NOTICE OF PROPOSED EXPEDITED RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 9. DEPARTMENT OF HEALTH SERVICES

~~PROCUREMENT ORGANIZATIONS~~ HUMAN REMAINS

PREAMBLE

1. Permission to initiate this rulemaking was granted under A.R.S. § 41-1039(A) by the governor on:

October 19, 2023

2. Article, Part or Sections Affected (as applicable)	**Rulemaking Action**
Article 1	Repeal
R9-9-101	Repeal
R9-9-102	Repeal
R9-9-103	Repeal
R9-9-104	Repeal
R9-9-105	Repeal
R9-9-106	Repeal
R9-9-107	Repeal
R9-9-108	Repeal
Table 1.1	Repeal
Article 2	Repeal
R9-9-201	Repeal
R9-9-202	Repeal
R9-9-203	Repeal
R9-9-204	Repeal
R9-9-205	Repeal
Article 3	Repeal
R9-9-301	Repeal
R9-9-302	Repeal
R9-9-303	Repeal
R9-9-304	Repeal
R9-9-305	Repeal
Article 4	Repeal

R9-9-401	Repeal
R9-9-402	Repeal
R9-9-403	Repeal
Subchapter 9A	New Subchapter
Article 1	New Article
R9-9A-101	New Section
R9-9A-102	New Section
R9-9A-103	New Section
R9-9A-104	New Section
R9-9A-105	New Section
R9-9A-106	New Section
R9-9A-107	New Section
R9-9A-108	New Section
R9-9A-109	New Section
Table 1.1	New Section
Article 2	New Article
R9-9A-201	New Section
R9-9A-202	New Section
R9-9A-203	New Section
Article 3	New Article
R9-9A-301	New Section
R9-9A-302	New Section
R9-9A-303	New Section
Subchapter 9B	New Subchapter

3. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):

Authorizing statutes: A.R.S. §§ 36-132(A) and 36-136(G)

Implementing statutes: A.R.S. §§ 36-851.01, 36-851.02, and 36-581.03

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

Notice of Rulemaking Docket Opening: 29 A.A.R. 3639, November 24, 2023

5. The agency's contact person who can answer questions about the rulemaking:

Name: Megan McMinn, Bureau Chief

Address: Arizona Department of Health Services

Bureau of Special Licensing
150 N. 18th Ave., Suite 410
Phoenix, AZ 85007
Telephone: (602) 364-3052
E-mail: megan.mcminn@azdhs.govor
or
Name: Stacie Gravito, Office Chief
Address: Arizona Department of Health Services
Office of Administrative Counsel and Rules
150 N. 18th Ave., Suite 200
Phoenix, AZ 85007
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6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

Laws 2023, Ch. 194, amended Arizona Revised Statutes (A.R.S.) § 32-1307(A)(4), which transferred the authority, powers, duties, and responsibilities of the State Board of Funeral Directors and Embalmers for regulating funeral establishments, crematories, funeral directors, and embalmers to the Arizona Department of Health Services ("Department"). The Board of Funeral Directors and Embalmers had established rules to comply with statutory requirements in Arizona Administrative Code (A.A.C.) Title 4, Chapter 12. The Department had adopted rules for procurement organizations, pursuant to A.R.S. § 36-851.01, in A.A.C. Title 9, Chapter 9. After receiving rulemaking approval pursuant to A.R.S. § 41-1039(A), the Department will be moving and amending the rules currently in 4 A.A.C. 12 into 9 A.A.C. 9, consistent with the statutory changes made by Laws 2023, Ch. 194. In addition, the Department plans to incorporate requirements for transportation protection agreements that are related to preparing human remains or cremated remains, according to requirements added by Laws 2023, Ch. 95. As part of this rulemaking, existing requirements for procurement organizations in 9 A.A.C. 9 are being consolidated, clarified, and reorganized. However, the substantive content of the rules will remain the same, except for some minor changes being made at the request of regulated persons to reduce the regulatory burden. To ensure that the rules for procurement organizations and for the funeral industry remain distinct, so as to avoid confusion on the part of regulated persons, the Department is splitting 9 A.A.C. 9 into two Subchapters, with 9 A.A.C. 9A being used for the

revised rules for procurement organizations, and 9 A.A.C. 9B being used for the rules governing the funeral industry. In this first phase of the rulemaking, the current rules in 9 A.A.C 9 are being repealed, new Subchapters 9A and 9B are being adopted, and revised rules for procurement organizations are being adopted in Subchapter 9A. The Department believes that these changes are consistent with the purpose for A.R.S. § 41-1027 in that this portion of the rulemaking does not increase the cost of regulatory compliance, increase a fee, or reduce a procedural right of regulated persons; but reduces or consolidates procedures or processes, amends rules that are outdated, and clarifies language of rules without changing their effects, while protecting health and safety.

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

The Department did not review or rely on any study for this rulemaking.

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

Not applicable

9. A statement that the agency is exempt from the requirements under A.R.S. § 41-1055(G) to obtain and file a preliminary summary of the economic, small business, and consumer impact under A.R.S. § 41-1055(D)(2):

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

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

Close of record: Monday, July 15, 2024, 4:00 p.m.

A person may submit written comments on the proposed expedited rules no later than the close of record to either of the individuals listed in item 5.

11. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

According to A.R.S. § 36-851.01, the Department is required to grant a procurement organization license to a person if the procurement organization is accredited by a nationally recognized accrediting agency approved by the Department or meets the requirements prescribed in rules adopted by the Department. A license is issued to a specific person at a specific location, so a general permit is not applicable, under A.R.S. § 41-1037(A)(2).

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

No federal law is applicable to the subject of the rule.

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

No business competitiveness analysis was received by the Department.

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

Not applicable

13. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 9. DEPARTMENT OF HEALTH SERVICES

~~PROCUREMENT ORGANIZATIONS~~ HUMAN REMAINS

ARTICLE 1. ~~PROCUREMENT ORGANIZATION LICENSURE~~ REPEALED

Section

ARTICLE 2. ~~ADMINISTRATION FOR A NON-ACCREDITED PROCUREMENT ORGANIZATION~~ REPEALED

Section

ARTICLE 3. ~~PHYSICAL PLANT; TRANSPORTATION FOR A NON-ACCREDITED PROCUREMENT ORGANIZATION~~ REPEALED

Section

ARTICLE 4. ~~ADMINISTRATION FOR AN ACCREDITED PROCUREMENT ORGANIZATION~~ REPEALED

Section

SUBCHAPTER 9A. PROCUREMENT ORGANIZATIONS

ARTICLE 1. PROCUREMENT ORGANIZATION LICENSURE

ARTICLE 2. ADMINISTRATION AND OPERATIONS FOR A PROCUREMENT ORGANIZATION

ARTICLE 3. ENVIRONMENTAL AND PHYSICAL PLANT STANDARDS FOR A NON-ACCREDITED PROCUREMENT ORGANIZATION

SUBCHAPTER 9B. RESERVED

ARTICLE 1. ~~PROCUREMENT ORGANIZATION LICENSURE~~ REPEALED

R9-9-101. ~~Definitions~~ Repealed

~~In addition to the definitions in A.R.S. § 36-841, the following apply in this Chapter unless otherwise specified:~~

1. ~~"Acceptability assessment" means the evaluation of available, if applicable, medical information about a donor to determine whether the donor meets qualifications as established by SOPs specified in R9-9-201(E)(4).~~
2. ~~"Accrediting body" means a nationally recognized agency, approved by the Department, that provides certification for a person operating a procurement organization.~~
3. ~~"Acquisition" means activities required to obtain a NTAD that is intended for use in education or research.~~
4. ~~"Administrative completeness review time-frame" has the same meaning as in A.R.S. § 41-1072.~~
5. ~~"Administrator" means the individual responsible for the services and activities provided by a procurement organization.~~
6. ~~"Applicant" means an individual or business organization requesting approval to operate a procurement organization.~~
7. ~~"Application packet" means the information, documents, and fees required by the Department for licensure of a procurement organization.~~
8. ~~"Authorization" means permission given for NTAD acquisition by a donor or individual authorized by law.~~
9. ~~"Business organization" means the same as "entity" in A.R.S. § 10-140.~~
10. ~~"Calendar day" means each day, not including the day of the act, event, or default from which a designated period of time begins to run, but including the last day of the period unless it is a Saturday, Sunday, statewide furlough day, or legal holiday, in which case the period runs until the end of the next day that is not a Saturday, Sunday, statewide furlough day, or legal holiday.~~
11. ~~"Controlling person" means an individual who, with respect to a business organization:~~
    a. ~~Has the power to vote at least 10% of the outstanding voting securities of the business organization;~~
    b. ~~If the business organization is a partnership, is a general partner or is a limited partner who holds at least 10% of the voting rights of the partnership;~~
    c. ~~If the business organization is a corporation, association, or limited liability company, is the president, the chief executive officer, the incorporator, an agent,~~

~~or any individual who owns or controls at least 10% of the voting securities; or~~

~~d. Holds a beneficial interest in 10% or more of the liabilities of the business organization.~~

~~12. "Contracted services" means functions pertaining to the acquisition, screening, testing, preparing, storage, and distribution of NAM that another establishment agrees to perform.~~

~~13. "Department" means the Arizona Department of Health Services.~~

~~14. "Distribution" means a process that includes selection and evaluation of intended use of NAM for release to another procurement organization, an education facility, or a research facility.~~

~~15. "Donor consent form" means the same as "document of gift" defined A.R.S. § 36-841.~~

~~16. "Environmental services" means activities such as housekeeping, laundry, facility maintenance, or equipment maintenance.~~

~~17. "Exceptional release" means NAM that is approved for usage before a donor acceptability assessment or by a researcher requesting NAM that would not normally meet the established acceptability criteria.~~

~~18. "Final disposition" means the disposal of NAM through incineration, cremation, bio-cremation, burial, fully depleted by virtue of a particular use, or by another legal means.~~

~~19. "Licensee" means a person to whom the Department has issued a license to operate a non-transplant procurement organization or person designated by the licensee.~~

~~20. "Medical director" means a physician licensed in this state pursuant to A.R.S. Title 32, Chapter 13 or 17 who provides medical guidance for a licensed procurement organization according to A.R.S. § 36-851.03 or person designated by the medical director.~~

~~21. "Misuse" means to use NTAD and NAM for purposes other than for:~~

~~a. Education or research, and~~

~~b. Uses specified on a donor consent form.~~

~~22. "Modification" means the substantial improvement, enlargement, reduction, alternation, or other substantial change in the facility or another structure on the premises at a procurement organization.~~

~~23. "Non-transplant anatomical donation" or "NTAD" means a donation of a whole body, organs or tissues authorized and used for education and research prior to release to distribution inventory.~~

~~24. "Non-transplant anatomical material" or "NAM" means a whole body or parts of a body donated for use in education or research that has been prepared, packaged, labeled, and released to distribution inventory.~~

25. ~~"Overall time-frame" means the same as in A.R.S. § 41-1072.~~

26. ~~"Person" means the same as in A.R.S. § 36-841.~~

27. ~~"Personnel member" means individuals identified as employees, students, or volunteer who provides services and activities for a procurement organization.~~

28. ~~"Pest control" means activities that minimize the presence of insects and vermin in a procurement organization to ensure the quality of NTAD and NAM and the health and safety of persons occupying or visiting.~~

29. ~~"Physical assessment" means a postmortem documented evaluation of a deceased donor's body that may identify evidence of: high-risk behaviors, signs of HIV infection or hepatitis infection, other viral or bacterial infections, and trauma.~~

30. ~~"Premises" mean a facility and surrounding grounds that are:~~

    a. ~~Designated by an applicant or a licensee;~~

    b. ~~Used for providing procurement organization services and activities; and~~

    c. ~~Licensed by the Department as a procurement organization.~~

31. ~~"Preparation" means any activity performed other than donor screening, donor testing, acquisition, storage, distribution, or dispensing functions to enable the use of NAM for education or research. It includes, but is not limited to, cleaning, preservation, disarticulation, dissection, skeletonization, plastination, packaging, and labeling of NAM.~~

32. ~~"Procurement organization" means the same as "non-transplant anatomical donation organization" as defined in A.R.S. § 36-841 and may be either accredited by an accrediting body or non-accredited.~~

33. ~~"Quality management program" means ongoing activities designed and implemented by a procurement organization to improve the delivery of services and activities related to NAM.~~

34. ~~"Quarantine" means the identification of NTAD or NAM as not acceptable or yet to be determined as eligible for use in education or research, including NTAD or NAM whose suitability has not been determined.~~

35. ~~"Release" means NAM approved by a procurement organization in accordance with criteria established by the medical director for transfer to an approved education and research facility.~~

36. ~~"Risk assessment" means collecting and evaluating relevant medical history and social behavior obtained from an individual or individuals who have knowledge about the donor.~~

37. ~~"Standard operating policies and procedures" or "SOPs" means a group of documents~~

~~detailing the specific purposes and services provided by a licensed procurement organization including activities and methods by staff and personnel members in support of conducting business operations.~~

