Department of Veterans Affairs **VHA DIRECTIVE 2013-007**
Veterans Health Administration
Washington, DC 20420 **March 27, 2013**

MANDATORY REPORTING FOR MISADMINISTRATIONS OF THERAPY MACHINE SOURCES OF IONIZING RADIATION

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes mandatory reporting of misadministrations for therapy machine sources of ionizing radiation.
AUTHORITY: Title 38 United States Code (U.S.C.) § 512.

2. BACKGROUND

a. The Nuclear Regulatory Commission (NRC) issued to VHA a master materials license for the use of by-product radioactive materials at VHA facilities. NRC regulatory authority does not include machine sources of ionizing radiation used for diagnostic imaging or therapy treatment.

b. The Under Secretary for Health established policies and assigned actions to implement the master materials license in VHA Directive 1105.01, and provides oversight through the National Radiation Safety Committee (NRSC). VHA Directive 1105.01, paragraph 4b(8), extends NRSC oversight to include machine sources of ionizing radiation.

c. The NRSC is the Department of Veterans Affairs (VA) principal organizational element to implement the oversight for machine sources of ionizing radiation with day-to-day implementation through the National Health Physics Program (NHPP).

d. The Director, VHA National Radiation Oncology Program (DRO) provides the clinical oversight for radiation oncology at VHA medical facilities including machine sources of ionizing radiation used for therapy treatment and serves as a NRSC member. The DRO is the primary subject matter expert for NRSC and NHPP actions related to therapy machine sources.

3. POLICY: The VHA policy is to ensure appropriate follow-up for possible adverse outcomes for uses of therapy machine sources of ionizing radiation by establishing a mandatory reporting requirement for any misadministration.

4. ACTION

a. **Under Secretary for Health.** The Under Secretary for Health establishes the policies and assigns actions for mandatory reporting for misadministrations of therapy machine sources of ionizing radiation to include the following.

(1) Requiring mandatory written reports for misadministrations.

(2) Completing evaluations for misadministration circumstances to identify corrective and preventive actions.

THIS VHA DIRECTIVE EXPIRES MARCH 31, 2018

b. **NRSC.** The NRSC functions as the VA's principal organizational element to provide oversight for mandatory reporting of misadministrations. The NRSC responsibilities include:

(1) Providing management oversight for NHPP and reporting of misadministrations through Chair, NRSC, and during quarterly committee meetings.

(2) Developing reporting criteria for misadministration to be consistent with consensus standards of practice. ***NOTE:*** *For more information on the reporting criteria see paragraph 4d*.

(3) Coordinating with the DRO as the subject matter expert for clinical oversight of therapy machine uses.

(4) Notifying the Under Secretary for Health of significant patient circumstances or adverse outcomes.

(5) Evaluating misadministration circumstances to identify corrective and preventive actions to include individual medical facility actions and VHA-wide preventive actions to preclude the same or similar circumstances at other medical facilities.

c. **NHPP Director.** The NHPP is the overall organizational element to receive reports of misadministration and to coordinate follow-up actions from the VA central office perspective. The NHPP Director is responsible for:

(1) Serving as the VA's principal advisor on reporting misadministration and coordinating follow-up actions through NRSC and the DRO.

(2) Coordinating with the DRO to evaluate misadministration reports and determine applicable follow-up actions to include, but not be limited to, the following:

(a) Updating NRSC within 24 hours after receipt of verbal or written reports and at the next scheduled quarterly meeting;

(b) Completing a reactive audit at the reporting medical facility to evaluate circumstances of the misadministration and confirm adequate and sufficient corrective actions; and,

(c) Preparing a generic report of the misadministration circumstances for forwarding to all medical facilities with machine sources for therapy and posting the report on the NHPP Intranet Web site.

(3) Providing assistance to the DRO for any additional follow-up actions or evaluations, either on-site or by tracking long-term corrective actions to include VHA-wide preventive actions.

(4) Maintaining a database for misadministration reports, corrective actions, and preventive actions.

d. **Medical Facility Directors.** Medical facility directors with therapy machine sources of ionizing radiation provide facility-level oversight for radiation oncology services to include the reporting of misadministrations. The directors must ensure reporting by the following:

(1) Requiring the facility level Radiation Safety Committee to provide oversight for therapy machine sources of ionizing radiation and establish local reporting procedures with training for applicable staff.

(2) Using this misadministration definition as any event in which the administration of a radiation therapy dose from a linear accelerator or other therapeutic machine source of ionizing radiation meets any one of the following criteria. An event is not required to be reported as a misadministration if dose deviation occurs due to the omission of a scheduled patient treatment, which resulted from equipment failure or for failure by the patient to be present for the treatment.

(a) Involves the wrong patient, wrong treatment site, or irradiation using the wrong treatment modality.

(b) Consists of 3 or fewer fractions and total administered dose differs from the total prescribed dose by more than 20 percent.

(c) Weekly administered dose differs from the prescribed dose by more than 30 percent.

(d) Total administered dose differs from prescribed dose by more than 20 percent.

(3) Providing initial telephone reports to NHPP, as appropriate to the circumstances, as soon as feasible after the misadministration circumstances are discovered but not later than 48 hours after discovery.

(4) Sending written reports of misadministration to NHPP within 30 days after discovery of the misadministration circumstances with the following minimal information but without any patient identification or privacy information, such as:

(a) Facility name;

(b) Prescribing physician name;

(c) Brief description of the misadministration circumstances;

(d) Why the misadministration occurred with identification of basic or root causes;

(e) Effect, if any, on the patient involved in the misadministration;

(f) Actions, if any, taken or planned to prevent recurrence; and,

(g) Certification the facility notified the patient, patient representative, responsible relative, or guardian.

(5) Routing written reports of misadministration 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

(6) Ensuring the Patient Safety Manager and/or other Quality, Risk Management, or Systems Redesign staff, Radiation Oncology Service staff, and other facility staff participate in evaluation of the misadministration circumstances by completing a causal analysis and taking corrective actions to prevent recurrence to include staff training (as needed).

(7) Conforming to patient notification criteria, timeframes, and requirements in VHA Handbook 1004.8 (Disclosure of Adverse Events to Patients).

(8) Submitting applicable notifications or other reports to the Office of the Deputy Under Secretary for Health for Operations and Management (10N) through the local Veterans Integrated Service Network (VISN).

5. REFERENCES

a. VHA Directive 1105.01, Management of Radioactive Materials.

6. FOLLOW-UP RESPONSIBILITY: The Office of Patient Care Services, National Health Physics Program Office (10P4X) is responsible for the contents of this Directive. Questions are to be directed to 501-257-1571 or e-mailed to: vhconhpp@va.gov.

7. RESCISSION: None. This VHA Directive expires the last working day of March 2018.

Robert A. Petzel, M.D.
Under Secretary for Health

DISTRIBUTION: E-mailed to the VHA Publications Distribution List 3/28/2013