NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* first as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council or the Attorney General. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Register* after the final rules have been submitted for filing and publication.

NOTICE OF FINAL RULEMAKING

TITLE 3. AGRICULTURE

CHAPTER 5. DEPARTMENT OF AGRICULTURE
STATE AGRICULTURAL LABORATORY

PREAMBLE

1. Sections Affected — **Rulemaking Action**

R3-5-101	Amend
R3-5-102	Amend
R3-5-103	Amend
R3-5-104	Amend
R3-5-105	Amend
R3-5-106	Amend
R3-5-107	Amend
R3-5-110	Amend
R3-5-111	New Section
R3-5-112	New Section
Table 1	Amend

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. § 3-107(A)(1)

Implementing statutes: A.R.S. §§ 3-146 and 3-147

3. The effective date of the rules:

November 13, 2004

4. A list of all previous notices appearing in the Register addressing the final rules:

Notice of Rulemaking Docket Opening: 9 A.A.R. 5333, December 12, 2003
Notice of Proposed Rulemaking: 10 A.A.R. 1061, March 26, 2004

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Steven Zraick, General Counsel

Address: Department of Agriculture
1688 W. Adams, Room 235
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6. An explanation of the rules, including the agency's reasons for initiating the rules:

The Department committed to update these rules in a Five-year-review Report accepted by the Governor's Regulatory Review Council on November 5, 2002.

Language usage is conformed to the current rulewriting standards of the Office of the Secretary of State.

Definitions of "embossing seal," "PTP," "SAL," and "testing" are added for clarity and to provide conciseness within the rules.

Additional certified agricultural services are identified at R3-5-103(A)(7). They are noxious weed identification and noxious weed seed identification.

A laboratory is now required to provide an employee organization chart as part of the application. The elements of the quality assurance manual maintained by a certified laboratory, R3-5-105(B), are amended.

Material incorporated by reference at R3-5-105(F) is updated to include the most recent edition.

Former subsection R3-5-102(H) is established as a separate rule, R3-5-112, Licensing Time-frames. It is now compatible with the structure used by the Department divisions, a separate rule to discuss time-frames, followed by the table that establishes the specific licenses and the calendar days for each review category. The time–frames table is amended to provide adequate time for the SAL to review requests for certification of services not currently offered. The longer time-frames are prescribed at R3-5-112.

R3-5-111 is a new Section that details the status of a certification if a laboratory is moved; the existing certification expires and an initial application is required.

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

None

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

Not applicable

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

A. *The Arizona Department of Agriculture*.

The Department will incur modest expenses related to training staff and educating the regulated community on the amendments. There are no increases in laboratory certification fees and revenue will not be affected.

B. *Political Subdivision.*

Other than the Department, no other agency will be affected by these rules.

C. *State Revenue*

This rulemaking has no impact on state revenue.

D. *Businesses Directly Affected By the Rulemaking.*

Laboratories regulated by the SAL will have the option of seeking certification to identify noxious weeds or noxious weed seeds.

The documentation required in the master file and the quality assurance manual are revised and restated.

Laboratories seeking certification for a service not currently established will be licensed under the time-frame stated in rule and the time-frame table is corrected to match the rule.

The rulemaking clarifies the SAL position that a certification is for a specific physical location and a laboratory that is moved during its 12-month certification period must apply for initial certification of the new location.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

Minor technical and grammatical changes have been made to the rule based on suggestions from Department and G.R.R.C. staff.

11. A summary of the comments made regarding the rules and the agency response to them:

The Arizona Department of Agriculture's State Agricultural Laboratory held a meeting with persons representing Arizona certified laboratories on March 4, 2004 to review the proposed rulemaking before it was filed with the Office of the Secretary of State. No concerns regarding the proposed amendments were raised at that meeting.

The Arizona Department of Agriculture's Advisory Council supported the rulemaking by motion during a meeting held on April 15, 2004. The Department thanks the Council and members of the regulated community for their support of this rulemaking.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

None

13. Incorporations by reference and their location in the rules:

40 CFR 261, July 1, 2003 Edition R3-5-105(F)

40 CFR 262, July 1, 2003 Edition R3-5-105(F)

14. Were these rules previously made as emergency rules?
No

15. The full text of the rules follows:

TITLE 3. AGRICULTURE

CHAPTER 5. DEPARTMENT OF AGRICULTURE
STATE AGRICULTURAL LABORATORY

ARTICLE 1. SAMPLING AND LABORATORY CERTIFICATION

Section
R3-5-101. Definitions
R3-5-102. Certification; Renewal; Termination
R3-5-103. ~~Certified~~ Agricultural Laboratory Services
R3-5-104. Fees
R3-5-105. Laboratory Requirements
R3-5-106. ~~Methods of Analyzing and~~ Testing Procedures
R3-5-107. ~~Check Sample~~ Proficiency Testing Program
R3-5-110. Referee Laboratory
R3-5-111. Certification Expiration; Laboratory Relocation
R3-5-112. Licensing Time-frames
Table 1. Time-frames (Calendar Days)

ARTICLE 1. SAMPLING AND LABORATORY CERTIFICATION

R3-5-101. Definitions
In addition to the definitions ~~provided~~ in A.R.S. §§ 3-101 and 3-141, the following terms apply to this Chapter:

~~1.~~ "Accuracy" means the closeness of an ~~observed measurement~~ observation to the true value.

"Embossing Seal" means a seal approved by the SAL.

~~2.~~ "Person" means an individual, partnership, corporation, or other legal entity that establishes, conducts, or maintains a laboratory as prescribed in A.R.S. § 3-145(A).

~~3.~~ "Precision" means the agreement of repeated observations made under the same conditions.

"Proficiency Testing Program" or "PTP" means a check sample testing program.

~~4.~~ "Quality assurance" means an integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of definable quality.

"SAL" means Arizona Department of Agriculture State Agricultural Laboratory.

"Testing" means a process employed to achieve a result for an agricultural service performed by a certified laboratory.

R3-5-102. Certification; Renewal; Termination

A. Initial laboratory ~~Laboratory~~ certification. ~~Any~~ A person who ~~operates operating a laboratory performing and~~ is seeking initial laboratory certification to provide an ~~certified~~ agricultural laboratory ~~services~~ service, ~~pursuant to~~ as prescribed in A.R.S. § 3-145, shall:

1. Provide the following information on ~~the Application For Laboratory Certification~~ an application form obtained from the Department ~~and submit it with the appropriate fee to the State Agricultural Laboratory~~:
   a. ~~The name~~ Name, business and mailing address, ~~and~~ telephone and ~~facsimile~~ fax numbers, and e-mail address of the laboratory;
   b. ~~The name~~ Name, address, telephone number, e-mail address, ~~social security number,~~ and signature of the owner; and
   c. ~~The name~~ Name, address, telephone number, e-mail address, and signature of ~~each person supervising the agricultural~~ the laboratory ~~service.~~ manager;
2. Provide a ~~comprehensive~~ description of all programs, services, and functions performed at the laboratory;
3. On the application form, ~~List each~~ list the service ~~requested for~~ certification that the certified laboratory will perform by commodity or sample-type, detailing the ~~method or~~ test procedure used, including specific references to any publication where the ~~method or~~ test procedure is described~~.~~;
4. Provide a current employee organization chart that includes employee name, title, and laboratory responsibility; and
5. Include the fee prescribed in R3-5-104 with the application.

