Standards for Accreditation for Non-Transplantable

Tissue Banks & Bioskills Facilities

3rd Edition

THE AMERICAN MEDICAL EDUCATION

AMERA

AND RESEARCH ASSOCIATION

American Medical Education and Research Association

Standards for Accreditation for Non-Transplantable Tissue Banks & Bioskills Facilities

3rd Edition

Dedication

It is only through the generous and selfless acts of individuals and their families that we may endeavor to bring hope to future generations. Without these precious gifts, the education of future health professionals and disease research would not be possible. This edition of the Standards is dedicated to all who have donated and will donate to further medical education and research. Their decision to better the lives of future generations through donation will leave a lasting legacy to others so they may follow in their footsteps in giving hope meaning.

Acknowledgment

The following individuals are to be recognized for their efforts in drafting this Third Edition of the American Medical Education and Research Associations Standards for Accreditation for Institutional Accreditation & Vendor Approval (In no particular order).

Mary Jean Gradisar
Matt Marcotte
Michelle Grabek
Robin Bozarth
Santina Harmon
Karl Rexroat
Alyssa Harrison
Liu Cheng
Garland Shreves
Amanda Rodgers
Andy Medvec

AMERA Board Members

John Cover (Chair)
William Bichard
April Salsbury
Richard Knott
David Little
Julie Treumann
James McElroy
David Irvin
Ken Willmott

AMERA Executive Director

Johnell Fleming

Introduction

History has recorded the anatomical study of the human body for education and research. This has been a critical component of medical innovation throughout the world. The use of human tissue for anatomical study has been responsible for the continuous education of new generations of medical professionals, i.e.; physicians, surgeons, nurses, physical therapists, and emergency services personnel. The use of human tissue for medical research has been the primary catalyst for medical innovation in many medical disciplines, i.e.; orthopedic device, medical device, drug delivery mechanisms, disease research and new surgical techniques.

Without human tissue for medical research and education the advancement of medical science would be severely limited, if not crippled. The use of human tissue to train medical practitioners and advance cures for disease causing pathogens is an invaluable service to mankind. Since donated human tissue is such a precious gift, the responsibility of proper stewardship of donors and protection of those handling the tissue is paramount.

The Revised Uniform Anatomical Gift Act (UAGA) is promulgated by the National Conference of Commissioners on Uniform State Laws (NCCUSL) and sets forth recommendations for each State to adopt regarding the recovery and use of tissue for transplantation and research and education. Each State's UAGA provides a base level of uniformity regarding the donation process but does vary from state to state on donation instruments and restrictions placed on who can donate and who can receive human tissue for transplant and medical research and education. The use of non-transplantable tissue for medical research and education is often considered a poorly understood emerging field with little regulatory oversight. Because there is still limited oversight, this Third edition of AMERA Standards represents a significant advancement in the control and proper stewardship of non-transplantable tissue.

These Standards offer an Organization that recovers, stores, distributes, transport and/or uses non-transplantable tissue for medical research and education a pathway towards higher Standards of performance and compliance. These Standards are designed to ensure that all donors and donations are treated with respect and dignity at all times, the safety of all that handle non-transplantable tissue and to ensure a strong supply of non-transplantable tissue for medical research and education for years to come. It is for these reasons that AMERA strongly encourages all organizations covered by these Standards to seek voluntary accreditation to set the highest Standards of excellence for the gift and stewardship of tissue for benefiting medical research and education.

Table of Contents

Preamble

These Standards, as adopted by AMERA's Board of Governors, should be viewed not only as a basis for accreditation, but also as an educational tool designed to increase awareness into the field of medical education & research and as a road map for institutions/organizations seeking to increase oversight and compliance within their organizations(s). These Standards should not be considered all inclusive of everything an institution/organization must do to operate at the level to which brings credibility and transparency to this industry. They should be viewed as the minimum Standards that an organization/institution must take to operate at a level that ensures compliance with law, protection of the public trust, assurance of safe tissue and the intolerance of individuals that would seek to undermine these values for personal gain at the expense of the public welfare.

AMERA is a strong proponent and vocal advocate for tissue transplantation because of its inherent lifesaving nature. AMERA believes that tissue for transplantation takes priority of tissue for medical research and education when potential exists for transplantation. However, AMERA equally believes that both donation options should be made available to donor families. All organizations must understand that both donation options are possible and should work together to maximize the gift and potential benefits for all mankind. AMERA is also a strong proponent of legislation that protects the public's right to choose donation options and the right to gift to the organization of their choosing.

These Standards encompass both Level 1 and level 2 requirements for accreditation. **The Standards for Level 1 accreditation are typed in normal font, whereas the Standards for Level 2 accreditation are delineated by an <u>underline</u>.** For ease of understanding and assimilation of information, both Level 1 and Level 2 Standards have been merged together in each section so the reader may gain a sense of the construction and relationship of each level of Standards to each other and the subject matter. When possible, these Standards have been constructed to be in compliance with applicable federal and state law and have been benchmarked against laws internationally in order to ensure that AMERA accredited institutions/organizations will be able to easily remain compliant regardless of where it conducts its activities.

The terms *Shall* and *Must* are interchangeable terms that indicate complete compliance with these Standards. The term *Should* indicates a recommendation by AMERA but is not required for accreditation to a Standard(s). The term *May* indicates an option given to the Organization as it pertains to adherence to a Standard(s).

1.0 Accreditation Policies

1.1 Applicability

1.1.1 All Organizations accredited by The American Medical Education and Research Association (AMERA) must voluntarily comply with all applicable requirements contained within these Standards.

1.2 Accreditation Process Overview

1.2.1 The accreditation process is managed by AMERA through written agreements with third party auditors. Because AMERA is a peer recognized authority that is comprised of individuals that represent the industry, AMERA representatives will not have access to any confidential/privileged information gained through the accreditation process. All information used to evaluate an Organization's compliance to these Standards will be sent directly to the third party auditors for evaluation. AMERA will be informed of the result of the accreditation audit/inspection process in order to issue the pertinent accreditation. This process will ensure complete transparency while protecting the proprietary and confidential material of each Organization.

1.2.2 All Organizational units that are either geographically separated or are registered distinct corporate entities must be accredited individually.

1.3 Level 1 Accreditation

1.3.1 Level 1 Accreditation is the baseline level accreditation offered to Organizations that have demonstrated adherence to AMERA's Level 1 Accreditation Standards. Level 1 Accreditation is a self-assessment based inspection process through with the Organization submits documentation (objective evidence) to AMERA that supports their claim of adherence to all applicable Level 1 Standards. Level 1 Accreditation is the entry level accreditation and represents a large step for an Organization to make when attempting to elevate its operations in recognition of its peers. Organizations that have achieved Level 1 Accreditation have chosen to hold themselves to a higher standard and code of conduct and have started down a path that will help elevate their own credibility and elevate the credibility of the entire industry.

1.3.2 Level 1 Process

1.3.2.1 Level 1 Accreditation begins when the Organization becomes an Institutional Member and applies for Level 1 Accreditation.

1.3.2.2 Once AMERA is contacted, a Level 1 Self-Assessment application is sent to the Organization. The Level 1 application packet contains an application and a self-assessment checklist. The completion of the self-assessment checklist requires substantial amounts of documentation to support the adherence claims made by the applicant Organization.

1.3.2.3 The applicant Organization must complete the packet and submit the completed packet and all supporting documentation directly to AMERA's independent auditing firm within 90 days from when the Organization received the packet.

1.3.2.4 If the completed application packet is not received within the 90 day time frame then the applicant Organization must submit an extension request to AMERA or be removed from the Level 1 Accreditation process and must forfeit any fees paid to that point.

1.3.2.5 Once the completed packet is received by the independent auditor AMERA will be notified by the auditor that the packet was received.

1.3.2.6 The independent auditor will have 14 days to review the packet and perform the following:

1.3.2.6.1 Notify the applicant Organization of all deficiencies and require corrective action to be completed to bring the applicant Organization into compliance within 60 days or;

1.3.2.6.2 Notify AMERA that the applicant Organization has met all the criteria for Level 1 Accreditation.

1.3.2.7 Once the applicant Organization has demonstrated compliance with Level 1 Accreditation Standards AMERA will then grant the Level 1 accreditation.

1.3.2.8 Level 1 Accreditation can only be granted for a time period of no greater than 18 months from the day of issuance. Organization s must apply for Level 2 Accreditation within this 18 month period or they will lose their Level 1 Accreditation and must reapply for Level 2 Accreditation prior to any further consideration.

1.3.2.9 If the Organization could not demonstrate adherence to the Level 1 Standards, then the Organization will fail the Level 1 Accreditation Process and must wait a minimum of 6 months (from the date of the previous inspection) to re-apply for Level 1 Accreditation.

1.4 Level 2 Accreditation

1.4.1 Level 2 Accreditation is the highest level accreditation offered to Organizations that have demonstrated adherence to AMERA's Level 2 Accreditation Standards. Organizations demonstrate adherence through the submission of objective evidence of adherence of Level 2 Standards to AMERA. Even though Level 1 Accreditation is the entry level accreditation it still represents a large step for an Organization to make. Organizations that have achieved Level 1 Accreditation have chosen to hold themselves to a higher standard and code of conduct and should be recognized for their efforts. Organizations that have achieved Level 2 Accreditation are the standard bearers for the industry.

1.4.2 Level 2 Process

1.4.2.1 Level 2 Accreditation process begins when the Organization has previously gained Level 1 Accreditation within the preceding 18 months and has applied for Level 2 Accreditation.

