



American Association of Tissue Banks

2017
TISSUE BANK SPECIALIST CERTIFICATION
EXAMINATION STUDY GUIDE

INTRODUCTION

The AATB Certified Tissue Bank Specialist Examination is comprised of 130 multiple-choice test items intended to assess the comprehensive knowledge, understanding and application of the current *Standards for Tissue Banking*, regulations, and best practices associated with tissue banking. The exam is not limited to memorization of facts alone, rather it is meant to assess the ability of the candidate to apply the subject materials and concepts. Study materials are not only limited to the current *Standards*; rather additional study materials will be necessary to adequately prepare for the exam. These additional study materials are included in the reference section of this Study Guide.

The list of general knowledge material is further divided into five (5) related categories. Although an exam candidate may not regularly perform tasks in all of these categories, it is expected that Tissue Bank Specialists develop a general knowledge of the materials, and are capable of applying that knowledge. Therefore, the candidate will be required, as part of this national certification program, to demonstrate basic knowledge from each category.

The candidate is permitted 3 hours to complete the exam. During the exam, the proctor will announce when half of the time has expired and when there are 30 minutes remaining to complete the exam. Candidates may wear a watch during the exam to monitor their pace. All testing materials, including pencils, will be provided.

A picture ID must be provided, as well as the confirmation letter mailed to each candidate for admission to the test site. Plan to arrive at least 20 minutes prior to the scheduled examination start time to complete your registration by signing in and showing your photo ID. Candidates who arrive after the exam has started **will not** be allowed to make up their lost time.

This Study Guide consists of:

- 1) A list of general knowledge materials related to a Tissue Bank Specialist's job performance, which may be included in the exam.
- 2) A list of publications used in exam development as well as recommended study materials.

CRITICAL KNOWLEDGE

GENERAL KNOWLEDGE

Items listed below apply to each of the subject categories that are listed in the subsequent sections. A candidate should have general knowledge in the following areas:

1. Human anatomy & physiology
 - a. Types of tissues recovered
 - i. Skin (functions, layers)
 - ii. Cardiac / Vascular (heart / blood vessels and functions)
 - iii. Musculoskeletal system (bone, tendon, fascia, ligaments and functions)
 - b. A candidate may also prepare for this section by reviewing anatomy textbooks or other related materials available in their workplace
2. Recovery techniques and procedures
3. Recovered tissue preparation, packaging and transport
4. Clinical applications of tissue grafts
5. Medical terminology commonly found in medical charting
6. Common Laboratory Tests and their normal values (WBC, differential)
7. Ethical and legal issues involved in tissue banking
8. Infectious diseases, bacteria, parasites, fungi, and their implications for infection and transmittal through tissue grafts
9. Donor confidentiality (HIPAA)
10. Documentation requirements
11. Informed Consent/Authorization
12. Post-donation concerns
13. Interactions with other related donation & transplant organizations, including, but not limited to:
 - a. Eye banks
 - b. Organ procurement organizations

- c. Funeral homes
 - d. Medical Examiners and Coroners
14. Regulatory and Standards documents including:
- a. Current Good Tissue Practices (cGTPs) including FDA 21CFR Part 1270 and Part 1271 and AATB Guidance Document No. 3, Current Good Tissue Practice (June 27, 2006) and FDA cGTP's 2011
 - b. Current Good Manufacturing Practices (cGMPs)
 - c. OSHA Standards
 - d. Quality System Regulations (QSRs) FDA 21CFR Part 820
 - e. Uniform Anatomical Gift Act
 - f. *AATB Standards for Tissue Banking*, (current edition) including published updates
 - g. Current AORN Guidelines for Perioperative Practice, Sterile Technique, Surgical Attire and Hand Hygiene

Knowledge of:

1. Physical assessment of the tissue donor
2. Donor Risk Assessment Interview (DRAI) criteria and rationale (e.g., medical history and social behavior) including available resources and terminology sufficient to obtain donor history information through medical record review, attending physician, family doctor, family, life partner, and other alternate sources
3. Tissues eligible for recovery
4. Required infectious disease testing and disclosure of test results
5. Risk Factors for Relevant Communicable Disease Agents or Diseases (RCDADs)
6. The purpose and interpretation of laboratory tests conducted on donor specimens
7. Applicable laws and regulations associated with Informed Consent/Authorization for donation and tissue recovery
8. Procedures for obtaining and documenting Informed Consent/Authorization for tissue donation (e.g., the steps to follow)
9. Plasma dilution algorithm for determining the acceptability of blood samples for infectious disease testing
10. Archived samples
11. Information sharing

