MANDATORY REPORTING OF MISADMINISTRATIONS BY THERAPY MACHINE SOURCES OF IONIZING RADIATION

1. SUMMARY OF MAJOR CHANGES: This directive:

a. Adds responsibilities for the Assistant Under Secretary for Health for Clinical Services; Assistant Under Secretary for Operations; the Chief Officer, Specialty Care Program Office; Chair, Department of Veterans Affairs (VA) medical facility Radiation Safety Committee; VA medical facility Chief of Radiation Oncology Service or Section; VA medical facility Chief Therapeutic Medical Physicist and VA medical facility Radiation Safety Officer; and updates responsibilities for the Executive Director, National Radiation Oncology Program; Executive Director, National Health Physics Program; Chairperson, National Radiation Safety Committee; Veterans Integrated Services Network Director; and VA medical facility Director in paragraph 2.

b. Updates language regarding reporting of misadministrations in paragraph 3.

2. RELATED ISSUES: VHA Directive 1004.08, Disclosure of Adverse Events to Patients, dated October 31, 2018; VHA Directive 1050.01(1), VHA Quality and Patient Safety Programs, dated March 24, 2023; VHA Directive 1129, Radiation Protection for Machine Sources of Ionizing Radiation, dated February 5, 2015.

3. POLICY OWNER: The National Radiation Oncology Program (11SPEC22), and the National Health Physics Program (11SPEC12) are responsible for the contents of this directive. Questions may be referred to vhconhpp@va.gov.

4. LOCAL DOCUMENT REQUIREMENTS: There are no local document requirements in this directive.

5. RESCISSIONS: VHA Directive 1129.01, Mandatory Reporting for Misadministrations by Therapy Machine Sources of Ionizing Radiation, dated March 21, 2019, is rescinded.

6. RECERTIFICATION: This Veterans Health Administration (VHA) directive is scheduled for recertification on or before the last working day of November 2029. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

7. IMPLEMENTATION SCHEDULE: This directive is effective upon publication.

BY DIRECTION OF THE OFFICE OF THE UNDER SECRETARY FOR HEALTH:

/s/ Erica Scavella, M.D., FACP, FACHE
Assistant Under Secretary for Health
for Clinical Services and Chief Medical Officer

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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CONTENTS

MANDATORY REPORTING OF MISADMINISTRATIONS BY THERAPY MACHINE SOURCES OF IONIZING RADIATION

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1. POLICY

It is Veterans Health Administration (VHA) policy that misadministration of ionizing radiation to patients from therapy machines must be reported by Department of Veterans Affairs (VA) medical facilities to the National Health Physics Program (NHPP) as specified by this directive. **AUTHORITY:** 38 U.S.C § 7301(b); 10 C.F.R. § 35.3045.

2. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Assistant Under Secretary for Health for Clinical Services.** The Assistant Under Secretary for Health for Clinical Services is responsible for:

(1) Supporting the National Radiation Oncology Program (NROP) and NHPP with implementation and oversight of this directive.

(2) Supporting the development of corrective actions to address noncompliance with this directive.

c. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary of Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Service Network (VISN) Directors.

(2) Assisting VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Overseeing VISNs to ensure compliance with and effectiveness of this directive.

d. **Chief Officer, Specialty Care Program Office.** The Chief Officer, Specialty Care Program Office (SCPO) is responsible for supporting the Executive Director, NROP and the Executive Director, NHPP, in executing their responsibilities as assigned in this directive.

e. **Executive Director, National Radiation Oncology Program.** The Executive Director, NROP, is the primary subject matter expert (SME) regarding radiation oncology for the National Radiation Safety Committee (NRSC) and NHPP actions related to therapy machine sources and is responsible for:

(1) Providing clinical oversight of radiation oncology at VA medical facilities where machine sources of ionizing radiation are used for therapy.

(2) Serving as an NRSC member.

(3) Collaborating with the Executive Director, NHPP to evaluate misadministration reports and determine applicable follow-up actions. See paragraph 2.g.(2) for additional details.

