



OFFICE OF THE
PRESIDENT
(301) 295-3013

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
4301 JONES BRIDGE ROAD
BETHESDA, MARYLAND 20814-4712
<http://www.usuhs.mil>



26 August 2015

Mr. Dennis Lawyer
Licensing Assistance Team
U.S. Nuclear Regulatory Commission Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, Pennsylvania 19406-2713

RE: Docket No. 03020775
Control No. 588409

Dear Mr. Lawyer:

The following information is provided for inclusion into the application for renewal of License No. 19-23344-01 submitted by the Uniformed Services University of the Health Sciences (USUHS) on 20 July 2015 in response to your letter of 11 August 2015.

A. Paragraph 1. -- RE: Uniformed Services University of the Health Sciences zip code.
Response: Enclosure 1 is the revised NRC Form 313 for USUHS. The current USUHS zip code is 20814-4712.

B. Paragraph 2. -- RE: Documentation of Radiation Safety Program change.
Response: Enclosure 2 is the revised Item 7 "Individual(s) Responsible for Radiation Safety Program and Their Training Experience".

C. Paragraph 3. -- RE: Safety evaluations consideration of facilities and equipment.
Response: Enclosure 2 is the revised Item 7 "Individual(s) Responsible for Radiation Safety Program and Their Training Experience".

D. Paragraph 4. -- RE: Emergency procedures for fire, explosions, or major emergencies.
Response: Enclosure 3 is the revised Item 10 "Radiation Safety Program".

E. Paragraph 5. -- RE: Decommissioning Funding Plan 2015.
Response: Enclosures 4, 5 and 6 comprise the submitted Decommissioning Funding Plan for USUHS dated 19 August 2015. The submitted Plan supersedes our Plan dated September 12, 2013 and serves to update the estimated costs and tasks required for the decommissioning of the University facilities. Upon review no changes from the 2013 DFP were deemed necessary. The submitted plan would be implemented in the event that the USUHS must terminate NRC licensed activities at some point in the future.

REC RG 1 09 02 15 AM 11:14

If you require further information please contact the Radiation Safety Officer, Major Kimberly D. Alston, MS, USA at (301) 295-3390.

A handwritten signature in black ink that reads "Charles L. Rice". The signature is written in a cursive style with a horizontal line at the end.

Charles L. Rice, MD
President

Enclosures:

- (1) NRC Form 313 dated 24 August 2015
- (2) Item 7 "Individuals(s) Responsible for Radiation Safety Program and Their Training Experience" revised 18 August 2015
- (3) Item 10 "Radiation Safety Program" revised 18 August 2015
- (4) Decommission Funding Plan dated 19 August 2015
- (5) Statement of Intent dated 19 August 2015
- (6) Certification of Assurance dated 19 August 2015



**APPLICATION FOR MATERIALS
LICENSE**

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to Infocollections.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

OFFICE OF FEDERAL & STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS
DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,

SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

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

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- A. NEW LICENSE
- B. AMENDMENT TO LICENSE NUMBER
- C. RENEWAL OF LICENSE NUMBER 19-23344-01

2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)

Uniformed Services University of the Health Sciences
4301 Jones Bridge Road
Bethesda, MD 20814-4712

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4301 Jones Bridge Road, Bethesda, Maryland
1530 East Jefferson Street, Rockville, Maryland

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Major Kimberly D. Alston, USA

BUSINESS TELEPHONE NUMBER (301) 295-3390	BUSINESS CELLULAR TELEPHONE NUMBER (443) 876-5778
---------------------------------------------	------------------------------------------------------

BUSINESS EMAIL ADDRESS
kimberly.alston@usuhs.edu

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (Fees required only for new applications, with few exceptions*) (See 10 CFR 170 and Section 170.31)

FEE CATEGORY AMOUNT ENCLOSED \$

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.
WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE

Charles L. Rice, MD, President USUHS

SIGNATURE

DATE

8.24.15

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

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Item 7: Individual(s) Responsible for Radiation Safety Program and Their Training Experience.

7.1 Senior Management

An organizational chart of the University is attached (enclosure 7-1). Senior management of the Uniformed Services University of The Health Sciences consists of the University President and Vice-Presidents and the Dean, School of Medicine. The Radiation Safety Office staff is under the Center for Environmental Health and Occupational Safety (EHS). EHS has direct access to the University President, USUHS through the Vice President, Finance and Administration. Management review of the Radiation Safety Program is integrated into the membership of the Radiation Safety Committee. The Chief of Staff to the University President (PRS) and the Director, Center for Environmental Health and Occupational Safety (EHS) are both permanent voting members of the committee.