Key words and concepts

- AIDS
- Hepatitis
 - HVC, HVB & HVA
- Antibody
- Antigen
- Asbestosis
- Autoimmune disease
 - Polyarteritis nodosa
 - Rheumatoid arthritis
 - Systemic lupus erythematosus
 - Sarcoidosis
- Autopsy

- Bacteria
 - Chlamydia trachomatis (Chlamydia)
 - Clostridium sp. (potential for sporulation)
 - Neisseria gonorrhoeae (Gonorrhea)
 - Drug resistant organisms
 - Vancomycin Resistant Enterococcus (VRE)
 - Methicillin resistant *Staphylococcus aureus* (MRSA)
 - Group A Streptococcus (Rheumatic fever)
 - Streptococcus pyogenes
 - Treponema pallidum (Syphilis)
- Clotting Factor Concentrate
- Dementia
- Diabetes
- Ebola
- Endocarditis
- Epilepsy
- Fungus
- Immunoglobulins: IgM vs. IgG
- Malignancy
- Marfan's Syndrome
- Multiple Sclerosis
- Mycoses
- Normal flora
- Nucleic Acids: Nucleic Acid Testing (NAT)
- Parasite: Protozoan
 - Chagas disease
 - Leishmaniasis
 - Malaria
- Parkinson
- Plasma dilution
- Prions: Transmissible Spongiform Encephalopathies (TSEs)
 - Creutzfeldt-Jakob Disease (CJD)
- Seizures
- Sepsis
- Steroids
- Toxic Substances
- Conditions with Unknown Etiology
- Vaccines
- Viruses
 - Epstein Barr Virus (EBV): Mononucleosis
 - Hepatitis A, B(HBV), & C(HCV)
 - Human Immunodeficiency Virus (HIV)
 - West Nile Virus (WNV)
 - Zika
- Viral window period

Knowledge of:

1. Verification procedures for tissue recovery
 2. Hospital/recovery site requirements as described in AATB Guidance Document Appendix II. Criteria for preventing transmission of Relevant Communicable Disease Agents and Diseases (RCDADs) through transplantation of human tissue. (January 1, 2017)
 - a. Hospital Operating Rooms and Morgue
 - b. Dedicated Recovery Suites
 - c. Medical Examiner Offices
 - d. Funeral Homes
3. Pertinent hospital and/or medical records review (including police, autopsy, and EMS reports)
4. Donor physical assessment as described in AATB Guidance Document No. 1 v2 Tissue Donor Physical Assessment Form (June 27, 2005)
 - a. Tissue Donor Physical Assessment Form & Requirements: Appendix III: (January 1, 2017)
 - b. Donor identification
 - i. Types of proper identification and verification
 - ii. Methods for verifying identification
 - iii. Minimal requirements
 - c. High risk behaviors and infections
 - i. Areas to assess
 - ii. Signs & symptoms to observe
 - d. Tissue quality
 - i. Trauma
 - ii. Surgical History
 - iii. Level of decomposition
 - e. What to do with information obtained
 - i. Report
 - ii. Investigate
 - iii. Close
 - iv. Document
5. Medical Examiner / Mortuary insight related to tissue recovery

- a. Donor release for recovery
 - b. Recovery observations and reporting requirements
 - c. Donor reconstruction

6. Operating room etiquette and terminology (AORN Standards)
 - a. Clean vs. dirty areas
 - b. OR equipment
 - c. Pre and post recovery cleaning

7. Handling of biohazard material and occupational safety procedures
 - a. OSHA requirements for biohazard materials
 - b. Required handling, disposal, and documentation.

8. Personal protective equipment and appropriate surgical attire
 - a. Types and their purpose (i.e., face masks, hair cover, etc.)

9. Normal tissue appearance or characteristics (anatomy)

10. Donor refrigeration and tissue recovery time limits as described in AATB Guidance Document No. 7, Evaluation of Body Cooling at Standard D5.400 (December 9, 2013)

11. Obtaining qualified blood samples for laboratory test
 - a. Required testing
 - b. Test kit manufacturer's requirements
 - c. Qualifying (Plasma dilution, time frames, hemolysis, etc.)

