DEPARTMENT OF THE ARMY HEADQUARTERS, WALTER REED ARMY MEDICAL CENTER WASHINGTON, DC 20307-5001

HEALTH PHYSICS OFFICE RADIOACTIVE MATERIAL AUTHORIZATION CONDITIONS

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2 October 1997

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APPENDIX A. DEFINITIONS AND ABBREVIATIONS

# GENERAL PROVISIONS FOR AUTHORIZED USE OF RADIOACTIVE MATERIAL AT WALTER REED ARMY MEDICAL CENTER

2 October 1997

#### 1. REFERENCES.

a. WRAMC Regulation 40-10, 6 September 1996, Health Physics.

b. AR 40-5, 15 October 1985, Preventive Medicine.

c. AR 40-14, 30 June 1995, Occupational Ionizing Radiation Personnel Dosimetry.

d. AR 385-11, 1 May 1980, Ionizing Radiation Protection (Licensing, Control, Transportation, Disposal, and Radiation Safety).

e. DA PAM 40-18, 30 June 1995, Personnel Dosimetry Guidance and Dose Recording Procedures for Personnel Occupationally Exposed to Ionizing Radiation.

f. Title 10, Code of Federal Regulations, Part 20, Standards for Protection Against Radiation.

2. PRINCIPAL USER RESPONSIBILITIES. Principal Users for WRAMC Radioactive Material Authorizations are responsible for compliance with all regulations governing radiation safety in the laboratory and for safe practices of individuals working under their supervision. Principal Users are obligated to:

a. Supervise and train individuals working under their control to enable safe working habits and prevent exposures or contamination to themselves or others. Provide initial and annual briefings to all personnel working in areas designated on their authorization concerning the safe handling of the radioactive materials listed in the authorization, their responsibilities and rights as occupational radiation workers.

b. Ensure individuals working with radioactive materials under their control are aware of all radiation hazards inherent in the work environment and the risks associated with the possession, use, and shipment of the radioactive materials.

# GENERAL PROVISIONS FOR AUTHORIZED USE OF RADIOACTIVE MATERIAL AT WALTER REED ARMY MEDICAL CENTER

c. Ensure individuals working with radioactive materials under their control understand how to avoid any unnecessary exposure, either to themselves or to other workers.

d. Ensure individuals working with radioactive materials know the Army, federal, and state regulations controlling the possession, use, and shipping of radioactive materials.

e. Maintain constant surveillance or adequate controls of all radioactive materials to prevent unauthorized removal or use.

f. Notify the Health Physics Office (HPO) of any personnel changes, changes of radioactive material use areas, or sealed source locations. The HPO must be made aware of any additions or deletions of radioactive materials users.

g. Maintain occupational and environmental ionizing radiation exposure as low is reasonably achievable (ALARA). Current dose limitations are included in Tables General-1, -2:

OCCUPATIONAL EXPOSURE					
Stochastic Limit (TEDE) ¹	5 rem in 1 year				
Nonstochastic Limit ${\rm H}_d$ and CEDE other than eye	50 rem in 1 year				
Shallow Dose Equivalent H, Skin or Extremity	50 rem in 1 year				
Lens of the Eye	15 rem in 1 year				
Dose to Embryo or Fetus ²	0.5 rem in gestation period				
Planned Special Exposures	Not Allowed Without Waiver				
Emergency Exposure Limits (Life Saving)	100 rem				
Emergency Exposure Limits (Not Life Saving)	10 rem				
¹ Total Effective Dose Equivalent (TEDE): = Ext cm in tissue $(H_d)$ , and committed effective dos internal exposure	ternal Exposure at a depth of 1 se equivalent (CEDE) from				
2 H _d to pregnant woman and dose to the embryo	or fetus				

Table General-1

Table General-2

FOR OCCASIONALLY EXPOSED INDIVIDUAL	S AND MEMBERS OF THE GENERAL PUBLIC
Members of the Public	0.1 rem in any one year
Occasionally Exposed Individuals ¹	0.5 rem in any one year
Occupationally exposed Minors (under 18 years of age)	10% of the annual dose limits for occupationally exposed adults

¹ Individuals who occasionally enter restricted areas must not receive radiation exposure in excess of that permitted for any member of the public, however, transient operations may exist which require exposure of individuals not normally occupationally exposed to be exposed to levels in excess of 0.1 rem limit. Approval for this practice must be obtained in advance from OTSG and the NRC as per 10 CFR 20 for licensees.

# GENERAL PROVISIONS FOR AUTHORIZED USE OF RADIOACTIVE MATERIAL AT WALTER REED ARMY MEDICAL CENTER

h. Obtain and use proper personnel dosimetry devices in accordance with Condition No. 1, Personnel Dosimetry Procedures, for Radioactive Material Authorizations.

i. Contact the HPO Dosimetry Coordinator of any declared pregnant radiation workers for the risks associated with working with radioactive materials while pregnant (Nuclear Regulatory Commission Regulatory (NRC) Guide 8.13 and AR 40-14, paragraph 3-20).

j. Maintain an inventory of the physical and chemical forms of all radioactive materials in accordance with AR 385-11, paragraph 2-11. Keep current records of the receipt and the disposition of all radioactive materials in their possession including research, waste disposal, transfer, and storage. Perform a 100% physical radioisotope inventory every 3 months.

k. Perform radiation surveys of authorized work areas in accordance with Condition No. 2, Area Survey Procedures, for Radioactive Material Authorizations. Surveys for contamination should include not only the work area but also any protective clothing used, bottoms of shoes, and all potentially exposed areas of the body.

(1) The HPO will be notified immediately if contamination during a radiation survey exceeds:

(2) 2000 dpm/100 cm² or;

(3) When radiation levels from X-ray or gamma radiation in an unrestricted area exceeds 2 mrem/hr at 30 cm (1 foot).

1. Comply with the provisions of Condition No. 3, General Rules for the Safe Use of Radioactive Material, for Radioactive Material Authorizations.

m. Ensure appropriate radiation warning signs and labels are posted in accordance with 10 CFR 20.1902, and removed when no longer required.

n. Ensure the proper disposal of radioactive materials in accordance with Condition No. 4, Radioactive Waste, for Radioactive Material Authorizations.

o. Notify the HPO promptly of any changes in the use, location, or possession of radionuclides from the terms of this authorization. GENERAL PROVISIONS FOR AUTHORIZED USE OF RADIOACTIVE MATERIAL AT WALTER REED ARMY MEDICAL CENTER

p. Secure all radioactive materials to prevent unauthorized removal from the place of storage. Materials kept in unrestricted areas must be under constant surveillance and immediate control of an authorized user.

q. Comply with applicable provisions of Condition No. 5, Procedures for Ordering, Receiving, and Safely Opening Packages Containing Radioactive Material, for Radioactive Material Authorizations. In particular, insure that all NRC licensed or DARA radioactive materials entering Walter Reed Army Medical Center or its supported activities are processed through the HPO unless a special waiver has been granted by the HPO.

r. Do not transfer NRC licensed or Department of the Army Radiation Authorization (DARA) radioactive materials to unauthorized users or outside of the control of WRAMC or its supported activities.

s. In the event of an emergency situation, follow the emergency procedures outlined in Condition No. 6, Emergency Procedures, for Radioactive Material Authorizations.

t. Comply with the applicable provision of Condition No. 7, Requirements for the Use of Radioactive Iodine, Tritium, and Phosphorus-32, for Radioactive Material Authorizations.

u. Comply with the applicable provisions of Condition No. 8, Ventilation Requirements for Radioactive Material Authorizations.

v. Comply with the applicable provisions of Condition No. 9, Gas Chromatograph Requirements for Radioactive Material Authorizations.

Approved:

WILLIAM B. JOHNSON COL, MS Chief, Health Physics Office

# CONDITION NO. 1 RADIOACTIVE MATERIAL AUTHORIZATIONS PERSONAL DOSIMETRY PROCEDURES

2 October 1997

1. REFERENCES.

a. WRAMC Regulation 40-10, 6 September 1996, Health Physics.

b. AR 40-14, 30 June 1995, Occupational Ionizing Radiation Personnel Dosimetry.

c. AR 385-11, 1 May 1980, Ionizing Radiation Protection (Licensing, Control, Transportation, Disposal, and Radiation Safety).

d. AR 385-30, 18 November 1971, Safety Color Code Markings and Signs.

e. DA PAM 40-18, 30 June 1995, Personnel Dosimetry Guidance and Dose Recording Procedures for Personnel Occupationally Exposed to Ionizing Radiation.

f. Title 10, Code of Federal Regulations, Part 20, Standards for Protection Against Radiation.

g. DD Form 1952, 1 November 1981, WRAMC Revision, 1 Nov 95, Dosimeter Application and Record of Occupational Radiation Exposure.

h. WRAMC Form 538, 1 November 1981, Radiation Worker Briefing.

2. PERSONNEL DOSIMETRY ASSIGNMENT LEVELS.

a. Appropriate personnel monitoring devices will be assigned to each individual as required by the Health Physics Office. In addition, other personnel monitoring techniques e.g., whole body counting or bioassay will be utilized to evaluate personnel dosimetry as deemed necessary by the Health Physics Officer.

b. Personnel monitoring devices will be assigned when adults could potentially receive an occupational exposure from external radiation in excess of 10% of the levels in the following table for occupational exposure in a calendar year (Tables 1-1, 1-2).

