NOTICE OF PROPOSED EXPEDITED RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 7. DEPARTMENT OF HEALTH SERVICES

RADIATION CONTROL

ARTICLE 9. PARTICLE ACCELERATORS

PREAMBLE

1. **Article, Part or Sections Affected (as applicable)** — **Rulemaking Action**

R9-7-902	Amend
R9-7-904	Amend

2. **Citations to the agency's statutory rulemaking authority to include the authorizing statute (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

3. **Citations to all related notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of the proposed rule:**

Notice of Rulemaking Docket Opening: 29 A.A.R. 3586, November 17, 2023

4. **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 200
Phoenix, AZ 85007

Telephone: (602) 542-1020

Fax: (602) 364-1150

E-mail: Stacie.Gravito@azdhs.gov

5. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking: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.) §§ 30-671(B) and 30-672 specify that the Department may require registration of sources of radiation. A.R.S. § 30-654 specifies requirements for the Department to regulate sources of radiation and those using these sources to protect health and safety. The Department has learned that some critical access hospitals are having difficulty in obtaining and retaining qualified medical professionals. These hospitals are generally located in remote areas of the State with few other sources of medical treatment, so patients may have to travel long distances to obtain radiation therapy if the radiation therapy cannot be provided at the critical access hospital. After obtaining approval for the rulemaking under A.R.S. § 41-1039(A), the Department is revising some requirements related to the type of supervision that may be provided, under specific circumstances, to a radiation therapy technologist providing radiation therapy in a critical access hospital, to include those circumstances under which radiation therapy technologists may provide radiation therapy under general supervision. To ensure patient safety while receiving radiation therapy, the Department is including additional requirements for a critical access hospital registrant planning to provide radiation therapy under general supervision. The Department believes that these changes will reduce the regulatory burden on critical access hospitals while protecting the health and safety of patients, staff, and the general public.

6. 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.

7. 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

8. The preliminary summary of the economic, small business, and consumer impact:

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

9. The agency's contact person who can answer questions about the economic, small business, and consumer impact statement:

Not applicable

10. Where, when, and how persons may provide written comment to the agency on the proposed expedited rule under A.R.S. § 41-1027(C):

Close of record: Monday, December 18, 2023, 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 4.

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 Department believes the registration of a particle accelerator issued to a person is a specific permit, under A.R.S. § 41-1037(A)(3) in that registration specifies the person, device, and facility location authorized by registration, as well as the scope of practice, which are necessary to protect health and safety, according to A.R.S. § 30-672.

b. 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:

Not applicable

c. 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 9. PARTICLE ACCELERATORS

Section

ARTICLE 9. PARTICLE ACCELERATORS

R9-7-902. Definitions

The following definitions apply in this Article, unless the context otherwise requires:

"Added filter" (See ~~Article 6~~ R9-7-602)

"Arc therapy" means radiation therapy that uses electrons to treat large, superficial volumes that follow curved surfaces, as in postmastectomy patients.

"Authorized medical physicist" means an individual who meets the requirements in R9-7-711. For purposes of ensuring that personnel are adequately trained, an authorized medical physicist is a "qualified expert" as defined in Article 1.

"Beam-limiting device" (See ~~Article 6~~ R9-7-602)

"Beam-monitoring system" means a ~~system~~ set of devices that will monitor the useful beam, as defined in R9-7-602, during irradiation and terminate irradiation when a preselected number of monitor units has been accumulated.

"Collimator" (See R9-7-602)

"Control panel" (See ~~Article 6~~ R9-7-602)

"Full beam detector" means a radiation detector of such size that the total cross section of the maximum size useful beam is intercepted.

"Gantry" means that part of a linear accelerator that supports the radiation source so that it can rotate about a horizontal axis.

"General supervision" means that a radiation therapy technologist is furnished with a procedure for performing therapy under an authorized user's overall direction and control, and the authorized user is responsible for ensuring that the procedure is followed, but the authorized user's presence is not required in a medical institution during the performance of the procedure.

"Intensity-Modulated Radiation Therapy (IMRT)" means an advanced mode of high-precision radiotherapy that uses computer-controlled linear accelerators to deliver precise radiation doses to a tumor or specific areas within the tumor.

~~"Interlock" (See Article 1)~~

"Isocenter" means the point of intersection of the collimator axis and the axis of rotation of the gantry.

"Monitor unit" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

"Moving beam therapy" means radiation therapy in which there is displacement of the useful beam relative to the patient. Moving beam therapy includes arc therapy, skip therapy, and

rotational beam therapy.

"Radiation therapy technologist" means an individual certified according to 9 A.A.C. 16, Article 6, whose scope of practice is specified according to A.A.C. R9-16-608(D).

