



Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 13-25-LSC & ASC

DATE: April 19, 2013

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Relative Humidity (RH): Waiver of Life Safety Code (LSC) Anesthetizing Location Requirements; Discussion of Ambulatory Surgical Center (ASC) Operating Room Requirements

Memorandum Summary

- ***RH of ≥ 20 Percent Permitted in Anesthetizing Locations:*** The Centers for Medicare & Medicaid Services (CMS) is issuing a categorical LSC waiver permitting new and existing ventilation systems supplying hospital and critical access hospital (CAH) anesthetizing locations to operate with a RH of ≥ 20 percent, instead of ≥ 35 percent. We are also recommending that RH not exceed 60 percent in these locations.
- ***This Waiver Does Not Apply:***
 - When more stringent RH control levels are required by State or local laws and regulations; or
 - Where reduction in RH would negatively affect ventilation system performance.
- ***Hospitals & CAHs Must Elect to Use the Categorical Waiver:***
 - Individual waiver applications are not required, but facilities are expected to have written documentation that they have elected to use the waiver.
 - At the entrance conference for any survey assessing LSC compliance, a facility that has elected to use this waiver must notify the survey team.
- ***Ongoing Requirements:***
 - Facilities must monitor RH in anesthetizing locations and take corrective actions when needed to ensure RH remains at or above 20 percent.
- ***ASCs:*** ASCs are not subject to all of the same LSC requirements as hospitals, but are required, consistent with 42 CFR 416.44(a)(1), to maintain RH in operating rooms in accordance with nationally accepted guidelines.
- ***State Operations Manual (SOM) Appendices A, I, L & W are being updated accordingly.***

A. Background

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. Section 5-4.1.1 of the 1999

edition of NFPA 99 requires that mechanical ventilation systems supplying hospital anesthetizing locations have the capability of controlling RH at a level of 35 percent or greater.

According to NFPA 99, anesthetizing locations are “Any area of a facility that has been designated to be used for the administration of nonflammable inhalation anesthetic agents in the course of examination or treatment, including the use of such agents for relative analgesia.” NFPA 99 defines relative analgesia as “A state of sedation and partial block of pain perception produced in a patient by the inhalation of concentrations of nitrous oxide insufficient to produce loss of consciousness (conscious sedation).” *(Note that this definition is applicable only for LSC purposes and does not supersede other guidance we have issued for other purposes concerning anesthesia and analgesia.)* Therefore, anesthetizing locations, such as operating rooms and certain procedure rooms, are required to maintain RH.

B. Categorical Waiver for RH Levels in Anesthetizing Locations

The 2012 edition of NFPA 99 has adopted the 2008 edition of the American Society for Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE) Standard 170, Ventilation of Health Care Facilities. Addendum D of the ASHRAE standard requires RH in anesthetizing locations to be maintained between 20 - 60 percent. In addition, this ASHRAE standard has been incorporated into the Facility Guidelines Institute (FGI) 2010 Guidelines for Design and Construction of Health Care Facilities, and has been approved by the American Society for Healthcare Engineering of the American Hospital Association and the American National Standards Institute.

ASHRAE’s decision to reduce the lower limit of its design specifications for ventilation systems in anesthetizing locations from their prior standard of 30 percent to 20 percent followed an extensive review process. The process included a review of the scientific literature and solicitation of input from ventilation experts, life safety consultants, clinicians and professional societies with expertise in infection prevention, including the Association for Professionals in Infection Control and Epidemiology (APIC) and the Association of Perioperative Registered Nurses (AORN). ASHRAE concluded a reduction of the acceptable minimum RH in anesthetizing locations to 20 percent would not adversely affect system performance, patient safety, or clinical outcomes.

In light of NFPA’s recent adoption of the ASHRAE Standard 170, as well as in response to industry feedback that the minimum 35 percent RH level is unduly burdensome, we are issuing via this memorandum a categorical waiver to permit hospitals and CAHs with new and existing ventilation systems supplying anesthetizing locations, as defined by the 1999 edition of NFPA 99, to operate with a RH level of ≥ 20 percent. Lowering the required minimum RH level to 20 percent, in accordance with ASHRAE Standard 170, should provide adequate humidity levels for patient health and safety, while alleviating unreasonable hardship on healthcare facilities.

The ASHRAE review also indicated that their previously established upper limit of 60 percent RH is an important element in reducing infections and preventing development of mold and mildew in anesthetizing locations. Therefore, ASHRAE retained this upper limit. The 1999 edition of NFPA 99 does not establish an upper limit for RH in anesthetizing locations; therefore this categorical waiver does *not* establish an upper limit for RH. However, in view of the ASHRAE findings, CMS strongly recommends that facilities maintain RH in a range of $\geq 20 - \leq 60$ percent in all anesthetizing locations.

C. Waiver Does Not Apply If:

- More stringent RH levels are required under State or local laws and regulations; or
- The reduction of RH would negatively affect ventilation system performance.

D. Facilities Option to Elect to Use the Waiver

Facilities that elect to use the categorical waiver must document their decision to do so. If a hospital or CAH conforms to the above requirements, they will not need to apply in advance to CMS, nor will they need to wait until being cited for a deficiency in order to apply to use this waiver. At the entrance conference for any survey assessing LSC compliance, a facility that has elected to use this waiver must notify the survey team of this fact, as well as the fact that it meets the minimum RH standard of ≥ 20 percent. The facility must provide documentation of its prior election to apply the waiver option. The absence of such evidence provided at the start of a survey means that the facility may be issued a citation if not in conformance with the 2000 LSC edition. It is not acceptable for a healthcare facility to first notify surveyors of waiver election after a citation related to RH has been issued, except as part of a plan of correction in response to the citation.

The survey team will review the facility's documentation, confirm the facility is meeting the minimum RH requirement of ≥ 20 percent, and reference under Tag K000 and in Part IV on the CMS-2786 form the use by the facility of this categorical waiver to achieve compliance. Categorical waivers do not need to be cited as deficiencies or require Regional Office approval, therefore the first page of the CMS-2786 form should be marked "The Facility Meets, Based Upon, 3."

E. Ongoing Requirements

Facilities must monitor RH levels in anesthetizing locations and be able to provide evidence that the RH levels are maintained at or above 20 percent. When outdoor humidity and internal moisture are not sufficient to achieve the minimum humidity level, then humidification must be provided by means of the hospital's or CAH's ventilation systems. In addition, facilities must provide evidence that timely corrective actions are performed successfully in instances when internal monitoring determines RH levels are below the permitted range.

F. Ambulatory Surgical Centers (ASCs)

Although Section 5-4.1.1 of NFPA 99 does not apply to ASCs, they are required under §416.44(a)(1) to design and equip their operating rooms in a manner that protects the lives and assures the physical safety of all individuals in the area. Accordingly, ASCs are expected to maintain RH in accordance with nationally accepted guidelines. Acceptable guidelines include adhering to nationally recognized standards for RH issued by organizations such as ASHRAE.

SOM Revisions

We are updating the pertinent portions of interpretive guidelines in SOM Appendices A, I, L and W. An advance copy of the updated SOM Appendices is attached, which may differ slightly from the final version to be released at a later date.

Questions: If you have questions regarding this memorandum please contact Lieutenant Commander Martin Casey at Martin.Casey@cms.hhs.gov.

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

Attachment - (1)

State Operations Manual Revisions Appendices A, I, L, and W

cc: Survey and Certification Regional Office Management