RADIATION PROTECTION FOR MACHINE SOURCES OF IONIZING RADIATION

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) Directive establishes policies and actions to implement and maintain a radiation protection compliance program for machine sources of ionizing radiation that are used for medical diagnosis and treatment.

2. SUMMARY OF MAJOR CHANGES: This is a new directive to address radiation protection compliance for machine sources of ionizing radiation.

3. RELATED ISSUES: VHA Directive 1105, VHA Directive 2013-007, and VHA Handbook 1105.04.

4. RESPONSIBLE OFFICE: The Office of Patient Care Services, National Health Physics Program Office (NHPP), 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: None.

6. RECERTIFICATION: This Directive is scheduled for recertification on or before the last working day of February 2020.

Carolyn M. Clancy, MD
Interim Under Secretary for Health

DISTRIBUTION: E-mailed to the VHA Publication Distribution List on 02/10/2015.

RADIATION PROTECTION FOR MACHINE SOURCES OF IONIZING RADIATION

1. PURPOSE: This Directive establishes policies and assigns actions for a radiation protection compliance program for machine sources of ionizing radiation used for medical diagnosis and treatment. The purposes are for VHA to have compliance oversight for the machine sources and to achieve conformity with regulatory and community standards such as the radiation safety aspects of Occupational Safety & Health Administration (OSHA) regulations, Veteran's Health Care Eligibility Reform Act of 1996, Food and Drug Administration (FDA) regulations, The Joint Commission healthcare standards, VHA handbooks, and with professional standards of practice of organizations such as American College of Radiology. **AUTHORITY:** 38 U.S.C. 7301(b).

2. BACKGROUND:

a. The goals for compliance audits are to complete technical reviews and consultative assistance consistent with the overall VHA commitment to high-quality patient care and to protect public health and safety. The compliance audit is based on the concept of the clinical audit with a focus on the best practices to protect patients and workers, and to improve the quality and the outcome of patient care, through a structured review whereby practices, procedures, and results are examined against agreed consensus standards, with modifications of the practices where indicated and the application of new standards if necessary.

b. OSHA has regulatory authority for protection of workers from ionizing radiation from machine sources at federal facilities. The Nuclear Regulatory Commission (NRC) has regulatory authority for by-product radioactive materials as defined in NRC regulations. In cases where an individual worker receives radiation exposure from both machine sources of ionizing radiation and radioactive materials, NRC regulations take precedence.

c. FDA regulates medical device products intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases, including machine sources of ionizing radiation. Machine sources of ionizing radiation must comply with FDA regulations at the time of installation. VA medical facilities must ensure machine sources of ionizing radiation maintain compliance with FDA regulations effective at the time of installation.

d. The Under Secretary for Health has established policies and assigned responsibilities for radiation protection for uses of ionizing radiation under the following directives and handbook:

(1) VHA Directive 1105, Management of Radioactive Materials.

(2) VHA Directive 2013-007, Mandatory Reporting for Misadministrations of Therapy Machine Sources of Ionizing Radiation.

(3) VHA Handbook 1105.04, Fluoroscopy Safety.

e. The Under Secretary for Health has established compliance oversight through the National Radiation Safety Committee (NRSC), which is the principal VHA Central Office organizational element to implement radiation protection policies for machine sources of ionizing radiation.

NRSC operates under a committee charter and delegation of authority approved by the Under Secretary for Health.

f. The National Health Physics Program (NHPP) implements the day-to-day NRSC radiation protection actions for the use of machine sources of ionizing radiation and coordinates NRSC activities. The NHPP Director functions as the executive secretary for NRSC.

3. POLICY: It is VHA policy to ensure radiation protection for machine sources of ionizing radiation and provide machine sources compliance oversight through this directive.

4. RESPONSIBILITIES:

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

(1) Delegating authority to the NRSC to schedule and ensure completion of periodic compliance audits by NHPP at VA medical facilities that use machine sources of ionizing radiation to include the following:

(a) Identifying non-conformances to applicable regulations or consensus best practices for radiation protection.