12. Zone or sequence recovery as described in AATB Guidance Document No. 2 v2, Appendix IV: Prevention of Contamination and Cross-contamination at Recovery: Practices and Culture Results (January 1, 2017)
 - a. Zone types and definitions
 - b. Order of tissues recovered (clean to dirty)
 - c. Requirements for draping
 - d. Separation of instruments and equipment
 - e. Requirements for recovery technicians operating in separate zones
 - f. Movement from one zone to another

13. Sterile equipment and supply set-up procedures (Ref. AORN Standards)

- a. Definitions of sterility, aseptic technique, contamination
 - b. Identification of sterile vs. dirty
 - c. Methods of addressing contaminated supplies, instruments, fields, etc.
14. Aseptic/sterile surgical (recovery) techniques and procedures
 15. Operative site preparation and sterile draping techniques
 16. Recovery procedures (e.g., the appropriate order, dissection technique, back table)
 17. Donor reconstruction techniques and procedures
 - a. Impact on autopsy and to funeral home and family viewing
 18. Requirements for culturing tissues and wrapping and labeling tissues for transport and/or interim storage as described in AATB Guidance Document No. 2, v2 Prevention of Contamination and Cross---contamination at Recovery: Practices and Culture Results (May 29, 2007)
 - a. Appendix IV: Prevention of contamination and cross-contamination at recovery: practices and culture results requirement (January ¹, 2017)
 19. Documenting all aspects of tissue recovery and donor reconstruction
 20. Proper handling, transporting and shipping of recovered tissues and documents

RECOVERY / SKIN

Knowledge of:

1. Anatomy and physiology of the skin (functions, parts of the skin i.e., different layers)
2. Safe handling of equipment (e.g. dermatome, sharps)
3. Normal appearance of skin and underlying soft tissues
4. Time limits for recovery
5. Skin processor specification or work instruction
6. Recovery techniques and procedures to meet processor specifications
7. Proper handling, transport/shipment of recovered tissue and documents
8. Clinical applications of split---thickness and full---thickness dermal skin tissues.

Key words and concepts

- Anatomy
 - Layers
 - Epidermis
 - Waterproof
 - Skin tone
 - Dermis
 - Connective Tissue
 - Vessels
 - Hair follicles
 - Sweat Glands
 - Hypodermis (subcutaneous)
 - Connective Tissue
 - Fat cells
- Physiology
 - Considered an organ (largest organ of the body)
 - Protective barrier (1st defense to prevent infection)
 - Insulation and regulation of body temperature
 - Sensory function
- Eligibility and exclusionary criteria for skin donation
 - Conditions and diseases that affect skin tissues
 - Culture results
 - Contraindications to skin recovery
 - Tattoos
 - Rash
 - Trauma
- Types of Skin Recovery

- Split-Thickness Skin Graft (STSG)
 - Epidermis and part of the dermis
 - Full-Thickness Skin Graft (FTSG)
 - Epidermis, all of the dermis and part of subcutaneous
- Equipment utilized for skin recovery
 - Scalpel (FTSG)
 - Dermatome (STSG)
- Components of a dermatome
 - Head
 - Handle
 - Power Supply
 - Disposable blades
 - Standards for culture collection of skin
 - Settings for STSG recovery
 - Optimal range
 - Angles
 - Skin processing apparatus: mesher
- Clinical Applications of donated skin
 - Single Thickness Skin Graft
 - Burn victims
 - Wound Care
 - Full Thickness Skin Graft
 - Hernia Repair
 - Evisceration

RECOVERY / CARDIOVASCULAR (Cardiac and Vascular) TISSUE

Knowledge of:

1. Anatomy and physiology of the heart and blood vessels
2. Safe handling of equipment (e.g. sharps)
3. Normal appearance of heart and blood vessels
4. Time limits for recovery
5. Heart and vessel processor specification or work instruction
6. Recovery techniques and procedures to meet processor specifications
7. Proper handling, transport and shipment of recovered tissue and documents
8. Clinical applications of CV tissues