(4) Tracking the number of misadministrations with the Executive Director, NHPP and the Chair, NRSC annually across VA medical facilities to assess causes and trends.

f. **Chair, National Radiation Safety Committee.** NRSC's authority for machine produced ionizing radiation is established by VHA Directive 1129, Radiation Protection for Machine Sources of Ionizing Radiation, dated February 5, 2015. NRSC oversees the reporting of misadministrations. In addition to the responsibilities outlined in VHA Directive 1129, the Chair, NRSC, is responsible for ensuring that the NRSC:

(1) Provides management oversight for processes related to reporting of misadministrations to NHPP, and during quarterly committee meetings.

(2) Develops reporting criteria for misadministrations.

(3) Collaborates with the Executive Director, NROP, as the SME for clinical oversight of therapy machine uses.

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

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

(6) Tracks the number of misadministrations with the Executive Director, NHPP and Executive Director, NROP annually across VA medical facilities to assess causes and trends.

g. **Executive Director, National Health Physics Program.** The Executive Director, NHPP, is responsible for:

(1) Serving as VHA's principal advisor on reporting of misadministrations and coordinating follow-up actions to reports of misadministrations through the NRSC and the Executive Director, NROP.

(2) Collaborating with the Executive Director, NROP, to evaluate misadministration reports and determine applicable follow-up actions. These actions include, but are not limited to:

(a) Notifying the Chair, NRSC within 24 hours of receipt of a verbal notification or written report of a misadministration from the VA medical facility Director or VA medical

facility Radiation Safety Officer and notifying NRSC at their next scheduled quarterly meeting.

(b) Consulting with the Executive Director, NROP, to determine the necessity of a site visit at the VA medical facility reporting a misadministration to evaluate the circumstances of the misadministration and, if a site visit is deemed necessary, performing or participating in the site visit.

(c) Collaborating with the Executive Director, NROP, to evaluate VA medical facilities' reports of misadministrations and confirming the adequacy of resulting corrective actions.

(d) Preparing a misadministration report for forwarding to all VA medical facilities with machine sources for therapy and posting the report on the NHPP Intranet website: https://dvagov.sharepoint.com/sites/vhanhppmain. ***NOTE:*** *The misadministration report must omit identifying particulars (e.g., personally identifiable information and protected health information) of the misadministration circumstances. This is an internal VA website that is not available to the public.*

(3) Assisting the Executive Director, NROP, with 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 and preventive actions.

(5) Tracking the number of misadministrations with the Executive Director, NROP and Chair, NRSC annually across VA medical facilities to assess causes and trends.

h. **Veterans Integrated Services Network Director.** The VISN Director is responsible for:

(1) Ensuring that all VA medical facilities within the VISN comply with this directive and informing the Assistant Under Secretary for Health for Clinical Services and the Assistant Under Secretary for Health for Operations when barriers to compliance are identified.

(2) Overseeing corrective actions to address noncompliance at the VISN and VA medical facilities within the VISN.

(3) Reviewing applicable notifications or other reports of misadministration from the VA medical facility Director and providing these reports to the Assistant Under Secretary for Health for Operations.

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

(1) Ensuring overall VA medical facility compliance with this directive and that corrective action is taken if noncompliance is identified.

(2) Requiring the VA medical facility Radiation Safety Committee to oversee therapy machine sources of ionizing radiation and to ensure proper coordination among appropriate VA medical facility staff to ensure radiation misadministration notification and reporting requirements are met.

(3) Providing initial telephone notifications of misadministrations to NHPP as specified in paragraph 3.a. ***NOTE:*** *The VA medical facility Director may delegate this responsibility to the VA medical facility Radiation Safety Officer.*

(4) Sending written reports of misadministrations to NHPP as specified in paragraph 3.b.

(5) Ensuring that a report of each misadministration is entered in the current patient safety reporting system (e.g., Joint Patient Safety Reporting System), as outlined in VHA Directive 1050.01(1), VHA Quality and Patient Safety Programs, dated March 24, 2023.