B. ~~The laboratory supervisor~~ A person shall ~~notify~~ provide written notification to the Assistant Director ~~in writing within 30 days~~ of any change ~~in the certification, including location, laboratory supervisor, owner, or other~~ to the information provided under subsection (A)(1) within 30 days after the change.

C. New service. If ~~the application for~~ a person is seeking laboratory certification ~~is~~ for a service not currently ~~conducted~~ performed by the ~~State Agricultural Laboratory~~ SAL, the application will be considered as a new service laboratory certification. ~~and~~ If the necessary expertise for review does not exist within the ~~State Agricultural Laboratory~~ SAL, the Director shall establish a committee ~~pursuant to~~ as prescribed in A.R.S. § 3-106 to advise the Department of the proper procedures for laboratory certification in that area.

~~**D.** Certified sampler.~~

~~Any person who collects certified samples shall provide the following information on the Sampler Certification Application and score at least 90% on a written sampling test determined by the type of sample certification requested:~~

~~1. The name and social security number of the sampler;~~
~~2. The name, street and mailing address, and telephone and facsimile number of the applicant's employer;~~
~~3. The name and signature of the employer;~~
~~4. The mailing address and telephone number of the owner, if different than subsection (D)(1)(b);~~
~~5. The date of the application;~~
~~6. The name and signature of the applicant's supervisor or manager;~~
~~7. The current certification number, if applicable;~~
~~8. Whether the applicant possesses a State Agricultural Laboratory-approved embossing seal;~~
~~9. A list of each service requested for certification.~~
~~10. A signature affirming that the sampler will collect samples as prescribed by the State Agricultural Laboratory and affix the embossing seal on each sample collection report.~~

~~**E.**~~**D.** Certification renewal.

1. A ~~laboratory owner or sampler~~ person shall file a renewal application obtained from the Department at least 30 days before the expiration date of the current certification and provide the ~~following~~ information required in subsection (A)(1)~~:~~.
   ~~a. The name, business and mailing address, and telephone and facsimile numbers of the laboratory;~~
   ~~b. The name, address, telephone number, social security number, and signature of the owner;~~
   ~~c. The name, address, telephone number, and signature of each person supervising a certified agricultural service.~~
2. An application received less than 30 days before the expiration date is untimely and the ~~applicant~~ person shall reapply ~~as~~ for an initial ~~applicant~~ laboratory certification.
3. ~~Any~~ If an application is received more than 60 days before the expiration date of the current certification, the Department shall ~~be returned~~ return the application to the person ~~applicant~~ for ~~resubmittal~~ resubmission.
4. The current certification ~~shall remain~~ remains valid until a determination is made on the renewal application.
5. A person shall pay the fee prescribed in R3-5-104 with the renewal application.

~~**F.**~~**E.** Certification termination. A ~~laboratory owner or sampler~~ person may terminate ~~the~~ a laboratory certification~~, either in part or in its entirety,~~ by notifying the Assistant Director in writing within 30 days before the effective date of the termination.

~~**G.** Additional services. A laboratory owner may add services to the current certification by following the certification procedure in subsections through (C), except that the Assistant Director may waive the on-site survey requirement.~~

~~**H.** Time-frames.~~

~~1. Overall time-frame. The State Agricultural Laboratory shall issue or deny a certification within the overall time-frames listed in Table 1 after receipt of the complete application. The overall time-frame is the total of the number of days provided for the administrative completeness review and the substantive review.~~
~~2. Administrative completeness review.~~
~~a. The appropriate administrative completeness review time-frame established in Table 1 begins on the date the State Agricultural Laboratory receives an application. The State Agricultural Laboratory shall notify the applicant in writing within the administrative completeness review time-frame whether the application is incomplete. The notice shall specify what information is missing. If the State Agricultural Laboratory does not provide notice to the applicant within the administrative completeness review time-frame, the application is complete.~~
~~b. An applicant with an incomplete certification application shall supply the missing information within the completion request period established in Table 1. The administrative completeness review time-frame is suspended from the date the State Agricultural Laboratory mails the notice of missing information to the applicant until the date the State Agricultural Laboratory receives the information.~~
~~c. If the applicant fails to submit the missing information before the expiration of the completion request period, the State Agricultural Laboratory shall close the file, unless the applicant requests an extension. An applicant whose file has been closed may obtain a certification by submitting a new application.~~
~~d. If a laboratory requests certification of a service not currently offered, 90 additional days shall be added to the administrative completeness review to establish a protocol for granting certification.~~
~~3. Substantive review. The substantive review time-frame established in Table 1 shall begin after the application is administratively complete.~~
~~a. On-site survey.~~

~~i. Within 30 days of receipt of a complete application, the State Agricultural Laboratory shall schedule an on-site survey of the applicant's laboratory facilities; or~~
~~ii. The Assistant Director may waive the on-site survey required for a renewal applicant if the renewal applicant is in compliance with this Article.~~
~~b. If the State Agricultural Laboratory makes a comprehensive written request for additional information, the applicant shall submit the additional information identified by the request within the additional information period provided in Table 1. The substantive completeness review is suspended from the date the State Agricultural Laboratory mails the request until the information is received by the State Agricultural Laboratory. If the applicant fails to provide the information identified in the written request within the response to additional information period, the State Agricultural Laboratory shall deny the license.~~
~~c. If the application is denied, the State Agricultural Laboratory shall send the applicant written notice explaining the reason for the denial with citations to supporting statutes or rules, the applicant's right to seek a fair hearing, and the time period in which the applicant may appeal the denial.~~

R3-5-103. ~~Certified~~ Agricultural Laboratory Services

A. ~~In addition to certification for the services established in A.R.S. § 3-141(1), The applicant~~ A person may apply for a laboratory certification to perform ~~for~~ any ~~or all~~ of the services listed in A.R.S. § 3-141(1) or any of the following agricultural laboratory services:
1. Determination of specific element and ion content of water for irrigation or livestock purposes;
2. Determination of specific element and ion content of plant tissue for the evaluation of plant nutrients;
3. Determination of specific element and ion content of soil for the evaluation of soil fertility and for element and ion content that may cause plant growth limitations;
4. Determination of ~~contents~~ the content of processed ~~meats and~~ meat or a meat food ~~products~~ product including the percentage of a meat ~~and~~ or nonmeat ~~ingredients~~ ingredient;
5. Verification of an analysis for the accuracy of the label ~~guarantees~~ guarantee of ~~feeds~~ a feed, ~~fertilizers~~ fertilizer, animal ~~manures~~ manure, plant growth ~~stimulants~~ stimulant, soil ~~amendments~~ amendment, soil ~~conditioners~~ conditioner, or ~~pesticides~~ pesticide;
6. Verification of planting seed germination~~,~~ percentages, purity analysis, or ~~other~~ another named seed or plant propagative material testing ~~procedures~~ procedure;
7. Identification of insects, plant pathogens, animal pathogens, nematodes, noxious weeds, noxious weed seeds, or animal parasites;
8. Testing of milk or milk ~~products~~ product for quality and market standards;
9. Determination of ~~mycotoxins~~ mycotoxin, ~~antibiotics~~ antibiotic, or drug ~~residues~~ residue in plant or animal tissue;
10. Determination of ~~mycotoxins~~ mycotoxin, ~~antibiotics~~ antibiotic, or drug ~~residues~~ residue in a plant or animal ~~products~~ product, animal feed, or feed ~~ingredients~~ ingredient;
11. Determination of a specific pesticide, or hazardous or toxic ~~elements~~ element in plant or animal tissue;
12. Determination of a specific pesticide or hazardous or toxic ~~elements~~ element in ~~air,~~ water used in livestock production, irrigation water, air, soil, agricultural product, or animal feed; or
13. Collection of samples.

