MANAGEMENT OF RADIOACTIVE MATERIALS

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive maintains policy for implementing and maintaining United States Nuclear Regulatory Commission (NRC) License No. 03-23853-01VA.

2. SUMMARY OF MAJOR CHANGES: This directive:
   a. Expands, adds and updates terminology in definitions section (see paragraph 3).
   b. Adds responsibilities for the VHA National Radiation Safety Committee (NRSC) (see paragraph 5).
   c. Clarifies, expands, and updates Department of Veterans Affairs (VA) medical facility Director responsibilities, including notifying the National Health Physics Program (NHPP) of proposed Positron Emission Tomography (PET) facilities and major modifications to existing PET facilities (see paragraph 5).
   d. Clarification and expansion of VA medical facility Radiation Safety Committee and Radiation Safety Officer (RSO) responsibilities (see paragraph 5).
   e. Clarifies and expands upon VA medical facility Director, VA medical facility Radiation Safety Officer, and VA medical facility Radiation Safety Committee roles and procedures in Appendix A.


4. RESPONSIBLE OFFICE: The National Health Physics Program (11SPEC12) is responsible for the contents of this directive. Questions may be referred to 501-257-1571 or VHCONHPP@med.va.gov.


6. RECERTIFICATION: This directive is scheduled for recertification on or before the last working day of February 2026. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.
BY DIRECTION OF THE OFFICE OF THE UNDER SECRETARY FOR HEALTH:

/s/ Kameron L. Matthews, MD, JD
Assistant Under Secretary for Health
For Clinical Services

NOTE: All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

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APPENDIX A

VA MEDICAL FACILITY RADIATION SAFETY COMMITTEE AND RADIATION SAFETY OFFICER REQUIREMENTS ................................................................................. A-1
MANAGEMENT OF RADIOACTIVE MATERIALS

1. PURPOSE

This Veterans Health Administration (VHA) directive maintains standards and responsibilities for the U.S. Nuclear Regulatory Commission (NRC) License No. 03-23853-01VA that was issued to the Department of Veterans Affairs (VA) on March 17, 2003. **AUTHORITY:** Title 38 United States Code (U.S.C.) § 7301(b); Title 10 Code of Federal Regulations (C.F.R.) 30.33 and 35.11.

2. BACKGROUND

NRC has regulatory authority for by-product radioactive materials as defined in NRC regulations, and NRC has issued VA a master materials license (MML). The MML authorizes the licensee to issue permits for the possession and use of licensed material under the license and provides a framework for oversight and licensee inspection of its permittees. The Under Secretary for Health is the named licensed official for the MML. The National Health Physics Program (NHPP) is the principal organizational element for implementation and maintenance of VHA’s national radiation control program for use of radioactive material in the VHA.

3. DEFINITIONS

   a. **Ionizing radiation.** Ionizing radiation means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons and other particles capable of producing ions when they interact with matter. Ionizing radiation does not include non-ionizing radiation, such as radio- or microwaves, visible light, infrared radiation, or ultraviolet radiation.

   b. **Master Materials License.** An MML is a license issued by the NRC to a Federal organization, authorizing the use of radioactive material at multiple sites.

   c. **Nuclear Regulatory Commission Agreement State.** An NRC Agreement State means any State with which NRC or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended. In Agreement States, most radioactive material is regulated by the States instead of the NRC.

   d. **Positron Emission Tomography.** Positron Emission Tomography (PET) is a nuclear medicine imaging modality that produces images of the distribution of positron emitting radionuclides in patients.

   e. **Radiation Control Program.** The Radiation Control Program (RCP) is implemented by the VHA National Radiation Safety Committee (NRSC). This includes the central control over all elements of the NRC-regulated radiation safety program and
the management of the permitting and inspection activities.

4. POLICY

It is VHA policy to ensure the safe and effective use of radioactive materials for the medical care of Veterans and for research by implementing and maintaining NRC Master Materials License No. 03-23853-01VA.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for:

   (1) Ensuring overall VHA compliance with this directive.

   (2) Serving as the named MML official.

   (3) Providing a delegation of authority for the MML.

   (4) Reviewing the annual report from the NRSC and taking action as necessary.

   (5) Assigning actions to implement and maintain the MML to achieve commitments in the license application and regulatory compliance by:

   (a) Using NRC licensing and inspection criteria to achieve commitments in the MML.

   (b) Following consensus best practices for the safe use of radioactive materials.

   (c) Maintaining potential exposure of ionizing radiation to workers and the public from radioactive materials as low as reasonably achievable.

b. **Assistant Under Secretary for Health for Clinical Services.** The Assistant Under Secretary for Health for Clinical Services is responsible for supporting the implementation and oversight of this directive.

c. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

   (1) Communicating the contents of this directive to each of the Veterans Integrated Service Networks (VISN).

