TITLE 9. HEALTH SERVICES

CHAPTER 9. DEPARTMENT OF HEALTH SERVICES - PROCUREMENT ORGANIZATIONS

The table of contents on page one contains links to the referenced page numbers in this Chapter. Refer to the notes at the end of a Section to learn about the history of a rule as it was published in the Arizona Administrative Register.

This Chapter contains rules that were filed to be codified in the Arizona Administrative Code between the dates of April 1, 2022 through June 30, 2022

This Chapter is new. Refer to the table of contents on page one for a list of rules codified in this supplement.

Questions about these rules? Contact:

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This Chapter is new.
PREFACE

Under Arizona law, the Department of State, Office of the Secretary of State (Office), Administrative Rules Division, accepts state agency rule notice and other legal filings and is the publisher of Arizona rules. The Office of the Secretary of State does not interpret or enforce rules in the Administrative Code. Questions about rules should be directed to the state agency responsible for the promulgation of the rule.

Scott Cancelosi, Director
ADMINISTRATIVE RULES DIVISION

RULES
The definition for a rule is provided for under A.R.S. § 41-1001. "'Rule' means an agency statement of general applicability that implements, interprets, or prescribes law or policy, or describes the procedures or practice requirements of an agency."

THE ADMINISTRATIVE CODE
The Arizona Administrative Code is where the official rules of the state of Arizona are published. The Code is the official codification of rules that govern state agencies, boards, and commissions.

The Code is separated by subject into Titles. Titles are divided into Chapters. A Chapter includes state agency rules. Rules in Chapters are divided into Articles, then Sections. The "R" stands for "rule" with a sequential numbering and lettering outline separated into subsections.

Rules are codified quarterly in the Code. Supplement release dates are printed on the footers of each Chapter.

First Quarter: January 1 - March 31
Second Quarter: April 1 - June 30
Third Quarter: July 1 - September 30
Fourth Quarter: October 1 - December 31

For example, the first supplement for the first quarter of 2022 is cited as Supp. 22-1. Supplements are traditionally released three to four weeks after the end of the quarter because filings are accepted until the last day of the quarter.

Please note: The Office publishes by Chapter, not by individual rule Section. Therefore there might be only a few Sections codified in each Chapter released in a supplement. This is why the Office lists only updated codified Sections on the previous page.

RULE HISTORY
Refer to the HISTORICAL NOTE at the end of each Section for the effective date of a rule. The note also includes the Register volume and page number in which the notice was published (A.A.R.) and beginning in supplement 21-4, the date the notice was published in the Register.

AUTHENTICATION OF PDF CODE CHAPTERS
The Office began to authenticate Chapters of the Code in Supp. 18-1 to comply with A.R.S. § 41-1012(B) and A.R.S. § 5302(1), (2)(d) through (e), and (3)(d) through (e).

A certification verifies the authenticity of each Code Chapter posted as it is released by the Office of the Secretary of State. The authenticated pdf of the Code includes an integrity mark with a certificate ID. Users should check the validity of the signature, especially if the pdf has been downloaded. If the digital signature is invalid it means the document’s content has been compromised.

HOW TO USE THE CODE
Rules may be in effect before a supplement is released by the Office. Therefore, the user should refer to issues of the Arizona Administrative Register for recent updates to rule Sections.

ARIZONA REVISED STATUTE REFERENCES
The Arizona Revised Statutes (A.R.S.) are available online at the Legislature’s website, www.azleg.gov. An agency’s authority note to make rules is often included at the beginning of a Chapter. Other Arizona statutes may be referenced in rule under the A.R.S. acronym.

SESSION LAW REFERENCES
Arizona Session Law references in a Chapter can be found at the Secretary of State’s website, www.azsos.gov under Services-> Legislative Filings.

EXEMPTIONS FROM THE APA
It is not uncommon for an agency to be exempt from the steps outlined in the rulemaking process as specified in the Arizona Administrative Procedures Act, also known as the APA (Arizona Revised Statutes, Title 41, Chapter 6, Articles 1 through 10). Other agencies may be given an exemption to certain provisions of the Act.

An agency’s exemption is written in law by the Arizona State Legislature or under a referendum or initiative passed into law by Arizona voters.

When an agency files an exempt rulemaking package with our Office it specifies the law exemption in what is called the preamble of rulemaking. The preamble is published in the Register online at www.azsos.gov/rules, click on the Administrative Register link.

Editor’s notes at the beginning of a Chapter provide information about rulemaking Sections made by exempt rulemaking. Exempt rulemaking notes are also included in the historical note at the end of a rulemaking Section.

The Office makes a distinction to certain exemptions because some rules are made without receiving input from stakeholders or the public. Other exemptions may require an agency to propose exempt rules at a public hearing.

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Rhonda Paschal, rules managing editor, assisted with the editing of this Chapter.
TITLE 9. HEALTH SERVICES

CHAPTER 9. DEPARTMENT OF HEALTH SERVICES - PROCUREMENT ORGANIZATIONS

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

Supp. 22-2

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ARTICLE 1. PROCUREMENT ORGANIZATION LICENSURE

R9-9-101. Definitions
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.
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.
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 in 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 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.
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).

Historical Note
New Section made by final rulemaking at 28 A.A.R. 1517 (July 1, 2022), with an immediate effective date of June 8, 2022 (Supp. 22-2).

R9-9-103. Individuals to Act for an Applicant or Licensee
When an applicant or licensee is required by this Chapter to provide information 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;

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.

