

## 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: The NRC issued this master materials license to the VHA on March 17, 2003.*
- 2. SUMMARY OF MAJOR CHANGES:** This is a major revision to establish policies and assign the actions to implement and maintain NRC License No. 03-23853-01VA. The emphasis is for actions by the National Radiation Safety Committee (NRSC), the National Health Physics Program (NHPP), and individual medical centers issued permits to receive, use, or possess radioactive materials. This Directive also establishes authority for the NRSC to provide oversight for other uses of ionizing radiation.
- 3. RELATED ISSUES:** None.
- 4. RESPONSIBLE OFFICE:** The NHPP (11/HP) is responsible for the contents of this Directive. Questions are to be directed to the NHPP at e-mail address: [vhconhpp@med.va.gov](mailto:vhconhpp@med.va.gov) or telephone (501) 257-1571.
- 5. RESCISSIONS:** VHA Directive 1105.1 dated March 13, 2000, and VHA Handbook 1105.1 dated March 13, 2000.
- 6. RECERTIFICATION:** This document will be recertified on or before the last working day of September 2009.

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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 Nuclear Regulatory Commission (NRC) License No. 03-23853-01VA. *NOTE: The NRC issued this master materials license to the VHA on March 17, 2003.*

### 2. BACKGROUND

a. NRC has regulatory authority for byproduct radioactive materials produced by using nuclear fission. Formerly, the NRC issued individual licenses to Department of Veterans Affairs (VA) medical centers to use byproduct radioactive materials. Under the master materials license, the VHA is authorized to issue individual permits to VA medical centers, replacing the 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 this VHA Directive 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. The NRSC is the principal headquarters-level organizational element to implement the master materials license. The NRSC maintains and implements the master materials license through the National Health Physics Program (NHPP). The NRSC operates under a committee charter and delegation of authority approved by the Under Secretary for Health.

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

e. The master materials license does not include the use of non-byproduct radioactive materials. However, the NHPP and the master materials license programmatic efforts do include use of non-byproduct radioactive materials (i.e., natural and accelerator-produced radioactive materials).

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

### 4. ACTION

a. **Under Secretary for Health.** The Under Secretary for Health functions as the named license official, establishes policies, provides a delegation of authority, and assigns the 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, and

(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.

b. **NRSC.** The NRSC functions as the principal 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 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 submitting amendment requests for program changes, if needed, to the NRC; and

(8) Reviewing, evaluating, and taking appropriate programmatic actions to protect worker and patient health and safety for other types of ionizing radiation, such as machine sources.

c. **Director, NHPP.** The Director, NHPP (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 headquarters-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 activities of the NRSC under the supervision of the committee chairperson and as authorized by the delegation of authority; and

(4) Developing policy and program guidelines for the master materials license and other uses of ionizing radiation.

d. **Medical Center Directors.** Medical center 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 the environment and to achieve regulatory compliance under the master materials license permit.

(3) Assigning staff with sufficient authority and resources to implement the radiation safety practices and procedures.

(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, the Institutional Review Board (IRB), and the Research and Development Committee. The consent of the research subject and the documentation of this in the research consent form must follow the requirements in VHA Directive 1200.5, Appendix C. Note: See section 4e(16) for requirements if the research only requires the use of the results of test using ionizing radiation that has been conducted for medical care purposes only.

(6) Reporting to the 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 the 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 and engage in other protected activities.

(9) Notifying the NHPP when the medical center is inspected, or otherwise contacted by the NRC.

(10) Notifying the NHPP when the medical center is contacted by an Agreement State or other regulatory authority regarding the use of radioactive materials.

e. **Radiation Safety Committee.** The Radiation Safety Committee functions in conjunction with the Radiation Safety Officer to support the Director and ensure the safe use of radioactive materials and regulatory compliance by:

- (1) Providing oversight for the safe use of radioactive materials to ensure occupational and public doses are as low as reasonably achievable (ALARA).
- (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 (which must include the Radiation Safety Officer and management representative) for meetings at least one-half of committee membership.
- (4) Preparing records and reporting committee results as required by executive management and/or Title 10 Code of Federal Regulations (CFR) 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 center committees, as needed.
- (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 uses.
  - (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 made available 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.
- (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/or 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 one 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 for sealed source inventories and leak tests to the NHPP, if requested.

(14) Providing oversight for security of radioactive materials by:

(a) Compliance with regulations per 10 CFR 20.1801 and 10 CFR 20.1802.

(b) Prevention of adversary or unauthorized removal of radioactive materials.

(c) Compliance with the security guidelines in VHA Handbook 1200.6.

(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 1200.5.

(c) Coordination with the IRB to ensure that for research requiring the use of ionizing radiation, the consent process and the written informed consent document informs the research subject about the study requirement for such a test and the risks associated with the tests. For research involving the use of test results where the test uses ionizing radiation and is conducted solely for medical care purposes, that the consent process and the written informed consent document informs the research subject that the test is not required for the research and only the results will be used.

(17) Using the Nuclear Regulatory Commission 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 21.6, as in the following:

(a) VHA Radioactive Material Permit No. [*insert specific permit number*] issued under VHA Nuclear Regulatory Commission 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 available for examination by contacting the 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 the NHPP intranet Web site, periodic newsletters, and other information resources made available to permittees.

## 5. REFERENCES

- a. Title 10 CFR 19, 20, 30-33, 35, and 71.
- b. Title 49 CFR 100 to 177.