1.4.2.2 Once AMERA is contacted, a Level 2 inspection is scheduled by the independent audit authority. The Organization is required to allow the auditor complete access to the Organization's facility, materials, and all files needed to effectively evaluate compliance to these Standards. Failure to allow access will result in a failed inspection. Full access is essential to independently verify the adherence claims made by the applicant Organization.

1.4.2.2.1 The Level 2 inspection will be scheduled no later than 60 days from the date the application was received by AMERA.

1.4.2.2.2 The Level 2 inspection can only be performed by AMERA's independent audit authority.

1.4.2.3 If the Level 2 audit cannot be completed within the 60 day time frame, the Organization must submit an extension request to AMERA. Only a single extension of 30 days can be granted to complete the inspection. If the

inspection cannot be completed within that time frame (as a result of the applicant Organization) then the applicant Organization must be removed from the Level 2 Accreditation process and must forfeit any fees paid throughout that point.

1.4.2.4 Once the inspection is completed by the independent auditor, AMERA will be notified of the inspection results without the disclosure of the exact inspection findings or any objective evidence gathered during the inspection.

1.4.2.5 The inspection results will be comprised of the nature of the deviations, the number of the deviations, the severity of the deviations and the recommendation for Accreditation status.

1.4.2.6 The independent auditor will have 14 days to complete the audit report and perform the following:

1.4.2.6.1 Notify the applicant Organization of all deficiencies and require corrective action to be completed to bring the applicant Organization into compliance within 90 days or;

1.4.2.6.2 Notify AMERA that the applicant Organization has met all the criteria for Level 2 Accreditation.

1.4.2.7 If the Organization has deficiencies identified in the audit, then the Organization shall have 30 days to respond to the auditor with a corrective action plan to bring the Organization into compliance.

1.4.2.7.1 The Organization shall then have an additional 60 days to complete the corrective action.

1.4.2.7.2 The independent auditor will determine if the corrective action objective evidence is sufficient or if a follow up inspection is required to determine compliance with AMERA standards.

1.4.2.7.3 AMERA's Board of Governors shall approve all requests for additional time to complete corrective action.

1.4.2.8 Once the applicant Organization has demonstrated compliance with Level 2 Accreditation Standards AMERA will then grant the Level 2 accreditation.

1.4.2.9 Level 2 Accreditation can only be granted for a time period of no greater than 36 months from the day of issuance. Organizations must renew Level

2 Accreditation within this 36 month period or they will lose their Level 2 Accreditation and must re-apply for Level 2 Accreditation prior to any further consideration.

1.4.3 Accreditation Completion:

1.4.3.1 Upon completion of either the Level 1 or Level 2 accreditation process, AMERA will:

1.4.3.1.1 Award the Organization a Certificate of Accreditation and Seal of Accreditation.

1.4.3.1.2 The Certificate and Seal must be posted in a conspicuous location for the entire term of the accreditation.

1.4.3.1.3 A duplicate Certificate may be obtained if requested in writing.

1.4.3.1.4 The Certificate and Seal may only be used by the Organizational unit that underwent the accreditation process and may not be used by another Organizational unit within the Organization.

1.4.3.2 Upon Completion of the Level 2 accreditation process, the independent audit authority will destroy all ancillary audit materials within 30 days and retain the final audit report indefinitely.

1.4.3.2.1 Documentation of destruction or return of the Organization's ancillary materials shall be provided to the Organization immediately upon the act of destruction or return of the materials.

1.5 Adherence to these Standards:

1.5.1 Organizations wishing to deviate from any applicable requirements contained within these Standards must request a variance to AMERA and gain written approval from AMERA prior to engaging in activities that deviate from these Standards.

1.5.2 Any intentional or undocumented deviation from these Standards without an approved variance from AMERA may result in the Organization losing their accreditation as directed by AMERA's Board of Governors.

1.6 Adherence to International, Federal, State & Local Law:

1.6.1 An Organization must obey the laws of any country, state or local authority in which the Organization conducts its operations. The Organization must immediately report to AMERA all investigations into criminal or civil conduct (by a law enforcement or governmental agency) that has occurred either by the Organization, its officer(s) or directors of the Organization and report all outcomes once culpability has been determined by a court of law.

1.6.2 If an Organization has been found to be in violation of applicable law in its operation of accredited activities, the Organization's accreditation status will be reviewed by AMERA's Board of Governors during a special session. AMERA's Board of Governors will determine if the Organization will be allowed to retain their accreditation.

1.6.3 If an officer or director of an Organization has been found guilty of a crime related to its operation of accredited activities, the Organization's accreditation status will be reviewed by AMERA's Board of Governors. AMERA's Board of Governors will determine if the Organization will be allowed to retain their accreditation.

1.6.4 Accredited Organizations must be in and remain in good standing with the State's designated authority over corporations and entities in which the Organization is registered with.

2.0 Tissue Bank Organization

2.1 Responsible Parties

2.1.1 The Organization shall:

2.1.1.1 Identify an individual that is ultimately responsible for all accredited activities that occur within the Organization. That individual will serve as the Organization Director in addition to any other title that individual may have within the Organization. The Organization Director has operational authority over all accredited activities within the Organization.

2.1.1.2 The Organization shall maintain documentation of those individuals and their responsibilities.

2.1.1.3 Have clearly defined management in place that is responsible for all functionally separated activities within the Organization.

2.1.1.4 Have a Governing Board or other group of designated individual(s) that are ultimately responsible for all accredited activities within the Organization.

2.1.1.5 Have clearly defined management in place at all levels of the Organization that is responsible for all accredited activities within the Organization.

2.1.1.6 Must identify a physician as required by state law or qualified medical professional. That individual will serve at the Organization's Medical Director in addition to any other title that individual may hold within the Organization. The Medical Director may have medical/scientific authority over all Organizational units regardless of the state to which those units are located.

2.1.1.7 Maintain current Organizational charts that delineate all functional departments of the Organization and the relationship to the individuals responsible for them.

2.1.1.8 If management responsibility is provided by one Organization to another through the use of management services agreements, then the Organization providing those services are subject to the requirements of the services rendered contained within these Standards.

2.2 Agreements

2.2.1 The Organization shall have written contracts and/or agreements in place with any person/organization (entity) to which the actions of the entity would jeopardize the accredited activities of the Organization.

2.2.2 All contracts and agreements for accredited activities must be retained and made available for inspection.

2.2.2.1 All contracts and agreements shall clearly delineate the nature of the relationship, the areas of responsibility and recourse for when either party does not conform to the terms of the agreement.

2.2.2.2 Any financial information contained within the agreements may be redacted at the discretion of the Organization if the redaction does not impact the integrity of the agreement.

2.2.3 All clients entering into a tissue usage agreement with the Organization shall be reviewed to ensure that the client has demonstrated:

2.2.3.1 Sufficient resources to ensure compliance with the Organization's tissue use agreement and the Standards for Tissue usage.

2.2.3.2 Project merit in relation to the promotion of medical education and research.

2.2.3.3 Compliance with ethical use considerations and consent constraints.

2.2.3.4 Disposition conditions (if applicable).

2.2.4 All agreements must be retained for at least 10 years from the date the contract was terminated.

3.0 Tissue Bank Community Support

3.1 Support for Transplantation

3.1.1 Accredited Organizations must offer donor families either directly or through another organization, the option of tissue transplantation when the potential exists for a possible donation for transplantation.

3.1.2 Accredited Organizations must refer donor families to a state designated organ procurement organization or tissue recovery organization if the donor families intend to pursue donation for transplantation.

3.1.3 Once the transplant entity has either completed recovery activities or has denied the donor due to eligibility reasons, the Organization may then pursue donation for medical research and education.

3.1.4 At no time can an Organization charge the transplant organ/ tissue recovery organization a fee for access to the donor.

3.2 Donors & Donor Families

3.2.1 Potential donors, tissue procured from donors and donor families must always be treated with respect and dignity throughout the donation process.

3.2.2 The Organization must provide potential donors and donor family's access to after care information concerning support services during the registration and donation process.

3.2.2.1 Those services should be either provided by the Organization or be referred out to reputable providers that should not be affiliated with the Organization.

3.2.2.2 Services should encompass emotional, spiritual, mental needs and/or administrative concerns regarding the death of the donor and the bereavement process of the family.

3.2.3 All personal property of the donor shall be preserved, secured, tracked and released as directed by the legal next of kin. If not directed by the legal next of kin, the personal property must be disposed of according to state and local law.

3.2.4 All donor remains shall be cremated and returned as directed by the legal next of kin. If not, the donor remains shall be disposed of according to state and local law.

3.3 Public Welfare

3.3.1 The Organization shall engage in activities that contribute to the common good of the community to which the Organization serves.

3.3.2 The Organization shall not mislead the public through statements made, false marketing claims, misleading information and/or defamation of other organizations/institutions.

3.3.2.1 Comparisons made by the Organization to other competing organizations/institutions should be made fairly and without malice in the best interest of the general public welfare.

3.3.3 The Organization shall dedicate resources to informing the community about donation options and the donation process.

3.3.3.1 Those activities shall include charitable donations to organizations not affiliated with the Organization or its Organizational units.

3.3.3.2 Those activities shall be promoted without cost to the community.

4.0 Tissue Bank Personnel

4.1 Qualifications

4.1.1 Personnel shall be qualified to perform assigned accredited functions of the Organization.

4.1.2 Personnel qualification shall be determined through an evaluation of education, training and experience commensurate with the assigned job functions.

4.1.3 Personnel qualification must be documented through the maintenance of signed job descriptions.

4.2 Documentation

4.2.1 All documentation of personnel qualification shall be maintained by the Organization at all times, be made available for inspection upon request and be retained for a minimum of 5 years after the staff member separated from the Organization .

4.2.2 The Organization must have sufficient technical and administrative staff necessary to perform the accredited functions of the Organization.