Key words and concepts

- General and relative anatomy of the heart
 - Apex
 - Endocardium
 - Esophagus
 - Left & right bronchi
 - Lungs
 - Myocardium
 - Pericardium
 - Pleural space
 - Thymus gland
 - Trachea
- Major vessels of the heart
 - Aorta
 - Brachiocephalic artery & vein
 - Coronary artery
 - Inferior and Superior vena cava
 - Left common carotid artery
 - Left subclavian artery
 - Pulmonary trunk
 - Pulmonary arteries and veins
- Chambers of the heart
 - Right and left atria
 - Right and left ventricles
- Valves of the heart
 - Bicuspid valve
 - Aortic and pulmonary
 - Mitral valve
- Cardiac cycle/circulation of blood through the heart and lungs
- Mid---line vs. "V" incisions
 - Know the landmarks used to make these incisions and the related

Medical Examiner/Funeral Home concerns for each incision

- Sternal Notch
- Xiphoid process
- Sternum/Sternotomy
- Clinical application of heart grafts: Ross Procedure
- Blood vessels
 - Greater saphenous vein
 - Femoral vein
 - Know the key differences between an artery and vein
 - Direction of blood flow relative to the heart
 - Physiological differences (understand why valves exist in veins and not arteries)
- Clinical application of vessels: Coronary Artery Bypass Graft (CABG), Peripheral Vascular Disease (PVD)
- Eligibility and exclusionary criteria for CV donation
 - Warm Ischemic Time (WIT)
 - Cold Ischemic Time
 - Conditions and Diseases that affect CV tissues exclusively
- Instrumentation used to perform a heart recovery
 - Kelly clamp
 - Lebsche knife
 - Mayo scissors
 - Metzenbaum scissors
 - Mosquito clamp
 - Non-traumatic tissue forceps (Debakey)
 - Rib Shear
 - Right-angle clamp
 - Sternal Retractor
- Cannula
- Tributary
- Infusion
- Perfusion

RECOVERY / MUSCULOSKELETAL TISSUE

Knowledge of:

1. The anatomy and physiology of the musculoskeletal tissues (e.g. bone, tendon, fascia)
2. Safe handling of equipment (e.g., sharps)
3. Normal appearance of musculoskeletal tissues
4. Time limits for recovery
5. Proper handling, transport and shipment of recovered tissue and documents
6. Clinical applications of MS tissues

Key words and concepts:

- Position
 - Anatomic
 - Supine (face up)
 - Prone (face down)
- Planes
 - Coronal (frontal)
 - Sagittal (median)
 - Transverse (Horizontal)
 - Oblique (angle)
 - Variations (such as mid---sagittal)
- Location
 - Anterior (in front of)
 - Posterior (behind)
 - Superior (above)
 - Inferior (below)
- Relative Location (can be combined with above ex: posteromedial)
 - Medial (toward the midline)
 - Lateral (away from the midline)
 - Proximal (close)
 - Distal (far away)
- Upper Extremities
 - Humerus (association with scapula and clavicle)
 - Biceps Muscle
 - Rotator Cuff
 - Radius
 - Ulna
- Upper Torso
 - Sternum
 - Xiphoid Process
 - Costal Cartilage
 - Ribs
 - Clavicle (know association with clavicle and humerus)

- Pericardium
- Lower Torso
 - Vertebral bodies
 - Ilium (vs. Hemi-pelvis)
 - Sacrum
 - Coccyx
 - Femur (know association of femur to ilium)
- Lower Extremities
 - Fascia (aka Iliotibial band)
 - Femur
 - Gracilis Tendon (should the tendons be grouped with their “associated” bone)
 - Semitendinosus Tendon
 - Tibia
 - Anterior Tibialis Tendon
 - Posterior Tibialis Tendon
 - Peroneus Longus Tendon
 - Fibula
 - Knee
 - Quadriceps tendon
 - Patella
 - Patellar Tendon
 - Tibia
 - Meniscus
 - Cartilage
 - Anterior Cruciate Ligament
 - Posterior Cruciate Ligament
 - Medial Cruciate Ligament
 - Lateral Cruciate Ligament
 - Tibial Plateau
 - Achilles Tendon
 - Gastrocnemius Muscle
 - Calcaneus
 - Talus
 - Saphenous Vein
 - Additional Terms Associated with Anatomy
 - Diaphysis
 - Metaphysis
 - Epiphysis
 - Periosteum
 - Endosteum
 - Tendon vs. Ligament
 - “Origin” vs. “Insertion” of a tendon or muscle
- Bone function
 - Attachment for soft tissues
 - Hematological
 - Calcium storehouse