38. ~~"Storage" means a designated area that contains equipment, instruments, and supplies to maintain NTAD or NAM until distribution or final disposition.~~

39. ~~"Substantive review time-frame" means the same as in A.R.S. § 41-1072.~~

40. ~~"Traceability" means the method to locate NTAD and NAM during any step of NTAD including obtaining authorization, acquisition, transport, assessing donor acceptability, preparation, packaging, labeling, storage, release, evaluation intended use, distribution, and final disposition.~~

41. ~~"Transfer" means the conveyance or relocation of NAM to:~~

~~a. An education facility,~~

~~b. A research facility,~~

~~c. Another procurement organization, or~~

~~d. A distribution inventory.~~

42. ~~"Transport" means a method for relocating NAM from one place to another in a manner that provides conditions necessary to maintain the quality of the NAM for its intended use.~~

43. ~~"Universal precautions" means the same as in A.R.S. § 32-1301.~~

44. ~~"Working day" means a Monday, Tuesday, Wednesday, Thursday, or Friday that is not a state and federal holiday or a statewide furlough day.~~

R9-9-102. ~~Licensure Requirements; Accreditation; Exemptions~~ Repealed

~~A.~~ ~~A person may not act as a procurement organization in this state unless the person is licensed by the Department as a procurement organization.~~

~~B.~~ ~~A procurement organization shall provide a designated area for tissue recovery that does not operate in a funeral establishment specified in A.R.S. § 32-1301, for the recovery of whole bodies for medical research and education according to A.R.S. §§ 36-851.02(3) and 36-851.03(A)(5)(b).~~

~~C.~~ ~~A non-accredited procurement organization is subject to inspection by the Department at any time to evaluate compliance with A.R.S. Title 36, Chapter 7, Article 3 and this Chapter according to A.R.S. § 36-851.03(A)(5)(a) and (C).~~

~~D.~~ ~~An accredited procurement organization is subject to inspection by the Department at any time to evaluate compliance with requirements in A.R.S. § 36-851.02(2) and the rules adopted pursuant to A.R.S. § 36-851.02(2).~~

~~E.~~ ~~An accredited procurement organization whose certificate of accreditation has expired or is~~

revoked, suspended, or denied by the accrediting body, shall provide written notification to the Department within ten working days of expiration or receipt of a revocation, suspension, or denial.

F. This Chapter does not apply to a procurement organization identified in A.R.S. § 36-851.01(F).

R9-9-103. Individuals to Act for an Applicant or Licensee Repealed

When an applicant or licensee is required by this Chapter to provide information on or sign an application form or other document, the following shall satisfy the requirement on behalf of the applicant or licensee:

1. If the applicant or licensee is an individual, the individual; and
2. If the applicant or licensee is a business organization, the individual who the business organization has designated to act on the business organization's behalf for purposes of this Chapter and who:
   a. Is a controlling person of the business organization,
   b. Is a U.S. citizen or legal resident, and
   c. Has an Arizona address.

R9-9-104. Application for Licensure Repealed

A. An applicant applying for a procurement organization license shall submit an application packet that contains:

1. An application, in a Department-provided format, according to A.R.S. § 36-851.01(A) that includes:
   a. The applicant's name, mailing address, email address, and telephone number;
   b. The name or proposed name of the procurement organization, including the:
      i. Business street address;
      ii. Business mailing address, if different from the street address;
      iii. Telephone number;
      iv. Email address; and
      v. Tax ID number;
   c. If part of a business institution, the institution's:
      i. Name;
      ii. Street address;
      iii. Mailing address, if different from the street address;
      iv. Telephone number; and
      v. Email address;
   d. Whether the procurement organization is ready for a licensing inspection by the Department, if applicable;

e. If the procurement organization is not ready for a licensing inspection specified in subsection (A)(1)(d), the date the Department may perform a licensing inspection, if applicable;

f. The name and contact information of an individual acting on behalf of the applicant specified in R9-9-103, if applicable;

g. If applicable, the medical director's:

i. Name,

ii Telephone number,

iii. Email address, and

iv. License number;

h. Whether the applicant complies with local zoning ordinances, building codes, and fire codes;

i. Whether the applicant agrees to allow the department to submit supplemental requests for information under R9-9-108; and

j. The applicant's signature and the date signed;

2. A copy of the procurement organization's current certificate of accreditation from an accrediting body, if applicable;

3. Documentation for the applicant that complies with A.R.S. § 41-1080;

4. A copy of the procurement organization labeled floor plan, including technical and administrative function areas, if applicable; and

5. A licensing fee of $2,000.

B. Upon receipt of the application packet in subsection (A), the Department shall conduct an inspection of the procurement organization, if applicable.

C. The Department shall issue or deny a license to an applicant as specified in R9-9-108.

R9-9-105. ~~Application for License Renewal~~ Repealed

A. A license is valid for two years from the date of issuance or renewal as specified in A.R.S. § 36-851.01(C).

B. At least 30 calendar days before the expiration date indicated on a procurement organization's license to operate a licensee shall submit to the Department an application packet for renewal of the license that contains:

1. An application, in a Department-provided format, that includes:

a. The applicant's name, mailing address, email address, and telephone number;

b. The procurement organization's licensing number; and

c. Whether the applicant agrees to allow the Department to submit supplemental

~~requests for information under R9-9-108;~~

~~2. If applicable, documentation of the most recent certificate of accreditation from an accrediting body; and~~

~~3. A licensing renewal fee of $2,000.~~

~~**C.** The Department shall renew or deny renewal of a license to operate as specified in R9-9-108.~~

R9-9-106. ~~Changes Affecting a License~~ Repealed

~~**A.** A licensee shall notify the Department in writing at least 30 calendar days before the effective date of:~~

~~1. Termination of operation, including:~~

~~a. The proposed termination date; and~~

~~b. The address and contact information for the location where the procurement organization records will be retained as required in R9-9-205;~~

~~2. A proposed modification, if applicable;~~

~~3. A change in the legal name of a procurement organization;~~

~~4. A change in the legal name of a licensee including the licensee's new name; and~~

~~5. A change in the address of a procurement organization, including the new address.~~

~~**B.** A licensee shall notify the Department in writing at least 30 calendar days after the effective date of a change in:~~

~~1. The email address or mailing address of a procurement organization including the new email address or mailing address;~~

~~2. The email address or telephone number of a licensee, including the new email address or telephone number;~~

~~3. An administrator, including the name, telephone number, and email address;~~

~~4. A medical director, including the name and email address; and~~

~~5. The name, telephone number, and email address of an individual acting on behalf of the licensee specified in R9-9-103.~~

~~**C.** If the Department receives the notification of termination of operation in subsection (A)(1), the Department shall void the licensee's license to operate a procurement organization as of the termination date specified by the licensee.~~

~~**D.** If the Department receives a notification in subsection (A)(2) of a proposed modification, the Department:~~

~~1. May conduct an inspection of the premises as allowed by A.R.S. § 36-851.03(C); and~~

~~2. Shall issue to the licensee an amended license that incorporates the modification and retains the expiration date of the existing license, if the procurement organization is~~

~~compliant with A.R.S. Title 36, Chapter 7, Article 3 and this Chapter.~~

~~**E.** If the Department receives a notification in subsection (A)(3) of a legal name change for a procurement organization, the Department shall issue to the licensee an amended license showing the licensee's legal name.~~

~~**F.** If the Department receives notice for a change in the legal name of a licensee in subsection (A)(4), the Department shall void licensee's license to operate upon issuance of a new license to operate.~~

~~**G.** If the Department receives the notice for a change in the address of a procurement organization in subsection (A)(5), the Department shall review the application for a new license, submitted consistent with R9-9-104.~~

~~**H.** An individual or business organization planning to take ownership of an existing procurement organization shall obtain a new license before beginning operation.~~

R9-9-107. ~~Denial, Suspension, Revocation, Enforcement~~ Repealed

~~**A.** The Department may:~~

~~1. Deny a license as specified in subsection (B);~~

~~2. Suspend or revoke a license under A.R.S. § 36-851.01(E) and subsection (B); or~~

~~3. Assess or impose a civil penalty under A.R.S. § 36-851.01(E) and subsection (B).~~

~~**B.** The Department may impose civil penalties, deny an application or suspend or revoke a license to operate a procurement organization, if:~~

~~1. An applicant or licensee does not meet the application requirements contained in R9-9-104 and R9-9-105, as applicable;~~

~~2. A licensee does not comply with requirements in A.R.S. §§ 36-851.01 through 36-851.03 and this Chapter, if applicable;~~

~~3. A licensee does not correct the deficiencies identified during an inspection according to the plan of correction;~~

~~4. An applicant or licensee provides false or misleading information to the Department; or~~

~~5. The nature or number of violations revealed by any type of inspection or investigation of a procurement organization poses a direct risk to the life, health, or safety of individuals on the premises.~~

~~**C.** In determining which action in subsection (A) is appropriate, the Department shall consider:~~

~~1. Repeated violations of statutes or rules,~~

~~2. Pattern of violations,~~

~~3. Severity of violations, and~~

~~4. Number of violations.~~

~~**D.** The Department may suspend or revoke an accredited procurement organization's license if the Department receives notice that the accredited procurement organization's accreditation has expired or has been suspended or revoked by the accrediting body.~~

~~**E.** An applicant or licensee may appeal the Department's determination in this Section according to A.R.S. Title 41, Chapter 6, Article 10.~~

R9-9-108. ~~Time-frames~~ Repealed

~~**A.** The overall time-frame for a license granted by the Department under this Chapter is set forth in Table 1.1. The applicant or licensee and the Department may agree in writing to extend the substantive review time-frame and the overall time-frame. An extension of the substantive review time-frame and the overall time-frame may not exceed 25% of the overall time-frame.~~

~~**B.** The administrative completeness review time-frame for a license granted by the Department under this Chapter is set forth in Table 1.1 and begins on the date that the Department receives an application packet:~~

~~1. The Department shall send a notice of administrative completeness or deficiencies to the applicant or licensee within the administrative completeness review time-frame:~~

~~a. A notice of deficiencies shall list each deficiency and the information or items needed to complete the application;~~

~~b. The administrative completeness review time-frame and the overall time-frame are suspended from the date that the notice of deficiencies is sent until the date that the Department receives all of the missing information or items from the applicant or licensee;~~

~~c. If an applicant or licensee fails to submit to the Department all of the information or items listed in the notice of deficiencies within 120 calendar days after the date that the Department sent the notice of deficiencies or within a time period the applicant or licensee and the Department agree upon in writing, the Department shall consider the application withdrawn; and~~

~~2. If the Department issues a license during the administrative completeness review time-frame, the Department shall not issue a separate written notice of administrative completeness.~~

~~**C.** The substantive review time-frame is set forth in Table 1.1 and begins on the date of the notice of administrative completeness:~~

~~1. As part of the substantive review of an application for a license, the Department may conduct an inspection according to A.R.S. § 36-851.03(C) that may require more than one visit to complete.~~

2. The Department shall send a license or a written notice of denial of a license within the substantive review time-frame.

3. During the substantive review time-frame, the Department may make one comprehensive written request for additional information, unless the applicant or licensee has agreed in writing to allow the Department to submit supplemental requests for information:

   a. The Department shall send a comprehensive written request for additional information that includes a written statement of deficiencies, stating each statute and rule upon which noncompliance is based, if the Department determines that an applicant or licensee, and the procurement organization, including the premises are not in substantial compliance with A.R.S. Title 36, Chapter 7, Article 3 or this Chapter;

   b. An applicant or licensee shall submit to the Department all of the information requested in a comprehensive written request for additional information or a supplemental request for information, including, if applicable, documentation of the corrections required in a statement of deficiencies, within 30 calendar days after the date of the comprehensive written request for additional information or the supplemental request for information or within a time period the applicant or licensee and the Department agree upon in writing;

   c. The substantive review time-frame and the overall time-frame are suspended from the date that the Department sends a comprehensive written request for additional information or a supplemental request for information until the date that the Department receives all of the information requested, including, if applicable, documentation of corrections required in a statement of deficiencies; and

   d. If an applicant or licensee fails to submit to the Department all of the information requested in a comprehensive written request for additional information or a supplemental request for information, including, if applicable, documentation of corrections required in a statement of deficiencies, within the time prescribed in subsection (C)(3)(b), the Department shall deny the application.

4. The Department shall issue a license if the Department determines that the applicant or licensee and the procurement organization, including the premises, are in substantial compliance with A.R.S. Title 36, Chapter 7, Article 3 and this Chapter.

