

September 12, 2000

**USE OF NON-BYPRODUCT RADIOACTIVE MATERIALS IN
VHA MEDICAL FACILITIES**

1. PURPOSE: This Veterans Health Administration (VHA) Directive provides current policy on the use of non-byproduct radioactive materials in VHA medical facilities.

2. BACKGROUND

a. The Department of Veterans Affairs (VA) seeks to protect patients, employees, the general public, facilities and the environment from the hazards associated with the use and disposal of all radioactive materials. This is accomplished through compliance with applicable regulatory mandates, through establishment of policy, and the development and execution of procedures that require the safe use and disposal of non-regulated radioactive materials.

b. Certain radioactive materials, which are either naturally occurring or are produced by methods which do not involve the use of nuclear fission reactions, e.g., particle accelerators such as cyclotrons, are exempted from the Federal regulatory controls imposed by the Nuclear Regulatory Commission (NRC). These materials are commonly referred to as Naturally-occurring and Accelerator-produced Radioactive Materials (NARM). Examples include clinical and research radionuclides such as Iodine-123, Gallium-67, Indium-111, Thallium-201, Radium-226 and Positron Emission Tomography (PET) radionuclides produced in cyclotrons. While uses of these are not Federally regulated, these materials have a hazard potential for health and the environment similar to regulated radioactive materials due to their comparable physical, chemical and radiation emission characteristics.

3. POLICY: It is VHA policy that radiation control programs include sources of radioactivity without regard for the method of production or natural origin. VHA medical facilities are required to adopt policies and procedures governing local approval for the receipt, use, storage, and disposal of NARM that are consistent with, and comparable to, the Federal regulatory controls for the uses of byproduct materials.

4. ACTION: The proposed uses of NARM at VHA facilities shall be processed as follows:

a. Each VHA facility Director shall ensure that detailed written procedures have been developed and implemented which require prior approval for the purchase, use, storage, and disposal of NARM. These procedures must establish standards for safe use and require that appropriate training has been conducted which promotes the safe use of these materials. Standards for training and experience and specific handling and storage procedures may be similar to those for existing radionuclide programs involving byproduct materials.

b. Approval and oversight of the use of NARM will be the responsibility of the facility's Radiation Safety Committee (RSC) and the Radiation Safety Officer (RSO). Detailed responsibilities of the RSC and the RSO are found in Title 10, Code of Federal Regulations

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(CFR) Part 35.22 and 10 CFR Part 35.21, respectively. The RSC and RSO are required for operations under any existing radionuclide programs licensed by the Nuclear Regulatory Commission. If there is no existing NRC license and NARM use is proposed, the Facility director will appoint a RSC and RSO using the regulatory standards of 10 CFR Part 35.

c. A written proposal shall be submitted to the RSC that includes specification of the type, physical form, and quantity of radioactive material to be possessed by the user. The proposal shall include information concerning the training and experience of the user and associated staff, procedures for use, storage, and disposal of the material and such other information as may be required for evaluation of the proposed uses and users.

d. The facility RSC shall review and approve or disapprove the proposed uses based on the user qualifications, available facilities and safety procedures. The RSO will perform on-going evaluations at least quarterly and report findings to the RSC.

e. Approved users are responsible and accountable for materials received, used, stored and disposed of. Area surveys, contamination surveys, and appropriate waste disposal procedures are required.

f. The RSC and RSO will be guided by the requirements of 10 CFR Part 20, Subparts A through L and Part 35, exclusive of NRC reporting requirements, in establishing the conditions and standards for use of NARM, except that limitations on personnel exposure are established by 29 CFR 1910.1096. Sound and appropriate health physics and radiation safety judgement is required by the Committee and the RSO in the application of established regulatory standards to possession, use and disposal of NARM.

g. Records relating to the approval, use and disposal of NARM will be maintained by the RSC, the RSO, and approved users for a period of 5 years or until a disposition of the records is directed by the National Health Physics Program (NHPP).

h. Actions of the RSC and minutes of meetings should be shared with the facility Safety Committee for information purposes.

i. The facility radiation safety staff shall immediately notify the NHPP Office (501-257-1571) of NARM incidents that threaten human health or safety and the environment, or result in patient misadministrations.

***NOTE:** This policy does not apply to the use in VA facilities of radioactive materials under general licensing authority, 10 CFR Part 31, or to the use of materials which are license exempt under 10 CFR Part 30.14 (exempt concentrations) or 10 CFR Part 30.18 (exempt quantities).*

5. REFERENCES

a. Title 10 CFR Part 20, Subparts A through L

b. Title 10 CFR Part 35.

c. Title 29 CFR Part 1910.1096

d. VHA Directive 1105.1.

e. VHA Handbook 1105.1.

6. FOLLOW-UP RESPONSIBILITY: Director, National Health Physics Program (NHPP), Patient Care Services (11), is responsible for the contents of this Directive.

7. RESCISSION: Directive 10-95-054 is rescinded. This VHA Directive will expire September 30, 2005.

Thomas L. Garthwaite, M.D.
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