B. ~~An applicant~~ A person may seek laboratory certification for an ~~may submit a written request to the State Agricultural Laboratory for a certified~~ agricultural laboratory service not ~~already established~~ listed in subsection (A) by complying with R3-5-102(A).

R3-5-104. Fees

A. ~~The applicant~~ A person shall ~~provide~~ pay ~~the Department with~~ the following ~~fees~~ fee to the Department before the ~~certification~~ SAL will review the application for laboratory certification to perform an agricultural laboratory service ~~is granted~~:
Initial fee, $200 per certification ~~certified service~~; or
2. Renewal fee, $100 per certification ~~certified service; and~~
~~3. Time and mileage as prescribed in A.R.S. Title 38, Chapter 4, Articles 1 and 2~~.

B. Except as provided in A.R.S. § 41-1077, the applicable fee is nonrefundable.

R3-5-105. Laboratory Requirements

A. A person who has obtained laboratory certification ~~certified~~ under this ~~Section~~ Article shall maintain ~~and update~~ a master file for ~~all~~ each ~~certified agricultural laboratory services~~ certification. The person shall update the master file within 30 days of any change. The master file shall contain:
1. ~~A~~ The most current letter of certification, stating the period of validity;
2. A quality assurance manual as described in subsection (B) ~~and all updates, approved by the Assistant Director~~;
~~3. Documentation of competence and experience in testing for the service requested;~~
3. An organizational chart that indicates:
   a. Each personnel position with responsibility for the agricultural laboratory service; and
   b. The reporting relationship of each position identified in subsection (A)(3)(a), including every administrative,

operational, and quality control relationship;

~~4. Documentation that establishes the laboratory personnel's capabilities;~~

4. The name and resume of the individual assigned to each position identified in subsection (A)(3)(a);

5. Documentation ~~for working knowledge of the applicable test standards and methods for approval of the service and the testing analyses for each service~~ of training for each staff member who performs all or part of the agricultural laboratory service;

~~6. A written standard operating procedure for testing when required and approved by the Assistant Director;~~

6. Documentation of the laboratory's competence and experience in the applicable test procedure for the agricultural laboratory service;

7. Reports of ~~all sample results~~ each sample result for the last ~~3~~ three years and all data generated during the testing. After three years, these records shall be maintained as prescribed in subsection (D). With the approval of the Assistant Director, a person may maintain records in electronic format;

8. Laboratory equipment lists, including:
   a. ~~The type~~ Type and manufacturer;
   b. ~~The serial~~ Serial and model number; ~~and~~
   c. ~~The date~~ Date of the last calibration, if applicable~~.~~; and
   d. Maintenance records;

9. Receiving and shipping records of all samples and supplies relating to the certification;

10. Quality control documentation;

~~12. Calibration certificates; and~~

11. Documentation of reference material, standards, and biological specimens as prescribed in subsection (B)(5); and

~~13.~~12. All correspondence relating to the certification and operation of the program.

B. ~~The testing laboratory~~ A person who has obtained laboratory certification shall maintain ~~and update~~ a quality assurance manual ~~that describes actions taken by the laboratory to ensure that routinely generated analytical data are scientifically valid and defensible and are of known and acceptable precision and accuracy~~. The person ~~manual~~ shall update the manual within 30 days of any change, except that any change to a testing procedure requires pre-approval from the Assistant Director based on a request made at least 30 days before the proposed implementation date. The manual shall contain:

1. A description of ~~the~~ laboratory management and the responsibilities of personnel related to the certification that includes:
   a. The legal name, address, and telephone number of the main office or parent company;
   b. The name, location of the laboratory, and telephone number, if different from subsection (B)(1)(a);
   ~~c. An organization outline or chart showing the titles or positions of all personnel relating to the certification and their reporting relationships relative to a certification request, including relationship between administration, operation, and quality control;~~
   c. The education, skill, and experience required of an individual in a position included in the organizational chart prescribed in subsection (A)(3); and
   ~~d. The names and resumes of the individuals assigned to each of the positions identified in subsection (B)(1)(c), or the personnel requirements for the individuals employed in those positions;~~
   d. A description of the method used to train each person in a position included in the organizational chart prescribed in subsection (A)(3);
   ~~e. Verification that personnel have a working knowledge of the applicable test standards and test methods, and are qualified by education, training, or experience to conduct tests and analyze data to ensure the accuracy, performance, and timeliness of testing and follow-up inspections.~~

~~2. A description of the receiving, handling, and shipping controls that includes:~~
   ~~a. The visual examination of samples, upon receipt, for evidence of shipping damage;~~
   ~~b. The storage of items, while awaiting disposition, regarding the safety of personnel and the degree of protection to preclude the possibility of damage to the shipment; and~~
   ~~c. The shipping and receiving data containing the date of receipt, the name of the manufacturer, and any other data necessary to accurately record and identify samples at the laboratory.~~

2. Procedures for receiving and handling samples, including:
   a. Transporting samples to the laboratory in a manner that protects the integrity of the sample;
   b. Performing a visual examination upon receipt for evidence of shipping damage;
   c. Recording date and time of sample receipt, carrier name, and method of shipment;
   d. Recording sample weight, temperature, or other physical parameters, as applicable;
   e. Completing chain of custody documentation for receipt, as applicable;
   f. Identifying a sample with a unique identification number;
   g. Storing a sample before and after testing; and
   h. Disposing of samples after completion of testing, including holding time;

3. Procedures for purchasing, receiving and storing reagents and laboratory consumable materials that affect the quality

of tests;

3.4. ~~A description of testing information that includes a written list of test procedures~~ A written standard operating procedure for each test as prescribed in R3-5-106. A ~~test~~ standard operating procedure for a test shall~~, when applicable,~~ contain, as applicable:

~~a. The nomenclature and identification of the sample;~~
~~b. Detailed steps and operations in sequence, including verifications made before each stage of testing;~~
~~c. Values for acceptance or rejection of analytical results based on permissible analytical variations;~~
~~d. A list of measuring equipment, specifying range, type, accuracy, and the name of the test;~~
~~e. An identification of any hazardous situations or operations;~~
~~f. A list of the precautions taken to ensure safety of personnel, and to prevent damage to test items and measuring equipment;~~
~~g. Test environments, conditions, and tolerances;~~
~~h. Special instructions for inspection or testing, such as special handling of fragile test items;~~
~~i. The nomenclature and designation of an applicable reference standard on which the test procedure is based;~~
~~j. Quality control measures for precision and accuracy using appropriate spikes, blanks, multiple sample analysis, or standard reference material controls to assure validity of test results.~~

a. An identification of the standard operating procedure, including the title, revision number, effective date, and authorizing signature;
b. The purpose of the procedure, including a description of the expected outcome;
c. The scope of the procedure, including a description of the type of samples and test parameters for which the procedure is applicable;
d. A list of reagents, apparatus, and equipment used, including technical performance requirements;
e. A list of necessary reference standards or reference materials;
f. A description of acceptable environmental conditions;
g. A sequential listing, in detail, of the steps and operations of the procedure;
h. An identification of any hazardous situation or operation;
i. A list of safety measures specific to the test procedure;
j. A list of precautions designed to prevent damage or contamination to a sample or testing equipment;
k. Any quality control measures that will be used to determine acceptability of a test result, including acceptance criteria;
l. A list of data to be recorded and the method for reporting the test result; and
m. The procedure's uncertainty or the method to be used for reporting uncertainty;

