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## Guidelines for Best Practices for Humidity in the Operating Room

### Introduction

The following Guidelines for Best Practices were researched and authored by the AST Education and Professional Standards Committee, and are AST approved.

AST developed the Guidelines to support healthcare delivery organization's (HDO) reinforce best practices in humidity in the operating room (OR) as related to the role and duties of the Certified Surgical Technologist (CST®), the credential conferred by the National Board of Surgical Technology and Surgical Assisting. The purpose of the guidelines is to provide information OR supervisors, risk management and surgical team members can use in the development and implementation of policies and procedures for humidity in the surgery department. The guidelines are presented with the understanding that it is the responsibility of the HDO to develop, approve, and establish policies and procedures for the surgery department regarding establishing humidity levels in the OR per HDO protocols.

### Rationale

The maintenance of the required level of *relative humidity (RH) in the operating room (OR)* has been essential to control the growth of microorganisms, prevent electrostatic discharge (ESD), and comfort of the OR team. Additionally, RH level is important to the *shelf life* of sterile supplies that are stored in the surgery department and the levels established by manufacturers of *electro-medical devices*. The subject of RH level involves a team of healthcare providers working together to identify the issues and develop solutions that includes CSTs, healthcare technology management (HTM; previously referred to as "Biomedical technicians"), and RNs.

In 2008 the American Society of Heating, Refrigeration, and Air Conditioning (ASHRAE) revised its standard for the lower level of RH in the OR from 30% to 20% while still keeping the upper level of 60% in place (range now being 20% to 60%).<sup>1</sup> Starting with the 2012 edition, the National Fire Protection Association (NFPA) included the ASHRAE standard in the *NFPA 99:Health Care Facilities Code* and the Facility Guidelines Institute has also placed the standard in the *Guidelines for Design and Construction of Hospitals and Outpatient Facilities*.<sup>2, 3</sup>

In September 2010 the American Society for Healthcare Engineering (ASHE) submitted the *Briefing for CMS on Reduction of Low-Level Humidity in Short-Term Patient Care Areas*.<sup>4</sup> Subsequently, in April 2013, the Centers for Medicare & Medicaid Services (CMS) announced it had lowered the RH requirement for anesthetizing locations from a minimum of  $\geq 35\%$  to 20%.<sup>4,5,6</sup> This was the final step in opening the door for HDOs to set the lower end of RH for anesthetizing locations at 20%.<sup>4</sup>

As previously mentioned, 30% RH was established as an aid in controlling microbial growth in the OR, prevent ESD, and comfort of the OR team. However over time these concerns lessened in particular with the development and use of non-flammable anesthetic gases, improved

ventilation systems, and improved materials used in the manufacturing of sterile drapes and gowns reducing their flammability and contribution to ESD.

The issue that has continued is the difficulty of maintaining the RH by HDOs that are located in regions of the country where cold weather and/or dry, desert-like conditions exist.<sup>7</sup> The dry environmental conditions present HDOs the challenge of maintaining a higher RH that is also affected by the use of air conditioning or heating. The following is stated in the ASHE briefing to the CMS: “In addition, RH is intimately tied to outdoor air conditions and local climate conditions. Many facilities in the United States are located in more arid climates or areas with variable seasons, which ambient local conditions often make maintaining a 30 percent RH impossible to achieve.”<sup>4</sup>

To achieve the higher level of RH HDOs report they often have to install additional expensive HVAC equipment that requires additional maintenance in order to maintain or increase the RH.<sup>7</sup> In the ASHE briefing to the CMS the following is stated: “Without jeopardizing patient outcomes, the is change is estimated to save the health care industry more than \$200 million in the next 10 years by reducing the initial ventilation system installation cost, eliminating the need to modernize existing systems to maintain 35 percent RH, and providing energy conservation savings.”<sup>4</sup>

In the summer of 2014 a CMS surveyor cited a hospital due to the RH level being lower than allowed as stated in the manufacturer’s instructions for use (IFU) for certain sterile products being used in the OR. This brought to light an important oversight – the change in the standard did not take into consideration the clinical impact that the lower RH could have on supplies and equipment used in anesthetizing locations including the IFUs.

