

## NOTICES OF RULEMAKING DOCKET OPENINGS

The Administrative Procedure Act (APA) requires the publication of Notices of Rulemaking Docket Opening whenever an agency opens a rulemaking docket to consider rulemaking. Under the APA effective January 1, 1995, agencies must submit a Notice of Rulemaking Docket Opening before beginning the formal rulemaking process.

### NOTICE OF RULEMAKING DOCKET OPENING

#### BOARD OF PHARMACY

1. **Title and its heading:** 4, Professions and Occupations  
**Chapter and its heading:** 23, Board of Pharmacy  
**Article and its heading:** 1, Administration  
**Section numbers:** 4-23-110
2. **The subject matter of the proposed rules:**  
This rulemaking amends Section R4-23-110 (Definitions) by repealing three definitions. These definitions were identified as unnecessary during work on the repeal of the industrial medical stations rule that was noticed in docket # R9605 published at 3 A.A.R. 328, January 31, 1997. This rule change will be processed as part of the industrial medical stations rulemaking.  
  
Agency docket number: R9702
3. **A citation to all published notices relating to the proceeding:**  
3 A.A.R. 328, January 31, 1997 (Notice of Rulemaking Docket Opening)
4. **The name and address of agency personnel with whom persons may communicate regarding the rules:**  
Name: Dean Wright, Compliance Officer  
  
Address: Arizona Board of Pharmacy  
5060 North 19th Avenue, Suite 101  
Phoenix, Arizona 85015  
  
Telephone: (602) 255-5125, ext. 131  
  
Facsimile number: (602) 255-5740
5. **The time during which the agency will accept written comments and the time and place where oral comments may be made:**  
The Board will accept written comments Monday through Friday, 8 a.m. to 5 p.m.  
  
The Board will accept oral comments Monday through Friday, 8 a.m. to 4:30 p.m. at the address and phone number listed above.  
  
Written and oral comments will be accepted until the close of record on a date and time as yet undetermined.
6. **A timetable for agency decisions or other action on the proceeding, if known:**  
None.

### NOTICE OF RULEMAKING DOCKET OPENING

#### RADIATION REGULATORY AGENCY

1. **Title and its heading:** 12, Natural Resources  
**Chapter and its heading:** 1, Radiation Regulatory Agency  
**Article and its heading:** 1, General Provisions  
2, Registration and Certification of Ionizing Radiation Machine Facilities, Registration of Services, and Licensing of Nonionizing Radiation Machine Facilities  
3, Licensing of Radioactive Material  
4, Standards for Protection Against Ionizing Radiation  
5, Radiation Safety Requirements for Industrial Radiographic Operations  
6, Use of X-Rays in the Healing Arts  
7, Use of Sealed Radioactive Sources in the Healing Arts (heading being changed to: Use of Radionuclides in the Healing Arts)  
8, Radiation Safety Requirements for Analytical X-Ray Operations  
9, Radiation Safety Requirements for Particle Accelerators  
10, Notices, Instructions, and Reports to Workers; Inspections  
12, Administrative Provisions  
13, License and Registration Fees

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**Section numbers:**

R12-1-102; R12-1-202 and Appendix A; R12-1-301 through R12-1-323 and Schedules A through E; R12-1-407 through R12-1-409, R12-1-411, R12-1-418, R12-1-419, R12-1-449, and R12-1-450; R12-1-511 and R12-1-541; R12-1-606 and R12-1-612; R12-1-701 through R12-1-708, R12-1-710 through R12-1-714, R12-1-716 through R12-1-719, and Schedule A; R12-1-801 through R12-1-806; R12-1-902 through R12-1-904, R12-1-908, and R12-1-911; R12-1-1001 through R12-1-1008 and Exhibit A; R12-1-1209 through R12-1-1220, R12-1-1222, and R12-1-1223; and R12-1-1301 through R12-1-1308.

**2. The subject matter of the proposed rules:**

The majority of the changes are the result of Five-year Reviews of the rules contained in the above listed Articles that occurred over the last three years. In three instances, the first two in Article 3 and the second in Article 12, rules are added as required by outside influences. Arizona's Agreement with the Nuclear Regulatory Commission requires that Arizona establish financial and decommissioning responsibilities for certain radioactive material licensees. In the second, the Secretary of State requires an agency publish in their rules information requested on application forms or publish copies of the forms in the rules. The requested licensing information will be listed in Schedule E of Article 3. In the last instance, the State Legislature requires the Agency place into rule "Action Time-frames" for processing requests for licenses, registrations, and amendments. A final major change in the addition of a \$3 million application/licensing fee for a radioactive waste disposal site which would be part of the federally mandated compact radioactive waste disposal system.