4.2.3 The Organization must have sufficient management staff present and supervising the accredited activities of the Organization at all times.

4.2.3.1 Administrative and technical staff performing accredited activities must be aware of the proper supervisory/management staff made available to handle problems or answer questions during the course of accredited activities.

4.2.3.2 In the absence of assigned supervisory/management staff, administrative and technical staff performing accredited activities must be made aware of a designee assigned to handle problems or answer questions during the course of accredited activities.

4.2.4 The Organization shall demonstrate adequacy of resources as delineated in the Organization's organizational chart approved by executive management.

4.3 Commitment

4.3.1 Personnel performing accredited operations shall commit to the adherence of AMERA's code of ethics. Documentation of this commitment must be maintained by the Organization.

4.3.2 The actions and public statements of all staff in the Organization must adhere to AMERA's code of ethics at all times and must not reflect poorly on AMERA or its accredited members in any way.

5.0 Tissue Bank Equipment & Facilities

5.1 Equipment

5.1.1 The Organization shall demonstrate control over the installation and use of all equipment required for accredited operations.

5.1.2 The Organization must have adequate facilities, equipment and a process in place to secure, protect and easily retrieve documentation of accredited activities.

5.1.2.1 The documentation includes both hard copy and electronic records.

5.1.3 Equipment utilized for accredited operations within the Organization shall be:

5.1.3.1 Appropriate for the intended use.

5.1.3.2 Used according to manufacturer's guidelines/instructions.

5.1.3.3 Maintained in such a way that safety and efficacy are not compromised.

5.1.3.3.1 Preventative maintenance completed as per manufacturer's instructions.

5.1.3.3.2 Post service qualification to ensure proper operation.

5.1.3.3.3 Proper annual electrical qualification to determine electrical safety.

5.1.3.4 Stored in a manner that protects the integrity of the equipment and its operation.

5.1.3.5 Qualified prior to its use.

5.1.3.6 Properly labeled with the following:

5.1.3.6.1 Equipment identifier.

5.1.3.6.2 Annual electrical qualification.

5.1.3.6.3 Calibration/qualification date (if applicable).

5.1.3.6.4 Out of service identifier (if applicable).

5.1.3.6.5 Biohazard indicator (if applicable).

5.1.4 All equipment used in accredited operations shall have equipment records maintained to retain documentation specific to:

5.1.4.1 Preventative maintenance.

5.1.4.2 Repair history.

5.1.4.3 Cleaning history (if applicable).

5.1.4.4 Manufacturer's manuals/materials.

5.1.4.5 Equipment qualifications.

5.1.4.6 Dates that equipment went in and out of service.

5.1.4.7 Use of all equipment that is utilized for critical operations shall be directed through the Organization's standard operating procedures/work instructions.

5.1.5 All equipment records must be maintained for a minimum of 5 years after the equipment was permanently removed from service.

5.2 Instrumentation

5.2.1 All instrumentation used in accredited operations shall be:

5.2.1.1 Appropriately designed for the function to which they are used.

5.2.1.2 Sterilized, sanitized, disinfected and/or cleaned to the degree that they pose no undue health or safety risk to those that handle or use them.

5.2.1.3 Each Bioskills facility must inform all client's/attendees as to the cleaning methodology used at the Bioskills facility and define what that cleaning level means in regards to bio burden and risk of transmissible disease.

5.2.1.4 All instrumentation cleaning processes must be validated to ensure that the promoted cleaning level is accurate and achievable under the Bioskills facility's cleaning processes/procedures.

5.3 Facilities

5.3.1 Facilities used for accredited operations must:

5.3.1.1 Be appropriate in size, design and construction for the use of human tissue for medical education and research and:

5.3.1.1.1 Have secured and designated wet lab and tissue storage areas.

5.3.1.1.2 Floors and surfaces must be made of non-permeable material(s) to mitigate cross-contamination between donors and disease transmission risk for staff.

5.3.1.1.3 Recovery rooms must have a dedicated unit(s) that is a source of good ventilation to allow for multiple air changes per hour.

5.3.1.1.4 Have biohazard, fire, chemical, nuclear and general safety meet standards as per federal, state and regulatory code(s).

5.3.1.2 Be appropriate in size, design and construction for production of documents and electronic data.

5.3.1.3 Have security measures in place to prevent unauthorized access to restricted areas/data.

5.3.1.4 Be free from visible signs of pestilence.

5.3.1.5 Must be maintained at a level which is appropriate to ensure a safe and sanitary environment and the respect & dignity of the donors.

5.3.1.5.1 Facility Maintenance must be standardized and documented, to include:

5.3.1.5.1.1 Cleaning

5.3.1.5.1.2 Security

5.3.1.5.1.3 Temperature Monitoring

5.3.1.5.1.4 Pestilence Control

5.3.1.5.1.5 Disinfectant use and change-out

5.3.1.5.2 Documentation of facility maintenance must be maintained by the Organization and retained for a period of 5 years after facility closure.

5.3.1.6 Must operate within appropriate local zoning ordinances and be properly permitted to conduct accredited operations.

6.0 Tissue Bank Training, Competency Assessment & Continuing Education

6.1 Training

6.1.1 The Organization must demonstrate control over how the training of all staff is conducted and maintained for accredited operations.

6.1.2 All employees performing accredited operations must be trained at all times.

6.1.3 All employees must be initially trained on all policies and procedures applicable to their respective job function and annually thereafter.

6.1.4 All training activities must be:

6.1.4.1 Documented and performed concordantly with the performance of each step in the training process.

6.1.4.1.1 Documentation of training shall be maintained in the individual's training file or other appropriate tracking system and must be easily retrievable.

6.1.4.2 Performed in a setting conducive to learning by an individual designated to perform training.

6.1.4.2.1 Documentation of this individual as a trainer shall be maintained in the individual's training file.

6.1.4.3 Reviewed and approved prior to the trainee being allowed to perform the functions being trained.

6.1.4.4 Documentation of training must be maintained for a minimum of 5 years from the date that the staff member separated from the Organization.

6.2 Competency Assessment

6.2.1 The Organization must demonstrate control over how staff competency is obtained and maintained for accredited operations.

6.2.2 All employees performing technical operations must be deemed competent at all times.

6.2.2.1 The Organization must have a process in place to determine which process steps are technical in nature and thus require competency assessments for staff.

6.2.2.2 Competency assessments must be completed initially and annually thereafter.

6.2.3 All competency assessment activities must be:

6.2.3.1 Documented and performed concordantly with the performance of each step in the assessment process.

6.2.3.1.1 Documentation of the assessment shall be maintained in the individual's training file or other appropriate filing system and must be easily retrievable.

6.2.3.2 Performed in a "live" environment by an individual designated to perform the assessment.

6.2.3.2.1 Documentation of this individual as an assessor shall be maintained in the individual's training file.

6.2.3.3 Reviewed and approved prior to the trainee being allowed to perform the functions being assessed.

6.2.3.4 Documentation of competency assessment must be maintained for a minimum of 5 years from the date the staff member is no-longer employed with the Organization.

6.3 Continuing Education

6.3.1 The Organization should promote continuing education activities (conferences, workshops, seminars, training events, college courses, etc.) for its staff.

6.3.2 If staff completes continuing education activities then documentation of such activities shall be kept in the employee's training file.

6.3.3 If staff is required to attend continuing education events (to renew certifications/licenses, etc.) then documentation of such activities shall be kept in the employee's training file.

7.0 Tissue Bank Quality Program

7.1 Quality Program Elements

7.1.1 The Organization shall have a quality program that encompasses the following activities related to accredited activities:

7.1.2 Deviation management system designed to detect, correct and prevent errors from occurring and to ultimately improve a process.

7.1.2.1 The Organization must have a process in place to document and correct any deviation from policy, procedure, AMERA Standards, or applicable law.

7.1.2.1.1 Management of and approval authority over the deviation management system should be performed by a designated individual responsible for quality and regulatory activities.

7.1.2.2 Documentation of deviations, resulting investigation, root cause analysis, immediate and corrective action must be maintained by the Organization for a minimum of 5 years from the date of creation.

7.1.2.2.1 If the deviation is related to the safety or identity of the donor or tissue, then the deviation must be maintained by the Organization for a minimum of 5 years from the date of the tissue distribution.

7.1.3 Internal audit program designed to appraise the Organization's accredited activities on a routine basis or as management directs.

7.1.3.1 The Organization must have a process in place to routinely audit its accredited activities.

7.1.3.2 These audits shall encompass:

7.1.3.2.1 Internal operations

7.1.3.2.2 Critical suppliers of services (crematory, blood testing, transport, etc.

7.1.3.2.3 End users of tissue to determine compliance with tissue use agreements.

7.1.3.2.4 Audits must be completed at least annually unless there is documentation to support a greater audit frequency to remain in compliance with these Standards.

7.1.3.2.5 End user audits may be performed using a sampling plan found in ANSI/ASQ Z1.4 (current version).

7.1.4 Document control program designed to maintain controlled documents and changes to them on an ongoing basis.

7.1.4.1 The Organization must have a process in place to control, track and approve all changes/revisions made to its Standard Operation Procedure Manual (SOPM).

7.1.4.1.1 All documents pertaining to accredited activities must be retained within the SOPM.

7.1.4.1.2 All revisions to the SOPM must be:

7.1.4.1.2.1 Approved by a designated individual responsible for accredited activities.

7.1.4.1.2.2 Approved by a designated individual responsible for quality & regulatory activities.

7.1.4.1.3 Approved by the Organization's Medical Director or Designee if related to medical review or tissue safety.

7.1.4.2 The SOPM must be made available to all staff performing accredited activities at the site to which they are performing those activities.

