic departments shall receive all radionuclide packages delivered to the University of South Alabama University Hospital, Children's and Woman's Hospital or Mitchell Cancer Institute. They shall accept these packages and check the following items.

- a. Package should be visually inspected for mechanical damage or wetness.
- b. Package exterior exposure rate shall not exceed:
 - 1. Three feet $-10^{\text{mR}}/\text{hr}$.
 - 2. Surface $-200 \text{ }^{\text{mR}}/_{\text{hr.}}$
- c. Record results and keep in an auditable form.
- d. Open package verify content against possession limits.
- e. Wipe leak test interior and exterior of package (contaminated if greater that 200 cpm over background).
- f. Obliterate radiation labels and survey the container prior to discarding.

Containers found to have more than 10,000 cpm per 100 cm square wipe area shall be reported immediately to the Alabama Department of Public Health. Appropriate precautions indicated by this survey shall be given to the permit holder when the material is delivered.

In rare instances on main campus, radionuclides may be delivered directly to the permit holder. Prior approval for this shall be obtained from the radiation safety officer before the material is delivered. The permit holder is then responsible for items a through f above. A copy of these results and the packing slip shall be forwarded to the Radiation Safety Office.

If this procedure is not followed, the University of South Alabama Radiation Safety Committee shall suspend the individual's permit for radionuclides.

PROCEDURE FOR STORING RADIONUCLIDES

Each permit holder shall designate specific locations for storing radionuclides. The radiation safety officer shall approve these areas prior to use. When the storage facility is located inside a laboratory or office, it shall have adequate shielding to ensure that the dose rate does not exceed 0.005 ^{rem}/_{hour} at one meter. Storage facilities, cabinets, or areas open to the public shall be kept locked. Radionuclides that are volatile, powdery, or that might become airborne shall be kept in a hood. All storage facilities shall be labeled with the conventional radiation symbol and bear the words "Caution-Radioactive Material". The word "Danger" may be used in lieu of "Caution".

All radionuclide storage containers shall be labeled with a standard radiation symbol and the identity of radionuclide.

SUMMARY OF STORAGE RULES

- a. Storage of all radionuclides shall be locked and the storage facility labeled with a standard radiation symbol.
- b. If radionuclides are stored in the same storage facility as non-radioactive material, they shall be segregated and easily identified. All radionuclide containers in storage shall be labeled with a standard radiation symbol and the identity, quantity, and assay date.
- c. Once radioactive material is declared waste, it shall not be stored with non-radioactive waste and shall be surveyed weekly (record shall be in an auditable form). The permit holder shall be the only individual to declare it radioactive waste. When declared waste material (drums, jugs, biological material in freezers, etc.) is present in the lab, it is part of your inventory and shall be segregated, surveyed, wiped, and recorded weekly.
- d. A standard radiation symbol shall be used only to identify where radionuclides are normally present. They shall not be used to scare people or to prevent pilferage.

Any Permit Holder that goes one year without actively using radioactive materials may be automatically placed on the inactive list. Permit Holders will be reactivated when they simply place an order or notify the radiation safety officer. Radionuclides on your inventory shall be:

- a. picked up for disposal (out of date),
- b. picked up for redistribution,
- c. picked up and held in the Radiation Safety Office for the permit holder, or
- d. transferred to another permit holder's inventory.

PROCEDURE FOR POSTING AND LABELING OF RADIONUCLIDES

The Radiation Safety Office shall maintain a supply of signs and labels for posting and labeling radiation areas and radionuclide containers. The permit holder is responsible for obtaining signs or labels needed to comply with the regulations of these procedures. All signs and labels must meet Alabama Department of Public Health specifications. The Radiation Safety Office shall be responsible for correctly labeling areas where radionuclides are kept and where radiation areas exist. The individual responsible for the radionuclides or for creating the radiation area shall inform the radiation safety officer of these situations.

Signs and labels are required as indicated below:

- a. Any accessible area where a major portion of the body, head, or gonads can receive in any one hour a dose of 0.005 rem at 30 cm (or about 1 foot) from the source shall be posted with a sign containing the conventional radiation symbol and the words "Caution-Radiation Area". Signs shall be posted so that they can be seen from any entrance.
- b. Any high radiation area where a major portion of the body, head, or gonads could receive in any one hour a dose in excess of 0.100 rem at 30 cm (or about 1 foot) from the source shall be posted with a sign containing the conventional radiation symbol and the words "Caution-High Radiation Area". These signs shall be posted so that they can be seen from any entrance. Each entry to a high radiation area shall be equipped with an interlock so that upon entry by an individual, the radiation level shall drop below 0.100 rem/hour or an audible or visible alarm shall be activated in such a manner that the individual and the supervisor shall be made aware of the entry.
- c. "Very high radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in one hour at 1 meter from a source of radiation or from any surface that the radiation penetrates. The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA". For each very high radiation area, created in a medical institution by the use of a registered medical particle accelerator, the word "Danger" may be substituted for the words "GRAVE DANGER".
- d. Each area or room in which radionuclides are kept shall be posted with a "Caution-Radioactive Material" sign.
- e. Each container of radioactive material shall be labeled with a "Caution-Radioactive Material" label. The radionuclide shall be stated on the label attached to the container.
- f. Packages used to ship or transfer radionuclides shall be labeled according to the radiation safety officer's direction and according to the United States Department of Transportation (DOT) requirements and regulations.

PROCEDURE FOR THE USE OF RADIONUCLIDES OR RADIATION PRODUCING EQUIPMENT

Prior to using any radionuclides or radiation producing equipment, an individual shall receive training by the permit holder and/or the radiation safety officer regarding the safe use of the material or equipment. Graduates from an accredited school of Radiologic Technology or employees holding ARRT certification are considered adequately trained for applications of radiology x-ray equipment. All users of radionuclides shall be permit holders or be a sub-permit holder supervised* by a permit holder. The individual shall be familiar with the contents of this University of South Alabama <u>RADIATION SAFETY PROCEDURES MANUAL</u> and any applicable administrative controls. When applicable, the user shall obtain a dosimeter from the Radiation Safety Department (Ext. 6-7063). If radionuclide quantities are large enough to require a bioassay, the necessary biological materials shall be submitted to the Radiation Safety Department prior to the start of the project (for additional information see Procedure for Personnel Monitoring and pages 9, 10 & 11).

*Supervision:

A licensee who permits the receipt, possession, use, or transfer of radioactive material by a subpermit holder under the supervision of a permit holder who is responsible to the University of South Alabama's Radiation Safety Committee for:

- a. ascertaining that the sub-permit holder is instructed in the principles of radiation safety appropriate to that permit holder's use of radioactive material,
- b. reviewing the sub-permit holder's use of radioactive material, provide re-instruction as needed, and review records kept to reflect this use,
- c. requiring the permit holder to be immediately available (by telephone within 10 minutes) to communicate with the sub-permit holder,
- d. requiring the permit holder to be physically present and available to the sub-permit holder on one-hour notice, and
- e. requiring that only those sub-permit holders specifically trained and designated by the permit holder be allowed to administer radionuclides or radiation to patients.

Any sub-permit holder receiving, possessing, using, or transferring radioactive material shall:

- a. follow the instructions of the supervising permit holder,
- b. follow the procedures established by the radiation safety officer, and
- c. comply with these rules and the license conditions with respect to the use of radioactive material.

The supervising permit holder need not be present for each use of radioactive material in a nonclinic setting.

PROCEDURES FOR WORKING WITH RADIONUCLIDES

Radioactive materials work shall be performed only in rooms that have been approved by the Radiation Safety Department and specified in the permit holder's application. If a permit holder intends to use radionuclides in the field, it must be approved by the RSO. If a permit holder intends to work outside of Alabama to use radioactive materials in the field, an NRC reciprocity license must be obtained by the RSO. Since it may take time, advanced notice is in your best interest.

Any work that may produce airborne contamination shall be performed in an exhaust fume hood that has an airflow recommended by the manufacturer. Only a few hoods have adequate filters to prevent radionuclides from dispersing to the outside air; therefore, the radiation safety officer shall approve any work with volatile or powdery radionuclides.

To reduce the probability of a costly clean-up operation, the work area should be lined with a protective covering. If liquids are involved, an absorbent material with a water repellent backing should be used as a liner. Trays may not be used in lieu of liners, but lined trays may be used.

An instrument capable of detecting the radionuclides involved must be available to monitor the area and the hands at frequent intervals. The permit holder or his designate shall monitor the work area when the work is finished or when leaving for the day; whichever is shorter.

A positive contamination wipe test is defined as 200 cpm above background on a 100 cm² surface wipe. All positive results will be reported to the individual performing the work. Contamination shall be removed at the first available opportunity. Any removable contamination greater than 1,000 cpm beta or gamma or 500 cpm alpha shall be cleaned immediately. The supervisor and the radiation safety officer shall be informed. The radiation safety officer shall evaluate non-removable contamination on an individual basis.

Records shall be kept by the permit holder for inspection by the radiation safety officer. The hands shall be monitored before leaving the work area.