While changes are made to Articles 1 and 2 for clarification purposes, the rules in Article 3 are renumbered to correct an error made when definitions for "decommissioning" and "emergency plan" were added in 1993. Also, a general list of requested information in a radioactive material license application will now be listed in Schedule E, and all of the specific rules governing the licensing for the medical use of radioactive material is removed from Article 3 and moved to Article 7.

In Article 4, certain licensees and registrants will be exempted from the need to maintain records of their radiation safety program as described in R12-1-407. The Article is amended to relocate standards for survey meter calibration and use to a separate rule that is more visible and to also add a rule governing radioactive sealed source use and accountability. The latter requirement is added after many years of being addressed in a license condition. The last change will help streamline radioactive material licenses. Other changes made to Article 4 are made for clarification purposes.

Changes are made to Articles 5 and 6 to improve clarity and understandability. Article 5 regulates both radiation sources and, in doing so, creates some confusion that is being addressed at this time.

As noted earlier in the notice, medical licensing requirements are moved to Article 7. Included is Schedule A, which is updated by adding the latest radiopharmaceuticals and the addition of the "product license application" (PLA), a designation used by the Food and Drug Administration (FDA) when approving certain kinds of drugs. In conjunction with this change, a number of additional requirements are added that have been previously addressed through license conditions and Nuclear Regulatory Commission guidance. In some cases, these requirements have been a part of federal regulations for over ten years. Other requirements are added as they address concerns associated with the latest medical technology using radioactive material in the healing arts.

After a thorough review of Article 8, it became apparent that it no longer followed current safety standards for analytic x-ray operations established by the Conference of Radiation Program Directors. Changes are made at this time to bring this Article up to standard. Included is the deletion of all references to radioactive material which should not be address in this Article. None of the proposed changes are substantive in nature and should not result in additional cost to the x-ray users.

Article 9 is revised to better delineate the requirements affecting medical users of particle accelerators from nonmedical users. In R12-1-911, the word "monitoring" is replaced with the word "survey" to eliminate any confusion. A quality management program requirement and physician training requirements, similar to those being added to Article 7, are also added to R12-1-904. Some form of quality assurance should already be in effect at most radiation therapy facilities. With these rule changes, the registrant will be required to formalize these activities for Agency review. The requirement to have a quality management program is already listed as a condition of use on a particle accelerator registration form.

Article 10 is undergoing a number of minor changes as a result of the last Five-year Review. Hopefully, clarity and understandability are improved.

One of the best ways to determine if a rule is meeting the needs established during the original rulemaking process is to field-test it. After field-testing the administrative sanction rules in Article 12, it has been determined a number of changes are needed. The changes will make the rules more useful in classifying violations and determining the penalties associated with them. The license and registration divisions are listed in tables rather than paragraphs for easier reference.

Article 13 requires a number of corrections because of incorrect rule references, an outdated incorporation by reference, and needed rule format changes to improve understandability and clarity. The rule references are incorrect because of changes to the rules being referenced. Other changes include authorization for broad scope licenses and certain Category D licenses to combine with other license categories; the addition of two additional categories that were inadvertently omitted when Article 13 underwent its first major revision; and the addition of a new waste disposal license category that is not addressed by the current waste disposal license category and a new separate medical particle accelerator category having an annual fee commensurate with its use hazard and staff compliance effort. Also, other license and registration fees are under review for possible adjustment. All fee adjustments are based on current Agency costs in maintaining the compliance program.

**Agency docket number:** 0043

*Arizona Administrative Register*  
**Notices of Rulemaking Docket Openings**

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3. **A citation to all published notices relating to the proceeding:**  
None published.
4. **The name and address of agency personnel with whom persons may communicate regarding the rules:**  
Name: Aubrey Godwin  
Address: Arizona Radiation Regulatory Agency  
4814 South 40th Street  
Phoenix, Arizona 85040
5. **The time during which the agency will accept written comments and the time and place where oral comments may be made:**  
The Agency will accept written comments Monday through Friday, 8 a.m. to 5 p.m. The Agency will accept oral comments at the address listed above Monday through Friday, 8 a.m. - 4:30 p.m.
6. **A timetable for agency decisions or other action on the proceeding, if known:**  
A timetable is not available at this time.