

Summary of Major Changes Radiation Safety Manual, version 07/22/2024

RSM Section	Previous	Updated	Reason
I.B.4.ii	(ii) Voting members may designate someone from their specialty area to attend a RCC meeting in their place if unable to attend a meeting. The designee shall hold a position of similar level and have authority to speak for the area being represented.	(ii) Voting members may not designate someone from their specialty area to attend a RCC meeting in their place if unable to attend a meeting.	Required IAW with 20.3.7.702.D
VI.A.5	5) Sealed sources shall be stored in lead pigs to minimize external radiation fields. An inventory log must be in place to track sealed source movement and ensure accountability. The log should contain removal date and time, worker initials, location of use, and return date and time.	5) Sealed sources may be stored in lead pigs to minimize external radiation fields. Radiation safety will determine if lead pigs are required based on the type of sealed sources and external radiation levels. The permit approval will document this requirement, if needed. An inventory log must be in place to track sealed source movement and ensure accountability. The log should contain removal date and time, worker initials, location of use, and return date and time.	Low activity sources, such as check sources, do not require lead pig shielding. This change provides additional flexibility.
VI.A.6	 RAM in quantities of concern (RAMQC) shall be stored in accordance with UNM policies regarding the physical protection of category 1 and category 2 sources. 	 Special nuclear material (SNM), source material, and reactor fuel shall be stored in accordance with applicable regulations. 	UNM does not have RAMQC that meet 20.3.4.467, Nationally Tracked Source thresholds.
IX.A) & D)	 A) Radiation Safety uses a commercial database (EHSA) to track the total activity of each radionuclide on the UNM campus at any point in time and across all UNM departments. This includes sealed and unsealed radiation sources as well as sources that are specifically licensed, exempt, and generally licensed. Tracking the RAM inventory is essential for demonstrating compliance with possession limits on the RAML and for general overall accountability. D) Radiation Safety tracks RAM inventory from package receipt to final disposition using the EHSA database using the receipt date, activity, lab #, and PH with accountability for 	 A) Radiation Safety uses a commercial database (EHSA) to track RAM inventory from package receipt to final disposition documenting the receipt date, supplier, radionuclide, activity, physical and/or chemical form, lab #, and PH/AU with accountability for decay. The total activity of each radionuclide on the UNM campus can be tracked at any point in time and across all UNM departments. This includes sealed and unsealed radiation sources as well as sources that are specifically licensed, exempt, and generally licensed. Tracking the RAM inventory is essential for demonstrating compliance with possession limits on the RAML and for general overall 	Combine IX.A) and D) into A) and update IAW with 20.3.4.432 and NUREG 1556 Vol 9, rev 3, appendix O.



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RSM Section	Р	revious		Updated	Reason
Section	decay.			accountability.	
IX.E	performed b as required authorities, s National So System (NS Nuclear Mat	inventories will be by Radiation Safety by regulatory such as the urce Tracking TS) and the terial Management ards System	E)	Other RAM inventories will be performed by Radiation Safety as required by regulatory authorities, such as the Nuclear Material Management and Safeguards System (NMMSS).	UNM no longer has category 1 or 2 sources.
IX.G		lear Material (SNM), erial, and RAMQC:	G)	Special Nuclear Material and Source Material:	UNM does not have radioactive materials in quantities of concern (RAMQC)
XI. E	dose in exce annual dose 2) The worker	is required to enter	1)	Adults who in the course of work may exceed in one calendar year 10% of the occupational limits in NMAC 20.3.4.405;	Update section for clarification requested by NMED during renewal review.
	in order to p HRA is an a radiation lev dose equiva	ation area" (HRA) erform their job. A rea in which rels could cause a lent in excess of n 1 hour at 30 cm	2)	Minors likely to receive a deep, lens, or shallow dose equivalent of 50 mrem, 150 mrem, or 500 mrem, respectively; Expecting mothers who have	
	from the sou	urce or from any source penetrates.	4)	declared pregnancy in writing; Individuals entering a high or very	
	a "very high	is required to enter radiation area"	.,	high radiation area, as defined in NMAC 20.3.4.7;	
	job. A VHRA radiation lev	rder to perform their A is an area in which vels could cause a	5)	Independent operators of medical fluoroscopic equipment; or	
	500 rad in 1 from the sou	lent in excess of hour at 100 cm urce or from any source penetrates.	6)	Any person or group of persons carrying out approved activities with radiation sources who, at the discretion of the appointed	
	within 6 feet excludes wo occasional r fluoroscopy involvement	operates a device or works of the device. This orkers with an need to enter a room and have no in operating or he operation of the		Radiation Safety Officer, requires individual monitoring for risk management purposes.	
		idiation worker r pregnancy (a fetal be issued).			



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RSM	Previous	Updated	Reason
Section		•	
XII.B	 6) Ring badges may be issued to workers who regularly handle RAM or whose hands may enter a machine-generated non-sterile radiation field. 7) As deemed appropriate by the RSO, for risk management purposes. B) <u>Nuclear Medicine:</u> a. End-of-workday surveys shall 	 B) <u>Nuclear Medicine</u>: a. Ambient surveys and wipe 	Required IAW with 20.3.4.404, 416, and
	 be performed with a survey instrument in all areas where radiopharmaceuticals were prepared or administered and recorded in mR/hr in Syntrac. b. If radiopharmaceuticals requiring a written directive were used, wipe tests to rule out contamination shall be done in those locations routinely used to prepare and administer the doses, at the end of the day, and recorded in dpm/100 cm². This would apply to the use of therapeutic radiopharmaceuticals or I-131 Nal > 30 uCi. c. Weekly wipe tests are not required by NMED but may be performed in key areas throughout the department at the discretion of the Nuclear Medicine Section Chief. d. Rooms used for in-patient radiopharmaceutical therapy shall be closed following patient discharge until radioactive waste is removed and contamination levels are below established tolerances. 	 tests will be conducted in accordance with 20.3.4.404(D), 20.3.4.416, and 20.3.7.703(H) NMAC, and recorded in mR/hr in the Nuclear Medicine recordkeeping system. End-of-workday (daily) surveys shall be performed with a survey instrument in all areas where radiopharmaceuticals are prepared or administered, except patient rooms. Weekly surveys shall be performed in all areas where radiopharmaceuticals or wastes are stored. Wipe tests shall be performed in all areas where radiopharmaceuticals are preformed and recorded in dpm/100 cm² end-of-workday (daily) in all areas where radiopharmaceuticals requiring a written directive are used and weekly for all other areas where radiopharmaceuticals are routinely prepared, administered, or stored. Rooms used for in-patient radiopharmaceutical therapy shall be closed following patient discharge until radioactive waste is removed and contamination levels are below established tolerances. 	20.3.7.703(H).



Office of Radiation Safety

Radiation Safety Manual

UNM RADIATION SAFETY

1 UNIVERSITY OF NEW MEXICO MSC 08-4560 Albuquerque, NM 87131

REVISION DATE: 07/22/2024

1 University of New Mexico | MSC08 4560 | Albuquerque, NM 87131 hsc.unm.edu/research/radiation-safety

RADIATION SAFETY MANUAL

Revision Date: July 22, 2024

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INTRODUCTION

Safe practices and regulatory compliance are important in all areas that use ionizing radiation sources. The University of New Mexico (UNM) leadership delegates responsibility for global oversight of ionizing radiation sources to the UNM Radiation Control Committee (RCC). Radiation safety policies and procedures are established to ensure the safety of students, employees, patients, and the public, and are consistent with industry standards of practice and regulations. The guidelines of this manual may use the words "shall" or "must", which means it is a mandatory action unless an exception is approved by the UNM Radiation Safety Officer (RSO). Use of the word "should" indicates a procedure or action that is recommended as best practice.

It is imperative that individuals who have been authorized to use radioactive material (RAM) or radiation-producing machines know the applicable regulations and follow established radiation safety policies and procedures. Failure to follow the established rules of practice places the University at risk of regulatory violations and possible suspension of the UNM radioactive materials license (RAML).

It is not the intent of this Radiation Safety Manual (RSM) to duplicate State and Federal codes that govern radiation use. The purpose is to highlight and summarize key requirements for authorized individuals to safely use radiation sources and has an emphasis on the research and academic (non-medical) environment. Medical human-use applications of radiation sources are governed by policies, procedures, protocols, and guidelines established by Radiology leadership at the University of New Mexico Hospital (UNMH), which includes Sandoval Regional Medical Center (SRMC). The RSO is responsible to develop and implement any additional rules and guidelines deemed necessary to support a safe radiological environment campus-wide.

New Mexico is an "Agreement State", which means that the State has entered into an agreement with the Nuclear Regulatory Commission (NRC) to regulate RAM, except for those related to nuclear power. The specific regulatory authority is the New Mexico Environment Department (NMED) and the regulatory code and statutes are found in the New Mexico Administrative Code (NMAC), with some NRC regulations incorporated by reference. Radiation-producing machines are regulated by NMED.

The RSM is listed as a license condition on the UNM RAML and thus carries the force of law. When the requirements of this RSM are more restrictive than the applicable regulation, this constitutes internal UNM policy and shall be followed. A violation of the more restrictive rules (or any regulation) becomes a matter for RCC review and may also be citable by NMED if discovered.

When license conditions, regulations, or operations change significantly, the RSM will be revised, and a copy submitted to NMED for approval. Once approved, the revised manual will be distributed to key stakeholders and posted to the Radiation Safety website. UNM Radiation Safety Office staff are available to provide consultation on radiation safety at any time. A "Radiation Safety Office Contact List" is posted in all areas where radiation sources are used and stored. A current copy of this list is available by contacting the UNM Radiation Safety Office.

All Permit Holders, Authorized Users, and supervised radiation workers shall review the Radiation Safety Manual at least annually and following any revision, with documentation maintained in the Laboratory Notebook or an equivalent record.

RADIATION SAFETY CULTURE

Ionizing radiation sources used at UNM are licensed by both NMED and the NRC and are overseen internally by the UNM Radiation Control Committee (RCC) and the UNM Radiation Safety Officer (RSO). Individuals authorized to possess, use, handle, store, and dispose of radiation sources are required to maintain a safe and secure radiological work environment and to enforce a philosophy of maintaining radiation dose as low as reasonably achievable (ALARA) for workers, students, patients, and the public. UNM supports a positive safety culture, where workers are encouraged to freely raise safety concerns without fear of retaliation.

NRC Definition of Safety Culture:

"The core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment."

Traits of a Positive Safety Culture:

The following are personal and organizational traits of a positive safety culture:

Leadership Safety Values and Actions	Problem Identification and Resolution	Personal Accountability
Leaders demonstrate a commitment to safety in their decisions and behaviors	Promptly and fully identify, evaluate, and correct safety issues regardless of significance	Take responsibility for safety and be accountable
Work Processes	Continuous Learning	Environment for Raising Concerns
Plan, implement, and control work activities so that safety is maintained	Seek out opportunities to learn, and stay abreast of emerging safety technology	Encourage raising safety concerns without fear of retaliation, intimidation, harassment, or discrimination
Effective Safety Communications	Respectful Work Environment	Questioning Attitude
Maintain a focus on safety by establishing open communication	Permeate trust and respect through the organization	Avoid complacency and continually challenge existing conditions to identify discrepancies that might result in inappropriate action

UNM Radiation Safety Culture Policy Statement:

UNM is committed to a positive safety culture extending to Permit Holders, Authorized Users, and supervised individuals. Positive safety culture shall be an integral part of all regulated activities and based on a foundation of function-specific training in routine operational and emergency response procedures. The goal is to optimize the beneficial uses of radiation, minimize radiation exposure to staff, patients, and members of the public, and ensure regulatory compliance. A culture where radiation workers feel free to openly raise any safety concern without fear of retaliation shall be fostered, and the UNM Radiation Safety Office and management shall respectfully address all concerns.

