REGULATIONS & GUIDELINES TO FOLLOW!
TJC, FGI, AND ASHRAE

William M. Wagner, ScD, CHSP, CHEP, CHCM
Vice President - Quality Compliance
TSIG Consulting, Inc
The Joint Commission®
Environment of Care Standards-2015

- Minimizing Waterborne Organisms
  (EC.02.05.01 EP14)
- Controlling Airborne Contaminates
  (EC.02.05.01 EP15)
- Providing Appropriate Environment
  (EC.02.06.01 EP13)
Design Criteria

Legionella: Risk Management for Building Water Systems
ASHRAE 188-2015
Ventilation of Healthcare Facilities
ASHRAE 170-2008
KEY RESOURCES


Historic New York City hotel located as source of Legionnaires’ disease outbreak

“The Opera House Hotel said it will go beyond newly imposed regulations in testing its cooling system as officials declare an end to the outbreak” (NY Times)
The hospital minimizes pathogenic biological agents in cooling towers, domestic hot and cold water systems, and other aerosolizing water systems.
WATER MANAGEMENT PROGRAM
ASHRAE 188

➤ Prevention-
   Establishing the program

➤ Precautions-
   Identifying potential & ongoing risks

➤ Response-
   Being prepared with corrective actions
WATER MANAGEMENT AUDIT

WATER MANAGEMENT RISK ASSESSMENT
SITE PLAN - MAIN CAMPUS

WATER MGMT. RISK ASSESSMENT LEGEND

- RISK AREA
- WATER SOURCE

- MAIN HOSPITAL
- SUPPLY AIR INTAKE 2ND FLOOR
- SUPPLY AIR INTAKE 3RD FLOOR
- WALKING PATH
- ERONG WALK FOUNTAIN
- 2-STORY UTILITY PLANT
- VEHICLE MACHNERY
- PAVING

TSG CONSULTING
WATER MANAGEMENT AUDIT

WATER MANAGEMENT ASSESSMENT
FIVE WEST

WATER MANAGEMENT ASSESSMENT LEGEND

SCHEDULES AND NOTES
High Risk Areas

- Cooling Towers*
- Hot and Cold Water Loops
- Whirlpools and Spas
- Decorative Indoor Fountains
- Inactive Patient Care Space
- Cardiac Heater-cooler Units

*8.2 Cooling Towers. Cooling towers shall be located so that drift is directed away from air-handling unit intakes.
IDENTIFY THE “CONTROL LOCATIONS” FOR RISKS

DETERMINE AND IMPLEMENT THE “CONTROL MEASURE” TO MINIMIZE RISK

DEFINE THE “CONTROL LIMITS” REQUIRED

MONITOR THE “CONTROL MEASURES”
- Document the risk analysis
- Identify the “control measures” implemented on drawings
- Monitor the “control limits”
- Record “corrective actions” for deficiencies
- Discuss concerns at EOCC meeting
PRECAUTIONS

- Spring-cleaning cooling towers
- Reopening closed patient units
- Fixing closed hot water loops
- Cleaning outdoor fountains
- Relocate patients
- Decontaminate systems
  - Heat
  - Chemical
- Test system for organisms
- Retreat as required
- Retest until appropriate
EC.02.05.01 EP15

- In areas designed to control airborne contaminants (such as biological agents, gases, fumes, dust), the ventilation system provides appropriate pressure relationships, air-exchange rates, and filtration efficiencies.
Environmental Criteria

- Original design of space
- Current clinical function of a space
- Capabilities of the existing utility system
- Utility support for clinical needs of space
- Current infection-related events
- Suitability of space for procedures
PARAMETERS

- Pressure relationships
- Directional airflow
- Air-exchange rates
- Filtration efficiencies
AREAS OF CONCERN

- Protective Environments (PE)
- Positive Pressure Areas
- Airborne Infection Isolation Rooms (AIIR)
- Negative Pressure Areas
PROTECTIVE ENVIRONMENTS (PE)

- Operating rooms
- Special procedural rooms
- Neonatal nurseries
- Bone marrow transplants
POSITIVE PRESSURE AREA

- Sterile processing
- Pharmacy
- Sterile supplies storage
- Clean storage rooms
AIRBORNE INFECTION ISOLATION ROOMS (AIIR)

