



Guidance Document

PREVENTION OF CONTAMINATION AND CROSS- CONTAMINATION AT RECOVERY: Practices & Culture Results

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AND CROSS-CONTAMINATION AT TISSUE RECOVERY**

I. INTRODUCTION

A. History and Purpose

In the spring of 2002, the Board of Governors assembled a Task Force to review reports of recipient infections that were allegedly associated with tissue allografts. In 2003, the Task Force made several recommendations that were considered by the Standards Committee. It was determined that additional steps could be taken to control the possibility of contamination and/or cross-contamination during recovery of tissue from deceased donors, and that the presence of certain microorganisms would necessitate discard of the tissue. The Committee also agreed that the interpretation of associated recovery (pre-processing) cultures from the same donor warrants scrutiny, and that the sharing of culture results was important.

The Board of Governors decided to include some of these recommendations in the AATB's *Standards for Tissue Banking*.¹ Other recommendations were more representative of good practices, and these recommendations were published in the original version of this Guidance Document (No. 2) on October 20, 2004.

In early 2006, a technical work group was formed to expand the content of this Guidance to include another factor that could prevent contamination and cross-contamination at recovery. Suitability of the site where tissue recovery takes place must be evaluated and determined to be acceptable prior to recovery (see revised Standard D5.500 Recovery Environment). The goal is to set specific guidelines/suitability parameters that define required controls. There is not an expectation that actual detailed monitoring be performed at each *Recovery Site*. Parameters have been developed that, when applied, can ensure that the environment in which recovery occurs meets minimum specifications and should not introduce, transmit, or spread contamination. These additional controls are appropriate and reasonable and have been formulated by this work group from practices tested and used by AATB-accredited tissue banks.

In January of 2007, another work group of subject matter experts was organized to collect information regarding how tissue banks were applying the *Zone Recovery* concept and *Sequencing* to their recovery operations. These practices were reviewed for consistency and common practices were added to this guidance. There is consensus that documentation methods that describe zones and *Sequencing* facilitate tissue suitability determinations. Version 2 of this Guidance Document includes updates for *Recovery Site* suitability, *Zone Recovery*, and *Sequencing*.

B. Definitions

As used in this *Guidance Document*, the following definitions apply:

Sequencing: A procedure utilized at tissue recovery that documents the order (sequence) that tissues were recovered from one donor.

Zone Recovery: A tissue recovery method by which specific, well-defined areas of the body are identified as zones and from which individual tissues are recovered using the same sterile instrumentation/equipment and sterile gloves. It is recommended that skin recovery be performed as a separate zone so that pre-processing culture results of other tissues can be independently reviewed.

Isolation Draping: A method used whereby areas adversely affected by trauma are first segregated (isolated) by entirely covering them to contain potential contamination and prevent cross-contamination to other tissues being recovered from the same donor. If tissues from these areas are retrieved, they should be sequenced as the last to be recovered.

Recovery Site: The immediate area or room where a tissue recovery takes place (e.g., dedicated tissue recovery suite, healthcare facility operating room, autopsy suite).

II. RECOVERY PRACTICES

A. Recovery Techniques

Certain tissue recovery practices may be helpful in controlling contamination and cross-contamination of individual tissues. These include recovery techniques such as *Sequencing* of the tissue recovery, use of well-defined *Zone Recovery* techniques, and *Isolation Draping* in the presence of trauma (see Standard D5.520). Recovery activities should be reviewed to help determine the likelihood of cross-contamination of individual tissues.

B. Recovery Site Qualification

Parts of applicable federal regulations can be referenced (at §1271.190 Facilities, and at §1271.195 Environmental Controls and Monitoring) and used as guides for practical application when determining that a *Recovery Site* is satisfactory. The evaluation of the suitability of the site of recovery must be documented and this record shared with

entities that receive tissues from the donor (at §1271.160 Quality Program, (b) Functions (2)). Due to many circumstances related to events that could occur after death, the donor body may be moved to various sites (e.g., dedicated tissue recovery suite, healthcare facility operating room, autopsy suite). The room in the building where tissue recovery takes place must offer a level of control that will not increase the potential to introduce contamination or cause cross-contamination. Minimum qualification parameters have been established that should ensure control of this environment and be qualified for tissue recovery.