Reference: NRC Final Safety Culture statement, NRC-2010-0282, Federal Register 76:34773–34778; 2011.

I. RADIATION CONTROL COMMITTEE (RCC) CHARTER and BYLAWS:

- A) <u>Purpose of the RCC:</u>
 - 1) The UNM President delegates global radiation safety oversight to the RCC, to ensure that all ionizing radiation sources, including radiation-producing machines and RAM, are used safely at all UNM facilities and in compliance with regulations and RAML conditions.
 - 2) The RSO, together with UNM departmental leadership, establishes policies, procedures, and guidelines to meet this responsibility.
 - 3) The RCC reports to the Vice President for Research, who represents "Licensee Management", and both, together with the RSO, make up the Management Triangle shown below, with responsibility for oversight of radiation safety activities. The organizational chart is shown in <u>Attachment A</u>.





- B) Organizational Details of the RCC:
 - 1) The name of this committee is the Radiation Control Committee, abbreviated "RCC".
 - 2) Membership:
 - (i) The membership shall consist of no fewer than five voting members and include an Authorized User (AU) for each type of use, the RSO, a nursing service representative, and an Executive Management representative or designee. The members shall be knowledgeable in radiation safety, or, have some special interest that may enhance the committee purpose, and should be members of the UNM faculty or staff, or on retainer for special UNM services. The Committee may designate non-voting ex-officio members. <u>Attachment B</u> contains the suggested RCC membership.
 - (ii) Appointments to membership will be made by the Vice President for Research for a three-year term, as recommended by the RSO and/or RCC. A member may be reappointed for more than one term.
 - 3) <u>Chair</u>:
 - (i) One voting member of the RCC will be appointed as Chair and one voting member may be appointed as Vice-Chair by the Vice President for Research.
 - (ii) The Chair of the RCC serves as the administrative officer in promulgating the policies, procedures, standards, and rulings of the Committee. Strict objectivity shall be exercised by the Chair to avoid any perceived conflict of interest, and specifically abstain from voting when such decisions impact the specialty area of the Chair (if an Authorized User or Permit Holder).
 - (iii) The Chair shall preside over RCC meetings and have authority to call special committee meetings. The Vice-Chair shall preside over meetings when the Chair is absent.

- (iv) In the absence of the Chair and Vice-Chair, one of the voting members may serve as Acting Chair, as approved by majority vote, and shall be duly recorded in the minutes.
- 4) <u>Quorum</u>:
 - (i) To establish quorum, 50% of the voting members must be present including the RSO and Executive Management representation.
 - (ii) Voting members may not designate someone from their specialty area to attend a RCC meeting in their place if unable to attend a meeting.
- 5) <u>Meeting Frequency</u>:
 - (i) The RCC shall meet at least quarterly and more frequently as needed. Dates, times, and locations of meetings will be set by the Chair. Minutes shall be recorded, distributed to committee members, and retained for inspection.
- 6) Authorized Representation Between Meetings:
 - (i) The RCC may be virtually mobilized at any time for a vote in cases of required, time sensitive modifications and approvals to existing programs, upon the recommendation of the RSO. Examples of such actions include adding a Permit Holder or Authorized User, adding a radionuclide, modifying a possession limit, or expanding a research project. The RSO will be responsible to submit details of the required action and monitor votes. The action shall be approved upon receipt of a majority vote (> 50% of membership). The approved action will be reported to the RCC at the next scheduled meeting.
 - (ii) The RSO is authorized to act for the RCC in between meetings for routine matters and administrative changes that pose no health and safety concerns. Examples include small possession limit changes, simple location of use (LOU) changes, or renewing a Permit with only minor changes.
- 7) <u>RCC Subcommittees</u>:
 - (i) A Human Use Subcommittee (HUS) is in place to review human research protocols that include the use of ionizing radiation.
 - (ii) The meeting frequency for HUS is quarterly, following each RCC meeting.
 - (iii) The HUS membership may include voting and ex officio members of the RCC who have responsibilities in clinical patient care areas such as Nuclear Medicine and Radiation Oncology. The RSO (or designee) and an Imaging Physicist shall also serve on the HUS.
 - (iv) The HUS is responsible to evaluate the use of ionizing radiation in the protocol, determine if the use is standard of care (SOC), research only, or a combination of both, and confirm that the proposed total effective dose equivalent to the research subject is correct and reasonable.
 - (v) The HUS shall advise the Principal Investigator (PI) named on the study and the UNM Institutional Review Board (IRB) of its decision upon conclusion of the assessment.
 - (vi) The RCC may establish additional subcommittees as needed to fulfill its responsibility.
- C) <u>Responsibilities of the RCC</u>:
 - 1) In fulfilling its authorized purpose, the RCC is charged with the following responsibilities:
 - (i) Assess radiological procedures for risk and propose special conditions, requirements, and/or restrictions as deemed necessary to minimize ionizing radiation hazards.

- (ii) Review and approve or disapprove, individuals in application for Authorized User (AU), Permit Holder (PH), Authorized Medical Physicist (AMP), RSO, and Associate RSO (ARSO), the latter two both requiring subsequent NMED approval.
- (iii) Review and approve or disapprove, new or revised protocols that involve radiation.
- (iv) Review and approve or disapprove, ministerial changes to the radiation safety program and other changes requiring approval by NMED such as license amendments and renewals.
- (v) Review quarterly ALARA reports and dosimetry data.
- (vi) Evaluate radiological incidents, medical events, reportable events, inspection outcomes and Notices of Violation (NOVs) as well as proposed solution(s) to prevent recurrence.
- (vii) Review the radiation protection program annually.
- (viii) Complaints and safety concerns regarding any radiological practice can be made to any committee member who shall bring the complaint to the full committee for consideration and action. Complaints shall be considered confidential if requested by the complainant.
- E) Appeals to Actions Taken by the RCC:
 - 1) An individual, department, or division may appeal actions taken by the RCC to the President of the University (via the Vice President for Research) for final decision, with the knowledge and consent of the Dean or Director of the College, School, or Department involved.
- F) <u>Annual Reviews by the RCC</u>:
 - 1) The RCC members shall review and approve the RCC Charter/Bylaws with each content change considered significant.
 - 2) The RSO will review (and revise as needed) the RSM biennially, with approval from the RCC. The revised manual will be forwarded to NMED for approval and incorporation into the RAML.
 - 3) The RSO will review the Radiation Safety Program annually and provide the report to the RCC and to the Vice President for Research.

G) Role of "Licensee Management": (NMAC 20.3.7.7M)

- 1) Licensee Management is defined as the Chief Executive Officer (CEO) or other individual having the authority to manage, direct, and approve the activities of the radiation safety program, or that person's delegate(s). The Vice President for Research serves in this role at UNM.
- 2) <u>Responsibilities of Licensee Management:</u> (NMAC 20.3.7.702E)
 - (i) Maintain familiarity with radiation safety program operations including security and control and routine and emergency operating procedures.
 - (ii) Promote complete and accurate radiation protection records and reports.
 - (iii) Approve licensing actions such as amendments and renewals.
 - (iv) Assist the RSO and RCC with matters of regulatory compliance when needed.
 - (v) Provide adequate resources (financial, space, equipment, personnel, time) for radiation safety and support regulatory compliance.
 - (vi) Jointly with the RCC, appoint a qualified and competent RSO.

II. RADIATION SAFETY OFFICER (RSO):

- A) The UNM radiation safety program is managed by the RSO, who is named on the RAML, and reports to the Vice President for Research through the Health Science Center (HSC) Executive Director. The RSO is responsible for developing, implementing, and overseeing an effective and compliant radiation safety program. The RSO shall support radiation safety improvement initiatives, facilitate the beneficial uses of radiation, take actions to minimize radiation risk and hazard, and to work cooperatively with the RCC and with Management.
- B) <u>RSO responsibilities</u>:
 - 1) Advise radiation workers on best radiation safety practices to avoid health and safety issues.
 - 2) Support proper selection of radiological controls, training, and procedures for end-users.
 - 3) Establish routine and emergency procedures for the Radiation Safety Office and update periodically to ensure accuracy and to conform with regulations.
 - 4) Oversee and approve function-specific radiation safety training content and competencies.
 - 5) Ensure that required radiation safety tasks (radiation surveys, inventory and leak tests, instrument QC, etc.) are performed and documented at the established frequency.
 - 6) Ensure that personnel monitoring devices are properly used and stored and that dosimetry and ALARA reports are issued to end-users.
 - 7) Notify NMED of reportable events such as medical events.
 - 8) Maintain the RAML and x-ray registrations.
 - 9) Institute corrective and preventative actions when needed, including shutdown of operations, when unsafe or non-compliant radiological conditions are identified.
 - 10) Maintain radiation safety records accurately, legibly, and in auditable and accessible format.
 - 11) Properly order, receive, store, label, transport, secure, and dispose of radiation sources.
 - 12) Ensure that RAM inventories in laboratories are performed at the required frequency.
 - 13) Supervise radioactive waste storage and final disposal.
 - 14) Prepare the agenda and minutes for RCC meetings.
 - 15) Perform the "Annual Audit of the Radiation Safety Program" each calendar year.

III. PERMIT HOLDERS and AUTHORIZED USERS:

- A) A <u>Permit Holder</u> (PH) is a UNM faculty member, physician, or other qualified professional who has made application to the RSO and has been approved by the RCC to use radiation sources in specific protocols. Once approved, a "Radiation Permit" is issued and includes a list of approved radiation sources and possession limits, authorized use locations, and conditions of use.
- B) An <u>Authorized User</u> (AU) is a physician who has been approved by the RCC to use radiation sources in specific amounts for human-use modalities. Approval is based on the applicant meeting the required training and experience specified for the category of use requested. An AU may be an individual Permit Holder or a Chief Permit Holder for a Master Radiation Permit in a specific division, which has related AU's listed under the same Permit. This latter model is used in Nuclear Medicine, Radiation Oncology, and Interventional Radiology.
- C) An Authorized Medical Physicist (AMP) is an Oncology physicist who has met the required training and experience qualifications and has been approved by the RCC.

D) <u>Responsibilities of PH and AU</u>:

- 1) Assure that survey instruments are available to supervised workers, sensitive to the types of radiation in use, in good operating condition, and calibrated at the appropriate frequency.
- 2) Provide training to supervised workers on use protocols, safe handling, storage, disposal, survey techniques, proper use of personal protective equipment (PPE), security and control, and routine and emergency procedures.
- 3) Enforce the use of personnel monitoring devices as assigned.
- 4) Perform area and contamination surveys at the required frequency.
- 5) If supervised workers are allowed to receive, ship, or transfer RAM, ensure that the required training program(s) are completed at the established frequency (see Attachment D).
- 6) Follow all UNM policies for RAM procurement, use, possession, storage, inventory, transfer, posting and labeling, and disposition of radiation sources.
- 7) Maintain strict security and control measures to prevent unauthorized access or removal.
- 8) Notify the RSO if a radiation incident occurs (major spill or contamination, fire, loss of RAM, medical event etc.), or if a radiation overexposure may have occurred.
- 9) Arrange for an Alternate Permit Holder to manage lab oversight during times of extended leave.
- 10) Maintain required records in auditable format in the Laboratory Notebook or the equivalent.

