

# Guidance Document

# Environmental Controls & Monitoring of a Dedicated Tissue Recovery Site

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# AATB GUIDANCE DOCUMENT Environmental Controls & Monitoring of a Dedicated Tissue Recovery Site

## I. INTRODUCTION

Via surveys performed by the American Association of Tissue Banks (AATB) covering tissue recovery activities in 2003, 2007, and 2010 [1], data reveals the increasing use of dedicated tissue recovery sites (DTRSs) by tissue recovery agencies in the United States (US). An increasing number of tissue recoveries are taking place at dedicated facilities, and when a recovery agency has one or more DTRSs, most of their tissue recoveries are performed there. Tissue banking professionals have discussed these survey results and, via this guidance document, are recommending certain environmental controls and monitoring for these specific, dedicated sites. Although not as robust as the controls and monitoring expected during tissue processing, adequate controls should be maintained for tissue recovery activities, especially when the recovery site is under the direct control of the tissue recovery agency and the site is dedicated (i.e., it is a DTRS, see definition).

For this guidance document, it's important to recognize specific use of "may," "should," "must," or "shall" to describe an expectation. The intent of this guidance is to identify general areas for consideration.

#### A. History and Purpose

For any site where tissue recovery takes place, site suitability parameters already exist and are required by AATB standards [2] and guidance [3], as well as federal rule [4] and guidance [5]. As the use of DTRSs expanded, they were being built to certain specifications (e.g., ventilation and air filtration systems, temperature and/or humidity controls) although facility specifications for a DTRS were not announced or otherwise published. Although the survey showed that routine inspections and cleaning of this recovery room was commonplace, some tissue recovery agencies maintained their sites using methods adapted from environmental monitoring programs established to maintain control of contamination and cross-contamination in a tissue processing facility. The costs to build and maintain a DTRS were reported to be a wide range but averages were considered substantial. Experiences were varied with monitoring the environment or following a schedule. The types of organisms reported as identified within the DTRS varied greatly, as did corrective actions taken to prevent recurrence. It became desirable to establish guidelines to address all of these areas.

This guidance document provides a variety of approaches for establishing and maintaining environmental controls and monitoring for any DTRS, and a tissue recovery agency should consider applying these guidelines to each DTRS it maintains. This document does not imply that all potential sites where tissue recovery can take place must meet these guidelines. To date, contamination from the site of recovery has not been determined to be the root cause of an adverse reaction in a tissue recipient.

#### **B.** Definitions

<u>As used in this Guidance Document</u> and, where relevant in AATB *Standards*, the following definitions apply:

**DEDICATED TISSUE RECOVERY SITE (DTRS)** – A tissue recovery room under control of, and with access restricted by, the tissue recovery agency(ies). Other than tissue recovery or other aseptic activities (e.g., organ perfusion or packaging), no other activities occur here, and controls include cleaning, decontamination, maintenance, and monitoring.

**DECONTAMINATION** - Cleaning the environment, facilities, and/or surfaces (sanitation), or instruments and equipment (sanitization), with intent to remove or reduce pathogenic microbes. Note: Disinfectants are used to decontaminate facilities, surfaces, instruments, and equipment.

**EFFECTIVENESS CHECKS** – Steps taken (and documented) to verify corrective actions were successful in eliminating root cause.

**EXCURSION** – Departure from an established parameter.

**HVAC** – Heating, ventilating, and air conditioning.

MAY – Used to indicate an acceptable method that is recognized but not essential.

**MUST** – Used to indicate a mandatory requirement. The same as *SHALL*.

**PERSONAL PROTECTIVE EQUIPMENT (PPE)** – Personal protective gear, that's not 'standard issue' clothing or equipment, worn by an employee for protection against a hazard, in particular blood-borne pathogens. Examples include: gloves, a gown, a face shield, eye protection, a nose/mouth mask, shoe covers. Reference OSHA, Bloodborne Pathogens Standard 29 CFR 1910.1030.

**RECOVERY SITE** – The immediate area or room where a tissue recovery takes place (e.g., dedicated tissue recovery site, healthcare facility operating room, autopsy suite).

**RESOLUTION** – Adjustment, clarification, and/or correction of practices and/or procedures that results in compliance with the SOPM and/or standards.

**SHALL** – Used to indicate a mandatory standard, same as *MUST*.

**SHOULD** – Used to indicate a recommendation; advisory, indicating a commonly accepted activity for which there may be effective alternatives.

