Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 1129.01
Transmittal Sheet
March 21, 2019

MANDATORY REPORTING OF MISADMINISTRATIONS BY THERAPY MACHINE SOURCES OF IONIZING RADIATION

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive updates Department of Veterans Affairs (VA) policy pertaining to the requirements for mandatory reporting of misadministrations of ionizing radiation to patients by therapy machine sources.

2. SUMMARY OF MAJOR CHANGES: None.

3. RELATED ISSUES: VHA Directive 1129, Radiation Protection for Machine Sources of Ionizing Radiation, dated February 5, 2015, VHA Directive 1004.08, Disclosure of Adverse Events to Patients, dated October 2, 2012.

4. RESPONSIBLE OFFICES: The National Radiation Oncology Program (10P11H), and the National Health Physics Program (10P11X) are responsible for the contents of this directive. Questions may be referred to 501-257-1571.

5. RESCISSIONS: VHA Directive 2013-007, Mandatory Reporting for Misadministrations of Therapy Machine Sources of Ionizing Radiation, dated March 27, 2013, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of March 2024. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

CERTIFIED BY

/s/ Lucille B. Beck, PhD
Deputy Under Secretary for Health
for Policy and Services

BY THE DIRECTION OF THE UNDER SECRETARY FOR HEALTH

/s/ Lucille B. Beck, PhD
Deputy Under Secretary for Health
for Policy and Services

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

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1. PURPOSE

This Veterans Health Administration (VHA) directive provides requirements for mandatory reporting of misadministrations of ionizing radiation to patients by therapy machine sources. This reporting is intended to ensure appropriate follow-up for possible adverse outcomes so that actions are taken to reduce the likelihood of future similar incidents. **AUTHORITY:** Title 38 United States Code (U.S.C.) 7301(b).

2. BACKGROUND

a. VHA Directive 1129, Radiation Protection for Machine Sources of Ionizing Radiation, dated February 5, 2015, establishes policy and assigns actions for a radiation protection program for machine sources of ionizing radiation used for medical diagnosis and treatment, and provides for oversight by the National Radiation Safety Committee (NRSC).

b. The NRSC is the Department of Veterans Affairs (VA) principal organizational element to provide oversight of machine sources of ionizing radiation. The National Health Physics Program (NHPP) implements the radiation safety program for machine sources.

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

d. Certain adverse events in the medical administration of radioactive material or radiation from radioactive material must be reported to the US Nuclear Regulatory Commission as medical events. This directive creates a similar requirement for the reporting of certain adverse events in the administration of machine-produced ionizing radiation for therapeutic purposes.

e. The NROP in collaboration with NHPP has deployed an Intranet Web-based Radiotherapy Incident Reporting and Analysis System (RIRAS) to collect, analyze, and provide feedback for all adverse events reported by VHA radiation oncology services (ROS). The feedback includes recommendations for mitigating future errors, protocols for safe operations, and information regarding best practices. The threshold for adverse events that require a corrective action plan is developed collaboratively by NROP and NHPP. This directive creates a requirement for reporting near misses, good catches, and adverse events in the administration of machine-produced ionizing radiation for therapeutic purposes.

3. DEFINITION

Misadministration. An incident in which the administration of radiation therapy to a patient using a linear accelerator or other therapeutic machine source of ionizing radiation meets any one of the following criteria.

a. Involves the wrong patient, wrong treatment site, or irradiation using the wrong treatment modality, or wrong radiation beam energy;

b. Daily fractionated dose differs from the prescribed dose by more than 50 percent;

c. Weekly administered dose, for example, that total dose delivered between the occurrence of weekends where radiation is not delivered, differs from the prescribed dose by more than 30 percent; or

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

NOTE: *An event is not required to be reported as a misadministration if a dose deviation occurs due to the omission of a scheduled patient treatment which resulted from equipment failure, or failure by the patient to be present for the treatment.*

4. POLICY

It is VHA policy that misadministrations of ionizing radiation to patients from therapy machines must be reported by VA medical facilities to the National Health Physics Program as specified by this directive.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health, or designee, is responsible for ensuring compliance with this directive.