(b) Issuing reports with requirements to correct or mitigate substantive safety issues and with recommendations to evaluate corrective actions for quality improvement purposes.

(c) Tracking corrective actions to completion.

(2) Requiring VA medical facilities to follow consensus best practices for the safe use of machine sources of ionizing radiation, to keep radiation exposures to workers and the public as low as reasonably achievable (ALARA), and to maintain optimum radiation exposure to patients.

(3) Evaluating possible quality improvements for radiation protection or patient safety for enterprise-wide implementation.

b. **National Radiation Safety Committee.** The National Radiation Safety Committee is responsible for:

(1) Requiring NHPP to implement day-to-day radiation protection compliance oversight for machine sources of ionizing radiation to include periodic compliance audits by NHPP.

(2) Maintaining headquarters level compliance oversight by holding quarterly committee meetings.

(3) Preparing an annual report to the Under Secretary for Health to include a radiation protection summary for machine sources of ionizing radiation and identifying possible quality improvements for enterprise-wide implementation.

(4) Establishing a therapy machine registration program for VA medical facilities that have linear accelerators for patient treatment.

(5) Evaluating significant programmatic actions (e.g., equipment registration, compliance audits results and corrective actions, response to incidents or reports of misadministrations, and response to allegations) and identifying possible enterprise-wide quality improvements.

(6) Reviewing, evaluating, and taking appropriate programmatic actions to protect workers, public, and patient health and safety for uses of machine sources of ionizing radiation.

c. **National Health Physics Program.** The National Health Physics Program (NHPP) is responsible for:

(1) Coordinating NRSC activities under the supervision of the committee chairperson and as authorized by the delegation of authority and this directive.

(2) Implementing the radiation protection compliance oversight program for machine sources of ionizing radiation to include:

(a) Maintaining the therapy machine registration program.

(b) Completing periodic radiation protection compliance audits for machine sources of ionizing radiation at the following frequencies:

1. Reactive or situational audits, as needed, to evaluate adverse outcomes, incidents, or reports of a misadministration;

2. Three-year audit cycle for VA medical facilities with machine sources such as linear accelerators used for patient treatments; and

3. Three-year audit cycle for VA medical facilities with machine sources used for diagnostic and interventional x-ray imaging with adjustments to the frequency approved by the NRSC based on the scope of use of machine sources of ionizing radiation.

(c) Evaluating reported incidents, adverse outcomes, allegations, or misadministrations.

1. Coordinating with national program directors (Director, National Radiology Program, Director, National Radiation Oncology Program, National Director, Nuclear Medicine Service, and the Assistant Secretary for Health for Dentistry) for radiation protection program guidance, recommendations for quality improvement, and resolution of worker, public, or patient safety issues.

2. Issuing stop work orders to VA medical facilities for any time urgent circumstances that significantly impact health and safety of workers, public, or patients and recommending to Deputy Under Secretary for Health for Operations and Management (10N) stop work orders (in coordination with the national program directors above) for other circumstances that impact health and safety of workers, public, or patients.

3. Developing and issuing radiation protection program guidance for machine sources of ionizing radiation.

d. **Director, National Radiation Oncology Program.** The Director, National Radiation Oncology Program serves as the principal VHA Central Office level advisor on policies and procedures for radiation oncology and serves as an NRSC member. This director is administratively organized under the Office of Patient Care Services (10P4).

e. **Director, National Radiology Program.** The Director, National Radiology Program serves as the principal VHA Central Office advisor on policies and procedures for diagnostic and interventional x-ray imaging and serves as an NRSC member. This director is administratively organized under the Office of Patient Care Services (10P4).

f. **National Director, Nuclear Medicine Service.** The National Director, Nuclear Medicine Service serves as the principal VHA Central Office level advisor on policies and procedures for nuclear medicine service and serves as an NRSC member. This director is administratively organized under the Office of Patient Care Services (10P4).

g. **Assistant Under Secretary for Health for Dentistry.** The Assistant Under Secretary for Health for Dentistry serves as the principal VHA Central Office level advisor on policies and procedures for dental x-ray imaging.

h. **VA Medical Facility Directors.** VA medical facility Directors at locations with machine sources of ionizing radiation are responsible for ensuring the safe and compliant use of such equipment by:

(1) Establishing and implementing radiation safety practices and procedures commensurate with the scope of use of machine sources of ionizing radiation.