Prior to recovery the following evaluations are performed and there must be:

1. adequate floor and tabletop space to allow separation of sterile instrumentation and performance of aseptic recovery procedures (i.e., *Zone Recovery*, *Sequencing*, draping, tissue wrapping);
2. adequate lighting to perform physical assessment and tissue recovery;
3. adequate plumbing and drainage for the intended purpose to include access to an adjacent or suitably located hand-washing area that can be used to perform a hand/forearm surgical scrub or wash;
4. a controlled, closed airflow system in the recovery area. This means there is no direct access to the outside of the building from the room at any time during, before, or after tissue recovery (i.e., doors, windows that can open, fans, air conditioners, etc.); In addition, all vents appear clean and there is no vented airflow noted to be directed and flowing onto sterile fields;
5. walls, floor, and work surfaces that are easily cleanable (i.e., non-carpeted, not porous) and in a good state of repair;
6. no visible signs of insects, rodents, or other pests;
7. an evaluation for any standing fluids or contaminated waste in the room that could be a source of airborne bacteria, mycobacteria, yeasts or fungi, and if present, it must be rectified prior to recovery; and
8. proper preparation of the *Recovery Site* by cleaning and disinfecting all working surfaces prior to recovery of tissue;

Concurrent with tissue recovery, the following site parameters must be controlled:

1. human traffic is restricted and all personnel entering the recovery area must be properly outfitted and their movement controlled; and
2. no other activities (i.e. embalming, autopsy, another tissue donor recovery) can occur simultaneously in the same room as this tissue recovery;

After tissue recovery, the following activities must be performed:

1. all contaminated/biohazardous re-usable supplies were decontaminated, and adequately contained for transport, and that contaminated/biohazardous waste was properly disposed, or contained and transported to a disposal site; and
2. all working surfaces and the floor were cleaned using approved solutions and equipment.

Recovery personnel must document whether the above parameters have been met, and if the *Recovery Site* has been determined to be suitable.

Note: If there is an ability to rectify certain parameters that may not be initially met (e.g., there is a need to cover room furniture, drains, sinks, or walls), this must be described in procedures, and such a scenario warrants review by a designated, responsible person prior to proceeding with recovery. There must be assurance that there is no evidence that the scenario would compromise the suitability of the *Recovery Site* by being a source of contamination or cross-contamination.

C. Zone Recovery and Sequencing

The primary objective of *Zone Recovery* is to reduce the potential spread of microorganisms (cross-contamination) from one region of the body to another by employing isolation techniques. Isolation is accomplished through evaluation of trauma, specific draping if necessary, placement of drapes after skin preparation has occurred, and by using dedicated instruments for each zone. The recovery technician must also make glove changes between zones and may change gowns when indicated (e.g., when they become soiled or contaminated, or when *Sequencing* recovery from a zone that is at increased risk for contamination to a zone of lesser risk). By performing these functions and documenting actions this will facilitate suitability determinations made from pre-processing culture results. These guidelines are reproducible in multiple settings and scenarios and, when followed, can reduce the risk of contamination and cross-contamination at recovery.

A zone is identified as a region of the body. Zones are recovered in a sequence that is recorded, but the sequence order cannot be prescribed due to many possible variables. If preferred, gloves can be changed following each tissue recovered within a zone. In the presence of trauma when *Isolation Draping* methods are used, these areas become zones that are prepped and excised only after recovery of all other tissues has occurred.

Some zones (i.e., skin, vertebrae/spine, the pelvis, thoracic cavity, traumatized areas) should be treated as inherently possessing an increased risk for contamination and warrant special consideration when recovering tissue in that zone (e.g., deciding the sequence of *Zone Recovery* and whether extra gown changes should occur). Recovery

records should include space to document unanticipated zones due to trauma or other factors.

Common zones:

- Skin - back, abdomen, left anterior leg, right anterior leg, left posterior leg, right posterior leg
- Ocular - corneas, sclera, whole globes
- Intracranial tissue - dura mater, brain
- Mandible
- Thoracic - heart, thoracic aorta, pericardium, ribs, nerves
- Abdomen - abdominal aorta, iliac artery and vein, nerves
- Upper extremity left - rotator cuff, humerus, radius, ulna, metacarpals, nerves
- Upper extremity right - rotator cuff, humerus, radius, ulna metacarpals, nerves
- Lower extremity right - vessels, assorted tendons, fascia lata, femur, tibia (with patellar tendon), tibia, fibula, Achilles tendon with calcaneous, talus, nerves
- Lower extremity left - vessels, assorted tendons, fascia lata, femur, tibia (with patellar tendon), tibia, fibula, Achilles tendon with calcaneous, talus, nerves
- Left hemi-pelvis/ilium,
Due to proximity of the hemi-pelvis to the viscera these tissues should be recovered after all other musculoskeletal tissues from the respective extremity have been recovered and packaged.
- Right hemi-pelvis/ilium
Due to proximity of the hemi-pelvis to the viscera these tissues should be recovered after all other musculoskeletal tissues from the respective extremity have been recovered and packaged.
- Vertebrae/spine - Cervical, thoracic, lumbar
Due to the proximity of the vertebrae/spine to CNS fluids and tissues, these tissues must be considered a separate zone.

