Department of Veterans Affairs Veterans Health Administration Washington, DC 20420 VHA DIRECTIVE 1105.01 Transmittal Sheet October 7, 2009

MANAGEMENT OF RADIOACTIVE MATERIALS

- **1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) Directive establishes policies and assigns the actions to implement and maintain Nuclear Regulatory Commission (NRC) License No. 03-23853-01VA. *NOTE:* NRC issued this master materials license to VHA on March 17, 2003.
- **2. SUMMARY OF MAJOR CHANGES:** The major changes in this Directive incorporate focus to a safety culture, oversight for facility-level Radiation Safety Committees, and undue reliance on affiliate universities or consultants.
- 3. RELATED ISSUES: None.
- **4. RESPONSIBLE OFFICE:** The Office of Patient Care Services, National Health Physics Program Office (11/HP) 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 RESCISSIONS:** VHA Directive 1105.1 dated September 22, 2004, is rescinded.
- **6. RECERTIFICATION:** This Directive is scheduled for recertification on or before the last working day of October 2014.

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MANAGEMENT OF RADIOACTIVE MATERIALS

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes policies and assigns actions to implement and maintain the Nuclear Regulatory Commission (NRC) License No. 03-23853-01VA. *NOTE:* NRC issued VHA a master materials license on March 17, 2003.

2. BACKGROUND

- a. NRC has regulatory authority for by-product radioactive materials as defined in applicable NRC regulations. Formerly, NRC issued individual licenses to Department of Veterans Affairs (VA) medical facilities to use by-product radioactive materials. Under the master materials license, VHA is authorized to issue individual permits to VA medical facilities; replacing previous NRC licenses.
- b. The Under Secretary for Health is the named license official for the master materials license. The Under Secretary for Health establishes policies for the master materials license through VHA Directive 1105.01, and commitments in the master materials license application. The Under Secretary for Health provides oversight for the master materials license through the National Radiation Safety Committee (NRSC).
- c. 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 the 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 the management of radioactive materials by implementing and maintaining NRC Master Materials License No. 03-23853-01VA.

4. ACTION

- a. <u>Under Secretary for Health</u>. 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, 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. <u>NRSC</u>. NRSC functions as the principal VA Central Office level organizational element to implement the master materials license. It 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 (e.g., permitting, inspections and enforcement, 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.
- c. <u>NHPP Director</u>. The NHPP Director (the overall programmatic organizational element to implement and maintain the master materials license) who functions concurrently as the Radiation Control Program Officer for the master materials license and Executive Secretary for the NRSC, 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. <u>Medical Facility Directors</u>. Medical facility directors with a master materials license permit, function 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. Establishing a Radiation Safety Committee and ensuring approval and continuous coverage by a Radiation Safety Officer.
- (4) Complying with master materials license permit commitments, conditions, and applicable regulations.
- (5) 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 1200.01. *NOTE:* See Section 4. e. (16) below for requirements if the research only requires the use of the results of tests using ionizing radiation that has been conducted for medical care purposes only.
- (6) Reporting to NHPP any incidents or medical events exceeding dose limits or contamination limits, unauthorized disposals or missing radioactive materials, or any significant program deficiencies.
 - (7) 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

- (8) 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.
 - (9) Notifying NHPP when the medical facility is inspected, or otherwise contacted by NRC.
- (10) Notifying NHPP when the medical facility is contacted by an Agreement State or other regulatory authority regarding the use of radioactive materials.
 - (11) Avoiding undue reliance on affiliate universities or consultants.

- e. <u>Radiation Safety Committee and Radiation Safety Officer</u>. The Radiation Safety Committee and 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. Overall, the actions by the Radiation Safety Committee and Radiation Safety Officer must include, but not be limited to:
- (1) Providing oversight for the safe use of radioactive materials with a focus to ensure occupational and public doses are ALARA and a safety conscious work environment is achieved.
- (2) Establishing committee membership to include the Radiation Safety Officer, a management representative, a representative for each type of authorized use and a representative from Nursing Service.
- (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 35 (e.g., 35.24 and 35.26).
- (5) Coordinating with other medical facility committees as needed, and reporting results of committee meetings to executive management or other medical facility oversight committees.
- (6) Completing or providing oversight for the radiation safety program through periodic reviews and audits, to include:
- (a) Annual radiation safety program review per 10 CFR 20.1101, to include locations of use with emphasis on decommissioning records per 10 CFR 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.
 - (7) Reviewing, at least every 6 months, occupational and public doses.

- (8) Reviewing, at least every 6 months, any identified health and safety issues or possible radiation safety program deviations from regulatory compliance or required practices.
- (9) Reviewing and approving training and experience for prospective Radiation Safety Officers, authorized users and other staff requiring regulatory approval.
- (10) Reviewing and approving proposed changes to training, equipment, facilities and radiation safety procedures or practices.
 - (11) 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 20, Appendix C.
- (b) Semiannually, for all other sealed sources except sources specifically exempted by 10 CFR 30
- (12) 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.
 - (13) Providing results if requested, for sealed source inventories and leak tests to NHPP.
 - (14) Providing oversight for security of radioactive materials by:
- (a) Compliance with regulations per 10 CFR 20.1801, 10 CFR 20.1802 and 10 CFR 37 (when issued).
 - (b) Prevention of adversary or unauthorized removal of radioactive materials.
 - (c) Compliance with the security guidelines in VHA Handbook 1200.06.
- (d) Focusing on adequate security commensurate with possible risks of radioactive materials unauthorized use.
- (15) 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.
 - (16) Reviewing and evaluating human subject research by:
- (a) Compliance with regulations per 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.

- (17) Using NRC documents (NUREG-1556 series) as guidance to prepare and submit requests for new, renewed, or amended permits.
- (18) 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.
- (19) Ensuring approvals for authorized users and locations of use (except as authorized per 10 CFR 35.14) are limited to broad-scope permittees.
- (20) Ensuring compliance with posting requirements per 10 CFR 19 and 10 CFR 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 number, mail stop, or telephone number] to examine the permit and supporting documents.
- (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.
- (21) 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.

5. REFERENCES

- a. Title 10 CFR 19-21, 30-33, 35, 37 (when issued), and 71.
- b. Title 49 CFR 100 to 177.5.
- c. VHA Handbook 1200.01.
- d. VHA Handbook 1200.05.
- e. VHA Handbook 1200.06.