Ta	h	1	0	1	-1	
	_	-	-	-	_	

OCCUPATIONAL EXPOSURE						
Stochastic Limit (TEDE) ¹	5 rem in 1 year					
Nonstochastic Limit $H_d$ and CEDE other than eye	50 rem in 1 year					
Shallow Dose Equivalent H, Skin or Extremity	50 rem in 1 year					
Lens of the Eye	15 rem in 1 year					

¹ Total Effective Dose Equivalent (TEDE) = External exposure at a depth of 1 cm in tissue  $(H_d)$ , and committed effective dose equivalent (CEDE) from internal exposure

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Table 1-2

MEMBERS OF THE GENERAL PUBLIC,	DECLARED PREGNANT WORKERS, AND MINORS
Members of the Public	0.1 rem in any one year
Dose to Embryo or Fetus ¹	0.5 rem in gestation period
Minors (under 18 years of age)	10% of the annual dose limits for occupationally exposed adults

 $^2\ H_{\rm d}$  to pregnant woman and dose to the embryo or fetus (after notifying the RPO in writing)

c. Dosimetry is required for all individuals entering a high or very high radiation area.

d. An ALARA investigation will be initiated if personnel dosimetry monitoring devices indicate an exposure level exceeding the amounts in Table 1-3:

ALARA INVESTIGATIONAL LEVELS						
(mrems per calendar quarter)	Level I	Level II				
Whole_Body ¹	125	375				
Lens of the Eye	375	1,125				
Other ²	1,250	3,750				

Table 1-3

- TEDE

 2  Other includes: Shallow-dose equivalent (H_s) to the skin or to any extremity, or the sum of the deep-dose equivalents (H_d) and the committed dose equivalents (H_T) to any individual organ or tissue other than the lens of the eye.

e. Personnel dose less than Investigation Level I - the RPO may make ALARA recommendations.

f. Personnel dose greater than Investigation Level I but less than Investigation Level II — the RPO will conduct an investigation of the dose and provide a report to the Radiation Control Committee (RCC) each guarter.

g. Personnel dose greater than Investigation Level II - RPO will investigate in a timely manner, take appropriate action to keep exposures ALARA, and provide a report to the Radiation Control Committee (RCC) each quarter.

3. APPLICATION FOR PERSONNEL DOSIMETRY SERVICE.

a. Supervisors of individuals who are potentially exposed to internal or external ionizing radiation hazards must require those individuals to submit a Dosimeter Application and Record of Occupational Radiation Exposure (DD Form 1952) to the WRAMC HPO prior to assignment.

b. The procedures and responsibilities for processing the application follow:

(1) Individual Application for Personnel Dosimetry Service: The applicant has the responsibility to furnish:

(a) Individual identification data;

(b) Previous occupational radiation exposure history.

(2) The supervisor has the responsibility to furnish:

(a) A statement of the type of exposures in the worker's environment (e.g., X-ray, neutron, radioactive isotopes);

(b) Complete WRAMC Form 538 indicating that the applicant has been instructed concerning the safe handling and usage of the radioactive materials listed in the authorization permit.

(c) The responsibilities and rights of an occupational radiation worker.

4. USE OF PERSONNEL MONITORING DEVICES.

a. Immediate supervisors must ensure that the dosimeter issued to one occupational worker is not used by another individual.

b. WRAMC issued dosimeters shall not be worn by any personnel when occupationally exposed at other facilities away from their designated Government job site. However, if an individual wears a different dosimeter while working at other facility, the individual will inform the Supervisor or Principal User and the HPO of the off-duty (moonlighting) dose records no later than 2 months after such records are received by the individual or 4 months following termination of such moonlighting employment, whichever is earlier.

c. Whole body dosimetry will be worn:

(1) Below the shoulders.

(2) Above the hips.

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(3) Outside the clothing.

(4) On the portion or area of the body nearest the radiation source.

(5) With the dosimeter window facing out (away) from the body, and towards the radiation source.

(6) For individuals wearing a protective garment such as a lead apron while practicing radiology, the whole-body dosimeter shall be worn inside of any protective garment.

(7) Personnel, such as those working with fluoroscopic or cardiac catheterization X-ray equipment, exposed to X-rays scattered from the patient will wear a collar dosimeter (above the protective garment) and a whole body dosimeter (under the protective garment).

d. When not being worn, the personnel monitoring devices will be stored in the designated location approved by the RPO.

e. The department dosimetry coordinator will ensure that the dosimeters are turned in to the activity dosimetry coordinator during the designated exchange periods.

5. TERMINATION OF PERSONNEL DOSIMETRY SERVICE. The Principal User will notify the HPO of the departure of any department personnel who are enrolled in the personnel dosimetry program.

6. BIOASSAY.

a. Individuals who are required to participate in the Bioassay Program due to use of radioactive iodine, tritium, or phosphorus will continue to participate in the Bioassay Program until released in writing by the Health Physics Officer.

b. The Principal User will ensure that personnel required to participate in the Bioassay Program:

(1) Appear for measurement at the designated time and place.

(2) Provide appropriate samples for in-vitro counting.

(3) Inform the Health Physics Officer of changes in working conditions or other factors that would influence the type, or frequency of bioassay measurement.

7. PREGNANCY SURVEILLANCE PROGRAM.

a. Declared pregnant radiation workers have lower permissible dose limits to the embryo or fetus during the course of the pregnancy. A female does not fall under the lower limits for pregnant radiation workers until she formally declares her pregnancy, in writing, to the RPO. A formal declaration of pregnancy is the prerogative of each female radiation worker.

b. The RPO must provide instructions regarding the prenatal exposure risks and concerns to the developing embryo or fetus. A copy of NRC Regulatory Guide 8.13 will be given to the declared pregnant radiation worker.

c. The written declaration shall be made on an SF 600 (Health Record - Chronological Record of Medical Care) and placed in the woman's health record.

d. Nursing mothers who are potentially exposed to the intake of radionuclides require special consideration to limit the dose to the child.

Approved:

WILLIAM B. JOHNSON COL, MS Chief, Health Physics Office

# CONDITION NO. 2 RADIOACTIVE MATERIAL AUTHORIZATIONS AREA SURVEY PROCEDURES

2 October 1997

## 1. REFERENCES.

a. WRAMC Regulation 40-10, 6 September 1996, Health Physics.

b. AR 40-5, 15 October 1985, Preventive Medicine.

c. Title 10, Code of Federal Regulations, Part 20, Standards for Protection Against Radiation.

d. NRC Regulatory Guide 8.23, Revision 1, Radiation Safety Surveys at Medical Institutions.

2. SURVEY REQUIREMENTS.

a. Surveys by the radioisotope user will be conducted if the activity of the unsealed radioactive material exceeds the activity listed in Table 2-1.

10% of 10 CFR 20 Appendix C limits for Radionuclides Commonly Us	ed at WRAMC
The user must conduct contamination surveys if the following activities per protocol or procedure are exceeded. ¹	ACTIVITY ((MCi)
³ H ¹⁴ C ⁴² K ⁵¹ Cr ⁶⁷ Ga ⁹⁹ ^m Tc ²⁰¹ Tl	100
⁵³ P ³⁵ S ⁴⁵ Ca ⁵⁴ Mn ⁵⁷ Co ⁸⁵ Sr ⁸⁶ Rb ⁹⁹ Mo ^{95m} Nb ¹⁰³ Ru ¹¹¹ In ¹²³ I ¹²⁵ Sb ¹⁴¹ Ce	10
²¹ Na ³¹ P ³⁶ Cl ⁴⁶ Sc ⁵⁹ Fe ⁸⁹ Sr	1
¹⁰⁹ Cd ¹²⁵ I ¹³¹ I	0.1

Table 2-1

¹ For any radionuclide not listed, contact the HPO for the appropriate activity limit.

b. Conduct the survey after completion of work, or at the end of the day if more than one protocol is performed during the day.

c. No daily survey is required if the activity of the isotope used is less than the activity shown in the table; however, it is always a good practice to survey work areas for contamination after using unsealed radioactive materials.

# CONDITION NO. 2 RADIOACTIVE MATERIAL AUTHORIZATIONS AREA SURVEY PROCEDURES

d. Weekly surveys by the Health Physics Office will be conducted if it is possible that more than 200 mCi of unsealed radioactive material could be used in the room.

e. Monthly surveys by the Health Physics Office will be conducted if less than 200 mCi and greater than 10 percent of the value in 10 CFR 20, Appendix C of unsealed radioactive material could be used in the room.

f. Quarterly surveys by the Health Physics Office will be conducted if less than 10 percent of the value in 10 CFR 20, Appendix C of unsealed radioactive material could be used in the room.