*Humidity* affects the shelf life and product integrity of sterile supplies. Therefore, shelf life and product integrity can be even more greatly affected if the IFU calls for 30-60% RH, but the HDO lowers the RH to 20%. Examples of products that are sensitive to humidity include biological and chemical indicators, and EKG electrodes.

Manufacturer’s test products at a specific RH, of which it can be assumed the testing level has been at 30%. If supplies are stored in the OR at a RH level different from the RH used during manufacturer testing, the shelf life could be affected, e.g. shortened. Which leads to the next challenge in that the only way for manufacturers to determine if the shelf life and integrity of sterile supplies is affected is to test at the lower RH; but this could involve manufacturers having to install testing equipment that provides the lower RH as well as allowing manufacturers a significant amount of time to test the myriad number of OR supplies at the lower RH.

The manufacturers of electro-medical devices (EMD) and healthcare technology management (HTM) have communicated concerns about lower RH levels. Problems with EMDs not working properly at lower RH levels have been reported by HTM technicians, and the lower levels causing problems with calibration.

Of additional concern is lower RH levels contributing to the release of ESDs that are destructive to EMDs as well as posing a safety hazard to OR personnel. ESD discharges can damage EMD internal parts that can lead to device failure and/or malfunctioning. In the lower RH level environment, OR staff could have a tendency to more easily become “charged” and receive an electrostatic shock when coming into contact with an EMD. But Dr. Farhad Memarzadeh, Director of the Division of Technical Resources at the National Institutes of Health, disputes the notion of an environmental hazard with the RH at a 20% level by indicating “there have been no reported or documented cases of static electricity being an issue in providing safe environments for patients. Databases from FDA’s Manufacturer and User Facility Device Experience (MAUDE)

report (FDA 2011) and Emergency Care Research Institute (ECRI) have been reviewed with no incidence of equipment malfunctions or fire due to static discharge.”<sup>8</sup>

Lastly, ESD can be a source of ignition completing the surgical fire triangle if the other sources are present: ignition source → oxygen → fuel.<sup>7</sup>

In regard to EMDs one last item to be taken into consideration – many EMDs are considered capital equipment purchases with the intention that the device(s) will last many years. The HDO needs to take into consideration that a mix of old and new devices may be in use in the OR as well as different models from one or more manufacturers; therefore, it cannot be assumed that a standard RH level applies to all devices.

The HDO should address the issue of RH in anesthetizing locations with a coordinated effort that may involve a committee such as the safety or environment committee that includes participation by CSTs, HTMs, RNs, and environmental services.<sup>6</sup> The best course of action, such as completing a risk assessment and establishing an appropriate RH level in the OR, can be determined by the committee and the decision documented.

### **Evidence-based Research and Key Terms**

The research of articles, letters, nonrandomized trials, and randomized prospective studies is conducted using the Cochrane Database of Systematic Reviews and MEDLINE®, the U.S. National Library of Medicine® database of indexed citations and abstracts to medical and healthcare journal articles.

The key terms used for the research of the guidelines include: electro-medical devices; humidity; relative humidity in the operating room; shelf life. Key terms used in the guidelines are italicized and included in the glossary.

### **Guideline I**

**Healthcare delivery organizations (HDO) should establish levels of RH for the OR that are in compliance with federal regulations as well as device manufacturers IFUs.**

1. Through a coordinated effort that includes input from CSTs, HTMs, RNs and environmental services, HDOs should consider any relevant scientific and technical issues that have come to the recent forefront and complete a risk assessment to establish policies for relative humidity level in the operating room.
2. It is important for CSTs and other OR personnel to know and understand the IFUs for the supplies and equipment that are stored and used in the OR. For additional information please refer to Appendix A.

### **Guideline II**

**The surgery department should review the policies and procedures (P&P) regarding humidity in the OR on an annual basis.**

1. The surgery department should include members of the surgical team and administration when reviewing the P&Ps, including CSTs, surgeons, RNs, risk management, and infection control officer.
  - A. The surgery department should document when the P&Ps were reviewed, revision completed (if necessary), and who participated in the review process.
2. CSTs should be familiar with the P&Ps for humidity in the OR. The orientation of new employees should include reviewing the P&Ps.

