

TITLE 3. AGRICULTURE**CHAPTER 5. DEPARTMENT OF AGRICULTURE
STATE AGRICULTURAL LABORATORY**

Authority: A.R.S. § 3-141 et seq.

Former Title 3, Chapter 5, Article 1, Sections R3-5-01 through R3-5-08, renumbered to Title 3, Chapter 2, Article 8, Sections R3-2-801 through R3-2-808; new Title 3, Chapter 5, Article 1, Sections R3-5-101 through R3-5-110 renumbered from Title 3, Chapter 1, Article 7, Sections R3-1-701 through R3-1-710 (Supp. 91-4).

**ARTICLE 1. SAMPLING AND LABORATORY
CERTIFICATION**

Article 1, consisting of Sections R3-5-101 through R3-5-110 renumbered from R3-1-701 through R3-1-710 (Supp. 91-4).

Title 3, Chapter 1, Article 7 consisting of Sections R3-1-201 through R3-1-210 renumbered without change as Article 7, Sections R3-1-701 through R3-1-710 (Supp. 89-1).

Title 3, Chapter 1, Article 7 consisting of Sections R3-1-201 through R3-1-210 adopted effective July 25, 1985.

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**ARTICLE 1. SAMPLING AND LABORATORY
CERTIFICATION****R3-5-101. Definitions**

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

“Accuracy” means the closeness of an observation to the true value.

“Embossing Seal” means a seal approved by the SAL.

“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).

“Precision” means the agreement of repeated observations made under the same conditions.

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

“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.

Historical Note

Adopted effective July 25, 1985 (Supp. 85-4). Former Section R3-1-201 renumbered without change as Section R3-5-101 (Supp. 89-1). Section R3-5-101 renumbered from R3-1-701 (Supp. 91-4). Amended by final rulemak-

ing at 5 A.A.R. 573, effective February 4, 1999 (Supp. 99-1). Amended by final rulemaking at 10 A.A.R. 3959, effective November 13, 2004 (Supp. 04-3).

R3-5-102. Certification; Renewal; Termination

A. Initial laboratory certification. A person who is seeking initial laboratory certification to provide an agricultural laboratory service, as prescribed in A.R.S. § 3-145, shall:

1. Provide the following information on an application form obtained from the Department:
 - a. Name, business and mailing address, telephone and fax numbers, and e-mail address of the laboratory;
 - b. Name, address, telephone number, e-mail address, and signature of the owner; and
 - c. Name, address, telephone number, e-mail address, and signature of the laboratory manager;
2. Provide a description of all programs, services, and functions performed at the laboratory;
3. On the application form, list the service that the certified laboratory will perform by commodity or sample-type, detailing the test procedure used, including specific references to any publication where the 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. A person shall provide written notification to the Assistant Director of any change to the information provided under subsection (A)(1) within 30 days after the change.

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

D. Certification renewal.

1. A 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 information required in subsection (A)(1).
2. An application received less than 30 days before the expiration date is untimely and the person shall reapply for an initial laboratory certification.
3. If an application is received more than 60 days before the expiration date of the current certification, the Department shall return the application to the person for resubmission.
4. The current certification 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.

E. Certification termination. A person may terminate a laboratory certification by notifying the Assistant Director in writing within 30 days before the effective date of the termination.

Historical Note

Adopted effective July 25, 1985 (Supp. 85-4). Former Section R3-1-202 renumbered without change as Section R3-5-102 (Supp. 89-1). Section R3-5-102 renumbered from R3-1-702 (Supp. 91-4). Amended by final rulemaking at 5 A.A.R. 573, effective February 4, 1999 (Supp. 99-1). Amended by final rulemaking at 10 A.A.R. 3959, effective November 13, 2004 (Supp. 04-3).

R3-5-103. Agricultural Laboratory Services

- A.** A person may apply for a laboratory certification to perform any 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 the content of processed meat or a meat food product including the percentage of a meat or non-meat ingredient;
 5. Verification of an analysis for the accuracy of the label guarantee of a feed, fertilizer, animal manure, plant growth stimulant, soil amendment, soil conditioner, or pesticide;
 6. Verification of planting seed germination percentages, purity analysis, or another named seed or plant propagative material testing procedure;
 7. Identification of insects, plant pathogens, animal pathogens, nematodes, noxious weeds, noxious weed seeds, or animal parasites;
 8. Testing of milk or milk product for quality and market standards;
 9. Determination of mycotoxin, antibiotic, or drug residue in plant or animal tissue;
 10. Determination of mycotoxin, antibiotic, or drug residue in a plant or animal product, animal feed, or feed ingredient;
 11. Determination of a specific pesticide, or hazardous or toxic element in plant or animal tissue;
 12. Determination of a specific pesticide or hazardous or toxic element in water used in livestock production, irrigation water, air, soil, agricultural product, or animal feed; or
 13. Collection of samples.
- B.** A person may seek laboratory certification for an agricultural laboratory service not listed in subsection (A) by complying with R3-5-102(A).