**TERMINAL CLEANING** - Thorough ceiling-to-floor cleaning and decontamination of a DTRS performed at prescribed intervals as determined by the tissue recovery agency (e.g., after each recovery event, daily, weekly), or after major disruptions (such as construction or repair).

### II. Environmental Controls

#### A. Site Suitability Parameters

AATB standard D5.501 Recovery Site Suitability Parameters first appeared in the Standards for Tissue Banking in 2007 and an update was issued concurrently to AATB Guidance Document No. 2 Prevention of Contamination and Cross-contamination at Recovery. The latter guidance included a sample form for use when documenting recovery site suitability and this satisfies the list of parameters from the relevant standard. 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. When a DTRS is used, this expectation can be met by periodically documenting that it has been evaluated using these well-established site suitability parameters, and is deemed qualified as a recovery site until the next scheduled inspection. Such inspections should occur at least annually.

This guidance and the standard do not include expectations for the area immediately outside the DTRS. Areas used for storage or where a surgical scrub sink may be located, or where the shave and cleansing of the donor body take place, are not addressed by this guidance document. Ideally, storage of supplies and equipment, performing a surgical scrub, and cleansing the donor body should take place outside of the DTRS.

Related standards follow from AATB's Standards for Tissue Banking, 14th edition (2016):

#### "D5.500 Recovery Environment

All *tissue shall* be *recovered* in an aseptic or clean fashion using standard surgical preparation with *sterile* packs, instrumentation, and technique. Prior to *recovery*, the *recovery site must* be evaluated for suitability using pre-established criteria designed to control contamination and *cross-contamination* (see Appendix IV). The *recovery site* evaluation *must* be documented, however, if the *recovery site* is an operating room in a heath care facility, no documented site evaluation is required.

#### **D5.510 Recovery Site Suitability Parameters**

These *must* address the control of:

- 1) size/space:
- 2) lighting;
- 3) plumbing and drainage for the intended use;
- 4) the physical state of the facility (i.e., state of repair);
- 5) ventilation;
- 6) cleanliness of room and furniture surfaces;
- 7) pests;
- 8) traffic;
- 9) location;
- 10) other activities occurring simultaneously;

- 11) sources of contamination; and
- 12) the ability to appropriately dispose of biohazardous waste and handle contaminated equipment."

#### **B.** Additional Parameters

When planning new construction of a DTRS or when modifying an existing one, there may be consideration of the following additional parameters:

#### 1. Temperature and humidity

Conditions inside the DTRS should be comfortable for properly attired personnel (e.g., gowned, gloved and wearing a face mask and hair cover). Comfort is a particular consideration where surgical attire and *personal protective equipment (PPE)* are worn for long periods of time and where temperature suitable for general work areas may be, or become, uncomfortably hot. This may result in recovery staff perspiration contaminating sterile fields. High relative humidity may promote microbial growth, especially molds, on environmental surfaces and thus increase bioburden.

Regarding storage of supplies in the DTRS, prolonged, low relative humidity may cause certain materials to become excessively dry. This may adversely affect integrity of materials used to contain sterile instruments and supplies. For example, paper or mesh packages of sterile goods may become brittle and may not maintain a sterile barrier.

Current Guidelines for Perioperative Practice from the Association of periOperative Registered Nurses<sup>1</sup> (AORN) suggest the following parameters for a restricted area:

- Temperature maintained between 68°F and 75°F (20°C to 24°C), but the range may be intentionally adjusted for a limited time based on the comfort of personnel; and
- Relative humidity maintained between 20% and 60%;

#### 2. Ventilation

Ideally, the ventilation system of the DTRS should be designed so airflow patterns will minimize entry of air contaminants. Therefore, positive pressure should be maintained inside the DTRS relative to adjoining spaces outside the DTRS. The American Society of Heating, Refrigerating and Air-Conditioning Engineers standards (ANSI/ASHRAE/ASHE #170) recommend a pressure differential of at least +0.01 inches [6]. Air movement within the DTRS should flow from clean to less clean areas. ANSI/ASHRAE/ASHE #170 recommends a minimum of 20 total air changes supplied per hour for operating room spaces.

<sup>&</sup>lt;sup>1</sup> See Guideline for a Safe Environment of Care, Part 2, at Recommendation IV.