- Contagious patient rooms
- Specific procedure rooms
- Contagious delivery rooms
- Bronchoscopy procedure rooms
NEGATIVE PRESSURE AREAS

- Laboratory
- High-level disinfection areas
- Soiled utility rooms
- Sterile processing (Decontamination area)
- Pharmacy (Hazardous drug prep area)
<table>
<thead>
<tr>
<th>Function of Space</th>
<th>Pressure</th>
<th>Min OA (ACH)</th>
<th>Min Total Air (ACH)</th>
<th>Air Exhausted</th>
<th>Air Recirculation by local unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class B and C operating rooms</td>
<td>Positive</td>
<td>4</td>
<td>20</td>
<td>N/R</td>
<td>No</td>
</tr>
<tr>
<td>Class A Operating/Procedure room</td>
<td>Positive</td>
<td>3</td>
<td>15</td>
<td>N/R</td>
<td>No</td>
</tr>
<tr>
<td>Airborne Infectious Isolation room</td>
<td>Negative</td>
<td>2</td>
<td>12</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Protective environment</td>
<td>Positive</td>
<td>2</td>
<td>12</td>
<td>N/R</td>
<td>No</td>
</tr>
<tr>
<td>X-ray (surgery/critical care and catheterization)</td>
<td>Positive</td>
<td>3</td>
<td>15</td>
<td>N/R</td>
<td>No</td>
</tr>
<tr>
<td>Bronchoscopy, sputum collection, and</td>
<td>Negative</td>
<td>2</td>
<td>12</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>ER Waiting Area</td>
<td>Negative</td>
<td>2</td>
<td>12</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Laboratory, general</td>
<td>Negative</td>
<td>2</td>
<td>6</td>
<td>N/R</td>
<td>N/R</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>Positive</td>
<td>2</td>
<td>4</td>
<td>N/R</td>
<td>N/R</td>
</tr>
<tr>
<td>Compounding Pharmacy Hazardous Prep (USP 797-800)</td>
<td>Negative</td>
<td>2</td>
<td>30 (15)</td>
<td>Yes</td>
<td>No (HEPA)</td>
</tr>
<tr>
<td>Gastrointestinal Endoscopy Procedure Room</td>
<td>NR</td>
<td>2</td>
<td>6</td>
<td>N/R</td>
<td>No</td>
</tr>
<tr>
<td>Endoscope cleaning</td>
<td>Negative</td>
<td>2</td>
<td>10</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Soiled or decontamination room</td>
<td>Negative</td>
<td>2</td>
<td>6</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Clean workroom</td>
<td>Positive</td>
<td>2</td>
<td>4</td>
<td>N/R</td>
<td>No</td>
</tr>
<tr>
<td>Sterile storage</td>
<td>Positive</td>
<td>2</td>
<td>4</td>
<td>N/R</td>
<td>N/R</td>
</tr>
<tr>
<td>Soiled linen storage</td>
<td>Negative</td>
<td>N/R</td>
<td>10</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Clean linen storage</td>
<td>Positive</td>
<td>N/R</td>
<td>2</td>
<td>N/R</td>
<td>N/R</td>
</tr>
<tr>
<td>Janitor's closet</td>
<td>Negative</td>
<td>N/R</td>
<td>10</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Hazardous material storage</td>
<td>Negative</td>
<td>2</td>
<td>10</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
PRESSURE DIFFERENTIAL

- Minimum 0.01” water column
  (FGI 7.2.1-2 & 7.4.1)
- Protective Environments (PE)
- Airborne Infection Isolation Rooms (AILR)
- Positive or Negative Areas ???
  (Risk assessment)
Relationship to adjacent areas
- Outward for clean environments
- Inward for dirty environments
- Not a measure of pressure
Air-Exchange Rates

- Outdoor air exchange
- Exhaust to outdoor
- Minimum requirements
When calculating ACH:

Positive environment, i.e. OR, Sterile Processing Area & Clean Storage

- measure the air supplied to the space

Negative environment, i.e. AIIR, Laboratory ER Waiting Room

- measure the air exhausted from the space
Design criteria
Percent efficiency
Performance maintenance
Minimum Reporting Efficiency (MERV) (0.3 to 10 μm, rating from 1 to 16)