3. SURVEY INSTRUMENTATION.

a. Gieger-Mueller (G-M) counter. A gas-filled detector that operates with a very high electric field where a single ionization event can trigger an avalanche of ionizations. The G-M detector is very sensitive, but all pulses from the G-M tube are of the same amplitude regardless of the number of the original ion pairs or energy of the incident ionizing radiation. Therefore, the G-M detector functions only as a simple counter of ionization events.

b. For high energy x-ray, beta, or gamma emitter, use a low-range thin-window G-M survey meter to survey all elution, preparation, and injection areas.

c. Liquid Scintillation Counter (LSC). The sample is placed inside a vial containing a suitable liquid scintillation fluid. Using an LSC eliminates problems related to sample self-absorption, attenuation of particles by detector windows, and beta backscattering from the detector. These advantages are particularly important for low-energy radiations such as beta particles emitted from carbon-14 and tritium.

d. Perform a swipe survey to measure contamination levels in those areas using low energy beta emitters such as tritium or carbon-14. The method for analyzing wipe tests will be sufficiently sensitive to detect 100 dpm per 100 cm² for the contaminant involved.

e. Ion Chamber. An air filled ion chamber is primarily used to measure gamma-ray exposure. Because exposure is defined as ionization charge created in air, measurement of the ionization current with an ion chamber will correspond to the exposure rate.

# CONDITION NO. 2 RADIOACTIVE MATERIAL AUTHORIZATIONS AREA SURVEY PROCEDURES

The exposure unit roentgen (R) is also closely related to the absorbed dose unit rad in air (1 R = 0.877 rad).

f. Use a survey instrument capable of measuring exposure rates as low as 0.1 mR/hr for areas where radiopharmaceuticals are prepared for use or administration.

g. Keep a record of all survey results, including negative results for a period of three years. The survey results record will include:

(1) Location, date, and type of equipment used.

(2) Name of person conducting the survey (signature or initials).

(3) Type, serial number, and calibration date of the portable survey instruments.

(4) A drawing of the areas surveyed with contamination levels and dose rate action levels.

(5) Measured dose rates in mR/hr or contamination levels in dpm/100 cm², as appropriate.

4. ACTION LEVELS FOR RESTRICTED AREAS.

a. The radioisotope user will clean or decontaminate the area for Action Level I where:

(1) Contamination exceeds 1000 dpm/100 cm²;

(2) The radiation level is two times the background, or 1 mrem/hr at 30 cm (1 foot) for X-ray or gamma radiation.

b. The radioisotope user will clean or decontaminate the area for Action Level II and contact the Health Physics Office immediately if:

(1) Contamination exceeds 2000 dpm/100 cm²;

(2) The radiation levels from X-ray or gamma radiation in an unrestricted area exceeds 2 mrem/hr at 30 cm (1 foot).

5. ACTION LEVELS FOR UNRESTRICTED AREAS. All unrestricted areas will be maintained at a removable contamination level of less than 200 dpm/100  $cm^2$ .

# CONDITION NO. 2 RADIOACTIVE MATERIAL AUTHORIZATIONS AREA SURVEY PROCEDURES

# 6. SECURITY OF RADIOACTIVE MATERIALS.

a. The Principal User is responsible to ensure that:

(1) Radioactive materials used within their authorization are properly secured.

(2) Radiation hazards are properly posted.

(3) The radioactive material is stored in a locked room, locked refrigerator, or locked container.

(4) If the room is unlocked, and the radioactive material is not secured in a locked container, then someone must be in the room at all times.

b. If any radioactive material is believed to be missing, call the Health Physics Office IMMEDIATELY (within the same day that the radioactive material is noticed missing). The Health Physics Office can then assist your laboratory in locating the radioactive material. In addition, if the quantity of material missing exceeds certain limits, the Health Physics Office may be required to notify the Nuclear Regulatory Commission within 24 hours upon discovery of the event.

Approved:

WILLIAM B. JOHNSON COL, MS Chief, Health Physics Office

# CONDITION NO. 3 RADIOACTIVE MATERIAL AUTHORIZATIONS GENERAL RULES FOR THE SAFE USE

2 October 1997

1. REFERENCES.

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a. WRAMC Regulation 40-10, 6 September 1996, Health Physics.

b. AR 40-5, 15 October 1985, Preventive Medicine.

AR 385-11, 1 May 1980, Ionizing Radiation Protection (Licensing, Control, Transportation, Disposal, and Radiation Safety).

d. Title 10, Code of Federal Regulations, Part 20, Standards for Protection Against Radiation.

e. DA Form 3862, 1 June 1972, Controlled Substances Stock Record.

2. RESPONSIBILITIES.

a. Principal Users of radioactive material at WRAMC are responsible for incorporating all applicable precautions listed in this Condition into their procedures and assuring their implementation by personnel listed on their Radioactive Material Authorization.

b. Principal Users of radioactive material at WRAMC are responsible for maintaining a current inventory of all radioactive material on DA Form 3862 or on a computer format that records the equivalent information.

3. LABORATORY PRECAUTIONS. The following are general rules for the safe use of radioactive materials:

a. Always wear laboratory coats or other protective clothing while actively involved in the use of unsealed radioactive material. To preclude the possible spread of contamination, only wear laboratory coats or other protective clothing in the designated work areas.

# CONDITION NO. 3 RADIOACTIVE MATERIAL AUTHORIZATIONS GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL

b. Always wear disposable gloves while handling radioactive materials, except:

(1) When quantities less than those specified by WRAMC general license for the use of byproduct material for certain in-vitro clinical or laboratory testing (less than 10  $\mu$ Ci of ¹²⁵I, ¹³¹I, ¹⁴C, and ⁷⁵Se; less than 20  $\mu$ Ci of ⁵⁹Fe; and 50  $\mu$ Ci of ³H).

(2) When handling totally encapsulated sealed sources of beta or gamma emitting radionuclides that are exempt from leak testing requirements (see WRAMC Reg 40-10).

(3) During injection of a radiopharmaceutical when the loss of tactile sensation would hinder venipuncture technique potentially resulting in infiltrations, thereby requiring repeat studies and increasing patient exposure.

c. Monitor hands and clothing for contamination after each procedure or before leaving the controlled area.

d. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is used or stored.

e. Do not store food, drink, or personal effects in areas where radioactive materiel is used or stored.

f. Always wear assigned personnel dosimetry while in radioactive materials use or storage areas. Whole body dosimeters should be worn at chest or waist level. Finger or extremity dosimeters should be worn close to and facing sources handled. When not being worn, store dosimeters in the approved low-background storage location.

g. Dispose of radioactive waste only in specifically designated, labeled, and if necessary shielded receptacles.

h. Never pipette by mouth.

i. Confine radioactive solutions in containers plainly identified and labeled with name of compound, radionuclide, date activity, and radiation level, if applicable.

j. Always store and transport radioactive materials in appropriate shielded containers.

k. When transporting radioactive materials and waste, use items such as carts or wheelchairs to avoid contact with the surface of the container.

# CONDITION NO. 3 RADIOACTIVE MATERIAL AUTHORIZATIONS GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL

4. NUCLEAR MEDICINE PRECAUTIONS. The following are additional general rules specifically applicable to preparation and use of radioactive materials for human use.

a. Use syringe shields for preparation of patient doses and administration to patients except in circumstances such as pediatric cases when their use would compromise the patient's well-being. Consider other protective methods such as remote handling if syringe shields cannot be used.

b. Assay each patient dose in the dose calibrator before administration. Do not use any doses that differ from the prescribed dose by more than 10%. Check the patient's name, identification, the prescribed radionuclide, chemical form, and dosage before administering to the patient.

c. Wear a finger dosimeter during elution of generator, preparation, assay, and injection of radiopharmaceuticals.

d. Survey Generator, kit preparation, and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.

5. VENTILATION IN RESTRICTED AREAS.

a. Conducting procedures resulting in the generation of radioactive aerosols, dusts, or gaseous products in a hood, dry box or other suitable closed system.

b. Store radioactive gases or material with gaseous radioactive daughters in gas tight containers in areas having approved ventilation.

c. Use an average velocity through openings of 100 fpm when handling low to moderate levels of radioactive materials. For highly toxic or high-level radioactive material, raise the velocity through the openings to an average of 125 - 150 fpm.

d. Multiuse containers of ¹³³Xe will be stored in the fume hood.

Approved:

WILLIAM B. JOHNSON COL, MS Chief, Health Physics Office

# CONDITION NO. 4 RADIOACTIVE MATERIAL AUTHORIZATIONS RADIOACTIVE WASTE

2 October 1997

## 1. REFERENCES.

a. WRAMC Regulation 40-10, 6 September 1996, Health Physics.

b. AR 40-5, 15 October 1985, Preventive Medicine.

c. AR 385-11, 1 May 1980, Ionizing Radiation Protection (Licensing, Control, Transportation, Disposal, and Radiation Safety).

d. Title 10, Code of Federal Regulations, Part 20, Standards for Protection Against Radiation.

e. Title 49, Code of Federal Regulations, Transportation.

2. GENERAL. Radioactive waste from Walter Reed Army Medical Center and tenant activities will be controlled, packaged, transported, and disposed of in accordance with AR 385-11, Ionizing Radiation Protection; Title 10, Code of Federal Regulations; Title 49, Code of Federal Regulations; Nuclear Regulatory commission Licenses issued to WRAMC; applicable provisions of State Government requirements for waste disposal sites located within their jurisdiction; and the guidelines delineated herein.