IV. <u>REGULATIONS AND LICENSES</u>:

A) NMAC regulations are available on-line at <u>http://www.env.nm.gov/rcb/regulations</u> and are also available from UNM Radiation Safety. The main NMAC sections follow:

1) New Mexico Administrative Code (NMAC):

- (i) Title 20 (Environmental Protection), Chapter 3 (Radiation Protection), Parts:
 - 1: General Provisions
 - 2: Registration of Radiation Machines and Services
 - 3: Licensing of Radioactive Materials
 - 4: Standards for Protection Against Radiation
 - 6: X-Ray in the Healing Arts
 - 7: Medical Use of Radionuclides
 - 8: Radiation Safety Requirements for Analytical X-Ray Equipment
 - 10: Notices, Instructions and Reports to Workers: Inspections
 - 11: Cabinet X-Ray Systems
 - 15: Licenses and Radiation Safety Requirements for Irradiators
 - 16: Fees for Licensure of Radioactive Materials
 - 20: Medical Imaging and Radiation Therapy Licensure

2) Nuclear Regulatory Commission (NRC) Regulations:

- (i) Title 10 CFR (Energy) regulations are at <u>www.nrc.gov</u>.
 - (a) Applicable Parts for Byproduct Material:
 - 19: Notices, Instructions and Reports to Workers: Inspections and Investigations
 - 20: Standards for Protection Against Radiation
 - 30: Rules of General Applicability to Domestic Licensing of Byproduct Material
 - 33: Specific Domestic Licenses of Broad Scope for Byproduct Material
 - 34: Licenses for Industrial Radiography Safety Requirements for Industrial Radiographic

Operations

- 35: Medical Use of Byproduct Material
- 36: Licenses and Radiation Safety Requirements for Irradiators
- 37: Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material
- 71: Packaging and Transportation of Radioactive Material
- (b) Applicable Parts for Research Reactors, Source, and Special Nuclear Material (SNM):
 - 37: Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material
 - 40: Domestic Licensing of Source Material
 - 50: Domestic Licensing of Production and Utilization Facilities
 - 55: Operators' Licenses
 - 70: Domestic Licensing of Special Nuclear Material
 - 73: Physical Protection of Plants and Materials
 - 74: Material Control and Accounting of Special Nuclear Material

3) US Department of Transportation (DOT) Hazardous Materials Regulations (HMR):

i) 49 CFR Parts: 171-185

171: General Information, Regulations, and Definitions

172: Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, Training Requirements, and Security Plans

173: Shippers - General Requirements for Shipments and Packagings

- 174: Carriage by Rail
- 175: Carriage by Aircraft
- 176: Carriage by Vessel
- 177: Carriage by Public Highway
- 178: Specifications for Packagings
- 179: Specifications for Tank Cars

180: Continuing Qualifications and Maintenance of Packagings

181 - 185 Reserved

4) <u>Radioactive Materials Licenses at UNM</u>:

- i) NMED BM233 Broad Scope Type A License
- ii) NRC AGN-201M Research Reactor License #R-102

V. <u>APPLICATIONS TO USE IONIZING RADIATION SOURCES:</u>

A) Application for RAM:

- 1) A UNM faculty member (or other approved individual) may apply to use radiation sources by submitting a completed application form (see <u>Attachment E</u>). The RSO will review the application and work with the applicant to obtain any additional information needed.
- 2) The RCC will review and approve Permit applications and a Radiation Permit issued by the RSO. An in-between-committee (IBC) process with mail ballot may be used to expedite approval of

applications and formally acted upon at the next scheduled RCC meeting.

- 3) Applications will include all types of RAM to be possessed, including those identified in the regulations as licensed, exempt, or generally licensed.
- 4) <u>Permit Application Content</u>:
 - (i) The Application Form with copies of all protocols being requested as well as types, forms, and quantities of RAM to be used, including sealed and unsealed radionuclides. For sealed sources, include the manufacturer, model number, radionuclide, source configuration, and activity should be provided. Manufacturer papers should be included with exposure rate(s) outside the source or source holder and safe handling and storage techniques.
 - (ii) Location(s) of use by building and room number including the exact use location within the room with information on security and access control.
 - (iii) Detailed description of how the RAM will be used and stored, including a justification for the use and amount of each radioisotope requested. Describe how the benefit from the use of the radiation source will outweigh the risk.
 - (iv) Training, education, and experience related to the radioisotopes and protocols being requested. If the applicant was ever named as a PH or AU on a previous RAML, a copy of the license should be attached. A condensed CV should be included.
 - (v) Instruments to detect and measure radiation should be described.
 - (vi) If radioisotopes are gaseous or can aerosolize, techniques and equipment to control release must be provided along with exhaust and filtration methods to ensure breathing zone safety.
 - (vii) A complete description of the radiation safety program to be employed to include shielding, protective clothing (PPE), handling techniques, posting and labeling, and training.
 - (viii) Describe all radioactive waste to be generated. A statement that mixed waste will not be generated is specifically required. The applicant must also provide a statement that commits to radioactive waste minimization and segregation.
 - (ix) Provide the names and titles of personnel who will work with RAM. A "Statement of Training and Experience Form" must be provided for workers.
 - (x) Name an "Alternate PH", with written confirmation of acceptance of that duty.

B) Application for Radiation-Producing Machines:

1) A separate application form is available for medical x-ray machines, cabinet x-ray units, analytical devices, electron microscopes, research accelerators, and any other device with an x-ray tube or that

produces radiation when energized, intentional or incidental. Information to be submitted for radiation-producing systems include:

- Machine specifications (kVp, mA, timer settings, target, beam dimensions, etc.).
- Associated equipment and safety tools (ventilation, lead shields, etc.).
- Detailed proposed use of the system with utilization.
- Complete analysis of all radiation hazards and methods to ensure safety.
- Routine preventative maintenance and quality control testing.
- Interlocks and monitoring systems.
- Shielding design, shown on a facility diagram (may require NMED approval).
- Administrative and engineering controls to minimize radiation exposure.
- C) <u>Animal use</u> protocols require special consideration and must be approved by the UNM Institutional Animal Care and Use Committee (IACUC). Injection and caging areas must have adequate ventilation to assure that adjacent areas comply with NMAC Subpart 4, Appendix B standards. Animal caretakers shall have function-specific radiation safety training.
- D) If a Permit Holder terminates, another qualified individual may assume operations by submitting an application and receiving RCC approval. A new Permit and Permit # may be issued or the Permit transferred to the individual as authorized by the RSO and RCC.
- E) If a Permit Holder wishes to terminate without Permit transfer, all radiation sources must be properly disposed according to UNM policy, a lab close-out survey completed by Radiation Safety, and the Radiation Permit terminated. The Permit Holder is responsible for all costs associated with RAM disposal or transfer and clearing equipment from the lab.
- F) RAM is not transferable between Permit Holders without RSO approval and completion of the required form. Transfer documents signed by the transferor and transferee must be prepared and include the radionuclide, activity, purpose, and location(s). RAM transfers between UNM Permit Holders and non-UNM collaborators must be coordinated by the RSO.
- G) Permit Holders may order and possess radioisotopes up to the quantities authorized on the Permit, and shall maintain a current inventory of radioisotopes, including waste.
- H) Permits are valid for 4 years. The Permit Holder shall request renewal at least 3 months before the expiration date, noting any changes and including PH and Alternate signatures. The Permit shall not expire until the next scheduled RCC meeting.
- Changes to an existing Permit may be requested in writing to the RSO. Possession limits may be modified to reflect actual usage, radionuclides added or deleted, or new use protocols proposed. Other changes requiring RSO notification include change of Alternate or adding or deleting RAM use locations. Permit Amendments will be issued once approved.
- J) A Radiation Permit that has been inactive for 4 years will be subject to termination. In special cases, the RSO may approve inactive Permit status without termination, on a case-by-case basis.

VI. <u>STORAGE OF RAM:</u>

- A) Storage areas for RAM shall meet the following criteria:
 - 1) Shielding or distance shall be used to reduce radiation levels to not more than 2 mrem in any one hour at 1 meter away from the source container. Shielding or distance must be adequate to ensure that radiation levels in adjacent areas are indistinguishable from normal background levels.
 - 2) Labs designated as restricted radiation areas shall be secured from unauthorized access. RAM shall be secured from unauthorized use or removal using locked refrigerators, freezers, or cabinets.

- 3) Unsealed RAM, such as liquids and powders, shall be stored in closed containers. Secondary containment shall be used to contain the entire contents in the event the primary container ruptures.
- 4) RAM capable of producing gas, fumes, vapors, or any amount of airborne particulate shall have the necessary engineering controls in place to control the hazard (ie. certified fume hood with appropriate filtration). Airflow rates shall be confirmed annually and comply with industry standards. For radioactive gases such as ¹³³Xe, negative pressure rooms are preferred, with gas clearance times calculated semi-annually and posted.
- 5) Sealed sources may be stored in lead pigs to minimize external radiation fields. Radiation safety will determine if lead pigs are required based on the type of sealed sources and external radiation levels. The permit approval will document this requirement, if needed. An inventory log must be in place to track sealed source movement and ensure accountability. The log should contain removal date and time, worker initials, location of use, and return date and time.
- 6) Special nuclear material (SNM), source material, and reactor fuel shall be stored in accordance with applicable regulations.
- B) <u>Radioactive Animals</u>:
 - 1) Biological waste such as animal carcasses and bedding must be sealed in leakproof containers and refrigerated for short term storage (days) or frozen when storage will exceed a week. A walk-in freezer for biological waste is available at the Radioactive Waste Facility (RWF).
 - 2) Animals injected with RAM shall be housed in separate cages from non-radioactive animals. The cages shall bear the standard "Caution-Radioactive Materials" sign. Identifying labels shall indicate the radionuclide, activity, date, and the responsible Permit Holder.
- C) Radioactive Waste (RAW) Storage (see Section X):
 - 1) Permit Holders are responsible to provide adequate space in their lab for RAW storage.
 - 2) Containers holding RAW shall have a plastic liner, maintained separately from non-radioactive waste, and labeled with waste form, isotope, date, activity, and the radiation warning symbol. Containers shall be approved by Radiation Safety.
 - 3) RAW containers shall be covered, large enough to hold the contents without overflow, leakproof, and shielded as needed to minimize exposure.
 - 4) When waste containers become filled to the maximum level allowed, complete the waste collection form and contact Radiation Safety for pickup.

VII. ORDER and RECEIPT of RADIATION SOURCES:

- A) An approved list of RAM vendors is maintained, with each provided a copy of the current RAML. To add a new vendor, send the company name, address, and contact number to Radiation Safety.
- B) RAM packages for research and some sealed sources are delivered to the UNM Radiation Safety Lab in Fitz Hall Room B89. The complete shipping address is:
 - 1) UNM Health Science Center Office of Research, Radiation Safety Office, Fitz Hall Room B-89, 2425 Camino de Salud, Albuquerque, NM 87131
 - 2) RAM orders must be scheduled to arrive Monday Friday during normal business hours, 8:00 AM 5:00 PM. Special arrangements must be made in advance with the RSO for after-hours deliveries.
- C) RAM orders must be approved by Radiation Safety and an authorization code issued before the order is placed, including exempt amounts and generally licensed radiation sources. To place an order:

(1) Order radioisotopes and amounts only as authorized by your Radiation Permit.