4.5. ~~Reference standards documenting that~~ Procedures for documenting applicable reference material, standards, and biological specimens that provide:

a. ~~The accuracy of all measurement~~ Traceability of each chemical ~~standards are traceable~~ standard of measurement to a primary ~~standards~~ standard;
b. ~~The biological specimens are verified by the Assistant Director or the Assistant Director's designee.~~ Verified and traceable biological specimens; and
c. Origin and traceability of reference material;

5.6. A description of an equipment maintenance program that includes:

a. ~~Manufacturer's~~ Each manufacturer's recommendations for the set-up and normal operation of each ~~instrument and, if appropriate, the specific instructions for periodic checking of the reproducibility of the system~~ piece of equipment;
b. A separate maintenance schedule for each piece of equipment, and a procedure for recording the date maintenance is performed and the date of any damage, malfunction, modification, or repair of the equipment; and
~~b.~~c. Quality control procedures for determining ~~instrument~~ equipment performance; and

7. Procedures for quality control activity, including:

~~c.~~a. Monitoring ~~of~~ temperature-controlled spaces;
~~d.~~b.~~Certification that thermometers~~ Certifying that each thermometer, ~~and~~ analytical ~~balances meet~~ balance, and biological hood meets federal or nationally-recognized standards, ~~if~~ as applicable;
~~e.~~c. ~~Calibration of~~ Calibrating glassware and volumetric equipment~~.~~, as applicable; and
d. Validating the quality of reagents and laboratory consumable material, as applicable.

C. ~~The testing~~ A person who has obtained laboratory certification ~~is responsible for~~ shall ensure the accurate calibration of testing equipment.

D. ~~The testing~~ A person who has obtained laboratory certification shall maintain records required under this Article for ~~5~~ five years, except pesticide residue sample results and data, which shall be ~~7~~ maintained for seven years;

E. ~~The construction and operation of the~~ A person who has obtained laboratory certification shall maintain a facility and conduct operations in compliance ~~comply~~ with the standards established by the Occupational Safety and Health Administration and any other applicable federal, state, ~~county and municipal~~ or local building, sanitary, safety, electrical, and fire

~~codes~~ code for the area in which the laboratory is located.

F. ~~The~~ A person who has obtained laboratory certification shall ~~comply with the disposal~~ dispose of hazardous waste ~~materials established~~ cataloged in the Identification and Listing of Hazardous Waste, 40 CFR 261, ~~amended August 12, 1997~~ July 1, 2003 edition, ~~and~~ as prescribed in the Standards Applicable to Generators of Hazardous Waste, 40 CFR 262, ~~amended August 12, 1997~~ July 1, 2003 edition. This material is incorporated by reference, does not include any later amendments or editions, and is on file with the ~~Office of the Secretary of State, and does not include any later amendments or editions of the incorporated matter~~ Department.

R3-5-106. ~~Methods of Analyzing and~~ Testing Procedures

A ~~laboratory shall, when~~ person complying with this Article shall:

1. Use ~~the methods and~~ testing procedures ~~for analyzing and testing which~~ that are referenced in professional journals or manuals and obtain the Assistant Director's approval of the ~~Assistant Director~~ procedures, or
2. Use ~~the methods and~~ testing procedures established by the ~~State Agricultural Laboratory~~ SAL.

R3-5-107. ~~Check Sample~~ Proficiency Testing Program

A. A ~~laboratory~~ person applying for laboratory certification shall ~~praticipate~~ participate in a ~~check sample program approved~~ PTP ~~by the Assistant Director~~ to demonstrate ~~it's~~ the ability of the laboratory to provide ~~those services~~ the agricultural laboratory service ~~for which certification is requested~~.

B. ~~An applying laboratory~~ A person participating in an outside PTP shall provide the Assistant Director with its identification number and a copy of the results. The person shall pay the cost of the PTP.

~~B.~~C. ~~Individual laboratory evaluation shall be~~ The Department shall evaluate each laboratory based on ~~the~~ comparative results obtained for each ~~check~~ PTP sample ~~in relationship to results, grouped by methods, received from all laboratories participating in that check sample program~~. If the Department discovers a deficiency ~~is noted during an on-site evaluation or in the examination of split-samples~~, the person applying for laboratory certification shall submit a ~~plan of~~ corrective action plan ~~designated to eliminate the deficiency~~ to the Assistant Director. ~~The applying laboratory shall provide the Assistant Director with its identification number and a copy of the results for all analysis submitted to the check sample program~~.

~~C.~~ ~~The applying laboratory shall bear the costs of all analyses performed and the cost of all subsequent check samples, including the cost of any check sample service used to determine proficiency.~~

R3-5-110. Referee Laboratory

If ~~2~~ the testing results from two certified laboratories ~~have differing testing results~~ differ or ~~if the results of a~~ certified laboratory results are challenged by a person or state agency that is ~~the~~ contracting ~~agency or other state agency~~ for agricultural laboratory services, the Director may designate a laboratory to serve as a referee ~~to~~ and assist in making a final determination. ~~In the case of a challenge of~~ If the test results are challenged, the party who loses the dispute shall pay all costs incurred by the referee laboratory ~~shall be borne by the party losing the dispute~~.

R3-5-111. Certification Expiration; Laboratory Relocation

A laboratory certification is valid for the physical location approved by the SAL in response to the initial or renewal application. If a laboratory relocates after initial certification or renewal of certification, the existing 12-month certification expires on the date of the move. A person seeking laboratory certification for the new location shall file an initial certification application to become certified at the new physical location and the Department shall perform an onsite review.

R3-5-112. Licensing Time-frames

1. Overall time-frame. The Department shall issue or deny a laboratory certification within the overall time-frames listed in Table 1 after receipt of an application. The overall time-frame is the total of the number of days provided for the administrative completeness review and the substantive review.
2. Administrative completeness review.
   a. The applicable administrative completeness review time-frame established in Table 1 begins on the date the Department receives an application. The Department shall notify the applicant in writing within the administrative completeness review time-frame whether the application is incomplete. The notice shall specify the information that is missing. If the Department does not provide notice to the applicant within the administrative completeness review time-frame, the application is complete.
   b. An applicant with an incomplete certification application shall supply the missing information within the completion request period established in Table 1. The administrative completeness review time-frame is suspended from the date that the Department mails the notice of missing information to the applicant until the date that the Department receives the information.
   c. If the applicant fails to submit the missing information before expiration of the completion request period, the Department shall close the file, unless the applicant requests an extension. An applicant whose file has been closed may obtain laboratory certification by submitting a new application.
   d. If an applicant requests laboratory certification of a new service, the Department shall add 90 days to the administrative completeness review time-frame to provide time for establishing a protocol for granting certification.
3. Substantive review. The substantive review time-frame established in Table 1 begins on the date that the application

is administratively complete.

a. Onsite survey.
   i. Within 30 days after receipt of a complete application, the SAL shall schedule an onsite survey of an applicant's laboratory facilities.
   ii. The Assistant Director may waive the onsite survey for a renewal applicant if the renewal applicant is in compliance with the other provisions of this Article.

b. If the Department makes a comprehensive written request for additional information, the applicant shall submit the additional information identified by the request within the additional information period provided in Table 1. The substantive review time-frame is suspended from the date that the Department mails the request until the information is received by the Department. If the applicant fails to provide the information identified in the written request within the additional information period, the Department shall deny the certification.

c. If laboratory certification is denied, the Department shall send the applicant written notice explaining:
   i. The reason for the denial with citations to supporting statutes or rules;
   ii. The applicant's right to appeal the denial;
   iii. The period for appealing the denial; and
   iv. The name and telephone number of a Department contact person who can answer questions regarding the appeals process.

