Sterile Processing Department Design and HVAC Considerations

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Objectives

- Understand what architects and engineers need to know to provide the safest environments for patients and staff from the perspective of an OR Nurse and an Infection Preventionist.

- Describe the extent to which the designer’s and clinician’s perspectives are addressed in AORN’s Guidelines for a Safe Environment of Care and the FGI Guidelines for Design and Construction of Health Care Facilities.

- Describe design engineers’ perspectives as they approach initial planning the perioperative environments in hospitals and ASCs.

- Learn the 2018 requirements for sterile processing and endoscopy and the Joint HVAC Task Force's recommendations on compliance.
The views and opinions expressed in this presentation are the opinion of the speaker and not the official position of the Health Guidelines Revision Committee.
AORN and FGI Collaboration
Joint HVAC Task Force
Joint Interim Guidance:  
HVAC in the Operating Room and Sterile Processing Department 
September 21, 2015

Background

Health care organizations are currently being challenged to meet a series of conflicting and sometimes unclear heating, ventilation, and air-conditioning (HVAC) standards and guidelines established by a variety of professional organizations. These organizations include the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE), the American Society for Healthcare Engineering (ASHE), the Association for the Advancement of Medical Instrumentation (AAMI), the Association for Professionals in Infection Control and Epidemiology (APIC), the Association of periOperative Registered Nurses (AORN), and the Facility Guidelines Institute (FGI).

The biggest challenge for owners and designers of health care facilities is to understand the purpose and scope of the various requirements so patient and staff safety and comfort can be managed. While some standards are written to be applied during design and renovation of a facility, others are intended to be used as daily operational guidelines. When hospital and ambulatory care organizations are surveyed by state agencies, Centers for Medicare & Medicaid Services (CMS), and other accrediting organizations, misunderstandings about the major difference between building and engineering design standards and clinical practice guidelines have led to a great deal of confusion and even conflict in the health care community.

Operating Room and Sterile Processing Department Applications
Issue 1: Inconsistent Titles

- Preparation and Packaging
- Prep and packaging and sterilizer loading/unloading
- Preparation and Packaging/clean workroom
- Clean workroom
## HVAC Task Force Proposed Titles
### SPD, OR and Endoscopy Areas

<table>
<thead>
<tr>
<th>Current Terms</th>
<th>Uniform Titles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decontamination area/dirty room</td>
<td>Decontamination Room</td>
</tr>
<tr>
<td>Clean area/Preparation area/Prep and packaging/Sterilizer loading and unloading</td>
<td>Clean workroom</td>
</tr>
<tr>
<td>Sterilizer access</td>
<td>Sterilizer equipment access room</td>
</tr>
<tr>
<td>Storage/clean storage/sterile storage</td>
<td>Sterile storage room</td>
</tr>
<tr>
<td>Substerile room/OR sterile processing</td>
<td>Satellite sterile processing room</td>
</tr>
<tr>
<td>Housekeeping</td>
<td>Environmental services room</td>
</tr>
<tr>
<td>GI endoscopy procedure room</td>
<td>Endoscopy procedure room</td>
</tr>
<tr>
<td>GI endoscope cleaning room</td>
<td>Endoscope processing room</td>
</tr>
</tbody>
</table>
Issue 2: Inconsistent Parameters - Temperature

- AAMI ST 7960-65 F, 16-18 C
- ASHRAE 170 72-78 F, 22-26 C
- Clinical Guideline vs. Design Standard
- TF Proposal 60 -73 F
### ASHRAE Addendum h to 170-2013