### Guideline III

#### CSTs should complete continuing education to remain current in their knowledge of humidity in the OR.<sup>9</sup>

1. The continuing education should be based upon the concepts of adult learning, referred to as andragogy. Adults learn best when the information is relevant to their work experience; the information is practical, rather than academic; and the learner is actively involved in the learning process.<sup>10</sup>
2. It is recommended surgery departments use various methods of instruction to facilitate the learning process of CSTs.
  - A. If the education is primarily lecture, methods to engage learners include presentation of case studies for discussion, and audience discussion providing suggestions for reinforcing humidity levels in the OR.
  - B. Other proven educational methods include interactive training videos, and computerized training modules and teleconferences.
  - C. The continuing education should be delivered over short periods of time such as in modules, and not in a one-time lengthy educational session.
3. Continuing education programs should be periodically evaluated for effectiveness including receiving feedback from surgery department personnel.
4. The surgery department should maintain education records for a minimum of three years that include dates of education; names and job titles of employees that completed the continuing education; synopsis of each continuing education session provided; names, credentials, and experience of instructors.

### Competency Statements

Competency Statements	Measurable Criteria
<ol style="list-style-type: none"> <li>1. CSTs can monitor and document the RH level of the ORs.</li> <li>2. CSTs can serve on as well as participate in the work of a committee assigned to complete a risk assessment, publish the results of the risk assessment, and make a recommendation to the HDO in regard to RH levels in anesthetizing locations.</li> </ol>	<ol style="list-style-type: none"> <li>1. Educational standards as established by the <i>Core Curriculum for Surgical Technology</i>.<sup>11</sup></li> <li>2. The didactic subject of humidity in the OR is included in a CAAHEP accredited surgical technology program.</li> <li>3. Students demonstrate knowledge of humidity in the OR in the lab/mock OR and during clinical rotation</li> <li>4. CSTs monitor and document the RH levels of the ORs.</li> <li>5. CSTs complete continuing education to remain current in their knowledge of HVAC standards for the OR including temperature and RH levels.<sup>9</sup></li> </ol>

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## Glossary

*Electro-medical devices (EMD)*: electronic instrument or equipment used for medical purposes and health care.

*Humidity*: a quantity representing the amount of water vapor in the atmosphere or a gas.

*Relative humidity in the operating room*: the amount of water vapor present in air expressed as a percentage of the amount needed for saturation at the same temperature.

*Shelf life*: the length of time for which an item remains usable and sterile, fit for use.

## References

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## Appendix A: Joint Communication To HDO's

### RELATIVE HUMIDITY LEVELS IN THE OPERATING ROOM JOINT COMMUNICATION TO HEALTHCARE DELIVERY ORGANIZATIONS January 2015



This is an important communication to the multiple stakeholders in healthcare whose work touches sterile supplies and electro-medical equipment used in delivering care to patients. The subject is about how relative humidity (RH) levels lower than 30% can impact the integrity and functionality of some of these products, with a special emphasis on RH levels in the operating room (OR). The following professional organizations have collaborated in the development of this communication: Ambulatory Surgery Center Association (ASCA), American College of Clinical Engineering (ACCE), American Hospital Association (AHA), American Society for Healthcare Engineering (ASHE), American Society of Anesthesiologists (ASA), American Society of Heating, Refrigeration and Air Conditioning Engineers (ASHRAE), Association for Healthcare Resource & Materials Management (AHRMM), Association for the Advancement of Medical Instrumentation (AAMI), Association of periOperative Registered Nurses (AORN), Association of Surgical Technologists (AST), Health Industry Distributors Association

(HIDA), and the International Association of Healthcare Central Service Materials Management (IAHCSMM).<sup>1</sup>

