Department of Veterans Affairs **VHA DIRECTIVE 1187**
Veterans Health Administration **Transmittal Sheet**
Washington, DC 20420 **April 2, 2018**

ADMINISTRATIVE PRACTICES FOR ENSURING SAFE INJECTION OF RADIO-LABELED BLOOD PRODUCTS

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive establishes policy for the administration of all radio-labeled blood products (e.g., Indium-111 labeled white blood cells, Technetium 99m hexamethylpropyleneamineoxime (HMPAO) labeled white blood cells, Chromium-51 labeled red blood cells, and Technetium 99m labeled red blood cells) to patients.

2. SUMMARY OF MAJOR CHANGES:

a. Oversight responsibilities have been added for the Under Secretary for Health, the Deputy Under Secretary for Health for Operations and Management, and the Veterans Integrated Service Network Director.

b. Existing responsibilities for the Radiation Safety Officer, Referring Physician, Nuclear Physician/Radiologist (Authorized User), and Nuclear Medicine Technologist have been clarified.

c. Responsibilities of the facility Patient Safety office has been added.

d. A new paragraph titled Administrative Practices has been added to more clearly delineate the process for ensuring the safe injection of radio-labeled blood products.

3. RELATED ISSUES: None.

4. RESPONSIBLE OFFICE: The Chief Officer, Specialty Care Services (10P11D) is responsible for the contents of this directive. Questions should be directed to the Program Director, Nuclear Medicine and Radiation Safety Service at 734-845-5027.

5. RESCISSIONS: VHA Directive 2010-037, Administrative Practices for Ensuring Safe Injection of Radio-Labeled Blood Products, dated August 17, 2010, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of April 2023. This VHA directive will continue to serve as national policy until it is recertified or rescinded.

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1. PURPOSE

This Veterans Health Administration (VHA) directive establishes policy for the administration of all radio-labeled blood products (e.g., Indium-111 labeled white blood cells, Technetium 99m hexamethylpropyleneamineoxime (HMPAO) labeled white blood cells, Chromium-51 labeled red blood cells, and Technetium 99m labeled red blood cells) to patients. **AUTHORITY:** Title 38 United States Code (U.S.C.) 7301(b), Title 10 Code of Federal Regulation (C.F.R.) 35, Subpart A, 35.1 and 35.2.

2. BACKGROUND

a. The potentially grave consequences and the prevalence of blood-borne diseases, such as hepatitis and Human Immunodeficiency Virus (HIV), mandate specific and controlled procedures to protect patients from needless risk when blood samples are removed, tagged with radio-pharmaceuticals, and re-injected for diagnostic or research purposes. ***NOTE:*** *For more information about radioactive contamination, please refer to VHA Handbook 1105.02, Nuclear Medicine and Radiation Safety Service, dated December 10, 2010, or subsequent policy.*

b. Consistent with 10 C.F.R. Part 35, responsibility for the control and supervision of the administration of radio-labeled blood products is assigned to the VA medical facility's constituted Radiation Safety Committee (RSC).

3. POLICY

It is VHA policy that all VA medical facilities must follow patient identity verification procedures and ensure patient safety by utilizing infection prevention and control practices when blood samples are removed, labeled, and reinjected in accordance with this directive.

4. RESPONSIBILITIES

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

b. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISN);

(2) Ensuring that each VISN Director has the sufficient resources to fulfill the terms of this directive in all of the VHA health facilities within that VISN; and

(3) Providing oversight of VISNs to assure compliance with this directive, relevant standards, and applicable regulations.

