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 17]

1. **Subject of the substantive policy statement and the substantive policy statement number by which the policy statement is referenced:**
   Bioassay Requirements for Medical Users

2. **Date the substantive policy statement was issued and the effective date of the policy statement if different from the issuance date:**
   Effective March 15, 1996

3. **Summary of the contents of the substantive policy statement:**
   Allows infrequent users of iodine 125 and iodine 131 up to 10 days post use to obtain a bioassay without penalty.

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

APPROVED BY (DIRECTOR) DATE 11/30/16

Policy Number: RAM 17
Effective Date: March 15, 1996

Subject Title: Bioassay Requirements for Medical Users

Policy No. 17, Bioassay Requirements for Medical Users

Purpose:
To provide for individual participation in a bioassay program.

Applicability:
This policy applies to users of radioiodine.

Reference:
Regulatory Guide 8.20

Attachment(s):
None.

Review:
Effective until superceded or revoked.

Policy:
In accordance with the reference, individual bioassays will be allowed up to ten days post use if the individuals are infrequent users of 1-125and 1-131. An inspector may use this policy to give a licensee an IOC if a bioassay is late by no more than ten days and the licensee's workload is low.

A. With the exclusion of medical administrations, individuals working with lodine-131 and lodine-125 in quantities greater than 1.0 millicuries per calendar quarter with chemical and physical forms that make it possible for radionuclides to be ingested, inhaled or absorbed shall be included in a bioassay program. Bioassay shall be performed within six to seventy-two hours after exposure to radioiodine.

B.1. Notwithstanding the requirement in Part A above, individuals participating in the medical administration of lodine-131 in quantities greater than 30 millicuries shall participate in a bioassay program in accordance with Part A above.

2. Individuals exposed to lodine-131 due to accident spill, crushed capsule, or patient vomiting as a result of medical administration, shall participate in a bioassay program in accordance with Part A above.

C. Bioassays shall consist of the measurement of the amount of radioiodine contained in the thyroid compared to a suitable standard.

D. 1. Thyroid burdens of less than 0.04 microcurie of lodine-131 or 0.12 microcurie of lodine-125 will require no action.

2. Thyroid burdens of 0.04 microcurie of lodine-131 or 0.12 microcurie of lodine-125 or greater shall be investigated as to the circumstances surrounding the uptake. Bioassays shall continue at weekly intervals until the thyroid burden has dropped below the levels specified in D.1.

3. Should the thyroid burdens exceed 0.14 microcurie of lodine-131 or 0.5 microcurie of lodine-125, the licensee shall restrict the worker from further radioiodine exposure until the burden falls below the levels specified in D.1.

E. Records of all bioassay measurements described above shall be kept for the life of the license and three years past the date of license termination.