- (2) Contact Radiation Safety to obtain approval and an authorization code. State your name, lab #, and name of Permit Holder, and identify the material to be ordered (radiochemical and activity). Provide the vendor name, expected delivery date, and tracking number when available.
 - (a) Note: If generating activation products from irradiation of materials, the same rules apply for acquiring, receiving, processing, and transferring RAM. The Permit Holder is bound by possession limits on the Radiation Permit.
- (3) Place the RAM order with the vendor making sure to:
 - (a) Instruct the vendor to reference the authorization code on the shipping papers.
 - (b) Ensure vendor has the "ship to" address for the Radiation Safety Lab in Fitz B-89.
 - (c) Have the vendor confirm the delivery date.
 - (d) Obtain a tracking number when available.
- D) Shipping radioactive samples or returning a spent radiation source to the manufacturer generally requires Radiation Safety assistance in preparing the package and associated paperwork, unless the end-user has been specially trained in this process. Contact Radiation Safety for specific instruction.
- E) Nuclear Medicine unit dose radiopharmaceuticals shall be delivered directly to UNMH, OSIS, and SRMC by a radiopharmacy courier or another authorized carrier such as FedEx. The package shall be promptly processed according to the UNMH RAM Package receipt policy.
- F) HDR sources for the UNMCCC will be delivered direct to the UNMCCC Radiation Oncology department by Fed Ex. Radiation Safety will be alerted to the delivery and will process the package.
- G) <u>Receipt of RAM by Radiation safety</u>:
 - 1) Process packages within 3 hours of receipt (NMAC 20.3.4.432) following radiation safety procedures. If received after working hours, process the next business day, according to the UNM "RAM Package Receipt Procedure".
 - 2) Packages will be promptly delivered to the end-user, requiring a signature by an authorized person. RAM packages will not be left unattended or without signature.
 - 3) The end-user shall place the RAM in its designated storage location. Radiation Safety will take the packing material and shipping box, deface (with a black sharpie) or remove all radiation symbols and markings, and discard as normal trash.
 - 4) If a vendor mistakenly ships a RAM package direct to the end-user, bypassing the Radiation Safety Lab, <u>do not open the package</u>. Contact the RSO to process the package.

VIII. TRAINING FOR RADIATION WORKERS:

- A) General:
 - Annual radiation safety training is required for workers likely to exceed 100 mrem per year from normal or abnormal situations. The training may be in the format of live presentations, computerbased self-learning programs, the UNM Learning Central platform, or other approved method. Training records shall be maintained and include the participants name, completion date, instructor name, results of a competency exam if applicable, and the content outline.
 - 2) All radiation workers issued a personnel dosimeter must complete HSC-181.
- B) <u>Research and Academic</u>:
 - 1) Personnel working with unsealed radiation sources in research must complete initial Radiation Safety training which is function-specific to the research environment and includes a practical

training component. This initial training is required before beginning independent work with research radioisotopes. The PH is also required to provide initial applications and operational training in all active protocols that utilize RAM. It is the responsibility of each PH to ensure that only trained and competent staff handle RAM, and that an adequate level of supervision is in place to ensure continuous safe practices. Annual refresher training is also required using the Learning Central course "HSC Radiation Safety Refresher Training" (HSC-180). Verification of completed training is done during routine lab audits by Radiation Safety.

- 2) For individuals using only industrial and analytical devices or sealed sources in research, initial and annual refresher Radiation Safety training is required through Learning Central course HSC-112-002. Workers must be initially trained by the PH on the use of the devices or sources with competency established before the worker's name is placed on the "Approved User List", which is posted near the device.
- 3) For workers and students in Nuclear Engineering, the Learning Central course HSC-180 is required. Additional courses of instruction are provided by the Nuclear Engineering department that includes function-specific training for the nuclear environment and includes radiation protection, instrumentation, detection and measurement, reactor safety, and radiation health effects.
- C) Nuclear Medicine:
 - 1) Certified Nuclear Medicine Technologists (CNMTs) work independently under the general supervision of AUs in Nuclear Medicine. The CNMT designation along with valid State of New Mexico licensure are required prerequisites for this job.
 - 2) Initial documented operational competencies are established for each new CNMT by Radiology management before independent handling of radiopharmaceuticals.
 - 3) Initial and annual refresher Radiation Safety training is required through Learning Central course HSC-212-001 and HSC-212-004 for spill response training. This is required for CNMTs and AUs in Nuclear Medicine and for staff in Interventional Radiology (IR) who work with Y-90 microspheres.
 - 4) DOT Hazardous Material training is required every 3 years for any UNM worker who is required to prepare RAM for shipment or receives RAM packages.
 - 5) Nuclear Medicine students in the UNM Allied Health School are required to complete an initial radiation safety orientation at the start of their school year. Students are not permitted to administer patient doses unless a CNMT has confirmed the radionuclide, dose, and patient ID, and has confirmed the details of the request form or written directive (WD). Students operate under the direct supervision of a CNMT for the purposes of dose ordering, receipt, preparation, and injection.

D) <u>UNMCCC</u>:

- 1) Radiation workers include AUs, AMPs, Radiation Therapists, and other care providers such as nurses and other advanced practice specialists assisting with patient care.
- 2) Radiation Therapists work independently under the general supervision of AUs in Radiation Oncology. The RT designation along with valid State of New Mexico licensure are required prerequisites for this job.
- An annual Radiation Safety in-service may be provided by the Chief AMP. Alternately a Learning Central course HSC-212-014 "Radiation Safety for Cancer Center Radiation Oncology Training" may be used.
- 4) Annual HDR Emergency Response training is required for all staff working with HDR. The training is provided by the HDR manufacturer or the equivalent.

- E) Radiology:
 - 1) X-Ray Technologists (XRTs) work independently under the general supervision of Radiologists and Radiology Management. The XRT designation, along with any additional certification specialty that is applicable, and with valid State of New Mexico licensure, are required prerequisites for this job.
 - 2) Annual radiation safety training is conducted using Learning Central course CE 032.9 "Radiation Safety for Radiology Staff".
 - 3) HSC-183 "Fluoroscopy Safety" is available on Learning Central. The intended audience are non-Radiologist physician providers in specialty areas such as Cardiology, Urology, Endoscopy, Pulmonary Care, Surgery, and Orthopedics. A collaborative effort is in place between the Medical Staff office and Radiation Safety to assign this course to all new incoming house staff who will work with fluoroscopy machines, as part of their orientation.
- F) Ancillary Staff:
 - A "Radiation Safety General Awareness training class" is available on Learning Central, CLT-2109, and intended for ancillary staff such as Environmental Services (EVS), EH&S, Security Officers, UNMPD, Facilities, and other groups who have no direct responsibilities for radiation sources but may need to frequent areas where they are used.

IX. RAM INVENTORY AND LEAK TESTING:

- A) Radiation Safety uses a commercial database (EHSA) to track RAM inventory from package receipt to final disposition documenting the receipt date, supplier, radionuclide, activity, physical and/or chemical form, lab #, and PH/AU with accountability for decay. The total activity of each radionuclide on the UNM campus can be tracked at any point in time and across all UNM departments. This includes sealed and unsealed radiation sources as well as sources that are specifically licensed, exempt, and generally licensed. Tracking the RAM inventory is essential for demonstrating compliance with possession limits on the RAML and for general overall accountability.
- B) Each Radiation Permit has defined activity limits (mCi) for each radionuclide. The Permit Holder is required to remain below the limits at all times including:
 - 1) Total activity of each radionuclide at any point in time (includes radioactive waste).
 - 2) Total activity of each radionuclide to be ordered in a single shipment (for research use).
- C) Strict inventory control methods must be employed by Permit Holders to track when radiation sources are removed from and returned to the authorized storage location. For stock vials of radio-chemicals, documentation of each aliquot removed is required, including the date, user initials, activity removed (uCi), and activity in waste or in samples. The contents of stock vials should be tracked on inventory logs (including decay) designed for that purpose.
- D) RAM inventory verifications are performed semiannually. Non-medical Permit Holders shall be provided with a "RAM Inventory Verification" (RMIV) log and shall promptly upon receipt:
 - 1) Compare the RMIV totals to the actual stock vials, samples, and waste present in the lab.
 - 2) Confirm that the lab physical inventory matches the RMIV. Account for any discrepancy.
 - 3) Sign the RMIV sheet confirming the inventory match and return to Radiation Safety.
- E) Other RAM inventories will be performed by Radiation Safety as required by regulatory authorities, such as the Nuclear Material Management and Safeguards System (NMMSS).

F) Sealed Sources:

- A physical inventory of sealed sources designed to emit gamma or beta radiation shall be performed semiannually by Radiation Safety. If the sealed source is designed to emit alpha particles, the frequency of the physical inventory is quarterly. An inventory of exempt and generally licensed sources will also be maintained. The inventory is updated each time a new source is added or deleted.
- Leak testing shall be performed at the time of the physical inventory. If the test result ≥ 0.005 uCi of radioactivity or integrity is compromised, the source will be removed from service, safely stored, and a report filed with NMED according to the requirements of NMAC 20.3.4.415.
- 3) Records will be maintained for 3 years. The record will identify the radionuclide, original activity, reference date, current activity, model and serial number, storage location, name of the person performing the test, instrument(s) used, and the results in uCi.
- 4) The department owning sealed sources shall continuously maintain a complete inventory.
- G) Special Nuclear Material and Source Material:
 - 1) A modified inventory procedure is permitted for reactor fuel and other NMMSS sources for safety and ALARA purposes. The procedure allows for confirming the presence of the source by monitoring instead of direct visual confirmation.

X. RADIOACTIVE WASTE (RAW) DISPOSAL:

- A) RAW is highly regulated and thus is subject to strict UNM policies relative to generation, storage, preparation, and final disposal, to ensure compliance with NMAC Code.
- B) RAW disposal is expensive, especially radionuclides with long physical half-lives or in forms that are difficult to manage, such as mixed waste. To minimize cost, emphasis is placed on segregation of different types of waste according to radionuclide, half-life, chemical form, physical form, and whether or not biological or hazardous materials are mixed in with the RAM.
- C) <u>Segregation by half-life</u> is critical to managing costs and waste volumes:
 - RAW (unsealed or sealed sources) with a half-life (T_{1/2}) *less than or equal to 120 days* can be stored for total decay with subsequent disposal to the normal trash as non-radioactive once radioactivity levels are indistinguishable from normal background. The minimum required decay-in-storage (DIS) time is ten (10) half-lives.
 - 2) RAW with a T_{1/2} greater than 120 days is not eligible for DIS and must be collected and packaged for transport by a licensed radioactive waste broker and disposed to an authorized disposal facility. Waste disposal sites charge by weight; therefore, all radionuclide users are asked to make a deliberate and conscious effort to minimize the volume of RAW generated in their laboratories. A simple procedure is to survey trash with an appropriate instrument before placing into RAW containers to confirm radioactivity. Use normal trash streams if no radioactivity is detected.
- D) Disposal of radioactive liquids using the sanitary sewer system is *not allowed* by the City of Albuquerque, which has an ordinance that specifies zero tolerance for RAM in the sanitary sewer system. Excreta (urine and feces) from patients who received diagnostic or therapeutic radioactive materials in medicine is an exception to this requirement.
- E) <u>Guidelines for the collection of RAW in labs</u>:
 - 1) <u>Waste Containers</u>:
 - (i) Use waste containers provided by UNM Radiation Safety.