Radionuclides shall not be left unattended. When working with radionuclides, a sign with the conventional radiation symbol shall be posted notifying anyone who enters the area that work is being conducted using radionuclides. All containers used to store radionuclides shall be labeled with a conventional radiation symbol and the radionuclide. Liquid scintillation vials do not require labeling.

PIPETTING OF RADIONUCLIDES BY MOUTH IS PROHIBITED. Eating, drinking, smoking, vaping and applying cosmetics shall not be permitted in areas where radionuclides are used. The individuals shall be aware of the potential hazard of the internal deposition of radionuclides. If there is any doubt of personal contamination, then the individual shall refrain from any activities until they have verified themselves to be free of contamination.

Normally, eating and drinking restrictions shall not apply to rooms or areas specifically set aside for counting areas. The Radiation Safety Office shall determine the areas where eating and drinking are allowed.

Minor skin breaks shall be covered with waterproof bandages before handling **ANY** radionuclides. Persons having deep cuts or large abrasions shall not be permitted to work with radionuclides. Protective gloves should be worn whenever hand contamination is possible.

PROCEDURES FOR WORKING WITH RADIONUCLIDES (Continued)

A REMINDER OF GOOD RADIONUCLIDE LABORATORY SAFETY PRACTICES

- 1. Never pipette by mouth.
- 2. No smoking, vaping or eating permitted in the work area.
- 3. Protective gloves, buttoned laboratory coat, and shoes should be worn when using unsealed radioactive materials.
- 4. Approved personnel monitors must be worn unless the RSO agrees otherwise.
- 5. Hands, shoes, and clothing should be frequently monitored.
- 6. Work with radionuclides in an approved hood or glove box, unless the safety of working on an open bench can be demonstrated.
- 7. Radionuclides should be conducted in an impervious tray or pan, lined with absorbent paper.
- 8. Whenever possible, utilize shielding and distance as protective measures.
- 9. Dispose of liquid and solid radionuclide waste in the approved containers provided.
- 10. Refrigerators containing radionuclides shall not be used for storing food.
- 11. Monitor radionuclide work areas at least once daily for contamination and make notation of this survey in laboratory records.
- 12. Thoroughly wash hands after manipulating radionuclides before eating or smoking, and upon completion of work.
- 13. Maintain records of receipt, use, transfer, and disposal of radionuclides.
- 14. Report accidental inhalation, ingestion, injury or spills to your supervisor and the Radiation Safety Office.
- 15. Review pertinent safety practices frequently, especially before using new radionuclides.

PROCEDURE FOR THE USE OF RADIONUCLIDES IN EXPERIMENTAL ANIMALS

The radiation safety officer shall be informed of all investigations requiring administration of radionuclides to experimental animals. Each investigator shall assume responsibility for notifying the radiation safety officer and the Comparative Medicine Department of the intended use of radionuclides in experimental animals and for the housing and care of those animals in their authorized laboratories.

The following items shall be carefully considered according to the type of radionuclides used and the requirements of the experiment.

- a. In most instances, it is preferred that animals given radionuclides be housed in a separate room. Special ventilation, surface preparation, drainage, or other room design requirements should be considered. All rooms containing radionuclides shall be properly posted.
- b. When high levels of radiation are anticipated, portable radiochemical glove boxes should be available for housing small numbers of rodents for short periods of time.
- c. Animals injected with radioactive materials shall be housed in cages made from plastic or another material suitable for incineration. Cages are not washed. Animals will be transferred to a clean cage and the dirty cage is either closed and incinerated or closed and placed in decay-in-storage, depending upon the radionuclide half-life and chemical compound.
- d. Adequate utensils and instructions shall be provided when radionuclides are added to food or drinking water.
- e. Radioactive animal bedding will not be handled outside of a closed plastic cage.
- f. Plastic backed absorbent pads, plastic bags, and other items should be used in animal wards for containment of radionuclide spillage or waste.
- g. Animal carcasses, contaminated bedding, and equipment shall be surveyed for radioactivity and provisions made for decontamination or disposal through the Radiation Safety Office.
- h. The PI shall be responsible for any necessary decontamination. The Radiation Safety Office shall provide supervision as needed.
- i. The PI shall give explicit instruction to animal care technologists and provide them with necessary protection.

Instructions for caretakers of animals containing radionuclides.

- a. All rooms and cages containing animals with radionuclides shall be labeled with a "Caution-Radioactive Materials" sign where appropriate.
- b. When this sign is posted, all routine handling and feeding shall be performed while wearing protective gloves.
- c. Cages shall not be cleaned. Animals shall be transferred to new cages instead.
- d. Protective gloves shall be worn while transferring urine or feces to storage containers for testing as needed. Care shall be taken not to spill urine or feces on clothing.
- e. Follow any special instructions given by the person conducting the experiment.
- f. In case of an accident or emergency, contact the radiation safety officer.

External Irradiation Using 320 kVp Cabinet Irradiators

Personnel dosimeters are not required while using these machines. Staff members of the Radiation Safety and Comparative Medicine Departments are available to the University of South Alabama investigators for consultation and assistance with animal experiments requiring the use of radionuclides and external beam irradiations.

PROCEDURE FOR NON-INSTITUTIONAL INVESTIGATORS

In order to meet the requirements of the Alabama Department of Public Health regarding the University of South Alabama's Broad Scope Medical Radioactive Materials License, this license shall be maintained separately from all other licenses (Nuclear Regulatory Commission and other Alabama licenses). The following procedures shall be followed.

- a. Investigators working at the University of South Alabama shall submit an application for use of radioactive material to the Radiation Safety Committee for approval even though the investigator may have a Nuclear Regulatory Commission license or institutional permit to work with radioactive material at another institution.
- b. A Radioactive Material Transfer form shall accompany any non-University of South Alabama radioactive material brought onto University property.
- c. Any radioactive waste generated while working at our institution shall be considered University of South Alabama's waste and disposed of according to the University of South Alabama's Radiation Safety Procedures Manual.
- d. Any survey instruments used at the University of South Alabama shall be considered under our administrative control and calibrated according to this Radiation Safety Procedures Manual.
- e. The investigator's primary employer shall furnish personnel monitoring dosimeters.
- f. Any contamination (internal or external) found shall be treated as the University's problem and shall be handled according to the University of South Alabama's Radiation Safety Procedures Manual.

PROCEDURE FOR INSTRUMENT CALIBRATION

Portable radiation survey instruments used for monitoring radiation areas and/or detecting radioactive contamination shall be calibrated by either the Radiation Safety Department or an authorized calibration facility such as the manufacturer. Calibrations shall be performed at least annually, after any repair, or whenever the constancy check fails. Unless a particular condition necessitates special procedures, the calibration shall be performed using a known amount of ¹³⁷Cs.

The instrument shall be labeled with the date of calibration and the initials of the person performing the calibration. The instrument shall have a dedicated check source with the check source reading conspicuously posted on the meter. Instruments shall be calibrated using two points (approximately 1/3 and 2/3 full scale readings) on each scale.

Response to the constancy source shall be checked prior to use. If the instrument does not respond as indicated on the label, check the batteries. If the batteries are not the cause of the incorrect reading, notify the Radiation Safety Office.

The Radiation Safety Office shall maintain records of instrument calibration for at least five years.

PROCEDURE FOR SURVEYS OF RADIONUCLIDES

Laboratory and personnel surveys are conducted to identify contaminated areas. Survey records must be kept at least three years.

Many situations that require monitoring are obvious, such as a spilled radionuclide liquid or an unshielded gamma source. There are more subtle situations, however, where contamination can only be found with proper instrumentation and technique. Every radionuclide user shall have the proper instrumentation available to survey themselves and their work area. The more frequent the surveys, the better informed the user is of the surrounding areas. Frequent surveys are very important when performing a new task or working with new radionuclides or compounds.

Personnel and area surveys shall be performed during work to assure compliance with Posting and Labeling of Radionuclides (see page 17 of the University of South Alabama's Radiation Safety Procedures Manual). The permit holder or designate shall record survey dates and results. Radiation safety personnel shall perform surveys of the permit holders' lab at least every six months and audit records. The audit shall include:

a. radionuclide permit limits,b. inventory records of radionuclides received,	e. labeling, f. storage, and	
c. area surveys,d. any other applicable conditions,	g. usage.	

It is the responsibility of the permit holder to ensure that surveys and wipe tests of radionuclide work areas are performed at the completion of each usage (at least daily) and that the results are documented. A positive wipe test is defined as **200 cpm above background on a 100-cm² surface wipe**. All positive results will be reported to the individual performing the work. Contamination shall be removed at the first available opportunity. Any removable contamination greater than 1,000 cpm beta or gamma or 500 cpm alpha shall be cleaned immediately. The supervisor and the radiation safety officer shall be informed. The radiation safety officer shall evaluate non-removable contamination on an individual basis.

Any skin contamination should be washed immediately with soap and water. If soap and water does not remove the contamination, contact the radiation safety officer. Care should be taken not to wash the contamination to another part of the body.