   (2) Assisting VISN Directors to resolve implementation and compliance challenges.

   (3) Providing oversight of VISNs to ensure compliance with this directive and its effectiveness.

d. **VHA National Radiation Safety Committee.** The NRSC is the primary national oversight body for all uses of ionizing radiation by the Department of Veterans Affairs authorized under the MML issued by the NRC and is responsible for:
(1) Serving as the principal VHA Central Office organizational element to implement, maintain and oversee the MML.

(2) Completing actions as designated by the Under Secretary for Health under the committee charter (see paragraph 5.a.(3)).

(3) Conducting quarterly committee meetings to include a management representative, Radiation Control Program Officer (RCPO) and two-thirds of the membership, to review the activities of the Radiation Control Program (RCP).

(4) Preparing an annual report to the Under Secretary for Health assessing the procedures, processes and workings needed to implement the MML and maintain its requirements and associated regulations.

(5) Monitoring the core performance indicators developed by the NRSC.

(6) Evaluating significant programmatic actions as reported by the National Health Physics Program (NHPP) Director for permits issued to VA medical facilities, inspections and enforcement actions taken, response to incidents and response to allegations.

(7) Maintaining the MML by periodically reviewing license policies and procedures and if needed, submitting amendment requests for program changes to NRC.


(9) Establishing procedures for procurement, acquisition, use, security, control and accountability of NRC-regulated radioactive material (e.g., byproduct, source and special nuclear material) to ensure compliance with the MML.

(10) Monitoring the performance of the RCP and the RCPO and auditing the implementation of the RCP.

(11) Ensuring that adequate resources are provided to implement the RCP, including implementation of permittee radiation safety programs.

(12) Ensuring that adequate resources are provided for the training of NHPP staff.

(13) Ensuring that permitting and inspection staff are appropriately qualified according to MML commitments and NRC regulations.

(14) Maintaining records under the MML.
(15) Establishing administrative and operational regulation of acquisition, receipt, storage, distribution, use, transfer and disposal of radioactive materials.

(16) Ensuring that inspections are conducted to assess permittee compliance with the provisions of the MML, NRC regulations and the specific permits.

(17) Initiates program policy and enforcement actions as delegated to the NRSC by the Under Secretary for Health.

(18) Advising senior management and NRC of all non-compliance items potentially categorized at severity levels I, II or III, as identified in the NRC enforcement policy.

(19) Reviewing reports from the NHPP Director.

e. **VHA National Health Physics Program Director.** The NHPP Director is the RCPO for the MML and Executive Secretary for the NRSC and is responsible for:

   (1) Overseeing programmatic organizational element to implement and maintain the MML.

   (2) Serving as the principal VHA Central Office advisor on VHA policies and procedures for the MML.

   (3) Directing the day-to-day implementation of the MML, such as: permitting, inspections and enforcement, directing the day-to-day operations of NHPP, preparing and sending reports to the NRSC, response to incidents and response to allegations.

   (4) Coordinating NRSC activities under the supervision of the NRSC chairperson and as authorized by the delegation of authority set by the Under Secretary for Health.

   (5) Developing VHA policy and program guidelines for the MML and other uses of ionizing radiation.

   (6) Reviewing incident reports, amendment requests and other programmatic information from VA medical facility Directors to include addition of a PET facility or major modifications to an existing PET facility.

f. **Veterans Integrated Services Network Director.** Each VISN Director is responsible for:

   (1) Ensuring that all VA medical facilities within the VISN comply with this directive and informing leadership when barriers to compliance are identified.

   (2) Serving as the liaison between the NRSC and VA medical facilities in their respective VISNs.

   (3) Intervening when NHPP findings are not resolved by the VA medical facility.
g. VA Medical Facility Director. The VA medical facility Director with an MML permit is the responsible official to ensure safe use of radioactive materials and regulatory compliance by:

1. Establishing and implementing radiation safety practices and procedures commensurate with the radioactive materials scope of use.

2. Ensuring protection of the health and safety of workers, the public and environment and to achieve regulatory compliance under the MML permit including commitments, conditions and applicable NRC and other Federal regulations with a focus on safety culture as defined by the NRC (emphasize safety over competing goals to ensure the protection of people and the environment).

3. Providing management oversight and support of the radiation safety program to include providing RSO with sufficient authority, organizational freedom, time, resources and management prerogative to:

   a. Identify radiation safety problems.
   
   b. Initiate, recommend or provide corrective actions.
   
   c. Stop unsafe operations.
   
   d. Verify implementation of corrective actions.