5. If the Department denies a license, the Department shall send to the applicant or licensee a written notice of denial setting forth the reasons for denial and all other information

~~required by A.R.S. §§ 41-1076 and 41-1092.03.~~

Table 1.1. ~~**Time-frames (in calendar days)**~~ **Repealed**

~~**Type of Approval**~~	~~**Statutory Authority**~~	~~**Overall Time-Frame**~~	~~**Administrative Completeness Review Time-Frame**~~	~~**Substantive Review Time-Frame**~~
~~Application for Licensure~~	~~A.R.S. § 36-851.01~~	~~90~~	~~30~~	~~60~~
~~Application for License Renewal~~	~~A.R.S. § 36-851.01~~	~~30~~	~~10~~	~~20~~
~~Modification Change Request Affecting License~~	~~A.R.S. § 36-851.01~~	~~60~~	~~30~~	~~30~~

ARTICLE 2. ~~ADMINISTRATION FOR A NON-ACCREDITED PROCUREMENT ORGANIZATION~~ REPEALED

R9-9-201. ~~Administration~~ Repealed

~~**A.** A licensee for a non-accredited procurement organization:~~

~~1. Is responsible for all issues of liability, ethical considerations, fiduciary issues, and compliance with applicable laws and regulations;~~

~~a. SOPs for all activities and services the procurement organization provides;~~

~~b. The qualifications for an administrator:~~

~~i. Who has at least a bachelor's degree in a health science or other science-related field, and~~

~~ii. Is responsible for all services and activities at a procurement organization; and~~

~~c. The qualifications for a medical director:~~

~~i. Who is licensed pursuant to A.R.S. Title 32, Chapter 13 or 17; and~~

~~ii. Provides medical guidance to determine donor eligibility;~~

~~2. Shall adopt a quality management program; and~~

~~3. Shall review and evaluate the effectiveness of the quality management program in R9-9-202 at least once every 12 months.~~

~~**B.** An administrator of a non-accredited procurement organization:~~

~~1. Is directly accountable to the licensee for the operation, including all services and activities, provided by or at the procurement organization;~~

~~2. Has the authority and responsibility to manage the procurement organization as specified in SOPs;~~

~~3. Designates, in writing, an individual who is on the procurement organization's premises and is available when the administrator is not present on the premises.~~

~~**C.** A medical director of a non-accredited procurement organization:~~

~~1. Shall provide medical guidance to determine and establish donor eligibility as established in R9-9-204; and~~

~~2. May be the same individual as the administrator, if the individual's qualifications include management for all services and activities provided at a procurement organization.~~

~~**D.** A licensee of a non-accredited procurement organization shall ensure that the following programs at the procurement organization are established and maintained in compliance with state and federal laws and regulations:~~

~~1. A safety awareness and blood-borne pathogen training program; and~~

2. A cleaning program that mitigates potential cross-contamination between NTAD.

E. A licensee of a non-accredited procurement organization shall ensure that:

1. The procurement organization complies with vital records requirements in A.R.S. § 36-325;
2. An identification system according to A.R.S. § 36-851.03(A)(3)(b) for donors:
   a. Is established and maintained, and
   b. Assigns a unique identification number according to A.R.S. § 36-851.03(A)(6)(a);
      i. For each donor, and
      ii. Used to identify all NAM from a donor that is recovered and distributed;
3. SOPs are established, documented, and implemented that includes:
   a. Job descriptions, duties, and qualifications, including required skills, knowledge, education, and experience for technicians and personnel members;
   b. Orientation and in-service education for technicians and personnel members;
   c. How a technician may submit a complaint related to services provided;
   d. Donor records, including electronic records;
   e. A quality management program, including incident reports;
   f. Ethical practices;
   g. An infectious control program;
   h. Security, including evacuation procedures in the event of fire or disaster;
   i. NTAD and NAM inventory controls; and
   j. Contracted services;
4. SOPs for all services and activities are established, documented, and implemented for:
   a. The proper use and maintenance of a donor consent form according to A.R.S. § 36-851.03(A)(3)(a);
   b. Protocols and materials used to screen end-users prior to release and transfer of NAM according to A.R.S. § 36-851.03(A)(3)(c);
   c. Donor screening and testing plan, including:
      i. Acceptability assessment,
      ii. Donor risk assessment,
      iii. Medical records review,
      iv. Donor eligibility, and
      v. Infectious disease testing;
   d. Acquisition of NTAD;

i. Donor verification;

ii. Donor identity;

iii. Acquisition records;

iv. Packaging, including packaging insert form that discloses disease status of tissue to the end-user;

v. Labeling;

vi. Transport; and

vii. Storage;

e. Preparation methods, including:

i. Receipt of NAM;

ii. Prevent airborne transmission, and

iii. Quarantine and storage, if applicable;

f. Release and transfer, including:

i. End-user eligibility review;

ii. Quality control review;

iii. Release of NAM;

iv. Exceptional release;

v. Failing review process; and

vi. Transfer to distribution for use, including out-of-state and international shipping;

g. Final disposition of donation according to A.R.S. § 36-851.03(A)(3)(f) and consistent with:

i. Board of Funeral Directors and Embalmers specified in 4 A.A.C. 12, Articles 3, 5, and 6;

ii. Vital Records and Public Health Statistics specified in A.R.S. Title 36, Chapter 3;

iii. Vital Records and Statistics specified in 9 A.A.C. 19;

iv. Health menaces specified in A.R.S. Title 36, Chapter 6, Article 1;

v. Disposition of Human Bodies specified in A.R.S. Title 36, Chapter 7; and

vi. Communicable Diseases and Infestations specified in 9 A.A.C. 6;

5. SOPs that all NTAD acquired by the procurement organization shall bear a label that:

a. Is written, printed, or graphic material used to identify NTAD/NAM, blood specimens, or other donor specimens; and

b. States according to A.R.S. § 36-851.03(A)(6)(b):

i. The NTAD or NAM is not for transplant or clinical use;

ii. Any condition and any limitation regarding the use of the NTAD or NAM;

iii. That universal precautions shall be used; and

iv. The contact information for the procurement organization;

6. SOPs are:

a. Maintained at the procurement organization and copies available to the Department for review upon request;

b. Reviewed at least once every three years and updated as needed; and

c. Available to technicians and personnel members; and

7. A loss or theft of NTAD or NAM is documented and reported to the appropriate law enforcement agency within 24 hours of discovery.

F. An administrator of a non-accredited procurement organization shall immediately report suspected misuse of NTAD or NAM.

G. An administrator of a non-accredited procurement organization shall ensure that a report specified in subsection (F) is documented and maintained in the donor's record as specified in R9-9-205(E).

H. A licensee of a non-accredited procurement organization shall ensure that the following information or documents are conspicuously posted on the premises:

1. The procurement organization's current license,

2. The name of the administrator and medical director,

3. The hours of operation, and

4. The evacuation plan listed in R9-9-302.

R9-9-202. ~~Quality Management~~ Repealed

A licensee of a non-accredited procurement organization shall ensure that:

1. A plan is established, documented, and implemented for an ongoing quality management program that, at a minimum, includes:

a. A method to identify, document, and evaluate incidents;

b. A method to collect data to evaluate procurement organization services provided;

c. A method to evaluate the data collected to identify a concern about the delivery of procurement organization services;

d. A method to make changes or take action as a result of the identification of a concern about the delivery of procurement organization services; and

e. The frequency of submitting a documented report required in subsection (2) to the licensee.

2. A documented report is submitted to the licensee that includes:

a. An identification of each concern about the delivery of procurement organization services; and

b. Any changes made or actions taken as a result of the identification of a concern about the delivery of procurement organization services.

3. The report required in subsection (2) and the supporting documentation for the report is maintained for 12 months by the procurement organization after the date the report is submitted to the licensee.

R9-9-203. ~~Contracted Services~~ Repealed

A licensee of a non-accredited procurement organization shall ensure that:

1. Contracted services are documented by agreement specified in SOPs.

2. If a procurement organization contracts with a laboratory for infectious disease testing of NAM, the contracted laboratory is registered with the Food and Drug Administration as a tissue establishment, specified in 21 C.F.R. § 1271.3, for testing and is either:

a. Certified to perform such testing on human specimens in accordance with Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. § 263a) and 42 C.F.R. Part 493; or

b. Meets equivalent requirements as determined by the Centers for Medicare and Medicaid Services.

3. A list of contracted service providers is maintained and includes a description of the specific services provided.

R9-9-204. ~~Medical Director, Administrator, Technicians, and Personnel Members~~ Repealed

A. A licensee of a non-accredited procurement organization shall ensure that the medical director:

1. Establishes, reviews, and approves all SOPs of a medical nature, including:

a. Donor eligibility related to:

i. Screenings,

ii. Testing plans,

iii. Acceptability assessment;

b. Sampling plan and methods verifying NTAD release;

c. Exceptional release criteria and processes of NAM; and

d. Pre-established release criteria;

2. Reviews all SOPs of a medical nature at least every three years;

3. Approves a designee having training and education for performing tasks and functions assigned by the medical director;

4. Has oversight and performs review of designee activities according to procedures established by the licensee;

5. Makes a determination regarding the eligibility criteria of each donor based on a comparison with predetermined donor criteria;

6. Prior to release for use or distribution, signs the donor eligibility statement and NAM disposition or release statement; and

7. Establish a criteria that ensures all appropriate parties are notified of confirmed positive infectious disease test results.

B. A licensee of a non-accredited procurement organization shall ensure that the administrator:

1. Has at least three years of experience in tissue banking or other related fields;

2. Shall define NTAD or NAM activities that a technician may provide;

3. Shall define the methods used to provide clinical oversight and training including when clinical oversight and training is provided to an individual or a group; and

4. Shall ensure a technician's personnel record includes:

a. Documentation of all completed training and education; and

b. A written job description, including all primary duties.

C. A licensee of a non-accredited procurement organization shall ensure that a technician:

1. Has the educational background, experience, and training sufficient to assure assigned tasks will be performed in accordance with the established SOPs;

2. Provides a copy of a transcript or diploma in health science or other field of science for which the technician received a degree or certificate, if applicable;

3. Demonstrates competency to perform assigned tasks; and

4. Has duties required by the technician described in a written job description.

D. A licensee of a non-accredited procurement organization shall ensure that:

1. The qualifications, skill, and knowledge required for each type of technician and personnel member is based on the activities and services a personnel member may provide as established in the personnel job description; and

2. A personnel member's qualifications, skills, and knowledge are verified and documented:

a. Before the personnel member provides procurement organization services and

b. According to SOPs.

E. A licensee of a non-accredited procurement organization shall ensure that a personnel member does not have direct interaction with NTAD and NAM unless specifically authorized by the

~~licensee or administrator.~~

~~**F.** A licensee of a non-accredited procurement organization shall ensure a personnel record is established for the administrator, technicians, and personnel members that includes:~~

~~1. The individual's name, date of birth, home address, and contact telephone number;~~

~~2. The individual's starting date of employment or volunteer service and, if applicable, the ending date; and~~

~~3. Documentation applicable to an individual's duties, as required by SOPs, including the individual's:~~

~~a. Education and experience;~~

~~b. In service education and continuing education, if applicable; and~~

~~c. Evidence of Hepatitis B vaccination or refusal of Hepatitis B vaccine for individuals whose job-related responsibilities involve the potential exposure to blood-borne pathogens, if applicable.~~

~~**G.** A licensee of a non-accredited procurement organization shall ensure that a personnel record is:~~

~~1. Maintained throughout an individual's period of employment or volunteer service in or for the procurement organization;~~

~~2. Maintained for at least three years after the last date that an individual's employment or volunteer service in or for the procurement organization; and~~

~~3. Provided to the Department when requested.~~

R9-9-205. ~~Donor Records~~ Repealed

~~**A.** A non-accredited procurement organization shall maintain a legible, reproducible record for each donor from whom it obtains NAM for at least 10 years beyond the date of final disposition according to A.R.S. § 36-851.03(A)(7).~~

~~**B.** To ensure traceability of NTAD and NAM, a non-accredited procurement organization shall:~~

~~1. Document each procedure performed on a NTAD and NAM related to processing and storing NAM;~~

~~2. For each document created in subsection (B)(1), include:~~

~~a. The date and time for each procedure completed; and~~

~~b. The name of the technician who performed the procedure; and~~

~~3. Submit information required to register the death of a NTAD within seven calendar days after receiving the NTAD according to A.R.S. § 36-325.~~

~~**C.** A non-accredited procurement organization shall ensure a donor record is:~~

~~1. Confidential and kept in a location with controlled access,~~

~~2. Stored in a manner to prevent unauthorized access, and~~

3. Maintained in a manner to preserve the donor record's completeness and accuracy.

D. A non-accredited procurement organization shall ensure a donor record shall include the following donor information:

1. The donor's name;
2. The donor's unique identifying number specified in A.R.S. § 36-851.03(A)(6);
3. The donor's date of birth and date of death; and
4. The name and contact information of the person responsible for a donor's anatomical gift; if applicable.