To remove contamination from clothing, press masking tape to the contaminated area, remove the tape, and monitor both the tape and clothing. If the tape does not remove the contamination notify the radiation safety officer. If a liquid is used to decontaminate the clothing, the garment should be removed. Never wear contaminated clothing home.

PRCEDURE FOR RADIOACTIVE SEALED SOURCE LEAK TESTS

All radioactive sealed sources of gamma or beta emitters (except general licensed devices) shall be leak tested every six months by the Radiation Safety Office. Sealed alpha sources (except general licensed devices) shall be leak tested quarterly. Leak testing of gamma or beta emitters shall be capable of detecting 0.005 microcuries of the radionuclide tested. Leak testing of alpha emitters shall be capable of detecting 0.001 microcuries of the radionuclide tested.

Sealed source wipe leak tests are presently analyzed using a crystal scintillation well counter for gamma emitters or a liquid scintillation counter for beta and alpha emitters. This system is not suitable for identifying unknown radionuclides.

Three measurements must be recorded. They are:

- background counts,
- wipe counts, and
- standard counts.

The standard counts refer to the counts per minute (cpm) collected from a known radionuclide of known activity. It shall be a NIST traceable standard. The standard source's current calculated activity as of the test date will be used. All counting times must be at least thirty seconds and will be converted and reported as cpm. Standards will be selected to closely match the energy of the wiped nuclide.

The wipe's trigger limit is calculated algebraically by ratio and proportion using the cpm from the known activity to calculate the cpm that 0.005 μ Ci or 0.001 μ Ci would produce from that radionuclide. (Actually, any result with 200 cpm over background would be investigated.)

Leak test reports for nuclear medicine elution vials may only be reported as "Neg" on the written report.

Any contamination on a sealed source in excess of 0.005 microcuries or greater shall be transferred immediately to the Radiation Safety Office. The Radiation Safety Office will in turn report the findings to the Alabama Department of Public Health's Radiation Control office. The Radiation Safety Office shall store the source until arrangements have been made to repair or dispose of the source.

PROCEUDRE FOR THE TRANSFER OF RADIONUCLIDES

The University of South Alabama is licensed to use radionuclides only in areas-of-use identified on the University of South Alabama radioactive materials license. Any radionuclides leaving these areas shall be transferred to another licensee or an amendment to the University of South Alabama license shall be obtained prior to the transfer. A copy of the license authorizing the receiving individual to possess the particular radionuclide shall be submitted to the Radiation Safety Office before any radionuclides can be transferred to another licensee.

A Radionuclide Transfer form shall be completed prior to the transfer of radionuclides within the University and for transfers between other institutions. In transferring radionuclides, the following list shall be observed.

- a. "Record of Radionuclides Transfer" forms shall be completed and sent to the Radiation Safety Office. (Call us and we will provide one to you (460-7063))
- b. Containers shall bear a radionuclide label if over exempt amounts or non-excepted packages.
- c. Material shall be shielded so that dose rates do not exceed 0.10 rem/hour at contact with the container and 0.01 rem/hour at one meter.
- d. Liquids shall be wrapped in material capable of absorbing all the radioactive material.
- e. Direct transfer shall be made.
- f. Material to be moved over the public highway or by commercial carrier shall be packaged and labeled by the radiation safety officer according to the United States Department of Transportation's regulations. The Radiation Safety Office shall provide additional instructions and a radiation survey shall be made of the package prior to shipping or upon receipt.

PROCEDURE FOR THE TRANSPORT OF RADIOACTIVE MATERIALS BETWEEN UNIVERSITY OF SOUTH ALABAMA FACILITIES (INCLUDING DAUPHIN ISLAND SEA LAB)

The Radiation Safety Department and/or licensed commercial carriers shall transport radioactive materials for all the University of South Alabama facilities and Dauphin Island Sea Lab. It is the obligation of the shipper, however, to ensure that all radioactive material is properly packaged.

- 1. If at all possible, packages should be shipped in vehicles with no passengers. This is especially true of packages with Radioactive Yellow-III labels. When these are transported, a yellow placard must be applied to the front, rear, and sides of the transporting vehicles.
- In case of an accident with suspected breakage, spillage, or contamination, the radiation safety
 officer should be called immediately to survey the area and supervise decontamination if
 necessary. The vehicle, building, or other area may not be returned to service until radiation
 activity levels published in Alabama Department of Public Health's <u>Alabama Regulations for
 Control of Radiation 420-3-26-.03 Appendix F</u> are met.

PROCEDURE FOR DISPOSAL OF RADIOACTIVE WASTE MATERIAL

All radioactive waste shall be disposed of under the administrative control of the Radiation Safety Office. "Exempt" waste (see chart on next page) is considered NON-RADIOACTIVE and may be disposed of through the normal waste stream. A record of date, isotope, quantity, and method of disposal shall be maintained and submitted upon request. The normal disposal method of radioactive waste at the University of South Alabama shall be by incineration, sanitary sewer, 'return to vendor,' or decay-in-storage for short-lived radionuclides until no observable activity remains. We may also use an approved waste vendor for waste that we cannot dispose of internally.

The Radiation Safety Office shall furnish each user with labeled containers for solid waste (plastic lined cardboard drums) and liquid waste (durable plastic jugs). If needed, the user shall furnish special non-corrodible and unbreakable containers.

Users must carefully evaluate the containers they use. For example, storing acidic liquids in an airtight glass jug will probably cause the jug to explode if 'off gassing' occurs from the solution. That might cause personal injury and will cause massive contamination.

All waste containers shall be labeled with the conventional radiation symbol and the words "Caution-Radioactive Material". In addition, the radionuclides and date should be noted on the waste container.

The permit holder shall be responsible for the storage of radioactive animal carcasses until the radiation safety personnel can dispose of them. The Radiation Safety Office shall assist anyone in the storage of these animals.

All radioactive shipping containers shall have the "Caution-Radioactive Material" signs obliterated prior to disposal as normal waste.

The permit holder should be aware that only limited quantities of material can be disposed without obtaining commercial assistance. Therefore, if two different radionuclides are equally well suited for an experiment, the shorter lived radionuclide or the radionuclide with the larger incineration limit should be used (i.e., use I-131, where possible, instead of I-125).

Disposal of some radionuclides and/or chemical forms must be accomplished only through authorized waste vendors. It is very costly. If permit holders order radionuclides that we cannot dispose of by incineration, 'return to vendor', pouring into the sewer or decay-in-storage, they will be charged a disposal premium before the radionuclide is ordered.

"Exempt" waste and "non-exempt" waste are subject to different methods of disposal.

"Exempt" Radionuclides

"Exempt" status for purchasing a radionuclide is determined by the activity quantity ordered within each received consignment. Purchase orders for quantities equal to or less than those indicated in the Radiation Safety Procedures Manual Appendix II are considered "exempt". A maximum <u>possession limit</u> to preserve exempt status is 10 times those quantities listed. "Exempt" radionuclides shall be disposed of as non-radioactive material.

Note: <u>Chemical biohazard requirements</u> of the Alabama Department of Environment Management, the US Environmental Protection Agency and/or the Department of Transportation still apply where necessary.

"Exempt" Radionuclide Waste Criteria

Under certain conditions, some "non-exempt" radionuclides (H-3, C-14, I-125) in liquid scintillation counting fluid or biological tissue may be considered "exempt" (non-radioactive) for waste disposal purposes, if they meet the criteria in the table below.

Exempt concentrations of waste.

Radionuclide	"Exempt Criteria"	Method of Disposal for All "Exempt" Waste
H-3 C-14 I-125	0.05 uCi/gm of biological tissue 0.05 uCi/gm of biological tissue 0.05 uCi/gm of biological tissue	• Same as for normal non-radioactive biological tissue
H-3	0.05 uCi/ml average in liquid scintillation counting fluid	 Same as for non-radioactive liquids <u>Water soluble</u> liquid goes into sanitary sewer or normal trash collection
C-14	0.05 uCi/ml average in liquid scintillation counting fluid	 b. <u>Water insoluble</u> liquid in plastic vials shall be emptied into durable plastic jugs¹.
I-125	0.05 uCi/ml average in liquid scintillation counting fluid	

See <u>Appendix II</u> (page 30) for more about "Exempt Quantities" not associated with waste.

"Non-exempt" Radionuclides

"Non-exempt" radionuclides are those that are ordered in quantities greater than the amounts listed in the Radiation Safety Procedures Manual Appendix II and/or those that do not meet the above "exempt" criteria. All "non-exempt" radioactive waste shall remain on your inventory until picked up by the Radiation Safety Office (Extension 6-7063) or disposed of in the sanitary sewer as shown below:

Radionuclide	University Yearly Limit for the Sanitary Sewer	Method of Disposal (Records Required)
		a. Daily limits for Sanitary sewer for water-soluble
H-3	5 Ci	liquid are shown in the Radiation Safety
		Procedures Manual Appendix III.
C-14	1 Ci	^{b.} Call the Radiation Safety Office (Extension
		6-7063) for all <u>water insoluble</u> radioactive waste
All other	1 Ci	held for disposal in durable plastic jugs. ¹

¹ Picked up by the Environmental Safety Office (Extension 6-7070).
PROCEDURE FOR COMPENSATION FOR CONTAMINATION OF PERSONAL ARTICLES

In the event that the personal property of any employee becomes contaminated from radionuclides requiring its removal and destruction, it shall be the responsibility of the radiation safety officer and the individual's supervisor to review the cause of contamination and to make recommendations regarding the disposition of the claim.