c. **National Radiation Safety Committee.** The National Radiation Safety Committee (NRSC) is responsible for tracking to resolution all medical events that are related to radiation safety, including events related to improper use of radiopharmaceuticals. This tracking takes the form of meeting minutes from the reoccurring meeting between the NRSC and the National Health Physics Program (NHPP). In each quarterly meeting, the NHPP reports when medical events are initially discovered, as well as any updates about the status of ongoing medical events, until they are resolved. ***NOTE:*** *It would be a rare occurrence for a medical event, as defined in 10 C.F.R. 35.3045, to occur during a procedure requiring radiolabeled blood, i.e. delivery of a dose of 5 REMs whole body or 50 REMs to a critical organ, with the isotope or activities involved. It would be considered a sentinel event if the radiolabeled product was given to the wrong patient and would be reportable to the VA National Center for Patient Safety (NCPS) program.*

d. **Veterans Integrated Service Network Director.** Veterans Integrated Service Network (VISN) Director is responsible for ensuring that the VA medical facility Director implements this directive, and that each VA medical facility has the resources needed to implement this directive.

e. **VA Medical Facility Director.** Each VA medical facility Director or designee, is responsible for ensuring that this directive is implemented.

f. **The Facility Patient Safety Office**. The facility Patient Safety Office has responsibility for reporting sentinel events to the NCPS and tracking to resolution all sentinel events related to a patient receiving the wrong blood during a nuclear medicine procedure requiring radiolabeled blood.

g. **Chief of Service.** Each Chief of service is responsible for ensuring that physicians and technologists implementing this directive are qualified and competent to follow requirements and procedures as outlined in this directive.

h. **Radiation Safety Officer.** The RSO is responsible for reporting all qualifying medical events to the National Health Physics Program, who is in turn responsible for reporting qualifying medical events to the NRSC.

i. **Referring Physician.** Referring physicians are primary care or other physicians that have the authority to refer patients for any nuclear procedures. They are responsible for determining when a patient should be evaluated by a nuclear medicine physician/radiologist (authorized user) to determine whether a specific nuclear procedure is appropriate.

j. **Nuclear Medicine Physician/Radiologist (Authorized User).** The nuclear medicine physician/radiologist (authorized user, as defined in 10 CFR. 35.2) is responsible for determining whether a patient who has been referred to them by a referring physician will receive the suggested nuclear procedure.

k. **Nuclear Medicine Technologist.** The nuclear medicine technologist is responsible for ensuring patient safety by accurately labeling blood products and by verifying patient identification prior to obtaining a blood sample and prior to the administration of all radiolabeled blood products.

5. ADMINISTRATIVE PRACTICES

Health care personnel must adhere to the following safety practices when a patient requires any procedure that necessitates blood samples to be removed, radiolabeled, and reinjected:

a. A referring physician creates a written or computer-generated requisition for the patient for any nuclear medicine procedure.

b. The nuclear medicine physician/radiologist (authorized user) details appropriate criteria to determine whether to approve the procedure as requested. ***NOTE:*** *The nuclear medicine physician/radiologist (authorized user) can conduct further discussion with the referring physician regarding the necessity of the nuclear medicine procedure if the nuclear medicine physician/radiologist needs more information than is included in the requisition.*

c. The patient's identity is verified by the participation of two healthcare personnel (MD, Nurse Practitioner (NP), RN, Certified Nuclear Medicine Technologist (CNMT), American Registry of Radiologic Technologists, Nuclear Medicine(ARRT) (N), Diagnostic Radiology Technician (DRT). When studies are completed on-call and/or in single-technologist services, another witness may perform the second verification. There are times when there is no one available to sign the second verification. In these cases, if there is only one patient receiving radio labeled blood products in the department, and only one blood sample is taken, the technologist may document the following in the second verifier signature block the words "alone on-call" or "single tech service". All attempts to secure a second witness must be made before this action is taken.

d. When obtaining a blood sample at least two of the following patient identifiers must be used:

(1) Accepting the patient's verbal statement of the patient's full name and full Social Security number (SSN) or Patient Unique Identifier. Query the patient as to the patient's identity by asking for the spelling of the patient's name. ***NOTE:*** *Do not merely ask if the patient is "X" and accept a "YES" response.*

(2) Examining the patient's identification armband, if available, (using bar code if available) confirming full name and full SSN or Patient Unique Identifier.

