Department of Veterans Affairs **VHA DIRECTIVE 2005-036**
Veterans Health Administration
Washington, DC 20420 **August 28, 2005**

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

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 - HMPAO labeled white blood cells, Chromium-51 labeled red blood cells and Technetium 99m labeled red blood cells) to patients.

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**.**

b. According to Title 10 Code of Federal Regulations (CFR), Parts 19, 20, 21, 30 and 35, and VHA Directive 1105.1, responsibility for developing local policies, control and supervision of the administration of radio-labeled blood products is assigned to the VHA medical facility's constituted Radiation Safety Committee (RSC).

3. POLICY: It is VHA policy that each VHA facility's RSC has the responsibility for developing local policies, and the control and supervision of the administration of radio-labeled blood products.

4. ACTION: Each medical facility Director is responsible for ensuring that an RSC is established at the facility and that:

a. A written or computer generated requisition from a referring physician for the nuclear procedure is obtained. The specialist nuclear physician or radiologist compares the request and pertinent diagnostic information to established appropriateness criteria to determine procedure approval.

b. The patient's identity is verified by the participation of two health care personnel when obtaining a blood sample using at least two of the following patient identifiers, i.e., by:

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

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

(3) A review of the patient's picture ID; i.e., VA hospital card, driver's license, or other documented forms of identification confirming full name and, if available, full SSN.

(4) The patient's verbal statement of date of birth, address, or phone number confirming the data in the patient's record.

(5) Verification by a surrogate, confirming the patient's full name and/or full SSN. ***NOTE:*** *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 who may be accompanying the patient must be able to accurately verify their identification.*

c. The original blood product container is identified with an adhesive label bearing the patient and/or recipient's full name, SSN, date, and signature of the person drawing the blood. Where and when available, bar code verification must be utilized.

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

(1) The container is clearly labeled with an adhesive identification label, and

(2) The patient's identity is again verified by two different measures, including bar code verification, and verified by two different medical and/or technical staff who possess current valid credentials, meet qualification standards, and have the required Competency reviews. ***NOTE:*** *Ideally, one or both staff members who initially identified the patient should be present at the time of the administration of the blood product. The administration must be accomplished by a certified technologist.*

e. VA Form 10-0130, Administration of Radio-Labeled Blood Products, which documents the preceding identification procedures, must be completed in the sequence described and must remain part of the patient's nuclear medicine record. An imbedded electronic copy of VA Form 10-0130 for local reproduction is found in Appendix A. ***NOTE:*** *The radio-pharmaceutical vendors may provide forms accompanying the agent. Such forms do <u>not</u> eliminate the need for Nuclear Regulatory Commission (NRC) records or VA Form 10-0130.*

f. The syringe used in re-injecting the radio-labeled blood product back into the patient (depending upon the radioactive material, type of waste, and method of disposal) must be disposed of according to the codified measures as recorded in 10 CFR Parts 20.2001, 20.2002. 20.2004, 20.2006, 30.51, and 35.92.

g. 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 radio-labeled blood products.

h. A medical event, resulting from failure to follow the proceeding, is reported via the facility Patient Safety Improvement Program mechanism and through the Quality Management Office. If appropriate, it must also be sent to the National Health Physics Program (NHPP) which conveys the information to the National Radiation Safety Committee (NRSC).

5. REFERENCES: Title 10 CFR, Subpart A, 35.1 and 35.33.

6. FOLLOW-UP RESPONSIBILITY: The Program Director, Nuclear Medicine and Radiation Safety Service (115B), is responsible for the contents of this Directive. Questions should be directed to Associate Director, Nuclear Medicine and Radiation Safety Service, at (734) 761-7885.

7. RESCISSION: VHA Directive 99-003 is rescinded. This VHA Directive expires on August 31, 2010.

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Under Secretary for Health

Attachment

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Department of Veterans Affairs

ADMINISTRATION OF RADIOLABELED BLOOD PRODUCTS

PATIENT INDENTIFICATION

PATIENT NAME (Last, First, Middle Initial)	SOCIAL SECURITY NUMBER

PROCUEDURE INFORMATION	PATIENT ID VERIFICATION
PROCEDURE	☐ ASK PATIENT NAME
	☐ PATIENT ID BRACELET
	☐ DOB BY PATIENT MATCHES RECORD
REQUESTED BY	☐ ADDRESS BY PATIENT MATCHES RECORD
M.D.	☐ SSN BY PATIENT MATCHES RECORD
	☐ PATIENT IS NON-RESPONSIVE; PROVIDE SOURCE OF DATA
APPROVED BY	
M.D.	

SAMPLE COLLECTION	LABEL PREPARATION	LABEL REINJECTION
The patient named above has been correctly identified, and the blood container receiving the blood sample is correctly and clearly labeled with the patient name, SSN, procedure and date.	The blood sample for the procedure requested above has been correctly identified, the sample has been labeled, and the product added to a correctly and clearly marked container.	The patient named above has been correctly identified, and the patient identification on the labeled blood product corresponds to the patient identified and the product has been reinjected.
WITNESSES	**WITNESSES**	**WITNESSES**
(1) NAME	(1) NAME	(1) NAME
POSITION	POSITION	POSITION
(2) NAME	(2) NAME	(2) NAME
POSITION	POSITION	POSITION
DATE	DATE	DATE

VA FORM **10-0130**
JAN 2005