3. RADIOACTIVE WASTE CONTROL IN THE LABORATORY OR CLINIC.

a. Principal Users are responsible for assuring that radioactive waste is controlled in a manner that meets the safety and security measures prescribed by U.S. Army, Federal, and applicable State Regulations.

b. All Users of radioactive materials are responsible for segregating their radioactive waste into the categories listed below:

(1) <u>Solid</u>. Short half-life, 65 days or less plus the following radionuclides; sulfer-35 (87.44 d), cobalt-58 (70.8 d), iridium-192 (74.02 d), and scandium-46 (83.8 d).

#### CONDITION NO. 4 RADIOACTIVE MATERIAL AUTHORIZATIONS RADIOACTIVE WASTE

(2) <u>Solid</u>. Long half-life, greater than 65 days except for the following radionuclides; sulfer-35 (87.44 d), cobalt-58 (70.8 d), iridium-192 (74.02 d), and scandium-46 (83.8 d).

(3) <u>Lead</u>. Shielding materials and pigs.

(4) <u>Scintillation Vials</u>. Biodegradable (Bio-safe, etc.) scintillation fluid.

(5) <u>Scintillation Vials</u>. Organic non-biodegradable scintillation fluid.

(6) <u>Aqueous Liquids</u>. Readily soluble (or readily dispersible biological material) in water and neutralized to pH > 2 and pH < 12.

(7) <u>Organic Liquids</u>. With MSDS and approved Waste Profile Sheet for each chemical.

(8) <u>Animal Carcasses/Excreta/Bedding</u>. Short half-life.

(9) <u>Animal Carcasses/Animal Waste</u>. Long half-life.

(10) <u>Animal Carcasses</u>.  $\leq$  0.05 µCi H-3 or C-14 per gram of animal tissue averaged over the entire weight of the animal.

(11) Gas. Contact the Health Physics Office.

(12) <u>Sharps</u>. See paragraph 5.e.

(13) Stock Source Vials. See paragraph 9.

c. Limiting the non-radioactive waste that is intermixed with radioactive waste to an absolute minimum.

d. Removing or obliterating all "Radioactive Material" labels on non-radioactive vendor shipping packages and on short half-life radioactive waste. Uncontaminated vendor shipping containers may be disposed of in the normal trash by the users. Short half-life waste will be delivered to Health Physics Office (HPO) collection points for subsequent storage, decay, and ultimate disposal in the normal trash when HPO personnel have determined that the waste has reached natural background radiation levels.

e. Storing used Mo-99/Tc-99m generators and other items of equipment containing radioactive material in designated areas only. The radiation labels will be removed on such items only when they reached levels indistinguishable from background and have been cleared by the HPO.

#### CONDITION NO. 4 RADIOACTIVE MATERIAL AUTHORIZATIONS RADIOACTIVE WASTE

f. Maintaining their inventory of radioactive waste to a practical minimum.

g. Controlling radioactive waste in their work areas to prevent unauthorized disposal by the custodial service. Properly labeled waste containers will be used for radioactive waste. Labeled radioactive waste containers will not be used for other purposes.

h. Ensuring that all radioactive waste is delivered to HPO collection point personnel for ultimate disposal.

i. Marking all radioactive waste containers with the radiation caution symbol and the words "Caution - Radioactive Waste" and/or "Caution - Radioactive Material" and "DO NOT EMPTY!".

j. Ensuring that radioactive material is not released into the sanitary sewage system without the specific approval of the Health Physics Officer.

k. Ensuring that decontamination of reusable equipment is only performed in laboratory sinks that have been authorized via their Radioactive Material Authorization. See paragraph 6. for specific requirements concerning this procedure.

1. Radioactive waste that is infectious waste must be properly disinfected before it is given to the HPO for disposal. INFECTIOUS WASTE WILL NOT BE GIVEN TO HPO.

4. DISPOSAL OF RADIOACTIVE MATERIALS. All Users of radioactive materials will package their materials for disposal as follows:

a. Segregate radioactive waste into the proper category as defined in paragraph 3.b.

b. Solid radioactive waste shall be placed in plastic bags or a receptacle lined with plastic bags. Only clear bags at least 4 mils thick will be used. Clear bags will allow visual inspection of the waste by HPO personnel at the time of turn-in. Bags will be taped closed and tagged with a radiation tag containing the authorization number, radioisotope(s), and activity.

c. Bulk liquid waste retained for disposal shall be collected in plastic bottles or sealed in cans to diminish breakage. Liquid waste that will chemically react with plastic should be placed in glass bottles. The containers will be tagged as stated above.

# RADIOACTIVE WASTE

d. Scintillation vials shall be packaged separately from other materials. They will be tightly closed and placed in a shipping tray that is labeled with the words "Caution -Radioactive Material." Care must be taken to prevent breakage of the vials while in storage or transport. The trays will be tagged as previously indicated.

e. All "Sharps" to include syringes with needles, needles and similar items must be separated from other radioactive waste, packaged in cardboard boxes or sharps containers and sealed to prevent personal injury. The sharps containers and boxes will be tagged as previously indicated. All sharps containers with long half-life waste may contain only minimal, residual liquid.

f. Short half-life materials and items contaminated with short half-life materials shall be separated from other materials. Radioactive warning labels must be obliterated on all vials and materials prior to placing the items in the plastic bags. The bags will be tagged identifying isotope(s), activity, and authorization number. Do not use "radiation tape" to seal these bags.

g. Biological wastes (animal carcasses or animal waste) shall be prepared by the User in a manner that allows the waste to be readily packed in alternating 10-inch layers of waste and packing materials. Prepared biological waste shall be placed in 4 mil clear bags and tagged as previously indicated.

5. RELEASE OF RADIOACTIVITY INTO THE SANITARY SEWAGE SYSTEM.

a. Liquid radioactive waste will not be released into the sanitary sewage system unless prior approval has been included in the WRAMC Radioactive Material Authorization.

b. Other conditions for the disposal of liquid radioactive waste material (as a byproduct of washing laboratory glassware or equipment) into the sewage system are:

(1) The total quantity of material released by the user in any one month will not exceed 100 microcuries. Assume emptied glassware retains one percent of the radioactivity originally contained within the glassware.

(2) The sink must be conspicuously posted with a sign bearing the Radioactive Caution Symbol and words, "Caution Radioactive Material Wash Sink," and with a notice to the user that radioactive material discharged through the sink must be readily soluble or dispersible in water.

# CONDITION NO. 4 RADIOACTIVE MATERIAL AUTHORIZATIONS RADIOACTIVE WASTE

(3) A record of the identity and activity of radionuclides released will be maintained by the Principal User. This record will be reviewed by HPO for compliance with regulatory limits.

6. COLLECTION, LOCAL TRANSPORTATION, AND STORAGE OF RADIOACTIVE WASTE.

a. Properly packaged radioactive waste will be brought to centralized collection points in Building 40, Building 2, or other designated locations. Under the supervision of the HPO, waste will be placed in barrels or other designated containers. Waste that has not been properly separated and tagged will not be accepted.

b. Principal users will ensure that packaged radioactive waste brought to the collection points is supervised until accepted by HPO to preclude the possibility of loss or theft.

c. All radioactive waste (except mixed waste that contains a percentage of EPA regulated material) will be transported from the above noted collection points to the Radioactive Material Storage Areas located in Building 516, Forest Glen Section, WRAMC, for ultimate disposal.

d. Building 516 may be used to store all categories of radioactive waste.

e. Storage areas are considered "Restricted Areas" and will remain locked to preclude the possibility of loss or theft and protect individuals from exposure to radiation or radioactive materials.

f. Radioactive Material Storage Areas will be posted by Health Physics personnel with the appropriate warning signs prescribed by Title 10 CFR 20.1902.

g. Waste will be packaged for ultimate shipment and disposal in accordance with the instructions furnished by the waste disposal contractor.

h. The waste disposal contractor is determined by the DOD Executive Agency for Low-Level Radioactive Waste, ATTN: AMSIO-DMW, Rock Island, IL 61299 in accordance with AR 385-11.

7. RADIOACTIVE WASTE DISPOSAL SUPPLIES.

a. Items of supply used for radioactive waste packaging are stocked by the Supply and Administration Branch, Material Division, Directorate of Logistics, WRAMC. All items will meet

# CONDITION NO. 4 RADIOACTIVE MATERIAL AUTHORIZATIONS RADIOACTIVE WASTE

Federal radioactive material packaging requirements for most types of the radioactive waste resulting from laboratory or clinical procedures at WRAMC.

b. Personnel involved with packaging of hazardous chemical radioactive waste will consult the HPO in order to ensure that the stockage items meet packaging requirements.

c. Principal users are responsible for funding for materials and supplies used to dispose of radioactive waste. The HPO will order supplies needed to collect and package the waste received at collection points and will designate Clinical Investigation, Department of Pathology and Laboratory Services, Department of Radiology, AFIP, or WRAIR as appropriate. All supply orders submitted by HPO will be prorated to the using services.

8. DISPOSAL OF STOCK SOURCE VIALS.

a. All original stock source vials, whether depleted, decayed, or partially used will be turned over to the Health Physics personnel along with the radiation waste.

b. A stock source vial is defined as having an initial activity of at least 50  $\mu$ Ci of any radionuclide.

c. Original stock source vials, whether depleted or not, which are turned in as waste shall be kept separate from other waste.

d. When source vials are turned in to Health Physics, please provide the source HPO identification number (Yellow Tag Number).

e. If there are multiple vials listed under the same identification number, list the vials still in your possession.

f. The inventory log will be adjusted to show the change in the authorization inventory. Health Physics personnel will sign the inventory log if provided at the time of turn-in. In addition, Health Physics personnel will provide a signed receipt for possession of the source vial(s).