Table 1. Time-frames (Calendar Days)

Certification	Authority	Administrative Completeness Review	~~Response to~~ Completion Request Period	Substantive Completeness Review	~~Response to~~ Additional Information Period	Overall Time-frame
Laboratory Certification	A.R.S. § 3-145					
~~New~~ Initial Renewal	R3-5-102	14 14	30 ~~7~~ 14	60 30	90 14	74 44
~~Certification request for~~ New service ~~not currently offered~~		~~14~~ 104	~~30~~ 90	60	~~90~~ 30	~~74~~ 164
~~Sampler Certification~~	~~A.R.S. § 3-145~~ ~~R3-5-102~~	~~14~~	~~30~~	~~90~~	~~90~~	~~104~~

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

PREAMBLE

1. Sections Affected — **Rulemaking Action**

R4-23-110	Amend
R4-23-411	New Section

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. § 32-1904(A)(1)

Implementing statutes: A.R.S. § 32-1901(21) and (66)

3. The effective date of the rules:

November 13, 2004

4. A list of all previous notices appearing in the Register addressing the proposed rules:

Notice of Rulemaking Docket Opening: 9 A.A.R. 5603, December 26, 2003

Notice of Proposed Rulemaking: 10 A.A.R. 1660, April 30, 2004

5. The name and address of agency personnel with whom persons may communicate regarding the rules:

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy 4425 W. Olive Ave., Suite 140 Glendale, AZ 85302
Telephone:	(623) 463-2727, Ext. 131
Fax:	(623) 934-0583
E-mail:	rxcop@cox.net

6. An explanation of the rules, including the agency's reasons for initiating the rules:

The Board received numerous inquiries from pharmacies, pharmacists, and pharmacy educators regarding the expanding role of pharmacists in the health care delivery system, specifically whether a pharmacist may administer immunizations. The Board's Assistant Attorney General advised the Board that the Pharmacy Act allows Arizona pharmacists to dispense and administer immunizations on the prescription order of a medical practitioner for a specific patient. The Board determined that it has the authority to write rules to set the standards for a pharmacist to administer immunizations. The rules amend R4-23-110 to add new definitions for "eligible patient" and "pharmacist-administered immunizations training program." The rules include a new Section (R4-23-411 Pharmacist-Administered Immunizations) that details the standards for pharmacist authorization to administer immunizations, pharmacist qualifications, immunization training programs, recordkeeping and reporting, confidentially, and renewal of authorization to administer immunizations. The rules include necessary style, format, grammar, and punctuation changes to comply with the rules of the Secretary of State and Governor's Regulatory Review Council.

The Board believes that approval of these rules benefits the public, pharmacists, and pharmacies by clearly establishing the standards for pharmacist-administered immunizations.

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

None

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

Not applicable

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

The rules will impact the Board, pharmacists, and pharmacies. The rules will have moderate economic impact on the Board. The impact on the Board will be usual rulemaking-related costs which are minimal. The major impact on the Board will be the costs of processing and issuing pharmacist-administered immunization certifications. The Board estimates that from 30 to 50 pharmacists may seek certification at an initial cost to the Board of $1230 to $2050. The cost of renewing the certification would be minimal because it would be tied to the pharmacist's biennial license renewal. The costs to a pharmacist to be certified to administer immunizations will not come from the Board directly. The Board will not charge a fee to issue pharmacist-administered immunization certifications. A pharmacist will have to pay the costs to meet the qualifications for authorization to administer immunizations. The qualifications include: a current, unrestricted license to practice pharmacy in Arizona, successful completion of a pharmacist-administered immunizations training program, and current certification in basic cardiopulmonary resuscitation. The Board estimates the cost to obtain CPR certification is $40 per person. The Board estimates the cost of a pharmacist-administered immunizations training program will be about $200 per person, based on the cost of an existing program provided by the American Pharmacist Association in other states. The total cost of training could increase when costs of travel, lodging, and food are added. The Board estimates that it will cost from $200 to $1000 per pharmacist to complete an immunizations training program. The rules will have no direct economic impact on the public. The public will benefit from increased access to immunization services provided by pharmacists, and there will be a minimal cost to the public for the service.

The public, Board, pharmacists, and pharmacies benefit from rules that are clear, concise, and, understandable. The rules benefit the public, the Board, and the pharmacy community by clearly establishing the standards for pharmacist-administered immunizations.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

There are no substantive changes in the final rules from the proposed rules. In the proposed rules, there was a subsection that required Board approval of pharmacist-administered immunizations training programs. The Board's statutory authority does not extend to approving training programs, but the Board does have authority to define the training requirements necessary for a pharmacist to administer immunizations. The final rules include a subsection

describing the pharmacist-administered immunizations training program requirements. There are minor changes to style, format, grammar, and punctuation requested by G.R.R.C. staff.

11. A summary of the comments made regarding the rules and the agency response to them:

One person representing the Arizona Pharmacy Association attended the public hearing and expressed the Arizona Pharmacy Association's support for the rules as noticed. The agency thanked the Association for their support.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

13. Incorporations by reference and their location in the rules:

None

14. Were these rules previously approved as emergency rules?

No

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

Section
R4-23-110. Definitions

ARTICLE 4. PROFESSIONAL PRACTICES

Section
R4-23-411. ~~Reserved~~ Pharmacist-administered Immunizations

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

In addition to definitions in A.R.S. § 32-1901, the following definitions apply to 4 A.A.C. 23:

"Active ingredient" No change
"Alternate physician" No change
"Approved course in pharmacy law" No change
"Approved provider" No change
"Authentication of product history" No change
"AZPLEX" No change
"Batch" No change
"Beyond-use date" No change
"Biological safety cabinet" No change
"Certified pharmacy technician" No change
"Class 100 environment" No change
"Community pharmacy" No change
"Component" No change
"Compounding and dispensing counter" No change
"Computer system" No change
"Computer system audit" No change
"Contact hour" No change
"Container" No change
"Continuing education" No change
"Continuing education activity" No change
"Continuing education unit" or "CEU" No change
"Correctional facility" No change
"CRT" No change
"Current good compounding practices" No change
"Current good manufacturing practice" No change
"Cytotoxic" No change
"Day" No change
"DEA" No change