- (ii) Waste containers must be leak-proof and have a tight-fitting lid.
- (iii) Do not place radioactive waste containers on high shelves or in high traffic areas.
- (iv) All containers must have a clear plastic liner.
- (v) Each waste container must have a:
 - (a) Visible radiation-warning label.
 - (b) Label or tag affixed which identifies the radionuclide(s) in the container.
 - (c) Waste container number (if tracked in the EHSA database).
 - (d) Waste container label affixed after the container is filled and closed with a lid.
 - (e) Waste entry log affixed to the container (each deposit is recorded).
 - (f) Shielding materials, if exposure rates exceed 2.0 mR/hr at 30 cm.
 - (g) A maximum fill level established to make it manageable to handle.
- 2) <u>Waste Minimization Program</u>:
 - (i) Survey potentially contaminated items with an appropriate instrument set on its most sensitive scale. Place only contaminated waste into the radioactive waste stream.
 - (ii) Do not use excessive supplies and materials in radiation work areas.
 - (iii) Use spill containment trays.
 - (iv) Conduct dry runs for new protocols to ensure proficiency with procedure before introducing RAM into operations.
 - (v) Use the smallest amount of RAM consistent with achieving the research objective.
- 3) <u>Segregation</u>: RAW shall be segregated as follows.
 - (i) <u>Physical Form</u>: Separate containers for dry solid, aqueous liquid, and LSV.
 - (ii) <u>Half-life</u>: Use different containers based on half-lives of radionuclides:
 - (a) < 30 days
 - (b) 30-60 days
 - (c) 61-120 days
 - (d) > 120 days

(iii) <u>Biological</u>: All biological waste must be collected separately:

- (a) Consists of animal carcasses, bedding, and animal excreta. It may also include specimens in vials or containers.
- (b) RAW containing biological, pathogenic, or infectious materials shall be treated to reduce the non-radiological hazard.
- (c) Waste with a half-life \leq 120 days must be segregated from longer-lived waste. Small animals may be bagged and kept frozen in the PH's approved area until the date of pick-up. The Animal Research Facility (ARF) will store radioactive bedding and cages (but not carcasses) until decayed to background.
- (d) Waste with a half-life >120 days shall be segregated into one of three different categories based on activity and radionuclides present:
 - ³H and ¹⁴C waste with an average activity $\leq 0.05 \ \mu$ Ci per gram of tissue, averaged over the weight of the entire animal.
 - ³H and ¹⁴C waste with an average activity > 0.05 μ Ci per gram of tissue.

- All other radionuclides other than ³H and ¹⁴C.
- (e) Use strong, tightly closed, leak-proof plastic bags for animal remains. Bags must be frozen and stored in the PH's approved freezer until pick-up.
- (f) Do not place sharps or needles in the bags. Collect paper, plastic, foil, syringes, and absorbents separately and treat to reduce non-radiological hazards.
- (g) Label bags with the radionuclide, date, PH name, and the total activity per gram weight, averaged over the initial weight of the disposed animal.
- (iv) <u>Uranium and Thorium</u>: Waste containing U/Th in any form must be collected separately:
 - (a) Dry uranyl acetate, uranyl nitrate, thorium nitrate, and solutions containing any concentration of these shall be collected and disposed of as radioactive waste.
 - (b) Never combine uranium or thorium waste with any other chemical such as lead citrate.
 - (c) The gram weight of uranium or thorium compounds in the container must be recorded on the label. Identify any other hazardous chemical in the container.
- (v) <u>Mixed Waste</u>:
 - (a) Mixed waste contains RAM and one or more hazardous chemical components. Most chemicals classified by the EPA as hazardous are regulated under the Resource Conservation and Recovery Act (RCRA). The hazardous component can be a listed hazardous waste (40 CFR 261, Sub-Part D), or exhibit any one of the hazardous waste characteristics (40 CFR Part 261, Subpart C).
 - (b) Due to the expense and difficulty of disposal, generation of mixed radioactive is specifically PROHIBITED unless approved in advance in writing by the RSO. The full cost incurred for disposal will be passed on to the Permit Holder.
 - (c) Mixed waste containing radionuclides with a half-life ≤ 120 days may be held for total decay by Radiation Safety in certain situations and disposed of as hazardous waste. Obtain the approval of the RSO before generating this waste.
 - (d) Do not mix any lead materials with RAW.
- (vii) Chelating Agents:
 - (a) Chelating agents include amine polycarboxylic acids (EDTA, DTPA) and hydroxycarboxylic acids (citric acid, gluconic acid) used as binding agents.
 - (b) High concentrations of chelating agents in RAW may affect stability. Identify the name and weight percentage of chelating agent(s) in excess of 0.1% by weight.
- 4) Dry Solid Waste (DSW):
 - (i) Common DSW includes absorbent pads, paper, plastic, gloves, disposable labware, and pipettes contaminated with RAM. Do not mix unabsorbed liquids, sharps, lead pigs, scintillation vials (including empty vials), chemicals, or biological waste with DSW.
 - (ii) DSW must be segregated by radionuclide and half-life, with containers clearly labeled with radioisotope name. Use shielding for gamma and high energy beta emitters.
 - (iii) Rules for DSW:
 - (a) No liquids shall be placed in DSW containers except for small amounts on absorbent.
 - (b) No lead items shall be discarded in the DSW stream. Store separately for pick-up.

- (c) No broken glass, loose needles, or unprotected sharps are permitted in DSW. Place these materials in a separate plastic container that protects handlers from injury and store separately for pickup.
- (d) No flammable, pyrophoric or water reactive materials are permitted.
- (e) No biological, pathogenic, or infectious material shall be placed into DSW.
- (f) Organic solvent-contaminated items or items capable of generating toxic gases, vapors or fumes are specifically prohibited from DSW.
- (g) Chelating agents must be less than 0.1% by weight.
- (h) Waste containers must have a label affixed with the Permit Holder's name, radionuclide, activity, date, and room #.
- 5) Aqueous Liquid Waste (ALW):
 - (i) ALW has water as the primary constituent, such as aqueous phase extractions from experiments and the first rinsing of RAM containers. Soluble organic or inorganic materials shall be present only in minute quantities to avoid phase separation or precipitation.
 - (ii) Avoid adding organic or inorganic components to ALW as even small amounts may result in a mixed waste. For example, a solution with 6% methanol in water is a mixed waste. Consult with Radiation Safety before adding any hazardous material to ALW.

(iii) <u>Rules for ALW</u>:

- (a) No solids are allowed in ALW.
- (b) Do not overfill or use large containers (> 10 liter), to avoid lifting issues. Use containers approved by Radiation Safety.
- (c) The pH of ALW shall be within the range of 5 to 9.
- (d) Do not add liquid scintillation fluid to ALW.
- (e) Waste must contain less than 0.1% by weight chelating agents.
- (f) Containers must bear a label that indicates Permit Holder's name, radionuclide, activity, and percentage of non-aqueous material.
- (g) Disposal via the sanitary sewer system is prohibited at UNM.
- 6) Liquid Scintillation Vial Waste (LSV):
 - (i) Liquid scintillation fluids may contain xylene or toluene which is hazardous. UNM recommends the use of non-hazardous scintillation fluid which is commercially available.
 - (ii) LSV should be segregated based on the radionuclides present and the average activity per gram of media as follows:
 - (a) 3 H and 14 C waste with an average activity $\leq 0.05 \ \mu$ Ci (approximately 111,000 dpm/ml) per gram of media.
 - (b) All other radionuclides of any activity in LS fluid, and ³H and ¹⁴C waste with an average activity of > 0.05 μ Ci per gram of media.
 - (iii)Collect waste vials upright in flats with caps secured. Do not collect bulk liquid LS fluid.
 - (iv) Estimate the total activity of the LSV using counts from the liquid scintillation counter (LSC) and known volume. Generators should be prepared to justify stated activities with documented calculations.

- (v) <u>Rules for LSW</u>:
 - (a) No solids allowed (except counting media).
 - (b) Segregate vials containing ${}^{3}H$ and ${}^{14}C$ from other radionuclides.
 - (c) Make sure vial caps are tightened to avoid leakage.
 - (d) If a hazardous LS fluid is present (toluene), it must be listed on the label.
 - (e) Use the tray flats to collect vials and store vertically to reduce leakage.
 - (f) If vials are collected in 5-gallon containers, they must be securely capped and carefully placed to prevent breakage and leaking.
 - (g) All waste containers must indicate Permit Holder's name, radionuclide, activity, and chemical percentages of waste.
- 7) <u>Sealed Sources</u>:
 - (i) Sealed sources at the end of their useful life or that are no longer needed by the Permit Holder may be transferred to Radiation Safety for secure storage pending:
 - (a) Return to the manufacturer.
 - (b) Repurposing for beneficial use, following completion of transfer documents.
 - (c) Final disposal with a licensed waste broker.
 - (d) Final disposal after DIS for 10 half-lives, finding radiation levels indistinguishable from normal background, and removal of radiation labels.

XI. <u>PERSONNEL RADIATION MONITORING (DOSIMETRY):</u>

- A) Occupational radiation monitoring of UNM workers is conducted according to NMAC Subpart 4.
- B) The devices used to monitor occupational exposure may be thermoluminescent dosimeters (TLDs), aluminum oxide (AlO₃) dosimeters, solid state (Instadose) dosimeters, or other approved technology. The provider shall be NVLAP-accredited (National Voluntary Laboratory Accreditation Program).
- C) UNM employees, contractors, or students who work in or frequent radiation areas may complete a "Dosimetry Enrollment Form" for review by Radiation Safety, who will determine if badge(s) are needed. If it can be shown that an individual is likely to receive an annual dose greater than 10% of the dose limit, they must be issued a badge. Others may be issued badges for risk management purposes.
- D) New badge participants must complete Dosimetry Training within 30 days of hire, which covers instructions on proper use and care of the badge and expectations of a radiation worker. Function-specific radiation safety training is also required that covers the safe operating practices of the participant's specific department.
- E) <u>Workers Will be Issued a Badge if Meeting one or more of the Following Conditions:</u>
 - Adults who in the course of work may exceed in one calendar year 10% of the occupational limits in NMAC 20.3.4.405;
 - 2) Minors likely to receive a deep, lens, or shallow dose equivalent of 50 mrem, 150 mrem, or 500 mrem, respectively;
 - 3) Expecting mothers who have declared pregnancy in writing;
 - 4) Individuals entering a high or very high radiation area, as defined in NMAC 20.3.4.7;
 - 5) Independent operators of medical fluoroscopic equipment; or

- 6) Any person or group of persons carrying out approved activities with radiation sources who, at the discretion of the appointed Radiation Safety Officer, requires individual monitoring for risk management purposes.
- F) <u>Rules for Badge Use</u>:
 - 1) The purpose of the badge is to document an individual's occupational radiation exposure and to demonstrate compliance with annual dose limits and ALARA levels. Badge data also provides information to the RSO about the effectiveness of the radiation safety program.
 - 2) Always wear the badge while working in radiation areas and place in a designated low background area after working hours. Do not remove from the workplace unless special conditions warrant (the employee works at 2 different locations, for example).
 - 3) Clip the badge onto personal clothing in the neck or chest area, with the label facing outward, and positioned so that the front of the badge faces the radiation source. Do not hang the badge on a lanyard or place on clothing that might allow the badge to shift to different positions.
 - 4) Wear the badge OVER the lead apron, not underneath it. Do not allow the apron to cover the badge even partially as it can cause false beta readings. One exception to this rule is the "fetal monitor" as issued to a declared pregnant worker (DPW), which is worn underneath the lead at abdomen level.
 - 5) Do not loan or borrow badges from co-workers; wear only the badge assigned to you.
 - 6) Do not wear or bring your badge if you are receiving a personal medical exam involving radiation.
 - 7) Promptly report missing, lost, or damaged badges to the RSO.
 - 8) Badges have an exchange frequency of monthly or quarterly (the wear period) based on risk. Return old badges to Radiation Safety on or about the last working day of the wear period and begin wearing the new badge. A "badge coordinator" is designated for each department to assist with the exchange process. Late fees may be assessed for unreturned badges or badges not returned on time.
 - 9) Ring dosimeters shall be worn on the hand most likely to receive the highest dose, with the label section towards the palm of the hand.
 - 10) Do not wear your badge at non-UNM locations (if moonlighting). The worker is responsible to notify the RSO at each location that they work so that badge data may be shared.
 - 11) Notify the RSO immediately upon termination of employment, badge loss, accidental badge exposures, or if job duties change relative to work with radiation.
- G) ALARA Levels and Guidelines:
 - 1) UNM shall use administrative procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses that are ALARA.
 - 2) Benchmarking data and published peer-reviewed articles should be used to compare occupational doses for specific user groups to national guidelines (as available).

