

August 17, 2010

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

**1. PURPOSE:** This Veterans Health Administration (VHA) Directive communicates established 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. 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, 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 the control and supervision of the administration of radio-labeled blood products and for developing local policies.

**4. ACTION:** Each medical facility Director must ensure that:

a. The facility meets the requirements for United States Pharmacopeia (USP) 797.

b. The written or computer-generated requisition from a referring physician for any nuclear procedure is obtained. The nuclear physician or radiologist compares the request and pertinent diagnostic information to determine if it meets the criteria for approval.

c. The patient's identity is verified by the participation of two health care personnel when obtaining a blood sample and by at least two patient identifiers according to facility policy. These may include:

(1) Accepting the patient's verbal statement of the patient's full name. **NOTE:** Do not merely ask if the patient is "X" and accept a "YES" response.

(2) Accepting the patient's verbal statement of the patient's full Social Security Number (SSN).

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

(4) Reviewing a picture identification (ID), i.e., Department of Veterans Affairs (VA) hospital card, driver's license, or other documented forms of identification confirming full name and, if available, full SSN.

(5) Obtaining the patient's verbal statement of date of birth or address confirming data in the patient's records.

(6) If the patient is confused, comatose, or otherwise unable to participate in the verbal verification of identity, verification of correct patient identification may also occur through a family member, significant other, or by a staff member who has an established relationship with the patient, confirming patient's full name and full SSN. If the patient's identity cannot be established, the procedure must be cancelled until such time that the patient's identity can be verified.

d. The original blood product container is identified with an adhesive label bearing the patient or recipient's full name, full SSN, date, procedure, and signature of the person drawing the blood. Where and when available, bar code verification must be utilized. **NOTE:** *Proper infection prevention and control practices are used when samples are removed, labeled, and reinjected.*

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, full SSN, procedure, and date. Blood labeled by a commercial radio-pharmacy must also bear two unique identifiers and date.

(2) The patient's identity is again verified by two unique measures, including bar code verification, if available, and verified by two different medical 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 will be present at the time of the administration of the blood product.*

(3) 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 and documented according to codified measures as recorded in 10 CFR, Parts 20.2001, 20.2002, 20.2007, 20.2108, 20.2110, 30.51, 30.52, 35.92, and 35.2092.

f. The administration of a blood product is accomplished by a certified technologist or a nuclear medicine technologist trainee under the direct supervision (physical presence) of a certified technologist. Nuclear medicine physicians may also administer blood products.

g. VA Form 10-0130, Administration of Radio-Labeled Blood Products, which documents the preceding identification procedures, is completed in the sequence described and remains a part of the patient's permanent medical record (electronic or scanned). *NOTE: An embedded electronic copy of VA Form 10-0130 for local reproduction is found in Attachment A.* VA Form 10-0130 may be adapted for local use; however, it must include all of the original form elements. *NOTE: The radio-pharmaceutical 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.*

h. 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.

i. A failure to follow the proceeding protocol must be reported to the facility Quality Management Office using the facility Patient Safety Improvement Program mechanism. If the failure meets the National Health Physics Program (NHPP) definition of a medical event, it must also be reported to the NHPP, which conveys the information to the National Radiation Safety Committee (NRSC) and to the local RSC through the Radiation Safety Officer.

## 5. REFERENCES

a. Title 10 CFR, Part 20 (Standards for Protection against Radiation), Part 30 (Rules of General Applicability to Domestic Licensing of Byproduct Material), and Part 35 (Medical Use of Byproduct Material).

b. USP Chapter 797 - "Pharmaceutical Compounding- Sterile Preparations (General Information Chapter <797>). In: The US Pharmacopeia, 32<sup>nd</sup> Rev. and The National Formulary, 27th ed. Rockville, MD: US Pharmacopeia Convention; 2009: 318 -354.

**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) 845-5029.

**7. RESCISSION:** VHA Directive 2005-036 is rescinded. This VHA Directive expires on August 31, 2015.

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

Attachment

DISTRIBUTION: E-mailed to the VHA Publication Distribution List 8/19/10

**ATTACHMENT A**

**VA FORM 10-0130, ADMINISTRATION OF RADIOLABELED BLOOD PRODUCTS**

Department of Veterans Affairs (VA) Form 10-0130, Administration of Radio-labeled Blood Products can be found on the VA Forms Web site at <http://vaww.va.gov/vaforms>. This is to be used for local reproduction. Since this is a low use form, it will not be stocked by the Hines Service and Distribution Center (formerly known as the Forms and Publications Depot).