(6) Ensuring that the VA medical facility Chief of Radiation Oncology and Chief Therapeutic Medical Physicist collaborate with the Radiation Safety Officer, the Patient Safety Manager and other appropriate staff in the evaluation of misadministration circumstances to determine root (basic) causes and to develop corrective actions to prevent recurrence, including any necessary VA medical facility staff training. ***NOTE:*** *This information must be included in the written misadministration report as outlined in paragraph 3.b.*

(7) Conforming to patient notification criteria, timeframes and requirements in VHA Directive 1004.08, Disclosure of Adverse Events to Patients, dated October 31, 2018, and reporting requirements of adverse events related to research in VHA Directive 1200.05(3), Requirements for the Protection of Human Subjects in Research, dated January 7, 2019.

(8) Submitting applicable notifications or other reports (e.g., issue briefs) to the VISN Director.

(9) Promoting a safety culture in which employees feel free to report misadministrations through their chain of command or directly to VA medical facility leadership (e.g., Patient Safety Manager or Radiation Safety Officer).

j. **Chair, VA Medical Facility Radiation Safety Committee.** The VA medical facility Radiation Safety Committee is established by the VA medical facility Director as required in VHA Directive 1105, Management of Radioactive Materials, dated February 24, 2021, and VHA Directive 1129. In addition to the responsibilities assigned in VHA Directive 1105 and VHA Directive 1129, the Chair, VA medical facility Radiation Safety Committee is responsible for ensuring the VA medical facility Radiation Safety Committee:

(1) Oversees therapy machine sources of ionizing radiation at the VA medical facility.

(2) Establishes VA medical facility reporting procedures for radiation misadministrations.

(3) Reviews reports of misadministrations to ensure the accurate identification of root (basic) causes and contributing factors.

(4) Assesses adequacy of proposed corrective actions and oversees implementation of corrective actions in response to misadministrations.

(5) Tracks the number of misadministrations reported to NHPP and NROP annually.

k. **VA Medical Facility Radiation Safety Officer.** The VA medical facility Radiation Safety Officer is responsible for:

(1) Notifying the VA medical facility Director or Chief of Staff of misadministrations, as defined in this directive.

(2) Collaborating with the VA medical facility Chief of Radiation Oncology, Chief Therapeutic Medical Physicist, Patient Safety Manager, and other appropriate VA medical facility staff in the evaluation of misadministration circumstances to determine root (basic) causes and to develop corrective actions to prevent recurrence, including VA medical facility staff training (as needed) and engaging with the aforementioned staff to prepare a written report of each misadministration as specified in paragraph 3.b.

(3) Ensuring that an initial telephone notification of NHPP has occurred as specified in paragraph 3.a.

(4) Collaborating with the VA medical facility Chief of Radiation Oncology to ensure the implementation of corrective actions and assisting the VA medical facility's Radiation Safety Committee in its accomplishments of the tasks in paragraph 2.j.

l. **VA Medical Facility Chief of Radiation Oncology Service or Section**. The VA medical facility Chief of Radiation Oncology is the VA medical facility's primary SME on clinical aspects of radiation oncology. The VA medical facility Chief of Radiation Oncology is responsible for:

(1) Notifying the VA medical facility Director, Chief of Staff, and Radiation Safety Officer of misadministrations, as defined in this directive.

(2) Ensuring appropriate care for the patient and assessing possible effects to the patient from the misadministration.

(3) Collaborating with the VA medical facility Chief Therapeutic Medical Physicist, Radiation Safety Officer, Patient Safety Manager, and other applicable VA medical facility staff in the evaluation of misadministration circumstances to determine root

(basic) causes and to develop corrective actions to prevent recurrence, including VA medical facility staff training, as needed, and engaging with the aforementioned staff to prepare a written report of each misadministration.

(4) Collaborating with the VA medical facility Radiation Safety Officer to ensure implementation of corrective actions for misadministrations of ionizing radiation.

(5) Coordinating with the VA medical facility Radiation Safety Officer and VA medical facility Chief Therapeutic Medical Physicist to prepare written reports of misadministrations as specified in paragraph 3.b.

m. **VA Medical Facility Chief Therapeutic Medical Physicist.** The VA medical facility Chief Therapeutic Medical Physicist is responsible for:

(1) Collaborating with the VA medical facility Chief of Radiation Oncology, Radiation Safety Officer, Patient Safety Manager, and other applicable VA medical facility staff in the evaluation of misadministration circumstances to determine root (basic) causes and to develop corrective actions to prevent recurrence, including VA medical facility staff training (as needed) and engaging with the aforementioned staff to prepare a written report of each misadministration.