E. A non-accredited procurement organization shall include the following donor records, as applicable:

1. Donor consent form or documentation of authorization for an anatomical gift includes:
   a. The intended use of the NAM;
   b. How the NAM may be used;
   c. A statement that the NAM will be treated with dignity at all times; and
   d. A statement that the NAM may require international export to an end-user;
2. Document of authorization – a legal record of the gift, to take place postmortem, permitting and defining the scope of the postmortem acquisition and use of NAM for education and research, signed or otherwise recorded by the authorizing person, pursuant to law;
3. Documentation of gift – the donor's legal record of the gift of NAM permitting and defining the scope of the postmortem acquisition and use of NAM for education and research. It must be signed or otherwise recorded by the donor or individual authorized under law to make a gift during the donor's lifetime;
4. Donor's death record specified in A.A.C. R9-19-303;
5. Human remains release form specified in A.A.C. R9-19-301;
6. Information for a death record specified in A.A.C. R9-19-302 for transporting human remains into the state;
7. Disposition-transit permit specified in A.A.C. R9-19-308;
8. Medical examiner's release of information specified in A.R.S. § 36-861;
9. All documents and permits that establish the chain of custody and identifies the individuals and organizations that had physical custody of the NAM;
10. Medical records, including:
    a. Donor's physical assessment;
    b. Risk assessment questionnaire;

c. Pathology and laboratory testing and reports;

d. Physician summaries;

e. Transfusion or infusion information; and

f. Plasma dilution calculations;

11. Information from the donor referral source;

12. Donor eligibility;

13. Donor acceptability assessment;

14. Physical assessment questionnaire;

15. Documentation related to distribution;

16. Serological results, when applicable;

17. Cremation authorization document;

18. Documentation related to NAM recovery, storage, and distribution activities;

19. Final disposition documentation, including all records demonstrating chain of custody; and

20. Documentation of the report in R9-9-201(F) and (G).

F. A donor's consent form shall be accessible to the donor's known consenter.

G. Upon demonstration of a legal right to acquire a donor's record, a non-accredited procurement organization shall provide access to:

1. An agent legally authorized or other individual designated at the time a donor gives consent;

2. An individual appointed by a court or authorized by state laws;

3. An individual of a procurement organization as identified by SOPs;

4. An individual from an approving accrediting body, if applicable; and

5. An individual from the Department or other regulatory agency authorized by state and federal laws or regulations.

H. Except for a donor record specified in subsection (A), a non-accredited procurement organization shall maintain documentation required by this Chapter for at least three years after the date of the documentation and provide copies of the documentation to the Department for review upon request.

ARTICLE 3. ~~PHYSICAL PLANT; TRANSPORTATION FOR A NON-ACCREDITED PROCUREMENT ORGANIZATION~~ REPEALED

R9-9-301. ~~General Plant Standards; Environmental Services~~ Repealed

~~**A.** A licensee of a non-accredited procurement organization shall ensure that a procurement organization facility:~~

~~1. Is in a building that:~~

~~a. Has a commercial occupancy according to the local zoning jurisdiction;~~

~~b. Is free of any plumbing, electrical, ventilation, mechanical, or structural hazard that may jeopardize the security and quality of the NTAD, NAM, and the health or safety of the public;~~

~~c. Has equipment and supplies to maintain NTAD and NAM in a safe and temperature-controlled state; and~~

~~d. Provides a separate and designated area for tissue recovery.~~

~~2. Has premises that are:~~

~~a. Sufficient to provide for a procurement organization's services and activities;~~

~~b. Cleaned and disinfected according to the procurement organization's SOPs to prevent, minimize, and control illness and infection and mitigate potential cross-contamination between NTAD and NAM;~~

~~c. Clean and free from accumulations of dirt, garbage, and rubbish; and~~

~~d. Free from a condition or situation that may cause an individual to suffer physical injury;~~

~~3. Provides a restroom for clients:~~

~~a. Free from contamination and cross-contamination of NAM; and~~

~~b. Does not contain any items, materials, or devices associated with the preparation activities or technicians and personnel members;~~

~~4. Implements and documents a pest control program that:~~

~~a. Requires a pest control service that uses certified applicators as specified in 3 A.A.C. 8, Article 2; and~~

~~b. Retains annual pest control service records for at least 12 months from date of service; and~~

~~5. Does not maintain a public health nuisance or engage in any act, condition, or thing, specified in A.R.S. § 36-601, or any practice contrary to the health laws of this state.~~

~~**B.** A licensee of a non-accredited procurement organization shall ensure that a procurement organization:~~

1. Has preparation rooms that:
    a. Are maintained in a clean and sanitary condition at all times;
    b. Are only used for examining and preparing NTAD;
    c. Contain equipment, instruments, and supplies necessary for examining and preparing NTAD and are disinfected or sterilized, as applicable, after each use to protect the health and safety of technicians and personnel members;
    d. Have sanitary flooring, drainage, and ventilation;
    e. Have proper and convenient receptacles for refuse, bandages, and all other waste materials; and
    f. Are thoroughly cleansed and disinfected with a 1% solution of chlorinated soda, or other suitable and effective disinfectant:
        i. Immediately after obvious spill of blood or other potentially infectious materials, and
        ii. At the end of each shift or on a regular basis that provides equivalent safety for all work surfaces;
2. Has refrigeration equipment used to store NTAD and NAM that:
    a. Is only used for NTAD and NAM;
    b. Is maintained in working order and kept in a clean and sanitary condition;
    c. If a walk-in cooler, maintains a temperature between 36°F and 45°F;
    d. If a freezer, maintains a temperature at or below 32°F;
    e. Is monitored by a temperature sensor system that:
        i. Measures temperatures continuously and document when a unit is out of the required temperature range, and
        ii. Alert technicians or other designated individuals when temperatures are outside of the acceptable limits; and
3. Has equipment at the procurement organization that is:
    a. Sufficient to support the service;
    b. Maintained in working condition;
    c. Maintained in a clean and sanitary condition;
    d. Used according to the manufacturer's recommendations;
    e. If used during an examination or preparation of NTAD, cleaned and sanitized specified in subsection (B)(1)(f)(ii); and
    f. If applicable, tested and calibrated according to the manufacturer's recommendations or, if there are no manufacturer's recommendations, as

specified in SOPs.

C. A licensee of a non-accredited procurement organization shall maintain documentation of equipment tests, calibrations, and repairs for at least 12 months after the date of testing, calibration, or repair.

D. A licensee of a non-accredited procurement organization shall ensure that:

1. Biohazardous material or medical waste and other potentially hazardous materials are removed and disposed by a facility licensed by the Arizona Department of Environmental Quality pursuant to 18 A.A.C. 8 and 13; and
2. Combustible or flammable liquids are stored in a labeled containers or safety containers in a secured area and properly identified to ensure individuals health and safety.

R9-9-302. Emergency and Safety Standards Repealed

A. An administrator of a non-accredited procurement organization shall ensure:

1. SOPs for emergency transfer of NTAD and NAM to a designated back-up storage facility with an acceptable coolant and monitoring system in the event of mechanical failure or loss of coolant, including:
    a. Tolerance limits or temperatures and time limits;
    b. Methods and actions to be taken; and
    c. Specific labeling indicating that the transported NTAD and NAM shall remain untouched until returned to the licensed non-accredited procurement facility after the mechanical failure or loss of coolant has been restored;
2. There is a first aid kit available at a procurement organization;
3. There are smoke detectors installed according to building size and local zoning jurisdiction;
4. A smoke detector required in subsection (A)(3):
    a. Is maintained in an operable condition; and
    b. Is battery operated or, if hard-wired into the electrical system of a procurement organization, has a back-up battery;
5. A procurement organization has a portable fire extinguisher that is labeled 2A-10-BC by the Underwriters Laboratory and is readily available for use;
6. A portable fire extinguisher required in subsection (A)(5) is:
    a. If a disposable fire extinguisher, replaced when the fire extinguisher's indicator reaches the red zone; or
    b. Serviced at least every 12 months and has a tag attached to the fire extinguisher that includes the date of service; and

7. A written fire and evacuation plan is established and maintained.

B. An administrator of a non-accredited procurement organization shall:

1. Obtain a fire inspection conducted according to the time-frame established by the local fire department or the State Fire Marshal;
2. Make any repairs or corrections stated on the fire inspection report; and
3. Maintain documentation of a current fire inspection for at least two years.

R9-9-303. Security Standards; NTAD/NAM Inventory Controls Repealed

A. A licensee of a non-accredited procurement organization shall ensure that access to the enclosed locked areas where NTAD and NAM is located is limited to individuals authorized by the licensee or administrator.

B. To prevent unauthorized access to NTAD and NAM inventory, an administrator of a non-accredited procurement organization shall:

1. Have personnel or security equipment to deter and prevent unauthorized entrance into limited access areas that includes:
    a. Devices or a series of devices to detect unauthorized intrusion, which may include a signal system interconnected with a radio frequency method, such as cellular, private radio signals, or other mechanical or electronic devices;
    b. Exterior lighting to facilitate surveillance; and
    c. Electronic monitoring using video cameras shall provide coverage of:
        i. Entrances to and exits from limited access areas;
        ii. Entrances to and exits from the buildings; and
        iii. Entrances and exits capable of identifying any activity occurring within the limited access area.
2. Maintain video recordings from the video cameras for at least 30 calendar days.
3. Have a failure notification system that provides an audible and visual notification of any failure in the electronic monitoring system.
4. Have battery backup for video cameras and recording equipment to support in the event of a power outage.
5. SOPs:
    a. That restricts access to the areas of the building that contain NTAD and NAM inventory and donor records;
    b. That provides for identification of authorized individuals; and
    c. For conducting electronic monitoring.

C. A licensee of a non-accredited procurement organization shall establish and implement a NTAD

~~and NAM inventory tracking system that:~~

~~1. Contains all NTAD received and NAM released for distribution;~~

~~2. Lists release documentation verified for each NAM prior to transferring NAM to inventory;~~

~~3. Documents the date, time, and location for NAM transferred for use, including the name of the individual performing the transfer;~~

~~4. Documents the date, time, and location for NAM that is moved between locations controlled by the procurement organization, including the name of the individual overseeing the move; and~~

~~5. Ensures NAM that can no longer be used is removed from inventory and disposed according to applicable SOPs.~~

R9-9-304. ~~Transportation Standards~~ Repealed

~~A.~~ ~~If a non-accredited procurement organization owns and maintains a vehicle for transporting NAM, an administrator shall ensure the vehicle is:~~

~~1. Not used for a purpose other than transporting NTAD and NAM or conducting procurement organization business;~~

~~2. Only operated by a procurement organization technician or designated individual authorized to transport NTAD or NAM;~~

~~3. Maintained in clean and sanitary condition; and~~

~~4. Locked and secured at all times during transport of NTAD or NAM.~~

~~B.~~ ~~If using another vehicle or type of transport for NTAD or NAM, an administrator of a non-accredited procurement organization shall ensure that another vehicle or type of transport:~~

~~1. Is properly equipped for the transportation of NTAD or NAM;~~

~~2. Is compliant with all state laws and rules pertaining to transporting human remains; and~~

~~3. If transport is by air, complies with applicable standards established by the International Air Transport Association and Transport Security Administration.~~

~~C.~~ ~~An administrator of a non-accredited procurement organization shall ensure that NTAD and NAM transported into the state has information of death documentation specified in A.A.C. R9-19-302 prior to transport.~~

R9-9-305. ~~Sanitation Standards and Reporting~~ Repealed

~~A.~~ ~~A licensee of a non-accredited procurement organization shall ensure that:~~

~~1. Areas used to receive, prepare, label, package, and store NAM are:~~

~~a. Properly ventilated, and~~

~~b. Protected from dust, dirt, flies, and other contamination.~~

2. All refuse and waste products produced from receiving, preparing, packaging, distributing, and transporting NAM are removed from the premises as needed.

3. All transport vehicles, trays, other receptacles, racks, tables, shelves, knives, saws, other utensils, or machinery used to move, handle, separate, package or other processes be cleaned as specified in SOPs and this Article.

B. A technician or personnel member of a non-accredited procurement organization shall report to the administrator or medical director:

1. Any concern related to receiving, preparing, packaging, distributing, or transporting NTAD or NAM that may adversely affect the health and safety of others.

2. Any personal health condition experienced related to receiving, preparing, packaging, distributing, or transporting NTAD or NAM.

C. If an administrator or medical director of a non-accredited procurement organization determines a health condition in subsection (B)(1) has occurred, the administrator or medical director shall:

1. Follow SOPs to secure the area and eliminate exposure to others;

2. Notify appropriate health and law enforcement agencies, as applicable; and

3. Report the incident to the Department within five working days of determination that a health condition in subsection (B)(2) has occurred.

D. A licensee, administrator, or medical director of a non-accredited procurement organization shall report a health condition experienced by a technician or personnel member to the Department within five calendar days of determination that the individual has a personal health condition specified in subsection (B)(1).