D. Documentation

If practices to control contamination and cross-contamination at recovery are utilized as described, recovery agencies should document these significant steps. Recovery

records (forms) should reflect the sequential recovery of all tissues and there should be a written statement acknowledging that “*Zone Recovery* techniques were utilized.” The individual zones for each donor should be identified on the paperwork so that all processors can utilize this information along with the results of the pre-processing cultures. The order of recovery of each zone cannot be prescribed but the sequence of zones must be recorded in the recovery records. It is recommended that order of recovery within a zone be recorded. Any deviation from established protocols for *Isolation Draping*, *Zone Recovery*, or *Sequencing*, must be approved by a responsible person and details documented. Records must be maintained and shared demonstrating that pre-established suitability parameters for the *Recovery Site* were determined to be acceptable prior to tissue recovery. A sample form is provided with this guidance that can be used when documenting *Recovery Site* suitability.

III. Pre-processing Culture Results

A. Results Reporting and Sharing

To facilitate tissue suitability determinations, pre-processing culture results should be provided to recovery agencies by testing laboratories or tissue processors within a reasonable amount of time after recovery.

Knowledge of a donor’s pre-processing culture results could affect the suitability determination made by different processors. Therefore, recovery agencies should share relevant tissue recovery (pre-processing) culture information with all processors to whom tissue from shared donors was sent. Procedures should be used that describe how this information is received and disseminated in a timely fashion so that proper tissue disposition decisions can be made. The “Current Good Tissue Practices for Human Cells, Tissues, and Cellular and Tissue-Based Product Establishments, Final Rule²” (CGTPs) describes the need for procedures for sharing of results from the same donor that relate to the possible contamination of the product or potential transmission of disease (at §1271.160 Quality Program, (b) Functions (2)). For details regarding expectations for sharing of records, refer to these new or revised AATB Standards: B1.510 Written Agreements/Contracts, D4.500 Information Sharing, F3.100 Unsuitable Donors, J1.200 Contents (of the SOPM), and K1.100 Basic Elements of a Quality Assurance Program.

B. Pathogenic, Highly Virulent Microorganisms

Two microorganisms (and others that have been identified for specific tissue types, see revised Standard E1.040), are considered pathogenic, highly virulent organisms. Individual tissues with culture results yielding *Clostridium* or *Streptococcus pyogenes* (group. A strep.) should be discarded (see Standard K2.210). Other individual tissues from the same donor that were recovered under conditions that could result in cross-contamination should also be discarded unless they can be treated with a validated

sterilization process. Tissue establishments (e.g. processors) who determine final donor suitability may consider that more organisms fit this classification.

IV. Considerations

A. Culturing Methods

There are different pre-processing culturing methodologies in use. The filter-culturing technique that is used for tissue types such as (C) cardiac and (V) vascular has a sensitivity that is likely higher than that experienced by the swabbing techniques that are most popular for use with (MS) musculoskeletal tissue types. Establishing quantifiable bioburden, actual colony forming units per ml (CFU/ml), can be accomplished via filter-culturing and fluid-extraction techniques³ but not by limitations of swabbing techniques and protocols used. The low accuracy, sensitivity, and reliability of swab culturing⁴⁻¹² plays heavily upon the decision to discard tissues with positive cultures of pathogenic, highly virulent microorganisms, since the level of bioburden cannot be established. Also, a negative swab culture may be a false negative result and any result can under-represent all organisms present⁴⁻¹². This is especially suspect if one tissue grows *Clostridium* or *Streptococcus pyogenes* yet another tissue sequentially recovered in the same recovery zone does not. Validated sterilization processes must be in place to allow processing tissues meeting this scenario.

B. Processing Methods

Generally, there are two processing methods: disinfection and sterilization. If a tissue type is processed in a fashion where it is not sterilized, only disinfected (e.g. cryopreserved (MS) tissues, like tendons; osteoarticular (OA) allografts, and (C) and (V) tissues), then considerations must be made if there is an associated culture result from that donor that is considered pathogenic, highly virulent. If tissue recovery controls are in place and documented that offer assurance that cross-contamination did not occur, then that tissue may be suitable if its own culture result is acceptable. If such controls are not in use and documented (e.g. *Sequencing*, *Zone Recovery*, trauma recovery protocols such as *Isolation Draping*), the intent of this *Guidance* would be to discard all tissues that were only disinfected (not sterilized).

V. References

1. AATB *Standards for Tissue Banking*, 11th edition, 2006.
2. 21 CFR Part 1271 Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement; Final Rule, Department of Health and Human Services, FDA, November 24, 2004.