(2) Coordinating with the VA medical facility Radiation Safety Officer and VA medical facility Chief of Radiation Oncology Service or Section to prepare written reports of misadministrations as specified in paragraph 3.b.

n. **VA Medical Facility Patient Safety Manager.** The VA medical facility Patient Safety Manager is responsible for collaborating with the VA medical facility Chief of Radiation Oncology, Chief Therapeutic Medical Physicist, Radiation Safety Officer, and other applicable VA medical facility staff in the evaluation of misadministration circumstances to determine root (basic) causes and to develop corrective actions to prevent recurrence, including VA medical facility staff training (as needed) and engaging with the aforementioned staff to prepare a written report of each misadministration.

3. REPORTING OF MISADMINISTRATIONS

a. **Telephone Notification.** The VA medical facility Director, or the VA medical facility Radiation Safety Officer if designated by the VA medical facility Director, must provide an initial telephone notification to NHPP within 2 business days 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.** The VA medical facility Director 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 VA medical facility where the misadministration occurred;

(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) Decisions and actions taken by the VA medical facility to notify, or not notify, the patient or another individual pursuant to the requirements of VHA Directive 1004.08.

(2) The report must not 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.*

4. OVERSIGHT AND ACCOUNTABILITY

a. **Internal Controls.** The internal controls in this directive are:

(1) Collaborative evaluation of misadministration circumstances by the VA medical facility Chief of Radiation Oncology, Chief Therapeutic Medical Physicist, Radiation Safety Officer, Patient Safety Manager and other applicable staff to determine root (basic) causes and to develop corrective actions to prevent recurrence as outlined in paragraph 2 of this directive.

(2) Collaborative evaluation of the misadministration reports by NHPP and NROP.

(3) NRSC oversight as outlined in paragraph 2 of this directive.

b. **Metrics.** To facilitate and implement the mandatory reporting of misadministration of ionizing radiation to patients from therapy machines, it is required that:

(1) The VA medical facility RSC tracks the number of misadministrations reported to NHPP and NROP each year.

(2) The Chair, NRSC, Executive Director, NHPP, and Executive Director, NROP track the number of misadministrations per year across VA medical facilities to assess causes and trends.

5. TRAINING

There are no formal training requirements associated with this directive.

6. RECORDS MANAGEMENT

All records regardless of format (for example, paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and

Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management can be addressed to the appropriate Records Officer.

7. BACKGROUND

a. The NRSC is VHA's principal organizational element to provide oversight of machine sources of ionizing radiation. NHPP implements the radiation safety program for machine sources.

b. Certain adverse events in the medical administration of radioactive material or radiation from radioactive material must be reported to the U.S. 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.

c. The National Radiation Oncology Program (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 good catches (also known as near misses), unsafe conditions and 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 the Executive Directors, NROP and NHPP. This directive encourages reporting good catches (also known as near misses) unsafe conditions and adverse events that do not reach the level of a misadministration as defined in this directive. ***NOTE:*** *Adverse events are defined in VHA Directive 1004.08.*

8. DEFINITIONS

Misadministration. Misadministration is 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. ***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.*

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

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

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%;

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

e. Total administered dose to an organ at risk exceeds the stated dose constraint by more than 20%; or

f. Any dose difference from the prescribed dose that has the potential for serious harm to the patient.

9. REFERENCES

a. 38 U.S.C § 7301(b).

b. 10 C.F.R. § 35.3045.

c. VHA Directive 1004.08, Disclosure of Adverse Events to Patients, dated October 31, 2018.

d. VHA Directive 1050.01(1), VHA Quality and Patient Safety Programs, dated March 24, 2023.

e. VHA Directive 1105, Management of Radioactive Materials, dated February 24, 2021.

f. VHA Directive 1200.05(3), Requirements for the Protection of Human Subjects in Research, dated January 7, 2019.

g. VHA Directive 1129, Radiation Protection for Machine Sources of Ionizing Radiation, dated February 5, 2015.