4. Establishing a VA medical facility Radiation Safety Committee as described in Appendix A and ensuring approval and continuous coverage by a VA medical facility RSO, including delegating in writing the authority necessary for the RSO to carry out his/her duties. NOTE: The RSO must meet the qualifications required by NRC regulations and must be named on VA medical facility’s radioactive material permit.

5. Ensuring compliance with MML permit commitments, conditions and applicable regulations.

6. Ensuring that research protocols requiring the use of ionizing radiation are reviewed by the VA medical facility Radiation Safety Committee and other appropriate committees and subcommittees (e.g., Research and Development Committee, Institutional Review Board, Institutional Animal Care and Use Subcommittee, Subcommittee on Research Safety). In particular, research protocols involving the administration of ionizing radiation or radioactive material to human subjects must be reviewed for conformance to 10 C.F.R. 35.6 and VHA Directive 1200.05, Requirements for the Protection of Human Subjects in Research, dated January 7, 2019.

7. Reporting to NHPP any incidents requiring reports to NRC pursuant to 10 C.F.R. Parts 20, 21, 30, 35 and 37, such as medical events, exceeding dose limits or contamination limits, unauthorized disposals, lost, stolen or missing radioactive materials, or any other significant program deficiencies. NOTE: Reports to NHPP are in addition to other reports required to be given to or coordinated with the Patient Safety
Manager and other appropriate Quality or Risk Management staff.

(8) Routing amendment requests or other programmatic information to NHPP to the address or email in Appendix A, paragraph 24.

(9) Ensuring radiation workers and other staff have information and assistance, as needed, to report safety concerns, engage in other protected activities and have a safety conscious work environment.

(10) Notifying NHPP by phone when the VA medical facility is:

(a) Inspected by NRC.

(b) Contacted by an NRC Agreement State or other regulatory authority regarding the use of radioactive materials.

(11) Avoiding undue reliance on and ensuring adequate oversight of contractors, consultants and affiliate university staff involved with the use of radioactive material.

(12) Reviewing and signing VA medical facility Radiation Safety Committee minutes not more than 45 days after the date of the meeting as described in Appendix A.

(13) Notifying NHPP when it is decided that the VA medical facility will add a PET facility or perform a major modification to its existing PET facility (e.g., changes of room layout or structural shielding). **NOTE:** Please see notification requirements in Appendix A paragraph 11.

h. **VA Medical Facility Radiation Safety Committee.** The VA medical facility Radiation Safety Committee is responsible for:

(1) Reviewing research protocols that require the use of ionizing radiation as part of the research and, if appropriate, granting approval for such research prior to such research being initiated.

(2) Supporting the VA medical facility Director to ensure the safe use of radioactive materials and regulatory compliance, including committee completion of the tasks and actions in Appendix A.

(3) Overseeing the VA medical facility’s radiation safety program and the VA medical facility RSO’s day to day operations as described in Appendix A.

(4) Sending meeting minutes to the VA medical facility Director.

i. **VA Medical Facility Radiation Safety Officer.** The VA medical facility Radiation Safety Officer (RSO) is an individual who is identified as an RSO on a radioactive material use permit issued by the NHPP. The RSO should report directly to the VA medical facility’s executive management (i.e., member of VA medical facility senior leadership such as Chief of Staff or Associate Director). The VA medical facility RSO is
responsible for:

(1) Ensuring safe use of radioactive materials and regulatory compliance along with the VA medical facility Radiation Safety Committee and VA medical facility Director.

(2) Completing day-to-day actions required by NRC regulations, the VA medical facility's radioactive materials permit and this directive, which include, but are not limited to, the tasks and actions described in Appendix A. NRC NUREG-1556, Vol. 9, Rev. 3, Appendix I, contains an example list of an RSO's duties regarding radioactive material; this document is available at: https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/index.html. **NOTE:** This linked document is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.


(b) VHA Directive 1129 requires each VA medical facility not holding a radioactive material use permit to designate an RSO to oversee machine sources of ionizing radiation.

(3) Performing periodic audits and surveys of services and sections using radioactive materials and reporting results to the RSC.

(4) Reviewing, at least quarterly, occupational and public doses and reporting the analysis, at each meeting, to the VA medical facility Radiation Safety Committee.

(5) Ensuring personnel training is conducted in accordance with regulatory requirements and is commensurate with the individual's duties regarding radioactive material.

(6) Ensuring the facility is prepared to respond to incidents, including medical events as defined in 10 C.F.R. Part 35, involving radioactive materials. This includes provisions for someone in or outside the facility to promptly contact the radiation safety officer or designee.