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<sup>1</sup>The contents of this communication were developed out of a multi-organization stakeholder meeting convened by AAMI on October 23, 2014. Attending organizations included: Accreditation Association for Ambulatory Health Care (AAAHC), Ambulatory Surgery Center Association (ASCA), American Association of Tissue Banks (AATB), American College of Clinical Engineering (ACCE), American Hospital Association (AHA), American Society for Healthcare Engineering (ASHE), American Society of Anesthesiologists (ASA), American Society of Heating, Refrigeration and Air Conditioning Engineers (ASHRAE), Association for Healthcare Resource & Materials Management (AHRMM), Association for the Advancement of Medical Instrumentation (AAMI), Association of periOperative Registered Nurses (AORN), Association of Surgical Technologists (AST), California Hospital Association (CHA), CMS, DNV, FDA/CDRH, Health Industry Distributors Association (HIDA), Healthcare Facilities Accreditation Program (HFAP), The International Association of Healthcare Central Service Materials Management (IAHCSMM), The Joint Commission, and Medical Equipment Compliance Associates (MECA). The attendees brought multiple perspectives to a rich discussion, which contributed to the knowledge and insights in this communication piece.

### Background

- In many locations across the country, cold weather or desert conditions create dry environmental conditions. In order to achieve higher levels of RH that are required in accordance with nationally recognized expert organizations whose guidelines have been incorporated into State or Federal regulatory standards, hospitals and ambulatory surgery centers have to add humidity into the building air, an activity that is expensive and creates its own unique challenges to patient safety.
- At the request of a number of healthcare delivery organizations (HDOs), ASHRAE (the American Society of Heating, Refrigeration and Air Conditioning Engineers) investigated and revised its international standard for HVAC design parameters in 2010 (Addendum D to the 2008 version). The environmental RH for anesthetizing locations, including operating rooms was changed to expand the minimum end of the range from 30% to 20% RH.<sup>2</sup> The upper limit remains at 60% RH. The 2012 edition of National Fire Protection Association (NFPA) 99 eliminated direct references to humidity requirements for anesthetizing locations and cross-referenced the 2008 ASHRAE Standard 170 Ventilation of Health Care Facilities, with Addendum D, and the 2013 version of the standard has also been incorporated into the 2014 edition of the Facility Guidelines Institute (FGI) *Guidelines for Design and Construction of Hospitals and Outpatient Facilities*. The American Society for Healthcare Engineering (ASHE) and the Association of periOperative Registered Nurses (AORN) also support the ASHRAE standard, as does The Joint Commission. Use of a 20% rather than a 30% minimum RH is becoming increasingly desirable from a facilities management perspective.

<sup>2</sup>The 1999 edition of NFPA 99, Health Care Facilities required  $\geq 35\%$  RH in anesthetizing locations, including the OR. For purposes of simplicity, these communication points refer to the prior ASHRAE limit of 30% rather than both the different prior ASHRAE and NFPA limits.

- The ASHRAE standard change does not address the impact of the reduction of the minimum acceptable RH range to 20% on the supplies and equipment used in anesthetizing locations, including the OR environment.
- The ASHRAE standard addresses new buildings, additions to existing buildings and those alterations to existing buildings that are identified with the standard. ASHRAE 170 includes design standards but it does not intend to be absolute. The numbers given are objectives for the design but there is no expectation to maintain the system operation at the design goals one hundred percent.
- Required environmental RH for supplies and equipment is stated in the manufacturer's Instructions for Use (IFUs, sometimes called Directions for Use or DFUs).

#### Certain Technology and Supplies Require Higher Relative Humidity Levels

- Relative humidity can impact the shelf life and product integrity of sterile supplies. Some products, such as biological indicators and chemical indicators used for sterilization monitoring and EKG electrodes used for patient monitoring are *very* sensitive to humidity (in fact, EKG electrodes are in foil pouches primarily to protect against changes in external humidity levels). Other consumables for some electrosurgical products are also humidity-sensitive.  
*→Key Point: It is important for personnel to know and understand the IFUs specific to all supplies and equipment, and in particular know what environmental humidity requirements are specified in the IFU.*
- Relative humidity may affect the operation of some electro-medical equipment used in the OR, particularly with older model electro-medical equipment. This equipment may malfunction unexpectedly. Too low humidity levels may also impact calibration. Larger electrostatic discharge (ESD) pulses may create a risk of destruction of parts, premature failure, and erratic behavior of software that is "confusion" from ESD pulses. And, in an environment where humidity is low, a person can more easily become "charged" and receive an electrostatic shock when coming in contact with medical equipment.
- Humidity regulation is difficult to control when weather changes occur. The humidification regulation system in a facility will take some time to compensate by returning the humidity to the nominal "setpoint" range.
- It is uncertain for how long the humidity for supplies can be below the manufacturer's recommended minimum level before the equipment or product is affected.