8.0 Tissue Bank Donation Administration

8.1 Donor Acceptance

8.1.1 The Organization shall demonstrate control over all interactions required to accept a donor into the Organization's program.

8.1.2 All donor information gathered shall be protected by the Organization in accordance with the Health Insurance Portability and Accountability Act and not released to third parties unless allowed by law.

8.1.3 Every donor must be given a unique identifier that ensures traceability of the donor and subsequent donated tissue as well as protects the anonymity of the donor at all times.

8.1.4 The Organization shall abide by all applicable provisions contained within the Uniform Anatomical Gift Act from the state in which the donor was originally sourced.

8.1.4.1 All donors must be properly consented prior to the Organization taking custody as allowed by local and state law.

8.1.4.2 Donation consent must be constructed in such a way as to read at a level that is easily understood by the general public and must also delineate all aspects of:

8.1.4.2.1 The donation process.

8.1.4.2.2 The cremation process.

8.1.4.2.3 Release of medical information.

8.1.4.2.4 Serological testing and reporting.

8.1.4.2.5 Tissue procurement and storage.

8.1.4.2.6 Disclosure that a final determination of donor acceptance may be made at the time of death (if applicable).

8.1.4.2.7 Return of remains not used for medical education and research.

8.1.4.2.8 Potential tissue usage and or transfer.

8.1.4.2.9 Disposition methods.

8.1.4.2.10 All costs to the donor, legal next of kin, or donor's estate associated with all donation activities, transportation and the return of cremated remains.

8.1.4.3 The donor or donor family must have the opportunity to ask questions or request clarification regarding all aspects of the consent and donation process.

8.1.4.4 The consent must be signed by the donor (pre-mortem) or the donor's legal next of kin (post-mortem) as determined by the state's Uniform Anatomical Gift Act.

8.1.4.5 The consent must be witnessed by an individual not affiliated with the Organization at the time the consent was signed by the donor or the donor's legal next of kin.

8.1.4.5.1 All consent requirements must meet state requirements for informed consent and witnessing.

8.1.4.6 The consent may be completed in the following methods:

8.1.4.6.1 In writing with original or faxed consent forms

8.1.4.6.2 In writing with electronic submission (email content or attachments).

8.1.4.6.3 Taped telephonically.

8.1.4.6.3.1 If taped telephonically, all parties must be aware of the conversation being recorded, have given their consent to record and must be identified by name and relationship in the recording.

8.1.4.6.3.2 If taped telephonically, the elements and verbiage of the taped consent must not deviate from that of the original written consent.

8.1.4.6.3.3 The taped consent must be maintained by the organization for a retention time no less than written consent.

8.1.5 No financial payments, coercion or misleading statements shall be used in:

8.1.5.1 Gaining the consent of the donor or donor's legal next of kin.

8.1.5.2 Influencing the donor or donor's legal next of kin from making a donation for tissue transplantation in addition to medical research and education.

8.1.5.3 Ensuring a third party (funeral home, hospice, etc.) influences a donor or the donor's legal next of kin to make a decision to donate.

8.1.6 The Organization shall abide by all state laws in regards to obtaining transit permits, the transport of donors across state lines, airline regulations, state anatomical board rules, and death certificate filings.

8.1.7 All records pertaining to donor acceptance must be maintained indefinitely.

8.2 Donor Quarantine

8.2.1 The Organization is responsible for the delineation and documentation of a quarantine protocol that restricts the movement of donors in such a manner that mitigates cross contamination and ensures the safety of staff and tissue users.

8.3 Donor Medical Clearance

8.3.1 All donors must be subject to a medical clearance process that mitigates reasonable safety hazards prior to the donor being released for procurement.

8.3.2 Until approval of medical clearance is obtained, all donors shall be kept under quarantine conditions.

8.3.2.1 The donor's risk for infectious disease agents shall be evaluated through information received from applicable medical records and/or the best medical historian available.

8.3.2.1.1 The donor assessment questionnaire shall encompass the following infectious disease/hazardous agents at a minimum:

8.3.2.1.1.1 Hepatitis A, B & C.

8.3.2.1.1.2 Human Immunodeficiency Virus (HIV) 1 & 2.

8.3.2.1.1.3 Tuberculosis.

8.3.2.1.1.4 Genetic or Variant Creutzfeldt-Jakob Disease (vCJD).

8.3.2.1.1.5 Antibiotic Resistant Bacterial Infection

8.3.2.1.1.6 Active viral/bacterial infection at the time of death.

8.3.2.1.1.7 Radioactive Seed Implants.

8.3.2.1.1.8 Pacemaker.

8.3.2.1.1.9 Any other disease or hazardous agent(s) that would continue to pose as a health risk after death and cold storage.

8.3.2.1.2 The donor assessment questionnaire shall encompass the following documentation requirements:

8.3.2.1.2.1 The individual documenting the assessment.

8.3.2.1.2.2 The medical historian being interviewed.

8.3.2.1.2.3 The date of the assessment.

8.3.2.1.2.4 The signature and date of the individual documenting the assessment.

8.3.2.2 The plasma dilution of the donor's serum/blood shall be evaluated if the donor had recently received fluids prior to death.

8.3.2.2.1 All plasma dilution testing algorithms must meet the regulation found in 21 CFR 1271.

8.3.2.2.2 The plasma dilution testing algorithms should be completed, documented in the donor file and approved prior to blood draw for serological testing but must occur prior to the procured tissue from being released from quarantine.

8.3.2.3 A physical assessment of the donor body must be performed once the assessment questionnaire has been completed, reviewed and approved.

8.3.2.3.1 The physical assessment must include:

8.3.2.3.1.1 Verification of donor identity and how that verification was obtained.

8.3.2.3.1.2 Complete notation of all:

1. Surgical scars.
2. Wounds.
3. Implants.
4. Deformities.
5. Decomposition.
6. Indications of disease traits.
7. Any other medical abnormality required to determine proper suitability.

8.3.2.3.1.3 Complete record of any/all personal property belonging to the donor.

8.3.2.3.1.4 Name, signature and date of the individual(s) performing the physical assessment.

8.3.2.4 A serological blood draw must be performed prior to donor acceptance.

8.3.2.4.1 The serological blood draw must not be performed until consent has been obtained from the donor or the donor's legal next of kin and the plasma dilution testing algorithms have been evaluated and determined acceptable (if applicable).

8.3.2.4.2 The serological samples must be sent to an FDA registered and CLIA licensed testing facility and tested for the following serological screening markers:

8.3.2.4.2.1 Anti-HIV 1/2 AB plus O.

8.3.2.4.2.2 Anti-HCV AB.

8.3.2.4.2.3 HBsAg.

8.3.2.4.3 All repeatedly reactive serological results must be reflexed to the appropriate confirmatory test prior to accepting or rejecting the donor.

8.3.2.4.4 All confirmed positive serological results must be reported to the appropriate state's health authority as per state law.

8.3.2.5 The Organization must have a process in place for determining donor acceptability based on serological testing.

8.3.2.5.1 If tissue(s) are procured from donors that have been confirmed positive for a serological marker, then the tissue must be maintained under quarantine conditions for the entire lifespan of the tissue.

8.3.2.6 Universal precautions must be observed and proper personal protective equipment must be utilized when exposure to donors or human tissue is likely.

8.3.2.7 Medical Clearance

8.3.2.7.1 A complete review and approval of all medical information pertaining to the donor must be made prior to releasing the tissue from quarantine.

8.3.2.7.2 <u>This review must be documented and performed by the Medical Director or a documented Designee.</u>

8.3.2.7.3 <u>At no time can tissue that has been determined to have disease agents be cleared or released.</u>

8.3.2.7.3.1 Exception: Low Post-Mortem Procurements, when the serological results are not available in time for the required post-mortem interval (PMI) to meet customer requirements.

8.3.2.7.3.2 Exception: If the client knowingly accepts such tissue and the acceptance is documented in writing, then the tissue may be released under exceptional release circumstances.

8.3.2.7.3.3 All tissue with known disease agents procured and released for distribution must be labeled as "Biohazard" and information about the specific communicable disease agents must delineated.

8.3.2.7.3.4 All tissue with known disease agents must be packaged and shipped as per IATA and CDC standards/guidelines for transport.

8.3.2.7.3.5 All tissue with known disease agents must be stored under quarantine conditions and must be segregated by physical barriers from all other tissue.

8.3.3 Donor Acceptance Approval

8.3.3.1 A complete review of all donor information pertaining to donor acceptance must be made prior to the release of the donor for procurement. This review shall include:

8.3.3.1.1 Verification of medical clearance.

8.3.3.1.2 Verification of appropriate state authorization(s) for transit and disposition or medical examiner release.

8.3.3.1.3 Verification of informed consent for donation.

8.3.3.1.4 Verification of informed consent for cremation.

9.0 Tissue Bank Tissue Administration

9.1 Tissue Procurement

9.1.1 Once donor acceptance has been determined tissue procurement may begin.

9.1.1.1 The tissue procurement must take place within the confines of a designated area within the Organization that is suitable for retrieval of human tissue for medical education and research.

9.1.1.1.1 At no time can the tissue procurement be performed by individuals not employed or contracted by the Organization.

9.1.1.1.2 At no time can the tissue procurement be performed outside the Organization's facility (funeral home, hospital, morgue, etc).

9.1.1.2 The tissue procurement must be performed by trained staff and must not occur within view of the general public.

9.1.1.3 The donor identity must be verified prior to tissue procurement. This verification must be documented.

9.1.1.4 Universal precautions must be observed and proper personal protective equipment must be utilized when exposure to donors or human tissue is likely.