7.2 Radiation Safety Committee

The RSC consists of a Chairperson (Michael J. Daly, Ph.D.), the Radiation Safety Officer, two representatives of management --the Chief of Staff to the University President (PRS) and the Director, Center for Environmental Health and Occupational Safety (EHS) -- and six (6) representatives from clinical and basic science departments. These individuals will be authorized users of radioactive material at USUHS. The RSC Chairman's credentials are attached (enclosure 7-2).

7.2.1 The RSC meets as often as necessary and at least once each calendar quarter. Business will be conducted only when a quorum, consisting of the Chairperson, RSO, a representative of management, and three of the Departmental representatives are present. The Chairperson may be counted as one of the three Departmental representatives to achieve a quorum. The RSC uses USUHS Form 6041, Application for Radionuclide Experimental Authorization and the USUHS Radiation Safety Guide in the review and approval of new users and uses of radioactive material. The duties and responsibilities of the RSC are contained in USUHS Radiation Safety Guide, Section I, paragraph B.

7.2.2 Radiation Safety Committee, Duties and Responsibilities

The RSC duties and responsibilities are governed by Section I, paragraph B of the USUHS Radiation Safety Guide. These duties and responsibilities of the RSC may be modified without notifying the NRC in order to comply with changes dictated by NRC rule changes. This committee is a group of professionals appointed by the University President to establish policy for the use of radioactive material, and to oversee all aspects of radiation safety at USUHS. The committee meets at least once each calendar quarter to review the University's radiation safety program. The duties of the RSC include:

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a. Reviewing recommendations on ways to maintain individual and collective doses ALARA.

b. Reviewing, and approving or disapproving, on the basis of safety and with regard to their training and experience, requests by investigators for permission to use radioactive material.

c. Reviewing the training and experience of the Radiation Safety Officer (RSO) and approving or disapproving appointment.

d. Reviewing on the basis of safety, and approving or disapproving with the advice of the RSO, any request for amendment or renewal of the NRC Byproduct Materials License.

- e. Reviewing on the basis of safety, and approving with the advice of the RSO, the use of any research laboratory located at USUHS for use of radioactive materials. Laboratories no longer using radioactive materials may be released by the RSO for general use after a complete closeout survey has been performed on the laboratory. The review on the basis of safety will include examination and/or inspection of:
 - The training and work experience of the users.
 - The facilities and equipment of the laboratory.
 - The operating and handling procedures.

f. Reviewing on the basis of safety, and approving with the advice of the RSO, changes in procedures and policies in the Radiation Safety Program at USUHS. The review on the basis of safety will include:

- The reason for the proposed change of procedure or policy.
- Determination the change is IAW current regulatory requirements.
- Determination the change will not decrease the effectiveness of the Radiation Safety Program.
- The requirement that the staff is trained in the revised procedures prior to implementation.
- The requirement for the audit program to evaluate the effectiveness of the change.
- Documentation of the proposal, discussion and approval of the change in the Radiation Safety Committee meeting minutes and supporting information.

g. Reviewing quarterly, with the assistance of the RSO, a summary of the occupational radiation dose records of all personnel working with byproduct material.

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h. Reviewing quarterly, with the assistance of the RSO, all incidents involving byproduct material with respect to the cause and subsequent actions taken.

i. Reviewing annually, with the assistance of the RSO, the radiation safety program at USUHS.

j. Reviewing for final action/disposition any program or procedure involving the use of radioactive material or a radiation producing device which has been suspended by the RSO.

7.2.3 Increase Flexibility for the RSC to Make Changes to the Radiation Safety Program or Procedures.

The USUHS requests to be granted the flexibility to make program changes and to revise procedures previously approved by the NRC without amendment of the license. Before implementing any program change or revised procedure, the Radiation Safety Committee (RSC) will ensure, as applicable, the following items are addressed:

a. Document and conduct a review and approval of permitted program and procedural changes.

b. Changes to the program or procedure will satisfy regulatory requirements, and that it does not change existing license conditions nor decrease the effectiveness of the radiation safety program.

c. Train radiation workers and staff in the revised procedures prior to implementation.

d. The Radiation Safety Audit Program evaluates the effectiveness of the changes and its implementation.

e. Documentation of approved changes will include at a minimum, the reason for the change and a summary of the radiation safety matters that were considered prior to approval of the change.