Approved:

WILLIAM B. JOHNSON COL, MS Chief, Health Physics Office

# CONDITION NO. 5 RADIOACTIVE MATERIAL AUTHORIZATIONS PROCEDURES FOR ORDERING, RECEIVING AND SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

2 October 1997

## 1. REFERENCES.

a. WRAMC Regulation 40-10, 6 September 1996, Health Physics.

b. AR 40-5, 15 October 1985, Preventive Medicine.

c. AR 385-11, 1 May 1980, Ionizing Radiation Protection (Licensing, Control, Transportation, Disposal, and Radiation Safety).

d. Title 10, Code of Federal Regulations, Part 20, Standards for Protection Against Radiation.

e. Title 49, Code of Federal Regulations, Transportation.

f. NRC Regulatory Guide 10.8, Revision 2, Guide for the Preparation of Applications for Medical Use Programs.

2. GENERAL. Radioactive material for Walter Reed Army Medical Center (WRAMC) and tenant activities will be ordered, received and secured in accordance with US Army Regulations, Title 10, Code of Federal Regulations, and the provisions of WRAMC's Nuclear Regulatory Commission License.

3. PRINCIPAL USER'S RESPONSIBILITIES.

a. WRAMC Principal Users are responsible for ordering and receiving radioactive material in accordance with the instructions outlined below.

b. A Principal User may procure only those radioisotopes currently authorized for his use by the WRAMC Radiation Control Committee, subject to the limitations of their authorization.

c. Unless specified prior arrangements have been made with the Health Physics Office, the maximum quantity that may be ordered at any time is limited by the maximum activity of that radioisotope permitted by the authorization.

d. Specific prior approval of a Health Physics Officer shall be required before receiving or transferring radioactive material. This procedure applies in those instances where normal supply channels are not utilized. All radioactive material will be delivered to the Health Physics Office unless alternate arrangements are specifically approved by the Health Physics Office.

4. ORDERING PROCEDURES.

a. The Principal User shall submit a completed Purchase Request through normal supply channels for the procurement of all radioactive materials.

b. In addition to the information required by WRAMC Procurement Regulations, each purchase request shall contain the following:

(1) Radionuclide, chemical form, and total activity [Activity is given as microcurie ( $\mu$ Ci), millicurie (mCi), or curie (Ci)]; for natural radioactive materials microgram ( $\mu$ g), milligram (mg), gram (g), kilogram (kg), or milligram radium equivalent (mg Ra eq) may be used where appropriate.

(2) The following notice will be typed after the item description:

RADIOACTIVE MATERIAL NOTIFY THE HEALTH PHYSICS OFFICE PRIOR TO PLACING AN ORDER TELEPHONE NUMBER (202) 356-0058

(3) The WRAMC Radioactive Material Authorization Number will be indicated in the "Attention Line" of the "Ship To" address.

(4) Date required or delivery date.

(5) The proper shipping address for any radioactive material not specifically exempted by the HPO is:

Health Physics Office Walter Reed Army Medical Center 6825 16th Street NW Building 41, Room 38 ATTN: Authorization No. Washington, DC 20307-5001

(6) Two specific approved exemptions are:

(a) The Forensic Toxicology Drug Testing Laboratory, Ft. Meade, MD is authorized to order I-125 drug testing kits to be shipped to the following address:

Radiation Protection Officer Forensic Toxicology Drug Testing Laboratory Building 2490 Fort Meade, Maryland 20755

(b) The WRAMC Nuclear Medicine Clinic is authorized by MOU dated 26 Jan 96 to order radiopharmaceuticals used for patient treatment. All chemical and physical forms of I-125 and sealed sources will be sent to the Health Physics Office address listed in paragraph 4.b.(5). Shipments to the Nuclear Pharmacy will be addressed to:

Walter Reed Army Medical Center Nuclear Pharmacy Building 2, Room 7A14 Washington, DC 20307-5001

5. RECEIVING PROCEDURES.

a. All incoming shipments of radioactive material will be sent to the Health Physics Office during duty hours and will be received in building 41, room 38. Shipments after duty hours or on weekends will be delivered to WRAIR, building 40, room B079. Shipments to Fort Meade or the WRAMC Nuclear Medicine Clinic will be delivered to the addresses shown in paragraph 4.b.(6)(a) or 4.b.(6)(b). The Health Physics Office must be notified immediately of any shipment delivered to an unapproved address.

b. All shipments will be processed using the model procedure in Appendix L to Regulatory Guide 10.8, Revision 2 for safely receiving and opening packages containing radioactive material. All incoming packages of radioactive material will be examined for damage immediately upon receipt. Any packages that appear to be wet, punctured, crushed, or otherwise damaged will be considered to be contaminated until it can be determined that they are not.

c. Incoming radioactive material shipments must be immediately secured against unauthorized removal or tampering.

d. The measured exposure rate adjacent to the secured storage area may not exceed 0.5 mR/hr.

6. SHIPMENT MONITORING & DELIVERY TO AUTHORIZED RECIPIENTS.

a. All shipments of radioactive material must be inspected to insure that the shipment does not exceed the possession limits of the Authorization under which it is ordered. Unauthorized shipments will be returned to the vendor when possible, disposed of as radioactive waste, or held by the Health Physics Office until the Principal User obtains an amended Radioactive Material Authorization allowing receipt of the material. Unauthorized shipments will not be held by Health Physics for more than ninety (90) days.

b. Shipments will be delivered to Principal User by the Health Physics Office after package receipt procedures have been completed.

7. FINAL SOURCE CONTAINER CHECK. The Principal User is responsible for making a final check of the radioactive materials source container once it is received. This check will follow the steps outlined below:

a. Put on gloves.

b. Visually inspect the package for any sign of damage. If any damage is noted, stop the procedure and call the Health Physics Office.

c. Open the outer package, following the manufacturer's directions, if supplied, and remove the packing slip.

d. Open the inner package and verify that the contents agree with the contents listed on the packing slip.

e. Check integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of packaging material. If anything is other than expected, stop and notify the Health Physics Office.

f. Before disposing of clean outer packaging, ensure that any "radioactive" labels or statements have been defaced or removed.

g. Verify that the items received are the correct items ordered and that a receiving report is completed for Logistics.

Approved:

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WILLIAM B. JOHNSON COL, MS Chief, Health Physics Office

# CONDITION NO. 6 RADIOACTIVE MATERIAL AUTHORIZATIONS EMERGENCY PROCEDURES

2 October 1997

#### 1. REFERENCES.

a. WRAMC Regulation 40-10, 6 September 1996, Health Physics.

b. AR 40-5, 15 October 1985, Preventive Medicine.

c. AR 385-11, 1 May 1980, Ionizing Radiation Protection (Licensing, Control, Transportation, Disposal, and Radiation Safety).

d. Title 10, Code of Federal Regulations, Part 20, Standards for Protection Against Radiation.

e. NRC Regulatory Guide 10.8, Revision 2, Guide for the Preparation of Applications for Medical Use Programs.

2. DETERMINATION OF MAJOR VERSUS MINOR SPILLS.

a. A spill is considered major if there is an accidental or uncontrolled release of 1 mCi or more of any radionuclide.

b. The exception to this rule is Tc-99m and Tl-201 used in the Nuclear Medicine pharmacy where a spill is considered major if 100 mCi or more is released.

c. The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident specific variables. Some variables to consider include;

(1) Number of individuals affected.

(2) Other hazards present.

(3) Likelihood of spread of contamination.

(4) Types of surfaces contaminated.

(5) Radiotoxicity of the spilled material.

# CONDITION NO. 6 RADIOACTIVE MATERIAL AUTHORIZATIONS EMERGENCY PROCEDURES

d. For some short-lived radionuclides, the best spill procedure may be restricting access to the area pending complete decay of the radionuclide.

3. MAJOR SPILLS OF LIQUIDS AND SOLIDS.

a. Clear the Area. Notify all persons not involved in the spill to vacate the room.

b. Prevent the spread of contamination by covering the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread of contamination.

c. Shield the source if possible. This should be done without further contamination or a significant increase in radiation exposure.

d. Notify the Health Physics Officer immediately.

e. Conduct limited decontamination by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with mild soap. Do not use brushes or any other abrasive substances. Limit the spread of contamination by consolidating and keeping contaminated personnel in one location. Wait for Health Physics personnel to arrive and evaluate personnel before attempting further decontamination. Retain contaminated clothing and materials used in decontamination for further analysis by the Health Physics Office.

f. Initiate a radioactive spill report. A sample radioactive spill report is included at the end of this Condition.

4. MINOR SPILLS OF LIQUIDS AND SOLIDS.

a. Notify persons in the area that a spill has occurred.

b. Prevent the spread of contamination by covering the spill with absorbent paper.

c. Clean up the spill wearing disposable gloves, using remote handling tongs and absorbent paper. Carefully fold the absorbent paper with clean side out and insert it into a plastic bag. Transfer the plastic bag to a radioactive waste container. Place other contaminated materials, such as disposable gloves, and any other contaminated disposable material into the plastic bag.