<table>
<thead>
<tr>
<th>Function of Space</th>
<th>Pressure Relationship to Adjacent Areas (n)</th>
<th>Minimum Outdoor achen</th>
<th>Minimum Total achen</th>
<th>All Room Air Exhausted Directly to Outdoors (j)</th>
<th>Air Recirculated by Means of Room Units (a)</th>
<th>Design Relative Humidity (k), %</th>
<th>Design Temperature (l), °F/°C</th>
</tr>
</thead>
<tbody>
<tr>
<td>CENTRAL MEDICAL AND SURGICAL SUPPLY - STERILE PROCESSING DEPARTMENT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Soiled or Decontamination room</td>
<td>Negative</td>
<td>2</td>
<td>6</td>
<td>Yes</td>
<td>No</td>
<td>NR</td>
<td>72–78/22–26 60–73/16-23</td>
</tr>
<tr>
<td>Clean workroom</td>
<td>Positive</td>
<td>2</td>
<td>4</td>
<td>NR</td>
<td>No</td>
<td>max 60</td>
<td>72–78/22–26 68–73/20-23</td>
</tr>
<tr>
<td>Sterile storage</td>
<td>Positive</td>
<td>2</td>
<td>4</td>
<td>NR</td>
<td>NR</td>
<td>max 60</td>
<td>72–78/22–26 Max 75/24</td>
</tr>
</tbody>
</table>

**Notes for Table 7.1:**

z. See AAMI Standard ST79 for additional information for these spaces.
AAMI Standard ST79 - 2017

Heating, ventilation, air conditioning (HVAC) operating parameters – The HCF should...

• Identify **which version of ANSI/ASHRAE/ASHE 170 will be used** - based on when the HVAC system was initially installed or last upgraded.

• The HCF should establish and implement a **systematic processes for monitoring** HVAC performance parameters and a mechanism for identifying & resolving variances within the rooms throughout the facility where sterile processing occurs.

• **Establish policies and procedures for monitoring and maintaining HVAC parameters** within the sterile processing areas.

• Procedures should include **maintaining records of monitoring results** that are retrievable either from a central system or a local log.

• **If a variance occurs**, sterile processing personnel in combination with a **multidisciplinary team** (e.g., facility engineer, infection preventionist, risk manager, sterile processing manager or other designated personnel) **should conduct a risk assessment**.

• The sterile processing department is defined by ANSI/ASHRAE/ASHE 170 as a critical area
Today’s Sterile Processing Department
Decontamination Room
Personal Protective Equipment

- Head cover
- Mask
- Face shield
- Gown
- Gloves
- Shoe covers
Clean Workroom

Inspect  Assemble  Package  Sterilize
Sterile Storage Room
Sterile Processing in the Surgical Suite

Must be functionally equivalent to SPD

Separate decontamination and clean workrooms

Physically separated by a wall containing either a door or a pass-through that can be closed and secured

One-way traffic flow of “dirty” to “clean”
Satellite Sterile Processing - AAMI
Two-room Sterile Processing - FGI
One Room Sterile Processing
## One Room Sterile Processing
### HVAC TF Recommendation

<table>
<thead>
<tr>
<th>Air changes/hour</th>
<th>Air pressure</th>
<th>Humidity</th>
<th>Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>NR</td>
<td>Maximum 60%</td>
<td>60-73°F</td>
</tr>
</tbody>
</table>
Endoscopy Suite
# Endoscopy Suite Components

<table>
<thead>
<tr>
<th>ASHRAE 170 (2013)</th>
<th>HVAC TASK FORCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endoscope Cleaning room</td>
<td>Endoscope Processing Room</td>
</tr>
<tr>
<td>Decontamination Room</td>
<td>Endoscope Processing Room, 2 Room Design, Decontamination Room</td>
</tr>
<tr>
<td>Clean Workroom</td>
<td>Clean Workroom</td>
</tr>
<tr>
<td>Clean/Sterile Storage Room</td>
<td>Clean/Sterile Storage Room</td>
</tr>
<tr>
<td>Endoscopy Procedure Room</td>
<td>Endoscopy Procedure Room</td>
</tr>
<tr>
<td>Bronchoscopy Procedure Room</td>
<td>Bronchoscopy Procedure Room</td>
</tr>
<tr>
<td>Sterilizer Service Access Room</td>
<td>Sterilizer Service Access Room</td>
</tr>
<tr>
<td>Environmental Services Closet</td>
<td>Environmental Service Closet</td>
</tr>
</tbody>
</table>
Endoscope Processing Room Design