7.3 Radiation Safety Officer (RSO)

7.3.1 The RSO (Major Kimberly D. Alston, MS, USA) is the Executive Manager of the USUHS radiation safety program, exercising staff supervision over the Radiation Safety Division, EHS, providing consultation and advice to Faculty, Staff, the RSC, and the Administration on the hazards associated with ionizing radiation, and formulating the Radiation Safety Program. The Radiation Safety Officer's credentials are attached (enclosure 7-3). A copy of the Radiation Safety Officer Delegation of Authority signed by the University President is attached (enclosure 7-4).

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7.3.2 The duties and responsibilities of the RSO are contained in the USUHS Radiation Safety Guide, Section I, paragraph C. The RSO is responsible for implementing the radiation safety program in accordance with DoD and NRC directives and regulations and policies formulated by the members of the USUHS RSC. The RSO is assisted by the professional and technical staff of the Center for Environmental Health and Occupational Safety (EHS). In addition to the responsibilities in 10 CFR 35.21, the RSO:

- a. Exercises staff supervision over the Radiation Safety Program.
- b. Provides consultation and advice on the degree of hazards associated with radiation and the effectiveness of control measures.
- c. Advises and assists all radiation workers in all matters pertaining to radiation safety, including instructing and training of workers and others in the safe use of radioactive materials and radiation sources.
- d. Ensures that all radioactive materials are properly received, used, stored, handled, shipped, and disposed of according to applicable directives.
- e. Formulates and implements the Radiation Safety Program.
- f. Formulates, implements, and supervises an active and documented program designed to keep radiation doses and releases to the environment at ALARA.
- g. Provides the RSC with summary information, each calendar quarter, on personnel radiation doses, ALARA investigations, and routine reports on the use, storage, and disposal of radioactive material.
- h. Assists the RSC in formulating policy for the Radiation Safety Program at the USUHS.
- i. Reviews all applications for use of Radioactive Materials to ensure completeness, and recommends approval or disapproval to the RSC.
- j. Provides an annual review of the Radiation Safety Program to the RSC.
- k. Reviews and approves procurement of all radioactive materials to ensure compliance with NRC License conditions.
- l. Evaluates hazards and adequacy of protective measures for existing and proposed operations.
- m. Investigates radiation accidents, incidents and overexposures to determine the cause and takes steps to prevent recurrence.

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n. Suspends a program or procedure involving the use of radioactive material or radiation producing devices which are determined to deviate from prescribed procedures and directives.

o. Maintains the NRC Byproduct Material Licenses, supporting documentation, and appropriate requests for amendments and renewals.

7.4 Radiation Safety Office Staff

7.4.1 The Radiation Safety Office is composed of civilian and military members. Current positions include an Assistant Radiation Safety Officer (civilian), a Radiation Protection Specialist (civilian), and four enlisted military health physics technicians. These staffing levels will be modified as appropriate. Their primary duties include:

a. Surveys of all areas where radioactive material or radiation producing equipment are used;

b. Collection of radioactive waste from user laboratories;

c. Preparation of iodination use areas; and,

d. Conduct training for new employees of USUHS in the safe use of radioactive material and current procedures for the procurement of RAM at USUHS.

7.4.2 This staffing level is adequate to support the Radiation Safety Program.

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Item 10: Radiation Safety Program.

USUHS currently possesses two USNRC licenses. License # 19-23344-01 is a Type A Specific License of Broad Scope and License # 19-23344-02 is for a ^{60}Co and two ^{137}Cs irradiators. This renewal applies only to #19-23344-01.

10.1 Radiation Safety Audit Program.

10.1.1 Audits of the overall radiation safety program are conducted annually and are performed by Radiation Safety Committee members, University Health physics personnel or by qualified health physics personnel assigned to another military, government or civilian facility in the National Capitol Region. The Chairman, RSC, also requests, from time-to-time, that a member or members of the RSC perform a focused audit of a specific area of the Radiation Safety program and report their findings to the Committee. The individual performing the audit will prepare appropriate checklists or use checklists prepared by the RSO. The checklists should be used to guide, but not to limit, the scope of the auditor's activities.