9.1.1.5 <u>All tissue procured for medical education and research must be assigned a unique identifier. That identifier must be either attached to the tissue or attached to the tissue container and must not be separated from the tissue through final disposition.</u>

9.2 Tissue Quarantine

9.2.1 The Organization is responsible for the delineation and documentation of a quarantine protocol that restricts the movement of tissue that does not conform to the Organization's SOPM and these Standards in such a manner that mitigates cross contamination and ensures that safety of staff and tissue users.

9.3 <u>Exceptional Release of Tissue</u>

9.3.1 <u>All tissue procured with confirmed positive serological results or prior to obtaining serological results shall conform to the following conditions:</u>

9.3.1.1 <u>Shall be handled under a documented exceptional release process.</u>

9.3.1.2 <u>The exceptional release process must be delineated in the Organization's SOPM.</u>

9.3.1.3 All aspects of tissue procurement, wrapping, labeling, storage, distribution, transport and use must be handled under the Organization's quarantine process.

9.3.1.4 All shipments must be labeled appropriately as per state, federal and international laws.

9.3.1.5 All clients receiving tissue distributed under exceptional release must have a signed exceptional release agreement on file that delineates the following:

9.3.1.5.1 The conditions under which the tissue will be transported and accepted by the client.

9.3.1.5.2 The reporting of the serological results when available.

9.3.1.5.3 The conditions under which the client can return tissue with confirmed positive serological results.

9.3.1.5.4 The conditions under which the client will use and safeguard its employees until the serological testing is complete and reported to the client.

9.3.1.5.5 Disposition of tissue if not returned to the Organization.

9.4 Wrapping and Labeling

9.4.1 All tissue procured must be wrapped and packaged in such a manner that:

9.4.1.1 Mitigates potential contamination/cross contamination.

9.4.1.2 Mitigates potential safety hazards.

9.4.1.3 Ensures the integrity of the tissue.

9.4.1.4 Ensures the dignity of the donor.

9.4.1.5 Meets customer requirements

9.4.2 All tissue procured must be labeled in such a manner that:

9.4.2.1 Ensures complete traceability of the tissue.

9.4.2.2 Are not easily marred or removed from tissue packaging by wear or by environment (temperature, moisture).

9.4.2.3 Must contain the following:

9.4.2.3.1 Unique donor identifier.

9.4.2.3.2 Tissue type.

9.4.2.3.3 Age.

9.4.2.3.4 Cause of death (if requested).

9.4.2.3.5 Name and contact information of the Organization.

9.4.2.3.6 Labeled as "Non-transplantable human tissue for medical research and education".

9.4.2.3.7 Labeled as "Not for transplantation".

9.4.2.3.8 A statement about the mandatory use of personal protective equipment and universal precautions when handling the tissue.

9.4.2.4 Label sets generated for tissue procurement shall remain physically segregated from label sets from other donors.

9.4.2.5 Labels generated but not used in tissue procurement shall be immediately destroyed and not re-used for other donors.

9.4.3 Upon completion of tissue wrapping, labeling and packaging all tissue must be inspected to ensure compliance with these Standards prior to being transferred into the Organization's inventory.

10.0 Tissue Bank Storage and Distribution

10.1 Donor Storage

10.1.1 All tissue shall be stored in such a manner that retards decomposition and preserves the donor until the time of procurement or disposition.

10.1.2 Each storage unit shall have its own unique identifier and must be maintained and as a piece of equipment used in accredited operations.

10.1.3 The Organization is responsible for setting appropriate temperature ranges for the storage of donors intended for medical research and education.

10.1.3.1 Donor storage conditions do not include conditions required for controlled thawing.

10.1.3.2 The temperature range for each storage unit shall be listed in that Organization's SOPM.

10.1.3.3 The temperature ranges shall be monitored and documented on a routine basis as established by the Organization's SOPM.

10.1.3.3.1 The monitoring of these ranges may be performed manually or by an automated method.

10.1.3.4 The Organization must have a documented course of action in place in the event of temperature excursions that would compromise the viability of the donor (natural disaster, loss of power, malfunction). This course of action shall be documented in the Organization's SOPM.

10.1.4 The Organization is responsible for ensuring that donors stored under quarantine must be labeled in such a way as to prevent cross contamination and mixed into donors that have been medically cleared for procurement or release into inventory.

10.2 Tissue Storage

10.2.1 All tissue shall be stored in such a manner that retards decomposition and preserves the tissue quality as long as possible.

10.2.2 Each storage unit shall have its own unique identifier and must be maintained and as a piece of equipment used in accredited operations.

10.2.3 The Organization is responsible for setting appropriate temperature ranges for the storage of tissue for medical research and education.

10.2.3.1 Tissue Storage conditions do not include conditions required for controlled thawing.

10.2.3.2 The temperature range for each storage unit shall be recorded in that Organization's SOPM.

10.2.3.3 The temperature ranges shall be monitored on a routine basis as established by the Organization's SOPM.

10.2.3.3.1 The monitoring of these ranges may be performed manually or by an automated method.

10.2.3.4 The Organization must have a documented course of action in place in the event of temperature excursions that would compromise the integrity of the tissue (natural disaster, loss of power, malfunction). This course of action shall be documented in the Organization's SOPM.

10.2.4 The Organization is responsible for ensuring that tissue stored under quarantine remains identified and segregated from tissue in inventory and must be labeled in such a way as to prevent it from being mixed into inventory.

10.3 Tissue Distribution

10.3.1 The Organization is responsible for ensuring that tissue is distributed under controlled conditions in such a manner that tissue(s) selected for distribution is reviewed and approved prior to transport.

10.3.1.1 Tissue intended for distribution shall be evaluated for the following prior to distribution approval:

10.3.1.1.1 Packaging integrity.

10.3.1.1.2 Labeling Integrity.

10.3.1.1.3 Tissue quality (if in question).

10.3.1.1.4 Positive identification.

10.3.1.2 Tissue shall be distributed in such a manner that ensures:

10.3.1.2.1 Conformance to customer requirements.

10.3.1.2.2 Conformance to state, federal and international laws and/or Standards (IATA) for packaging and labeling.

10.3.1.2.3 Conformance to common carrier rules and/or Standards for packaging, labeling weight, size container type container strength and refrigerant type and quantity.

10.3.1.2.4 Conformance to state, federal and international laws and/or standards for shipping untested human tissue under exceptional release protocols.

10.3.1.3 Tissue shipments shall be inspected by the individual performing the distribution activities and should be approved by another individual prior to shipment to ensure accuracy with the shipment and compliance to the Standards.

10.3.2 Records of all tissue distributed by the Organization to each client shall be maintained for a minimum of 5 years after the date of distribution.

11.0 Tissue Bank Tissue Transport

11.1 Tissue Transport via Forwarders and Common Carriers

11.1.1 Tissue intended for medical research and education shall be shipped by forwarders or common carriers that:

11.1.1.1 Have been approved by the Organization.

11.1.1.2 Specialize in the shipment of human tissue.

11.1.1.3 Have been approved by the Transportation Security Administration.

11.1.1.4 Have adequacy of resources to ensure the safe and effective transport, storage and delivery of human tissue both domestically and/or internationally.

11.1.2 All shipment receipts and delivery confirmations shall be maintained for a minimum of 5 years after the shipment date.

11.2 Tissue Transport via couriers

11.2.1 Shipment of human tissue via normal couriers (FedEx, DHL, UPS, etc.) are prohibited unless the shipment contents have been fully disclosed to the carrier and the carrier is willing to accept the shipment.

11.2.1.1 Documentation of this disclosure and acceptance shall be maintained by the Organization for a minimum of 5 years after the shipment date.

11.2.2 All shipment receipts and delivery confirmations shall be maintained for a minimum of 5 years after the shipment date.

12.0 Tissue Bank Tissue Use

12.1 Tissue Use Conditions:

12.1.1 The Organization is ultimately responsible for the adherence of the client to these tissue use Standards.

12.1.2 All tissue use by the Organization and its clients shall:

12.1.2.1 Conform to the conditions set forth in the informed consent.

12.1.2.2 Conform tissue usage must conform to local, state, federal and international law and the laws in the country to which the tissue is being used.

12.1.2.3 Conform to reasonable ethical standards.

12.1.2.4 Contribute to the field of medical education and research.

12.1.2.5 Ensure the respect and dignity of the donor.

12.1.2.6 Not reveal the identity of the donor.

12.1.3 In addition, the organization shall ensure that all tissue users and intermediaries:

12.1.3.1 Not remove the affixed donor identification tags that the organization placed on the tissue for traceability.

12.1.3.2 Not store the tissue for any extensive period of time greater than that which was disclosed on the tissue request forms or use agreements.

12.1.3.3 Not receive, prepare, process, store or alter human tissue in the same manner, using the same equipment, in the same room as animal tissue is received, prepared processed or stored.

12.1.3.4 Not allow general public access to, purchase of or transference of donated tissue or its derivatives.

12.1.3.5 Not allow viewing of, purchase through, or cataloging of specimens through general public accessible web sites or catalogues.

12.1.3.6 These provisions do not apply to animal tissue used in conjunction with human tissue in surgical simulations/Bioskills activities that contribute to the surgical experience and/or xenograft simulations.

12.1.4 Facilities utilized for the use of human tissue for medical education and research must conform to the following conditions:

12.1.4.1 Must conform to local, state and federal law.

12.1.4.2 Must not have general public access.

12.1.4.3 Must have proper security measures in place to prevent unauthorized access.

12.1.4.4 Must have proper tissue storage, tissue tracking and disposition methods (if required).

12.1.4.5 Must be constructed in such a way that minimizes contamination of the facility.

12.1.4.6 Must not be located in a funeral home, morgue, personal residence or other facility not zoned or considered appropriate for the use of human tissue for medical research and education.