- 3) ALARA action levels are established and approved by the RCC, which are well below the annual dose limits and serve as a trigger for review and follow-up. The quarterly ALARA action levels at UNM are:
 - (i) <u>Whole Body</u>: Level I = 300 mrem (3 mSv); Level II = 600 mrem (6 mSv)
 - (ii) Extremity: 6000 mrem (60 mSv)
 - (iii) Lens of Eye: 1800 mrem (18 mSv)
- 4) If a participant exceeds ALARA Level I, and the exposure cannot be justified by the RSO, a notification letter will be sent to the individual. A list of all affected personnel will be presented to the RCC at the next scheduled meeting.
- 5) If a participant exceeds ALARA Level II, an ALARA investigation letter may be sent to the individual if the RSO cannot justify the exposure. The individual may be sent an alert notification for general awareness. A list of Level II personnel will be presented to the RCC.
- I) <u>Annual Dose Limits</u>:
 - 1) <u>Whole Body</u>: The more limiting of the total effective dose equivalent (TEDE) equal to 5.0 rem (0.05 Sv), or the sum of the deep dose equivalent (DDE) and the committed dose equivalent (CDE) to any individual organ other than the lens equal to 50.0 rem (0.5 Sv).
 - 2) Lens: A lens dose equivalent (LDE) equal to 15.0 rem (0.15 Sv).
 - 3) <u>Skin or Extremity</u>: Shallow dose equivalent (SDE) of 50.0 rem (0.5 Sv) to skin or extremity.
 - 4) <u>Minor</u>: For a minor under the age of 18, the limit is 10% of any of the adult dose limits.
 - 5) <u>Embryo/Fetus of a DPW</u>: The dose limit over the gestational period is 0.5 rem (5 mSv), with an additional guideline of uniform delivery (≤ 50.0 mrem per each gestational month).
 - 6) <u>Member of the public (MOP)</u>: Defined as any individual who is not a badged radiation worker or contractor or a patient receiving prescribed radiation. The annual limit is a TEDE of 0.1 rem (1 mSv) in a year. If the exposure is infrequent, a limit of 0.5 rem (5 mSv) applies. Unrestricted areas shall not exceed 2.0 mrem (0.02 mSv) in any one hour.
 - 7) <u>Patients</u>: For patients receiving prescribed diagnostic or therapeutic radiation as ordered by an Authorized User, there are no radiation limits. The licensee shall make all reasonable attempts to ensure that patient doses are as low as possible.
- J) <u>Reports and Records:</u>

1) **Dosimetry Reports**:

- (i) Reports are promptly reviewed and signed by the RSO or designee upon receipt.
- (ii) The review will include evaluation and justification of worker dose, error codes, trend analysis, ALARA review, absent and unused badges, and fetal dose.
- (iii) An immediate investigation will be conducted if any regulatory limit is exceeded. Communication with the affected individual and evaluation of working conditions will be used by the RSO to determine if the reported dose could be accurate. If so, the RCC will be notified and a report sent to NMED as a reportable event. The RSO and the RCC shall determine if restrictions should be made to limit any further radiation exposure.
 - (a) If the investigation definitively concludes that the reported dose is not a true and accurate representation of the worker's dose, the RSO shall adjust the dose of record by providing a request in writing to the badge vendor.
 - (b) Examples of situations where dose of record may be legally adjusted:

- Worker wore their badge during a CT scan or radiation treatment.
- Workers badge was missing for a period of time and found under a fluoroscopy table.
- Badge left on an apron and worn by multiple workers over time.
- (iv) If a badge is lost or unreturned 90 days from the end of a wear period, a dose estimate will be calculated by Radiation Safety or the badge vendor and added to the dose of record. The standard vendor formula for estimation will be used.
- (v) The RSO will send dosimetry reports to the Manager or Supervisor of each department, who will make them available to participants.
- (vi) The RSO maintains dosimetry reports for the life of the license.

2) Form 5 - Annual Report of Worker Dose (20.3.10.1003.B):

- (i) A summary report of total annual exposure for the preceding calendar year will be issued to each participant who received in excess of 100 mrem (1.0 mSv) TEDE or TODE for the year in question or if they request one. Managers will be made aware that the reports are available and communicate this to their staff.
- (ii) Reports are distributed as confidential following receipt of all badge data from the dosimetry vendor. Persons in receipt of a Form 5 are instructed to preserve the report for future reference.

3) <u>Termination and History Reports</u>:

- (i) A final dosimetry report will be sent to terminating employees upon request and following receipt of the last calendar year dosimetry report.
- (ii) At the request of a former employee who was badged at UNM, or at the request of their new employer, Radiation Safety will provide the badge data in writing to the requestor in a timely manner. This information will be released to a third party only if the request is signed and dated by the former employee, authorizing release of their badge data.
- (iii) New UNM employees who were badged at another location during the current calendar year are required to provide their previous badge data to Radiation Safety. Alternately they may authorize the UNM RSO to obtain their current year history from previous employer(s) by signing a form designed for that purpose.

4) Bioassay:

- (i) Individuals involved in open bench operations with unsealed RAM above the activity levels in Section XII of this manual shall have their use scenario evaluated by the RSO to determine if bioassay testing should be performed, and the method and frequency to be employed.
- (ii) Exemptions to bioassay include radionuclides present as metallic foils, plated sources, therapeutic radiopharmaceuticals administered in unopened capsular form or intravenously, and other material forms not likely to disperse.
- (iii) For therapeutic administration of liquid ¹³¹I NaI, or for researchers performing protein iodination, thyroid bioassay shall be performed within 24-48 hrs following use. A thyroid uptake probe shall be used with results recorded in a log maintained for that purpose. Baseline bioassays should be performed for new staff before first use.
- (iv) Bioassay samples may be analyzed at UNM using methods appropriate for the radionuclide, chemical form, and route of excretion. The RSO shall provide guidance on a case-by-case basis.

XII. LAB SURVEYS:

- A) <u>Research Lab Self-Surveys</u>:
 - 1) Permit Holders shall periodically assess radiation levels in all authorized use locations. The survey frequency is monthly for active use labs. Inactive labs need only survey the radiation source storage area. No survey is required if the Permit Holder is inactive and has no RAM inventory.
 - 2) Part I of the lab survey consists of making radiation measurements throughout the lab at key locations, using an appropriate portable instrument that is sensitive to the radiation types in use. Key locations include workstations, RAM use, storage and disposal areas, high touch surfaces, and adjacent unrestricted areas. Results of the area survey should be recorded in mR/hr or cpm.
 - 3) Part II of the lab survey consists of wipe testing to check for removable contamination on surfaces. If contamination is found that exceeds the established tolerance, the area shall be decontaminated and resurveyed. Results of wipe tests should be recorded in dpm/100 cm².

B) Nuclear Medicine:

- Ambient surveys and wipe tests will be conducted in accordance with 20.3.4.404(D), 20.3.4.416, and 20.3.7.703(H) NMAC, and recorded in mR/hr in the Nuclear Medicine recordkeeping system.
- 2) End-of-workday (daily) surveys shall be performed with a survey instrument in all areas where radiopharmaceuticals are prepared or administered, except patient rooms. Weekly surveys shall be performed in all areas where radiopharmaceuticals or wastes are stored.
- 3) Wipe tests shall be performed and recorded in dpm/100 cm² end-of-workday (daily) in all areas where radiopharmaceuticals requiring a written directive are used and weekly for all other areas where radiopharmaceuticals are routinely prepared, administered, or stored.
- 4) Rooms used for in-patient radiopharmaceutical therapy shall be closed following patient discharge until radioactive waste is removed and contamination levels are below established tolerances.

C) Cancer Center:

- For low dose rate (LDR) brachytherapy implants, survey the area after administration to account for any sources that have not been implanted and to assess patient radiation levels at 1 meter and at contact. Immediately after removing the last temporary implant from a patient, survey the patient to confirm that all sources have been removed.
- 2) For high dose rate (HDR), after treatment but before releasing a patient, survey the patient and HDR unit to confirm that the radiation source has returned to the shielded position in the device.
- 3) Upon installation of a new HDR source or after repairs to the source shielding, driving unit, or electromechanical components, survey to verify that maximum and average radiation levels from the surface of the main source safe are within SSDR tolerances.

D) Radiation Safety Office Surveys:

- 1) UNM Radiation Safety shall conduct periodic surveys in labs where unsealed licensed RAM is used, stored, and disposed, at a frequency commensurate with risk. Audits shall document key compliance items, observation of work practices, and measurement of area radiation levels.
- 2) Analytical and industrial devices which produce x-ray shall be surveyed periodically by Radiation Safety to ensure safe and secure operating and storage conditions.
- 3) Surveys of areas where SNM and source material are used and stored shall be performed at least annually by Radiation Safety to confirm external radiation fields, security, functionality of system interlocks and alarms, and regulatory compliance.

- (i) <u>Close-out Surveys and Release for Unrestricted Use</u>:
 - After disposal/transfer of all RAM, Radiation Safety performs surface radiation (a) measurements and wipe tests in the lab, evaluates RAM use and spill history, and authorizes release when results are indistinguishable from background.
- (ii) New Radioisotope Lab Commissioning:
 - Before a new Permit Holder may begin using RAM, the new lab shall be inspected by (a) Radiation Safety to ensure all required equipment, signs and labels, storage containers, lab notebook and required forms and procedures are available.
- (iii) Radiopharmaceutical Therapy Rooms (inpatient or outpatient):
 - Radiation measurements of the patient at 1 meter and at contact will be made by Radiation (a) Safety staff or a designee. Following inpatient dose administration, radiation levels in all accessible adjacent areas shall be made and documented.
 - (b) Clinical spaces used by patients undergoing radiopharmaceutical therapy will be released from licensee control when area radiation and contamination levels are in compliance with regulatory limits (no individual, when continuously present, could receive a dose in excess of 2.0 mR in any one hour.
- E) Survey Action Levels:
 - 1) Permit holders shall be responsible to take actions to reduce ambient dose rate and/or contamination levels below the established action levels listed in Tables 1 and 2 below.
 - 2) Survey results shall be maintained in the Lab Notebook or equivalent auditable record.
 - 3) <u>Survey Action Levels</u>:

Table 1		
Ambient Dose Rate Action Levels		
Area Surveyed Action Level (mR/hr)		
Unrestricted Area	0.1	
Restricted Area	2.0	

Table 2		
Loose Surface Contamination Levels ^{1,2}		
Area Surveyed Action Level (dpm/100 cm ²)		
Unrestricted Area	200	
Restricted Area	2000	

1 More restrictive loose surface contamination limits may be enforced on specific permits based on radiotoxicity, hazard group (see Table 4), and radiation emitted by radionuclides in use.

