

NOTICE OF PROPOSED EXPEDITED RULEMAKING
TITLE 9. HEALTH SERVICES
CHAPTER 7. RADIATION CONTROL

PREAMBLE

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| <u>1.</u> | <u>Article, Part, of Section Affected (as applicable)</u> | <u>Rulemaking Action</u> |
| | R9-7-1302 | Amend |
| | Table 13.1 | Amend |
| <u>2.</u> | <u>Citations to the agency’s statutory authority for the rulemaking to include the authorizing statute (general) and the implementing statute (specific):</u> | |
| | Authorizing Statutes: A.R.S. §§ 30-654(B)(5) and 36-136(G) | |
| | Implementing Statutes: A.R.S. §§ 30-654, 30-656, 30-657, 30-671 through 30-672.01, 30-681 through 30-689, and 30-721 | |
| <u>3.</u> | <u>Citations to all related notices published in the <i>Register</i> as specified in R1-1-409(A) that pertain to the record of the proposed expedited rulemaking:</u> | |
| | Notice of Rulemaking Docket Opening: 27 A.A.R. XXXX, December XX, 2021 (to be entered by <i>Register</i> editor) | |
| <u>4.</u> | <u>The agency’s contact person who can answer questions about the rulemaking:</u> | |
| | 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: | Robert Lane, 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: Robert.Lane@azdhs.gov

5. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, under A.R.S. § 41-1027, to include an explanation about the rulemaking: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. Pursuant to A.R.S. § 30-654(B)(17), the Department has established a schedule of fees to be charged to categories of licensees and registrants of radiation sources in Article 13 of the Chapter. Laws 2021, Ch. 409, § 26 requires the Department to reduce revenue generated by the fees specified in Article 13 by \$300,000. As part of the review for a five-year-review report fees, the Department has also identified that it is unclear under which category and type of license persons who service devices containing radioactive materials are regulated. These persons are currently licensed under category/type (D)(8) Health Physics Class A, but the rules would be improved by better describing the license type under which they are regulated without changing the fee currently paid by these persons. The Department believes that these changes are consistent with the purpose for A.R.S. § 41-1027 in that this rulemaking does not increase the cost of regulatory compliance, does not increase a fee, or reduce a procedural right of regulated persons. In fact, the rulemaking will not only make the rules compliant with Legislative requirements, but also reduce the regulatory burden of both persons who service devices containing radioactive materials and those who will pay the reduced fees.

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, January 3, 2022, 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:

According to A.R.S. Title 30, Chapter 2, Article 2, as amended by Laws 2017, Ch. 313, 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 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.

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:

These rules rely on statutory authority from state statutes, not from federal regulations.

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 such analysis was submitted.

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

In R9-7-1302(D)(11): 10 CFR 61, revised January 1, 2015

13. The full text of the rule follows:

TITLE 9. HEALTH SERVICES
CHAPTER 7. RADIATION CONTROL
ARTICLE 13. LICENSE AND REGISTRATION FEES

R9-7-1302. License and Registration Categories

Table 13.1. Table of Fees

ARTICLE 13. LICENSE AND REGISTRATION FEES

R9-7-1302. License and Registration Categories

- A.** Category A licenses are those specific licenses that authorize a school, college, university, or other teaching facility to possess and use radioactive materials for instructional or research purposes.
1. A broad academic class A license is any category A license that meets the specifications of R9-7-310(A)(1).
 2. A broad academic class B license is any category A license other than a broad academic class A license that meets the specifications of R9-7-310(A)(2).
 3. A broad academic class C license is any category A license other than a broad academic class A or B license that meets the specifications of R9-7-310(A)(3).
 4. A limited academic license is any category A license that authorizes only those radioisotopes, forms, and quantities individually specified in the license.
- B.** Category B licenses are those specific or general licenses that authorize the application of radioactive material or the radiation from it to a human being for medical diagnostic, therapeutic, or research purposes, or the use of radioactive material in medical laboratory testing. Except for a type B6, general medical license, the Department shall not combine a category B license with a license of any other category.
1. A broad medical license is any category B license that meets the specifications of R9-7-310(A)(1) and meets the requirements of 9 A.A.C. 7, Article 7. A broad medical license may authorize any medical use other than teletherapy.
 2. A medical materials class A license is any specific category B license other than a broad medical license, that authorizes the use of radiopharmaceuticals and sealed sources containing radioactive materials for a therapeutic purpose in quantities that require hospitalization of the patient for radiation safety purposes. The license may authorize other radioactive materials and other medical uses, except teletherapy.
 3. A medical materials class B license is any specific category B license that authorizes the diagnostic or therapeutic use, other than teletherapy, of radioactive materials only in limited quantities such that the patient need not be hospitalized for radiation safety purposes.
 4. A medical materials class C license is any specific category B license that authorizes possession of specified radioisotopes only in the form of sealed sources for treatment of the eye or skin or for use in diagnostic medical imaging devices.