Historical Note

Adopted effective July 25, 1985 (Supp. 85-4). Former Section R3-1-203 renumbered without change as Section R3-5-103 (Supp. 89-1). Section R3-5-103 renumbered from R3-1-703 (Supp. 91-4). Amended by final rulemaking at 5 A.A.R. 573, effective February 4, 1999 (Supp. 99-1). Amended by final rulemaking at 10 A.A.R. 3959, effective November 13, 2004 (Supp. 04-3).

R3-5-104. Fees

- A.** A person shall pay the following fee to the Department before the SAL will review the application for laboratory certification to perform an agricultural laboratory service:
1. Initial fee, \$200 per certification; or
 2. Renewal fee, \$100 per certification.
- B.** Except as provided in A.R.S. § 41-1077, the applicable fee is nonrefundable.

Historical Note

Adopted effective July 25, 1985 (Supp. 85-4). Former Section R3-1-204 renumbered without change as Section R3-5-104 (Supp. 89-1). Section R3-5-104 renumbered from R3-1-704 (Supp. 91-4). Amended by final rulemaking at 5 A.A.R. 573, effective February 4, 1999 (Supp. 99-1). Amended by final rulemaking at 10 A.A.R. 3959, effective November 13, 2004 (Supp. 04-3).

R3-5-105. Laboratory Requirements

- A.** A person who has obtained laboratory certification under this Article shall maintain a master file for each certification. The person shall update the master file within 30 days of any change. The master file shall contain:
1. The most current letter of certification, stating the period of validity;
 2. A quality assurance manual as described in subsection (B);
 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. The name and resume of the individual assigned to each position identified in subsection (A)(3)(a);
 5. Documentation of training for each staff member who performs all or part of the agricultural laboratory service;
 6. Documentation of the laboratory's competence and experience in the applicable test procedure for the agricultural laboratory service;
 7. Reports of each sample result for the last 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. Type and manufacturer;
 - b. Serial and model number;
 - c. 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;
 11. Documentation of reference material, standards, and biological specimens as prescribed in subsection (B)(5); and
 12. All correspondence relating to the certification and operation of the program.
- B.** A person who has obtained laboratory certification shall maintain a quality assurance manual. The person 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 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. The education, skill, and experience required of an individual in a position included in the organizational chart prescribed in subsection (A)(3); and
 - d. A description of the method used to train each person in a position included in the organizational chart prescribed in subsection (A)(3);

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;
 4. A written standard operating procedure for each test as prescribed in R3-5-106. A standard operating procedure for a test shall contain, as applicable:
 - 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;
 5. Procedures for documenting applicable reference material, standards, and biological specimens that provide:
 - a. Traceability of each chemical standard of measurement to a primary standard;
 - b. Verified and traceable biological specimens; and
 - c. Origin and traceability of reference material;
 6. A description of an equipment maintenance program that includes:
 - a. Each manufacturer's recommendations for the setup and normal operation of each 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
 - c. Quality control procedures for determining equipment performance; and
 7. Procedures for quality control activity, including:
 - a. Monitoring temperature-controlled spaces;
 - b. Certifying that each thermometer, analytical balance, and biological hood meets federal or nationally-recognized standards, as applicable;
 - c. Calibrating glassware and volumetric equipment, as applicable; and
 - d. Validating the quality of reagents and laboratory consumable material, as applicable.
- C. A person who has obtained laboratory certification shall ensure the accurate calibration of testing equipment.
 - D. A person who has obtained laboratory certification shall maintain records required under this Article for five years, except pesticide residue sample results and data, which shall be maintained for seven years;
 - E. A person who has obtained laboratory certification shall maintain a facility and conduct operations in compliance with the standards established by the Occupational Safety and Health Administration and any other applicable federal, state, or local building, sanitary, safety, electrical, and fire code for the area in which the laboratory is located.
 - F. A person who has obtained laboratory certification shall dispose of hazardous waste cataloged in the Identification and Listing of Hazardous Waste, 40 CFR 261, July 1, 2003 edition, as prescribed in the Standards Applicable to Generators of Hazardous Waste, 40 CFR 262, July 1, 2003 edition. This material is incorporated by reference, does not include any later amendments or editions, and is on file with the Department.

Historical Note

Adopted effective July 25, 1985 (Supp. 85-4). Former Section R3-1-205 renumbered without change as Section R3-5-105 (Supp. 89-1). Section R3-5-105 renumbered from R3-1-705 (Supp. 91-4). Section repealed, new Section adopted by final rulemaking at 5 A.A.R. 573, effective February 4, 1999 (Supp. 99-1). Amended by final rulemaking at 10 A.A.R. 3959, effective November 13, 2004 (Supp. 04-3).