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## ASHRAE Standard 170
### 2013 Endoscopy Suite Requirements

<table>
<thead>
<tr>
<th>Functional Area</th>
<th>Minimum Total Air Changes per Hour</th>
<th>Settings for Air Flow Patterns (Pressure)</th>
<th>Humidity</th>
<th>Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endoscope Cleaning</td>
<td>10</td>
<td>Negative</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Decontamination Room</td>
<td>6</td>
<td>Negative</td>
<td>NR</td>
<td>60°F to 73°F (15°C to 23°C)</td>
</tr>
<tr>
<td>Clean Workroom</td>
<td>4</td>
<td>Positive</td>
<td>Maximum 60%</td>
<td>68°F to 73°F (20°C to 23°C)</td>
</tr>
<tr>
<td>Clean/Sterile Storage Room</td>
<td>4</td>
<td>Positive</td>
<td>Maximum 60%</td>
<td>72°F to 78°F (22°C to 26°C)</td>
</tr>
<tr>
<td>Endoscopy Procedure Room</td>
<td>6</td>
<td>NR</td>
<td>20% - 60%</td>
<td>68°F to 73°F (20°C to 23°C)</td>
</tr>
<tr>
<td>Bronchoscopy Procedure Room</td>
<td>12</td>
<td>Negative</td>
<td>NR</td>
<td>68°F to 73°F (20°C to 23°C)</td>
</tr>
<tr>
<td>Sterilizer Service Access Room</td>
<td>10</td>
<td>Negative</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Environmental Services Closet</td>
<td>10</td>
<td>Negative</td>
<td>NR</td>
<td>72°F to 78°F (22°C to 26°C)</td>
</tr>
</tbody>
</table>
## AORN: Flexible Endoscopes

### Table 1. HVAC Design Parameters for Endoscopy Suites

<table>
<thead>
<tr>
<th>Functional Area</th>
<th>Minimum Total Air Changes per Hour</th>
<th>Settings for Air Flow Patterns (Pressure)</th>
<th>Humidity</th>
<th>Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endoscopy processing room - One room design</td>
<td>10</td>
<td>NR</td>
<td>Maximum 60%</td>
<td>60°F to 73°F (16°C to 23°C)</td>
</tr>
<tr>
<td>Endoscopy processing room - Two room design</td>
<td>10</td>
<td>negative</td>
<td>Maximum 60%</td>
<td>60°F to 73°F (16°C to 23°C)</td>
</tr>
<tr>
<td>Decontamination room</td>
<td></td>
<td>negative</td>
<td>Maximum 60%</td>
<td>58°F to 73°F (20°C to 23°C)</td>
</tr>
<tr>
<td>Clean workroom</td>
<td>10</td>
<td>positive</td>
<td>Maximum 60%</td>
<td>&lt; 75°F (24°C)</td>
</tr>
<tr>
<td>Clean/sterile storage room</td>
<td>4</td>
<td>positive</td>
<td>Maximum 60%</td>
<td>58°F to 73°F (20°C to 23°C)</td>
</tr>
<tr>
<td>Endoscopy procedure room</td>
<td>6</td>
<td>NR</td>
<td>Maximum 60%</td>
<td>58°F to 73°F (20°C to 23°C)</td>
</tr>
<tr>
<td>Bronchoscopy procedure room</td>
<td>12</td>
<td>negative</td>
<td>NR</td>
<td>58°F to 73°F (20°C to 23°C)</td>
</tr>
<tr>
<td>Sterilizer service access room</td>
<td>10</td>
<td>negative</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Environmental services closet</td>
<td>10</td>
<td>negative</td>
<td>NR</td>
<td>NR</td>
</tr>
</tbody>
</table>