Current Guidelines for Perioperative Practice from the Association of periOperative Registered Nurses<sup>2</sup> (AORN) suggest the following parameters for a restricted area:

- Air changes at least 20 per hour with a minimum of five air changes of outdoor air per hour or at the rate that was applicable at the time of design or of the most recent renovation of the HVAC system; and
- Positive airflow (pressure) relationship to adjacent areas.

#### C. **Cleaning and Decontamination**

Cleaning and decontamination of DTRSs can be considered Core CGTP activities under 21 CFR Part 1271 at §1271.190 Facilities, §1271.195 Environmental Control and Monitoring, and §1271.215 Recovery.

Agencies with DTRSs should document the selection of appropriate cleaning chemicals, materials, tools, and equipment. Cleaning records shall be maintained for 3 years after their creation [§1271.190 (d) (2)].

- Policies and procedures for the implementation of environmental cleaning must be developed.
  - o Policies and procedures regarding the principles and processes of environmental cleaning should include:
    - cleaning and decontamination steps;
    - frequency of cleaning and decontamination;
    - identification of responsible personnel;
    - cleaning chemicals, materials, and equipment approved for use; and
    - maintaining cleaning records.

AATB Standard D5.510, Recovery Cleansing and Preparation (Environment) references the Guideline for environmental cleaning in Guidelines for Perioperative Practice Denver, CO: AORN, Inc. (current edition) [7]. Specific recommendations from the 2016 edition are included here and adapted for use in this guidance:

- A multidisciplinary team should select appropriate cleaning chemicals, cleaning materials, tools, and equipment for use in the DTRS. Consideration should be given for establishing specifications and selecting functional and reliable products that are safe, cost-effective, and environmentally friendly.
- The selection process for disinfectants should evaluate factors including:
  - Environmental Protection Agency (EPA) registration and rating as hospital-grade<sup>3</sup>;

<sup>&</sup>lt;sup>2</sup> See Guideline for a Safe Environment of Care, Part 2, at Recommendation IV.

<sup>&</sup>lt;sup>3</sup> See "Selected EPA-registered Disinfectants" at <a href="http://www.epa.gov/oppad001/chemregindex.htm">http://www.epa.gov/oppad001/chemregindex.htm</a>

- o targeted microorganisms;
- o dwell times (i.e., contact times);
- o compatibility with surfaces, cleaning materials, and equipment;
- o manufacturers' instructions for use;
- o cost;
- o safety; and
- o effect on the environment.
- The selection process for cleaning materials, tools, and equipment should evaluate factors including:
  - o manufacturers' instructions for use on specific surface types to be cleaned (e.g., steel, ceramic tile, etc.);
  - o manufacturers' instructions for use for cleaning materials and equipment;
  - o compatibility with detergents and disinfectants;
  - o personnel ergonomics and safety;
  - o cost;
  - o safety;
  - o effect on environmental conditions in the DTRS (e.g., temperature, humidity); and
  - o effect on the environment.
- Environmental protection agency-registered hospital-grade disinfectants should be used to decontaminate surfaces in the DTRS.
- High-level disinfectants or liquid chemical sterilants (e.g., glutaraldehyde) should not be used to clean and decontaminate environmental surfaces or noncritical devices. These chemicals are not intended for use on environmental surfaces and are not labeled for use as low-level disinfectants.
- Disinfectants have different modes of action and are not interchangeable. Consideration should be given to the types of disinfectants used and the role they have in the process of reducing bioburden in your environment.
  - Alcohol, an intermediate-level disinfectant, should not be used as the only disinfectant on large environmental surfaces, because although it is bacteriocidal, tuberculocidal, fungicidal and virucidal, it may not be effective against some spores.
- Cleaning materials (e.g., mop heads, cloths) may be reusable (after laundering) or disposable (single-use).
  - o If reusable, cleaning materials should be changed after each use;
  - o Disposable cleaning materials should be discarded after each use;
  - o Microfiber or low-linting cotton cleaning materials (e.g., mop heads, cloths) may be used;
  - o Mops that dispense cleaning solutions may be used; and
  - Used cleaning materials (e.g., mop heads, cloths) should not be returned to the cleaning solution container.
- A multidisciplinary team should establish cleaning schedules for objects and surfaces frequently touched or used.