6. TRAINING

Individuals who work with or in the vicinity of radioactive material must receive training as required by regulatory requirements.

7. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and Records
Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1 or as required by 10 C.F.R. Parts 1 through 199, whichever is more restrictive. Questions regarding any aspect of records management should be addressed to the appropriate Records Manager Liaison and the facility Radiation Safety Officer.

8. REFERENCES


   c. 10 C.F.R. Parts 1 – 199.

   d. 29 C.F.R. 1910.1096.

   e. 49 C.F.R. Parts 171 – 177.


   h. VHA Directive 1129.01, Mandatory Reporting of Misadministrations by Therapy Machine Sources of Ionizing Radiation, dated March 21, 2019.

   i. VHA Directive 1200.01, Research and Development Committee, dated January 24, 2019.


   l. NRC documents (NUREG-1556 series) available at: https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/.
VA MEDICAL FACILITY RADIATION SAFETY COMMITTEE AND RADIATION SAFETY OFFICER REQUIREMENTS

The activities of the Department of Veterans Affairs (VA) medical facility Radiation Safety Committee and the Radiation Safety Officer (RSO) must include but are not limited to the tasks and actions listed in this appendix (consistent with the scope of uses of radioactive materials and machine sources of ionizing radiation):

1. Providing oversight for safe use of radioactive materials to ensure that occupational and public doses are as low as reasonably achievable and to achieve a safety conscious work environment.

2. Maintaining committee membership as established by the VA medical facility Director to include the Chair, RSO, a representative of VA medical facility management (hereinafter known as “management representative”), a Nursing Services representative and other key staff such as a clinical representative for each type of medical authorized use, a representative for research use and work center representatives (based on potential health and safety or patient safety risks) from among nursing staff, nuclear medicine technologists or other ancillary workers and subject matter experts such as a biomedical engineer. **NOTE:** Because a primary role of the Radiation Safety Committee (RSC) is to maintain oversight of the facility’s radiation safety program, it is generally preferable that the RSC Chair is not the RSO.

3. Holding meetings at intervals not to exceed 6 calendar months and establishing a committee quorum of at least one-half of committee membership for meetings, which must include the RSO and management representative.

4. Preparing records and reporting committee results as required by executive management and Title 10 Code of Federal Regulations (C.F.R.) Part 35 and ensuring the records document executive management approvals for actions under 10 C.F.R. Part 35 to include these administrative requirements:

   a. Coordination with other VA medical facility committees as needed and administrative oversight of the VA medical facility Radiation Safety Committee minutes by submitting a copy of VA medical facility Radiation Safety Committee minutes to another medical center oversight committee (such as Medical Executive Committee, Environment of Care Committee, or Safety and Risk Management Committee) within 45 days after the date of the VA medical facility Radiation Safety Committee meeting.

   b. Review and signature by the VA medical facility Director, as an individual, for VA medical facility Radiation Safety Committee minutes not more than 45 days after the date of the VA medical facility Radiation Safety Committee meeting. This review must not be delegated to other executive managers, except in documented situations when the director is away from the facility for an extended period. In such situations, the director must review and sign the minutes promptly upon return to the facility. **NOTE:** A
person designated as Interim Director, when a VA medical facility Director has permanently ceased that duty, may sign the minutes.

c. Use of an agenda format with old business, new business and specific standing agenda items listed to include agenda items for dosimetry results for workers, status of all procedures requiring a written directive, status of footprint management and status of security of radioactive materials.

d. Use of an attendance matrix, listing committee members and documenting which members attended each meeting.

e. Use of a tracking matrix with unresolved items assigned a tracking number when first identified at a VA medical facility Radiation Safety Committee meeting and items tracked to closure.

f. Use of a consistent format for the committee minutes to include an organized file with supporting documents used during meetings stored in hard copy or digital format for ease of review by external inspectors.

5. Maintaining oversight for the radiation safety program through periodic reviews and audits, to include:

a. Reviewing annually the radiation safety program as specified in 10 C.F.R. 20.1101, to include locations of use with emphasis on decommissioning records as specified in 10 C.F.R. Part 30.

b. Reviewing or auditing as needed based on the radioactive materials scope of use.

c. Evaluation of results from audits, reviews and inspections to determine possible systemic issues or trends. For regulatory violations, adverse incidents, “near misses”, and programmatic deficiencies, identify root causes, specify and implement corrective actions and other actions to prevent recurrence and determine if any results are applicable to other uses of radioactive materials.

d. Distribution of results of audits, reviews and inspections to appropriate work centers and availability to the staff working with or around radioactive materials.

e. Oversight and follow-up to resolve health and safety issues and radiation safety program deviations as needed.

f. Evaluation of possible undue reliance on and maintaining oversight of contractors, consultants and affiliate university staff involved with the use of radioactive material.