12.1.4.7 Must have a designated individual responsible for the tissue and its usage on site at the time of the tissue receipt, storage, usage and possible disposal.

13.0 Tissue Bank Tissue Disposition

13.1 Disposition of Donor Remains

13.1.1 The Organization is responsible for the proper transfer and disposition of donor remains through the organization itself, the use of a licensed funeral establishment or crematory, as permitted by state and local laws.

13.1.2 The Organization must abide by all local and state laws regarding the cremation of donor remains.

13.1.3 Donor remains are considered human tissue not used for medical education and research.

13.1.3.1 The disposition of donor remains shall consist of one or more of the following:

13.1.3.1.1 Cremation and return to the legal next of kin or their designee.

13.1.3.1.2 Cremation and disposal via:

13.1.3.1.2.1 Lawful spreading of ashes on land.

13.1.3.1.2.2 Lawful spreading of ashes by sea or air.

13.1.3.1.2.3 Lawful internment of ashes in a public or private ossuary.

13.1.3.1.2.4 Lawful burial.

13.1.3.1.2.5 Disposal by any other lawful means.

13.1.3.2 At no time can un-cremated donor remains be returned to the legal next of kin.

13.2 Disposition of human tissue used or intended for medical research and education.

13.2.1 The Organization is responsible for the proper transfer and disposition of human tissue through the use of a licensed crematory, funeral home and/or incinerator as allowable by law.

13.2.2 The Organization must abide by all local, state and international laws regarding the disposal of human tissue.

13.2.3 At no time can un-cremated/non-incinerated human tissue be disposed of.

13.2.3.1 The disposition of donor remains shall consist of one or more of the following:

13.2.3.1.1 Cremation and return to the legal next of kin or their designee.

13.2.3.1.2 Cremation and disposal via:

13.2.3.1.2.1 Lawful spreading of ashes on land.

13.2.3.1.2.2 Lawful spreading of ashes by sea or air.

13.2.3.1.2.3 Lawful internment of ashes in a public or private ossuary.

13.2.3.1.2.4 Lawful burial.

13.2.3.1.2.5 Disposal by any other lawful means. Human tissue used for medical education and research are NOT considered donor remains and must not be returned to the next of kin unless specifically agreed to in advance of donor acceptance.

14.0 Bioskills Facility Organization

14.1 Responsible Parties

14.1.1 The Organization shall:

14.1.1.1 Identify an individual that is ultimately responsible for all accredited activities that occur within the Organization. That individual will serve as the Facility Director in addition to any other title that individual may have within the Organization. The Facility Director has operational authority over all accredited activities within the Organization.

14.1.1.2 The Organization shall maintain documentation of those individuals and their responsibilities.

14.1.1.3 Have clearly defined management in place that is responsible for all functionally separated activities within the Organization.

14.1.1.4 Have a Governing Board or other group of designated individual(s) that are ultimately responsible for all accredited activities within the Organization.

14.1.1.5 Have clearly defined management in place at all levels of the Organization that is responsible for all accredited activities within the Organization.

14.1.1.6 Maintain current Organizational charts that delineate all functional departments of the Organization and the relationship to the individuals responsible for them.

14.1.1.7 <u>If management responsibility is provided by one Organization to another through the use of management services agreements, then the Organization providing those services are subject to the requirements of the services rendered contained within these Standards.</u>

14.2 Agreements

14.2.1 The Organization shall have written contracts and/or agreements in place with any person/organization (entity) to which the actions of the entity would jeopardize the accredited activities of the Organization.

14.2.2 <u>Contract Requirements:</u>

14.2.2.1 <u>All contracts and agreements shall clearly delineate:</u>

14.2.2.1.1 The nature of the relationship, the areas of responsibility and recourse for when either party does not conform to the terms of the agreement.

14.2.2.1.2 A requirement that each party agrees to comply with all applicable AMERA standards.

14.2.2.1.3 A requirement that each party subcontracting out any portion of a service to which these Standards apply, shall ensure that the sub-contractor complies with all applicable Standards.

14.2.3 All contracts and agreements for accredited activities must be retained and made available for inspection.

14.2.3.1 Any financial/proprietary information contained within the agreements may be redacted at the discretion of the Organization if the redaction does not impact the integrity of the agreement.

14.2.4 All clients entering into a tissue usage/event agreement with the Organization shall be reviewed to ensure that the client has demonstrated:

14.2.4.1 Sufficient resources to ensure the client's compliance with the signed tissue use agreement, to include tissue consent, suitability, procurement, storage distribution and disposition.

14.2.4.2 Compliance with all state, federal law and IATA standards in regards to the transport of human tissue to the Organization's facility for use.

14.2.5 All agreements must be retained for at least 10 years from the date the contract was terminated.

15.0 Bioskills Facility Community Support

15.1 Donor Dignity & Respect

15.1.1 All tissues used by the Organization in their Bioskills Facility must always be treated with respect and dignity throughout the duration of custody of the Bioskills Facility.

15.1.2 All tissue usage must strictly conform to the conditions expressly documented in the donation authorization from the Tissue Bank where the tissue came from.

15.2 Public Welfare

15.2.1 The Organization shall engage in activities that contribute to the common good of the community to which the Organization serves.

15.2.2 The Organization shall not mislead the public through statements made, false marketing claims, misleading information and/or defamation of other organizations/institutions.

15.2.2.1 Comparisons made by the Organization to other competing organizations/institutions should be made fairly and without malice in the best interest of the general public welfare.

15.2.3 The Organization shall dedicate resources to give back to the community to which it serves while also informing the community about the use and benefit of human tissue for medical education.

15.2.3.1 Those annual activities shall include either:

15.2.3.1.1 Charitable donations to organizations not affiliated with the Organization or its Organizational units.

15.2.3.1.2 Activities to support the community in a meaningful way. Those activities shall be promoted without cost to the community.

16.0 Bioskills Facility Personnel

16.1 Qualifications

16.1.1 Personnel shall be qualified to perform assigned accredited functions of the Organization.

16.1.1.1 Personnel qualification shall be determined through an evaluation of education, training and experience commensurate with the assigned job functions.

16.1.1.2 Personnel qualification must be documented through the maintenance of signed job descriptions.

16.1.1.3 All documentation of personnel qualification shall be maintained by the Organization at all times, be made available for inspection upon request and be retained for a minimum of 5 years after the staff member separates from the Organization .

16.2 Adequacy

16.2.1 The Organization must have sufficient technical and administrative staff necessary to perform the accredited functions of the Organization.

16.2.2 The Organization must have sufficient management staff present and supervising the accredited activities of the Organization at all times.

16.2.2.1 Administrative and technical staff performing accredited activities must be aware of the proper supervisory/management staff made available to handle problems or answer questions during the course of accredited activities.

16.2.2.2 In the absence of assigned supervisory/management staff, administrative and technical staff performing accredited activities must be made aware of a designee assigned to handle problems or answer questions during the course of accredited activities.

16.2.3 The Organization shall demonstrate adequacy of resources as delineated in the Organization's organizational chart approved by executive management.

16.3 Commitment

16.3.1 Personnel performing accredited operations shall commit to the adherence of AMERA's Code Of Ethics. Documentation of this commitment must be maintained by the Organization.

16.3.2 The actions and public statements of all staff in the Organization must adhere to AMERA's code of ethics at all times and must not reflect poorly on AMERA or its accredited members in any way.

17.0 Bioskills Facility Equipment & Facilities

17.1 Equipment

17.1.1 The Organization shall demonstrate control over the installation and use of all equipment required for accredited operations.

17.1.2 The Organization must have adequate facilities, equipment and a process in place to secure, protect and easily retrieve documentation of accredited activities.

17.1.2.1 The documentation includes both hard copy and electronic records.

17.1.3 Equipment utilized for accredited operations within the Organization shall be:

17.1.3.1 Appropriate for the intended use.

17.1.3.2 Used according to manufacturer's guidelines/instructions.

17.1.3.3 Maintained in such a way that safety and efficacy are not compromised.

17.1.3.3.1 Preventative Maintenance completed as per manufacturer's instructions.

17.1.3.3.2 Post service qualification to ensure proper operation.

17.1.3.3.3 Proper annual electrical qualification to determine electrical safety.

17.1.3.4 Stored in a manner that protects the integrity of the equipment and its operation.

17.1.3.5 Qualified prior to its use.

17.1.3.6 Properly labeled with the following:

17.1.3.6.1 Equipment identifier.

17.1.3.6.2 Annual electrical qualification.

17.1.3.6.3 Calibration/qualification date (if applicable).

17.1.3.6.4 Out of service identifier (if applicable).

17.1.3.6.5 Biohazard indicator (if applicable).

17.1.4 All equipment used in accredited operations shall have equipment records maintained to retain documentation specific to:

17.1.4.1 Preventative maintenance (if applicable).

17.1.4.2 Repair history.

17.1.4.3 Cleaning history (if applicable).

17.1.4.4 Manufacturer's manuals/materials.

17.1.4.5 Equipment qualifications.

17.1.4.6 Dates that equipment went in and out of service.

17.1.4.7 Use of all equipment that is utilized for critical operations shall be directed through the Organization's standard operating procedures/ work instructions.

17.1.5 All equipment records must be maintained for a minimum of 5 years after the equipment was permanently removed from service.

17.1.6 Radiological Equipment:

17.1.6.1 All associated radiological equipment must be stored, operated, maintained and controlled in accordance with all state and local laws.

17.1.6.2 All associated radiological equipment must be operated by qualified personnel as defined by state and local law.

17.1.6.3 All associated radiological personal protective equipment must be qualified annually to be free from defect in order to provide proper protection to the user.