10.1.2 The RSC has established a schedule to ensure all required internal radiation safety program audits are performed. This schedule will include, at a minimum:

- a. A quarterly review by the Radiation Safety Committee, with the assistance of the RSO, of occupational radiation exposure records of all individuals who work with radioactive material;
- b. A quarterly review by the Radiation Safety Committee, with the assistance of the RSO, of all incidents involving radioactive material, including incident causes and corrective actions;
- c. A quarterly review of all radiation safety practices involving inventory, receipt, disposal, and release of radioactive materials to the environment.
- d. An annual review of the ALARA Program by the Radiation Safety Committee to ensure that individuals make every effort to maintain occupational doses, doses to members of the public and radioactive releases As Low As Reasonably Achievable (ALARA).
- e. An annual review by the Radiation Safety Committee of the radioactive material program and the radiation protection program (referred to collectively as the radiation safety program).

10.1.3 Scope of the Audits

- a. The quarterly audit of occupational radiation exposure records will

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include:

- A review of all exposure records, with special attention to any records that indicate ALARA investigational levels have been approached or exceeded;
- A review of any corrective actions taken in response to individuals exceeding prescribed action levels;
- Analysis of collective occupational doses for each quarter;
- Development of a summary report, including trends and corrective actions for approval by the RSC.

b. The quarterly review of all incidents involving radioactive material, should include, at a minimum:

- A review of all incidents reported;
- A verification that each report addresses the regulatory requirements for those reports;
- Incident causes and corrective actions;
- Analysis of reported incidents over a representative period of time to identify possible positive or adverse trends;
- Development of a summary report, including trends and corrective actions for approval by the RSC.

c. The annual review of the ALARA Program will include, at a minimum:

- A review of summaries of the types and amounts of radioactive materials used;
- A review of occupational dose reports;
- A review of the education and training for all occupationally exposed individuals;
- Analysis of the information listed above, to detect possible positive or adverse trends; and
- Development of a summary report, including trends and corrective actions for approval by the RSC.
- A review of releases to the environment and public exposures from environmental monitoring.

d. The annual review of the radiation safety program will include, at a minimum, a review of each functional element of the radiation safety program to determine the extent of compliance with applicable regulatory and license requirements, USUHS policies, programs and procedures, and other commitments (e.g., responses to previously issued Notices of Violation), and current industry standards. The RSO may identify the functional elements of the radiation safety program as necessary to facilitate conduct of the audit. In general, the functional elements of the radiation safety program includes:

- Radiation safety program organization and administration;
- ALARA program;

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- Fetal protection;
- Radiation safety training;
- Radioactive material procurement, receipt, and use;
- Radioactive material control/access control;
- Area monitoring and instrument calibration;
- Contamination control;
- Individual monitoring program;
- Sealed radioactive source accountability and leak testing;
- Radioactive effluent release monitoring;
- Posting and labeling program;
- Radiation safety recordkeeping and reporting; and
- Radioactive material transportation;
- Radioactive waste disposal program.
- Facility and radioactive materials security and security practices.

10.1.4 User Laboratory Audits. Audits of User laboratories are conducted by University health physics personnel on a frequency determined by the assigned Laboratory Type (A, B, or C). The scope of the user laboratory audit is discussed in section X of the USUHS radiation safety guide. These inspections also include:

- a. Review of user inventory and survey records;
- b. Evaluation of user and technician training through discussion and observation of work practices;
- c. Performance of independent surveys of user work areas;
- d. Evaluation of compliance with NRC regulations, the conditions of the license, the REA and Radiation Safety Guide requirements.

10.1.5 Records and Reports.

a. Radiation safety records will be created and maintained consistent with the requirements of 10 CFR 20.2102. Records of radiation safety audits will include:

- The name and signature of the individual(s) performing the audits;
- Date(s) on which the audit was conducted;
- Completed audit procedures or checklists, as appropriate;
- Audit findings, including any strengths or weaknesses.

b. Reports. There are no specific reports associated with the Radiation Safety Audit Program. However, a radiation safety program audit could reveal a reportable event requiring a written report and or notification to the NRC.

10.2 Radiation Monitoring Instruments.

10.2.1 The RSC reviews all applications for Radionuclide Experimental Authorizations. The RSC, with the assistance of the RSO, will make a determination,

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approve, and prescribe the appropriate type(s) of radiation monitoring instruments to be used by authorized users in their facility or lab. Criteria used for approval of radiation monitoring instruments include:

- a. Ability to detect the type of radiation being measured;
- b. Proper calibration for the type of radiation the instrument is designed to measure;
- c. Sufficient sensitivity to measure the desired level of radiation.