Bacteria, droplet nuclei (sneeze), cooking oil, most smoke and insecticide dust, most face powder, most paint pigments

- MERV 13-16 @ 1.0–0.3 μm for Surgery
- Inventory appropriate spaces
- Classify *clinical* function (invasive, support, etc.)
- Determine original design of space
- Define capabilities of the utility system
- Conduct a “Ventilation Audit”
VENTILATION AUDIT

TYPICAL CENTRAL STERILE PROCESSING DEPARTMENT
VENTILATION AUDIT

VENTILATION AUDIT LEGEND
- SINGLE DIRECTION AIRFLOW - OK
- SINGLE DIRECTION AIRFLOW - DEFICIENT
- BI-DIRECTIONAL AIRFLOW - OK
- BI-DIRECTIONAL AIRFLOW - DEFICIENT
- POSITIVE PRESSURE AREA
- NEGATIVE PRESSURE AREA

VENTILATION AUDIT IDENTIFIER SYSTEM
### UNIQUE POINT IDENTIFIER AS LISTED IN VENTILATION AUDIT REPORT

VENTILATION AUDIT STANDARDS

ACH - AIR CHANGES PER HOUR
NEGATIVE ACH: MINIMUM = 6
POSITIVE ACH: MINIMUM = 4

REQUIREMENT: EC.02.05.01 EPB
DIFFERENTIAL PRESSURE RELATION .01 INCH OF WATER COLUMN.

NOTE:
ALL POINTS SHOWN IN RED REQUIRE ADJUSTMENT FOR EITHER DIRECTIONAL AIRFLOW OR PRESSURE DIFFERENTIAL.

SCHEDULES AND NOTES

AIR CHANGES VALUES

<table>
<thead>
<tr>
<th>PRESSURE AREA</th>
<th>PRESSURE TYPE</th>
<th>ACH VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>POSITIVE</td>
<td>8.8</td>
<td></td>
</tr>
<tr>
<td>NEGATIVE</td>
<td>10.1</td>
<td></td>
</tr>
</tbody>
</table>
# Ventilation Audit

## General Hospital

### Points

<table>
<thead>
<tr>
<th>Points</th>
<th>Location</th>
<th>Adjacent Space</th>
<th>Required Directional Airflow</th>
<th>Measured Directional Airflow</th>
<th>Differential Pressure (&quot; of water)</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td>B Corridor</td>
<td>Decontamination Area (1BB203)</td>
<td>Positive</td>
<td>Positive</td>
<td>0.02</td>
<td>None</td>
</tr>
<tr>
<td>#2</td>
<td>B Corridor</td>
<td>Decontamination Area (1BC206)</td>
<td>Positive</td>
<td>Positive</td>
<td>0.02</td>
<td>None</td>
</tr>
<tr>
<td>#3</td>
<td>B Corridor</td>
<td>Central Sterile Supply (1BC212)</td>
<td>Negative</td>
<td>Positive</td>
<td>0.02</td>
<td>Pressure adjustment</td>
</tr>
<tr>
<td>#4</td>
<td>C Corridor</td>
<td>Central Sterile Supply (1BC212)</td>
<td>Negative</td>
<td>Positive</td>
<td>0.04</td>
<td>Pressure adjustment</td>
</tr>
<tr>
<td>#5</td>
<td>C Corridor</td>
<td>Central Sterile Supply (1BC209)</td>
<td>Negative</td>
<td>Positive</td>
<td>0.04</td>
<td>Pressure adjustment</td>
</tr>
<tr>
<td>#6</td>
<td>Decontamination Area (1BB203) through hole</td>
<td>Central Sterile Supply (1BC209)</td>
<td>Negative</td>
<td>Positive</td>
<td>0.005</td>
<td>Seal hole</td>
</tr>
<tr>
<td>#7</td>
<td>Decontamination Area (1BB203) through hole</td>
<td>Central Sterile Supply (1BC209)</td>
<td>Negative</td>
<td>Positive</td>
<td>0.003</td>
<td>Seal hole</td>
</tr>
<tr>
<td>#8</td>
<td>Decontamination Area (1BB203) through window</td>
<td>Central Sterile Supply (1BC209)</td>
<td>Negative</td>
<td>Positive</td>
<td>0.005</td>
<td>Pressure adjustment</td>
</tr>
<tr>
<td>#9</td>
<td>Equipment Room (EPS)</td>
<td>Storage</td>
<td>Should not be an opening</td>
<td>-</td>
<td></td>
<td>Remove door and make solid wall</td>
</tr>
<tr>
<td>#10</td>
<td>Central Sterile Supply (1BC212) Hallway</td>
<td>Decontamination Area 1BC206</td>
<td>Positive</td>
<td>Neutral</td>
<td>0.003</td>
<td>Pressure adjustment Keep door closed</td>
</tr>
<tr>
<td>#11</td>
<td>Decontamination Area (1BC206)</td>
<td>Equipment Room (EPS)</td>
<td>Negative</td>
<td>Negative</td>
<td>0.00</td>
<td>None</td>
</tr>
<tr>
<td>#12</td>
<td>Central Sterile Supply (1BC209) Wrapping Area</td>
<td>Storage Area</td>
<td>Positive</td>
<td>Positive</td>
<td>0.002</td>
<td>Increase pressure differential</td>
</tr>
</tbody>
</table>
VENTILATION AUDIT