ARTICLE 4. ~~ADMINISTRATION FOR AN ACCREDITED PROCUREMENT ORGANIZATION~~ REPEALED

R9-9-401. ~~General Responsibilities~~ Repealed

~~A.~~ ~~A licensee of an accredited procurement organization shall provide a copy of a renewed accreditation to the Department within 30 calendar days from the date of issuance.~~

~~B.~~ ~~A licensee of an accredited procurement organization shall ensure that a procurement organization facility is in a building that provides a separate and designated area for tissue recovery according to A.R.S. § 36-851.02(3).~~

~~C.~~ ~~A licensee of an accredited procurement organization shall ensure SOPs are established, documented, and implemented that cover:~~

~~1. Labeling;~~

~~2. Packaging, including a packaging insert form that discloses disease status of tissue to end-user according to A.R.S. § 36-851.02(2)(d);~~

~~3. Transport;~~

~~4. Distribution; and~~

~~5. Final disposition.~~

R9-9-402. ~~Donor Consent; NTAD and NAM Identification~~ Repealed

~~In addition to the requirements in Article 1, a licensee of an accredited procurement organization shall ensure that:~~

~~1. A donor consent form includes:~~

~~a. The intended use of the NAM,~~

~~b. How the NAM may be used,~~

~~c. A statement that the NAM will be treated with dignity at all times, and~~

~~d. A statement that the NAM may require international export to an end-user.~~

~~2. A donor consent form is maintained in the donor's record and retained for at least 10 years beyond the date of final disposition.~~

~~3. An electronic identification system for donors is established and maintained for NTAD or NAM;~~

~~a. Assigns a unique identification number according to A.R.S. § 36-851.03(A)(6)(a);~~

~~b. Tracks the complete history of all NAM; and~~

~~c. Records the date and staff member involved in each significant step of the operation from the time of NTAD acquisition through final disposition.~~

~~4. The information required to register the death of a NTAD is submitted within seven~~

~~calendar days after receiving the NTAD according to A.R.S. § 36-325.~~

R9-9-403. ~~Tissue End-Users~~ Repealed

~~**A.** A licensee of an accredited procurement organization shall establish, document, and implement SOPs to properly screen an end-user that includes:~~

~~1. A written request for NAM, including:~~

~~a. The name, address and affiliation of educator and research accepting responsibility for the acceptance, use, and disposition of the NAM;~~

~~b. A description of the intended use;~~

~~c. The date and the approximate duration of NAM use;~~

~~d. A description of the venue in which the NAM will be used and the security measures for the safe and ethical utilization of the venue;~~

~~e. An assurance that universal precautions will be used when handling NAM;~~

~~f. The proposed final disposition of the NAM;~~

~~g. An agreement to comply with procurement organization's policies, as applicable;~~

~~h. An outline of proposed promotional materials to be disseminated in connection with the use of NAM; and~~

~~i. Other supporting documentation that is relevant to the request; and~~

~~2. The criteria for approving requested NAM for use, including:~~

~~a. The acceptability of the educator and researcher for NAM utilization;~~

~~b. The appropriateness of the intended use;~~

~~c. Type of venue in which the NAM will be used;~~

~~d. Proposed final disposition of the NAM unless returned to the procurement organization; and~~

~~e. Proposed promotional materials.~~

~~**B.** A licensee of an accredited procurement organization shall establish, document, and implement a procedure that allows an end-users to request an exceptional release of NAM.~~

SUBCHAPTER 9A. PROCUREMENT ORGANIZATIONS

ARTICLE 1. PROCUREMENT ORGANIZATION LICENSURE

R9-9A-101. Applicability

This Subchapter does not apply to a procurement organization identified in A.R.S. § 36-851.01(F).

R9-9A-102. Definitions

In addition to the definitions in A.R.S. § 36-841, the following apply in this Subchapter, unless otherwise specified:

1. "Acceptability assessment" means the evaluation by a procurement organization of available medical and social information about a donor to determine whether the donor meets criteria for making a non-transplant anatomical donation.
2. "Accredited" means having a current and valid certificate of accreditation as a procurement organization from a nationally recognized agency that is approved by the Department.
3. "Acquisition" means activities required to obtain a non-transplant anatomical donation.
4. "Administrator" means the individual responsible for the provision by a procurement organization of services and related activities.
6. "Applicant" means an individual or business organization requesting approval to operate a procurement organization.
7. "Application" means the information, documents, and fees required by the Department for licensure of a procurement organization.
8. "Business organization" means the same as "entity" in A.R.S. § 10-140.
9. "Calendar day" means each day, not including the day of the act, event, or default from which a designated period of time begins to run, but including the last day of the period unless it is a Saturday, Sunday, statewide furlough day, or legal holiday, in which case the period runs until the end of the next day that is not a Saturday, Sunday, statewide furlough day, or legal holiday.
10. "Department" means the Arizona Department of Health Services.
11. "Distribution" means the process for release and transfer of non-transplant anatomical material to another procurement organization, an education facility, or a research facility, including the selection and evaluation of non-transplant anatomical material for the intended use.
12. "Donor consent form" means the same as "document of gift" as defined in A.R.S. § 36-841.

13. "Exceptional release" means the distribution of non-transplant anatomical material that:
    a. Has been approved for usage before a donor acceptability assessment has been completed; or
    b. Would not normally meet the established acceptability criteria, at the request of a researcher.
14. "Final disposition" means the same as in A.R.S. § 36-301.
15. "Licensee" means a person to whom the Department has issued a license to operate a procurement organization.
16. "Medical director" means a physician who meets the requirements in A.R.S. § 36-851.03.
17. "Non-transplant anatomical donation" means an anatomical gift intended to be used for education or research.
18. "Non-transplant anatomical material" means a non-transplant anatomical donation that has been prepared, packaged, labeled, and released to distribution inventory.
19. "Personnel member" means an individual who is identified as an employee, student, or volunteer for a procurement organization and performs activities directly related to acquisition, evaluation of a non-transplant anatomical donation, preparation, or distribution of non-transplant anatomical material.
20. "Physical assessment" means a postmortem evaluation of a non-transplant anatomical donation to determine whether there is evidence of a condition, such as a viral or bacterial infection, that may affect the suitability of the non-transplant anatomical donation for use in education or research.
21. "Premises" mean a facility and surrounding grounds that are designated by an applicant or a licensee and licensed by the Department as part of a procurement organization.
22. "Preparation" means an activity:
    a. Performed to make a non-transplant anatomical donation ready for distribution; and
    b. Includes cleaning, preservation, disarticulation, dissection, skeletonization, plastination, packaging, and labeling of the non-transplant anatomical donation.
23. "Procurement organization" means the same as "non-transplant anatomical donation organization," as defined in A.R.S. § 36-841, and includes both accredited and non-accredited facilities.
24. "Quality management program" means ongoing activities designed and implemented by a procurement organization to improve acquisition, evaluation of a non-transplant anatomical donation, preparation, or distribution of non-transplant anatomical material.
25. "Standard operating procedure" means a documented process for carrying on business,

providing services, or performing activities, with instructions for performing routine or repetitive tasks.

26. "Storage" means the process of maintaining non-transplant anatomical donations and non-transplant anatomical material in a designated area that contains relevant equipment, instruments, and supplies until distribution or final disposition.

27. "Transfer" means to convey responsibility and oversight for non-transplant anatomical material to another person.

R9-9A-103. Individuals to Act for an Applicant or a Licensee

When an applicant or a licensee is required by this Subchapter to provide information on or sign an application form or other document, the following shall satisfy the requirement on behalf of the applicant or licensee:

1. If the applicant or licensee is an individual, the individual; and
2. If the applicant or licensee is a business organization, the individual who the business organization has designated to act on the business organization's behalf for purposes of this Subchapter and who:
   a. Is a U.S. citizen or legal resident;
   b. Has an Arizona address; and
   c. Meets one of the following, as applicable:
      i. If the business organization is a partnership, is a general partner or is a limited partner who holds at least 10% of the voting rights of the partnership;
      ii. If the business organization is a corporation, association, or limited liability company, is the president, the chief executive officer, the incorporator, an agent, or any individual who owns or controls at least 10% of the voting securities; or
      iii. Holds a beneficial interest in 10% or more of the liabilities of the business organization.

R9-9A-104. Application for Licensure

A. A person may not act as a procurement organization in this state unless the person is licensed by the Department as a procurement organization.

B. An applicant for a procurement organization license shall submit to the Department an application that contains:

1. The following, according to A.R.S. § 36-851.01(A), in a Department-provided format:
   a. The applicant's name, mailing address, email address, and telephone number;

b. The name or proposed name of the procurement organization, including the:

i. Physical address;

ii. Mailing address, if different from the physical address;

iii. Telephone number;

iv. Email address; and

v. Tax ID number;

c. Whether the applicant is a business organization and, if so, the type of business organization;

d. Whether the applicant is accredited as a procurement organization;

e. If the applicant is not accredited as a procurement organization, the name, email address, telephone number, and professional license number of the medical director;

f. Whether the facility is ready for a licensing inspection by the Department;

g. If the facility is not ready for a licensing inspection specified in subsection (B)(1)(f), the date the facility will be ready for a licensing inspection;

h. The name, title, and contact information of an individual acting on behalf of the applicant, as specified in R9-9A-103;

i. Whether the applicant complies with local zoning ordinances, building codes, and fire codes;

j. Whether the applicant agrees to allow the Department to submit supplemental requests for information under R9-9A-109; and

k. The applicant's signature and the date signed;

2. If applicable, documentation that the procurement organization is accredited;

3. A floor plan, drawn to scale, of each building where the procurement organization will be located, showing the function of each room;

4. Documentation for the applicant that complies with A.R.S. § 41-1080;

5. Documentation that shows that the applicant is in good standing with the Arizona Corporation Commission; and

6. An application fee of $2,000.

C. Upon receipt of the application in subsection (B), the Department shall conduct an inspection of the procurement organization, if applicable.

D. The Department shall issue or deny a license to an applicant as specified in R9-9A-109.

R9-9A-105. Application for License Renewal

A. A license is valid for two years from the date of issuance or renewal as specified in A.R.S. § 36-

851.01(C).

B. At least 30 calendar days before the expiration date indicated on a procurement organization's license, a licensee shall submit to the Department an application for renewal that contains:

1. The following, in a Department-provided format:
   a. The licensee's name, mailing address, email address, and telephone number;
   b. The procurement organization's license number; and
   c. Whether the applicant agrees to allow the Department to submit supplemental requests for information under R9-9A-109; and
   d. The licensee's signature and the date signed;
2. If applicable, documentation that the procurement organization is accredited; and
3. An application fee of $2,000.

C. The Department shall renew or deny renewal of a license as specified in R9-9A-109.

R9-9A-106. Changes Affecting a License

A. A licensee shall notify the Department in writing at least 30 calendar days before the effective date of termination of procurement organization operations, including the following information, in a Department-provided format:

1. The name and license number of the licensee;
2. The name, email address, and telephone number of an individual who may be contacted by the Department;
3. The proposed termination date; and
4. The address and contact information for the location where the procurement organization records will be retained, according to R9-9A-201(B)(1)(b).

B. A licensee of an accredited procurement organization, whose certificate of accreditation has expired or has been revoked, suspended, or denied, shall notify the Department in writing no later than 14 calendar days after expiration or the receipt of a revocation, suspension, or denial.

C. A licensee shall:

1. Notify the Department in writing at least 30 calendar days before a change in the legal name of a procurement organization that does not affect the structure or ownership of the business organization, including the following information:
   a. The name and license number of the licensee,
   b. The current name of the procurement organization,
   c. The proposed name of the procurement organization, and
   d. The name, email address, and telephone number of an individual who may be contacted by the Department; and

2. Within seven calendar days after the effective date of the name change, submit to the Department documentation of the name change from the Arizona Corporation Commission that indicates no change in structure or ownership of the procurement organization.

D. A licensee shall:

1. Notify the Department in writing at least 30 calendar days before a change in the legal name of the licensee, which does not affect the structure or ownership of the business organization if the licensee is a business organization, including the following information:
   a. The current name and license number of the licensee,
   b. The proposed name of the licensee, and
   c. The name, email address, and telephone number of an individual who may be contacted by the Department; and
2. Within seven calendar days after the effective date of the name change, submit to the Department either:
   a. If the licensee is an individual, documentation of the individual's legal name change; or
   b. If the licensee is a business organization, documentation of the name change from the Arizona Corporation Commission that indicates no change in structure or ownership of the business organization.

E. A licensee shall notify the Department in writing no later than 30 calendar days after a change in any of the following, including the name and license number of the procurement organization:

1. The email address or mailing address of the procurement organization, including the new email address or mailing address;
2. The email address or telephone number of the licensee, including the new email address or telephone number;
3. An administrator, including the name, telephone number, and email address of the new administrator;
4. A medical director, including the name, email address, and professional license number of the new medical director; or
5. The name, telephone number, and email address of the individual acting on behalf of the licensee specified in R9-9A-103.

F. A licensee shall notify the Department in writing at least 30 calendar days before the effective date of a proposed modification, which includes a substantial improvement, enlargement,

reduction, alteration, or other substantial change in the facility or another structure on the premises at the procurement organization, including;

1. The following information:
   a. The name and license number of the licensee;
   b. A description of the proposed modification;
   c. Whether the modification will comply with local zoning ordinances, building codes, and fire codes;
   d. The estimated date of completion of the modification;
   e. The date the facility will be ready for a licensing inspection; and
   f. The name, email address, and telephone number of an individual who may be contacted by the Department;
2. A floor plan, drawn to scale, of each building in which a change will be made:
   a. Showing the function of each room, and
   b. Indicating the changes to be made; and
3. A plan for ensuring the quality and security of non-transplant anatomical donations and non-transplant anatomical material are maintained during the modification.