(3) Reviewing a photo ID, i.e., VA hospital card, driver's license or other documented forms of identification confirming full name and, if available, full SSN or Patient Unique Identifier.

(4) Accepting the patient's verbal statement of date of birth or address, confirming data in the patient's records.

(5) If the patient is confused, comatose, or otherwise unable to participate in the verbal verification of the patient's identity, a member of the staff, relative, or other individual that may be accompanying the patient must be able to accurately verify the patient's identification. This surrogate must confirm the patient's full name and full SSN or Patient Unique Identifier.

(6) The original blood product container is identified with an adhesive label. If created by a radiopharmacy it must bear the patient or recipient's full name (first, middle initial, last) full SSN or Patient Unique Identifier, date, procedure, and legible signature of the person labeling the blood. The radiopharmacy is able to verify infection control practices when requested, by providing their infection control reports. If blood is drawn and radiolabeled by the technologist, all infection control procedures and labeling procedures are followed including a legible signature. The Nuclear Medicine technologist or other qualified staff is responsible for checking this label to ensure that the required information is present, including the patient's full name (first, middle initial, last), full SSN or Patient Unique Identifier, date, procedure, and legible signature of the person drawing the blood. Where and when available, bar code verification must be utilized.

e. Prior to the administration of the prepared radio-labeled product:

(1) The container is clearly labeled with an adhesive identification label, bearing the patient's full name, SSN, procedure, and date by the Nuclear Medicine Technologist or other qualified staff. Blood labeled by a commercial radiopharmacy must also bear the patient or recipient's full name (first, middle initial, last) full SSN or Patient Unique Identifier, date, procedure, and legible signature of the person labeling the blood.

(2) The patient's identity is again verified by two different measures, including barcode verification, if available, and verified by two different clinical staff who possess current valid credentials. ***NOTE:*** *Ideally, one or both staff members who initially identified the patient will be present at the time of the administration of the blood product.* The administration must be accomplished by a certified nuclear medicine technologist or qualified physician, or a nuclear medicine technologist trainee, under the direct supervision of a certified technologist or physician trainee under the direct supervision (physical presence) of an authorized user.

(3) The syringe used in re-injecting the radiolabeled blood product back into the patient (depending upon the radioactive material, type of waste, and method of disposal) must be disposed of by the Nuclear Medicine Technologist or authorized physician according to codified measures as recorded in 10 C.F.R. sections 20.2001, 20.2002, 20.2004, 20.2006, 30.51, and 30.52.

NOTE: *Proper infection prevention and control practices are used when samples are removed, labeled, and reinjected.*

(4) The Nuclear Medicine physician/Radiologist (Authorized User) ensures that VA Form 10-0130, Administration of Radio-Labeled Blood Products which documents the preceding identification procedures, is completed in the sequence described on the form and remains a part of the permanent medical record (electronic or scanned). ***NOTE:*** *The radiopharmaceutical vendors may provide forms accompanying the agent. Such forms do not eliminate the need for Nuclear Regulatory Commission (NRC) records or VA Form 10-0130* (http://vaww.va.gov/vaforms/medical/pdf/vha-10-0130-fill.pdf). *This form will soon be available on the Nuclear Medicine SharePoint site (*https://vaww.infoshare.va.gov/sites/diagnosticservices/NRP/NuclearMedicine/default.aspx*). These are internal VA Web sites that are not available to the public.*

(5) The performance plan and competency record for each nuclear medicine technologist emphasizes the importance of ensuring patient safety by including patient identification and verification prior to the administration of all radiolabeled blood products.

(6) An error resulting from failure to follow the preceding is reported using the facility Patient Event reporting mechanism, such as ePERTS (electronic Patient Event Reporting System), or current reporting system. If event falls within the parameters of a "medical event" as defined by 10 C.F.R. 35.3045, Report and Notification of a Medical Event (https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-3045.html), the RSO must call to report the medical event to the National Health Physics Program (NHPP), which conveys the information to the National Radiation Safety Committee (NRSC) in quarterly meetings. The NRSC will record the progress of each medical event in the meeting minutes until the medical event is resolved. ***NOTE:*** The above linked document is outside of VA control and may not be conformant with Section 508 of the Rehabilitation Act of 1973.

f. If a medical event involves injury to VA staff, the staff member must report the incident to their supervisor, who then implements an Automated Safety Incident Surveillance and Tracking System (ASISTS) entry. See VHA Directive 2011-020, Automated Safety Incident Surveillance and Tracking System (ASISTS), dated April 19, 2011, or subsequent policy.