PHARMACY DEPARTMENT WITH COMPOUNDING SUITE
VENTILATION AUDIT

VENTILATION AUDIT LEGEND
- SINGLE DIRECTION AIRFLOW - OK
- SINGLE DIRECTION AIRFLOW - DEFICIENT
- BI-DIRECTIONAL AIRFLOW - OK
- BI-DIRECTIONAL AIRFLOW - DEFICIENT
- POSITIVE PRESSURE AREA
- NEGATIVE PRESSURE AREA

VENTILATION AUDIT IDENTIFIER SYSTEM
### UNIPOINT IDENTIFIER AS LISTED IN VENTILATION AUDIT REPORT

VENTILATION AUDIT STANDARDS

ACH - AIR CHANGES PER HOUR
GENERAL PHARMACY: MINIMUM = 4
COMPOUNDING SUITE: MINIMUM = 30

REQUIREMENT:
EC/22.06.01 EPB
USP <787>

DIFFERENTIAL PRESSURE RELATION
GENERAL PHARMACY: 0.01 INCH OF WATER COLUMN
COMPOUNDING SUITE: 0.02-0.05 INCH OF WATER COLUMN.

KEY PLAN
VENTILATION AUDIT

PHARMACY DEPARTMENT WITH COMPOUNDING SUITE
VENTILATION AUDIT

VENTILATION AUDIT LEGEND
- SINGLE DIRECTION AIRFLOW - OK
- SINGLE DIRECTION AIRFLOW - DEFICIENT
- BI-DIRECTIONAL AIRFLOW - OK
- BI-DIRECTIONAL AIRFLOW - DEFICIENT
- POSITIVE PRESSURE AREA
- NEGATIVE PRESSURE AREA

VENTILATION AUDIT IDENTIFIER SYSTEM
### UNIQUE POINT IDENTIFIER AS LISTED IN VENTILATION AUDIT REPORT

VENTILATION AUDIT STANDARDS
- ACH (AIR CHANGES PER HOUR)
  - GENERAL PHARMACY: MINIMUM = 4
  - COMPOUNDING SUITE: MINIMUM = 30
  - REQUIREMENT:
    - EC 20.03.01 EPA
    - USP <797>

- DIFFERENTIAL PRESSURE RELATION:
  - GENERAL PHARMACY: 0.01 INCH OF WATER COLUMN
  - COMPOUNDING SUITE: 0.02-0.05 INCH OF WATER COLUMN

KEY PLAN

Tsig Consulting
NON-COMPLIANCE

- Identify areas of non-compliance on drawing
- Inspect utility system for problems and correct issues when possible
- Conduct risks assessment with IP and clinical staff
- Implement Interim Patient Safety Measures*

*(cease procedures when appropriate)*
CORRECTIVE ACTIONS

- Determine if space was appropriately designed for current use
- Review the capabilities of utility system
- Develop a PFI with $$$
- Decide if patient care can continue
DEMONSTRATE COMPLIANCE