- Protection
- Mature long bone anatomic areas
 - Diaphysis
 - Metaphysis
 - Epiphysis (and epiphyseal plate)
- Bone structure
 - Cortical (aka compact)
 - Cancellous (aka trabecular or spongy)
- Wolff's Law
- Bone remodeling, repair and replacement
 - Osteoclasts
 - Osteoblasts
 - Osteocytes
- Bone regeneration
 - Osteogenesis
 - Osteoinduction
 - Osteoconduction
 - Creeping Substitution

Knowledge of:

1. Aseptic processing environment and facility set-up and procedures (e.g., equipment necessary, supplies needed)
2. "Clean" processing environment and facility set-up and procedures (e.g., necessary equipment and supplies)
3. Care, preparation, and use of instruments/equipment used in tissue processing
4. Biohazard containment and universal precautions
5. Sterile area classifications and requirements (e.g., ISO 5 / Grade A / Class 100 laminar flow unit or work area)
6. Sterilization techniques for appropriate tissues
7. Graft acceptability requirements (e.g., how to test/determine the acceptability of a graft)
8. Cryopreservation methods/techniques and problem recognition/trouble-shooting (e.g., supercooling, verification, crystallization, etc.)
9. Tissue refrigeration procedures (e.g., methods, tissue handling procedures, its effects on tissues)
10. Lyophilization process (e.g., methods, procedures)
11. Tissue processing quality assurance/control techniques (e.g., bacteriological culturing, testing)
12. Tissue storage techniques and procedures (e.g., fresh frozen, cryopreserved, etc.)
13. Disposition procedures associated with tissue for research or discard
14. Procedures for handling sharps/instruments and contaminated tissues (e.g., safety concerns)
15. Tissue packaging and labeling methods and procedures

Key words and concepts

- Ambient temperature
- Aseptic
- Audit

- Autoclave
- Bioburden
- Biohazard
- Clean Room
- Calibration
- Contamination
- Decontamination
- Ethylene Oxide (ETO)
- Environmental Monitoring Program
- Gamma radiation
- Irradiation
- ISO
- Lyophilization
- Osteobiologics (OB)
- Residual calcium
- Super cooling
- Validation
- Variance
- Verification
- Work instruction

Knowledge of:

1. Labeling and record-keeping procedures
2. Product integrity control procedures (e.g., tissue storage, laboratory testing, bacteriological cultures)
3. The purpose and interpretation of microbiology laboratory tests conducted on tissue samples
4. The purpose and interpretation of serology laboratory tests
5. Tissue bank safety procedures (e.g., types of safety hazards, methods to avoid problems, OSHA requirements)
6. Control measures for work with hazardous chemicals, including carcinogens, potential carcinogens, and biohazards
7. Procedures for the release of tissue (e.g., type of documentation required in terms of serology, microbiology, and pathology, transplant records for tissue utilization documentation)
8. Recall, complaint and adverse reaction requirements from AATB, FDA and other regulatory agencies
9. Current Good Manufacturing Practice (cGMPs) as they relate to tissue processing (e.g., materials used in processing, expiration dates, and documentation procedures)
10. Current Good Tissue Practice (cGTPs)
11. Types and uses of colloid and crystalloid solutions and blood products in donor management
12. Responsibilities of Quality Assurance and Quality Control programs
13. Donor information sharing process
14. Document control requirements

Knowledge of:

1. Types of allograft tissues and their application (e.g., types, functions, and biology)
 - a. Musculoskeletal grafts (bone, connective and soft tissue)
 - b. Skin grafts
 - c. Cardiac valve and vascular grafts
2. Shipping techniques (e.g., validation, dry ice amounts, and expiration dates of products and shipping containers)
3. Proper manufacturing of tissue grafts (e.g., identity of graft types, proper packaging, proper labeling)
4. Procedures for returned grafts (e.g., documentation)
5. Appropriate storage for all types of grafts
6. Basic surgical procedures utilizing tissue grafts
7. Tissue traceability requirements
8. Types of storage (short and long term) and acceptable temperature and time ranges
9. OC grafts and their applications

Key words and concepts:

