NOTICE OF PROPOSED EXPEDITED RULEMAKING TITLE 9. HEALTH SERVICES

CHAPTER 7. DEPARTMENT OF HEALTH SERVICES RADIATION CONTROL

ARTICLE 7. MEDICAL USES OF RADIOACTIVE MATERIAL

PREAMBLE

1. Permission to initiate this rulemaking was granted under A.R.S. § 41-1039(A) by the governor on:

May 2, 2023

2. Article, Part or Sections Affected (as applicable) Rulemaking Action

R9-7-708 Amend

3. <u>Citations to the agency's statutory rulemaking authority to include the authorizing statute</u> (general) and the implementing statute (specific):

Authorizing statutes: A.R.S. §§ 30-654(B)(5), 36-132(A)(1), 36-136(G)

Implementing statutes: A.R.S. §§ 30-654, 30-657, 30-671, 30-672, and 30-673

4. <u>Citations to all related notices published in the Register as specified in R1-1-409(A) that</u> pertain to the record of the proposed rule:

Notice of Rulemaking Docket Opening: 31 A.A.R. XXXX, May 9, 2025 [Added by Register editor]

5. The agency's contact person who can answer questions about the rulemaking:

Name: Brian D. Goretzki, Chief, Bureau of Radiation Control

Address: Arizona Department of Health Services

Public Health Licensing Services

4814 South 40th Street Phoenix, AZ 85040

Telephone: (602) 255-4840 Fax: (602) 437-0705

E-mail: Brian.Goretzki@azdhs.gov

or

Name: Stacie Gravito, Office Chief

Address: Arizona Department of Health Services

Office of Administrative Counsel and Rules

150 N. 18th Ave., Suite 540

Phoenix, AZ 85007

Telephone: (602) 542-1020 Fax: (602) 364-1150

E-mail: Stacie.Gravito@azdhs.gov

6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

Arizona Revised Statutes (A.R.S.) § 30-654(B)(5) requires the Arizona Department of Health Services (Department) to make rules deemed necessary to administer A.R.S. Title 30, Chapter 4, Control of Ionizing Radiation. The Department has adopted these rules in A.A.C. Title 9, Chapter 7. Arizona is an Agreement State by the Document negotiated between the U.S. Atomic Energy Commission (now U.S. Nuclear Regulatory Commission or NRC) and the Governor of Arizona in March of 1967 under A.R.S. § 30-656. In order to remain in compliance with the Agreement, Arizona must adopt regulations related to the control of radioactive material in a manner that is consistent with federal regulations. The NRC recently conducted an audit of the rules in 9 A.A.C. 7, and noted that one rule needed to be revised to meet NRC requirements. Under an approval for the rulemaking received according to A.R.S. § 41-1039(A), the Department is revising the rules in A.A.C. Title 9, Chapter 7, by expedited rulemaking to make changes to conform to the NRC requirements.

A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The Department did not review or rely on any study for this rulemaking.

8. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. A statement that the agency is exempt from the requirements under A.R.S. § 41-1055(G) to obtain and file a preliminary summary of the economic, small business, and consumer impact under A.R.S. § 41-1055(D)(2):

Under A.R.S. § 41-1055(D)(2), the Department is not required to provide an economic, small business, and consumer impact statement.

10. Where, when, and how a person may provide written comment to the agency on the

proposed expedited rule under A.R.S. § 41-1027(C):

Close of record: Thursday, May 29, 2025, 4:00 p.m.

A person may submit written comments on the proposed expedited rules no later than the close of record to either of the individuals listed in item 5.

- 11. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:
 - a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

The rule being revised does not require the issuance of a permit or license. However, the requirements in 9 A.A.C. 7, Article 7, do include provisions for licensing. According to A.R.S. Title 30, Chapter 2, Article 2, the Department is authorized to issue licenses and registrations for sources of ionizing radiation and those persons using these sources. This licensing and registration must be compatible with requirements in the Agreement. The rules in 9 A.A.C. 7 refer to permits both general and specific. The general permit applies to certain levels of radioactive material, and specific permits are issued by rule for quantities and uses that are specific to the user and their training or scope of practice.

Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

The rule is not more stringent than federal law. Applicable federal law includes 10 CFR 35.41.

Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

No business competitiveness analysis was received by the Department.

12. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rules:

Not applicable

13. The full text of the rules follows:

TITLE 9. HEALTH SERVICES CHAPTER 7. DEPARTMENT OF HEALTH SERVICES RADIATION CONTROL ARTICLE 7. MEDICAL USES OF RADIOACTIVE MATERIAL

Section

R9-7-708. Procedures for Administrations Requiring a Written Directive

CHAPTER 7. DEPARTMENT OF HEALTH SERVICES - RADIATION CONTROL ARTICLE 7. MEDICAL USES OF RADIOACTIVE MATERIAL

R9-7-708. Procedures for Administrations Requiring a Written Directive

- **<u>A.</u>** For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:
 - 1. The patient's or human research subject's identity is verified before each administration; and
 - 2. Each administration is in accordance with the written directive.
- **B.** At a minimum, the procedures required by subsection (A) must address the following items that are applicable to the licensee's use of byproduct material:
 - 1. Verifying the identity of the patient or human research subject;
 - 2. Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;
 - 3. Checking both manual and computer-generated dose calculations;
 - 4. Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by Exhibit A Group 600 or 1000 of this Article;
 - <u>5.</u> Determining if a medical event, as defined in R9-7-745, has occurred; and
 - 6. Determining, for permanent implant brachytherapy, within 60 calendar days after the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.