# CONDITION NO. 6 RADIOACTIVE MATERIAL AUTHORIZATIONS EMERGENCY PROCEDURES

d. Survey the area with a low-range radiation detector survey meter. Check the area around the spill, hands, shoes, and clothing for contamination.

e. Report the incident to the Health Physics Officer.

f. Initiate a radioactive spill report. A sample radioactive spill report is included at the end of this Condition.

5. EMERGENCY NOTIFICATION. In the event of an emergency notify the Health Physics Officer at (202) 356-0058.

Approved:

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WILLIAM B. JOHNSON COL, MS Chief, Health Physics Office

# Radioactive Spill Report

The spill occurred	at:	am pm on	/	/ Room	
Instrument used to	check for	decontami	nation:		
Meter Model:	SN:	Probe	Model:	SN:	
Personnel Present	Personnel	Contamin	ation Resu	ults	
On the back of this monitoring, or care i	sheet, list nstituted.	personnel,	any decont	amination, ac	ditional
Survey the spil decontamination.	l area to Conduct a p	o identif oost-decon	fy hot tamination	spots and n wipe test	begin.
Radioisotopes pres	ent or susp	pected in [.]	the spill	:	
mCi of		as		, <u>, , , , , , , , , , , , , , , ,</u>	
mCi of		as			
mCi of		as			

Give a brief description of the accident:

Give a brief description of the follow-up actions taken to prevent reoccurrence:

WRAMC	Health	Physics	Office	Name:	
(202)	356-005	8 Date:			

# CONDITION NO. 7 RADIOACTIVE MATERIAL AUTHORIZATIONS USE OF RADIOACTIVE IODINE, TRITIUM, AND PHOSPHORUS-32

2 October 1997

#### 1. REFERENCES.

a. WRAMC Regulation 40-10, 6 September 1996, Health Physics.

b. AR 40-5, 15 October 1985, Preventive Medicine.

c. AR 385-11, 1 May 1980, Ionizing Radiation Protection (Licensing, Control, Transportation, Disposal, and Radiation Safety).

d. Title 10, Code of Federal Regulations, Part 20, Standards for Protection Against Radiation.

e. Title 10, Code of Federal Regulations, Part 35, Medical Use of Byproduct Material.

f. NRC Regulatory Guide 10.8, Revision 2, Guide for the Preparation of Applications for Medical Use Programs.

g. ICRP Publication 26, Recommendations of the International Commission on Radiological Protection.

h. ICRP Publication 30, Limits for Intakes of Radionuclides by Workers.

2. GENERAL. This condition delineates responsibilities and requirements for utilizing radioactive iodine, tritium or phosphorus-32 in amounts of 1.0 millicurie or greater. Principal Users of radioactive material at WRAMC and tenant activities are responsible for incorporating all applicable precautions listed in this condition into their procedures and assuring that all applicable precautions are followed by the personnel listed on their Radioactive Material Authorizations.

3. RADIOACTIVE IODINE RADIATION SAFETY PRECAUTIONS.

a. The general rules for the safe use of radioactive material specified in Condition 3 for Radioactive Material Authorizations will be followed.

# CONDITION NO. 7 RADIOACTIVE MATERIAL AUTHORIZATIONS USE OF RADIOACTIVE IODINE, TRITIUM, AND PHOSPHORUS-32

b. All laboratory facilities authorized to use radioactive iodine will be equipped with a suitable survey meter. Survey meters will be calibrated by the Health Physics Office. The individual user is responsible for conducting a thorough survey of the work area and immediate vicinity upon completion of all procedures involving more than 0.1 microcurie of radioactive iodine.

c. Perform all procedures involving the use of 1.0 millicurie or more of radioactive iodine in a Health Physics Office approved iodinization box within a ventilation hood. Procurement of the Iodination Box is the responsibility of the individual department and users. Charcoal filters for the iodination boxes will be exchanged by the Health Physics Office on a periodic basis.

d. Perform procedures involving less than 1.0 millicurie of radioactive iodine in ventilation hoods approved by the Health Physics Office. Iodination boxes are not required for these procedures.

e. In the case of therapeutic usage, vent the radioactive iodine vial inside an approved iodination box prior to transport to the patient care area.

f. Coordinate Nuclear Medicine procedures involving the administration of 33 millicuries or more of radioactive iodine-131 with the Health Physics Office as soon as possible in advance of a scheduled treatment.

g. Air monitoring requirements.

(1) In order to assure personnel safety, the following air samples will be collected and evaluated.

(a) Breathing Zone: Collect a sample of the air from the vicinity of the user's mouth and nose throughout each procedure involving volatile radioactive iodine. The user collects this sample using the equipment and instructions provided by the Health Physics Office. Secure breathing zone samples in a container to prevent contamination and turn in to the Health Physics Office for analysis.

(b) Room Air: Continuously collect an air sample that is representative of the air within the room where iodination procedures for a period of one week. Installation, removal and analysis of the filter are the responsibility of the Health Physics Office. Users will assure the sample collection system

## CONDITION NO. 7 RADIOACTIVE MATERIAL AUTHORIZATIONS USE OF RADIOACTIVE IODINE, TRITIUM, AND PHOSPHORUS-32

is operational and report duration of all accidental sampling interruption to the Health Physics Office.

(c) Environmental Effluent Air: Collect a sample of air that is representative of the air being discarded to the environment by the fume hood used for iodination procedures continuously for a period of one week. Installation, removal and analysis of these filters are the responsibility of the Health Physics Office. Users will assure the sample collection system is in continuous operation, and report the duration of all accidental sampling interruptions to the Health Physics Office.

h. Use the below listed equipment (or its equivalent) for collecting air samples:

(1) Vacuum System: A vacuum pump or an in-house vacuum line capable of maintaining a flow rate of 10 liters per minute (lpm) is acceptable. In all cases where an in-house vacuum line is utilized, an additional charcoal impregnated filter will be installed between the vacuum source and the filter used for the same collection.

(2) Collection Filters: The Health Physics Office will supply the two-inch charcoal filters for the collection of the air samples.

i. Bioassay requirements.

(1) The Health Physics Office conducts the bioassay program. Objectives of the program are to:

(a) Indicate whether entry of radionuclides into the body (above background levels) has occurred.

(b) Determine the activity of the intake, dose equivalent to thyroid and committed effective dose equivalent resulting from ingestion or inhalation of radionuclides.

(c) Determine how, when, and why the ingestion or inhalation of the radionuclide occurred to prevent the problem and possible reoccurrence.

(d) Identify any systemic problems with procedures, engineering controls, or protective equipment.

(2) An investigation will be performed when bioassay results indicate the 72-hour thyroid scan exceeds the derived investigation level (DIL) for I-131 where the ALI is 2.0E6 Bq:

Time Post Intake	IRF Total Body	IRF 24-hour urine	IRF Thyroid	DIL Total Body (Bq)	DIL 24-hour urine (Bq)	DIL Thyroid (Bq)
1 day	0.274	0.304	0.133	450	500	219
5 day	0.125	0.00131	0.120	1,027	10.8	986

Table 7-1

(3) The Health Physics Office will determine which personnel require bioassay monitoring and the frequency of monitoring based on the minimum detectable activity (MDA) of the counting system and the time post intake that would exceed 5% of the ALI.

(4) The Principal User will monitor the amounts of iodine used by personnel working under their authorizations and assure their participation in the bioassay program as required.

(5) Monitoring for acute internal deposition of radionuclides will normally be performed under the following circumstances:

(a) When laboratory surveys indicate frequent or gross contamination.

(b) When air sampling indicates levels of airborne contamination exceeding 10% of maximum permissible concentration.

(C) When internal deposition of radioactive material is known or suspected.

(d) When the total amount of I-125 or I-131 handled in any three-month period exceeds the value listed below, all individuals handling this material will participate in a thyroid uptake bioassay program.

Type of Operation	Volatile or Dispersible	Nonvolatile Agent		
Processes in open room or bench with possible escape of iodine from process vessels	0.1 mCi	1 mCi		
Processes with possible escape of iodine carried out within a fume hood of adequate design face velocity, and performance reliability	l mCi	10 mCi		
Processes carried out within glove boxes, ordinarily closed, but with possible release exposure to contaminated box and box leakage	10 mCi	100 mCi		

Table 7-2

# CONDITION NO. 7 RADIOACTIVE MATERIAL AUTHORIZATIONS USE OF RADIOACTIVE IODINE, TRITIUM, AND PHOSPHORUS-32

(e) In compliance with 10 CFR 35, bioassays of each individual that helped prepare or administer at least 33 millicuries of I-131 in either capsules or liquid will be performed within three days after administering the I-131.

(f) All personnel in the Nuclear Medicine Service that works with or around I-125 or I-131 will have routine quarterly bioassay's performed.

4. TRITIUM SAFETY PRECAUTIONS.

a. The general rules for the safe use of radioactive material specified in Condition No. 3 for Radioactive Material Authorizations will be followed.

b. All procedures involving the use of 10.0 millicuries or more of tritium in one month (1.0 millicurie for processes utilizing nucleoside precursors) should be performed in ventilation hoods approved by the Health Physics Office.

c. Bioassay requirements.

(1) The Health Physics Office will conduct the bioassay program. Objectives of the program are to:

(a) Indicate when entry of radionuclides into the body has occurred.