5. A medical teletherapy license is a specific category B license that solely authorizes radioisotopes in the form of multi-curie sealed sources for use in external beam therapy. The Department shall not combine a medical teletherapy license with any other type of category B license.
 6. A general medical license is one that authorizes the use of radioactive material pursuant to R9-7-306(D) or R9-7-306(E). A general medical license may be combined into a broad medical, medical materials class A, or medical materials class B license.
- C. Category C licenses are those specific or general licenses that authorize the use of radioactive materials in any activity other than those authorized by a category A, B, or D license. Except as specifically authorized in this Section, the Department shall not combine a category C license with any other type of license.
1. A broad industrial class A license is any category C license that meets the specifications of R9-7-310(A)(1). The Department may combine a broad industrial class A license with any other category C license except industrial radiography, open field irradiator, or well logging licenses.
 2. A broad industrial class B license is any category C license other than a broad industrial class A license that meets the specifications of R9-7-310(A)(2). The Department may combine a broad industrial class B license with any other category C license except industrial radiography, open field irradiator, or well logging licenses.
 3. A broad industrial class C license is any category C license other than a broad industrial class A or B license that meets the specifications of R9-7-310(A)(3). The Department may combine a broad industrial class C license with any other category C license except industrial radiography, open field irradiator, or well logging licenses.
 4. A limited industrial license is a specific category C license that authorizes the possession of the radioactive materials authorized in R9-7-305(A), or R9-7-306(A), (C), or (F) for uses authorized in those subsections, but in quantities greater than authorized by those subsections.
 5. A portable gauge license is a specific category C license that authorizes radioactive materials in the form of sealed sources for use in measuring or gauging devices designed and manufactured to be transported to the location of use. The Department may combine a portable gauge license with any broad scope industrial license or a fixed gauge class A license.
 6. A fixed gauge class A license is a specific category C license that authorizes the possession of 50 or more measuring or gauging devices containing radioactive materials,

where each device is permanently mounted for use at a single location.

7. A fixed gauge class B license is a specific category C license that authorizes the possession of 1 through 49 measuring or gauging devices containing radioactive materials, where each device is permanently mounted for use at a single location.
8. A leak detector license is a specific category C license that authorizes the use of radioisotopes in the form of a gas to test hermetic seals on electronic packages.
9. A gas chromatograph license is a specific category C license that authorizes the use of radioactive materials as ionization sources in gas chromatography or electron capture devices.
10. A general industrial license is one that authorizes the use of a material, source, or device generally licensed pursuant to R9-7-305 or R9-7-306, except R9-7-305(B), R9-7-306(D), or R9-7-306(E).
11. An industrial radiography class A license is a specific category C license that authorizes industrial radiography using sealed radioisotope sources at specific facilities identified in the license conditions or at temporary field job sites.
12. An industrial radiography class B license is a specific category C license that authorizes industrial radiography using sealed radioisotope sources only at specific facilities identified in the license conditions.
13. An open field irradiator license is a specific category C license that authorizes the use of radioisotopes in the form of sealed sources not permanently mounted within a shielding container, for irradiation of materials.
14. A self-shielded irradiator license is a specific category C license that authorizes the use of radioisotopes in the form of sealed sources for irradiation of materials in a shielding device from which the sources are not removed during irradiation. The Department may combine a self-shielded irradiator license with any broad license.
15. A well logging license is a specific category C license that authorizes the use of radioactive material in sealed or unsealed sources for wireline services or field tracer studies.
16. A research and development license is a specific category C license that authorizes a licensee to utilize radioactive material in unsealed and sealed form for industrial, scientific, or biomedical research, not including administration of radiation or radioactive material to human beings.
17. A laboratory license is a specific category C license that authorizes a licensee to perform specific in-vitro or in-vivo medical or veterinary testing, while possessing quantities of

radioactive material greater than the general license quantities authorized in R9-7-306.

D. Category D licenses are the following specific or general radioactive material licenses. Except for type D4, general industrial; type D5, depleted uranium; type D8 and D9, health physics; and type D14, additional facilities licenses, the Department shall not combine a category D license with any other license.