"Rotational beam therapy" means radiation therapy that is administered to a patient from a radiation source that rotates around the patient's body or the patient is rotated while the beam is held fixed.

"Skip therapy" means rotational beam therapy that is administered in a way that maximizes the dose to an area of interest and minimizes the dose to surrounding healthy tissue.

"Special procedure" means a type of therapy through which radiation is delivered to a patient through five or fewer fractions or with a dose per fraction greater than 6 Gy.

"Spot check" (See ~~Article 6~~ R9-7-602)

"Stationary beam therapy" means radiation therapy that involves a beam from a radiation source that is aimed at the patient from different directions. The distance of the source from the isocenter remains constant irrespective of the beam direction.

"Virtual source" means a point from which radiation appears to originate.

R9-7-904. Registration of Particle Accelerators Used in the Practice of Medicine or Human Research

A. The requirements in this Section supplement the registration requirements in R9-7-903.

B. An applicant that is a "medical institution," as defined in ~~9 A.A.C. 7,~~ Article 7 of this Chapter, and performing human research shall appoint a radiation safety committee that ~~meets the following requirements~~:

1. ~~The committee shall consist~~ Consists of at least four individuals ~~and shall include~~ including:
   a. An authorized user of each type of use permitted by the registration,
   b. The Radiation Safety Officer,
   c. A representative of the nursing service, ~~and~~
   d. A representative of management who is neither an authorized user nor a Radiation Safety Officer, and
   e. Any other members the registrant selects;
2. ~~The committee shall meet~~ Meets at least once in each 12-month period, unless otherwise specified by registration condition;
3. ~~To conduct~~ Only conducts business if at least 50 percent of the membership of the committee ~~shall be~~ are present~~,~~ including the Radiation Safety Officer and the

management representative;

4. ~~The~~ Includes in the minutes of each radiation safety committee meeting ~~shall include~~ a reference ~~of~~ to any discussion or documents related to the review required in R9-7-407(C);
5. ~~Review~~ Reviews the radiation safety program for all sources of radiation as required in R9-7-407(C);
6. ~~Establish~~ Establishes a table that contains investigational levels for occupational and public dose that, when exceeded, will initiate an investigation and consideration of actions by the Radiation Safety Officer; and
7. ~~Establish~~ Establishes the safety objectives of the quality management program required by subsection (E).

C. The applicant shall ensure that an individual designated as an authorized user is an Arizona licensed physician~~;~~, approved by the radiation safety committee, if applicable~~;~~ ~~and is~~ who has documentation that the individual is either:

1. Certified in radiation oncology by the:
   a. ~~Radiology, therapeutic radiology, or radiation oncology by the~~ American Board of Radiology; ~~or~~
   b. ~~Radiation oncology by the~~ American Osteopathic Board of Radiology; or
   ~~c. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or~~
   ~~d.~~c. ~~Therapeutic radiology by the Canadian~~ Royal College of Physicians and Surgeons of Canada; or
2. Engaged in the active practice of therapeutic radiology~~,~~ and has completed:
   a. At least 200 hours of instruction in basic techniques applicable to the use of a particle accelerator, ~~500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.~~ including
      ~~a.~~ ~~To satisfy the requirement for instruction, the~~ classroom and laboratory training ~~shall include~~ in all of the following subjects:
         i. Radiation physics and instrumentation,
         ii. Radiation protection,
         iii. Mathematics pertaining to the use and measurement of radiotherapy, and
         iv. Radiation biology~~.~~;
   b. ~~To satisfy the requirement for~~ At least 500 hours of supervised work experience~~,~~ ~~training shall occur~~ under the supervision of an authorized user at a medical

institution, ~~and shall include~~ including:

i. Reviewing full calibration measurements and periodic spot checks,

ii. Preparing treatment plans and calculating treatment times,

iii. Using administrative controls to prevent misadministration,

iv. Implementing emergency procedures to be followed in the event of the abnormal operation of a particle accelerator, and

v. Checking and using survey meters~~.~~;

c. ~~To satisfy the requirement for a period of supervised clinical experience, training shall include~~ A minimum of three years of supervised clinical experience:

i. Consisting of:

(1) At least one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and

(2) At least an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution~~. The supervised clinical experience shall include:~~; and

ii. Including:

~~i.~~(1) Examining individuals and reviewing their case histories to determine their suitability for treatment, noting any limitations or contraindications;

~~ii.~~(2) Selecting the proper dose and how it is to be administered;

~~iii.~~(3) Calculating the therapy doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses, as warranted by patients' or human research subjects' reaction to radiation; and

~~iv.~~(4) Post-administration follow up and review of case histories; and

d. Is qualified to independently act as an authorized user, signed by the individual supervising the clinical experience in subsection (C)(2)(c).