- A multidisciplinary team should designate personnel responsible for cleaning DTRS areas and equipment.
- A multidisciplinary team should develop cleaning and decontamination procedures for circumstances that may require special cleaning procedures (such as construction, renovation, repair, demolition, disaster remediation, environmental contamination, or multidrug-resistant organisms).
- The recovery staff should document a visual inspection of the DTRS for cleanliness before supplies and equipment are brought into the room.
- All horizontal surfaces in the DTRS (e.g., furniture, surgical lights, booms, equipment) should be damp dusted before the first scheduled recovery of the day.
  - o A clean, low-linting cloth moistened with an EPA-registered hospital-grade disinfectant should be used to damp dust;
  - o Damp dusting should be performed methodically, from top to bottom; and
  - Damp dusting should be completed before case carts, supplies, and equipment are brought into the room.
- Spray and misting methods (e.g., a spray bottle) should not be used to apply cleaning chemicals in the DTRS.
  - Cleaning chemicals that are sprayed produce more aerosols than solutions that are poured or ready to use. If the cleaning solution is contaminated, the spray mechanism may aerosolize microorganisms and lead to airborne transmission of disease. Aerosols generated may contaminate sterile supplies or the sterile field, or may cause respiratory symptoms (acute or chronic) in personnel.
- Floors should be mopped with damp or wet mops. Dry methods of environmental cleaning (i.e., dusting, sweeping) should not be used in the DTRS.
- Environmental surfaces should be cleaned with a detergent prior to decontamination, according to the manufacturer's instructions for use. This may be accomplished, for example, by either a one-step (i.e., combined detergent and disinfectant product) or a two-step (i.e., two separate detergent and disinfectant products) process. The presence of visible soil, dirt, and organic material inhibits the process of decontamination by preventing the disinfectant from interacting with the surface.
  - Safety data sheets must be available and reviewed for each cleaning chemical used in the DTRS.
  - Cleaning chemicals must be prepared, handled, stored, and disposed of according to manufacturers' instructions for use and local, state, and federal regulations.
  - o If the cleaning chemical is removed from the original container, the secondary container should be labeled with the chemical name, concentration, and expiration date.

- Disinfectants should be applied and reapplied as needed, per manufacturers' instructions, for the dwell time required to kill the targeted microorganism (e.g., *Clostridium difficile*).
- A protective barrier covering should be used to protect noncritical equipment surfaces if the surface cannot withstand decontamination or is difficult to clean (e.g., computer keyboards, foot pedals).
  - o If a protective barrier covering is used, the cover should be replaced or cleaned and decontaminated per the manufacturer's instructions after each recovery event.
- Noncritical items in the DTRS that cannot be covered and cannot withstand decontamination (e.g., monitor screens, telephones, other electronic devices) should be cleaned in accordance with the equipment manufacturers' cleaning recommendations.
- Equipment should be cleaned and decontaminated before being brought into the DTRS.
- Mattresses and padded positioning device surfaces [e.g., Operating Room (OR) beds, transport carts] should be moisture-resistant and all surfaces intact.
- Reusable cleaning equipment should be disassembled according to manufacturers' instructions for use, cleaned, decontaminated with an EPA-registered hospital-grade disinfectant, and dried before storage and reuse.
- Cleaning of high-touch objects after each recovery event should include cleaning of any
  frequently touched areas of the item (e.g., control panel, switches, knobs, work area,
  handles) as well as any soiled surface of the item.
- Environmental cleaning should not begin until the recovered tissue has been removed from the area.
  - o Trash and used linen should be removed from the room.
- Items that were used during tissue recovery should be cleaned and decontaminated, including
  - o OR bed attachments (e.g., arm boards, stirrups, head rests);
  - o positioning devices;
  - o body transfer devices (e.g., roll boards);
  - o overhead procedure lights;
  - o tables and Mayo stands; and
  - o mobile and fixed equipment.
- The floors of the DTRS should be cleaned and decontaminated after each recovery event.
  - Floors may be cleaned with either a wet vacuum or a single-use mop and a disinfectant.
  - o The floor should be wet with the disinfectant for the dwell time indicated on the manufacturer's instructions for use.
  - o Cleaning should progress from the cleanest to dirtiest areas of the floor.