2 Contamination in restricted areas should be well below 2000 dpm/100 cm² as much as possible.

Table 3					
Activity Levels Requiring Surveys Same Day of Use (10 X Schedule B Quantities)					
Radioisotope Activity (uCi) Radioisotope Activity (uCi)					
Hydrogen-3	10,000	Chromium-51	10,000		
Carbon-14	1,000	Technetium-99m	1,000		
Phosphorus-32	100	Iodine-125	10		
Sulphur-35	1,000	Iodine-131	10		
Fluorine-18	10,000	Gallium-68	1,000		

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Table 4						
	Radionuclide Hazard Groups (*gamma emission)					
Group 1 Very High 0.1 mCi Pb-210* Po-210 Ra-223	Group 2 High 1 mCi Na-22 [*] Ca-34		Group 3 Medium 10 m Y-90 Y-91 Zr-93*		Group 4 Low 100 mCi	
Ra-226* Ra-226* Ra-228* Ac-227 Th-228 Th-230 Np-237 Pu-238 Pu-239 Pu-239 Pu-240 Pu-241 Pu-242 Am-241* Cm-242 Cf-252	Sc-46* Co-60* Sr-90 Ru-106* I-125 I-129 I-131* Cs-137* Ce-144* Eu-154* Ta-182* Bi-210 At-211 Ra-224 U-233	S-35 Cl-36 K-42* Sc-47 V-48* Cr-51* Mn-54* Mn-56* Fe-55 Fe-59* Cu-64* Zn-65* Ga-72* As-76* Rb-86* Sr-89	Nb-95* Mo-99* Ru-103* Pd-103 Ag-105 Ag-111 Cd-109* Sn-113* I-123 Te-127* Te-129 ^{m*} Ba-140* La-140* Pr-143 Pm-147	Re-183* Ir-190* Ir-192 Pt-191* Pt-193* Au-196* Au-198* Au-199* Tl-200* Tl-201* Tl-201* Tl-202 Tl-204 Pb-203* Rn-220 Rn-222* U-235	H-3 Be-7 [*] O-15 F-18 Ga-68 Ni-59 Zn-69 Ge-71 Tc-99 ^m U-238 Natural Thorium Natural Uranium Noble Gases	

Table 4

XIII. <u>RADIOLOGICAL INSTRUMENTS</u>:

- A) Portable Instrument Calibration:
 - 1) Portable survey meters shall be calibrated before first use, annually, and following any major repair that could affect the calibration. Radiation Safety may calibrate UNM survey meters or use a third party commercially licensed firm for instrument calibration.
 - 2) Instruments used only for low-level contamination monitoring may be electronically calibrated using a pulser. Instruments used for making exposure rate measurements will be calibrated using a certified NIST-traceable gamma radiation source. For each type of calibration, the requirements of 20.3.7.703(C) will be met.
 - 3) All instruments used to comply with the requirements of 20.3.7 shall have a dedicated check source, preferably attached to the instrument, and proper operability confirmed each day of use by comparing the measured value to that indicated on the calibration sticker. Records of this daily operability check are not required.
 - 4) A calibration label will be affixed that identifies the instrument and serial number, calibration date and next due date, calibration source, check source reading (if applicable), correction factors (if any) and the name or initials of the person performing the calibration. Instrument calibration records are stored in accordance with 20.3.7.715(F) for 3 years.

XIV. RADIATION SAFETY RECORDS and REPORTS:

A) Radiation Safety will maintain records required by NMAC in a central location. The informational contents and radiological data in each record shall be consistent with NMAC expectations and retention frequencies. Records shall be maintained in an auditable format and organized to facilitate quick access.

- B) End-users shall maintain radiation safety records in a lab notebook. The contents shall include the current Radiation Permit, instrument calibration records, source inventory and accountability, leak test reports, lab surveys, radioactive waste records, and all radiation safety training records. A link to the NMAC regulations and to the UNM Radiation Safety Manual shall be readily accessible to all lab personnel.
- C) External Reporting:
 - The RSO, with the RCC and Management, shall determine if radiation incidents are to be reported to a regulator. Under no circumstances (except as noted in the "Notice to Employees" Form), shall an enduser, AU, Permit Holder, or any supervised worker carry out external reporting. UNM supports a centralized communication process, after a thorough investigation conclusively determines that an event is reportable, and consensus has been reached by all key stakeholders. This shall be considered the point of discovery.
 - 2) The RSO shall maintain open communications with NMED, make notifications as required, and promptly respond to inquiries and requests for information from NMED.

XV. POSTING AND LABELING:

- A) <u>Radiation Signs</u>:
 - 1) Signs shall be posted to make individuals aware of a radiation hazard before that individual enters an area, so that the proper precautions can be taken to minimize radiation exposure.
 - 2) Each sign shall bear the universal warning symbol and colors for radiation hazard as defined in NMAC 20.3.4.427. The wording on the sign shall be:
 - (i) <u>Caution Radioactive Material</u>: Areas where licensed RAM is used or stored, in quantities > 10x that listed in NMAC 20.3.4.462 Appendix C "Labeling Requirements".
 - (ii) <u>Caution Radiation Area</u>: Radiation levels exist that could expose an individual to 5 mrem (0.05 mSv) in one hour at 30 cm from the source or surface the source penetrates.
 - (iii)<u>Caution High Radiation Area</u>: Radiation levels exist that could expose an individual to 100 mrem (1.0 mSv) in one hour at 30 cm from the source or surface the source penetrates.
 - (iv) <u>Caution Very High Radiation Area</u>: Radiation levels exist that could expose an individual to 500 rad (5.0 Gy) in one hour at 100 cm from the source or surface the source penetrates. The words "Grave Danger" should be used unless the words would cause undue stress to patients.
 - (v) <u>Caution X-Ray</u>: In areas where stationary x-ray producing equipment is used.
 - 3) <u>Exemptions to Posting Requirements</u>:
 - (i) For periods of < 8 hours, when the radiation source is constantly attended by an individual who takes the necessary precautions to prevent exposure to others.
 - (ii) Hospital rooms housing radiation patients who meet the release criteria.
 - (iii) Rooms having a sealed source or radiation-producing device with radiation levels ≤ 5.0 mrem/hour at 30 cm.
- B) Notice to Employees Form (NRC-3 and NMED-045):
 - 1) "Notice to Employees" forms shall be visibly posted in a sufficient number of places in each department where licensed activities are conducted. Workers should be able to observe this posting in their normal course of duties.

- 2) The NMAC regulations, UNM operating procedures, licenses, license conditions, and other documents associated with the license should be posted as required by NMAC 20.3.10.1001. A posted statement identifying where these documents are stored is acceptable in lieu of the posting.
- C) Radiation Safety Contact Information:

All labs using RAM or registered radiation sources are required to post the current contact information for UNM Radiation Safety. The most current version is available by contacting UNM Radiation Safety at <u>HSC-radiationsafety@salud.unm.edu</u>

- D) X-Ray Machine Registration and Operator Certificates:
 - 1) Valid registration certificates shall be maintained for all x-ray producing units. Radiation Safety shall initiate renewals within 30 days of an expiration.
 - 2) Registration certificates shall be posted in areas where x-ray equipment is used.
 - 3) Only qualified individuals may operate x-ray equipment. This includes individuals certified by NMED (NMAC 20.3.20.300) or exempt under NMAC 20.3.20.300 (licensed practitioners or supervised students and residents in a formal program of study). X-ray operators are responsible to renew certificates in a timely manner. Certificates of licensure shall be publicly displayed.
- E) Labeling:
 - 1) Containers holding licensed RAM shall be clearly labeled with the radiation symbol and the words "Caution Radioactive Material". Other required information on the label includes the radionuclide, activity, date, and lab number. Exemptions to container labeling are:
 - (i) Containers holding RAM in quantities less than that listed in NMAC 20.3.4.462. An abbreviated list of quantities requiring labeling is in Attachment C.
 - (ii) Containers holding RAM in concentrations less than Table III of NMAC 20.3.4.461.
 - (iii) Containers while in use and under constant surveillance by a radiation worker.
 - 2) Containers that are exempt from full labeling continue to require a "Caution Radioactive Material" label. Exceptions are allowed for physically small containers such as microcentrifuge tubes or liquid scintillation vials where the label will interfere with the intended use. In those cases, the tray or box holding the containers should be labeled.
 - 3) Before moving empty containers to the normal trash that formerly held RAM:
 - (i) Survey the container inside and out with an appropriate survey meter set on its most sensitive scale and with no interposed shielding, to demonstrate that radiation levels are indistinguishable from background. For low energy beta emitters such as ³H, ¹⁴C, and ³⁵S, wipe test the container and count wipes with a LSC.
 - (ii) Remove or obliterate all symbols, wording, and markings indicating radiation hazard.
 - (iii) If the end-user wishes to keep an empty container for future use, an "Empty" label should be placed over the radiation markings.
 - 4) X-ray producing devices shall have a label at the console that contains the radiation symbol, and the words "WARNING: this x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed".
 - 5) X-ray producing devices for analytical or industrial use shall have a label at the console with the words "Caution-high intensity x-ray ray beam", or the equivalent. In addition, the words "Caution: x-rays produced when energized" must be present near the operating switch.

F) <u>"Lab Safety Rules" shall be posted with the following content:</u>

- 1) Keep RAM, contaminated equipment, and sealed sources in designated and properly labeled containers. Set up your lab to facilitate contamination control.
- 2) Keep RAM work areas clean, uncluttered, and organized.
- 3) Secure RAM after business hours or when the lab is unoccupied, even for short periods of time and for any quantity of radioactivity. Security of RAM shall be continuous.
- 4) Wear whole body and ring dosimeters (as applicable) when working with RAM.
- 5) Operations in which radionuclides may become airborne require special consideration in regard to monitoring and sampling. Contact the RSO for instructions.
- 6) Do not smoke, eat, drink, or store food or beverages in any posted RAM lab.
- 7) Use mechanical devices to pipette radioactive solutions.
- 8) Survey the work area and your entire person after every use of unsealed RAM.
- 9) Store and transport RAM in a manner to prevent breakage or spillage.
- 10) Wear lab coats and other PPE to prevent contamination commensurate with the amount of RAM in use. Wear disposable gloves when handling anything potentially contaminated.
- 11) Use absorbent paper to line work areas and exchange when necessary. Secondary containment (spill trays) is required when working with radioactive liquids.
- 12) Immediately contain and attend to any spill of RAM. Clear the area of persons not involved in the spill and contact the RSO for assistance as necessary.
- 13) Potentially contaminated equipment may not leave a RAM Lab for service, calibration, repair, disposal etc. without first being cleared by the RSO or designee.
- 14) Pressure may build up in vials of radioactive solutions and could be released by inserting a hypodermic syringe needle through the rubber seal. A cotton or wool plug is recommended to trap this spray. In the case of a screw cap vial, surround the rim of the cap with cotton and, unscrew the cap slowly until pressure is equalized. Always work over a tray in a fume hood.

XVI. SPILL AND EMERGENCY RESPONSE:

- A) Major and Minor Radioactive Material (RAM) Spills:
 - 1) RAM spills can be minor or major. Minor spills generally involve low levels of radioactivity, are easily contained, and are relatively simple to clean up. A major spill has more significance and must be reported to Radiation Safety. A major spill has one or more of the following characteristics:
 - (i) Involves a large (mCi) quantity of radioactivity.
 - (ii) Causes a radiation level that exceeds 2.0 mR/hr at 30 cm.
 - (iii) Involves radionuclides with high radiotoxicity (see Section XII Table 4).
 - (iv) Is spread over a large area or irregularly shaped area.
 - (v) Difficult to immediately contain and clean.
 - (vi) Involves skin contamination, an injury, and/or radiation exposure to any individual.
 - (vii) Occurs in an unrestricted area.
 - (viii) Threatens to be released into air, water, or sanitary sewer.
 - (ix) Is beyond the worker's comfort level or abilities.