Since claims of this nature must be presented through the Alabama Board of Adjustment, the University of South Alabama shall assist the individual in the preparation of the necessary forms.

RADIATION PRODUCING EQUIPMENT

Radiation Producing Equipment located in the Radiology Department shall be administratively controlled by departmental procedures. Radiology's Technical Director shall be responsible for compliance with these procedures.

The Radiation Safety Office shall be notified upon receipt of any radiation producing equipment. The Radiation Safety Office will register the equipment with the appropriate Agency. The Radiation Safety Office will maintain the x-ray registrations for the University system.

PERMIT HOLDER RECORDS

Every permit holder is required to keep a record of receipt, use, transfer, survey, and disposal of ALL radionuclides received. "Exempt" permits are excluded from maintaining a record of use of radionuclides. These records shall clearly show the quantity of material on hand at any time. The Radiation Safety Office shall provide a log sheet for ALL radionuclides received. (A copy is in a binder in each lab.) Permit holder records shall be made available to the Radiation Safety Office personnel during normal working hours. The Radiation Safety Office shall not place any order for radionuclides unless the individual permit holder maintains these records.

RADIATION SAFETY OFFICE RECORDS

The Radiation Safety Office shall generate and retain the following records for the indicated time period:

- 1. Personnel monitoring records - permanently,
- 2. Survey records - 3 years,
- 3. Leak test records - 5 years,
- 4. Disposal records - 3 years, and
- 5. Instrument calibration records - 3 years.

All records since the previous ADPH inspection shall be kept in the Radiation Safety Office.





event of an emergency.

APPENDIX 1

APPENDIX II

EXEMPT QUANTITIES

Certain small quantities of radioactive materials are treated with much more relaxed radiation safety and radiation control requirements. While they have been known as "Exempt Quantities" for decades, we know they are not truly exempted as radioactive materials. However, waste disposal, strict inventory record keeping and daily contamination wipes and surveys are not necessary when working with such small quantities. You must still be approved by the USA Radiation Safety Committee to use them and they must still be reflected on your radioactive materials inventory.

However, when small quantities per consignment do not exceed the following amounts, the radioactive materials received in that shipment are exempt from many rules in this manual. You are encouraged to consult with the Radiation Safety Department regarding the regulatory and safety treatment that these consignments require.

The following table is based upon Alabama Regulations and identifies quantities under which no labeling requirements exist. If your radioactive material of interest is not included in this table, it doesn't mean it will not be treated favorably at very low activities. It just means that the writer of this section did not expect it to be used at University of South Alabama. To determine under what activity your radionuclide must fall to be included in USA's "Exempt" status, examine Alabama Radiation Control's table of "Quantities of Licensed Materials Requiring Labeling" in Appendix C of Alabama Regulation 420-3-26-03. If it isn't included on their list, or if you have a mixture of radionuclides, then your radionuclide of interest must be included in the last entry on that table.

Radioactive Material	Microcuries	Microcuries		Radioactive Material	Microcuries
Hydrogen 3	≤1,000	Carbon 14 ≤1,000		Sodium 22	≤10
Silicon 32	≤1	Phosphorus 32	≤10	Phosphorus 33	≤100
Sulfur 35	≤100	Chlorine 36	Chlorine 36 ≤ 10 Calcium 45		≤100
Scandium 46	≤10	Chromium 51	Chromium 51 $\leq 1,000$ M		≤100
Iron 55	≤100	Cobalt 57	≤100	Cobalt 58	≤100
Iron 59	≤10	Nickel 59	≤100	Cobalt 58m	≤1,000
Nickel 63	≤100	Zinc 65	≤10	Cobalt 60	≤1
Strontium 85	≤100	Strontium 89	≤10	Strontium 90	≤0.1
Technetium 99	≤100	Cadmium 109	≤1	Indium 114m	≤10
Iodine 125	≤1	Iodine 129	≤1	Iodine 131	≤1
Barium 133	≤100	Cesium 137	≤10	Cerium 141	≤100
Bismuth 210	≤1	Radium 226	≤ 0.1		

APPENDIX III - SANITARY SEWER DISPOSAL

Disposal via this method is restricted to sanitary sewers that are connected to the Mobile Area Water & Sewer System. Disposal to on-site septic systems is not permitted.

The quantity of licensed or registered radioactive material that is released into the sewer in one month divided by the average volume of water released into the sewer by USA must not exceed the concentration published by ADPH. The total quantity of licensed radioactive material that the entire University of South Alabama campus releases into the sanitary sewerage in a year must not exceed 185 GBq (5 Ci) of hydrogen-3, 37 GBq (1 Ci) of carbon-14, and 37 GBq (1 Ci) of all other radioactive materials combined, regardless of the total amount of sewer effluent. See page 32 for more information about the listed quantities below.

You may call the Radiation Safety Department to collect and dispose of your liquid waste for you. However, if you choose to dispose of your liquid radioactive waste, follow the steps below. SEWER DISPOSAL IS NOT AUTHORIZED AT DISL.

Step 1: Determine if the liquid is acceptable for sewer disposal. Use a properly posted sink.

• The chemical matrix of the radioactive liquid must be readily soluble (or readily dispersible non-hazardous biological material) in water. All liquids that do not conform to these conditions must be tagged for collection by the Radiation Safety Department.

• Determine the activity of the radioisotope through process knowledge or direct testing. Combine the activity to be disposed with activities previously disposed in the current month and make sure you don't exceed values published below.

Step 2: Prepare for disposal.

• Stage a survey meter near the sink to monitor for contamination during the disposal process.

• Use absorbent padding on surfaces where containers are staged to prevent contamination.

• Don appropriate PPE (e.g., laboratory coat, gloves and eye protection).

Step 3: Perform the disposal.

• Order containers from least to greatest activity to minimize potential for spread of contamination.

• Pour the waste directly into the drain minimizing contact with the sink bottom and splashing. Step 4: Cleanup.

• Flush the sink thoroughly with water (15 to 30 minutes is recommended).

• Survey the sink and counter. Wipe the area and measure wipes using liquid scintillation.

• If contamination is present, clean and re-survey. Continue process until contamination is less than 200 cpm based on a survey area of at least 100 cm².

Sanitary Sewer Disposable Limits for Radionuclides in Water Soluble Solutions:

Isotope	1. ^{µCi} / _{ml} concentration	2. uCi/day*	3. mCi/day*
Carbon-14 (C-14)	3E-4	36,150	36.1
Calcium-45 (Ca-45)	2E-4	24,100	24.1
Chromium-51 (Cr-51)	5E-3	602,495	602.5
Hydrogen-3 (H-3)	1E-2	1,204,991	1,205.0
Sodium-22 (Na-22)	6E-5	7,230	7.2
Iodine-125 (I-125)	2E-5	2,410	2.4
Phosphorus-32 (P-32)	9E-5	10,845	10.8
Phosphorus-33 (P-33)	8E-4	96,399	96.4
Silicon-32 (Si-32)	4E-4	48,200	48.2
Sulfur-35 (S-35)	1E-3	120,499	120.5

*The table on page 31 is based upon average monthly concentrations published in Alabama Regulations at the time of this writing. The monthly average concentrations are published in

Alabama Radiation Control Regulations, "Standards for Protection – General Provisions; Table III; Release to Sewers." Those regulatory concentrations are shown on the previous page of this manual on page 31 in Column 1 (in $\mu^{Ci}/_{ml}$). The two columns to the right of that are based on historical water consumption at USA's main campus as described below.

Mobile Area Water & Sewer System's total water delivery to main campus varies greatly from month to month depending on student population. Total water delivery from Aug 2021 through July 2022 averaged 6,366,500 gallons per month with a range from 7,576,000 to 4,068,000. However, discharge volume is not monitored and three discharge points exist. Furthermore, not all of it is returned in the sanitary sewer. If a water well suffers pump failure for irrigation, HVAC cooling towers and swimming pools, MAWSS water will be used to make up the difference, decreasing the amount of effluent returned to the sanitary sewer.

Therefore, exact effluent volumes are not available for each discharge point. Columns 2 & 3 conservatively assume that only fifteen percent $({}^{15}/{}_{100}{}^{th})$ of the university's average water consumption is drained from the discharge point where the liquid radioactive waste is discharged. So, the Column 2 value is calculated by converting milliliters into gallons and multiplying the regulatory average monthly concentration limit by 15%* of daily consumption based on an average monthly usage of 6,366,500 gallons. Such a manipulation preserves the regulatory concentration while offering guidance on absolute radionuclide activity discharge.