R3-5-106. Testing Procedures

A person complying with this Article shall:

1. Use testing procedures that are referenced in professional journals or manuals and obtain the Assistant Director's approval of the procedures, or
2. Use testing procedures established by the SAL.

Historical Note

Adopted effective July 25, 1985 (Supp. 85-4). Former Section R3-1-206 renumbered without change as Section R3-5-106 (Supp. 89-1). Section R3-5-106 renumbered from R3-1-706 (Supp. 91-4). Amended by final rulemaking at 5 A.A.R. 573, effective February 4, 1999 (Supp. 99-1). Amended by final rulemaking at 10 A.A.R. 3959, effective November 13, 2004 (Supp. 04-3).

R3-5-107. Proficiency Testing Program

- A. A person applying for laboratory certification shall participate in a PTP to demonstrate the ability of the laboratory to provide the agricultural laboratory service.
- B. 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.

- C. The Department shall evaluate each laboratory based on comparative results obtained for each PTP sample. If the Department discovers a deficiency, the person applying for laboratory certification shall submit a corrective action plan to the Assistant Director.

Historical Note

Adopted effective July 25, 1985 (Supp. 85-4). Former Section R3-1-207 renumbered without change as Section R3-5-107 (Supp. 89-1). Section R3-5-107 renumbered from R3-1-707 (Supp. 91-4). Amended by final rulemaking at 5 A.A.R. 573, effective February 4, 1999 (Supp. 99-1). Amended by final rulemaking at 10 A.A.R. 3959, effective November 13, 2004 (Supp. 04-3).

R3-5-108. Repealed

Historical Note

Adopted effective July 25, 1985 (Supp. 85-4). Former Section R3-1-208 renumbered without change as Section R3-5-108 (Supp. 89-1). Section R3-5-108 renumbered from R3-1-708 (Supp. 91-4). Section repealed by final rulemaking at 5 A.A.R. 573, effective February 4, 1999 (Supp. 99-1).

R3-5-109. Repealed

Historical Note

Adopted effective July 25, 1985 (Supp. 85-4). Former Section R3-1-209 renumbered without change as Section R3-5-109 (Supp. 89-1). Section R3-5-109 renumbered from R3-1-709 (Supp. 91-4). Section repealed by final rulemaking at 5 A.A.R. 573, effective February 4, 1999 (Supp. 99-1).

R3-5-110. Referee Laboratory

If the testing results from two certified laboratories differ or certified laboratory results are challenged by a person or state agency that is contracting for agricultural laboratory services, the Director may designate a laboratory to serve as a referee and assist in making a final determination. If the test results are challenged, the party who loses the dispute shall pay all costs incurred by the referee laboratory.

Historical Note

Adopted effective July 25, 1985 (Supp. 85-4). Former Section R3-1-210 renumbered without change as Section R3-5-110 (Supp. 89-1). Section R3-5-110 renumbered from R3-1-710 (Supp. 91-4). Amended by final rulemaking at 5 A.A.R. 573, effective February 4, 1999 (Supp. 99-1). Amended by final rulemaking at 10 A.A.R. 3959, effective November 13, 2004 (Supp. 04-3).

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 on-site review.

Historical Note

New Section made by final rulemaking at 10 A.A.R. 3959, effective November 13, 2004 (Supp. 04-3).

R3-5-112. Licensing Time-frames

- A. 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.

B. Administrative completeness review.

1. 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.
2. 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.
3. 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.
4. 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.

C. Substantive review. The substantive review time-frame established in Table 1 begins on the date that the application is administratively complete.

1. On-site survey.
 - a. Within 30 days after receipt of a complete application, the SAL shall schedule an on-site survey of an applicant's laboratory facilities.
 - b. The Assistant Director may waive the on-site survey for a renewal applicant if the renewal applicant is in compliance with the other provisions of this Article.
2. 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.
3. If laboratory certification is denied, the Department shall send the applicant written notice explaining:
 - a. The reason for the denial with citations to supporting statutes or rules;
 - b. The applicant's right to appeal the denial;
 - c. The period for appealing the denial; and
 - d. The name and telephone number of a Department contact person who can answer questions regarding the appeals process.

Historical Note

New Section made by final rulemaking at 10 A.A.R. 3959, effective November 13, 2004 (Supp. 04-3).

Table 1. Time-frames (Calendar Days)

Certification	Authority	Administrative Completeness Review	Completion Request Period	Substantive Completeness Review	Additional Information Period	Overall Time-frame
Laboratory Certification	A.R.S. § 3-145					
• Initial	R3-5-102	14	30	60	90	74
• Renewal		14	14	30	14	44
New service		104	90	60	30	164

Historical Note

Table 1 adopted by final rulemaking at 5 A.A.R. 573, effective February 4, 1999 (Supp. 99-1). Amended by final rulemaking at 10 A.A.R. 3959, effective November 13, 2004 (Supp. 04-3).