10.2.2 The criteria and procedures used to conduct individual monitoring for occupational radiation exposure are described in section III of the USUHS radiation safety guide. Both whole body and extremity personnel monitoring dosimeters are provided by the Naval Dosimetry Center, Bethesda, Maryland. Persons working with gamma-emitting or high energy beta radioactive material or ionizing radiation producing equipment are required to wear, as appropriate, either whole or extremity monitoring devices. In addition, extremity monitoring is required for all persons working with more than one mCi of activity, except for those working with ^3H and ^{14}C .

10.2.3 Radiation monitoring instruments will be calibrated by a vendor licensed by the NRC or an Agreement State to perform instrument calibrations. Instruments are calibrated for the radiation(s) measured at least every twelve months, unless otherwise specified by regulation or license condition. The most recent calibration date will be indicated on each instrument so that the user can verify the calibration prior to use. EHS will collect instruments due for calibration and ensure the instruments are calibrated, repaired, or removed from service, as appropriate.

10.3 Material Receipt and Accountability.

10.3.1 Control of Procurement and Use of radioactive material is contained in section V of the USUHS radiation safety guide.

a. Authorized users place orders for radioactive materials using an electronic ordering system (EOS). The EOS's currently used at USUHS include the Defense Agencies Initiative (DAI) or the Henry Jackson Foundation Oracle iProcurement (USUHS) system. All purchase orders for radioactive materials are reviewed and approved by EHS before a purchase order is issued. This review includes verification that the principal investigator has been authorized to order the radionuclide in the quantities and chemical forms requested.

b. Each source of radioactive material approved for purchase is assigned a source control number by EHS. This number is used for radioisotope accountability and tracking purposes within the University.

10.3.2 Review and approval or disapproval of proposed uses and users of radioactive material is contained in section IV of the USUHS radiation safety guide.

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a. The RSC reviews and approves/disapproves all applications for the use of radioactive material within the University. The review encompasses safety evaluations conducted by both the RSO and the RSC of proposed uses and authorized users. This includes evaluation of handling procedures being proposed, the fate of all radioactive material used in the experiments, waste minimization efforts within the laboratory, potential releases of radioactive material to the environment, and potential personnel exposures. The RSO conducts an initial review of supporting documentation submitted by authorized users (Principal Investigators) or applicants for new authorizations. The review is based on material submitted in accordance with section IV of the USUHS radiation safety guide and includes the type of radioactive material; the activity limits; the physical processes or procedures including the application of heat, vacuum, etc; and, the training and experience of the users. The RSC will review for approval the same material with comments provided by the RSO.

b. Applications for authorizations are made by submitting USUHS Form 6041, Application for Radionuclide Experimental Authorization (REA), to the Radiation Safety Officer at the Center for Environmental Health and Occupational Safety (EHS). Information required for the REA application includes:

- Names of all personnel who will handle the radioactive material and their formal training and experience;
- Source description including: where the isotopes will be used and stored; the types and amounts (activity) of isotopes which will be ordered at any one time, the maximum amount stored in the laboratory at any one time, and the maximum amount used in any single experimental procedure;
- Security measures for storage of radioisotopes and radioactive waste;
- The total anticipated volume of radioactive waste that will be generated. Procedures for handling and minimizing the amount of radioactive waste by laboratory personnel should also be described;
- Description of experimental procedures in which the radioactive material will be used. This description should include details on the use of shielding, chemical fume hoods, counting equipment and steps taken to limit personnel radiation exposure.

Authorizations granted to principal investigators are specific with respect to these five items. Any changes to the granted authorization due to procedural or personnel changes must be submitted for approval as an authorization amendment.

c. Authorizations expire one year from the date of approval and must be renewed at that time if work with radionuclides is to continue. An authorization or amendment request may be recommended for interim approval by the RSO, and

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granted interim approval by the Chairman, RSC. All requests for REA renewals must be approved or disapproved by the RSC at its next regularly scheduled meeting.

10.3.3 Licensed material inventory and accountability information is contained in section VI of the USUHS radiation safety guide.

10.3.4 EHS personnel will inspect and take possession of a radioactive package from the Receiving Section and transport it to the EHS radioanalytical lab for a receipt survey. This survey includes an evaluation of removable surface contamination and external radiation levels, as required by 10 CFR Part 20.1906. Following the receipt survey, the source is then transported by authorized personnel to the appropriate authorized user's lab.