6. Reviewing, (at least every 6 months by RSC and at least quarterly by the RSO) occupational and public doses and reporting the analysis at each meeting. **NOTE: The RSO conducts the reviews and prepares the reports, which are reported to the Radiation Safety Committee.**
7. Reviewing, at least every 6 months, any identified health and safety issues or possible radiation safety program deviations from regulatory compliance or required practices.

8. Reviewing and approving training and experience for prospective RSOs, authorized users and other staff requiring regulatory approval.

9. Reviewing and approving proposed changes to training, equipment, and radiation safety procedures or practices.

10. Ensuring compliance with master materials license (MML) permit conditions regarding radioactive materials used, amounts of radioactive material possessed, and obtaining a permit amendment before obtaining materials or allowing uses not currently authorized by the permit.

11. Permittees planning to construct a new Positron Emission Tomography (PET) facility or make changes to an existing PET facility that could significantly increase radiation doses in adjacent areas must:
   a. Notify the National Health Physics Program (NHPP) at the beginning of the initial planning stage for guidance and design consultation.
   b. Submit a structural shielding design assessment to specify required radiation shielding for NHPP review prior to finalization of construction plans.
   c. Maintain documentation, for NHPP review during routine inspection, of a radiation protection survey to verify the adequacy of installed shielding.

12. Conducting a physical inventory every 6 months to account for all radioactive sources and/or devices received and possessed under the permit. NOTE: Sources or devices acquired from and labeled (or otherwise described in an accompanying written brochure) by distributors as “exempt” or “generally licensed” per Nuclear Regulatory Commission or Agreement State regulations are excepted from the 6-month inventory but may be included.

13. Ensuring sealed source records are maintained for transfer or disposition to document leak test results if the sealed source was required by regulation or permit condition to have a leak test.

14. Providing results if requested, for sealed source inventories and leak tests to NHPP.

15. Providing oversight for security of radioactive materials by:
   b. Prevention of adversary or unauthorized removal of radioactive materials.
c. Compliance with the security guidelines in VHA Directive 1200.08, Safety of Personnel and Security of Laboratories Involved in VA Research, dated April 24, 2019.

d. Ensuring adequate security commensurate with possible risks of radioactive materials unauthorized use.

16. Classifying sealed sources, not in active use for their intended clinical or research purpose for a period of 24 months, as disused sources and evaluating the disused sources for disposal as expeditiously as possible.

17. Reviewing and evaluating research involving human subjects (unless the research only requires use of the results of tests using ionizing radiation that have been conducted for medical care purposes only) by:

a. Compliance with regulations in 10 C.F.R. 35.6 for radioactive materials use in human subject research.

b. Compliance with VHA Directive 1200.05, Requirements for the Protection of Human Subjects in Research, dated January 7, 2019, for obtaining and documenting informed consent.

18. Using NRC documents (NUREG-1556 series) as guidance to prepare and submit requests for new, renewed or amended permits.

19. Restricting radiation safety program implementation to be consistent with the program codes (i.e., whether broad-scope or limited-scope medical or research uses) and permitting conditions approved for the permittee.

20. Ensuring approvals for authorized users and locations of use (except as authorized per 10 C.F.R. 35.14) are limited to broad-scope permittees.

21. Ensuring compliance with posting requirements specified in 10 C.F.R. Part 19 and 21.6, including posting the following, on or with NRC Form 3:

a. VHA Radioactive Material Permit No. [Insert specific permit number] issued under VHA NRC License No. 03-23853-01VA authorizes the use of radioactive materials at this location. Contact [insert RSO name] at [insert location information such as room].

b. VHA license, amendments and supporting application are available for examination by contacting NHPP at 501-257-1571, or at mailing address NHPP (115HP/NLR), Bldg. 101, Room 208, 2200 Fort Roots Drive, North Little Rock, AR 72114.

22. Providing information to workers at the various locations of use or work centers, especially satellite locations of use, on current radiation safety program and regulatory issues, as needed, using NHPP SharePoint/Intranet website, periodic newsletters and other information resources made available to permittees.

24. Amendment requests or other programmatic information should be routed to NHPP at:

    National Health Physics Program (11SPEC12)
    Department of Veterans Affairs
    Veterans Health Administration
    2200 Fort Roots Drive, Bldg. 101, Room 208
    North Little Rock, AR 72114
    Or via email at VACO NHPP (VHCONHPP@va.gov).