



Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 15-27-Hospital, CAH & ASC

DATE: February 20, 2015

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Potential Adverse Impact of Lower Relative Humidity (RH) in Operating Rooms (ORs)

Memorandum Summary

- **Information on OR RH** is provided for Ambulatory Surgical Centers (ASCs) & Supplemental Information for Hospitals & Critical Access Hospitals (CAHs) Using the Categorical Waiver of Life Safety Code (LSC) Anesthetizing Location RH Requirements
 - The Association for the Advancement of Medical Instrumentation (AAMI) coordinated the release on January 5, 2015 of a Joint Communication of multiple healthcare-related organizations on how a RH of <30% in ORs may affect the performance of some sterile supplies and electro-medical equipment.
- **S&C 13-25-LSC & ASC** permits hospitals and CAHs to use a LSC categorical waiver to establish an RH level <35% in anesthetizing locations. Before electing or continuing to use this categorical waiver, hospitals and CAHs are expected to ensure that the humidity levels in their ORs are compatible with the manufacturers' instructions for use (IFUs) for the supplies and equipment used in that setting.
- **ASCs do not require a categorical waiver** in order to use a lower RH level in their ORs but also need to ensure they comply with the IFUs for their OR supplies and equipment.

Regulations governing hospitals and CAHs require compliance with the 2000 Edition of the National Fire Protection Association (NFPA) 101: LSC, including the mandatory references of the LSC, such as the 1999 Edition of NFPA 99: Health Care Facilities. The NFPA 99 requires that mechanical ventilation systems supplying hospital anesthetizing locations, as defined by NFPA 99, have the capability of controlling RH at a level of 35 % or greater.

The Centers for Medicare & Medicaid Services (CMS) previously issued a categorical waiver via S&C 13-25-LSC & ASC, which permits hospitals and CAHs with new and existing ventilation systems supplying anesthetizing locations to operate with a RH level of 20 % or greater in accordance with American Society for Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE) Standard 170, Ventilation of Health Care Facilities. Lowering the required minimum RH level to 20 % was intended to provide adequate humidity levels for

patient health and safety, while alleviating unreasonable hardship on healthcare facilities. . . (Note that ASCs are not subject to all of the same LSC provisions as hospitals and CAHs, and thus the categorical waiver is not needed in an ASC that chooses to use lower RH in its ORs.)

Subsequently it has come to light that an RH level <30% is not compatible with the instructions for use (IFUs) for some sterile supplies and electro-medical equipment used in operating rooms. Multiple health-care related organizations convened by AAMI in 2014 to discuss this topic came to a consensus and released a Joint Communication on January 5, 2015. (See http://www.aami.org/news/2015/Humidity_in_OR_Joint_Communication_to_HDOs_January_2015.pdf). Among other things, the Joint Communication notes that, while manufacturers of supplies and equipment will be expanding the lower level of the RH range in which their products may function to 20%, the pace of this change is likely to take time. Moreover, for facilities that continue to use older equipment it could be many years before this older equipment is replaced and all of the equipment they use will function appropriately at lower RH levels. The Joint Communication offers a number of useful questions health care facility leadership should ask when assessing the risk of reducing RH in their ORs in light of the potential impact on equipment and supplies.

The CMS expects hospitals, CAHs and ASCs to follow the current IFUs for supplies and equipment used in their ORs. Failure to adhere to the IFUs must be cited, even if the facility has opted to use the categorical waiver of the LSC RH requirements. Citations would fall under §482.41(c)(2) for hospitals, §485.623(b)(1), for CAHs, and §415.44(a)(1) for ASCs.

Questions: If you have questions regarding this memorandum please contact hospitalscg@cms.hhs.gov, CAHSCG@cms.hhs.gov, or ascscg@cms.hhs.gov, as applicable.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management