D. With the application the applicant shall provide the name of each authorized user to the Department so the names can be listed on the registration form, and so that the Department can

determine whether the authorized user's training and experience satisfies the requirements in subsection (C).

E. Each registrant shall establish and maintain a written quality management program to provide high confidence that the radiation produced by the particle accelerator will be administered as directed by an authorized user. The quality management program shall include, at minimum, the tests and checks listed in Appendix A.

F. Each registrant shall ensure that a particle accelerator is calibrated by an authorized medical physicist who meets the training and experience qualifications in R9-7-711.

G. At the time of application for registration or when a therapy program is expanded to multiple sites, each applicant or registrant shall provide the Department with:

1. ~~a~~ A description of the quality management program, developed, maintained, and implemented according to the American Society for Radiation Oncology's 2019 "Safety is No Accident: A Framework for Quality Radiation Oncology Care," incorporated by reference, available under R9-7-101, and containing no future editions;
2. ~~a~~ A listing of the professional staff assigned to the facility~~,~~; and
3. ~~the~~ The expected ratio of patient workload to staff member ~~for programs involving multiple therapy sites~~.

H. If the staffing ratio exceeds the recommended levels in ~~Radiation Oncology in Integrated Cancer Management, Report of the Inter-Society Council for Radiation Oncology, December 1991~~ the document incorporated by reference in subsection (G)(1), the applicant shall provide to the Department for approval the justification for the larger ratio and the safety considerations that have been addressed in establishing the program. ~~This report is incorporated by reference and available under R9-7-101. The incorporated material contains no future editions or amendments. The report is available from the American Association of Physicists in Medicine: online at http://www.aapm.org/pubs/reports; print copies may be purchased from Medical Physics Publishing, 4513 Vernon Blvd., Madison, WI 53705; toll free at (800) 442-5778.~~

I. A registrant shall ensure that:

1. Two radiation therapy technologists are at the treatment console for all procedures;
2. An authorized user and authorized medical physicist are:
   a. At the treatment console for all single fraction special procedures, such as stereotactic radiosurgery (SRS), a method of external beam radiotherapy that delivers a precisely targeted high dose of radiation in a single session;
   b. At the treatment console for the first fraction of all special procedures using multiple fractions, such as:

i. Stereotactic radiotherapy (SRT), a method of external beam radiotherapy in which radiotherapy is delivered from many different angles around the body of a patient, with the beams meeting at the tumor in such a manner that the tumor receives a high dose of radiation and the tissues around the tumor receive a much lower dose; or

ii. Stereotactic body radiation therapy (SBRT), a method of external beam radiotherapy that delivers a precisely targeted high dose of radiation to an extracranial target in five or fewer fractions; and

c. On-site and within range for patient care access for subsequent fractions of the special procedures specified in subsection (I)(2)(b);

3. For all Intensity-Modulated Radiation Therapy (IMRT), the planned doses are verified by direct measurement;

4. Except as provided in subsection (J), an authorized user is on-site and available for consultation about patient care; and

5. The health and safety of a patient are maintained.

J. If a registrant meets the requirements of a Critical Access Hospital, according to 42 CFR, Part 485, Subpart F, Conditions of Participation: Critical Access Hospitals, the registrant may allow a radiation therapy technologist to perform a procedure under general supervision if the registrant ensures that:

1. The registrant or an authorized user:

a. Has established a written protocol for the application of radiation to a patient for each procedure that may be conducted by a radiation therapy technologist under the general supervision of an authorized user, including follow-up instructions for the patient;

b. Reviews and, as necessary, revises the written protocols in subsection (J)(1)(a) at least annually; and

c. Documents the review in subsection (J)(1)(b) with a signature and date of signature;

2. The procedure is not a special procedure;

3. A radiation therapy technologist follows the applicable written protocol established according to subsection (J)(1)(a) when delivering radiation to a patient; and

4. At least every six months, an authorized user:

a. Observes each radiation therapy technologist, while the radiation therapy technologist is performing a procedure, for adherence to the applicable written

protocol in subsection (J)(1)(a); and

b. Documents the observation and the assessment in subsection (J)(4)(a);

5. An authorized user is on-site and available for consultation about patient care at least once every five working days, as shown in documentation maintained by the registrant; and

6. The health and safety of a patient are maintained.

K. A registrant that uses the general supervision in compliance with subsection (J) shall develop, maintain, and implement policies and procedures to monitor:

1. The performance of a procedure by a radiation therapy technologist under general supervision, and

2. The quality of patient care.