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

c. **National Radiation Safety Committee.** The National Radiation Safety Committee (NRSC) oversees the reporting of misadministrations. The NRSC responsibilities include:

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

(2) Developing reporting criteria for misadministrations.

(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.

d. **National Health Physics Program Director.** The National Health Physics Program (NHPP) Director receives reports of misadministrations and coordinates VA Central Office follow-up actions. As the Executive Secretary for the NRSC, the NHPP Director is responsible for:

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

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

(a) Notifying the NRSC Chairperson within 24 hours after receipt of verbal or written reports, and notifying the NRSC at the next scheduled quarterly meeting.

(b) Performing, when deemed necessary in consultation with the DRO, a reactive audit at the reporting medical facility to evaluate the circumstances of the misadministration, and confirm adequacy of corrective actions.

(c) Preparing a report, omitting identifying particulars 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 of misadministration reports, corrective actions, and preventive actions.

e. **Veterans Integrated Services Network Director.** Each Veterans Integrated Service Network (VISN) Director is responsible for ensuring that all VHA health care providers within their area of responsibility comply with this directive.

f. **VA Medical Facility Director.** If therapeutic machine sources of ionizing radiation are used by Radiation Oncology or another service, the Medical Facility Director is responsible for:

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

(2) Providing initial telephone notifications of misadministrations to NHPP as specified below.

(3) Requiring the Radiation Safety Officer to send written reports of misadministrations to NHPP as specified in paragraph 8.b.

(4) Requiring the Chief Therapeutic Medical Physicist to engage the Radiation Safety Officer, the Patient Safety Officer, and other applicable staff in the evaluation of misadministration circumstances to determine root (basic) causes and to develop corrective actions to prevent recurrence, including staff training (as needed).

(5) Conforming to patient notification criteria, timeframes, and requirements in VHA Directive 1004.08, Disclosure of Adverse Events to Patients, dated October 31, 2018.

(6) Submitting applicable notifications or other reports to the Office of the Deputy Under Secretary for Health for Operations and Management through the local VISN.

(7) Promoting a safety culture in which employees feel free to report misadministrations through their chain of command.

6. TRAINING

There are no formal training requirements associated with this directive.

7. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created by this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Manager or Records Liaison.

8. REPORTING OF MISADMINISTRATIONS

a. **Telephone notification.** Each VA medical facility must provide an initial telephone notification to NHPP as soon as reasonably feasible after a misadministration is discovered, but not later than the end of the second working day after discovery. This notification must be made directly to an NHPP staff member. ***NOTE:*** *Leaving a recorded message or sending an electronic message does not constitute notification*.

b. **Written report.** Each VHA medical facility must send a written report of a misadministration to NHPP within 30-calendar days after discovery of the misadministration.

(1) The report must contain the following information:

(a) Name of the facility;

(b) Brief description of the misadministration circumstances;

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

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

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

(f) Certification the facility notified the patient or another individual as specified in VHA Directive 1004.08, Disclosure of Adverse Events to Patients, dated October 31, 2018.

(2) The report cannot contain any of the patient's personally identifiable information.

NOTE: *Written reports must be submitted to NHPP either by the United States Postal Service to VHA NHPP (115HP/NLR), 2200 Fort Roots Drive, Bldg. 101, Room 208, North Little Rock, AR 72114, or as an attachment to an Email message to vhconhpp@va.gov, or by facsimile to (501) 257-1570.*

9. REFERENCES

a. VHA Directive 1004.08, Disclosure of Adverse Events to Patients, dated October 31, 2018.
https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=8120

b. VHA Directive 1129, Radiation Protection for Machine Sources of Ionizing Radiation, dated February 5, 2015.
https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=3081