1. A distribution license is one that authorizes the commercial distribution of radioactive materials or radioisotopes in products to persons holding an appropriate general or specific license. The Department shall ensure that a distribution license does not:
 - a. Authorize distribution of radiopharmaceuticals or distribution to persons exempt from regulatory control, or
 - b. Authorize any other use of the radioactive material. An appropriate category C license is required for possession of radioisotopes and their incorporation into products.
2. A nuclear pharmacy license is one that authorizes the preparation, compounding, packaging, or dispensing of radiopharmaceuticals for use by other licensees.
3. A nuclear laundry license is one that authorizes the collection and cleaning of items contaminated with radioactive materials.
4. A general industrial gauging device license is one that authorizes the use of a gauging device in accordance with R9-7-306(A). The Department may combine a general industrial gauging device license with a class A, B, or C broad industrial, limited industrial, portable gauge, or class A or B fixed gauge license.
5. A general depleted uranium license is one that authorizes the use of the general license authorized pursuant to R9-7-305(C) or the use of depleted uranium as a concentrated mass or as shielding for another radiation source within a device or machine. The Department may combine a general depleted uranium license with a medical teletherapy; class A, B, or C broad industrial; portable gauge; class A or B fixed gauge; class A or B industrial radiography; or self-shielded irradiator license. For licensing purposes, an applicant shall follow the requirements in R9-7-305(C).
6. A veterinary medicine license is one that authorizes the use of radioactive materials for specific applications in veterinary medicine as authorized in the license.
7. A general veterinary medicine license is one that authorizes the use of the general license authorized in R9-7-306(E) in veterinary medicine.
8. A health physics class A license is one that authorizes the use of radioactive materials for performing instrument calibrations, processing leak test or environmental samples, or

providing radiation dosimetry services or the performance of maintenance on devices containing radioactive materials.

9. A health physics class B license is one that authorizes only the collection, possession, and transfer of radioactive materials in the form of leak test samples for processing by others.
10. A secondary uranium recovery license is one that authorizes the extraction of natural uranium or thorium from an ore stream or tailing that is being or has been processed primarily for the extraction of another mineral. The Department shall not combine a secondary uranium recovery license with any other license.
11. A low-level, radioactive waste disposal facility license is a license that is issued for a “disposal facility,” as that term is used in R9-7-439 and R9-7-442, that has a closure or long-term care plan and is constructed and operated according to the requirements in 10 CFR 61, revised January 1, 2015, incorporated by reference, available under R9-7-101 and containing no future editions or amendments.
12. A waste processor class A license is one that authorizes the incineration, compaction, repackaging, or any other treatment or processing of low-level radioactive waste prior to transfer to another person authorized to receive or dispose of the waste. The Department shall not combine a waste processor class A license with any other license.
13. A waste processor class B license is one that authorizes a waste broker to receive prepackaged, low-level radioactive waste from other licensees; combine the waste into shipments; and transfer the waste without treating or processing the waste in any manner and without repackaging except to place damaged or leaking packages into overpacks. The Department shall not combine a waste processor class B license with any other license.
14. An additional storage and use site license is an endorsement, by license condition to an existing specific license, authorizing one or more additional separate facilities where radioactive material may be stored or used for a period exceeding six months.
15. A possession-only license is a license of any other category that authorizes only the possession in storage, but no use of, the authorized materials. A license that has been suspended as an enforcement action is not considered a possession-only license.
16. A reciprocal license is the general license authorized by R9-7-320. This license is subject to a special fee as provided by R9-7-1306(C) but is exempt from annual fees.
17. Reserved
18. An “unclassified” radioactive material license is one that authorizes radioisotopes, physical or chemical forms, possession limits, or uses not included in any other type of

license specified in this Section.

19. A NORM commercial disposal site license is one that authorizes the receipt of waste material contaminated with naturally occurring radioactive material from other licensees for permanent disposal, provided the concentration of the radioactive material does not exceed 74kBq (2,000 picocuries)/gram.

E. Category E registrations are those that register the possession of x-ray machine(s) under 9 A.A.C. 7, Article 2. The Department shall not combine category E registrations with any other registration.

1. An X-ray machine class A registration is one authorizing the possession of X-ray machines in a hospital or other facility offering inpatient care.
2. An X-ray machine class B registration is one authorizing the possession of X-ray machines in a medical, osteopathic, or chiropractic office or clinic not offering inpatient care; or the possession of X-ray machines in a school, college, university, or other teaching facility.
3. An X-ray machine class C registration is one authorizing the possession of X-ray machines in dental, podiatry, or veterinarian offices or clinics.
4. An industrial radiation machine registration is one authorizing the possession of X-ray machines, or the possession of particle accelerators not capable of producing a high radiation area, in a nonmedical facility.
5. An accelerator facility registration is one authorizing the possession and operation of one or more particle accelerators of any kind capable of accelerating any particle and producing a high radiation area.
6. An “other” ionizing radiation machine registration is one authorizing possession or use of an ionizing radiation machine not included in any other category specified in subsection (E).

F. Category F registrations are those that register non-ionizing radiation producing sources regulated under 9 A.A.C. 7, Article 14. The Department shall not combine category F registrations with any other registration categories that have a difference in fee per unit.

