Tissue Environmental Controls and Monitoring

Presenter:
Kelly Patrick, BFA, CTBS
Quality Systems Specialist for
Community Tissue Services
Objectives

1. To outline the regulatory requirements and definitions for tissue environmental controls and monitoring

2. To discuss routine environmental monitoring methods and periodic requalification methods of tissue recovery and processing environments.

3. To share best practices for ensuring a robust Tissue Environmental Monitoring Program.
DEFINITION:
Activities performed to systematically observe and record data to characterize the environment to identify conditions under which the potential may exist for contamination or cross-contamination of tissue.
Objective #1 (cont’d)

14th Ed. AATB Standards for Tissue Banking:
- D5.500 (Recovery Environment)
- D5.510 (Recovery Site Suitability Parameters)
- E2.200 (Processing Environment)
- E2.210 (Environmental Control and Monitoring)
- J4.300 (Environmental Monitoring)
- Guidance Document No. 8, Sept. 28, 2016
Objective #1 (cont’d)

FDA 21 CFR Part 1271.195

SUMMARY DEFINITION:
You must control & monitor environmental conditions to provide proper conditions for operations (where conditions could reasonably be expected to cause contamination or cross-contamination of HCT/Ps or equipment, or accidental exposure to communicable disease agents.)
Objective #1 (cont’d)

FDA 21 CFR reference standards:

- Part 1271.160 (Establishment and Maintenance of a Quality Program)
- Part 1271.190 (Facilities)
- Part 1271.195 (Environmental Control and Monitoring)
- Part 1271.200 (Equipment)
- Part 1271.215 (Recovery)
- Part 1271.220 (Processing & Process Controls)
Objective #1 (cont’d)

Parameters

1) Recovery Site Suitability
2) Processing Room Suitability
3) Temperature, Humidity, and Ventilation
4) Cleaning and Decontamination
5) Microbial Monitoring
   - Viable Airborne Particles (Passive)
   - Surface Particles (Active)
Objective #2
(Routine Monitoring and Requalification Methods)

• Must recover and process in a manner that does not cause contaminants or cross-contamination.
• Must recover and process in a manner that does not introduce or increase the risk of communicable disease transmission.

So how do we ensure and control this???
### Objective #2 (cont’d)

Room Inspections before and after use:

<table>
<thead>
<tr>
<th>Section 1: Pre- Recovery Activities</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Adequate floor and tabletop space to allow separation of sterile instrumentation and performance of aseptic recovery process (i.e., zone recovery, sequencing, draping, tissue wrapping) is present.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Adequate lighting to perform physical assessment and tissue recovery is present.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. The walls, floor, and work surfaces are easily cleanable (i.e., non-carpeted, not porous) and in a good state of repair.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Signs of insects, rodents, or other pests are not visible.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Standing fluids or contaminated waste in the room, that could be a source of airborne bacteria, mycobacterium, yeasts or fungi, are not present.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. The recovery room was properly prepared by cleaning and disinfecting all working surfaces prior to recovery of tissue.</td>
<td>Initial:</td>
<td>Initial:</td>
</tr>
</tbody>
</table>
Objective #2 (cont’d)

Use of sterile supplies/barriers and easily cleanable surfaces:
Objective #2 (cont’d)

Room cleaning after use:

| Record time all grafts are removed from the room: | Time: |
| Inspection and Removal of gross debris Performed: | By: |

Select Cleaning Session:

- [ ] Traditional MS Processing
- [ ] Traditional Packaging / Non-MS Process

Application of 70% Isopropyl Alcohol (IPA)

(Verify LPH was made less than 24hrs) LpH Verified by:

Application of LpH Solution

Start Contact Time (Application End time) | End Contact Time | Total Contact Time (Minimum 10 minutes) | Initials |
Objective #2 (cont’d)

Environmental Monitoring

1) Set alert and action levels
2) Validate your testing methods
3) Monthly, Quarterly, Semi-Annual, and Annual testing
4) Trending of test results
5) Processes to handle alert and action levels (CAPA)
Objective #2 (cont’d)

<table>
<thead>
<tr>
<th>Item</th>
<th>Lot Number</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thioglycolate Tubes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TSB Tubes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sterile Water</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sterile Swabs</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Sites Cultured

1st Culture Time:

Place a check mark (v) if site is cultured, “NA or Dash” if site not cultured.

<table>
<thead>
<tr>
<th>Site</th>
<th>Table</th>
<th>Back Table</th>
</tr>
</thead>
<tbody>
<tr>
<td>North Wall</td>
<td>Table 7</td>
<td>Back Table 1</td>
</tr>
<tr>
<td>SE Floor</td>
<td>Table 8</td>
<td>Back Table 2</td>
</tr>
<tr>
<td>Table 1</td>
<td>Table 9</td>
<td>Prep Table 1</td>
</tr>
<tr>
<td>Table 2</td>
<td>Table 10</td>
<td>Prep Table 2</td>
</tr>
<tr>
<td>Table 3</td>
<td>Table 11</td>
<td>Mayo Stand</td>
</tr>
</tbody>
</table>
Objective #2 (cont’d)
Objective #2 (cont’d)

<table>
<thead>
<tr>
<th>ACTION’S ARE AS FOLLOWS:</th>
</tr>
</thead>
<tbody>
<tr>
<td>If organism is a spore former, site or room must be re-cleaned with Spore Klenz.</td>
</tr>
</tbody>
</table>

**Action Level due to Category 3**
- Re-clean affected site
- Re-culture affected site

**Action Level due to Trend in Suite/Room**
- Re-clean entire suite/room and equipment
- Re-culture entire suite/room/contents

**Action Level for Ancillary Areas:**
- Water source:
  - Initiate work order to change hose, re-culture
Objective #3
(Best Practices)

• The more monitoring, the less risk
• Vary the methods of monitoring using 4 senses:
  ➢ Daily monitoring through sight, sounds, touch, and smell
• Document your daily and periodic monitoring
• Validate your monitoring methods
• Have an action plan for less than desired results
• Qualify those that play a role in your Environmental Monitoring Program
Questions???

Presenter:
Kelly Patrick, BFA, CTBS
Quality Systems Specialist for
Community Tissue Services
Acronyms

• AATB (American Association of Tissue Banks)
• CAPA (Corrective Action and Preventative Action)
• CFR (Code of Federal Regulations)
• EM (Environmental Monitoring)
• Ed. (Edition)
• FDA (Food and Drug Administration)
• HCT/P (Human Cells, Tissues, or cellular or tissue-based Products)
Definitions

• Environmental Monitoring (AATB Definition): Activities performed to systematically observe and record data to characterize the environment to identify conditions under which the potential may exist for contamination or cross-contamination of tissue.

• Environmental Monitoring (FDA Paraphrased Definition): You must control & monitor environmental conditions to provide proper conditions for operations (where conditions could reasonably be expected to cause contamination or cross-contamination of HCT/Ps or equipment, or accidental exposure to communicable disease agents.
Definitions (cont’d)

• **Contamination:** For tissue purposes, making something impure or unsuitable by contact with a material that is unclean.

• **Cross-Contamination (per AATB):** For tissue purposes, the transfer of infectious agents from one tissue to another from either the same donor or a different donor.

• **Recovery (Per AATB and FDA):** Obtaining tissue (other than reproductive) from a donor that is intended for use in human transplantation, therapy, research, or education.

• **Processing (Per AATB and FDA):** Any activity performed on tissue other than donor screening, donor testing, tissue recovery, collection, or acquisition functions, storage, distribution, or dispensing. (Note – packaging is included in Processing for AATB, but not FDA)