17.1.6.4 Radiological personal protective equipment must be qualified as per state and local law and must be made available to all upon request but are mandatory for all within 12 feet of an operating unit.

17.1.6.5 Dosimetry badges must be worn by all within 12 feet of an operating unit for facility staff and or/when requested by non-facility staff.

17.1.7 Instrumentation/Equipment Cleaning:

17.1.7.1 All instrumentation that has come in contact with biological agents, i.e. tissue, blood, must be disinfected to the degree that properly mitigates any potential disease transmission.

17.1.7.1.1 Documentation must be maintained that demonstrates the efficacy of the disinfection method/protocol employed.

17.1.7.1.2 Facility instrumentation must be disinfected after contact and prior to next use.

17.1.7.1.3 Vendor instrumentation must be disinfected after contact and prior to being returned to vendor.

17.1.7.1.3.1 If vendor declines instrumentation disinfection, the facility must have a process in place to contain and properly identify the contaminated instrumentation prior to return to vendor.

17.2 Facilities

17.2.1 Designated Bioskills facilities used for accredited operations must:

17.2.1.1 Be appropriate in size, design and construction for storage and use of human tissue for medical education and:

17.2.1.1.1 Floors and surfaces must be made of non-permeable material(s) to mitigate cross-contamination between donors and disease transmission risk for staff.

17.2.1.1.2 Rooms must have a source of good ventilation, and allow for multiple air changes per hour.

17.2.1.1.3 Have biohazard, fire, chemical, nuclear and general safety meet standards as per applicable federal, state and regulatory code(s).

17.2.1.2 Be appropriate in size, design and construction for production of documents and electronic data.

17.2.1.3 Have security measures in place to prevent unauthorized access to restricted areas/data.

17.2.1.4 Be free from visible signs of pestilence.

17.2.1.5 Must be maintained at a level which is appropriate to ensure a safe and sanitary environment and the respect & dignity of the donors.

17.2.1.5.1 Facility Maintenance must be standardized and documented, to include:

17.2.1.5.1.1 Cleaning

17.2.1.5.1.2 Security

17.2.1.5.1.3 Temperature Monitoring

17.2.1.5.1.4 Pestilence Control

17.2.1.5.1.5 Disinfectant use and change-out

17.2.1.5.2 Documentation of facility maintenance must be maintained by the Organization and retained for a period of 5 years after facility closure.

17.2.1.6 Must comply with state and local ordinances/laws to conduct accredited operations.

17.2.2 Contracted Bioskills facilities that are used for medical education, as an extension of the Bioskills Facility or Tissue Bank must ensure compliance with the

following measures to ensure the facilities used are appropriate for medical education.

17.2.2.1 Must conform to local, state and federal law.

17.2.2.2 Must not permit general public access.

17.2.2.3 Must have proper security measures in place to prevent unauthorized access.

17.2.2.4 Must be constructed in such a way that minimizes contamination of the facility and cross contamination from one donor to the next.

17.2.2.5 Must not be located in a funeral home, morgue, personal residence or other facility not zoned or considered appropriate for the use of human tissue for medical education.

17.2.2.6 Must not in any way allow viewing or demonstration of any surgical event to the general public.

17.2.2.7 Hotels: If located within a hotel, the space designated for tissue use or storage must NOT be:

17.2.2.7.1 Located in a hotel room

17.2.2.7.2 Located in a room to which public access cannot be controlled.

17.2.2.7.3 Located in a room to which cross contamination cannot be controlled

17.2.2.7.4 If egress must be through a general public area then the tissue and contaminated equipment or instrumentation must be properly packaged to contain potential biological hazards and conceal the identity of the contents.

18.0 Bioskills Facility Training, Competency Assessment & Continuing Education

18.1 Training

18.1.1 The Organization must demonstrate control over how the training of all staff is conducted and maintained for accredited operations.

18.1.2 All employees performing accredited operations must be trained at all times.

18.1.3 All employees must be initially trained on all policies and procedures applicable to their respective job function and annually thereafter.

18.1.4 All training activities must be:

18.1.4.1 Documented and performed concordantly with the performance of each step in the training process.

18.1.4.1.1 Documentation of training shall be maintained in the individual's training file or other appropriate tracking system and must be easily retrievable.

18.1.4.2 Performed in a setting conducive to learning by an individual designated to perform training.

18.1.4.2.1 Documentation of this individual as a trainer shall be maintained in the individual's training file.

18.1.4.3 Reviewed and approved prior to the trainee being allowed to perform the functions being trained.

18.1.4.4 Documentation of training must be maintained for a minimum of 5 years from the date that the staff member separated from the Organization.

18.2 Competency Assessment

18.2.1 The Organization must demonstrate control over how staff competency is obtained and maintained for accredited operations.

18.2.2 All employees performing technical operations must be deemed competent at all times.

18.2.2.1 The Organization must have a process in place to determine which process steps are technical in nature and thus require competency assessments for staff.

18.2.2.2 Competency assessments must be completed initially and annually thereafter.

18.2.3 All competency assessment activities must be:

18.2.3.1 Documented and performed concordantly with the performance of each step in the assessment process.

18.2.3.1.1 Documentation of the assessment shall be maintained in the individual's training file or other appropriate filing system and must be easily retrievable.

18.2.3.2 Performed in a "live" environment by an individual designated to perform the assessment.

18.2.3.2.1 Documentation of this individual as an assessor shall be maintained in the individual's training file.

18.2.3.3 Reviewed and approved prior to the trainee being allowed to perform the functions being assessed.

18.2.3.4 Documentation of competency assessment must be maintained for a minimum of 5 years from the date the staff member is no-longer employed with the Organization.

18.3 Continuing Education

18.3.1 The Organization should promote continuing education activities (conferences, workshops, seminars, training events, college courses, etc.) for its staff.

18.3.2 If staff completes continuing education activities then documentation of such activities shall be kept in the employee's training file.

18.3.3 If staff is required to attend continuing education events (to renew certifications/licenses, etc.) then documentation of such activities shall be kept in the employee's training file.

19.0 Bioskills Facility Quality Program

19.1 Quality Program Elements

19.1.1 The Organization shall have a quality program that encompasses the following activities related to accredited activities:

19.1.2 Deviation management system designed to detect, correct and prevent errors from occurring and to ultimately improve a process.

19.1.2.1 The Organization must have a process in place to document and correct any deviation from policy, procedure, AMERA Standards, or applicable law.

19.1.2.1.1 Management of and approval authority over the deviation management system should be performed by a designated individual responsible for quality and regulatory activities.

19.1.2.2 Documentation of deviations, resulting investigation, root cause analysis, immediate and corrective action must be maintained by the Organization for a minimum of 5 years from the date of creation.

19.1.2.2.1 If the deviation is related to the safety or identity of the donor or tissue, then the deviation must be maintained by the Organization for a minimum of 5 years from the date of the tissue distribution.

19.1.3 Internal audit program designed to appraise the Organization's accredited activities on a routine basis or as management directs.

19.1.3.1 The Organization must have a process in place to routinely audit its accredited activities.

19.1.3.2 Audits must be completed at least annually unless there is documentation to support a greater audit frequency to remain in compliance with these Standards.

19.1.4 Document control program designed to maintain controlled documents and changes to them on an ongoing basis.

19.1.4.1 The Organization must have a process in place to control, track and approve all changes/revisions made to its Standard Operation Procedure Manual (SOPM).

19.1.4.1.1 All documents pertaining to accredited activities must be retained within the SOPM.

19.1.4.1.2 All revisions to the SOPM must be:

19.1.4.1.2.1 Approved by a designated individual responsible for accredited activities.

19.1.4.1.2.2 Approved by a designated individual responsible for quality & regulatory activities.

19.1.4.2 The SOPM must be made available to all staff performing accredited activities at the site to which they are performing those activities.

20.0 Bioskills Facility Tissue Use

20.1 Positive Identification

20.1.1 The Organization shall demonstrate control over all interactions required to maintain the integrity of the tissue's identification.

20.1.2 Copies of the Tissue Bank's (blank) current controlled donation authorizations must be obtained and retained in the Bioskills Facility for a period of 5 years from date of use.

20.1.3 All original labeling information (from packaging) must either be retained with the tissue or must be transcribed onto another document and retained with the tissue at all times.

20.1.4 All original documentation that accompanied the tissue must remain on file at the Bioskills facility where the tissue is stored and used at all times. This includes:

20.1.4.1 Copy of official serological testing report

20.1.4.2 Package inserts

20.1.4.3 Risk assessment questionnaires (if obtained)

20.1.4.4 Unique tissue identifier

20.1.4.5 All other relevant medical information

20.1.5 All tissue accepted into the facility must have a unique identifier attached to the tissue prior to being accepted into the facility.

20.1.6 Tissue without unique identifiers affixed to the tissue may not be used until a unique identifier is affixed to the tissue and verified by a second party to be accurate.

20.1.7 The tissue unique identifier affixed to the tissue must not be removed under any circumstance during the receipt, storage or disposition.

20.1.7.1 If the unique identifier was inadvertently or was required to be removed or could not be located, then a replacement unique identifier must be affixed to the tissue immediately upon discovery and verified by a second party to be accurate.

20.2 Tissue resection/disarticulation:

20.2.1 At no time may tissue be further resected /disarticulated without the express permission of the Tissue Bank from which the tissue has been sourced.

20.2.1.1 If the Tissue Bank agrees to the resection/disarticulation then the facility must document and track and affix a unique identifier to each piece of tissue throughout the use, storage and disposition of the tissue.

20.3 Tissue Suitability:

20.3.1 All tissue entering the facility must have undergone a proper suitability determination by the Bioskills facility prior to being accepted into the facility.

