

Quality Advisory

January 21, 2015

NEW GUIDANCE ON HUMIDITY LEVELS IN THE OPERATING ROOM

THE ISSUE

A change in the standards regulating a hospital's physical environment in the operating room (OR) may conflict with the instructions for use on some equipment and supplies routinely used in surgery. To ensure patient safety during surgery, the AHA in collaboration with its personal membership groups, the American Society for Healthcare Engineering (ASHE) and the Association for Healthcare Resource & Materials Management (AHRMM), urge hospitals to examine their humidity levels in the OR and consider the effects on equipment and products used during surgery. This advisory and associated attachments will assist in your assessment.

BACKGROUND

Many safety codes and standards regulating the health care physical environment now require relative humidity levels in **ORs** (not other areas of the facility) to be at least 20 percent, a change from the 30 percent minimum humidity required by some previous editions of codes. The 20 percent threshold provides hospitals with flexibility during construction and saves operational costs by requiring less humidification. **Although the change to a 20 percent minimum level is a positive development, it may pose challenges for hospitals using equipment and supplies originally designed to be used in an OR environment with at least 30 percent relative humidity.**

The AHA, ASHE and AHRMM have been exploring this issue with other organizations, including the Association for the Advancement of Medical Instrumentation (AAMI). [New guidance](#) from this group of stakeholders outlines some of the issues raised by moving to a minimum 20 percent humidity level in ORs. The attached joint guidance explains that:

- Relative humidity can affect the shelf life and product integrity of some sterile supplies. Some products, such as EKG electrodes used for patient monitoring, are especially sensitive to humidity.

- Some electro-medical equipment, particularly older model equipment, may be affected by electrostatic discharge commonly occurring at low humidity levels.
- Supplies and equipment have manufacturer's instructions for use (IFUs) that explain any required environmental parameters, which may or may not include relative humidity requirements.
- IFUs from the manufacturer should be followed.
- Health care facilities should consider the effects on equipment and/or supplies before reducing OR relative humidity below 30 percent.
- Many supplies can be used outside of the minimum humidity requirements but should not be stored for long periods in low humidity conditions.

NEXT STEPS

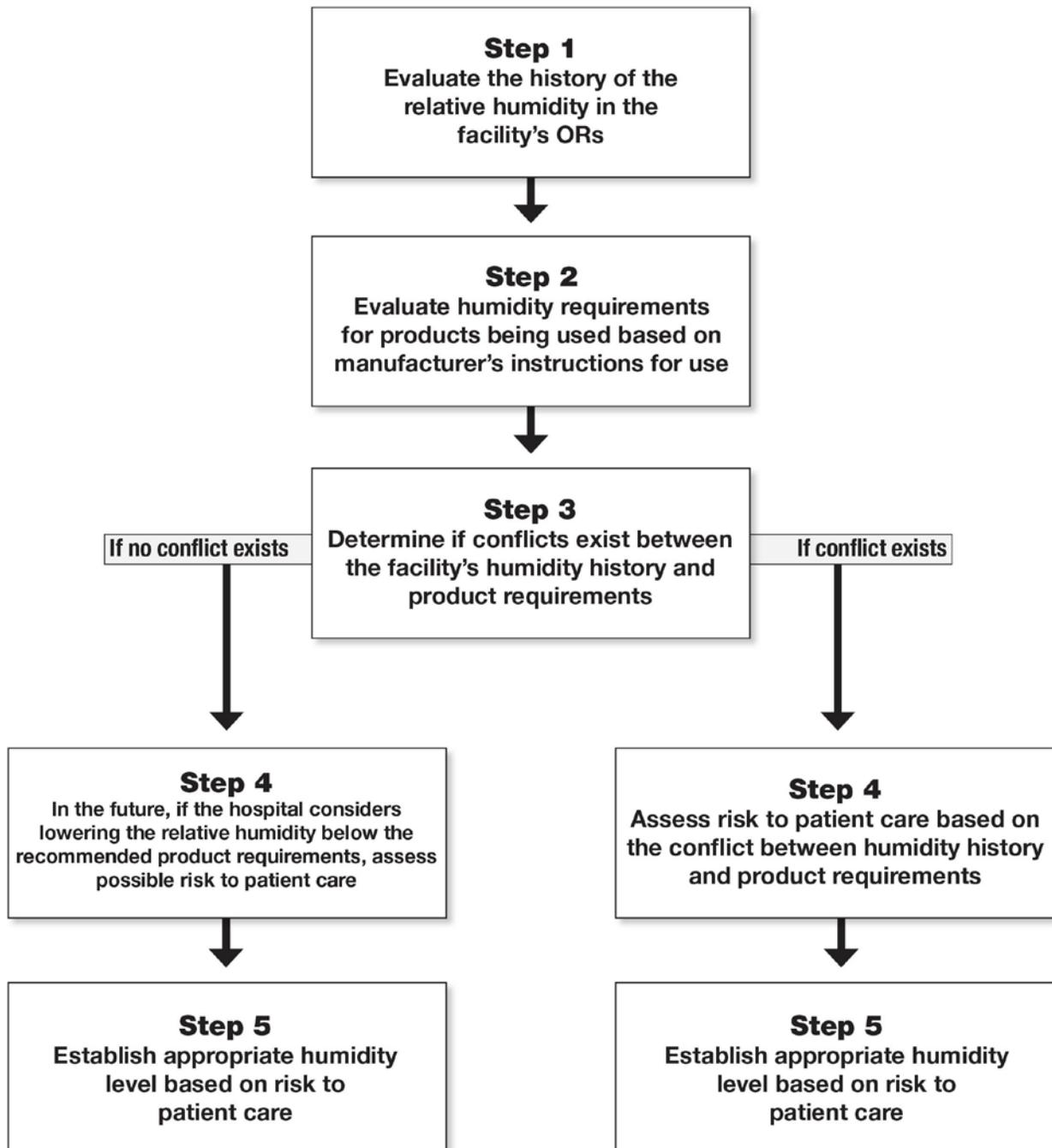
- Share this advisory with your chief operating, information, nursing and medical officers, head of surgery, facilities manager, engineer, materials manager, risk manager and other relevant staff.
- Ask that they review the attached guidance and consider its implications for your ORs.
- The guidance outlines eight questions for health care facilities to consider before using relative humidity levels below 30 percent in ORs. In addition, ASHE created a flow chart to help facilities determine whether a lower relative humidity is appropriate (see the following page). Use these tools to consider whether additional action is needed in your facility to ensure continued safety in your ORs.

Further Questions

If you have additional questions, please contact ASHE's Jonathan Flannery, CHFM, FASHE, senior associate director of advocacy, at jflannery@aha.org; AHRMM's Michael Schiller, CMRP, director of supply chain, at mschiller@aha.org; or AHA's Evelyn Knolle, senior associate director of policy, at eknolle@aha.org.



Suggested Process for Establishing Appropriate Humidity Levels in the Operating Room



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 (IAHCMM).¹

¹ 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 (IAHCMM), 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.² 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.
- 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

² 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.

(in fact, EKG electrodes are in foil pouches primarily to protect against changes in external humidity levels). Other consumables for some electrosurgical products also are 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.