G. For an anticipated change in the address of a procurement organization, a licensee shall:

1. Notify the Department in writing at least 30 calendar days before the anticipated change in the address, including;
   a. The name and license number of the licensee,
   b. The new address of the procurement organization,
   c. The estimated date that the procurement organization plans to suspend acquisition, preparation, and distribution at the current address in anticipation of the change of address, and
   d. The estimated date that the procurement organization plans to be ready to begin operations at the new address;
2. Submit to the Department:
   a. The application information, documentation, and fee required in R9-9A-104(B);
   b. A plan for ensuring the quality and security of non-transplant anatomical donations and non-transplant anatomical material are maintained during the change of location; and
   c. Documentation from the Arizona Corporation Commission that shows the change of address and indicates no change in structure or ownership of the procurement organization;

3. Ensure that the quality and security of non-transplant anatomical donations and non-transplant anatomical material are maintained during the change of address; and

4. Not begin procurement organization activities at the new address until a new license has been issued according to subsection (M).

H. For an anticipated change of ownership of a procurement organization:

1. A licensee shall:

a. Notify the Department in writing at least 30 calendar days before the anticipated change of ownership, including the following information, in a Department-provided format:

i. The name and license number of the licensee;

ii. The name, email address, and telephone number of the person who is anticipated to assume ownership of the procurement organization;

iii. The estimated date that the procurement organization plans to suspend acquisition, preparation, and distribution in anticipation of the change of ownership;

iv. The estimated date that the change of ownership will occur;

v. The address and contact information for the location where the procurement organization records will be retained, according to R9-9A-201(B)(1)(b); and

vi. The name, email address, and telephone number of an individual who may be contacted by the Department;

b. If the licensee anticipates that any non-transplant anatomical donations or non-transplant anatomical material in the possession of the licensee will be transferred to the new owner, submit to the Department a plan for ensuring that the quality and security of the non-transplant anatomical donations and non-transplant anatomical material are maintained during the change of ownership; and

c. If the licensee anticipates that any non-transplant anatomical donations or non-transplant anatomical material in the possession of the licensee will not be transferred to the new owner, submit to the Department a plan for final disposition of the non-transplant anatomical donations and non-transplant anatomical material, consistent with the standard operating procedure for the final disposition of non-transplant anatomical donations and non-transplant anatomical material, according to R9-9A-201(B)(8); and

2. The person identified in subsection (H)(1)(b) shall:

a. Submit to the Department the application information, documentation, and fee required in R9-9A-104(B);

b. Ensure that the quality and security of non-transplant anatomical donations and non-transplant anatomical material transferred from the licensee are maintained during the change of ownership; and

c. Not begin procurement organization activities until a license has been issued by the Department to the person according to R9-9A-109(C)(4).

I. If the Department receives the notification of termination of operation in subsection (A) or notice of a change in ownership in subsection (H)(1), the Department shall void the licensee's license to operate a procurement organization as of the termination date specified by the licensee.

J. If the Department receives a notification in subsection (B) of a procurement organization's loss of accreditation, the Department may conduct an inspection of the procurement organization to ensure compliance with the requirements in A.R.S. § 36-851.03 and this Subchapter.

K. If the Department receives a notification in subsection (C) or (D) of a change in the legal name of the procurement organization or licensee, the Department shall:

1. Determine whether the change affects the structure or ownership of the business organization;

2. If the change does not affect the structure or ownership of the business organization, issue to the licensee an amended license showing the new legal name of the procurement organization or licensee and keeping the current license expiration date; and

3. If the change affects the structure or ownership of the business organization:

a. Notify the licensee that the procurement organization is required to suspend acquisition, preparation, and distribution as of the date of the documentation required in subsection (C)(2) or (D)(2)(b), as applicable;

b. Require the licensee to specify the address and contact information for the location where the procurement organization records will be retained, according to R9-9A-201(B)(1)(b);

c. Notify the licensee that the licensee is responsible for ensuring that the quality and security of non-transplant anatomical donations and non-transplant anatomical material are maintained until:

i. A new license is issued under the new structure or ownership of the business organization; or

ii. The licensee no longer possesses any non-transplant anatomical

donations or non-transplant anatomical material;

d. If the procurement organization plans to continue operations under the new structure or ownership of the business organization:

i. Require the submission of the application information, documentation, and fee required in R9-9A-104(B);

ii. Conduct an inspection of the procurement organization if appropriate; and

iii. Specify that procurement organization activities may not resume until a new license has been issued by the Department according to R9-9A-109(C)(4); and

e. Terminate the licensee's current license when the Department:

i. Issues a new license to the procurement organization under the new structure or ownership of the business organization, or

ii. Receives notification that the licensee no longer possesses any non-transplant anatomical donations or non-transplant anatomical material.

L. If the Department receives a notification in subsection (F) of a proposed modification, the Department:

1. May conduct an inspection of the premises; and

2. If the procurement organization is compliant with A.R.S. Title 36, Chapter 7, Article 3, and this Subchapter, shall issue to the licensee an amended license that incorporates the modification and retains the expiration date of the existing license.

M. If the Department receives a notification, information, and documentation in subsection (G) for a change of address, regardless of whether the change affects the structure or ownership of the business organization, or a notification in subsection (H) that indicates a change in ownership, the Department:

1. Shall notify the licensee that:

a. The procurement organization is required to suspend acquisition, preparation, and distribution as of the date specified in subsection (G)(1)(c) or (H)(1)(a)(iii), as applicable;

b. The licensee is responsible for ensuring that the quality and security of non-transplant anatomical donations and non-transplant anatomical material are maintained until:

i. A new license is issued to the licensee at the new address or to the new owner, as applicable; or

ii. The licensee no longer possesses any non-transplant anatomical donations or non-transplant anatomical material; and

c. Procurement organization activities may not occur after the date specified in subsection (G)(1)(c) or (H)(1)(a)(iii), as applicable, until a new license has been issued by the Department according to R9-9A-109(C)(4);

2. May conduct an inspection of the procurement organization;

3. If the application is compliant with A.R.S. Title 36, Chapter 7, Article 3, and this Subchapter, shall issue a new license to the applicant according to R9-9A-109(C)(4); and

4. Shall terminate the licensee's current license when the Department:

a. Issues a new license to the procurement organization at the new address or to the new owner, as applicable; or

b. Receives notification that the licensee no longer possesses any non-transplant anatomical donations or non-transplant anatomical material.

R9-9A-107. Inspections

A. A non-accredited procurement organization is subject to inspection by the Department at any time to evaluate compliance with A.R.S. Title 36, Chapter 7, Article 3, and this Subchapter according to A.R.S. § 36-851.03(A)(5)(a) and (C).

B. An accredited procurement organization is subject to inspection by the Department at any time to evaluate compliance with requirements in A.R.S. § 36-851.02(2) and the rules adopted pursuant to A.R.S. § 36-851.02(2).

C. If the Department determines that a procurement organization is not in compliance with the applicable requirements in A.R.S. Title 36, Chapter 7, Article 3, and the rules in this Subchapter, the Department may:

1. Take an enforcement action as described in R9-9A-108; or

2. Require that the licensee submit to the Department, within 30 calendar days after written notice from the Department, a plan of correction acceptable to the Department to address issues of compliance that:

a. Describes how each identified instance of noncompliance will be corrected and reoccurrence prevented,

b. Includes a date for correcting each instance of noncompliance that is appropriate to the actions necessary to correct the instance of noncompliance, and

c. Includes the signature of the individual acting for the licensee according to R9-9A-102 and date signed.

R9-9A-108. Denial, Suspension, Revocation, Enforcement

A. The Department may:

1. Deny a license as specified in subsection (B),
2. Suspend or revoke a license under A.R.S. § 36-851.01(E) and subsection (B), or
3. Assess or impose a civil penalty under A.R.S. § 36-851.01(E) and subsection (B).

B. The Department may impose civil penalties, deny an application, or suspend or revoke a license to operate a procurement organization, if:

1. An applicant or a licensee does not meet the application requirements contained in R9-9A-104 or R9-9A-105, as applicable;
2. A licensee does not comply with applicable requirements in A.R.S. §§ 36-851.01 through 36-851.03 and this Subchapter;
3. A licensee does not correct the deficiencies identified during an inspection according to the plan of correction;
4. An applicant or a licensee provides false or misleading information to the Department; or
5. The nature or number of violations revealed by any type of inspection or investigation of a procurement organization poses a direct risk to the life, health, or safety of a personnel member or member of the public.

C. In determining which action in subsection (A) is appropriate, the Department shall consider:

1. Repeated violations of statutes or rules,
2. The pattern of violations,
3. The severity of violations, and
4. The number of violations.

D. If the Department receives notice that a previously accredited procurement organization's accreditation has expired or has been suspended or revoked, the Department may suspend or revoke the procurement organization's license if the procurement organization does not comply with A.R.S. § 36-851.03 and this Subchapter.

E. An applicant or a licensee may appeal the Department's determination in this Section according to A.R.S. Title 41, Chapter 6, Article 10.

R9-9A-109. Time-frames

A. The overall time-frame, as defined in A.R.S. § 41-1072, for a license granted by the Department under this Subchapter is set forth in Table 1.1. The applicant or licensee and the Department may agree in writing to extend the substantive review time-frame, as defined in A.R.S. § 41-1072, and the overall time-frame. An extension of the substantive review time-frame and the overall time-frame may not exceed 25% of the overall time-frame.

B. The administrative completeness review time-frame, as defined in A.R.S. § 41-1072, for a license granted by the Department under this Subchapter is set forth in Table 1.1 and begins on the date that the Department receives an application from an applicant or a licensee.

1. The Department shall send a notice of administrative completeness or deficiencies to the applicant or licensee within the administrative completeness review time-frame:
   a. A notice of deficiencies shall list each deficiency and the information or items needed to complete the application;
   b. The administrative completeness review time-frame and the overall time-frame are suspended from the date that the notice of deficiencies is sent until the date that the Department receives all of the missing information or items from the applicant or licensee; and
   c. If an applicant or a licensee fails to submit to the Department all of the information or items listed in the notice of deficiencies within the time-frame in Table 1.1 after the date that the Department sent the notice of deficiencies or within a time period the applicant or licensee and the Department agree upon in writing, the Department shall:
      i. Consider the application withdrawn; and
      ii. Send to the applicant or licensee a written notice setting forth the information required by A.R.S. § 41-1092.03.
2. If the Department issues a license during the administrative completeness review time-frame, the Department shall not issue a separate written notice of administrative completeness.

C. The substantive review time-frame is set forth in Table 1.1 and begins on the date of the notice of administrative completeness.

1. As part of the substantive review of an application for a license, the Department may conduct an inspection that may require more than one visit to complete.
2. The Department shall issue a license or send a written notice of denial of a license within the substantive review time-frame.
3. During the substantive review time-frame, the Department may make one comprehensive written request for additional information, unless the applicant or licensee has agreed in writing to allow the Department to submit supplemental requests for information:
   a. The Department shall send a comprehensive written request for additional information that includes a written statement of deficiencies, stating each statute and rule upon which noncompliance is based, if the Department determines that

an applicant or a licensee, or the procurement organization, including the premises, are not in substantial compliance with A.R.S. Title 36, Chapter 7, Article 3, or this Subchapter;

b. An applicant or a licensee shall submit to the Department all of the information requested in a comprehensive written request for additional information or a supplemental request for information, including, if applicable, documentation of the corrections required in a statement of deficiencies, within the time-frame in Table 1.1 after the date of the comprehensive written request for additional information or the supplemental request for information or within a time period the applicant or licensee and the Department agree upon in writing;

c. The substantive review time-frame and the overall time-frame are suspended from the date that the Department sends a comprehensive written request for additional information or a supplemental request for information until the date that the Department receives all of the information requested, including, if applicable, documentation of corrections required in a statement of deficiencies; and

d. If an applicant or a licensee fails to submit to the Department all of the information requested in a comprehensive written request for additional information or a supplemental request for information, including, if applicable, documentation of corrections required in a statement of deficiencies, within the time-frame in Table 1.1, the Department shall:

i. Deny the license, and

ii. Send to the applicant or licensee a written notice of denial setting forth the reasons for denial and all other information required by A.R.S. §§ 41-1076 and 41-1092.03.

4. The Department shall issue a license if the Department determines that the applicant or licensee and the procurement organization, including the premises, are in substantial compliance with A.R.S. Title 36, Chapter 7, Article 3, and this Subchapter.

