

MANAGEMENT OF RADIOACTIVE MATERIALS

- 1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) Directive establishes the policies and assigns actions to implement and maintain Nuclear Regulatory Commission (NRC) License No. 03-23853-01VA.
- 2. SUMMARY OF MAJOR CHANGES:** The major changes in this Directive incorporate the prescriptive requirements for facility level Radiation Safety Committees, refer to other directives and a handbook for radiation protection, and revise wording for clarity.
- 3. RELATED ISSUES:** VHA Directive 1129, VHA Directive 2013-007, and VHA Handbook 1105.04.
- 4. RESPONSIBLE OFFICE:** The Office of Patient Care Services, National Health Physics Program Office, is responsible for the contents of this Directive. Questions are to be directed to 501-257-1571 or e-mail address: vhconhpp@va.gov.
- 5. RESCISSIONS:** VHA Directive 1105.01, dated October 7, 2009, is rescinded.
- 6. RECERTIFICATION:** This Directive is scheduled for recertification on or before the last working day of February 2020.

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Interim Under Secretary for Health

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MANAGEMENT OF RADIOACTIVE MATERIALS

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes the policies and assigns actions to implement and maintain the Nuclear Regulatory Commission (NRC) License No. 03-23853-01VA that was issued to the Department of Veterans Affairs on March 17, 2003. **AUTHORITY:** Title 38 U.S.C. 7301(b).

2. BACKGROUND:

a. NRC has regulatory authority for by-product radioactive materials as defined in applicable NRC regulations. Under the master materials license issued by NRC, VHA is authorized to issue permits to individual VA medical facilities to approve the facilities use of radioactive materials.

b. The Under Secretary for Health is the named licensed official for the master materials license. The Under Secretary for Health has established overall policies in, this directive and commitments in the master materials license application and subsequent license amendments.

c. The National Radiation Safety Committee (NRSC) is tasked to provide oversight of the master materials license on behalf of the Under Secretary for Health. NRSC is the principal VA Central Office level organizational element to implement the master materials license. NRSC maintains and implements the master materials license through the National Health Physics Program (NHPP). NRSC operates under a committee charter and delegation of authority approved by the Under Secretary for Health.

d. NHPP directs day-to-day implementation of the master materials license and coordinates NRSC activities. The NHPP Director is concurrently the VHA Radiation Control Program Officer and NRSC Executive Secretary.

3. POLICY: It is VHA policy to ensure management of radioactive materials by implementing and maintaining NRC Master Materials License No. 03-23853-01VA.

4. RESPONSIBILITIES:

a. **Under Secretary for Health.** The Under Secretary for Health functions as the named master materials license official, establishes policies for the master materials license, provides a delegation of authority for the master materials license, and assigns actions to implement and maintain the master materials license to achieve commitments in the license application and regulatory compliance by:

(1) Using NRC licensing and inspection criteria.

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

(3) Maintaining potential exposure of ionizing radiation to workers and the public from radioactive materials to a level that is as low as reasonably achievable (ALARA).

b. **National Radiation Safety Committee.** The National Radiation Safety Committee (NRSC) functions as the principal VA Central Office level organizational element to implement the master materials license and is responsible for:

- (1) Implementing and maintaining the master materials license.
- (2) Completing actions under the committee charter using the delegation of authority.
- (3) Providing management oversight through quarterly committee meetings.
- (4) Preparing an annual report to the Under Secretary for Health based on a series of program assessments.
- (5) Monitoring results of the core performance indicators.
- (6) Evaluating significant programmatic actions for permits issued to facilities, inspections and enforcement actions taken, response to incidents, and response to allegations.
- (7) Maintaining the master materials license by periodically reviewing license policies and procedures, and if needed, submitting amendment requests for program changes to NRC.
- (8) Reviewing, evaluating, and taking appropriate programmatic actions to protect worker and patient health and safety from other types of ionizing radiation, such as machine sources, to include oversight under the following directives and handbook:
 - (a) VHA Directive 1129, Radiation Protection for Machine Sources of Ionizing Radiation.
 - (b) VHA Directive 2013-007, Mandatory Reporting for Misadministrations of Therapy Machine Sources of Ionizing Radiation.
 - (c) VHA Handbook 1105.04, Fluoroscopy Safety.