- Floor surfaces at the perimeter of the room should be decontaminated before floor surfaces in the center of the room.
  - The center of the room, where the majority of donor recovery occurs, is most likely to have higher levels of contamination.
- The entire floor surface should be decontaminated, including areas under the OR bed and mobile equipment.
- The walls should be cleaned and decontaminated if soiled or potentially soiled (e.g., by splash, splatter, or spray).
- The frequency of terminal cleaning and decontamination of DTRS areas should be described in the SOPM.
  - For terminal cleaning in the DTRS, a multidisciplinary team should determine the frequency and extent of cleaning required when areas are not occupied for extended periods (e.g., unused rooms, weekends).
- Terminal cleaning of operating and procedure rooms should include cleaning and decontamination of all exposed surfaces, including wheels and casters, of all items, including
  - o IV poles;
  - o OR beds:
  - OR bed attachments (e.g., arm boards, stirrups, head rests);
  - o positioning devices;
  - o body transfer devices (e.g., roll boards);
  - o overhead procedure lights;
  - o tables and Mayo stands;
  - o mobile and fixed equipment (e.g., surgical waste management (suction) devices);
  - o storage cabinets, supply carts, and furniture;
  - o light switches;
  - o door handles and push plates;
  - o telephones and mobile communication devices;
  - o computer accessories (e.g., keyboard, mouse, touch screen);
  - o chairs, stools, and step stools; and
  - o trash and linen receptacles
- Ventilation ducts, including air vents and grilles, should be cleaned and have their filters changed on a routine basis according to manufacturers' instructions for use.
  - Clean ventilation ducts and filters support optimal performance of the ventilation system.

# III. Environmental Monitoring

#### A. Types and Data Analysis

1. Temperature and Humidity

The DTRS should be maintained under controlled temperature and humidity to reduce the likelihood of microbial growth on environmental surfaces. Each recovery agency should establish and document temperature and humidity parameters in written policies and procedures.

The recovery agency should conduct and document a risk assessment of the environment and the rational for control levels selected.

If temperature and humidity controls are in place, the agency should establish policies and procedures for monitoring and documentation.

#### 2. Ventilation

If the DTRS has positive pressure ventilation, the pressure differential should be monitored using a defined schedule. Agencies should follow manufacturer's recommendations for preventive maintenance of HVAC equipment, when available. Any filters used (e.g., HEPA filters) should be inspected and replaced per manufacturer's recommendations.

To qualify these controls, annual environmental and operational qualification procedures can be considered (e.g., filter integrity testing, air exchange and pressure measurements, airborne particle counts, temperature and humidity measurements). Qualification is not required unless instructed by the manufacturer or a regulatory authority. Instrumentation used for such measurements must be properly maintained and calibrated, and used according to the manufacturer's instructions.

#### 3. Microbial

The recovery agency should conduct and document a risk assessment to determine the necessity for microbial monitoring. The assessment should analyze the ability of existing contamination control procedures to minimize cross-contamination between donors and maintain a safe environment for recovery personnel. The type(s) and frequency, if any, of microbial monitoring of the DTRS should be established based on this assessment.

It is important to establish a program that outlines room locations and objects to be sampled, the sampling method, the number and frequency of sampling. To assess microbial contamination, microbial detection methods should be suitable for intended use to ensure there is no interference with residual disinfectants. Policies and procedures for evaluating and trending data and determination of corrective action should be established prior to the commencement of monitoring activities.

Monitoring of a DTRS can involve passive and/or active sampling methods. If it's determined the recovery agency will undertake microbial testing, the following recommendations can be used:

#### a. Viable Airborne Particles (Passive)

Among the simplest and most cost effective of these methods is the monitoring of viable airborne particles through the use of settling plates. Settling plates are relatively low cost and may be employed in large numbers for better coverage, depending upon the size of the recovery environment. Air settling plates should

utilize a general microbial growth medium in consultation with the testing laboratory.

Settling plates should be placed in varied locations throughout the recovery area as well as near water sources if present. Plates should be left in place for the time recommended by the manufacturer. It's recommended that foot traffic be kept to a minimum during sampling to prevent staff from bringing additional microbes into the area that may skew results. Each plate should be labeled with the location, date, and time of sampling. All data must be recorded and evaluated to determine if growth is within an acceptable pre-set tolerance limit for the location and the type of organism identified.

#### b. Surface (Active)

Active microbial sampling measures, such as swab sticks or contact plates, can be employed for the monitoring of hard surfaces.

Contact plates should also utilize a general microbial growth medium in consultation with the testing laboratory. It is important to supplement these media with an additive to negate any residual effect from a disinfecting agent used in surface cleaning (e.g., lecithin and polysorbate 80). Contact plates will leave a residue, so the sampled area should be cleaned and decontaminated prior to recovery activities.