10.3.5 Radioactive sources may only be delivered to individuals who are listed as radionuclide users on the authorized user's REA. The authorized person who accepts the source will sign USUHS Form 6033, which is then filed by EHS. They are given a copy of USUHS Form 6034, "Radionuclide Source Utilization Log," or USUHS Form 6045, "Iodine Utilization Log," when the nuclide is I-125. The PI is responsible for maintaining USUHS Form 6034, the Source Utilization Log. Source logs issued to authorized users are stored in a folder or binder and located in the user's laboratory in a location accessible to EHS personnel. Logs are updated each time radionuclides are used or disposed of as waste. Activity of radionuclides on hand may be corrected for decay at the discretion of the user. Logs for depleted sources are returned to EHS after all radioactive material is used or is no longer needed.

10.3.6 The principal investigator is responsible for assuring that all sources are physically present in the laboratory. A printout of all isotopes maintained in a laboratory is sent to the principal investigator on a quarterly basis. Any discrepancies are reported to the RSO, who will investigate and resolve the discrepancy.

10.4 Occupational Dose.

10.4.1 Pursuant to 10 CFR 20.1502(a), external dose monitoring will be conducted in accordance with the provisions of Sections III, VII and X of the USUHS Radiation Safety Guide.

10.4.2 Pursuant to 10 CFR 20.1502(b), Internal monitoring (bioassay) will be conducted in accordance with the provisions of section XIII of the USUHS Radiation Safety Guide for thyroid bioassay and section III for tritium bioassay. Methods for evaluation of bioassay data are those addressed in NRC Regulatory Guide 8.34, Monitoring Criteria and Methods to Calculate Occupational Radiation Doses.

10.4.3 For radioiodine (iodinations) the following additional air sampling procedures will be performed:

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a. Three air-sampling tubes filled with activated charcoal are used for air sampling during the iodination procedure. Zones that are continuously sampled during this procedure include:

- Researcher breathing zone (no greater than 8 inches from the nose and mouth);
- Room air (room exhaust) at the vent nearest the fume hood;
- Air exhausted from the inner isotope handling/isolation box into the fume hood.

b. Immediately after the iodination procedure, EHS personnel will conduct monitoring of the laboratory area and chemical fume hood to check for contamination. Areas found to have greater than 200 pCi/100 cm² (450 dpm/100 cm²) of removable contamination will be decontaminated.

c. Researchers who perform iodination procedures must be evaluated for the presence of radioiodine in his/her thyroid. The pre-study baseline evaluation must be performed within the 48-hour period preceding the iodination procedure. A post-iodination evaluation will be performed from 24 to 72 hours following the iodination procedure. All thyroid screenings will be performed with the appropriate radiation detector. EHS will maintain copies of the thyroid evaluations. If the measured activity is greater than 0.05 µCi, a follow-up evaluation will be scheduled and obtained one to two weeks later. Additionally, the experimental protocol will be reviewed for possible improvement in handling procedures and radioactive material containment. If thyroid activity is greater than 0.10 µCi, the researcher will not perform further iodinations until containment methods are improved and/or experimental procedures are modified and training is conducted with the researcher for any changes of modifications made.

10.4.4 For tritium bioassay the following procedures apply:

a. USUHS standards for tritium bioassay (section III, USUHS radiation safety guide) state that individuals using more than 10 mCi ³H on a laboratory bench top, or more than 100 mCi ³H per month in a chemical fume will be required to submit a urine sample to EHS for analysis once each calendar quarter.

b. Those Individuals handling ³H in the same quantities as above, in a single procedure, will submit a urine sample within 48 hours prior to the start of the procedure, and another sample within 72 hours immediately following the procedure.

10.5 Public Dose.

10.5.1 Radiation exposure to the general public is monitored with environmental monitors. These data are reviewed by the RSC at each quarterly meeting.

10.6 Safe Use of Radionuclides and Emergency Procedures.

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10.6.1 Routine operating and handling procedures are contained in the USUHS Radiation Safety Guide under section VII.

a. All persons using radioactive materials at USUHS are required to be familiar with the following rules and procedures as well as specific procedures and safety precautions specified in the radionuclide experimental authorization. PIs are responsible for seeing that all personnel handling radioactive materials within their jurisdiction follow NRC rules and regulations, the USUHS License, and conditions of their authorization. EHS personnel are available for guidance, training, and review of procedures being used in the laboratory upon request of the Principal Investigator.