Historical Note
New Section made by final rulemaking at 28 A.A.R. 1517 (July 1, 2022), with an immediate effective date of June 8, 2022 (Supp. 22-2).

R9-9-104. Application for Licensure
A. An application 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;
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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.

Historical Note

New Section made by final rulemaking at 28 A.A.R. 1517 (July 1, 2022), with an immediate effective date of June 8, 2022 (Supp. 22-2).

R9-9-105. 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 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.

Historical Note

New Section made by final rulemaking at 28 A.A.R. 1517 (July 1, 2022), with an immediate effective date of June 8, 2022 (Supp. 22-2).

R9-9-106. Changes Affecting a License

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

   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 the licensees’ license to operate a procurement organization as of the effective date 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.

Historical Note

New Section made by final rulemaking at 28 A.A.R. 1517 (July 1, 2022), with an immediate effective date of June 8, 2022 (Supp. 22-2).

R9-9-107. 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 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.

Historical Note
New Section made by final rulemaking at 28 A.A.R. 1517 (July 1, 2022), with an immediate effective date of June 8, 2022 (Supp. 22-2).

R9-9-108. Time-frames

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:

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 that 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 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.

Historical Note
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New Section made by final rulemaking at 28 A.A.R. 1517 (July 1, 2022), with an immediate effective date of June 8, 2022 (Supp. 22-2).

Table 1.1. Time-frames (in calendar days)

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<th>Overall Time-Frame</th>
<th>Administrative Completeness Review Time-Frame</th>
<th>Substantive Review Time-Frame</th>
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<td>30</td>
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<tr>
<td>Application for License Renewal</td>
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<td>Modification Change Request Affecting License</td>
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<td>60</td>
<td>30</td>
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</tr>
</tbody>
</table>

Historical Note

New Table 1.1 made by final rulemaking at 28 A.A.R. 1517 (July 1, 2022), with an immediate effective date of June 8, 2022 (Supp. 22-2).

ARTICLE 2. ADMINISTRATION FOR A NON-ACCREDITED PROCUREMENT ORGANIZATION

R9-9-201. Administration

A. A licensee of 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;
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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)(3)(f):

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.

Historical Note
New Section made by final rulemaking at 28 A.A.R. 1517 (July 1, 2022), with an immediate effective date of June 8, 2022 (Supp. 22-2).

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.

Historical Note
New Section made by final rulemaking at 28 A.A.R. 1517 (July 1, 2022), with an immediate effective date of June 8, 2022 (Supp. 22-2).

R9-9-203. Contracted Services
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.

Historical Note
New Section made by final rulemaking at 28 A.A.R. 1517 (July 1, 2022), with an immediate effective date of June 8, 2022 (Supp. 22-2).
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R9-9-204. Medical Director, Administrator, Technicians, and Personnel Members

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.

Historical Note
New Section made by final rulemaking at 28 A.A.R. 1517 (July 1, 2022), with an immediate effective date of June 8, 2022 (Supp. 22-2).

R9-9-205. Donor Records

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); and
3. The donor’s date of birth and date of death; and...
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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.

Historical Note
New Section made by final rulemaking at 28 A.A.R. 1517 (July 1, 2022), with an immediate effective date of June 8, 2022 (Supp. 22-2).

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

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

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. Retains annual pest control service records for at least 12 months from date of service; and
   e. Transfusion or infusion information; and
   f. Plasma dilution calculations;

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. Provides a separate and designated area for tissue recovery.

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
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 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 (A)(5)(ii);
 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.

 Historical Note
 New Section made by final rulemaking at 28 A.A.R. 1517 (July 1, 2022), with an immediate effective date of June 8, 2022 (Supp. 22-2).

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

 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;
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9 A.C. 9

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

A. If a non-accredited procurement organization owns and main

B. If using another vehicle or type of transport for NTAD or

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

R9-9-304. Transportation Standards

A. If a non-accredited procurement organization owns and main

B. If using another vehicle or type of transport for NTAD or

C. An administrator of a non-accredited procurement organiza

Historical Note

New Section made by final rulemaking at 28 A.A.R.
1517 (July 1, 2022), with an immediate effective date of
June 8, 2022 (Supp. 22-2).

R9-9-305. Sanitation Standards and Reporting

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

B. A technician or personnel member of a non-accredited pro

C. If an administrator or medical director of a non-accredited pro

Historical Note

New Section made by final rulemaking at 28 A.A.R.
1517 (July 1, 2022), with an immediate effective date of
June 8, 2022 (Supp. 22-2).

ARTICLE 4. ADMINISTRATION FOR AN ACCREDITED PROCUREMENT ORGANIZATION

R9-9-401. General Responsibilities

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.

**Historical Note**
New Section made by final rulemaking at 28 A.A.R. 1517 (July 1, 2022), with an immediate effective date of June 8, 2022 (Supp. 22-2).

**R9-9-402. Donor Consent; NTAD and NAM Identification**
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 identifier using a combination of letters, numbers, and symbols for NTAD or NAM;
   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.

**Historical Note**
New Section made by final rulemaking at 28 A.A.R. 1517 (July 1, 2022), with an immediate effective date of June 8, 2022 (Supp. 22-2).

**R9-9-403. Tissue End-Users**
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.

**Historical Note**
New Section made by final rulemaking at 28 A.A.R. 1517 (July 1, 2022), with an immediate effective date of June 8, 2022 (Supp. 22-2).