"Delinquent license" No change
"Dietary supplement" No change
"Dispensing pharmacist" No change
"Drug sample" No change
"Drug therapy management" No change
"Drug therapy management agreement" No change
"Eligible patient" means a patient who a pharmacist determines is eligible to receive an immunization using professional judgment after consulting with the patient regarding the patient's current health condition, recent health condition, and allergies.
"Extreme emergency" No change
"FDA" No change
"Immediate notice" No change
"Inactive ingredient" No change
"Internal test assessment" No change
"Limited-service correctional pharmacy" No change
"Limited-service long-term care pharmacy" No change
"Limited-service mail-order pharmacy" No change
"Limited-service nuclear pharmacy" No change
"Limited-service pharmacy permittee" means a person who holds a current limited-service pharmacy permit in compliance with A.R.S. §§ 32-1929, 32-1930, 32-1931, and A.A.C. R4-23-606.
"Limited-service sterile pharmaceutical products pharmacy" No change
"Long-term care consultant pharmacist" No change
"Long-term care facility" or "LTCF" No change
"Lot" No change
"Lot number" or "control number" No change
"Materials approval unit" No change
"Mediated instruction" No change
"MPJE" No change
"NABP" No change
"NABPLEX" No change
"NAPLEX" No change
"Other designated personnel" No change
"Outpatient" No change
"Outpatient setting" No change
"Patient profile" No change
"Pharmaceutical patient care services" No change
"Pharmaceutical product" No change
"Pharmacist-administered immunizations training program" means an immunization training program for pharmacists that meets the requirements of R4-23-411(C).
"Pharmacy counter working area" No change
"Pharmacy law continuing education" No change
"Pharmacy permittee" means a person who holds a current pharmacy permit that complies with A.R.S. §§ 32-1929, 32-1930, 32-1931, 32-1934, and A.A.C. R4-23-606 and R4-23-652.
"Prepackaged drug" No change
"Proprietor" means the owner of a business permitted by the Board under A.R.S. §§ 32-1929, 32-1930, 32-1931, and 32-1934.
"Provider pharmacy" No change
"Radiopharmaceutical" No change
"Radiopharmaceutical quality assurance" No change
"Radiopharmaceutical services" No change
"Red C stamp" No change
"Remodel" No change
"Remote drug storage area" No change
"Resident" No change
"Responsible person" No change
"Score transfer" No change
"Sight-readable" No change
"Single-drug audit" No change
"Single-drug usage report" No change

"Sterile pharmaceutical product" No change
"Strength" No change
"Supervision" No change
"Supervisory physician" No change
"Supplying" No change
"Support personnel" means an individual, working under the supervision of a pharmacist, trained to perform clerical duties associated with the practice of pharmacy, including cashiering, bookkeeping, pricing, stocking, delivering, answering non-professional telephone inquiries, and documenting third-party reimbursement. Support personnel shall not perform the tasks of a pharmacist, pharmacy intern, graduate intern, pharmacy technician, or ~~certified~~ pharmacy technician trainee.
"Transfill" No change
"Wholesale distribution" No change
"Wholesale distributor" No change

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-411. ~~Reserved~~ Pharmacist-administered Immunizations

A. Authority to administer hepatitis, influenza, meningococcal, pneumonia, smallpox, and tetanus toxoid immunizations and, in an emergency, epinephrine. If a pharmacist meets the qualifications and standards specified by this Section and the Board certifies the pharmacist, the pharmacist may administer hepatitis, influenza, meningococcal, pneumonia, smallpox, and tetanus toxoid immunizations and, in an emergency, epinephrine to an eligible patient 18 years of age and older upon receipt of a valid prescription order. The Board shall certify a pharmacist who meets the qualifications established in subsection (B). A pharmacist who has authority to administer hepatitis, influenza, meningococcal, pneumonia, smallpox, and tetanus toxoid immunizations and, in an emergency, epinephrine shall not delegate the authority to any other pharmacist or employee.

B. Qualifications for authorization to administer hepatitis, influenza, meningococcal, pneumonia, smallpox, and tetanus toxoid immunizations and, in an emergency, epinephrine. After receipt of an completed application form, the Board shall issue a certificate authorizing the administration of hepatitis, influenza, meningococcal, pneumonia, smallpox, and tetanus toxoid immunizations and, in an emergency, epinephrine to a pharmacist who meets the following qualifications:
1. Has a current, unrestricted license to practice pharmacy in this state;
2. Successfully completes a training program specified in subsection (C); and
3. Has a current certificate in basic cardiopulmonary resuscitation.

C. Pharmacist-administered immunizations training program requirements. A training program for pharmacists to administer hepatitis, influenza, meningococcal, pneumonia, smallpox, and tetanus toxoid immunizations and, in an emergency, epinephrine shall include the following courses of study:
1. Basic immunology and the human immune response;
2. Mechanics of immunity, adverse effects, dose, and administration schedule of available vaccines;
3. Response to an emergency situation as a result of the administration of an immunization, including administering epinephrine based on a patient-specific prescription order received before administering of an immunization;
4. Administration of intramuscular injections;
5. Other immunization administration methods; and
6. Recordkeeping and reporting requirements specified in subsection (D).

D. Recordkeeping and reporting requirements.
1. In addition to filing the prescription order as required in A.R.S. § 32-1964, a pharmacist granted authorization under this Section to administer hepatitis, influenza, meningococcal, pneumonia, smallpox, and tetanus toxoid immunizations and, in an emergency, epinephrine shall maintain in the pharmacy for a minimum of seven years the following documentation regarding each immunization administered:
   a. The name, address, and date of birth of the patient;
   b. The date of administration and site of injection;
   c. The name, dose, manufacturer's lot number, and expiration date of the vaccine or, in an emergency, epinephrine;
   d. The name and address of the patient's primary health care provider, as identified by the patient;
   e. The name and address of the prescribing medical practitioner, if different from the patient's primary health care provider;
   f. The name of the pharmacist administering the immunization;
   g. A record of the pharmacist's consultation with a patient determining that the patient is an eligible patient as defined in R4-23-110;
   h. The date that the written report specified in subsection (D)(2) was sent to the patient's primary health care provider;
   i. Consultation or other professional information provided to the patient by the pharmacist; and
   j. The name of the vaccine information sheet provided to the patient.

2. The pharmacist shall provide a written report to the patient's primary health care provider of documentation required in subsection (D)(1) within 14 days of the immunization. The required records specified in this subsection shall be available in the pharmacy for inspection by the Board or its designee.

E. Confidentiality of records. The records identified in subsection (D) that include specific patient information are confidential. A pharmacist, pharmacy permittee, or pharmacist-in-charge shall comply with applicable state and federal privacy statutes and rules when releasing patient health information.

F. Renewal of a certificate for pharmacist-administered immunizations. A certificate authorizing a pharmacist to administer hepatitis, influenza, meningococcal, pneumonia, smallpox, and tetanus toxoid immunizations and, in an emergency, epinephrine shall be renewed biennially by November 1. Any pharmacist desiring to renew the certificate shall provide proof of the following:

1. Current certification in basic cardiopulmonary resuscitation, and
2. Completion of a minimum of two contact hours (0.2 CEU) of continuing education related to immunizations. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal.

NOTICE OF FINAL RULEMAKING

TITLE 12. NATURAL RESOURCES

CHAPTER 2. RADIATION REGULATORY AGENCY
MEDICAL RADIOLOGIC TECHNOLOGY BOARD OF EXAMINERS

PREAMBLE

1. Sections Affected — **Rulemaking Action**

R12-2-101	Amend
R12-2-401	Amend
Article 5	New Article
R12-2-501	New Section
R12-2-502	New Section
R12-2-503	New Section
R12-2-504	New Section
R12-2-505	New Section
R12-2-506	New Section
Article 6	New Article
R12-2-601	New Section
R12-2-602	New Section
R12-2-603	New Section
R12-2-604	New Section
R12-2-605	New Section

2. The specific authority for the rulemaking, including both the authorizing state (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. § 32-2803(A)

Implementing statute: A.R.S. § 32-2815

3. The effective date of the rules:

November 13, 2004

4. A list of all previous notices appearing in the register addressing the final rules:

Notice of Rulemaking Docket Opening: 9 A.A.R. 4013 September 12, 2003
Notice of Proposed Rulemaking: 9 A.A.R. 3922 September 12, 2003
Notice of Public Information: 9 A.A.R. 4770 October 31, 2003

5. The name and address of agency personnel with whom persons may communicate regarding the rules:

Name: John Gray

Address: 4814 S. 40th St.
Phoenix, AZ 85040
(602) 255-4845, Ext. 241

Fax: (602) 437-0705

E-mail: jgray@arra.state.az.us

6. An explanation of the rules, including the agency's reasons for initiating the rules:

The majority of the rules, Articles 5 and 6, are new sections resulting from legislation that requires certification of nuclear medicine and peripheral bone mineral densitometry technologists. There are two amendments to R12-2-101. The first restricts the radiography of human tissue, such as breast tumors, to radiologic technologists by amending the definition of "diagnostic application" to include human tissue thereby excluding limited scope technologists from performing the exam because breast tissue is outside the scope of their practice. The second expands the definition of "extremity" to include the anatomical area of the shoulder.