- Determine appropriate ranges for various areas
- Establish “realistic” monitoring frequencies
- Record the appropriate data
- Document corrective actions
- Calibrate monitors
EC.02.06.01 EP13

- The hospital maintains ventilation, temperature, and humidity levels suitable for the care, treatment, and services provided.
AREAS OF CONCERN

- Surgery
- Nursery
- Invasive Radiology
- Sterile Storage
<table>
<thead>
<tr>
<th>Function of Space</th>
<th>Design Humidity (%)</th>
<th>Temp (F)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class B and C operating rooms</td>
<td>20 - 60</td>
<td>68 - 75</td>
</tr>
<tr>
<td>Class A Operating/Procedure room</td>
<td>20 - 60</td>
<td>70 - 75</td>
</tr>
<tr>
<td>Airborne Infectious Isolation room</td>
<td>max 60</td>
<td></td>
</tr>
<tr>
<td>Protective environment anteroom</td>
<td>N/R</td>
<td>N/R</td>
</tr>
<tr>
<td>X-ray (surgery/critical care and catheterization)</td>
<td>20- 60</td>
<td>70 - 75</td>
</tr>
<tr>
<td>Bronchoscopy, sputum collection, and pentamidine administration</td>
<td>N/R</td>
<td>68 - 73</td>
</tr>
<tr>
<td>Laboratory, general</td>
<td>N/R</td>
<td>70 - 75</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>N/R</td>
<td>N/R</td>
</tr>
<tr>
<td>Compounding Pharmacy Hazardous Prep</td>
<td>max 60</td>
<td>&lt;= 68</td>
</tr>
<tr>
<td>Gastrointestinal Endoscopy Procedure Room</td>
<td>20 - 60</td>
<td>68 - 73</td>
</tr>
<tr>
<td>Endoscope cleaning</td>
<td>N/R</td>
<td>N/R</td>
</tr>
<tr>
<td>Soiled or decontamination room</td>
<td>N/R</td>
<td>72 - 78</td>
</tr>
<tr>
<td>Clean workroom</td>
<td>max 60</td>
<td>72 - 78</td>
</tr>
<tr>
<td>Sterile storage</td>
<td>max 60</td>
<td>72 - 78</td>
</tr>
<tr>
<td>Soiled linen storage</td>
<td>N/R</td>
<td>N/R</td>
</tr>
<tr>
<td>Clean linen storage</td>
<td>N/R</td>
<td>72 - 78</td>
</tr>
<tr>
<td>Janitor's closet</td>
<td>N/R</td>
<td>N/R</td>
</tr>
<tr>
<td>Hazardous material storage</td>
<td>N/R</td>
<td>N/R</td>
</tr>
</tbody>
</table>
CMS Condition of Participation - Memorandum Summary: Anesthesia

- S&C 13-25 April 13, 2013
  - Reduced humidity level for 35% to 20%
- S&C 15-27 February 20, 2015
  - Re-established earlier level based on Quality Advisory - January 21, 2015 for IFU
ASSESS EQUIPMENT AND SUPPLIES

- Identify area where anesthesia is used
  - Surgery, Invasive Radiology, etc.
- Classify items used in area of anesthesia
  - In-use or storage
- Review manufacturer’s IFU
  - Medical equipment & surgical supplies
- Review packaging of supplies
  - Duration of supplies in low humidity area
DEMONSTRATE COMPLIANCE

- Determine appropriate ranges for various areas
- Establish “realistic” monitoring frequencies
- Record the appropriate data
- Document corrective actions
- Calibrate monitors
Policy on acceptable ranges, monitoring frequency & required corrective actions

Policy developed by clinical, IC and FM

Data of monitoring with readings

Records of corrective actions
Joint Interim Guidance:

HVAC in the Operating Room and Sterile Processing Department

September 21, 2015

- Design - FGI & ASHRAE
- Operational – AAMI & AORN

There is a difference based on clinical need!!!
Infection Prevention and Facilities Management must focus on the good of the patient!!!
QUESTIONS

William M. Wagner, ScD, CHSP, CHEP
Vice President Quality Compliance
347-867-5128