20.3.2 This suitability determination must include:

20.3.2.1 Original negative or non-confirmed serological results for the required serological screening tests in standard 8.3.2.4.2.

20.3.2.2 Documentation from the Tissue Bank that delineates:

20.3.2.2.1 The intended use of the tissue

20.3.2.2.2 The risks of handling/using human tissue.

20.3.2.2.3 Instructions for using Universal Precautions.

20.3.2.2.4 Emergency contact information for the tissue bank.

20.3.3 The Bioskills Facility shall only use tissue that has been properly consented to the use for which the tissue is intended.

20.4 Tissue Storage

20.4.1 All tissue shall be stored in such a manner that retards decomposition and preserves the tissue until the time of use and disposition.

20.4.2 Each storage unit shall have its own unique identifier and must be maintained as a piece of equipment used in accredited operations.

20.4.3 The Organization is responsible for setting appropriate temperature ranges for the storage of tissue intended for medical research and education.

20.4.3.1 Tissue storage conditions do not include conditions required for controlled thawing.

20.4.3.2 The temperature range for each storage unit shall be listed in that Organization's SOPM.

20.4.3.3 The temperature ranges shall be monitored and documented on a routine basis as established by the Organization's SOPM.

20.4.3.3.1 The monitoring of these ranges may be performed manually or by an automated method.

20.4.3.4 The Organization must have a documented course of action in place in the event of temperature excursions that would compromise the viability of the donor (natural disaster, loss of power, malfunction). This course of action shall be documented in the Organization's SOPM.

Glossary

Accredited Operations	Any application, event, or action of an accredited Organization that corresponds to a Code of Ethics, AMERA Standards or Accreditation Policy.
Agreement	A signed, complete written account of a business relationship between two or more parties that delineates the responsibilities of all parties and the relationship between them.
Applicant	The Organization that is applying for AMERA accreditation.
Audit	The process by which an appraisal of accredited systems is performed. Audits can be performed as first party, second party or third party in nature and are under the direction of the audit authority. AMERA audits are third party audits performed by an independent auditor.
Auditor (Independent)	The third party individual contracted by AMERA to perform Level 1 and Level 2 Accreditation audits. Such audits are requested by the Organization for accreditation purposes but are under the audit authority of AMERA,
Bioskills Facility	An entity that engages in the education or skill training of relevant medical professionals, emergency service personnel, etc. utilizing human tissue. The Bioskills facility may be an independent (fixed or mobile) facility, an organizational unit of an institution/hospital or an organizational unit of a tissue bank.
Coercion	The process by which an individual is forced to act in an involuntary manner. This could either be due to action or inaction, threats, intimidation or other forms of pressure by another to the donor, donor's estate, legal next of kin or anyone in a position to influence these parties to make a donation contrary to each State's Uniform Anatomical Gift Act..
Competency Assessment	The process by which the training program is validated by evaluating the information and skill a staff member has been given to determine the effectiveness of the training process.
Consent (Informed)	The ethical requirement that donors and donor's legal next of kin should have a sufficient amount of information about the donation and cremation process to make a truly informed decision about whether to proceed with the donation process. The consent conditions further limit and restrict the Organization's ability to operate outside those conditions.
Contamination	The presence of potential infectious disease agents that have been transmitted from a donor or human tissue to another donor (cross contamination), surface, equipment or barrier to staff (personal protective equipment).
Corrective Action	The process by which action is taken to investigate the root cause of a problem or deviation to policies, procedures, AMERA standards and applicable law.

Cremation	The act of reducing a human body to its fundamental chemical compounds through the process of controlled burn in a cremation retort by a licensed crematory.
Creutzfeldt–Jakob disease	A degenerative neurological disorder characterized by spongiform encephalopathy, profound dementia, speech and motor function due to the buildup of abnormal prion proteins.
Deficiency	An observed deviation from AMERA Standards that is derived from an AMERA accreditation audit and is supported by objective evidence gathered during the course of that audit.
Disease Agent	Any disease-producing agent or microorganism that is likely to be transmissible from person to person via contact with blood, tissue or bodily fluids.
Disposition	The act to which human tissue or donor remains are transformed to an inert form that renders it safe for legal disposal and also the act of disposing of that inert material.
Documentation	Objective evidence of the concurrent performance of an accredited activity in either paper or electronic format (See Records).
Donor:	An individual that donated their whole body or portions of their body for the purposes of medical education and/or research. An individual whose body or portions of their body have been donated by their legal next of kin for the purposes of medical education and research.
Donor Acceptance	The process to which all information related to the donation is evaluated by the Organization Director or designee to determine if a donor has been medically cleared, consented and legally able to be acceptable for medical research and education.
Donor Remains	The remaining tissues from the donor that were not recovered for medical research and education.
Equipment	Any instrumentation that is used in the procurement, storage transport and disposition of human tissue for medical education and research. Equipment does not include the facility the facilities furnishings or supplies.
Exceptional Release	The process by which tissue under quarantine is distributed by the Organization to an end user for medical education and research.
General Public Access	Areas of a facility that have incidental or dedicated general public traffic to which a reasonable person would be able to assume that some level of contact or viewing of a medical education or research event is likely.
Hepatitis A	The hepatitis A Virus that is responsible for acute infectious disease in the liver and is transmitted through fecal-oral or water contamination vectors.
Hepatitis B	The hepatitis B Virus that is responsible for both acute and chronic liver disease and is transmitted through contact with bodily fluids.
Hepatitis C	The hepatitis C Virus that is responsible for the inflammation and long term liver damage and is transmitted through contact with bodily fluids.

HIV	The Human Immunodeficiency Virus is responsible for the condition Acquired Immunodeficiency Syndrome in humans and is transmitted through sexual contact and blood vectors.
Human Tissue	Donated anatomical segments, cells, collections of cells, bodily fluids, or the complete body that are recovered for medical education and research.
Incinerator	A facility whose function is to burn medical/ pathological waste to render it inert for safe disposal according to state law.
Inducement	Incentive or reward that causes a person to act in a specific way. Specifically , an act to which the donor, donor's estate, legal next of kin and anyone in the position of influencing these parties are incentivized or rewarded to donate or make a donation to the Organization contrary to each State's Uniform Anatomical Gift Act.
Infectious Disease	A clinically diagnosed illness/event in a person to which resulted from the presence of pathogenic/microbial agents that were transmitted to that person by various transmission routes.
Legal Next Of Kin	The individual or collective group of individuals that comprise the highest order of a consenting class as defined by each state's Uniform Anatomical Gift Act for donation for medical education and research.
Level 1 Accreditation	The first step in the AMERA accreditation process to which a desktop inspection process determines compliance to Level 1 accreditation standards.
Level 2 Accreditation	The final step in the AMERA accreditation process to which a complete inspection of the Organization is required to demonstrate compliance with both Level 1 and Level 2 accreditation standards.
Medical Clearance	The process to which all information related to potential disease transmission is evaluated by a Medical Director or Designee to determine of a donor is medically acceptable for medical research and education without remaining under quarantine conditions.
Medical Director	A licensed physician that is ultimately responsible for the AMERA accredited medical and scientific activities of the Organization. This title is in addition to any other title that this individual may have with the Organization.
Medical Education	The act of using human tissue to train and/or educate physicians, medical personnel, emergency service personnel, or other group of individuals to which the education and training will better humanity through the advancement of medical science and application of healthcare. Such work must conform to the specific conditions set forth in the donation consent.
Organization:	1. Is a tissue bank as defined under each states Uniform Anatomical Gift Act that provides non-transplantable tissue for medical education and research purposes. The tissue bank may be an independent whole body donor program, an organizational unit of an institution, or an organizational unit of a transplant tissue bank.

2. Is a Bioskills facility that engages in the education or skill training of relevant medical professionals, emergency service personnel, etc. utilizing human tissue. The Bioskills facility may be an independent (fixed or mobile) facility, an organizational unit of an institution/hospital or an organizational unit of a tissue bank.

Organization Director	The individual that is ultimately responsible for AMERA accredited activities of the Organization. This title is in addition to any other title that this individual may have with the Organization.
Physical Assessment	The act of evaluating a donor's body to determine disease transmission risks and tissue usability for medical education and research.
Plasma Dilution	A significant dilution of a donor's plasma by the infusion/transfusion of blood or blood related products to such a degree as to reduce the ability of serological testing to detect infectious disease agents in the plasma.
Procurement	The act of collection, surgical removal, disarticulation, vivisection or resection of human tissue from a donor under controlled circumstances.
Qualify, Qualification	To meet standard requirements for demonstration of fitness for use (equipment); to meet standard requirements for demonstration of fitness for performance of position requirements (personnel).
Quarantine	The process to which human tissue that has not yet been deemed suitable for medical research and education is recovered and stored by the Organization.
Records	Objective evidence of the concurrent performance of an accredited activity in either paper or electronic format (See Documentation).
Research	The act of using human tissue as a conduit to the improvement of medical science and the application of healthcare innovation. Such work may be authorized through research projects that have met a standard set of protocols derived from a recognized review board and must conform to the specific conditions set forth in the donation consent.
Serological Testing	The process by which an FDA registered and CLIA licensed testing laboratory employs FDA approved testing kits to detect antibodies produced from donor exposure to infectious agents and/or antigens from infectious agents in donor blood.
Tissue	See Human Tissue
Training	The process by which information is instructed by the trainer and assimilated by the trainee in order to transfer knowledge or skill to the trainee.
Transplantation	The process by which human tissues are recovered, stored, distributed and transplanted into a person. Transplantation can be directed to either allogeneic (different person) or autologous (self).
Universal Precautions	The process by which no tissue is considered safe and precautions in practice and protective equipment are utilized to prevent transmission of potential disease agents to an individual.

Index