

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

For operating room (OR) and sterile processing department (SPD) HVAC system design and construction, the standard most often cited by surveyors is ANSI/ASHRAE/ASHE Standard 170-2013: *Ventilation of Health Care Facilities*, which establishes minimum HVAC design parameters. ASHRAE/ASHE 170-2013 was incorporated as part of the 2014 FGI *Guidelines for Design and Construction of Hospitals and Outpatient Facilities*. For maintaining temperature and humidity levels once a space has been occupied, the most often cited clinical practice guidelines are the AORN *Guideline for a Safe Environment of Care, Part 2* and AAMI ST79: *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*.

Design requirements are NOT the same as clinical practice recommendations. Each has a distinct purpose and intent. The ASHRAE/ASHE standards and FGI guidelines are intended to establish the minimum design requirements and criteria that must be met to construct an HVAC system that will support clinical functions during the life of a building. The AAMI and AORN guidelines are intended to guide the daily operation of the HVAC system and clinical practice once the health care facility is occupied.

Unfortunately, owners, designers, and surveyors often confuse the two types of guidance and use design standards to assess the daily operation in health care facilities. Not only are the design and operational methodologies different, but the temperature and humidity ranges indicated for each vary significantly. There is no single, simple solution that suits both design and operations, and there is very little evidence regarding optimal HVAC operating parameters within an OR or SPD. The effect of the HVAC system parameters falling out of range is variable. A small variance for a short period of time may not be of clinical concern, whereas a large variance for a longer period may have clinical significance. Many variables, with wide-ranging implications for patient and health care worker safety and comfort, have to be taken into account. Prudent, reasonable, achievable, safe, practical, evidence-based guidance that is in alignment across all the standards and guidelines is needed to help designers, owners, and surveyors appropriately regulate ventilation in health care spaces.

Health care associations and the medical device manufacturing community have formed a joint HVAC task force to address these issues. The task force, with representatives from ASHRAE, ASHE, FGI, AORN, the Association for Professionals in Infection Control and Epidemiology (APIC), and AAMI, met in Annapolis, Maryland, on April 29, 2015, to begin to work toward the goal of harmonizing the HVAC guidance in the various standards and guidelines.

One of the first challenges is to agree on terminology. The documents published by ASHRAE/ASHE, FGI, AAMI, and AORN use different terms to describe similar spaces. The task force proposes the following common terms to describe the various spaces located in typical SPD, OR, and endoscopy areas:

- Decontamination room
- Clean workroom
- Sterilizer service access room
- Sterile storage room
- Satellite sterile processing room
- Environmental services room
- Endoscopy procedure room
- Endoscope processing room

The second challenge is to harmonize design and operational requirements for room pressurization, total air changes per hour, relative humidity, and temperature in each of these spaces. The task force will develop a common set of proposals for consideration by each organization. The groups will return comments on these proposals to the task force, which will then finalize consensus recommendations for the groups to incorporate into their respective guidelines and standards.

Interim Guidance

Achieving consensus among task force members, developing proposals, and getting each organization to accept the revisions will take time. In the meantime, the joint task force is extremely concerned about health care organizations being cited by surveyors for not maintaining appropriate temperature and humidity control in ORs and SPDs. Therefore, the task force is recommending that the following measures be taken:

For health care organizations

Every health care organization that provides surgical services should determine the HVAC operating parameters for ORs, the SPD, endoscopy procedure rooms, and sterile storage rooms that meet their patient, personnel, and product storage needs. Pulling together a multidisciplinary team to review the current HVAC operating practice and perform a risk assessment of the affected area(s) is a good first step. The team should enter the values/parameters they will follow on a day-to-day basis into their organization's HVAC system policy, along with appropriate corrective measures to mitigate risk and restore the HVAC system to the desired parameters when conditions fall outside of those values. The team should identify medical products and devices that require tightly controlled storage conditions and move those products to a location where the humidity and temperature are maintained within the manufacturer-prescribed parameters (eg, a temperature and humidity controlled cabinet).

For medical device manufacturers

Some products and devices commonly used within the OR and SPD and other areas where sterilization is performed may be sensitive to variations in environmental conditions over extended periods of time. Manufacturers of biological and chemical indicators commonly recommend that these products be stored in locations (eg, a temperature and humidity controlled cabinet) where the relative humidity can routinely be maintained between 30% and 60%.

For accreditation surveyors

The joint task force will send correspondence to the CMS, The Joint Commission, the Accreditation Association of Ambulatory Health Care, DNV, the Healthcare Facilities Accreditation Program, and state licensing agencies explaining the conflicts in the standards and what is being done to resolve conflicts. The goal of this correspondence is to request that survey organizations work with health care organizations to set appropriate temperature and humidity control parameters and to establish a plan for resolving variances.

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