### In Light of the Increasing Use of the ASHRAE 20% Minimum Relative Humidity Standard

- All stakeholders involved in the discussions that led to this communication want to achieve two goals. The first and most important goal is to ensure patients are protected through the safe and effective use of equipment and products during surgery. The second goal is to eliminate the potential waste of resources for installation, energy and ongoing maintenance that don't improve patient outcomes so that the resources can be better utilized.
  
- Manufacturers of supplies and equipment want to support the needs of HDOs to expand the lower range of acceptable RH to 20% but the pace of this change will depend on the products and whether the lower humidity level can actually harm the integrity, safe use or performance of the products. It will take some time for manufacturers to modify products and/or packaging to accommodate or verify the lower minimum RH, complete testing requirements for these typically regulated products, and have those products available for HDOs. The IFUs should be followed because they provide the up-to-date parameters of what the particular products have been tested for, whether there are differences for long-term storage versus short-term use, whether short-term deviations (or excursions) are acceptable (and for how long), and the like. If the IFUs do not answer your questions, contact the manufacturer for more details.
  
- Healthcare facility leaders should think about whether lower humidity levels are desirable and appropriate in their facility—and the answer may vary depending on the climate where the facility is located, the services offered, and the products and equipment used in their location.
  - For example, new electro-medical equipment is moving toward lower acceptable humidity levels.
  - However, if an organization continues to use equipment of various ages and from various manufacturers, it will be many years before its leaders can assume that all of the electro-medical equipment can safely withstand lower humidity levels.
  
- Healthcare facility leaders, clinicians, engineers and supply chain professionals must understand that the lower RH level can actually harm the integrity of the products they use, and they need to consider carefully the ramifications of low RH levels.

### What Should Happen Now?

Before establishing or re-establishing the low end design RH levels below 30% in the OR, healthcare facilities should assess the impact of lower RH on the equipment and supplies being used.

Here is an initial set of questions and key points to consider:

**Risk Assessment: Steps to Prepare for Lower OR Humidity Levels:**

1. What is the desired minimum humidity level and range in the OR and what is the actual level of humidity the HVAC system is able to achieve and maintain in a variety of weather conditions?
2. Have you assessed humidity level data over a sufficient time to know whether, when, and for how long the humidity falls below 30% due to environmental conditions with all seasonal variations? The method of assessment should be conducted in consultation with facilities engineers.
3. Have you determined what the IFUs say about humidity levels for each item in the HDO's existing inventory of supplies and equipment used in the OR?
4. What are the likely risks of using equipment that calls for a humidity level of 30% or higher (which may be especially prevalent with older electro-medical equipment)? What are the potential impacts on performance?
5. Request data from manufacturers documenting the variance of time (excursion data) that products can be out of range before their package integrity or performance are impacted. Learn and understand how integrity and performance are affected when supplies and equipment are stored and used out of range.  
*Note: This data may not be available from all manufacturers as of the date of this communication.*
6. For any planned new supplies and equipment, what are the anticipated recommended humidity levels for storage and use?
7. Using all of the available information, have you done an overall assessment to determine whether the benefits of lowering the humidity level threshold below 30% override the potential risks?
8. If the decision is made to maintain humidity levels below 30%, consider moving supplies that call for humidity levels of 30% or higher to a humidity-controlled closet.

Note: Supplies that currently require minimum RH levels of 30% or higher are used throughout a healthcare facility (e.g., EKG electrodes). While this risk assessment is specific to the OR, the same process should be considered for other areas where RH levels are going below 30% by design or effect.