(b) Determine the activity resulting from the ingestion or inhalation of radionuclides.

(c) Determine how, when, and why the ingestion or inhalation of the radionuclide occurred to prevent the problem and possible reoccurrence.

(d) Identify any systemic problems with procedures, engineering controls, or protective equipment.

(2) An investigation will be performed when bioassay results indicate the 24-hour urine sample exceeds the derived investigation level (DIL) where the ALI is 3.0E9 Bq:

Time Post Intake	IRF Total Body	IRF 24-hour urine	DIL Total Body (Bq)	DIL 24-hour urine (Bq)
l day	0.932	0.0392	2,296,000	96,660
5 day	0.705	0.0296	8,690,000	364,900

Table 7-3

(3) The Health Physics Office will determine which personnel require bioassay monitoring and the frequency of monitoring based on the minimum detectable activity of the counting system (MDA) and the time post intake that would exceed 5% of the ALI.

(4) The Principal User will monitor the amounts of tritium used by personnel working under their authorizations and assure their participation in the bioassay program as required.

(5) Monitoring for acute internal deposition of radionuclides will normally be performed under the following circumstances:

(a) When laboratory survey indicates frequent or gross contamination.

(b) When internal deposition of radioactive material is known or suspected.

(c) When the total amount of tritium processed by an individual at any one time, or the total amount processed in any one month exceeds the values listed below, the using individual will participate in the bioassay program.

Type of Operation	RTO & Other Tritiated Compounds including nucleotide precursors	HT or T ₂ Gas in Sealed Process Vessels	HTO Mixed with more than 10 kg of Inert H ₂ O or Other Substances
Processes in open room or bench with possible escape of tritium from process vessels	10 mCi	10 Ci	1 mCi/kg
Processes with possible escape of tritium carried out within a fume hood of adequate design face velocity, and performance reliability	100 mCi	100 Ci	10 mCi/kg
Processes carried out within glove boxes, ordinarily closed, but with possible release of tritium from process & occasional exposure to contaminated box and box leakage	1 Ci	1000 Ci	100 mCi/kg

Table 7-4

# CONDITION NO. 7 RADIOACTIVE MATERIAL AUTHORIZATIONS USE OF RADIOACTIVE IODINE, TRITIUM, AND PHOSPHORUS-32

5. PHOSPHORUS-32 RADIATION SAFETY PRECAUTIONS.

a. Phosphorus-32 is the highest energy radionuclide commonly encountered in research laboratories and as such requires special care. If millicurie quantities are used, finger dosimeters should be worn. The production of bremsstrahlung (x-rays) from  $\beta$ -particles increases with the density of the material, therefore low density materials such as Plexiglas are used as shielding material when quantities greater than 10 mCi are being handled.

b. Always use remote handling tools or lead impregnated rubber gloves.

c. Avoid direct contact with containers of Phosphorus-32.

d. Always use safety glasses.

e. The applicable general rules for the safe use of radioactive material specified in Condition No. 3 for Radioactive Material Authorizations will also be followed.

f. Bioassay requirements.

(1) The Health Physics Office will conduct the bioassay program. Objectives of the program are to:

(a) Indicate when entry of radionuclides into the body has occurred.

(b) Determine the activity resulting from the ingestion or inhalation of radionuclides.

(c) Determine how, when, and why the ingestion or inhalation of the radionuclide occurred to prevent the problem and possible reoccurrence.

(d) Identify any systemic problems with procedures, engineering controls, or protective equipment.

(2) An investigation will be performed when bioassay results indicate the following limit for class D inhalation of P-32 has been exceeded where the ALI is 3.0E7 Bq:

Time Post Intake	IRF Total Body	IRF 24-hour urine	DIL Total Body (Bq)	DIL 24-hour urine (Bq)		
l day	0.523	0.0676	12,896	1,667		
5 day	0.319	0.0171	39,329	2,108		

Table 7-5

(3) The Principal User will determine which personnel require bioassay monitoring based on the amounts and usage of P-32. The Principal User will monitor the amounts of P-32 used by personnel working under their authorizations and assure their participation in the bioassay program as required.

(4) Monitoring for internal deposition of radionuclides will normally be performed under the following circumstances:

(a) When laboratory Survey indicate frequent or gross contamination.

(b) When internal deposition of radioactive material is known or suspected.

(c) When the total amount of Phosphorus-32 processed by an individual at any one time exceeds 25 millicuries the individual will participate in the bioassay program.

Approved:

WILLIAM B. JOHNSON COL, MS Chief, Health Physics Office

# CONDITION NO. 8 RADIOACTIVE MATERIAL AUTHORIZATIONS VENTILATION REQUIREMENTS

2 October 1997

#### 1. REFERENCES.

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a. WRAMC Regulation 40-10, 6 September 1996, Health Physics.

b. AR 40-5, 15 October 1985, Preventive Medicine.

C. AR 385-11, 1 May 1980, Ionizing Radiation Protection (Licensing, Control, Transportation, Disposal, and Radiation Safety).

d. Title 10, Code of Federal Regulations, Part 20, Standards for Protection Against Radiation.

2. GENERAL. Procedures resulting in the generation of radioactive aerosols, dusts or gaseous products shall be conducted in hood, dry box, iodine box or other suitable closed system. Radioactive gases or material with radioactive gaseous daughters shall be stored in gas tight containers and kept in areas having approved ventilation. For handling low to moderate levels of radioactive material, the average velocity through openings in the hood shall be 100 fpm. For highly toxic or high-level radioactive material, the velocity through the opening will be raised to an average of 125 - 150 fpm. The ventilation system will be designed to permit air flow in such a direction that any radioactive material picked up by air will flow away from the worker. The air flow should always be from a non-contaminated area toward the contaminated area. Laboratory ventilation will confine the toxic contaminant, exhaust it with suitable duct work and fans, and pass the material through a collector, scrubber or filter as needed before releasing it to the environment. The ventilation system will also provide sufficient air to make up for the amount exhausted

3. EQUIPMENT DESIGN.

a. Hood design.

# CONDITION NO. 8 RADIOACTIVE MATERIAL AUTHORIZATIONS VENTILATION REQUIREMENTS

(1) A laboratory hood is a simple enclosure in which work can be carried out without toxic materials escaping. In order to keep the material from escaping the enclosure, sufficient air must be exhausted to create an indraft through the face of the hood. This indraft must be strong enough to overcome the actions that allow materials to escape.

(2) Instrument checks on the velocity of air entering the hood will be performed under various conditions encountered during actual operations. Checking air flow patterns with a small source of smoke will be performed indicate the presence of cross drafts that could pull material from the hood.

(3) In general, a hood should be located well away from any doorway where supply air must enter in order to avoid cross drafts.

(4) During periods when the hood is unattended, it may be practical to use somewhat lower velocities, 75 to 80 fpm. Dual speed fans will permit operation at the higher velocity while the hood is in use at the lower velocity when it is closed.

b. Exhaust System.

(1) The exhaust system is designed to remove the airborne materials that are picked up in the hood. To safely vent the contaminated air, it may need to be filtered, or otherwise treated, before discharge to the environment. Cleaning equipment will be selected with view to the corrosive and toxic materials handled and the varying requirements for removal of radioactive materials.

(2) The duct work inside the building will be under negative pressure. Under these conditions any leakage in the duct system will be into the ducts and the radionuclides will be confined. To accomplish this, the fan must be located at the point where the exhaust leaves the building. Duct work connecting several hoods will have streamlined connections. Branch duct should enter at angles of 30 to 45 degrees in order to permit better passage of air at high velocities. In such multiple installations, care should be taken to see that the exhaust system is balanced so that one hood does not provide the bulk of the air for the system.

(3) Velocities of air in ducts should be great enough to maintain minimum transport velocities for the material being conveyed. Usual range of transport velocities for particulate material is 3500 to 4500 fpm.

# CONDITION NO. 8 RADIOACTIVE MATERIAL AUTHORIZATIONS VENTILATION REQUIREMENTS

(4) In hoods where large quantities of water are handled, it is necessary to provide some means of removing the condensation that collects in the duct. When the system is intended to handle corrosive materials, the duct work should be of material resistant to corrosion.

(5) The discharge should be at least five to ten feet above the laboratory roof, located so the fumes will not be carried back into the laboratory or into the air, intake of adjacent buildings.

(6) Clean air must be supplied to replace the air removed by the exhaust system. If adequate air is not supplied to the room, the capacity of the exhaust system and the air velocity at the face of the hood is reduced. If there are multiple exhaust hoods and no makeup air, the airflow may be reversed through a hood that has a smaller fan or is turned off.

4. PROPER USE OF HOODS.

a. Inspect the hood and insure all components are in proper working conditions. Defective components must be repaired or replaced.

b. Insure the direction of air flow into the hood.

c. When the hood door must be partially closed to achieve the proper flow rate, assure the hood door is positioned at the proper heights.

d. Keep sources of contamination, vapor, and flames at least six inches inside the hood.

e. Avoid leaning into the hood.

 $f_{2}$ . In the event that the hood requires maintenance or is broken, notify the Health Physics Office at (202) 356-0058.