c. **National Health Physics Program Director.** The National Health Physics Program (NHPP) Director is the overall programmatic organizational element to implement and maintain the master materials license. The NHPP Director functions concurrently as the Radiation Control Program Officer for the master materials license and Executive Secretary for the NRSC and is responsible for:

- (1) Serving as the principal VA Central Office level advisor on policies and procedures for the master materials license.
- (2) Directing the day-to-day implementation of the master materials license, such as: permitting, inspections and enforcement, response to incidents and response to allegations.
- (3) Coordinating NRSC activities under the supervision of the committee chairperson and as authorized by the delegation of authority.
- (4) Developing policy and program guidelines for the master materials license and other uses of ionizing radiation.

d. **VA Medical Facility Directors.** The Director of a VA medical facility with a master materials license permit functions as 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) Providing executive management oversight to ensure protection of the health and safety of workers, the public, and environment, and to achieve regulatory compliance under the master materials license permit with a focus to a safety culture.
- (3) Assigning staff with sufficient authority and resources to implement the radiation safety practices and procedures.
- (4) Establishing a Radiation Safety Committee and ensuring approval and continuous coverage by a Radiation Safety Officer.
- (5) Complying with master materials license permit commitments, conditions, and applicable regulations.
- (6) Requiring research protocols that require the use of ionizing radiation as part of the research be reviewed by the 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 accordance with VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research.
- (7) Reporting (to NHPP) any incidents such as medical events, exceeding dose limits or contamination limits, unauthorized disposals, 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/or other Quality, Risk Management, or Systems Redesign staff.

- (8) Routing amendment requests or other programmatic information to NHPP at:

National Health Physics Program (115HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive, Bldg 101, Room 208
North Little Rock, AR 72114

Or via e-mail at VACO NHPP (vhconhpp@va.gov).

- (9) Ensuring radiation workers and other workers and 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 when the medical facility is inspected by NRC.
- (11) Notifying NHPP when the medical facility is contacted by an Agreement State or other regulatory authority regarding the use of radioactive materials.

(12) Avoiding undue reliance on affiliate universities or consultants.

e. **Radiation Safety Committee and Radiation Safety Officer.** The Radiation Safety Committee and the Radiation Safety Officer function together to support the Director and take all actions necessary to ensure the safe use of radioactive materials and regulatory compliance. In the usual organizational arrangements, the Radiation Safety Officer completes day-to-day actions with oversight by the Radiation Safety Committee.

(1) Overall, the actions by the Radiation Safety Committee and Radiation Safety Officer must include, but not be limited to, the tasks and actions in Appendix A.

(2) For organizational alignment, the Radiation Safety Officer should report directly to the facility's executive management (i.e., member of facility senior leadership such as chief of staff or associate director).

5. REFERENCES:

- a. Title 10 CFR Parts 19-21, 30-33, 35, 37, and 71.
- b. Title 29 CFR 1910.1096.
- c. Title 49 CFR 171 to 177.
- d. VHA Handbook 1200.01, Research and Development (R&D) Committee.
- e. VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research.
- f. VHA Handbook 1200.06, Control of Hazardous Agents in VA Research Laboratories.
- g. VHA Directive 1129, Radiation Protection for Machine Sources of Ionizing Radiation.
- h. VHA Directive 2013-007, Mandatory Reporting for Misadministrations of Therapy Machine Sources of Ionizing Radiation.
- i. VHA Handbook 1105.04, Fluoroscopy Safety.