In Article 4, the Board is changing the time-frame for the course of study at schools of practical technology in radiology from not less than 6 months or more than nine months to not less than six months or more than 24 months.

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

None

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

Not applicable

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

The changes to Article 1 will not pose a financial burden to licensees or employers. The changes improve the clarity and understandability of the rules and specifically clarify the scope of practice for practical radiologists in radiology.

Article 4 slightly expands the practical technologist is radiology scope of practice but will have a minimal economic impact on businesses and licensees.

Article 5 will have minimal economic impact on licensees and businesses. Article 5 is new and requires certification of individuals who perform diagnostic nuclear medicine examinations on human beings. Approximately 350-400 individuals perform such studies. Over 95% of the individuals are nuclear medicine technologists nationally certified by the Nuclear Medicine Technology Certification Board (NMTCB) or the American Registry of Radiologic Technologists (ARRT). Under R12-2-506, proof of certification by either national certifying body fulfills Medical Radiologic Technology Board of Examiners requirements for certification. Under A.R.S. § 32-2812(A) the application fee is $60. Under R12-2-206, the renewal fee for 2 years is also $60. The remaining individuals practicing nuclear medicine are eligible for a temporary certification allowing them to practice through December 31, 2004. To continue practicing after December 31, 2004 they must pass the Board's certification exam. The Gateway Community College Nuclear Medicine Program Director has developed an online class designed to prepare individuals with temporary certification to successfully complete the Board's certification exam. The course is $158 and is self-pacing. The director of the this program offers additional assistance to students at no additional cost. Additional online resources are also provided. The Board's certification exam is provided through a contract with the American Registry of Radiologic Technologists and the cost is $75.

Article 6 will not result in any economic impact. The use of full body densitometry machines and the reduced cost of ultrasound machines that perform the same functions as bone densitometry machines have almost made this Article a moot point. If an application is received for certification as a practical technologist in bone densitometry, the application fee is $60 and the renewal fee for 2 years of certification is $60. The exam fee is also $60.

10. A description of the changes between the proposed rules, including supplemental notices, and the final rules:

Minor nonsubstantive changes were made at the request of G.R.R.C. staff.

11. A summary of the comments made regarding the rules and the agency response to them:

There were no written or oral comments regarding the rules. The proposed rules were cooperatively developed over an 18-24 month period by several entities that included the Society of Nuclear Medicine Technologists, educators of nuclear medicine technology including the director of the Gateway Community College N.M.T. program, department managers and individual nuclear medicine technologists.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

None

13. Incorporations by reference and their location in the rules:

None

14. Were the rules previously adopted as emergency rules?

No

15. The full text of the rules follows:

TITLE 12. NATURAL RESOURCES

CHAPTER 2. RADIATION REGULATORY AGENCY
MEDICAL RADIOLOGIC TECHNOLOGY BOARD OF EXAMINERS DIVISION

ARTICLE 1. GENERAL PROVISIONS

Section
R12-2-101. Definitions

ARTICLE 4. SCHOOLS OF PRACTICAL RADIOLOGIC TECHNOLOGY

Section
R12-2-401. Course Time-frame

ARTICLE 5. NUCLEAR MEDICINE TECHNOLOGIST

Section
R12-2-501. Definitions
R12-2-502. Use of Title
R12-2-503. Display of Certificate
R12-2-504. Application for Approval of Nuclear Medicine School
R12-2-505. Standards for Nuclear Medicine Technology Schools; Approved Nuclear Medicine Technology Schools
R12-2-506. Certification and Grandfather Provisions

ARTICLE 6. PRACTICAL TECHNOLOGIST IN BONE DENSITOMETRY

Section
R12-2-601. Definitions
R12-2-602. Recognized Certificate-granting Bodies
R12-2-603. Limitation
R12-2-604. Education
R12-2-605. Qualified Instructors

ARTICLE 1. GENERAL PROVISIONS

R12-2-101. Definitions

The definitions in A.R.S. § 32-2801 apply to this Article. In addition, the terms in this Chapter have the following meaning, unless the context otherwise requires:

"Assistance" means any activity except the following: Positioning of the patient and x-ray tube, selecting technical settings, and exposing a patient to x-rays.

"Certification" means the process by which the Board grants permission and recognition to an individual to engage in radiologic technology upon finding the individual has met the qualifications specified by statute and rule.

"Chest radiography" means radiography performed to visualize the heart and lungs only.

"Contrast media" means material intentionally administered to the human body to define a part or parts that are not normally radiographically visible.

"Diagnostic application" means the use of ionizing radiation for diagnostic purposes, including but not limited to measuring and positioning patients or human tissue, selecting technical settings on x-ray equipment, and making x-ray exposures.

"Extremity" means the shoulder girdle to the phalanges and the lower 2/3 of the femur ~~distally~~ to the phalanges.

"Foot" means the distal part of the human leg upon which an individual stands and walks.

"Practical radiologic technologist" for the purposes of this Chapter is equivalent to "practical technologist in radiology"; however, this title is further defined as a person authorized to use radiography, not including fluoroscopy and the use of contrast media, and limited to the chest and extremities, on humans, at the direction of a licensed practitioner; unless

The person is certified as a practical radiologic technologist in podiatry, in which case the person is limited to radiography of the foot and leg; or

The person is certified as an "unlimited" practical radiologic technologist, in which case the person is not limited to radiography of the body areas in this definition.

"Practical radiologic technologist in podiatry" for purposes of this Chapter is equivalent to "practical technologist in podiatry".

"Practical radiologic technology" means radiography limited to the chest or extremities and not including the use of fluoroscopy and the use of contrast media. For purposes of this Chapter "practical radiologic technology" is equivalent to "practical technology in radiology".
"Radiograph" means the record of images which represents anatomical details of the part radiographically examined and is formed by the differential absorption of ionizing radiation within the part.
"Radiography" means the use of ionizing radiation in making radiographs.
"Special permit" means a certificate issued by the Board exempting an individual from the specific provisions of A.R.S. §32-2802 through 32-2813.
"Specific direction" means the application of x-radiation to a specific area of the human body for diagnostic purposes while under the specific supervision of a licensed practitioner.
"Temporary certificate" means a certificate issued by the Board to any person who has completed a training program approved by the Board and whose certification is pending.
"Therapeutic application" means the use of ionizing radiation including, but not limited to setting up the treatment position, delivering the required dose prescribed by the physician, certifying the record of the technical details of the treatment, selecting the required filter and treatment distance, making beam directional shells and molds, using diagnostic x-ray equipment for tumor localization, assisting the physicist in calibration procedure, and assisting in treatment planning procedures. Therapeutic application does not include taking x-rays for diagnostic purposes.
"Therapeutic purpose" means the use of x-radiation to treat human disease.
"X-radiation" means penetrating electromagnetic radiation with wave-lengths shorter than those of visible light that is usually produced by bombarding a metallic target with fast electrons in a high vacuum, creating photons that originate from the extranuclear part of the atom.