- Allograft vs. Autograft / Xenograft / Synthetic
- Package label vs. package insert
- Returned graft procedure
 - Requirements for inspection, temperature, and documentation required
- Shipping techniques
 - Shipping/transport container validation
 - Quantity of wet or dry ice
 - Product and shipping container expiration
 - Requirements for finished product

LIST OF REFERENCE PUBLICATIONS

The following list of publications is not a comprehensive listing of study material, but rather it reflects the basic materials from which we suggest you study:

AATB Standards for Tissue Banking (current edition) including published updates

Curriculum Guide for the AATB Certified Tissue Bank Specialist Training Course

AATB Guidance Document No. 1 v2, Tissue Donor Physical Assessment Form (June 27th 2005)

AATB Guidance Document No. 2 v2, Appendix IV. Prevention of Contamination and Cross-Contamination at Recovery: Practices & Culture Results (January 1, 2017)

AATB Guidance Document: No. 3, Current Good Tissue Practice (June 27, 2006)

AATB Guidance Document No. 4, Providing Service to Tissue Donor Families (March 10, 2007)

AATB Interim Guidance Document No. 5, Standard K2.210 Pre-Sterilization/Pre-Disinfection Cultures
(January 4, 2011)

AATB Guidance Document No. 6, Recovery Partner Audit Toll (September 1, 2011)

AATB Guidance Document No. 7, v2 Evaluation of Body Cooling at Standard D5.400 (December 9, 2013)

AATB/ICCBBA Interim Guidance Document, For Use of ISBT 128 by North American Tissue Banks
(January 2011)

Center for Disease Control - <http://www.cdc.gov>

Association of periOperative Registered Nurses (AORN) Guidelines for Perioperative Practice -
Current Version – (Sterile Technique, Hand Hygiene and Surgical Attire) www.aorn.org

Guidance for Industry Eligibility Determination for Donors of Human Cells, Tissues, and Cellular
and Tissue-Based Products (HCT/Ps), FDA, August 27, 2007

<http://www.fda.gov/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/tissue/ucm073964.htm>

Final Rule: Human Tissue Intended for Transplantation (21 CFR, Part 1270)

Federal Register / Vol. 62, No. 145 / Tuesday, July 29, 1997

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=1270>

Final Rule: Registration and Listing Regulations; (21 CFR, Part 1271, Subpart B)
Federal Register / Vol. 66, No. 13/ Friday, January 19, 2001

Final Rule: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue – Based Products; (21 CFR, Part 1271, Subpart C)
Federal Register / Vol. 69, No. 101/ Tuesday, May 25, 2004

Final Rule: Good Tissue Practices (CGTPs); (21 CFR, Part 1271, Subpart D) Federal Register / Vol. 69, No. 236/ Wednesday, November 24, 2004
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1271>

National Organ Transplant Act
<http://www.organdonor.gov/legislation/>

Occupational Safety Hazardous Administration
<http://www.osha.gov>

Uniform Anatomical Gift Act
<http://www.uniformlaws.org/ActSummary.aspx?title=Anatomical%20Gift%20Act%20%282006%29>

United Network of Organ Sharing
<http://www.unos.org>

Guidance for Industry: Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). (PDF - 265KB) - 2011
<http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM285223.pdf>

Guidance for Industry: Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) - Small Entity Compliance Guide – 2007
<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm073366.htm>

Guidance for Industry: Compliance with 21 CFR Part 1271.150(c)(1) – Manufacturing Arrangements - 2006
<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm073991.htm>

Guidance for Industry: MedWatch Form FDA 3500A: Mandatory Reporting of Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) - 2005
<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm074000.htm>

Guidance for Industry: Recommendations for Obtaining a Labeling Claim for Communicable Disease Donor Screening Tests Using Cadaveric Blood Specimens from Donors of Human Cells,

Tissues, and Cellular and Tissue-Based Products (HCT/Ps) - 2004

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm073972.htm>

Guidance for Industry: Validation of Procedures for Processing of Human Tissues Intended for Transplantation - 2002

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm073429.htm>

Guidance for Industry: Availability of Licensed Donor Screening Tests Labeled for Use with Cadaveric Blood Specimens – 2000

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm073976.htm>

Communicable Disease & Travel Reference

<https://wwwnc.cdc.gov/travel/diseases/>