 $\left(\frac{\mu \text{Ci}}{\text{ml}} \times \frac{3,785.41 \text{ml}}{\text{gallon}} \times \frac{15\% \text{ of } 6,366,500 \text{ gallons}}{\text{month}} \times \frac{\text{month}}{30 \text{ days}} = \frac{\mu \text{Ci}}{\text{day}}\right)$

If you want to discharge your own waste, you must initially consult with the radiation safety officer to assess the compliance with "Table III" limits.

If a radionuclide is not shown on this list, it doesn't mean it cannot be discharged. It means the writer didn't expect it to be used in a liquid, water soluble form suitable for discharge into the public sanitary sewer by a lab at USA. It may still be discharged after a suitable chemical assessment and calculations are accomplished to show compliance with the regulations.

Remember, there are absolute maximum activities allowed. Just because we can discharge 1 curie of H-3 per day doesn't mean we can discharge more than 5 curies per year. Be sure to pay attention to the bold print near the top of page 31. You must report the activities you discharge to the Radiation Safety Department.

^{*} Fifteen percent is used simply because it is about half of three discharge points *if* the discharge is equally distributed at 33.3%, which is unknown.

APPENDIX IV PROCEDURE FOR RADIATION EMERGENCY

Definition of a <u>radiation emergency</u>: An emergency shall be any incident pursuant to the use of radionuclides which produces contamination of personnel, areas and atmosphere or which may cause an overexposure of individuals working in or visiting these areas in excess of 0.002 rem in any one hour, or 0.100 rem in any seven consecutive days (0.6 mR/hr in a 100% occupied area.)

Classification of type of radiation emergency:

- 1. fire,
- 2. explosion,
- 3. uncontrolled release of radionuclides in air and /or water,
- 4. persons contaminated from an accident involving radionuclides,
- 5. injured or deceased persons contaminated with radionuclides, and
- 6. loss of control of "non-exempt" radionuclides by a permit holder.

If the emergency occurs on the main campus, notify the RSO (460-7063) immediately after activating EMS (911) and USA Police (460-6312).

Responsibilities and Authority during a Community Radiation Emergency Response at USA Hospitals

- 1. The nuclear medicine physician or radiologist will advise the physician-in-charge of treatment of any injured person (whether injury is due to radiation or injured person is contaminated with a radionuclide).
- 2. Radiation Safety Office personnel shall be in charge of checking the level of radioactivity present and then will advise the institutional physician of the necessary steps to be taken to protect the safety of the attending staff. <u>Triage will be immediately instituted, if necessary, consistent with good medical practice and the needs of the patient regardless of the levels of contamination involved</u>. Radiation Safety personnel will monitor decontamination procedures for both patient and radiation emergency personnel.
- 3. The Radiation Safety Office will dispose of all non-clinical radioactive waste. All waste containers shall be labeled with the conventional radiation symbol and the words "Caution-Radioactive Materials". The normal method of waste disposal shall be by incineration or by disposal into the normal waste stream after decay-in-storage.
- 4. The administrative representative shall be in complete charge of the hospital facilities and shall be authorized to make any needed decisions after consulting with the radiation safety officer.
- 5. The representative knowledgeable about fires and explosions shall be responsible for taking the necessary steps to ensure that no additional fire hazards exist and will supervise the clean-up procedure in conjunction with the decontamination clean up at the accident site.

An example of a Decontamination Team may be:

- 1. One radiologist or nuclear medicine physician,
- 2. Two registered nurses,
- 3. Several allied health personnel,
- 4. Radiation safety officer and/or radiation safety personnel, and
- 5. Nuclear medicine technologists.

PROCEDURE FOR RADIATION EMERGENCY (Continued)

The hospital disaster response team, upon receiving word that patients involved in a radiation accident will be arriving shortly, should immediately contact one or more of the following:

- 1. radiologist or nuclear medicine physician,
- 2. nuclear medicine technologists,
- 3. radiation safety officer and/or radiation safety personnel, and/or
- 4. the Alabama Department of Public Health.

When victims arrive at one of the University of South Alabama hospitals, they must be surveyed for radioactivity. <u>Triage shall be instituted immediately</u> in the emergency room <u>if the medical situation warrants</u>, **regardless of contamination level**. If a beta-gamma type survey meter is available, the criteria of $0.1 \text{ }^{\text{mrem}/\text{hour}}$ or 0.1 mR/hr, which is twice background in Mobile, might be used as a starting point for decontamination procedures. At least one survey meter is available on site in the nuclear medicine hot lab.

Medical judgment should accompany all meter readings, and if possible, all patients should be surveyed inside the vehicle in which they are transported, and then, if need be, transported directly to the decontamination area. The decontamination room or area has showers and stalls where the patient can be hosed down with running water. YOU MUST REMEMBER TO "CONTAIN" RADIOACTIVE MATERIAL. Therefore, ventilation systems may be turned off, if possible. All other personnel are to remain in assigned areas and are to be used as required by the monitoring team. Keep staff to a minimum on the hot side of the decontamination line.

PROCEDURE FOR RADIATION EMERGENCY (Continued)

The following persons presently fill responding positions. Administration shall contact one in each category before moving on to the next category.

1. Radiation Safety Officer and/or	OFFICE TELEPHONE Michelle Taylor, RSO Office: 460-7063	<u>CELL PHONE</u> (251) 269-8077
Radiation Safety Staff	Wesley Myrick, ARSO Office: 460-7063	(251) 366-1081
2. Radiologist or Staff Radiologist	471-7155	
3. Nuclear Medicine Physician	471-7155	
4. Emergency Room	471-7300	
5. Nuclear Medicine Technologist	471-7132	

If none of the above is available, and/or a **disaster** exists, contact one or more of the following individuals/departments:

	OFFICE TELEPHONE
6. The Alabama Department of Public Health	(800) 582-1866 or
1	(334) 290-6244 or
	(334) 324-0076
7. 24-hour State EOC Communication Center	(205) 280-2310
	(800) 843-0699
8. Mobile Fire Chief	(251) 208-7351 or
	(251)208-5813
9. Radiation Emergency Assistance Center in Oak Ridge, TN:	: (865) 576-3131
(REAC/TS) (Medical Management of Radiation Incidents) After	hours: (865) 576-1005

As part of its mission to strengthen medical response to radiation emergencies, REAC/TS staff is available 24 hours a day/seven days a week to deploy and provide emergency medical consultation for incidents involving radiation anywhere in the world. If they deem it necessary, their drill is 'wheels up within three hours' and will fly a team and equipment directly to the area. It is free of charge and they are truly experts. The telephone numbers above provide USA ED nurses & physicians access to telephone consultations with REAC/TS nurses & physicians. treatment See the radiation patient algorithm you should use at: https://orise.orau.gov/reacts/infographics/radiation-patient-treatment-algorithm.pdf

If an individual on the above list is called, he/she should immediately report to the University of South Alabama University Hospital Emergency Department and be prepared to act as the radiation expert on scene. Being prepared includes possession of the proper survey equipment. Survey equipment is available in the Nuclear Medicine Department at both University of South Alabama hospitals and the Radiation Safety Office located on campus in the 'College of Medicine's Central Services and Administration Building' Room 330.

Do not be timid about calling REAC/TS. Better to call & not need than to need and not call!

APPENDIX V

REPORTING A "MISADMINISTRATION"

A medical misadministration of radiopharmaceuticals must be reported to the Alabama Department of Public Health within 24 hours of discovery and the radiation safety officer must submit a written investigational report within 15 days of discovery.

It is imperative that the radiation safety officer receives this information within the 24-hour period to prevent a citation from the Alabama Department of Public Health.

Telephone Numbers:	20.00	Business	Cell
Radiation Safety Officer	Michelle Taylor	460-7063	(251) 269-8077
Associate Radiation Safety Officer Radiation Safety Technologist	Wesley Myrick Grace Hofer	460-7063 460-7063	(251) 366-1081 (251) 487-8657
Alabama Department of Public Health	Radiation Control	(800) 582-1860	5
24-hour State EOC Communication Center		(205) 280-2310 (800) 843-0699	

CLINICAL (DIAGNOSTIC & THERAPY) MISADMINISTRATION DEFINITION

<u>A misadministration is:</u> (other than events that result from intervention by a patient or human research subject) any event in which the administration of radioactive material or radiation from radioactive material results in:

1. A dose that differs from the prescribed dose by more than 5 millisieverts (500 millirem) effective dose equivalent, 0.05 sieverts (5 rem) to an organ or tissue, or 0.05 sieverts (5 rem) shallow dose equivalent to the skin; and either

(i) The total dose delivered differs from the prescribed dose by 20 percent or more;

(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

2. A dose that exceeds 5 millisieverts (500 millirem) effective dose equivalent, 0.05 sieverts (5 rem) to an organ or tissue, or 0.05 sieverts (5 rem) shallow dose equivalent to the skin from any of the following:

(i) An administration of a wrong radioactive drug or the wrong radionuclide for a brachytherapy procedure;

(ii) An administration of a radioactive drug containing radioactive material by the wrong route of administration;

(iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) A leaking sealed source.