b. General Rules for all Radioactive Materials Usage

- The area within the laboratory where the experiment is to be performed is covered with absorbent material surrounded with yellow tape or tape with the standard radiation caution symbol. When appropriate, work is conducted in a tray lined with absorbent paper and in a chemical or radionuclide fume hood;
- Disposable gloves and lab coats or other protective garments are worn at all times when handling radioactive materials. Protective garments are not taken from the lab to University common grounds or to areas outside the University;
- All radioactive wastes are placed in properly labeled containers which have been approved by EHS;
- Laboratories are locked or the radioactive materials secured when authorized personnel are not present;
- Solutions are never pipetted by mouth;
- The smallest quantity of radioactivity compatible with the objective of the experiment is used;
- After using radioactive materials, users must wash hands and monitor hands, clothing, and soles of shoes before leaving a posted laboratory;
- Users are required to work carefully and regularly monitor the work area to avoid accidental contamination;
- Containers of radioactive material are marked clearly, indicating nuclide, total activity, and date;
- Application of cosmetics, eating, drinking, smoking, or chewing in a posted laboratory are prohibited in radiation posted labs;
- Storage of food, drink or personal effects with radioactive material is not allowed;
- Users know how to react in case of a spill or personal contamination;
- Personnel must wear assigned dosimetry devices when working with radioactive material.

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10.6.2 Security of Radioactive Materials.

a. Control of access to laboratories is covered in sections XII, XIII, and XIV of the USUHS radiation safety guide. Internal procedures used by EHS personnel are documented by SOP and are not forwarded with this renewal application.

b. All laboratories at the USUHS in which radioactive materials are used are posted with the yellow and magenta radiation-warning symbol. Wording on the symbol will depend on the following conditions:

- "Caution Radioactive Materials": Laboratories approved for radionuclide use but not containing significant radiation fields;
- "Caution Radiation Area": Laboratories in which there are areas with dose rates greater than 2 mrem/hr.

c. All laboratories are locked or the radioactive materials are secured in a locked container, refrigerator or freezer when authorized personnel are absent. Minors (persons under 18 years of age) are not allowed to enter or work in laboratories containing radioactive material without permission of the RSO or his/her designated representative. The PI is responsible for notifying the RSO when minors desire to work in a posted laboratory. Other visitors (non-minor) must receive permission from the responsible PI before entering posted areas.

d. Individuals not granted permission by the RSO or his/her designated representative are prohibited from entering into a Type B or Type A laboratory or a laboratory posted with a "Caution Radiation Area" sign.

e. Containers of radioactive material will be secured against unauthorized removal from the laboratory at all times. When sources of radioactive material are in a room they will be:

- Be under constant surveillance by an authorized radionuclide user of the laboratory staff when outside a locked container, or;
- Be secured in a locked container such as a refrigerator, freezer, drawer, or;
- Be secured by locking the entrance door to the lab.

10.6.3 Emergency procedures are contained in section XI of the USUHS radiation safety guide.

a. Emergency Planning

- It is the responsibility of the Principal Investigator (PI) to anticipate situations that may arise in the routine use of radionuclides leading to spills or exposure to radiation. Careful planning of experimental procedures is conducted to reduce the probability of spills or

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exposure. The proposed procedures are reviewed by the RSO and RSC and monitored by the Radiation Safety staff;

- The PI ensures that all personnel using radioactive materials under his/her supervision know how to manage a spill or personnel contamination incident.

b. Immediate Action for Simple Spills. The following guidelines are provided in the USUHS radiation safety guide, section XI for use by users of radioactive material and are extracted for this application. If radioactive material is spilled in a laboratory, the following actions will be taken:

- Warn nearby personnel. Take steps to avoid contaminating others with the spilled material, and prevent the spread of contamination to otherwise "clean" areas;
- Prevent the spread of contamination. Put absorbent paper over the visible spill areas;
- Prevent traffic through the spill area;
- Call the Radiation Safety Division (EHS). The phone extension is 295-9443/3390. After normal working hours or on weekends call Security on 295-3038. EHS personnel are always on call to respond to spills and other radionuclide emergencies;
- Under the direction of EHS personnel, clean up the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated material in the bag. After clean up, survey the area, your hands, clothing and shoes to insure that decontamination was successful;
- EHS personnel will follow up on the cleanup of the spill and will perform an independent survey.

c. Additional actions for spills involving contamination of clothing or skin:

- Remove contaminated clothing. Uncontaminated laboratory coats or surgical gowns can be used to preserve modesty. Contaminated clothing should be placed in a plastic bag and turned over to radiation safety personnel
- Wash contaminated skin with mild soap and warm water. Do not use abrasives or solvents on the skin.