- 2) Spill Response:
 - (i) STOP work activities and attend to the spill, using PPE commensurate with the risk, including gloves and shoe covers at a minimum.
 - (ii) Medical care of injured individuals shall take priority over radiation issues.
 - (iii) If multiple hazards are present, the primary hazard such as a fire, flood etc. shall take precedence. Assist the injured, extinguish the fire, pull the fire alarm, control the source of flooding etc., and then attend to the spill. Immediately placing absorbent material on the spill to prevent spread is a recommended concurrent initial action.
 - (iv) If the spill could involve a release of RAM to the air, causes high radiation levels (10's-100's of mR/hr), or otherwise involves complex circumstances requiring assistance, evacuate the area, lock the door, and contact the RSO. Remain in the area until the RSO arrives on the scene. Additional assistance may be requested of UNM Security, UNM Police Department (UNMPD), or the hospital Safety Alert System (333).
 - (v) Take steps to minimize the spread of contamination.
 - (vi) Warn others to stay away from the affected area. If individuals may be contaminated, detain them until they can receive a full body survey.
 - (vii) Persons with skin contamination shall immediately flush the affected area with warm water and gently scrub with mild soap, taking care not to abrade the skin. Document the area of skin affected, initial cpm or mR/hr measured at 1 cm, the date and time, and radiation readings and times following all decontamination efforts.
 - (viii) Delineate the spill boundary. Use barriers or rope to maintain security.
 - (ix) Obtain the spill kit. Set up a container to collect radioactive waste. Decontaminate the area working from areas of low to high contamination (perimeter to center). Continue until radiation readings are indistinguishable from background or no further reductions are achievable. Gloves shall be changed frequently.
 - (x) Write an incident report identifying radiation levels, affected locations, affected personnel, root cause, contributing factors, and steps to prevent reoccurrence.
- 3) Other Radiation Emergencies and Incidents:
 - (i) Fire, smoke, or flooding in any RAM use area.
 - (ii) A natural disaster event that threatens the integrity or security of radiation sources.
 - (iii) Unauthorized entry into a radiation area or other security breach.
 - (iv) Loss or theft of RAM or radiation-producing device.
 - (v) Malfunction of any device designed to maintain radiation source safety.
 - (vi) An in-house therapeutic radiation patient who codes, requires transfer from their assigned room due to a medical emergency, or dies.
 - (vii) A therapeutic radiation patient who is released to home with radiation precautions, but who presents in the ER due to a medical condition, or who otherwise cannot follow the radiation precautions issued at the time of discharge.
 - (viii) A radiation accident victim in the ER who is contaminated and injured (requires activation of the Hospital Radiation Incident Response Plan)

XVII. RADIATION SAFETY PROGRAM CHANGES:

- A) UNM possesses a Type A Broad Scope RAML, which allows flexibility in making internal radiation safety decisions. Approval of Permit Holders is an example of such an internal decision. Documentation of the basis for all internal decisions is required to be maintained for review by NMED during routine inspections.
- B) UNM may make radiation safety program changes or revisions to procedures when approved by the RCC and the change increases efficiency and safety with no negative impact.
- C) The RCC will review and approve changes based on an assessment of any impact to regulatory compliance, license conditions, and general radiation safety. The RCC may consider other sources of information in the review and approval process. Documentation of the RCC review and approval and the reason for the change will be in the RCC meeting minutes and the relevant department location.

ATTACHMENTS

- A. UNM HSC Office of Research Radiation Safety Organizational Chart
- B. Radiation Control Committee (RCC) Member Guidelines
- C. Quantities of Radioactive Material Requiring Labeling
- D. UNM Radiation Safety Training Courses
- E. Radiation Safety Forms
- F. Acronyms Used throughout the RSM Definitions
- G. Signature Page

Attachment A - UNM HSC Office of Research Organizational Chart



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- I. The RCC membership follows the NMED regulations in Title 20 Chapter 3, Part 7.702(D).
- II. The membership must include an AU for each type of use permitted by the RAML, the RSO, a nursing service representative, and an Executive Management representative (not an AU or the RSO), and others as appropriate.
- III. A Chair will be appointed who is not the RSO or the Management representative. A Vice-Chair may be appointed.
- IV. The following is the suggested membership (department representation):
 - A. Radiation Safety Officer (RSO)
 - B. Licensee Executive Management
 - C. Nursing Representative
 - D. Basic Research Sciences (Biology, Chemistry, Physics)
 - C. Nuclear Engineering
 - D. Interventional Radiology
 - E. Nuclear Medicine
 - F. General Radiology
 - G. Blood Bank
 - H. Cardiology
 - I. Cancer Center (AU and AMP)
 - J. Diagnostic Imaging Physicist
 - K. UNMH Sandoval Regional Medical Center (SRMC)

Radionuclide	Quantity (microcuries)
Н-3	1,000
C-14	100
F-18	1,000
Na-22	100
P-32	10
P-33	100
S-35	100
Cl-36	10
Ca-45	100
Cr-51	1,000
Mn-54	100
Fe-55	100
Fe-59	10
Co-57	100
Co-60	1
Ni-63	100
Zn-65	10
Ga-68	1,000
Ge-68	10
Sr-89	10
Sr-90	0.1
Y-90	10
Tc-99m	1,000
Cd-109	1
In-111	100
I-123	100
I-125	1
I-131	1
Cs-137	10
Ba-133	100
Sm-153	100
Gd-153	10
Th-201	1,000
Ra-223	0.1
Ra-226	0.1
Th-230	0.001
Th-232	100
Thorium-natural	100
U-232	0.001
U-235	0.001
U-238	100
Uranium-natural	100
Pu-239	0.001
Am-241	0.001

(partial listing from NMAC 20.3.4.462)

A. "Introduction to Radiation Safety"

HSC-112-001 is an introductory live class for workers with minimal experience working with RAM. Successful completion of this course is a prerequisite to working <u>independently</u> under a Permit Holder. The course also serves as an excellent refresher course for experienced staff or new faculty.

The course is offered as needed and consists of a combination of didactic lectures, practical experiences, on-line learning, and a final exam. Certificates are issued upon successful course completion. The course may be challenged by successfully passing the exam and demonstrating sufficient technical proficiency, or if a certificate of equivalent training, education, and/or experience is presented that occurred within the preceding 3-year period from date of application, along with a course outline.

The course content includes radiation physics fundamentals, a review of research radioisotopes, radiation detection and measurement, radiation biology and health effects, dose reduction techniques, methods for safe handling, storage, and disposal of RAM, regulations and compliance, applicable UNM policies and procedures, a review of required records and reports, and identification and response to abnormal situations and radiological emergencies.

B. "Radiation General Awareness"

This Learning Central Course #HSC-182 is intended for ancillary workers and non-radiation workers, who have a business need to work in or around areas where radiation sources are used and stored but have no responsibility for them. This is a "right-to know", lay person overview of radiation information so that workers can identify radiation source areas and understand that safety measures are in place, with an emphasis on visual recognition and response to warning signs. UNM Physical Plant employees and non-radiation workers in research laboratories are required to complete this course.

C. "HSC Radiation Safety Refresher Training"

This Learning Central Course #HSC-180 is intended for any radiation worker who has completed initial radiation safety training and fulfills the annual refresher training requirement of NMAC 20.3.10.1002. The course reinforces key concepts, reminds workers of important practices and regulatory requirements, and reviews radiation safety operating procedures.

D. "Radiation Safety for Animal Resource Facility (ARF) Personnel"

This Learning Central Course #HSC-211-002 provides radiation safety instruction for individuals who work with and around small live animals injected with RAM as well as sacrificed animals. Unique challenges such as safely managing the cage environment are covered as well as a review of what could go wrong and how to respond. ARF personnel are required to take this course annually.

E. "Personnel Radiation Monitoring with Radiation Badges"

This Learning Central Course #HSC-181 must be completed within 30 days of hire for new radiation workers. Course content includes basic terminology, radiation protection, dosimeter use and care guidelines, exposure limits, ALARA, and DPW instruction.

F. "X-Ray Diffraction Safety Training"

This Learning Central Course #HSC-112-002 presents information regarding hazards, best practices, and regulations associated with the use of x-ray diffraction (XRD) devices. The training must be completed

before working with any XRD equipment and supplemented by function-specific training administered by the XRD owner or key operator.

G. "Radiation Safety Training for Nurses"

Regulations dictate that nurses may not render care to radiation patients without first completing an appropriate course of instruction, with refresher training required annually thereafter. The course content includes discussion of all types of radiation sources that may be encountered in patient treatments including pictures and graphics of the sources and related safety equipment. Nurses will not be issued radiation badges or be permitted to care for a radiation patient without official documentation of having completed this course within the past 12-month period. This is a self-learning computer-based instructional program and includes a competency quiz. This course was developed by the RSO and is managed through the nurse educators at UNMH.

H. "Fluoroscopy Training"

This course with competency quiz is on Learning Central Course # HSC-183 for workers whose job description require them to operate or assist in the operation of fluoroscopy machines. The class teaches radiation safety techniques and strategies in helping to reduce radiation dose to patient and operator while optimizing image quality. The course was developed by the UNMH Medical Physics group and is managed through radiology educators at UNMH. A refresher course, HSC-184, with the same content is also available on Learning Central to assist in meeting required clinical competencies.

I. "Radiation Safety for Cancer Center Radiation Oncology Training"

Course #HSC-212-014 on Learning Central is function-specific training for workers in Radiation Oncology at the UNM Cancer Center, to include Radiation Therapists, Radiation Oncologists, Dosimetrists, and Medical Physicists. Others at the Cancer Center (nurses, managers) may also benefit from this course content.

J. Nuclear Medicine Radiation Safety Training Programs

a. "Radiation Safety Training for Nuclear Medicine"

The intended audience includes Nuclear Medicine Technologists and Physician Authorized Users. The course is required initially and annually thereafter. The course is available as a self-learning computer-based training program with a competency quiz or on Learning Central Course #HSC-212-001.

b. "DOT HazMat IATA Training for Class 7 Radioactive Materials".

This course is required for workers whose job description requires the receipt, processing, or shipping of radioactive material packages. The course must be completed initially and at 3-year intervals, with documentation readily available in the applicable department. This course is available as a self-learning computer-based training program with a competency quiz.

c. "Nuclear Medicine Spill Response". This annual course is available as a self- learning computer-based training program with a competency quiz or on Learning Central Course #HSC-212-004.

FORM #:NAME OF FORM:

RSF-01	"Permit Application to Use Radioactive Materials (fillable pdf file)
RSF-02	"Permit Application to Use Radiation-Producing Machines" (fillable pdf file)
RSF-03	"Radioactive Waste Pick-up Request"
RSF-04	"Dosimetry Enrollment Form" (may be completed on-line)
RSF-05	"Statement of Training & Experience Form"
RSF-06	"Shielding Evaluation Request Form"
RSF-07	"Request for Radiation Safety Wipe Sample Form"
RSF-08	"Radiation Survey of RAM Use Area"
RSF-09	"Declaration of Pregnancy for Radiation Workers"
RSF-10	"Radiation Incident and Spill Report Form"

Common Radiation Safety Forms can be accessed at the HSC Office of Research Radiation Safety Website at <u>https://hsc.unm.edu/research/compliance/radiation-safety/</u>

Attachment F - Acronym Definitions

Acronym	Definition
ALARA	As low as reasonably achievable
AMP	Authorized Medical Physicist
AU	Authorized User
CFR	Code of Federal Regulations
CNMT	Certified Nuclear Medicine Technologist
DIS	Decay-in-storage
DOT	Department of Transportation
DPM	Disintegrations per minute
DPW	Declared pregnant worker
HRA	High radiation area
HSC	Health Sciences Center
HUS	Human Use Subcommittee
IACUC	Institutional Animal Care and Use Committee
IATA	International Air Transport Association
IRB	Institutional Review Board
NMAC	New Mexico Administrative Code
NMED	New Mexico Environment Department
NMMSS	Nuclear Material Management and Safeguard System
NRC	Nuclear Regulatory Commission
NSTS	National Source Tracking System
PH	Permit Holder
RAM	Radioactive materials
RAML	Radioactive materials license
RCB	Radiation Control Bureau
RCC	Radiation Control Committee
RSM	Radiation Safety Manual
RSO	Radiation Safety Officer
SOU	Supervisor of Use
SRMC	Sandoval Regional Medical Center
UNM	University of New Mexico
UNMH	University of New Mexico Hospital
UNMPD	University of New Mexico Police Department
VHRA	Very high radiation area
WDS	With direct supervision
WOS	Without supervision

Attachment G - Signature Page

UNM Radiation Safety Manual Revision: July 22, 2024

Approved By:	UNM Radiation Safety Officer	Date
Approved By:	UNM Radiation Control Committee Chair	Date
Approved By:	Licensee Management Representative	Date