Surface monitoring should be completed for recovery suite areas such as floors, walls, tables, light fixtures, water fixtures and any room equipment. Surface monitoring may be completed through the use of swabs or contact plates. Each sample should be labeled with the location, date and time of sampling.

#### 4. Analysis of data

All data should be reviewed and evaluated for compliance with pre-determined acceptability parameters set by the tissue bank. Results should be tracked and trended by the individual or department responsible for environmental monitoring. Action is expected if results do not meet predetermined acceptability parameters. Policies and procedures for analyzing results over a period of time should consider contributing factors: various locations; types, quantity and pathogenicity of organisms identified; and staff.

Based upon this review, management or the responsible party should make a determination of corrective action that could include, but is not limited to, closing the suite for recovery operations, re-cleaning of the suite, resampling, and/or staff retraining.

# IV. Corrective Action and Preventive Action (CAPA)

The recovery agency should establish policies and procedures for corrective and preventive action to provide *resolution* when an *excursion* occurs. Investigation should include a documented risk analysis regarding any impact to control of contamination of the DTRS,

determination of root cause, and appropriate action to take. *Effectiveness checks* should be part of the plan.

Example: After surface sampling for microbial contamination, colony forming units (CFUs) were found to exceed preset tolerance limits for specified organisms. An action plan should be developed. An alert level may require the immediate re-cleaning of the recovery suite followed by resampling after a specified lapse of time. Action level growth might require a review of the organisms identified by management-level responsible parties. A review of preventive cleaning and maintenance procedures and their associated logs should occur to ensure that proper cleaning has been completed and that required events, such as filter replacements, have occurred according to schedule.

Example: Recovery agency X conducted surface sampling for microbial contamination. Colony forming units (CFUs) on the back table sample were found to exceed preset tolerance limits for a specified organism. Agency X's SOP stated that a range of 0-3 CFU/plate was acceptable, 4-5 CFU was at an Alert Level and >5 CFU was an Action Level. The floor sample resulted at 6 CFU. Agency X's SOP required the following Action Level steps:

- Reporting thru the Quality Event Management Systems (Variance System)
- Quality Management review and assessment for possible further steps:
  - o Closure of the room and terminal cleaning
  - o Review of cleaning logs, verification of HEPA filter maintenance
  - o Analysis of procurement culture results
  - o Resampling of room
  - o Reopen room when results are acceptable.

Example: Recovery Agency X identified recurring excursions in floor samples for microbial monitoring in the DTRS. Through a root cause analysis, the agency determined that the process for cleaning re-usable mop heads was not adequate and a usable life for re-usable mop heads, after which they must be discarded, had not been defined. The agency's corrective actions included establishing a new cleaning process for the re-usable mop heads. This included choosing a new product for decontaminating mop heads and adding a requirement to discard mop heads after a certain number of days of use. To determine the effectiveness of these corrective actions, a comparison of environmental sample data from the floor was performed for three months pre- and three months post-implementation. Statistical t-test analysis confirmed that there was a statistically significant improvement in environmental floor data following the implementation of corrective actions.

# V. References

- [1] DTRS Survey Results July 2011.pdf (accessed 8-5-2016) <a href="http://www.aatb.org/aatb/files/ccLibraryFiles/Filename/000000000459/DTRSSurveyResultsJuly2011.pdf">http://www.aatb.org/aatb/files/ccLibraryFiles/Filename/000000000459/DTRSSurveyResultsJuly2011.pdf</a>
- [2] AATB Standards for Tissue Banking, McLean, Virginia (current version)

- [3] AATB Guidance Document No. 2 Prevention of Contamination and Cross-contamination at Recovery (current version)
- [4] U.S. Department of Health and Human Services, Food and Drug Administration, Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement; Final Rule (69 FR 68612, November 24, 2004). See § 1271.195 Environmental control and monitoring.
- [5] U.S. Department of Health and Human Services, Food and Drug Administration, Final Guidance for Industry: Current Good Tissue Practice and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products, dated December 2011. See ENVIRONMENTAL CONTROL AND MONITORING (§ 1271.195), at H. What Environmental Control and Monitoring Issues Should be Considered for Recovery of HCT/Ps?
- [6] Ventilation of Health Care Facilities. ANSI/ASHRAE/ASHE Standard 170-2013
- [7] Guideline for Environmental Cleaning, and Guideline for a Safe Environment of Care, Part 2 in *Guidelines for Perioperative Practice* Denver, CO: AORN, Inc. (2016 edition).