(2) Providing executive management oversight to ensure protection of the health and safety of patients, workers, and the public, and to achieve a focus to safety culture.

(3) Establishing and implementing quality assurance (QA) program(s) for machine sources of ionizing radiation consistent with The Joint Commission standards, with annual program reviews by a qualified medical physicist(s).

(4) Assigning a Radiation Safety Officer (RSO) with sufficient training and experience and with the authority and resources to implement radiation safety practices and procedures.

(a) For organizational alignment, the RSO should report directly to executive management (i.e., member of facility senior leadership such as chief of staff or associate director).

(b) The VA medical facility Director will normally assign a single RSO with responsibility for overall oversight for all sources of ionizing radiation at the facility and to coordinate with the facility level Radiation Safety Committee (RSC).

(c) Based on the scope of use of machine sources, the VA medical facility Director has the option to assign or designate a radiation protection supervisor or work center point of contact for radiation safety practices at that work center and to coordinate with the designated RSO. Given the size or other unique circumstances, a facility has the option to have staff or contract diagnostic physicist support for the RSO or committee to achieve machine source requirements.

(5) Establishing a RSC or other oversight committee as outlined below.

(a) The general committee tasks are established in the appendix to VHA Directive 1105 Paragraph 4i below assigns committee tasks specific to machine sources.

(b) Based on the scope of use of machine sources, the VA medical facility Director has the option to assign or designate subcommittees or working groups at specific work centers to provide oversight for machine sources and to coordinate with the RSC and designated RSO.

(c) The VA medical facility Director that does not have a RSC established for uses of radioactive materials under a VHA permit has the option to designate an existing facility oversight committee to complete the functions for a RSC.

(6) Complying with applicable worker safety standards, including OSHA regulations, The Joint Commission healthcare standards, and applicable VHA regulations and policies.

(7) Demonstrating conformance to FDA regulations and the Conference of Radiation Control Program Director's (CRCPD) *Suggested State Regulations for Control of Radiation, Part F, Diagnostic X-rays and Imaging Systems in the Healing Arts* or current document.

(8) Reporting to NHPP any occupational exposure reportable under OSHA regulations, any *serious injury* or death to a patient related to x-ray procedures or equipment, or any radiation dose from x-ray equipment that exceeds 1 millisievert per year to a non-radiation worker or member of the public. Serious injury under OSHA regulations means an injury or illness that:

(a) Is life-threatening,

(b) Results in permanent impairment of a body function or permanent damage to a body structure,

(c) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure, or is a reviewable sentinel event, as defined by The Joint Commission, involving ionizing radiation to a patient.

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.*

(9) For VA medical facilities with linear accelerators used for patient treatment:

(a) Registering each linear accelerator with NHPP and providing a shielding design report prior to installation. The linear accelerator shielding design report must comply with NCRP Report No. 151 or current document.

(b) Appointing a Chief Therapeutic Medical Physicist and RSO and submit a request to NHPP that these individuals be named on the facility's registration certificate.

(c) Receiving an approved registration certificate before installing the linear accelerator.

(d) Notifying NHPP within two working days if the Chief Therapeutic Medical Physicist or RSO permanently ceases duties at the facility.

(e) Complying with the registration certificate; VHA Directive 2013-007, Mandatory Reporting for Misadministrations of Therapy Machine Sources of Ionizing Radiation; The Joint Commission healthcare standards; and other applicable regulations.