3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.05 sieverts (5 rem) or more than the expected dose to an organ or tissue and 50 percent or more than the expected dose from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

APPENDIX VI CLINICAL REQUIREMENTS

- A. The University of South Alabama requires an authorized user of radioactive materials used to treat patients with High Dose Rate (HDR) afterloaders to be physically present at the console accompanied by an authorized medical physicist throughout the entire treatment. The physician or medical physicist authorized user can step away only as far as can be communicated in a normal tone of voice without the use of any device such as a speaker, intercom, cell phone, other people or a loud voice. They cannot close a door between them and the console. This is an absolute requirement without compromise.
- B. The University of South Alabama requires all other authorized users of radiation to be immediately available (within 10 minutes) by telephone AND an ability to be physically present on-site with the supervised individual on **one-hour notice**. The supervisory authorized user need not be present for each P.O. or parenteral use of radioactive material, including therapeutic administrations.
- C. Written quality control procedures for equipment used to obtain images from radionuclide studies are required for dose calibrator, survey instruments, gamma camera, etc.
- D. Daily area and removable contamination surveys and weekly storage surveys are required. A dedicated radioactive check source is required for all survey instruments.
- E. Photonic radiopharmaceutical dosages shall be assayed within 30 minutes or within 10% of the half-life before medical use. (See item 22, page 47 for exceptions.)
- F. Brachytherapy sources are required to have:
 - semiannual inventories,
 quarterly area surveys with sketch, and
 semiannual wipe leak test.
- G. All syringes shall be contained in syringe shields and labeled with the radiopharmaceutical name and procedure and/or patient's name.
- H. Calculate and post the amount of time needed, after a gaseous release, to reduce the concentration in the area of use to the acceptable derived air concentrations (DAC). Exhaust velocity shall be measured semiannually and compared to the room posting.
- I. Yearly: provide oral and written radiation safety instruction for all personnel caring for inpatients undergoing radiopharmaceutical therapy.
- J. Hospitalized patients receiving implant radiopharmaceutical therapy shall be provided a private room with a private sanitary facility.
- K. Measure the thyroid burden of each individual who helped prepare or administer a dosage of I-131 (>8 mCi liquid or >15 mCi in capsule form) within 3 days after administering the dosage.

Iodine Bioassay for Staff Administering Iodine-131

The daily calibration is done every day that the uptake probe is used. The Cs137 button source is positioned within the probe using the source holder provided by the manufacturer and is counted for 60 seconds. Two values are checked: full width half max (FWHM) and the energy in the peak channel. The FWHM characterizes the quality of the spectrum peak and should be below 10%. The Cs137 (661keV) energy peak should be between channels 430-480. There is an option to evaluate constancy, but we do not as it was not required by the manufacturer.

Iodine Bioassay for Staff Administering Iodine-131 (Continued)

Isotope efficiency is tested yearly per manufacturer recommendation to ensure accurate results for daily calibration, employee bioassay and thyroid uptake. For our purposes, isotopes tested include Cs137, I131, and I123. The lab background is counted followed by counting of a standard dose of the desired isotope placed in the neck phantom. The amount of activity, time and date of calibration, and distance from source to probe are entered. Distance is adjusted to avoid flooding the probe. A spectrum is provided to monitor counts, and the APOT (Analyzed Pulses Over Total Pulses) is monitored and should stay within 95-100% to ensure activity and/or distance does not need to be modified. Isotope efficiency is displayed and results can be accepted or rejected. Isotope efficiency is affected by the age of the probe and will vary year over year.

For employee thyroid bioassays, the user is required to obtain a background count and a count of their thyroid. The system calculates the minimum detectable activity and provides a net cpm reading and a net activity amount for the user. The minimum detectable activity for the system is based on the isotope efficiency which is tested yearly per manufacturer's recommended procedure. The trigger limit is set at 0.04uCi per manufacturer recommendation. The unit produces a pass or fail response based on the data collected.

If the results are high (greater than 0.18 μ Ci), ensure there are no dosed patients in the room. Survey yourself to verify you aren't contaminated with Tc-99m. Repeat the test. If the reading still indicates a dose greater than the <u>Thyroid Burden Review Level</u> (0.18 μ Ci) discussed on page 11, then contact the radiation safety officer.

PROCEDURE FOR THE CARE OF PATIENTS BEING TREATED WITH RADIONUCLIDES

Hospital personnel are expected to give the best possible care to every patient. The care given to a patient containing radionuclides is no exception. Good nursing care involves relieving anxiety and, since many people have a fear of radiation, the attitude of the hospital personnel can temper this fear and instill a respect of radiation to others. There is no reason to be more concerned about caring for a patient containing radioactive material than one in isolation. The radiation safety officer shall advise the nurse supervisor of any special precautions that need to be implemented for these patients.

Therapeutic administrations of radiopharmaceuticals requiring an in-patient stay have slowed to only one every few years as they have become out-patient procedures. All nursing personnel authorized to care for in-patients containing therapeutic quantities of radionuclides will attend annual radiation safety instruction in the necessary precautions consistent with the ALARA program. They shall be considered occupational radiation dose recipients and as such, shall be issued personnel monitors when and where applicable. If the radionuclide therapy patient requires additional care other than routine nursing support, this shall be recommended by both the admitting physician and the authorized user. The Radiation Safety Department shall be provided timely notification by the authorized user (in writing and at least 24 hours in advance, if possible) to obtain radiation monitors and provide instruction for the appropriate hospital personnel. In life threatening emergencies, the Radiation Safety Department should be contacted immediately, but health care personnel should proceed with life support.

A radiation survey shall be accomplished after loading the patient. A copy of the radiation survey (conservatively reporting the highest exposures around the patient and patient's room) and any written or oral instructions will be given to the charge nurse. A second copy of the radiation survey shall be placed in the patient's radiation therapy chart.

Caution signs shall be placed outside the patient's door and on the patient's chart.

PROCEDURE TO BE USED WITH ALL INPATIENTS BEING TREATED WITH THERAPEUTIC QUANTITIES OF RADIONUCLIDES

INPATIENTS

- 1. Patients receiving Na¹³¹I radiation therapy should be placed in an end room (private with bathroom).
- 2. A representative maximum exposed radiation survey shall be made around a patient receiving therapeutic quantities of radionuclides and inserted in the patient's chart.
- 3. An employee or student under eighteen years of age shall not be permitted to take care of a patient where the dose rates are 0.0002 rem/hr (0.2 mrem/hr) or greater.
- 4. The radiation safety officer shall be informed whenever a pregnant employee is caring for a patient containing radionuclides.
- 5. Shields shall be placed by the bed when exposure rates exceed 0.025 $^{\text{rem}}/_{\text{hr}}$ (25 $^{\text{mrem}}/_{\text{hr}}$) two feet from the patient at the pelvic level.
- 6. The bedside time limit for nurses and visitors shall be established at the time of the survey and the information given to the nurse supervisor and placed in the patient's chart.

PROCEDURE TO BE USED WITH ALL INPATIENTS BEING TREATED WITH THERAPEUTIC QUANTITIES OF RADIONUCLIDES (continued)

- 7. The Radiation Safety Office is to be notified if a visitor insists on staying longer than the specified time limit.
- 8. Dose rates to other patients and uncontrolled areas shall not exceed 0.002 $^{\rm rem/}_{\rm hr}$ and 0.100 $^{\rm rem/}_{\rm week}.$
- 9. The radiation safety officer shall be notified when any patient containing therapeutic quantities of radionuclides expires, transfers to another hospital, or leaves the hospital against medical advice.
- 10. Bedding and utensils shall be surveyed before releasing them into the normal hospital waste stream or linen flow to ensure that they are not contaminated or to hold them for decay if contamination is greater than 200 cpm over background.
- 11. Survey and provide the patient with radiation safety instructions prior to release.

PROCEDURE FOR PRIVATE DUTY NURSES CARING FOR PATIENTS BEING TREATED WITH THERAPEUTIC QUANTITIES OF RADIONUCLIDES

Although a private duty nurse is not an employee of the University of South Alabama, the hospital is responsible for the radiation exposure received by any individual while in the hospital facilities.

A private duty nurse shall be considered an occupational radiation dose recipient and as such, shall be issued a personnel monitor when and where applicable. The radiation safety officer shall provide appropriate instruction that shall be followed explicitly. Occupational radiation dose recipients may receive exposure of 5 $^{\text{rem}/\text{year}}$ and up to 0.1 $^{\text{rem}/\text{week}}$. Any private duty nurse employed by a patient receiving therapeutic quantities of radionuclides shall be required to wear a personnel monitor and abide by the procedures set forth in this manual. The Radiation Safety Department shall provide radiation exposure records upon request.

OUTPATIENT PROCEDURES

- 1. Parenteral and oral therapeutic administrations (such as Na¹³¹I, Metastron, Quadramet, Pluvicto, Lutathera, Xofigo and even Y-90 microsphere administrations) shall be handled as any other parenteral administration in which the authorized user must be available by telephone within 10 minutes and an hour's distance from the administration location. HDR afterloader treatments shall include the authorized user physician and physicist at the console as described in item A of this appendix.
- 2. Alabama Rules for, "Release of Individuals Containing Radioactive Drugs or Implants," permits a licensee to "authorize the release from its control any individual who has been administered radioactive drugs or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem)." In compliance with this rule, we must therefore objectively document our basis for release of a patient containing radioactive materials by:
 - a. using individualized dose activity and output measurements to calculate dose to bystanders for the purpose of limiting dose to members of the public, or
 - b. administer a dose of activity not to exceed the following table on page 41.