6. REPORTING REQUIREMENTS

a. **Medical Events.** When a medical event occurs, staff notifies the VA medical facility Director or RSO designee who then must report this event to the NHPP immediately. Reports during normal working hours must be made by telephone to the appropriate NHPP Service Area office or the NHPP Director's Office. Outside of normal working hours or if an NHPP staff member cannot be reached during normal working hours, call the NHPP emergency contact service at 800-815-1016 and ask for an NHPP staff member to be contacted. Tell the operator your name, a call-back telephone number, and your facility name. Telephone reports must be made directly to an NHPP staff member; it is not sufficient to leave a recorded message.

NOTE: *Appendix A, Example of Incident Information Form, outlines the format and required information for the report.*

b. **Sentinel Events.** Sentinel events are a type of adverse event. The Joint Commission defines sentinel events as a patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in any of the following: death, permanent harm, severe temporary harm.

Staff involved with incidents that meet the Joint Commission criteria to be reviewable sentinel events must report the sentinel event to their supervisor, who must then report the event to the Patient Safety Manager (PSM), Chief of Staff, and/or Director immediately upon discovery. Follow up and further investigation will be determined by the PSM and facility leadership, including report to the VISN Director.

7. REFERENCES

a. Title 10 C.F.R., Subpart A, 20.2001, 20.2002, 20.2004, and 20.2006.

b. Title 10 C.F.R., Subpart A, 35.1 and 35.2.

c. Title 10 C.F.R., 35.3045.

d. VHA Directive 2011-020, Automated Safety Incident Surveillance and Tracking System (ASISTS), dated April 19, 2011, or subsequent policy.

e. VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009, revised September 20, 2017, or subsequent policy.

f. VHA Handbook 1105.02, Nuclear Medicine and Radiation Safety Service, dated December 10, 2010, or subsequent policy.

g. VA Form 10-0130 (http://vaww.va.gov/vaforms/medical/pdf/vha-10-0130-fill.pdf).
NOTE: *This is an internal VA Web site and is not available to the public.*

h. VA National Center for Patient Safety (http://vaww.ncps.med.va.gov/guidelines.html#directives).

i. NRC Inspection Manual Chapter 1301 https://www.nrc.gov/reading-rm/doc-collections/insp-manual/manual-chapter/mc1301.pdf

j. Joint Commission Standards related to Sentinel Events.

EXAMPLE INCIDENT INFORMATION FORM

NATIONAL RADIATION SAFETY COMMITTEE (NRSC) SOP 05

1. Date and Time Notified:

2. Person Making Notification:

3. Permittee:

Description of Incident

1. What Happened:

2. Dates and Times of Incident and of Discovery:

3. Location(s):

Radioactive Materials Involved

1. VHA Master Materials License: 03-23853-01VA

2. VHA MML Permit:

3. Nature of Material (e.g., sealed sources, etc.):

4. Radionuclide(s) and Activity(ies):

5. Sealed Source Model and Serial Number:

6. Commercial Carrier (if applicable):

7. Radiopharmaceutical Supplier (if applicable):

Contamination Involved

1. Monitoring Results/Radiation Levels (mR/h, dpm/100cm^2, etc.)

2. Surfaces and Dimensions of Area Contaminated

3. Concentration(s) Released (known or estimated)

4. Instruments and Method Used for Survey or Estimate

Persons Involved/Exposed

1. Name VA Staff/Member of Public/Patient

2. If internal contamination suspected or medical event, have appropriate medical actions been taken to minimize uptake and retention?