(f) Complying with FDA regulations and the CRCPD *Suggested State Regulations for Control of Radiation, Part I, Radiation Safety Requirements for Particle Accelerators.*

(g) Reporting to NHPP any misadministrations as defined by VHA Directive 2013-007, any occupational radiation over-exposure reportable under OSHA regulations, or any radiation dose from a linear accelerator that exceeds 1 mSv per year to a non-radiation worker or a member of the public.

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.*

(10) Requiring research protocols that involve medical use of machine sources of ionizing radiation to be reviewed and approved by the RSC and any other appropriate committees or subcommittees (e.g., Research and Development Committee, Institutional Review Board, Institutional Animal Care and Use Subcommittee, Subcommittee on Research Safety) per VHA Handbook 1200.01.

(11) Ensuring radiation 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.

(12) Notifying NHPP when the VA medical facility is inspected, or otherwise contacted by external regulatory agencies (e.g., OSHA or FDA) for radiation safety issues involving machine sources of ionizing radiation.

(13) Routing registration amendments or reports, as described above, to NHPP at:

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

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

i. **Radiation Safety Committee and Radiation Safety Officer.** The RSC and RSO function together to support the medical facility director and take actions necessary to ensure radiation protection for machine sources of ionizing radiation. In the usual organizational arrangements, the RSO completes day-to-day actions, with support from radiation protection supervisors or work center points of contact for specific uses of machine sources, with overall compliance oversight by the RSC. The usual actions are listed in VHA Directive 1105,

Management of Radioactive Materials, Appendix A, with additional actions specific to machine sources as follows:

(1) Providing radiation protection oversight for machine sources of ionizing radiation during routine committee meetings and as part of an annual radiation safety program review.

(2) Including committee membership for appropriate functional areas using machine sources (e.g., radiation oncology, radiology, and cardiology, etc.).

(3) Completing ALARA reviews and evaluating occupational and public doses related to the use of machine sources.

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

(5) Providing structural shielding design reports for linear accelerators to NHPP for approval before installation of the equipment and shielding survey reports before first clinical use of the equipment. Ensuring structural shielding design reports and shielding surveys conform to NCRP Report No. 151 or current document.

(6) For diagnostic and interventional x-ray equipment:

(a) Ensuring the equipment inspection frequency is every 14 months and deficiencies identified in the inspection process are corrected in a timely fashion.

(b) Ensuring rooms where x-ray equipment is used are shielded per NCRP Report No. 147 or current document and documentation demonstrating compliance is maintained.

(c) Ensuring compliance with the VHA Fluoroscopy Safety Handbook 1105.04.

(d) Providing ongoing reviews for computed tomography (CT) scanning protocols to help reduce possible radiation dose for those procedures.

5. EFFECTIVE DATE: This Directive is effective when issued. VA medical facility Directors must evaluate the requirements in the directive and ensure compliance not later than one year from the issue date. NHPP will evaluate compliance and implementation during routine audits.

6. REFERENCES:

a. Title 10 CFR 19, 20, 30, 35.

b. Title 29 CFR 1910.1096.

c. Title 21 CFR 803.

d. VHA Directive 1105, Management of Radioactive Materials.

e. VHA Directive 2013-007, Mandatory Reporting for Misadministrations of Therapy Machine Sources of Ionizing Radiation.

f. VHA Handbook 1105.04, Fluoroscopy Safety.

g. VHA Handbook 1200.01, Biomedical Laboratory Research and Development (BLR&D) and Clinical Science Research and Development (CSR&D) Services Merit Review Award Program Process.

h. National Council on Radiation Protection and Measurements Report Number 147, Structural Shielding Design for Medical X-Ray Imaging Facilities.

i. National Council on Radiation Protection and Measurements Report Number 151, Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities.

j. Conference of Radiation Control Program Director's (CRCPD) Suggested State Regulations for Control of Radiation, Part F, Diagnostic X-rays and Imaging Systems in the Healing Arts and Part I, Radiation Safety Requirements for Particle Accelerators.