The Administrative Procedure Act requires the publication of substantive policy statement currently in use, including its full text, if practicable. (A.R.S. § 41-1091.01). Substantive policy statements are written expressions which inform the general public of an agency's current approach to rule or regulation practice. This substantive policy statement is advisory only. A substantive policy statement does not include internal procedural documents that only affect the internal procedures of the agency and does not impose additional requirements or penalties on regulated parties or include confidential information or rules made in accordance with the Arizona administrative procedure act. If you believe that this substantive policy statement does impose additional requirements or penalties on regulated parties you may petition the agency under section 41-1033, Arizona Revised Statutes, for a review of the statement.

NOTICE OF SUBSTANTIVE POLICY STATEMENT

ARIZONA RADIATION REGULATORY AGENCY

[RAM 36]

1. **Subject of the substantive policy statement and the substantive policy statement number by which the policy statement is referenced:**
   Radiopharmaceuticals for Human Use

2. **Date the substantive policy statement was issued and the effective date of the policy statement if different from the issuance date:**
   Effective February 10, 1997

3. **Summary of the contents of the substantive policy statement:**
   Grants New Drug Application equivalency to biological products which have received a Product License Approval.

4. **A statement as to whether the substantive policy is a new statement or a revision:**
   This is a current policy statement.

5. **The agency contact person who can answer questions about this substantive policy statement:**

   Name: Brian Goretzki, RAM Program Manager

   Address: Arizona Radiation Regulatory Agency
   4814 South 40th Street
   Phoenix, AZ 85040

   Telephone: (602) 255-4840

11/30/06

APPROVED BY (DIRECTOR) DATE

Policy Number: RAM 36
Effective Date: February 10, 1997

Subject Title: Radiopharmaceuticals for Human Use

Policy No. 36, Radiopharmaceuticals for Human Use

Purpose:
To establish a policy granting New Drug Application (NDA) equivalency to biological products having received a Product License Approval (PLA).

Applicability:
This policy applies to all licensees using radioactive materials on human beings.

Reference:
(a) Title 12, Chapter 1, AAC.
(b) U.S.N.R.C. Memorandum of August 6, 1993, subject: Product License Approval (PLA)

Attachment(s):
None.

Review:
Effective until superceded or revoked.

Policy:
A PLA is a Food and Drug Administration (FDA) mechanism by which radiopharmaceuticals, and kits and generators used to produce radiopharmaceuticals, may be approved as functionally equivalent to the NDA used by the Center for Biologics Evaluation and Research. The rules in reference (a) do not address radiopharmaceuticals for human use under a PLA. However, Article 3, Schedule C of reference (a) does address the NDA.

In reference (b), the Nuclear Regulatory Commission (NRC) encouraged agreement states (Arizona is one) to allow the use of PLA-approved radiopharmaceuticals through whatever mechanism is most efficient for each state. Therefore, this policy considers the PLA equivalent to the NDA with respect to biological products already having a PLA. Further, this policy authorizes the use of any radiopharmaceutical approved by the FDA under a PLA. In addition, the use of any radiopharmaceutical-producing kit or generator which has been approved by the FDA is authorized.

For clarification, the following information is provided:

> "Biological products are controlled by the Public Health Service Act (PHS Act) (42 U.S.C. 262), the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 301 et. seq.) and the regulations promulgated thereunder. The PHS Act requires that biological products be licensed before their sale, barter, or exchange in interstate commerce. The Bureau of Biologics of the Food and Drug Administration is responsible for licensing biological products. To be licensed, an investigational biological product must be developed and tested to ensure that it is safe, pure, potent, and effective. A biological product undergoing development is subject to the investigational new drug regulations prescribed in 21 CFR 312.1 and 601.21..." [Reference (b)]