d. Actions for Contaminated Wounds:

- In the case of contaminated wounds it is important to notify EHS as soon as possible. Rapid treatment of the wound will help reduce the possibility of internal absorption of radioactive material;

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- Flush the wound with water and treat using appropriate first aid measures. Never withhold first aid to a contaminated person.

e. Actions for Possible Airborne Contamination. Spills of dry or powdered radioactive material, or spills of iodine or other large sources in solution, are potential sources of airborne contamination. After spills in this category:

- Carefully cover the spill with absorbent material;
- Leave the lab immediately and close the door;
- Notify EHS;
- Remain in place until EHS personnel arrive.

f. The USU Radiation Safety Program adopts the procedures for fire, explosions, or major emergency as written in Appendix R of NUREG-1556, Volume 11, "Program-Specific Guidance About Licenses of Broad Scope."

10.7 Radiation Surveys.

10.7.1 PIs are responsible for containing radioactive material being used in their laboratories and will ensure surveys are performed in the laboratory after each experimental procedure involving radionuclides. The method of conducting these surveys and the minimum level of activity allowed on exposed laboratory surfaces are outlined in part VII of the USUHS radiation safety guide.

10.7.2 Surveys for most nuclides will be conducted using a calibrated survey meter issued by EHS personnel, unless otherwise approved by the RSO. Surveys in laboratories using ^3H , ^{14}C , and/or ^{35}S will be conducted by wiping surfaces with filter paper swipes and then counted in a liquid scintillation counter.

10.7.3 Surveys will be documented at the time of the survey and kept in a laboratory radiation survey log record. Each log entry must include date, location of survey measurements, results of the wipe sample counts and/or survey meter readings, and the initials or name of the worker who conducted the survey. The survey log will be available for inspection during routine laboratory surveys by EHS personnel.

10.7.4 EHS personnel will conduct bi-weekly surveys of all Type B laboratories and monthly surveys of all Type C laboratories. The surveys consist of swipe samples and room radiation levels taken at appropriate locations within the laboratory, with emphasis on radionuclide work areas, phone receivers, handles/knobs, and high traffic areas.

10.7.5 Any bench top, floor, or other laboratory or equipment surface with removable contamination greater than $200 \text{ pCi}/100 \text{ cm}^2$ ($450 \text{ dpm}/100 \text{ cm}^2$) is considered contaminated, and will be decontaminated by laboratory personnel. If laboratory personnel identify a level of removable contamination that is greater than

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450 pCi/100 cm² (1000 dpm/100 cm²) they are to immediately notify EHS personnel. For contamination levels above 450 pCi/100 cm² (1000 dpm/100 cm²), laboratory personnel will decontaminate the area under the direction and supervision of EHS personnel. Surfaces of some equipment and hoods may be allowed greater surface contamination levels with the approval of the RSO.

10.7.6 Survey records will include the following:

- Date of survey;
- A diagram of the area surveyed;
- A list of items and equipment surveyed;
- Specific locations on the survey diagram where wipe test was taken;
- Ambient radiation levels with appropriate units;
- Contamination levels with appropriate units;
- Make and model number of instruments used;
- Background radiation levels; and,
- Name of person conducting the survey.

10.7.7 Control of liquid radioactive effluent releases into the sanitary sewer system are managed through internal procedures used by EHS personnel and are documented by SOP. Procedures used by USUHS meet the limits in 10 CFR 20.1301 and 20.2003, respectively.

10.7.8 The USUHS will implement the model leak test program published in Appendix T of NUREG-1556, Volume 11, "Program-Specific Guidance about Licenses of Broad Scope."

10.8 Transportation of radioactive material is managed through internal procedures used by EHS personnel and are documented by SOP. Procedures used by the USUHS meet the requirements of NRC and U.S. Department of Transportation (DOT) regulations.

10.9 The USUHS requests the flexibility to revise procedures contained in this part without amendment of the license. Permitted changes will be revised and implemented using the procedures described in Item 7, subparagraph 7.2.3, titled Increase Flexibility for the RSC to Make Changes to the Radiation Safety Program or Procedures. These procedures may be applied to the following areas:

- the audit mechanism implemented by the RSO,
- instrument specifications and procedure for calibrations of instruments,
- administrative procedures to assure control of procurement and use of byproduct material,
- administrative controls and provisions relating to material control, accounting and security,

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- personnel dosimetry program,
- safe use and emergency procedures, and
- the survey or leak test program.