	COLUMN 1		COLUMN 2		
	Radionuclide Activity at or Below		Dose Rate at 1 Meter, at or Below		
	Which Patients May Be Released		Which Patients May Be Released		
		-	-		
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)	
Ag-111	19	520	0.08	8	
Au-198	3.5	93	0.21	21	
Cr-51	4.8	130	0.02	2	
Cu-64	8.4	230	0.27	27	
Cu-67	14	390	0.22	22	
Ga-67	8.7	240	0.18	18	
I-123	6	160	0.26	26	
I-125 implant	0.33	9	0.01	1	
I-131	1.2	33	0.07	7	
In-111	2.4	64	0.2	20	
Ir-192 implant	0.074	2	0.008	0.8	
Lu-177 (Pluvicto)	8.14	220	0.02	2	
Lu-177 (Lutathera)	8.14	220	0.02	2	
P-32	*	*	*	*	
Pd-103 implant	1.5	40	0.03	3	
Ra-223 (Xofigo)	*	*	*	*	
Re-186	28	770	0.15	15	
Re-188	29	790	0.2	20	
Sc-47	11	310	0.17	17	
Se-75	0.089	2	0.005	0.5	
Sm-153 (Quadramet)	26	700	0.3	30	
Sn-117m	1.1	29	0.04	4	
Sr-89 (Metastron)	*	*	*	*	
Tc-99m	28	760	0.58	58	
T1-201	16	430	0.19	19	
Y-90 (microspheres)	*	*	*	*	
Yb-169	0.37	10	0.02	2	

Activities and Dose Rates for Authorizing Patient Releaset

† The activity values were computed based on 5 millisieverts (0.5 rem) total effective dose equivalent.
* Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

Details of the calculations used for this chart are provided in NRC Regulatory Guide 8.39 Revision 1 except for Xofigo, Pluvicto and Lutathera which are published in proprietary releases.

PROCEDURE FOR HANDLING SEALED RADIONUCLIDE BRACHYTHERAPY SOURCES

The purpose of this procedure is to:

- 1. prevent unauthorized use of sealed radionuclide sources (needles, ribbons, seeds, tubes, etc.),
- 2. minimize radiation exposure to radiation workers and non-radiation workers (i.e., visitors, ward personnel, GYN physicians),
- 3. prevent accidental loss of radionuclide sources, and
- 4. insure proper accountability of radionuclide sources at all times.

Radiation Oncologists / Radiotherapists shall be responsible for:

- 1. obtaining a permit to use sealed radionuclides (permit issued by Radiation Safety Committee),
- 2. prescribing patient dosage (i.e., kind and activity of sources, number of sources, position of sources, and treatment time) on the radionuclide therapy prescription form,
- 3. timely notification to radiation safety officer and radionuclide curator of kind and date of scheduled radionuclide therapy. (The Radiation Safety Department must also be given timely notification of any changes, including cancellation, in the scheduled therapy), and
- 4. providing timely and appropriate instructions to hospital staff pertaining to specific radionuclide procedures as required by the radiation safety officer.

The Radionuclide Curator* shall be responsible for:

- 1. placing a timely order for kind and activity of prescribed radionuclide,
- 2. inspection, identification, and loading of sources in accordance with written orders on the radionuclide therapy prescription form,
- 3. securing source safe and room, recording identity of sources withdrawn from safe in accountability logbook,
- 4. transporting sources in shielded container to room designated by permit holder,
- 5. assisting permit holder as required,
- 6. assuring the proper location of portable shield(s), the correct posting of radiation sign(s) on door, and label(s) on bed. The ORIGINAL of the radionuclide therapy prescription form shall be placed in the patient's clinical record and a CAUTION: RADIOACTIVE MATERIAL label shall be placed on the outside cover of the clinical record holder,
- 7. maintaining a file copy of prescription form in room containing source safe and returning a file copy to patient's radiation therapy record. Maintaining file copy of record of appropriate radiation survey(s) for each patient in source room,
- 8. removing sign(s) and label(s) from patient's room and chart and completing applicable part of prescription form after sources have been removed from patient,

^{*} For all procedures involving sealed radionuclides, the duties of Radionuclide Curator will be performed by the authorized medical physicists or therapists.

PROCEDURE FOR HANDLING SEALED RADIONUCLIDE BRACHYTHERAPY SOURCES *(continued)*

- 9. surveying patient and room(s) with survey meter to assure that all sources have been removed,
- 10. transporting and securing sources in the safe in the source room. Completing logbook, surveying source room. Assuring that all sources have been inventoried,
- 11. removing sources from shipping container, wipe testing and storing in an appropriate shielded container held in the source room ready for transport to a room designated by the radiation safety officer on the day preceding insertion in patient. Conducting appropriate assay of sources. Maintaining records of these tests and assays,
- 12. IMMEDIATELY NOTIFYING THE RADIATION SAFETY OFFICER if a source is lost or damaged, and
- 13. timely notifying the radiation safety officer if unavailable for a scheduled radionuclide therapy procedure.

The radiation safety officer shall be responsible for:

- 1. maintaining a radiation safety surveillance of each inpatient radionuclide therapy procedure and/or operation (i.e., assuring that patient's bed is in a safe position, radiation signs are appropriately posted, etc.),
- 2. providing timely radiation safety instructions to all hospital personnel charged with care of radionuclide therapy patients,*
- 3. designation of room(s) for insertion of sources in patient and for holding patient during treatment (after consultation with permit holder). Providing record of appropriate radiation safety survey,
- 4. ensuring that a calibrated working survey meter is available to the curator for surveying patient, safe and rooms,
- 5. being available for radiation safety assistance and emergencies,
- 6. leak testing of all sources in accordance with applicable regulations and maintaining records of such tests,
- 7. conducting timely inventories of all sources. Maintaining records of such inventories,
- 8. notifying the appropriate administrative and regulatory authorities in a timely manner in the event a source is lost, and
- 9. assuming responsibility for conducting a timely search for lost sources.

^{*} The radiation safety officer is responsible for the timely dissemination of ALL radiation safety instructions to hospital personnel. However, the RSO may require that the permit holder and/or the radiotherapy physicist prepare appropriate instructions pertaining to specific radionuclide procedures.

PROCEDURE FOR THE CARE OF PATIENTS BEING TREATED WITH THERAPEUTIC QUANTITIES OF AN UNSEALED RADIONUCLIDE

In addition to external exposures, the use of unsealed radionuclides creates contamination concerns. Normally, there are few contamination problems associated with materials that are injected into a body cavity. Seepage around the incision may likely be contaminated. Material given orally or intravenously will be excreted to some extent in the feces, urine, and in some instances, may be discharged through the skin and mouth. Caution should be exercised in handling these patients and their excreta.

- 1. Determine inpatient or outpatient status prior to dosing based on reliability of the patient to follow instructions.
- 2. Protective gloves, gowns, and shoe covers (if needed) shall be worn when changing dressings, bathing patients, changing bed linens and handling bedpans. Never wear these items out of patient's room.
- 3. Any material suspected of having radioactive contamination (i.e., bed linens, culinary materials, etc.) shall be saved for monitoring by Nuclear Medicine personnel.
- 4. Within 72 hours after a Na¹³¹I therapy treatment procedure (greater than 10 mCi), all involved personnel shall have a thyroid uptake performed. The radiation safety officer shall serially follow any positive thyroid uptake until iodine removal from thyroid is shown to be complete.
- 5. In the event of suspected contamination (i.e. spilled urine, vomit, etc.), the Nuclear Medicine Department and Radiation Safety Department must be notified immediately.

The purpose of this procedure is to:

- 1. prevent unauthorized use of unsealed radionuclide sources,
- 2. minimize radiation exposure to radiation workers and non-radiation workers,
- 3. prevent accidental loss of radionuclide sources, and
- 4. insure proper accountability of radionuclide sources at all times.

The Nuclear Medicine Physician shall be responsible for:

- 1. obtaining a permit to use therapeutic quantities of unsealed radionuclides (issued by the Radiation Safety Committee),
- 2. having a good understanding of the patient's medical problem,
- 3. awareness of previous clinical findings and interpreting the data obtained from the prescribed radionuclide dose,
- 4. deciding patient's reliability in their commitments to follow discharge instructions as a part of the patient's basis for release,
- 5. being within an hour's presence of the administration of the therapeutic radionuclides by injection/ingestion,
- 6. notifying the Radiation Safety Department of the type and date of scheduled radionuclide therapy (the Radiation Safety Department must also be given timely notification of any changes, including cancellation, in the scheduled therapy),
- 7. providing appropriate instructions to hospital staff pertaining to specific radionuclide procedures,
- 8. determining treatment time and when inpatients might be released from hospital (i.e., when I-131 exposure is less than 5 mR per hour at 1 meter *or* when other acute condition warrants discharge), and
- 9. ascertaining what other tests (i.e., blood, urine, routine x-ray) could be influenced or contaminated by radioactive materials and should be completed before injection or ingestion.