**RADIATION SAFETY COMMITTEE AND RADIATION SAFETY OFFICER
REQUIREMENTS**

The overall actions by the Radiation Safety Committee and the Radiation Safety Officer must include, but not be 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 with a focus to ensure occupational and public doses are as low as reasonably achievable (ALARA) and a safety conscious work environment is achieved.
2. Establishing committee membership to include the Chair, Radiation Safety Officer, a 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.
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 Radiation Safety Officer and management representative.
4. Preparing records and reporting committee results as required by executive management and/or Title 10 Code of Federal Regulations (CFR) Part 35 and ensuring the records document executive management approvals for actions under 10 CFR Part 35 to include these administrative requirements:
 - a. Coordination with other facility committees as needed and administrative oversight of the Radiation Safety Committee minutes by submitting a copy of Radiation Safety Committee minutes to a higher-level committee within 45 days after the date of the Radiation Safety Committee meeting.
 - b. Review and signature by the director, as an individual, for Radiation Safety Committee minutes not more than 45 days after the date of the 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.
 - 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 for security.
 - d. Use of an attendance matrix listing committee members and whether a member attended each individual meeting.
 - e. Use of a tracking matrix with unresolved items assigned a tracking number when first identified at a 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 electronic format for ease of review by external inspectors.

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

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

b. Reviews or audits as needed based on the radioactive materials scope of use.

c. Evaluation of results from audits, reviews and inspections to determine possible generic issues or trends. Identify root causes, specify corrective actions and 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 all 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 affiliate universities or consultants.

6. Reviewing, at least every 6 months, occupational and public doses.

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 Radiation Safety Officers, authorized users and other staff requiring regulatory approval.

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

10. Ensuring sealed source inventories are completed:

a. Quarterly, for sealed sources with either current activity greater than 1 millicurie or current activity greater than 1000 times the quantities in 10 CFR Part 20, Appendix C.

b. Semiannually, for all other sealed sources except sources specifically exempted by 10 CFR 30.

11. 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.

12. Providing results if requested, for sealed source inventories and leak tests to NHPP.
13. Providing oversight for security of radioactive materials by:
 - a. Compliance with regulations in 10 CFR 20.1801, 20.1802, and 10 CFR Part 37.
 - b. Prevention of adversary or unauthorized removal of radioactive materials.
 - c. Compliance with the security guidelines in VHA Handbook 1200.06, Control of Hazardous Agents in VA Research Laboratories.
 - d. Focusing on adequate security commensurate with possible risks of radioactive materials unauthorized use.
14. 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.
15. Reviewing and evaluating human subject research (if the research only requires use of the results of tests using ionizing radiation that has been conducted for medical care purposes only) by:
 - a. Compliance with regulations in 10 CFR 35.6 for radioactive materials use in human subject research.
 - b. Compliance with guidelines for obtaining and documenting research informed consent as required by VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research.
16. Using NRC documents (NUREG-1556 series) as guidance to prepare and submit requests for new, renewed, or amended permits.
17. 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.
18. Ensuring approvals for authorized users and locations of use (except as authorized per 10 CFR 35.14) are limited to broad-scope permittees.
19. Ensuring compliance with posting requirements specified in 10 CFR Part 19 and 21.6, as in the following:
 - 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 Radiation Safety Officer 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.

20. 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 Intranet Web site, periodic newsletters, and other information resources made available to permittees.

Taylor, Tiresha

From: Null, Kevin
Sent: Tuesday, March 01, 2016 4:25 PM
To: Tomczak, Tammy
Cc: Taylor, Tiresha
Subject: FW: VHA Directive 1105
Attachments: VHA_DIR_1105_02_10_2015.pdf; NRCform665VAmmIVHAdirective1105032016.docx

Tammy, the attached document (VHA Directive 1105) is information from the VA, and is not an amendment request, and should not be processed in as an action.

It needs to get into ADAMS. Attached is a 665.

Thanks,

Kevin

From: Adams, Craig L. [mailto:Craig.Adams@va.gov]
Sent: Tuesday, March 01, 2016 3:33 PM
To: Null, Kevin <Kevin.Null@nrc.gov>
Cc: Offutt, Lisa M <lisa.offutt@va.gov>; Mayo, Kelly <Kelly.Mayo@va.gov>
Subject: [External_Sender] VHA Directive 1105

Kevin,

This is in response to the February 9, 2016 letter, representing Amendment No. 12 to NRC License No. 03-23853-01VA. Attached is a copy of VHA Directive 1105. It can be found on the internet. Please let us know if this fulfills the request or if you desire additional information in this regard. Thank you.

v/r

CRAIG L. ADAMS, MPH
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