ARTICLE 4. SCHOOLS OF PRACTICAL RADIOLOGIC TECHNOLOGY

R12-2-401. Course Time-frames

The administrator of a school of practical radiologic technology shall ensure that the time-frame for the course of study ~~shall~~ not ~~be~~ less than ~~6~~ six months or more than 24 months for completion of 210 hours of didactic training and 480 hours clinical training.

ARTICLE 5. NUCLEAR MEDICINE TECHNOLOGIST

R12-2-501. Definitions

"ARRT" means the American Registry of Radiologic Technologists.
"ASCP" means the American Society of Clinical Pathology.
"Authorized user" means a physician licensed in Arizona to practice medicine and who is identified as:
An authorized user on an Agency, Nuclear Regulatory Commission (NRC), or Agreement State license that authorizes the specified medical use; or
A user in a medical use board scope program, licensed by the Agency, NRC, or Agreement State to select its own authorized users.
"Board" means the Medical Radiologic Technology Board of Examiners.
"Brachytherapy" means a method of radiation therapy in which a sealed source or group of sealed sources is used to deliver beta or gamma radiation at a distance of up to a few centimeters, by surface, intracavitary, intraluminal, or interstitial application.
"Certification" means the process by which the Board grants permission and recognition to an individual to engage in nuclear medicine technology upon finding the individual meets the qualifications specified by statute and rule.
"Certified nuclear medicine technologist" means a person who:
has obtained certification from the Board in accordance with this Article but does not mean a licensed practitioner who performs in-vitro detection and measurement of radioactivity; or
administers radiopharmaceuticals to human beings for diagnostic or therapeutic purposes; or with Board-approved training, performs the CT portion of a PET/CT scan while under the general supervision of a licensed practitioner.
"Diagnostic dosage" means a prescribed amount of a radionuclide or radiopharmaceutical, which is used for a diagnostic purpose.
"Direct supervision" means an authorized user who is: personally aware of, and maintains independent professional responsibility for, the procedure intended for a given patient; present in the facility; and available for immediate assistance.
"General supervision" means guidance, direction, and instruction by an authorized user who is available, but not necessarily within the supervised individual's place of employment.
"Immediate supervision" means in-room presence for instruction, direction, and guidance by an authorized user who is available to assume control of the given procedure.
"Medical use" means the intentional internal or external administration of byproduct material or the radiation from byproduct material to patients or human research subjects under the supervision of an authorized user.

"Misadministration" means:
The administration of a radiopharmaceutical or the radiation from a sealed source, administered for therapy purposes and involving:
The wrong radiopharmaceutical or sealed source
The wrong patient
The wrong route of administration; or
A dosage that differs from the prescribed dosage by 20%; or
The administration of a diagnostic dosage of a radiopharmaceutical involving:
The wrong patient
The wrong radiopharmaceutical
The wrong route of administration; or
A dosage to an individual that exceeds 5 rems effective dose equivalent or 50 rems dosage equivalent to any individual organ;
or
A therapeutic radiation dose from a sealed source such that errors in the source calibration, time of exposure, and treatment geometry result in a calculated total treatment dose differing from the final, prescribed total treatment dose by more than 10%.
"NMTCB" means the Nuclear Medicine Technology Certification Board.
"Nuclear medicine technologist" means a person who uses radiopharmaceutical agents on humans for diagnostic or therapeutic purposes. A.R.S. § 32-2815.
"Radionuclide" means a radioactive element of a radioactive isotope.
"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide generator that is intended to be used in the preparation of the drug.
"Radiopharmaceutical agent" means a radionuclide or a radionuclide compound designed and prepared for administration to human beings.
"Therapeutic dosage" means a prescribed amount of a radionuclide or radiopharmaceutical, which is used for a therapeutic purpose.

R12-2-502. Use of Title
A person without a valid certificate shall not use the title of nuclear medicine technologist or the letters "NMT" after the person's name to indicate or imply that the person is a certified nuclear medicine technologist or represent the person in any way as a certified nuclear medicine technologist. A person who holds a valid certificate issued by the Board may use the title nuclear medicine technologist.

R12-2-503. Display of Certificate
Each nuclear medicine technologist, including any part-time or temporary technologist provided through a temporary employment agency or service, shall display proof of certification by the Board.

R12-2-504. Application for Approval of a Nuclear Medicine Technology School
A. An applicant that seeks approval for a nuclear medicine technology school shall apply by letter and shall address all of the requirements for school approval in R12-2-505.
B. The Board shall review the application in a timely manner, as required in R12-2-301, and approve or deny the application.

R12-2-505. Standards for Nuclear Medicine Technology Schools; Approved Nuclear Medicine Technology Schools
A. Based on the following factors, the Board may approve a school of nuclear medicine technology as maintaining a satisfactory standard if its course of study:
1. Is for a period not less than 12 months of full-time study or the equivalent and is accredited by the Joint Review Committee on Education in Nuclear Medicine or meets or exceeds the standards of the Joint Review Committee on Education in Nuclear Medicine as determined by the Board.
2. Includes not less than 1900 contact hours, including but not limited to: methods of patient care, radiation safety and protection, nuclear medicine, physics and radiation physics, nuclear instrumentation, statistics, radionuclide chemistry and radiopharmacy, departmental organization and function, radiation biology, nuclear medicine in-vivo and in-vitro procedures, radionuclide therapy, computer application, clinical education, and medical law and ethics.

B. The Board shall maintain a list of approved nuclear medicine technology schools.

R12-2-506. Certification and Grandfather Provisions
A. A person who has practiced nuclear medicine without a certificate from the Board before the effective date of these rules and who wishes to continue practicing shall apply for a temporary certificate as required in A.R.S. § 32-2814 (C) and (D).
B. A person who applies under subsection (A) shall pass the Board's certification no later than December 31, 2004.
C. Effective January 1, 2005, each applicant seeking certification by the Board as a nuclear medicine technologist shall pro-

vide proof of minimum education and training either by passing the Board's certification examination or presenting a valid certificate issued on the basis of an examination by a certificate-granting body recognized by the Board.

ARTICLE 6. PRACTICAL TECHNOLOGIST IN BONE DENSITOMETRY

R12-2-601. Definitions

"Practical technologist in bone densitometry" means a person authorized by the Board to perform a bone mineral densitometry limited to the extremities.

"Qualified instructor" means a person who is recognized by the Board, provides education or training in the application of ionizing radiation to extremities through the use of a bone densitometry machine, and has a relevant certification from the Board or a recognized certificate-granting body.

R12-2-602. Recognized Certificate-granting Bodies

The Board shall maintain a list of recognized certificate-granting bodies in the field of bone mineral densitometry.

R12-2-603. Limitation

The practical technologist in bone densitometry certificate authorizes the practical technologist in bone densitometry to perform densitometry only on an extremity as defined in R12-2-101.

R12-2-604. Education

An applicant for a certificate issued under this Article shall provide evidence of having completed a total of 80 hours of instruction from qualified instructors in the following subjects: radiation safety, conventions in densitometry, densitometry techniques, anatomy, precision and accuracy, quality control, osteoporosis overview, and understanding data.

R12-2-605. Qualified Instructors

The Board shall maintain a list of qualified instructors.