Approved:

WILLIAM B. JOHNSON COL, MS Chief, Health Physics Office

# CONDITION NO. 9 RADIOACTIVE MATERIAL AUTHORIZATIONS GAS CHROMATOGRAPH REQUIREMENTS

2 October 1997

#### 1. REFERENCES.

a. WRAMC Regulation 40-10, 6 September 1996, Health Physics.

b. AR 40-5, 15 October 1985, Preventive Medicine.

c. AR 385-11, 1 May 1980, Ionizing Radiation Protection (Licensing, Control, Transportation, Disposal, and Radiation Safety).

d. Title 10, Code of Federal Regulations, Part 20, Standards for Protection Against Radiation.

2. GENERAL. Some gas chromatograph detectors currently used at WRAMC have a radioactive source as a supply of electrons to effect the detection of gasses according to their molecular weights and holdup times.

a. Tritium Foil Type Detectors. Tritium is usually bound to a copper or stainless steel foil as titanium tritide. The binding agent may begin to break down and allow liberation of tritium at temperatures as low as  $150^{\circ}$  C. The gas chromatograph units should have a built-in thermocouple to shut the unit off at  $220^{\circ}$  C since the tritium would probably be entirely evolved at this temperature.

b. ²²⁶Ra, ²¹⁰Pb, ⁹⁰Sr and ⁶³Ni Type Detectors. Temperatures below 500° C are not sufficient to break down the binding of these metallic isotopes to the detector foils. Therefore, moderately high temperatures are not a consideration in their operation. These sources may be partially exposed when dismantling the detector unit and therefore the detector units shall not be dismantled without Health Physics Office approval.

c. Vented Detectors. Some of the detectors are equipped with exit ports for venting potentially contaminated gases. These detectors while in use should be vented into an operating Health Physics approved fume hood.

# CONDITION NO. 9 RADIOACTIVE MATERIAL AUTHORIZATIONS GAS CHROMATOGRAPH REQUIREMENTS

3. RESPONSIBILITIES.

a. The gas chromatograph detector shall be used only by, or under the supervision of, the Principal User. The Principal User is responsible for:

(1) Control, safe operation and security of the gas chromatograph unit.

(2) Training selected individuals in its safe use and operation in accordance with the procedures outlined herein.

(3) Ensuring that these instructions, WRAMC Regulation 40-10, and other pertinent documents are available at all times and are complied with.

(4) Promptly reporting any accident that could result in an unsafe condition to the WRAMC Health Physics Officer at (202) 356-0058.

b. Individual operators are responsible for:

(1) Operating the unit in a safe manner at all times.

(2) Being familiar with the contents of these instructions, WRAMC Regulation 40-10, and other data as prescribed by the Principal User.

(3) Reporting all accidents or abnormal operating conditions that could result in an unsafe condition or exposure of personnel promptly to the Principal User.

4. EMERGENCY PROCEDURES.

a. In the event of an emergency, the following individuals will be notified after turning the power to the instrument off:

- (1) The Principal User.
- (2) Health Physics Officer, WRAMC (202) 356-0058.

b. In the event of **FIRE** in the room, the following will be done **immediately**:

(1) Notify the WRAMC Fire Department (Main Section -(202) 782-3317; Forest Glen Section - (301) 295-7543.

# CONDITION NO. 9 RADIOACTIVE MATERIAL AUTHORIZATIONS GAS CHROMATOGRAPH REQUIREMENTS

(2) Notify the Principal User.

(3) Notify the Health Physics Officer, (202) 356-0058.

(4) The senior individual at the site should clear the area of personnel and attempt to turn off the power to the instrument.

c. Power Failure: In the event of a power failure, no danger exists.

d. Health Physics notification is required prior to any maintenance, change of location, or turn-in of the gas chromatograph. Health Physics coordination must be requested through the Chief, Operations, Health Physics Office.

Approved:

WILLIAM B. JOHNSON COL, MS Chief, Health Physics Office

# APPENDIX A DEFINITIONS AND ABBREVIATIONS

2 October 1997

## 1. DEFINITIONS.

4.10 4.4.74

a. <u>Activity</u>: The rate of disintegration (transformation) or decay of radioactive material. The units of activity are the curie (Ci =  $3.7 \times 10^{10}$  disintegrations per second), and the becquerel (Bq = 1 disintegration per second).

b. Adult: An individual 18 or more years of age.

<u>c. ALARA</u>: Acronym for "As Low As is Reasonably Achievable" means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relations to utilization of nuclear energy and licensed materials in the public interest.

d. <u>Annual Limit on Intake (ALI)</u>: The derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. The ALI is the smaller of the value of intake that would result in a committed effective dose equivalent of 5 rems or a committed dose equivalent of 50 rems to any organ or tissue.

e. <u>Background Radiation</u>: Radiation from cosmic sources; naturally occurring radioactive materials, including radon (except as a decay product of source or special nuclear material) and global fallout as it exists from the testing of nuclear explosive devices. "Background radiation" does not include radiation from source, byproduct, or special nuclear materials regulated by the Nuclear Regulatory Commission.

f. <u>Bioassay</u>: The determination of kinds and quantities or concentrations of radioactive material in the human body. Can be made using direct measurements (in vivo counting) or by analysis of materials excreted or removed from the human body (in vitro). g. <u>Byproduct Material</u>: Such material includes the following:

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material. Generally, byproduct material is any radioactive material inevitably produced as a byproduct from the neutron-induced fission process within nuclear reactors.

(2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" regulated by the NRC under 10 CFR.

h. Code of Federal Regulations (CFR)

i. <u>Committed Dose Equivalent</u>: The dose equivalent to organs or tissues that will be received from intake of a radioactive material by an individual during the 50-year period following intake.

j. <u>Committed Effective Dose Equivalent</u>: The sum of the products of the weighting factors applicable to each of the body organs or tissues and the committed dose equivalent to these organs or tissues.

# k. Department of the Army Radiation Authorization: DARA

1. <u>Declared Pregnant Woman</u>: A woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

m. <u>Deep-dose Equivalent</u>: External whole body exposure dose equivalent at a tissue depth of 1 cm.

n. <u>Derived Investigation Level</u>: Based on ICRP 26 recommendation of 0.3 * f * ALI, where f is the fraction of the year to which the monitoring applies and ALI is the annual limit on intake from ICRP 30.

o. <u>Dose Equivalent</u>: The product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem or sievert (Sv).

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p. <u>Half-life, Radioactive:</u> Time required for half the atoms in a radioactive substance to disintegrate to another nuclear form. Also called physical half-life, and each radionuclide has its own unique half-life.

q. <u>Dose Equivalent</u>: The product of the absorbed dose in tissue and the quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).

r. <u>Gray (Gy)</u>: The SI unit of absorbed dose. One Gy is equal to an absorbed dose of 1 Joule/kilogram (1 Gy = 100 rad).

s. <u>High Radiation Area</u>: An area accessible to individuals in which radiation levels could result in an individual receiving a dose equivalent in excess of 100 mrem in 1 hour at 1 foot from the radiation source or any surface the radiation penetrates.

t. <u>Health Physics Office</u>: HPO

- u. Minimum Detectable Activity: MDA
- v. Nuclear Regulatory Commission: NRC

w. <u>Quality Factor</u>: A modifying factor for the type of radiation to derive dose equivalent from absorbed dose.

x. <u>Rad</u>: The special unit of absorbed dose. One rad is equal to a dose of 100 ergs/gram (1 rad = 0.01 Gy).

y. <u>Radioactive Material</u>: Any material or combination of materials that spontaneously emits gamma rays, X-rays, alpha particles, beta particles, neutrons, or other atomic particles that are capable of producing ions, directly or indirectly by their passage through matter.

z. <u>Radioactive Waste</u>: Solid, liquid, and gaseous materials from nuclear operations that are radioactive or become radioactive and for which there is no further use. Property contaminated with radioactive material to the extent that decontamination is economically unsound.

(1) <u>Short Half-life Radioactive Waste:</u> Radioactive waste containing one or more radionuclides having a radiological half-life of 65 days or less plus the following radionuclides; sulfer-35 (87.44 d), cobalt-58 (70.8 d), iridium-192 (74.02 d), and scandium-46 (83.8 d).

(2) Long Half-life Radioactive Waste: Radioactive waste containing one or more radionuclides having a radioactive half-life of more than 65 days except for the following radionuclides; sulfer-35 (87.44 d), cobalt-58 (70.8 d), iridium-192 (74.02 d), and scandium-46 (83.8 d).

aa. <u>Rem</u>: The special unit of dose equivalent. The absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 Sv).

ab. <u>Restricted Area</u>: An area where access is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials.

ac. <u>Sievert (Sv)</u>: The SI unit of the dose equivalent. The absorbed dose in Gy multiplied by the quality factor (1 Sv = 100 rem).

ad. <u>Specific Activity</u>: Total activity of a given radionuclide per unit mass or volume of a compound, element, or radioactive nuclide.

ae. <u>Total Effective Dose Equivalent</u>: The sum of the deep-dose equivalent and the committed effective dose equivalent.

af. <u>Very High Radiation Area</u>: An area accessible to individuals in which radiation levels could result in an individual receiving an absorbed dose in excess of 500 rads in 1 hour at 1 meter from the radiation source or any surface the radiation penetrates.

ag. <u>Whole Body</u>: For the purpose of external exposure, head, trunk, arms above the elbow, and legs above the knee.