Table 1.1. Time-frames (in calendar days)

Type of approval	Authority (A.R.S. § or A.A.C.)	Overall Time-frame	Time-frame for applicant to complete application	Administrative Completeness Time-frame	Substantive Review Time-frame	Response Time for Request in R9-9A-603(X)
Application for an initial procurement	A.R.S. § 36-851.01 and R9-	90	90	30	60	30

organization license	9A-104					
Renewal of a procurement organization license	A.R.S. § 36-851.01 and R9-9A-105	30	30	10	20	30
Application for a facility or licensee name change	A.R.S. § 36-851.01 and R9-9A-106(C)	60	30	30	30	30
Application for another change affecting licensure	A.R.S. § 36-851.01 and R9-9A-106(C)	90	90	30	60	30

ARTICLE 2. ADMINISTRATION AND OPERATIONS FOR A PROCUREMENT ORGANIZATION

R9-9A-201. General Administration Requirements for a Procurement Organization

A. A licensee of a procurement organization:

1. Is responsible for all issues of liability, ethical considerations, fiduciary issues, and compliance with applicable laws and regulations;
2. Shall comply with:
   a. A.R.S. § 36-325 and, as applicable, A.A.C. R9-19-303 or A.A.C. R9-19-304 related to death certificate registration, and
   b. A.R.S. § 36-326, A.A.C. R9-19-301, A.A.C. R9-19-308, and, if applicable, A.A.C. R9-19-311 related to the movement of non-transplant anatomical donations and non-transplant anatomical material; and
3. Shall adopt, maintain, and implement standard operating procedures, as applicable to the procurement organization.

B. A licensee of a procurement organization shall ensure that standard operating procedures are established, documented, and implemented that cover:

1. The proper use and maintenance of donor consent forms, including that a donor consent form:
   a. Includes:
      i. The intended use of the non-transplant anatomical material,
      ii. How the non-transplant anatomical material may be used,
      iii. A statement that the non-transplant anatomical material will be treated with dignity at all times, and
      iv. A statement that the non-transplant anatomical material may require international export to an end-user; and
   b. Is maintained in the donor's record and retained for at least 10 years beyond the date of final disposition;
2. An electronic identification system for donors, which is established and maintained for non-transplant anatomical donations and non-transplant anatomical material, that:
   a. Assigns a unique identification number to the donor and the associated non-transplant anatomical donation and non-transplant anatomical material,
   b. Tracks the complete history of all non-transplant anatomical material, and
   c. Records the date and staff member involved in each significant step of the operation from the time of acquisition of the non-transplant anatomical donation

through final disposition;

3. The screening of end-users prior to release and transfer of non-transplant anatomical material that:

a. Require a written request for non-transplant anatomical material, containing:

i. The name and address of the educational or research establishment making the request;

ii. The name, title, and contact information of the individual at the educational or research establishment who will be accepting responsibility for the receipt, use, and disposition of the non-transplant anatomical material;

iii. A description of the intended use;

iv. The date and the approximate duration of use of the non-transplant anatomical material;

v. A description of the venue in which the non-transplant anatomical material will be used and the environmental and security measures of the venue to ensure the safe and ethical utilization of the non-transplant anatomical material;

vi. An assurance that universal precautions will be used when handling the non-transplant anatomical material;

vii. The proposed final disposition of the non-transplant anatomical material;

viii. An outline of proposed descriptive materials to be disseminated in connection with the use of the non-transplant anatomical material; and

ix. Other supporting documentation that is relevant to the request; and

b. Include the criteria for approving requested non-transplant anatomical material for use, including:

i. The standards for acceptability of the educator or researcher for the use of non-transplant anatomical material;

ii. The appropriateness of the intended use;

iii. The types of venues in which the non-transplant anatomical material may be used;

iv. What final disposition of the non-transplant anatomical material may be proposed, unless the non-transplant anatomical material is returned to the procurement organization; and

v. The suitability of the proposed descriptive materials;

4. The process for requesting and criteria for approving the exceptional release of non-transplant anatomical material;

5. The labeling of non-transplant anatomical donations and non-transplant anatomical material with:

   a. The unique identification number specified in subsection (B)(2)(a),

   b. That the non-transplant anatomical donation or non-transplant anatomical material is not for transplant or clinical use,

   c. Any condition or limitation regarding the use of the non-transplant anatomical donation or non-transplant anatomical material,

   d. That universal precautions must be used in handling the non-transplant anatomical donation or non-transplant anatomical material,

   e. A disclosure of any disease state in the non-transplant anatomical donation or non-transplant anatomical material, and

   f. The name and contact information for the procurement organization;

6. The packaging and transport of non-transplant anatomical donations and non-transplant anatomical material to:

   a. Preserve the quality of the non-transplant anatomical donation or non-transplant anatomical material,

   b. Prevent potential cross-contamination between non-transplant anatomical donations or non-transplant anatomical material, and

   c. Protect the health and safety of personnel members and the public;

7. The distribution of non-transplant anatomical donations and non-transplant anatomical material, including methods for:

   a. Ensuring the quality and suitability of non-transplant anatomical donations and non-transplant anatomical material;

   b. Handling non-transplant anatomical donations and non-transplant anatomical material that do not meet quality control standards;

   c. Ensuring the eligibility of an end-user or other person to which non-transplant anatomical donations and non-transplant anatomical material may be transferred;

   d. Handling an end-user request that does not meet the criteria in subsection (B)(3)(b);

   e. The release of:

      i. Non-transplant anatomical donations to use, and

      ii. Non-transplant anatomical material to an end-user or other person to

which non-transplant anatomical material may be transferred; and

f. The exceptional release of the non-transplant anatomical material; and

8. The final disposition of non-transplant anatomical donations or non-transplant anatomical material, consistent with requirements in:

a. A.R.S. Title 32, Chapter 12; A.R.S. Title 36, Chapter 7; and Subchapter B, related to funeral arrangements, cremation, or other final dispositions;

b. A.R.S. Title 36, Chapter 3, and 9 A.A.C. 19, related to the movement of non-transplant anatomical donations or non-transplant anatomical material and reporting of the final disposition; and

c. A.R.S. Title 36, Chapter 6, Articles 1, 2, and 4, related to non-transplant anatomical donations or non-transplant anatomical material infected with an agent causing a communicable disease.

C. A licensee of a procurement organization shall ensure that copies of standard operating procedures are:

1. Maintained at the procurement organization, and

2. Available for review by the Department within two hours of the Department's request.

R9-9A-202. Additional Administrative Requirements for an Accredited Procurement Organization

A. A licensee of an accredited procurement organization shall provide a copy of a renewed accreditation to the Department within 30 calendar days after the date of issuance.

B. A licensee of an accredited procurement organization shall ensure that a procurement organization facility is in a building that provides a separate and designated area for tissue recovery, according to A.R.S. § 36-851.02(3).

R9-9A-203. Additional Administrative Requirements for a Non-accredited Procurement Organization

A. A licensee of a non-accredited procurement organization shall:

1. Appoint an administrator who:

a. Has at least a bachelor's degree in a health science or other science-related field,

b. Has at least three years of experience in tissue banking or other related fields, and

c. Is responsible for all services and activities at the procurement organization;

2. Appoint a medical director who:

a. Is licensed under A.R.S. Title 32, Chapter 13 or 17;

b. Provides medical guidance to determine donor eligibility; and

c. May be the same individual as the administrator, if the individual's qualifications

satisfy the requirements in both subsections (A)(1) and (2)(a);

3. Adopt a quality management program that, at a minimum, includes:
   a. A method to identify, document, and evaluate incidents;
   b. A method to collect data to evaluate the provision of procurement organization services;
   c. A method to evaluate the data collected to identify a concern about the provision of procurement organization services;
   d. A method to make changes or take action as a result of the identification of a concern about the provision of procurement organization services; and
   e. The frequency of submitting a documented report required in subsection (A)(4) to the licensee;
4. Ensure that a documented report of quality management program activities is:
   a. Submitted to the licensee that includes:
      i. An identification of each concern about the provision of procurement organization services, and
      ii. Any changes made or actions taken as a result of the identification of a concern about the provision of procurement organization services; and
   b. Maintained by the procurement organization for at least 12 months after the date of the report;
5. Review and evaluate the effectiveness of the quality management program in subsection (A)(3) at least once every 12 months;
6. If any instance of use of a non-transplant anatomical donation or non-transplant anatomical material for a purpose other than for research, education, or another use specified in the donor consent form is detected:
   a. Report the incident to the Department within seven calendar days after the incident is detected,
   b. Maintain documentation of the report in a donor record, and
   c. Ensure that the incident is reviewed through the quality assurance process with any steps taken to prevent a reoccurrence;
7. Unless otherwise specified in this Subchapter, ensure that any records or documentation required by this Subchapter are maintained for at least three years after the latest date entered on the report or document; and
8. Ensure that the following information is conspicuously posted on the premises:
   a. The procurement organization's current license,

b. The names of the administrator and medical director,

c. The hours of operation, and

d. The evacuation plan listed in R9-9A-302(A)(5).

B. An administrator of a non-accredited procurement organization:

1. Is directly accountable to the licensee for the operations of the procurement organization, including all services and activities provided by or at the procurement organization;

2. Has the authority and responsibility to manage the procurement organization, as specified in standard operating procedures; and

3. Shall designate, in writing, an individual who is on the procurement organization's premises and is available and responsible for procurement organization operations when the administrator is not present on the premises.

C. A licensee of a non-accredited procurement organization shall ensure that the medical director:

1. Establishes, reviews, and approves standard operating procedures related to:

a. Donor eligibility, including:

i. The content and conducting of an acceptability assessment;

ii. The content and conducting of a physical assessment; and

iii. Screening for a condition, such as a viral or bacterial infection, that may affect the suitability of the non-transplant anatomical donation for use in education or research;

b. The criteria for and methods of verifying the suitability of a non-transplant anatomical donation for release for preparation;

c. The criteria and processes for the exceptional release of non-transplant anatomical material; and

d. Pre-established criteria for release of non-transplant anatomical material to an end-user;

2. Reviews and, if necessary, revises all standard operating procedures of a medical nature at least every three years;

3. Establishes a process for determining the eligibility of a donor, based on a comparison of the non-transplant anatomical donation with predetermined donor criteria;

4. Prior to release for use or distribution, signs the donor eligibility statement and non-transplant anatomical material disposition or release statement;

5. If designating another individual to perform tasks or functions assigned by the medical director, ensures that the individual:

a. Has the required training and education for performing the tasks or functions;

b. Has oversight when performing the tasks or functions assigned by the medical director; and

c. Performs the tasks or functions assigned by the medical director according to standard operating procedures, including, if applicable, the functions described in subsections (C)(3) and (4);

6. Reviews activities performed by a designee at least once every three months according to standard operating procedures established by the licensee; and

7. Establishes the criteria for ensuring that all appropriate parties are notified of confirmed positive infectious disease test results.

D. A licensee of a non-accredited procurement organization shall ensure that:

1. The following are established, maintained, and implemented in compliance with applicable state and federal laws and regulations:

a. A safety awareness and blood-borne pathogen training program, and

b. A cleaning program that mitigates potential cross-contamination between non-transplant anatomical donations; and

2. The medical director reviews and approves standard operating procedures related to the programs in subsections (D)(1)(a) and (b)

E. A licensee of a non-accredited procurement organization shall ensure that the administrator:

1. Specifies activities involving non-transplant anatomical donations and non-transplant anatomical material that a technician may provide;

2. Specifies the methods used to provide clinical oversight and training to personnel members, including when clinical oversight and training are provided to an individual or a group; and

3. Creates and maintains a technician's personnel record that includes:

a. Documentation of all completed training and education; and

b. A written job description, including all primary duties.

F. A licensee of a non-accredited procurement organization shall ensure that a technician:

1. Is only assigned duties described in a written job description;

2. Has the educational background, experience, and training sufficient to ensure that assigned tasks will be performed in accordance with the applicable standard operating procedures;

3. Provides a copy of a transcript or diploma in health science or other field of science for which the technician received a degree or certificate, if applicable; and

4. Demonstrates competency to perform assigned tasks.

G. A licensee of a non-accredited procurement organization shall ensure that:

1. The qualifications, skill, and knowledge required for each type of personnel member is based on the activities and services the personnel member may provide, as established in the personnel member's job description; and
2. A personnel member's qualifications, skills, and knowledge are verified and documented:
   a. Before the personnel member provides procurement organization services, and
   b. According to standard operating procedures.

H. A licensee of a non-accredited procurement organization shall ensure that a personnel member does not have direct interaction with non-transplant anatomical donations or non-transplant anatomical material unless specifically authorized by the licensee or administrator.

I. A licensee of a non-accredited procurement organization shall ensure a personnel record is established for the administrator, technicians, and other personnel members that includes:

1. The individual's name, date of birth, home address, and contact telephone number;
2. The individual's starting date of employment or volunteer service and, if applicable, the ending date; and
3. Documentation applicable to an individual's duties, as required by standard operating procedures, including the individual's:
   a. Education and experience;
   b. In-service education and continuing education, if applicable; and
   c. Evidence of Hepatitis B vaccination or refusal of Hepatitis B vaccine for individuals whose job-related responsibilities involve the potential exposure to blood-borne pathogens.

J. A licensee of a non-accredited procurement organization shall ensure that a personnel record is:

1. Maintained throughout an individual's period of employment or volunteer service in or for the procurement organization,
2. Maintained for at least three years after the last date that an individual's employment or volunteer service in or for the procurement organization, and
3. Provided to the Department when requested.