3. Ronholdt CJ, Bogdansky S: "A Fluid Extraction Technique for Detection of Microbial Contamination on Human Allografts"; AATB Posters and Abstracts, 28th Annual Meeting (2004).
4. von Garrel T, Knaepler H, Mutters B: "Quality of Microbiological Testing Methods for Evaluation of Bacterial Contamination of Allogeneic Cancellous Bone Grafts"; AATB Abstracts, 16th Annual Meeting (1993), and, in *Transfusion*, Vol. 33, No. 7, 1993.
5. Veen MR, Petit P, Bloem RM: "Sensitivity of Swab Cultures in Musculoskeletal Allograft Procurement"; AATB Abstracts, 16th Annual Meeting (1993), and, in *Transfusion*, Vol. 33, No. 7, 1993.
6. Taylor AK, Zanzi KP, Burchardt H, Forsell JH: "The Reliability of Using a Dry Swab Culturing Method to Validate Tissue Sterility After Lyophilization"; AATB Abstracts, 16th Annual Meeting (1993), and, in *Transfusion*, Vol. 33, No. 7, 1993.
7. Veen MR, Bloem RM. Petit PL: "Sensitivity and Negative Predictive Value of Swab Cultures in Musculoskeletal Allograft Procurement"; *Clinical Orthop*, 259-63, 1994.
8. Perry JL: "Assessment of Swab Transport Systems for Aerobic and Anaerobic Organism Recovery"; *Journal of Clinical Microbiology*, May 1997, p. 1269-1271.
9. Perry JL: "Inhibitory Properties of a Swab Transport Device"; *Journal of Clinical Microbiology*. Vol. 35, p. 3367-3368, 1997.
10. Wilson DA, Tuohy MS, Procop GW, Hall GS: "Effects of Storage Temperature on the Recovery of Bacteria from Three Swab Transport Systems..."; Abstracts, American Society for Microbiology, 101st General Meeting, May 2001.
11. Mills AR, Roberts MR: "Evaluation of Culturing Methods at Predicting Allograft Sterility for Aseptically Processed Tissue"; AATB Posters and Abstracts, 25th Annual Meeting (2001).
12. Ronholdt CJ, Bogdansky S: "Quantitative Microbial Comparison of Swab Culturing Systems on Human Allografts"; AATB Posters and Abstracts, 28th Annual Meeting (2004).

AATB Sample TISSUE DONOR RECOVERY SITE ASSESSMENT Form

Tissue Donor ID #: _____ Recovery Site Name: _____

Recovery Site Location (circle one):

Dedicated Recovery Suite

Healthcare Facility Operating Room

Autopsy Suite

Other Area (describe): _____

Check the appropriate box. Any "No" answer must be described in detail, rectified if possible, and requires review by a responsible person.

Pre-Recovery Evaluation:	Yes	No
1. Adequate floor and tabletop space to allow separation of sterile instrumentation and performance of aseptic recovery procedures (i.e., zone recovery, sequencing, draping, tissue wrapping) is present.		
2. Adequate lighting to perform physical assessment and tissue recovery is present.		
3. Adequate plumbing and drainage for the intended purpose to include access to an adjacent or suitably located hand-washing area that can be used to perform a hand/forearm surgical scrub or wash is present.		
4. The recovery area has a controlled, closed airflow system. This means there is no direct access to the outside of the building from the room at any time during, before, or after tissue recovery (i.e., doors, windows that can open, fans, air conditioners, etc.); In addition, all vents appear clean and there is no vented airflow noted to be directed and flowing onto sterile fields.		
5. The walls, floor, and work surfaces are easily cleanable (i.e., non-carpeted, not porous) and in a good state of repair.		
6. Signs of insects, rodents, or other pests are not visible.		
7. Standing fluids or contaminated waste in the room, that could be a source of airborne bacteria, mycobacteria, yeasts or fungi, are not present.		
8. The recovery room was properly prepared by cleaning and disinfecting all working surfaces prior to recovery of tissue.		
Concurrent with Recovery:	Yes	No
1. Human traffic is restricted and all personnel entering the recovery area are properly outfitted and their movement controlled.		
2. Other activities (e.g., embalming, autopsy, another tissue donor recovery) did not occur simultaneously in the same room as this tissue recovery.		
Post-Recovery Activities:	Yes	No
1. All contaminated/biohazardous re-usable supplies were decontaminated, and adequately contained for transport, and that contaminated/biohazardous waste was properly disposed, or contained and transported to a disposal site.		
2. All working surfaces and the floor were cleaned using approved solutions and equipment.		

Comments: _____

The above parameters have been met and the recovery site has been determined to be suitable (check one): Yes _____ No _____

Completed By: _____ Date/Time: _____