NR = No Recommendation  
1 Check IFUs for storage requirements (e.g., reusable linens, CIs, BLs)  
2 Check sterilizer manufacturer’s specifications  

NOTE: The terminology and parameters noted above represent the consensus of a joint heating, ventilation, and air-conditioning (HVAC) task force brought together on April 29, 2015 in Annapolis, Maryland for the purpose of harmonizing the conflicting and sometimes unclear HVAC standards and guidelines established by a variety of professional organizations. The task force included representatives from American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE), the American Society for Healthcare Engineering (ASHE), the Association for the Advancement of Medical Instrumentation (AAMI), the Association of periOperative Registered Nurses (AORN), the Facility Guidelines Institute (FGI), and other sterile processing experts and consultants.
Sinks: Sterile Processing vs. Endoscopy

- Decontamination room - SPD FGI 2018
  - Three-basin sink with counter for two-room
  - Two-basin sink for one-room
- Decontamination Room – Endoscopy - FGI 2018
  - Two-basin sink with a backsplash at least 12 inches high

*Decontamination sink: A sink used for endoscope processing tasks

To avoid splash, the decontamination sink shall be separated from the clean work area by 4-foot distance from the edge of the sink or a separating wall or screen. FGI 2018
Instrument Air*: Sterile Processing vs. Endoscopy

- Instrument air provided for both
  - Endoscopy Processing room
  - Sterile Processing room

- Necessary for drying/clearing lumens

- NFPA 99 permits the use of portable medical compressed air for single applications.

*Instrument air: A medical gas that is not respired, is filtered to 0.01 micron, free of liquids and hydrocarbon vapors, and dry to a dew point of -40º F (-40º C)
Ventilation Requirements – Testing and Documenting

- HVAC monitoring in the OR and CSP is a regulatory and accreditation requirement
  
  - TJC EC.02.05.01
  - TJC EC.02.05.01 EP 16
  - CMS Tag §482.42
  - CMS Tag §482.41 (d)(4)

- Documentation frequency and method are not specified
HVAC Failure Assessment

• Multidisciplinary team

• Risk-assessment based corrective actions
  – Evaluate materials
  – Consider patient impact (delay cases?)

• Document process in a policy
FGI Guidelines
Major Revisions For 2018

Hospital and Outpatient
- Option for combined pre- and post-procedure patient care areas
- New telemedicine guidance
- Revised chapter on mobile/transportable medical units
- “Patients of size” replaces “bariatric patients”; POS requirements placed in common elements to apply across facility types: Added clearances for lifts
- Two-room sterile processing now the minimum requirement; exception for use of table-top sterilizer only

Hospital
- Adult and pediatric CCU rooms are single-patient (not NICU)
FGI Guidelines
Major Revisions For 2018

• Now standalone document, separate from Hospital Guidelines
• Two approaches to applying Outpatient requirements:
  – Project types comprehensively described in chapter
  – Project types that don’t fit neatly; can pick and choose relevant requirements
• Two new chapters:
  – General and specialty medical services facilities (flexibility for different facility types – formerly primary care/neighborhood clinic)
  – Freestanding imaging facilities
• Urgent care exam rooms more flexible; expanded infusion and cancer treatment facilities; increased flexibility in outpatient OR sizes; room sizes added for clinical areas in outpatient psych center
FGI Guidelines
Major Revisions For 2018

• Honed Residential material since inaugural publication
• Reduced circular cross-references
• Aligned content with new CMS rule requiring each resident room in a nursing home to have a dedicated bathroom with at least one toilet and sink; maximum capacity is two residents per room
• Refined acoustic requirements to better meet residential needs and added guidance based on acoustics research conducted in a continuing care retirement community
• Two new chapters:
  – Long-term substance abuse treatment facilities
  – Settings for individuals with Intellectual and/or developmental disabilities
Questions?