K. A licensee of a non-accredited procurement organization shall ensure that a donor record:

1. Includes:
   a. A copy of the donor consent form and any amendment to the consent form;
   b. The name and contact information of the person responsible for the donor's anatomical gift; if applicable;
   c. The donor's unique identifying number specified in R9-9A-201(B)(2)(a);

d. Documentation for registering the donor's death, as specified in A.A.C. R9-19-303 or A.A.C. R9-19-304, as applicable;

e. A disposition-transit permit specified in A.A.C. R9-19-308;

f. Any information from the donor referral source, including, as applicable:

i. Donor acceptability assessment, and

ii. Donor eligibility;

g. All documents and permits that establish the chain of custody and identification of the individuals and organizations that had physical custody of the non-transplant anatomical donation or non-transplant anatomical material;

h. Medical records, including as applicable:

i. The donor's physical assessment,

ii. Pathology and laboratory testing and reports,

iii. Physician summaries,

iv. Serological results,

v. Transfusion or infusion information, and

vi. Plasma dilution calculations;

i. Documentation related to activities involved in:

i. Recovery of the non-transplant anatomical donation,

ii. Preparation and storage of the non-transplant anatomical material, and

iii. Distribution of the non-transplant anatomical material; and

j. Final disposition documentation, including all records related to chain of custody;

2. Includes, if applicable:

a. A human remains release form specified in A.A.C. R9-19-301;

b. Information for transporting human remains, as defined in A.R.S. § 36-301, into the state, as specified in A.A.C. R9-19-311;

c. The release of information by a medical examiner, as specified in A.R.S. § 36-861;

d. Cremation authorization documents; and

e. Documentation related to the use of the non-transplant anatomical donation or non-transplant anatomical material for a purpose other than for research, education, or another use specified in the donor consent form; and

3. Is:

a. Confidential and kept in a location with controlled access;

b. Stored in a manner to prevent unauthorized access;

c. Maintained in a manner to preserve the donor record's completeness and accuracy; and

d. Made available to:

i. The donor's known consenter;

ii. An agent legally authorized by the donor or other individual designated at the time a donor gives consent;

iii. An individual appointed by a court or authorized by state laws;

iv. An individual of a procurement organization as identified by standard operating procedures;

v. An individual from an approving accrediting body, if applicable; and

vi. An individual from the Department or other regulatory agency authorized by state and federal laws or regulations.

L. A technician or other personnel member of a non-accredited procurement organization shall report to the administrator or medical director:

1. Any concern related to receiving, preparing, packaging, distributing, or transporting non-transplant anatomical donations or non-transplant anatomical material that may adversely affect the health and safety of others; and

2. Any personal health condition experienced by the technician or other personnel member related to receiving, preparing, packaging, distributing, or transporting non-transplant anatomical donations or non-transplant anatomical material.

M. If an administrator or medical director of a non-accredited procurement organization receives a report specified in subsection (L), the administrator or medical director shall:

1. Follow standard operating procedures to secure the area and eliminate exposure to others;

2. Notify appropriate health and law enforcement agencies, as applicable; and

3. Report the incident to the Department within seven calendar days after determining that a health condition in subsection (L) has occurred.

N. If a non-accredited procurement organization owns or maintains a vehicle for transporting non-transplant anatomical donations and non-transplant anatomical material, an administrator shall ensure the vehicle is:

1. Not used for a purpose other than transporting non-transplant anatomical donations and non-transplant anatomical material or conducting procurement organization business, and

2. Only operated by a procurement organization technician or designated and authorized individual when transporting non-transplant anatomical donations or non-transplant

anatomical material.

O. If using another vehicle or type of transport for non-transplant anatomical donations or non-transplant anatomical material, an administrator of a non-accredited procurement organization shall ensure that the other vehicle or type of transport:

1. Is properly equipped for the transportation of non-transplant anatomical donations or non-transplant anatomical material;
2. Is compliant with all state laws and rules pertaining to transporting human remains; and
3. If transport is by air, complies with applicable standards established by the International Air Transport Association and Transport Security Administration.

ARTICLE 3. ENVIRONMENTAL AND PHYSICAL PLANT STANDARDS FOR A NON-ACCREDITED PROCUREMENT ORGANIZATION

R9-9A-301. Environmental and Physical Plant Standards

A. A licensee of a non-accredited procurement organization shall ensure that the procurement organization:

1. Is in a building that:
   a. Has a commercial occupancy according to the local zoning jurisdiction;
   b. Is free of any plumbing, electrical, ventilation, mechanical, or structural hazard that may jeopardize:
      i. The security or quality of non-transplant anatomical donations or non-transplant anatomical material, or
      ii. The health or safety of a personnel member or the public; and
   c. Provides a separate and designated area for tissue recovery;
2. Has premises that are:
   a. Sufficient to provide for a procurement organization's services and activities;
   b. Cleaned and disinfected according to the procurement organization's standard operating procedures to prevent, minimize, and control illness and infection and mitigate potential cross-contamination between non-transplant anatomical donations and non-transplant anatomical material;
   c. Clean and free from accumulations of dirt, garbage, and rubbish; and
   d. Free from a condition or situation that may cause an individual to suffer physical injury;
3. Provides a restroom for clients that:
   a. Is free from contamination from a non-transplant anatomical donation or non-transplant anatomical material;
   b. Does not contain any items, materials, or devices associated with the preparation of non-transplant anatomical donations or non-transplant anatomical material; and
   c. Is not used by technicians or other personnel members unless personal protective equipment is removed before entering; and
4. If the non-accredited procurement organization owns or maintains a vehicle for transporting non-transplant anatomical donations and non-transplant anatomical material:
   a. Maintains the vehicle in a clean and sanitary condition,
   b. Ensures that the floor of the vehicle or other locations on which non-transplant

anatomical donations and non-transplant anatomical material are placed during transport have a surface capable of being cleaned and sanitized or disinfected, and

c. Requires that the vehicle is locked and secured at all times during transport of non-transplant anatomical donations or non-transplant anatomical material.

B. A licensee of a non-accredited procurement organization shall ensure that:

1. A pest control program is implemented and documented that requires:

a. A pest control service that uses certified applicators as specified in 3 A.A.C. 8, Article 2; and

b. Annual pest control service records to be retained for at least 12 months after the date of service; and

2. The procurement organization does not engage in any practice or create any condition that would constitute a public health nuisance, as specified in A.R.S. § 36-601, or is contrary to the health laws of this state.

C. A licensee of a non-accredited procurement organization shall ensure that:

1. Areas used to receive or prepare non-transplant anatomical donations or to label or package non-transplant anatomical material:

a. Are properly ventilated;

b. Have sanitary flooring and drainage;

c. Are protected from dust, dirt, flies, and other contamination;

d. Are only used, as applicable, for examining and preparing non-transplant anatomical donations or for labeling or packaging non-transplant anatomical material;

e. Are thoroughly cleansed and disinfected with a 1% solution of chlorinated soda, or other suitable and effective disinfectant, immediately after an obvious spill of blood or other potentially infectious bodily fluid or material;

f. Contain the equipment, instruments, and supplies necessary for accomplishing the tasks for which the areas are used that are:

i. Sufficient to accomplish the tasks;

ii. Maintained in working condition;

iii. Maintained in a clean and sanitary condition and disinfected or sanitized, as applicable, after each use;

iv. Used according to the manufacturer's recommendations; and

v. If applicable, tested and calibrated according to the manufacturer's

recommendations or, if there are no manufacturer's recommendations, as specified in standard operating procedures;

g. Are disinfected after each use to protect the health and safety of technicians and other personnel members;

h. Are maintained in a clean and sanitary condition at all times; and

i. Have proper and convenient receptacles for refuse, bandages, and all other waste materials; and

2. All refuse and waste products produced from receiving, preparing, packaging, distributing, and transporting non-transplant anatomical donations or non-transplant anatomical material are removed from the premises as needed.

D. A licensee of a non-accredited procurement organization shall ensure that the procurement organization has refrigerated areas for storing non-transplant anatomical donations and non-transplant anatomical material that:

1. Are only used for non-transplant anatomical donations or non-transplant anatomical material;
2. Are maintained in working order;
3. Are kept in a clean and sanitary condition;
4. If a walk-in cooler, maintains a temperature between 36°F and 45°F;
5. If a freezer, maintains a temperature at or below 32°F; and
6. Are monitored by a temperature sensor system that:
   a. Measures temperatures continuously and documents when a unit is out of the required temperature range, and
   b. Alerts technicians or other designated individuals when temperatures are outside of the acceptable limits.

E. A licensee of a non-accredited procurement organization shall maintain documentation of equipment tests, calibrations, and repairs for at least 12 months after the date of testing, calibration, or repair.

F. A licensee of a non-accredited procurement organization shall ensure that:

1. Biohazardous material or medical waste and other potentially hazardous materials are removed and disposed of by a facility licensed by the Arizona Department of Environmental Quality pursuant to 18 A.A.C. 8 and 13; and
2. Combustible or flammable liquids are stored in labeled containers or safety containers in a secured area and properly identified to ensure the health and safety of personnel members and the public.

R9-9A-302. Emergency and Safety Standards

A. An administrator of a non-accredited procurement organization shall ensure that:

1. Standard operating procedures are developed, documented, and maintained for the emergency transfer of non-transplant anatomical donations and non-transplant anatomical material to a designated back-up storage facility when the quality or security of non-transplant anatomical donations or non-transplant anatomical material may be compromised, including:
    a. The situations that would require an emergency transfer, including time limits and temperature tolerance for loss of refrigeration capability;
    b. The location of the back-up storage facility;
    c. The actions to be taken by the administrator and personnel members;
    d. The methods to be used for the emergency transfer;
    e. Specific labeling indicating that the transported non-transplant anatomical donations and non-transplant anatomical material must remain untouched until returned to the licensed non-accredited procurement facility after the situation has been resolved; and
    f. Requirements for the situation that resulted in an emergency transfer to be reviewed through the quality management program in R9-9A-203(A)(3) to prevent a recurrence;
2. A first aid kit is available at the procurement organization;
3. Smoke detectors are:
    a. Installed according to building size and the requirements of the local zoning jurisdiction;
    b. Maintained in an operable condition; and
    c. Either battery operated or, if hard-wired into the electrical system of the procurement organization, have a back-up battery;
4. A portable fire extinguisher that is labeled 2A-10-BC by the Underwriters Laboratory:
    a. Is readily available for use;
    b. For a disposable fire extinguisher, is replaced when the fire extinguisher's indicator reaches the red zone; and
    c. For a non-disposable fire extinguisher, is serviced at least every 12 months and has a tag attached to the fire extinguisher that includes the date of service; and
5. A written fire and evacuation plan is established and maintained.

B. An administrator of a non-accredited procurement organization shall:

1. Obtain a fire inspection conducted according to the time-frame established by the local fire department or the State Fire Marshal,
2. Make any repairs or corrections stated on the fire inspection report, and
3. Maintain documentation of a current fire inspection.

R9-9A-303. Security Standards; Inventory Controls

A. A licensee of a non-accredited procurement organization shall ensure that access to the enclosed-locked areas where non-transplant anatomical donations and non-transplant anatomical material are located is limited to individuals authorized by the licensee or administrator.

B. An administrator of a non-accredited procurement organization shall ensure that:

1. Standard operating procedures are developed, documented, and maintained to prevent unauthorized access to non-transplant anatomical donation or non-transplant anatomical material inventory that:
   a. Restricts access to the areas of the building that contain non-transplant anatomical donations or non-transplant anatomical material inventory and donor records,
   b. Provides for identification of authorized individuals, and
   c. Specifies the methods for conducting electronic monitoring;
2. Personnel or security equipment to deter and prevent unauthorized entrance into limited access areas are present and operational include:
   a. Devices or a series of devices to detect unauthorized intrusion, which may include a signal system interconnected with a radio-frequency device or other mechanical or electronic devices;
   b. Exterior lighting to facilitate surveillance; and
   c. Electronic monitoring using video cameras to provide coverage of:
      i. Entrances to and exits from limited access areas, and
      ii. Entrances to and exits from the buildings;
3. Video recordings from the video cameras required in subsection (B)(2)(c) are retained for at least 30 calendar days;
4. The electronic monitoring system in subsection (B)(2)(c) has a failure notification system that provides an audible and visual notification of any failure in the electronic monitoring system; and
5. Battery backup is present and operational to ensure the functioning of video cameras and recording equipment in the event of a power outage.

C. A licensee of a non-accredited procurement organization shall establish and implement an

inventory tracking system for non-transplant anatomical donations and non-transplant anatomical material that:

1. Contains information about all non-transplant anatomical donations received and non-transplant anatomical material released for distribution;
2. Includes release documentation related to requirements in R9-9A-201(B), and R9-9A-203(C) and (K), for each item of non-transplant anatomical material prior to transferring the item of non-transplant anatomical material to inventory;
3. Documents the date, time, and location for non-transplant anatomical material transferred for use, including:
    a. The name of the individual performing the transfer, and
    b. The name and contact information for an end-user or other person to which non-transplant anatomical material may be transferred;
4. Documents the date, time, and location for items of non-transplant anatomical material that are moved between locations controlled by the procurement organization, including the name of the individual overseeing the move; and
5. Ensures non-transplant anatomical material that can no longer be used is removed from inventory and disposed of according to applicable standard operating procedures for final disposition.