PROCEDURE FOR THE CARE OF PATIENTS BEING TREATED WITH THERAPEUTIC QUANTITIES OF UNSEALED RADIONUCLIDE (Continued)

The Nuclear Medicine Technologist shall be responsible for:

- 1. placing a timely order with the vendor for the kind and activity of prescribed radionuclide,
- 2. inspection and identification of radionuclide(s) in accordance with written orders on the radionuclide therapy prescription,
- 3. removing the radionuclide(s) from its shipping container, wipe testing and storing it in an appropriate shielded container ready for transport to a room designated by the radiation safety officer,
- 4. conducting the appropriate assay of sources,
- 5. maintaining records of these tests and assays,
- 6. preparing the room to prevent contamination by covering any item that may be contaminated when coming into contact with patient's emissions and excretions (body fluids),
- assuring the correct posting of radiation sign(s) on door, and label(s) on bed. (a <u>CAUTION:</u> <u>RADIOACTIVE MATERIALS</u> label shall be placed on the outside cover of the patient's hospital chart.),
- 8. transporting radionuclide in shielded container to room designated by permit holder,
- 9. assisting permit holder as required,
- 10. removing sign(s) and label(s) from patient's room and chart and completing applicable part of prescription form after patient has been dismissed by the Nuclear Medicine Physician,
- 11. surveying patient (to determine when they can be released), material, equipment and the room(s) to assure that all sources have been accounted for and that room is free from contamination, and
- 12. IMMEDIATELY NOTIFYING the radiation safety officer if radioactive material is lost or damaged or if room is found to be contaminated (> 1000 cpm).

The radiation safety officer shall be responsible for:

- 1. maintaining a radiation safety surveillance of each radionuclide therapy procedure and /or operation (i.e., assuring that patient's bed is in a safe position, radiation signs are appropriately posted, etc.),
- 2. the timely dissemination of ALL radiation safety instructions to hospital personnel (However, the RSO may require that the permit holder and/or the medical physicist(s) prepare appropriate instructions pertaining to specific radionuclide procedures.),
- 3. designating room(s) for injection/ingestion of sources into patient and for holding patients during treatment (after consultation with permit holder),
- 4. providing and maintaining record of appropriate radiation safety survey(s),
- 5. ensuring that a calibrated survey meter is available for the survey of patients and their rooms,
- 6. being available for radiation safety assistance and emergencies,
- 7. conducting timely inventories of all sources and maintaining records of such inventories,
- 8. notifying the appropriate administrative and regulatory authorities in a timely manner in the event of a lost source,
- 9. assuming responsibility for conducting a timely search for lost sources,
- 10. appropriate and timely disposal of source and maintaining appropriate records of receipt and disposal of such sources, and
- 11. supervising all clean-up if contamination (greater than 1000 cpm) is found in the room.

PROCEDURES FOR NUCLEAR MEDICINE

- 1. Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy this requirement, the check must be done on a frequently used clinical setting with a sealed source of not less than 3700 kilobecquerels (100 microcuries) for any photon-emitting radionuclide with a half-life greater than 90 days.
- 2. An Authorized User permit holder must **select the patients** to undergo any nuclear medicine procedure, **prescribe the radiopharmaceutical** dosage and/or dose to be administered through the issuance of a written directive or reference to the diagnostic clinical procedures manual; and **interpret the results** of tests, studies, or treatments.
- 3. Dose calibrator shall be checked for linearity at three-month intervals and should be compared to a known standard at intervals not to exceed one year.
- 4. Physical inventories shall be conducted and recorded at intervals not to exceed 6 months.
- 5. Flood fields shall be recorded for all nuclear medicine cameras each morning or prior to the first patient of the day.
- 6. Resolution and linearity of nuclear medicine cameras should be checked with a Bar or Dot Phantom as recommended by the camera manufacturer.
- 7. Radioactive elution from the technetium generator shall be assayed by a dose calibrator or by other appropriate methods as recommended by the manufacturer.
- 8. Contaminated used syringes, vials, kits, etc., shall be stored behind adequate shielding until normal room background is reached. After these materials reach background level, they shall be disposed of as normal waste.
- 9. Records of receipt, use, transfer, and disposal of radionuclides shall be maintained. Radioactive Material, Radiation Area and Notice to Employees signs shall be posted. Copies of Permits shall be available in the Nuclear Medicine Lab.
- 10. Gaseous radionuclides shall be ventilated outside. Calculate and post the amount of time needed, after a gaseous release, to reduce the concentration in the area of use to the occupational limit (semiannually).
- 11. Extremity dosimeters (rings) and protective gloves are required while preparing radionuclides.
- 12. When working with radionuclides, maximum utilization of shielding, distance, and time of exposure shall be employed.
- 13. No food or drink shall be stored in refrigerators with radionuclides.
- 14. Hands, shoes, and clothing shall be monitored daily for all personnel who go into radionuclide areas.
- 15. A wipe test for contamination (200 cpm over background) shall be performed daily in scanning areas and hot labs. Corrective actions shall be initiated if contamination is found. Results shall be recorded daily.
- 16. The hot lab shall have a drawing showing where the daily area surveys are performed. Survey meter calibration shall be current and have a dedicated check source to verify working condition.
- 17. All incoming radionuclide shipments shall be surveyed and wipe tested and results recorded.
- 18. In case of a radionuclide spill, the supervising technologist and/or the radiation safety officer shall be notified immediately.
- 19. Wash hands between each patient and immediately after handling radionuclides.
- 20. Never pipette a radionuclide by mouth.
- 21. DO NOT smoke, eat, drink, or apply cosmetics in the radionuclide preparation area.

PROCUDURE FOR NUCLEAR MEDICINE (Continued)

- 22. Check every photonic radiopharmaceutical dose in a dose calibrator, and administer to the patient within no more than 30 minutes or 10% of the half-life (such as ¹²⁵I). We do not measure weak beta emitters (such as ⁸⁹Sr) in the dose calibrator. Measure the ¹²⁵I and take it to the patient administration area for the authorized user to administer. If preparation and set-up exceeds 30 minutes, do not return to the dose calibrator. It has a 60-day half-life and the activity will not have changed appreciatively. The same is true for ²²³Ra (Xofigo), which has a half-life of 11.5 days. You may perform non-direct calculations to determine patient administrations when necessary. Consult with the RSO or a medical physicist.
- 23. Quality control procedures for radionuclides not prepared in the hospital laboratory shall be as indicated by the manufacturer and as required or deemed necessary by the University of South Alabama Radiation Safety Committee.
- 24. DO NOT stay in hot lab any longer than is necessary.
- 25. Only authorized personnel are allowed in radionuclide preparation areas and these areas shall be locked when unattended. If you see an unknown individual in your preparation area (hot lab), politely challenge their reason for being there.
- 26. Be certain the requisition is for the exam indicated by the patient diagnosis, e.g., liver scan request to rule out pulmonary embolism is incorrect.
- 27. Use syringe shield in preparation of radionuclide for injecting.
- 28. Weekly survey and wipes shall be performed in the nuclear medicine storage area to verify that the dose rate does not exceed 5 mR/hr. Record of results shall be maintained.
- 29. Nuclear Medicine Lab counter tops shall be made of stainless steel or covered with plastic backed absorbent paper.
- 30. Dose calibrators shall be checked yearly for accuracy with a NIST traceable ¹³⁷Cs source and another NIST traceable gamma emitting source between 100-500 keV of known activity not less than 3700 kilobecquerels (100 microcuries).
- 31. The dose calibrator geometry shall be checked upon installation and every time it is moved (far enough to require being unplugged) or repaired. Dose calibrator accuracy reports shall be retained for three years. Dose calibrator geometry reports shall be retained indefinitely or until another one is performed. In other words, the last geometry dependence check will always be on file no matter how old it is.

PROCEDURE AFTER THE DEATH OF PATIENT CONTAINING RADIONUCLIDES

The radiation safety officer shall be notified in the event a patient (who has received therapeutic quantities of radionuclides) expires, prior to removal from the room. If an autopsy is to be performed on a body that contains radionuclides greater than 30 millicuries, the radiation safety officer shall be present. The "Report of Radioactivity in a Corpse" form shall accompany a body that is to be released from the hospital.

CRITERIA FOR EVALUATING PHYSICIANS APPLYING FOR USE OF RADIONUCLIDES

A physician Authorized User of radionuclides for diagnostic or therapeutic human use must apply through the University of South Alabama Radiation Safety Committee for a permit **prior to use**. The committee will review evidence that required training has been achieved. Required training or criteria for acceptance will be assessed according to the criteria put forth by the Alabama Department of Public Health's <u>Alabama Regulations for Control of Radiation</u>. (http://www.adph.org/radiation/assets/RulesPart07renumbered.pdf)