1. A tanning registration authorizes the commercial operation of one or more tanning booths, beds, cabinets, or other devices in a single establishment.
2. A Class A laser registration authorizes the operation of one to 10 laser devices subject to R9-7-1433.
3. A Class B laser registration authorizes the operation of 11 to 49 laser devices subject to R9-7-1433.

4. A Class C laser registration authorizes operation of 50 or more laser devices subject to R9-7-1433.
5. A laser light show or laser demonstration registration authorizes the operation of a laser device subject to R9-7-1441.
6. A medical laser registration authorizes the operation of one or more laser devices subject to R9-7-1440.
7. A Class II surgical device registration authorizes the operation of one or more Class II surgical devices subject to R9-7-1438. A device is designated as a Class II surgical device by the USFDA and is labeled as such by the manufacturer.
8. A cosmetic radiofrequency device registration authorizes the operation of one or more medical radiofrequency devices for non-ionizing cosmetic procedures.
9. A class A industrial radiofrequency device registration authorizes the operation of one to five radiofrequency devices.
10. A class B industrial radiofrequency device registration authorizes the operation of six to 20 radiofrequency devices.
11. A class C industrial radiofrequency device registration authorizes the operation more than 20 radiofrequency devices.
12. A medical radiofrequency device registration authorizes the operation of one or more medical radiofrequency devices for non-ionizing, non-cosmetic procedures.
13. An “other” non-ionizing radiation device registration authorizes the operation of a non-ionizing radiation device or other device not included in any other category specified in subsection (F).

Table 13.1. Table of Fees

Category	Type	Application/Annual Fee
A1	Broad academic class A	\$10,000
A2	Broad academic class B	\$10,000
A3	Broad academic class C	\$10,000
A4	Limited academic	\$2,500
B1	Broad medical	\$20,000
B2	Medical materials class A	\$4,000
B3	Medical materials class B	\$4,000
B4	Medical materials class C	\$4,000
B5	Medical teletherapy	\$8,000
B6	General medical	\$500
C1	Broad industrial class A	\$20,000
C2	Broad industrial class B	\$20,000
C3	Broad industrial class C	\$6,000
C4	Limited industrial	\$1,500
C5	Portable gauge	\$2,000
C6	Fixed gauge class A	\$2,000
C7	Fixed gauge class B	\$2,000
C8	Leak detector	\$2,000
C9	Gas chromatograph	\$2,000
C10	General industrial	\$300
C11	Industrial radiography class A	\$10,000
C12	Industrial radiography class B	\$10,000
C13	Open field irradiator	\$10,000
C14	Shelf-shielded irradiator	\$5,000
C15	Well logging	\$5,000
C16	Research and development	\$5,000
C17	Laboratory	\$3,000
D1	Distribution	\$5,000
D2	Nuclear pharmacy	\$10,000
D3	Nuclear laundry	\$25,000
D4	General industrial gauging device	\$500
D5	General depleted uranium	\$200
D6	Veterinary medicine	\$2,000
D7	General veterinary medicine	\$500
D8	Health physics class A	\$5,000
D9	Health physics class B	\$3,000
D10	Secondary uranium recovery	\$8,000
D11	Low-level radioactive waste disposal facility	According to R9-7-1306(B)
D12	Waste processor class A	\$10,000
D13	Waste processor class B	\$8,000
D14	Additional storage and use site	30% of the applicable fee for each additional site
D15	Possession-only	50% of the applicable fee for the category under which storage will occur

D16	Reciprocal	According to R9-7-1306(C)
D17	Reserved	
D18	Unclassified radioactive material	Full Cost, according to R9-7-1306(D) or (E)
D19	NORM commercial disposal site	\$600,000
E1	X-ray machine class A (per tube)	\$195 \$145
E2	X-ray machine class B (per tube)	\$145 \$95
E3	X-ray machine class C (per tube)	\$95 \$90
E4	Industrial radiation machine (per device)	\$95
E5	Accelerator facility	\$2,500
E6	Other ionizing radiation machine	Full Cost, according to R9-7-1306(D) or (E)
F1	Tanning device (per device)	\$50
F2	Class A laser (1 to 10 laser devices)	\$300
F3	Class B laser (11 to 49 laser devices)	\$600
F4	Class C laser (50 or more laser devices)	\$1,000
F5	Laser light show or laser demonstration	\$500
F6	Medical laser (per laser device)	\$100
F7	Class II surgical device (per device)	\$100
F8	Cosmetic radiofrequency device (per device)	\$100
F9	Class A industrial (1 to 5 radiofrequency devices)	\$150
F10	Class B industrial (6 to 20 radiofrequency devices)	\$350
F11	Class C industrial (more than 20 radiofrequency devices)	\$600
F12	Medical radiofrequency (one or more device)	\$100
F13	Other non-ionizing radiation device	Full Cost, according to R9-7-1306(D) or (E)