
CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal

(Advance Copy)

Date:

SUBJECT: Revised State Operations Manual (SOM) Appendices A, I, L, and W

I. SUMMARY OF CHANGES: Clarification is provided in the SOM appendices for permitting certain new and existing health care facility ventilation systems to operate at a relative humidity equal to or greater than 20 percent, in accordance with the 2012 edition of NFPA 99, *Health Care Facilities* and the referenced 2008 edition of ASHRAE Standard 170, *Ventilation of Health Care Facilities*, Addendum D.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix A / §482.41 / §482.41(c)(4)
R	Appendix I / Task 1 & Task 2
R	Appendix L / §416.44 / §416.44(a)
R	Appendix W / §485.623 / §485.623(b)(5)

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2011 operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

State Operations Manual

Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

A-0726

(Rev.)

§482.41(c)(4) - There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

Interpretive Guidelines §482.41(c)(4)

There must be proper ventilation in at least the following areas:

- Areas using ethylene oxide, nitrous oxide, guteraldehydes, xylene, pentamidine, or other potentially hazardous substances;
- Locations where oxygen is transferred from one container to another;
- Isolation rooms and reverse isolation rooms (both must be in compliance with Federal and State laws, regulations, and guidelines such as OSHA, CDC, NIH, etc.);
- Pharmaceutical preparation areas (hoods, cabinets, etc.);
- Laboratory locations; *and*
- *Anesthetizing locations. 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 supercede other guidance we have issued for other purposes concerning anesthesia and analgesia.)*

There must be adequate lighting in all the patient care areas, and food and medication preparation areas.

Temperature, humidity and airflow in *anesthetizing locations* must be maintained within acceptable standards to inhibit *microbial* growth, *reduce risk of* infection, *control odor*,

and promote patient comfort. *Hospitals must maintain relative humidity (RH) levels at 35 percent or greater in each anesthetizing location, unless the hospital elects to use the CMS categorical waiver, which permits it to maintain a RH of at least 20 percent (see Appendix I, Section II for additional information). Hospitals must maintain records that demonstrate they have achieved the required levels. Although not required, CMS recommends that hospitals maintain the upper range of RH at 60 percent or less, as excessive humidity is conducive to microbial growth and compromises the integrity of wrapped sterile instruments and supplies. Each operating room should have separate temperature control. Acceptable standards such as from the Association of Operating Room Nurses (AORN) or the Facilities Guidelines Institute (FGI) should be incorporated into hospital policy.*

The hospital must ensure that an appropriate number of refrigerators and/or heating devices are provided and ensure that food and pharmaceuticals are stored properly and in accordance with nationally accepted guidelines (food) and manufacturer's recommendations (pharmaceuticals).

Survey Procedures §482.41(c)(4)

- Verify that all food and medication preparation areas are well lighted.
 - Verify that the hospital is in compliance with ventilation requirements for patients with contagious airborne diseases, such as tuberculosis, patients receiving treatments with hazardous chemical, surgical areas, and other areas where hazardous materials are stored.
 - Verify that food products are stored under appropriate conditions (e.g., time, temperature, packaging, location) based on a nationally-accepted source such as the United States Department of Agriculture, the Food and Drug Administration, or other nationally-recognized standard.
 - Verify that pharmaceuticals are stored at temperatures recommended by the product manufacturer.
 - Review *monitoring records for* temperature to ensure that appropriate levels are maintained.
 - *Review humidity maintenance records for anesthetizing locations to ensure, if monitoring determined humidity levels were not within acceptable parameters, that corrective actions were performed in a timely manner to achieve acceptable levels.*
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Appendix I – Survey Procedures and Interpretive Guidelines for Life Safety Code Surveys

(Rev.)

II. The Survey Tasks

Task 1 – Offsite Survey Preparation

The surveyor or survey team will review the facility file for:

- Recent licensure and/or certification surveys, including any deficiencies from the previous, bed capacity, change in ownership, facility waivers;
- Corrective action status (if applicable);
- Complaint investigations;
- Facility floor plans, including the location of individual rooms, exits and commons areas; and
- Correspondence to or from the SA and the facility.

If more than one surveyor is participating in the survey designate a team coordinator. The team coordinator will conduct a brief presurvey meeting with team members, such as the State Agency or State Fire Authority, to: review previous findings, make specific assignments, and discuss efficient approaches to surveying the facility.

Determine the occupancy or use of the facility such as a hospital, nursing home, ambulatory surgical center, etc. Then determine which chapters of the Life Safety Code (LSC) should be used in the survey process based on the occupancy or use of the building. The basic fire safety requirement for participating facilities at this time is compliance with the National Fire Protection Association (NFPA) 101, Life Safety Code, 2000 edition. Specific Interpretive Guidelines and survey procedures pertaining to the various participating facilities can be found in their respective sections of the SOM.

Review the date the facility first applied for admission into the program. The use of the EXISTING or NEW chapters of the LSC depends on the date of plan approval or the date of construction (if there is no plan approval process) for the facility's building(s). If the facility's building plans were approved or a building permit was issued or construction started after the effective date, (March 13, 2003), of the final regulation, the building or addition must be surveyed under 2000 NEW LSC.

If the facility's building plans were approved by a State Agency or building permit issued or construction started prior to the effective date, (March 13, 2003), of the final regulation, the building must be surveyed under 2000 EXISTING LSC.

CMS has defined the terms “major” or “minor” for alterations, modernization or renovation of buildings as follows: If the building has undergone a modification (usually more than 50 percent or more than 4,500 square feet, of the smoke compartment involved) it is considered “major,” if the building has undergone a modification (usually less than 50 percent or less than 4,500 square feet, of the smoke compartment involved) it is considered “minor.” If a building undergoes a “major” modification after March 13, 2003 then the building would be surveyed under 2000 NEW LSC. The replacement of a system such as a fire alarm system would be considered “major” for that system only. Thus, that system only would have to meet the LSC requirements for 2000 NEW, not the entire building.

Cosmetic changes such as painting and wallpapering by themselves would not constitute a “major” modification regardless of the size of the area involved.

A building, which is a conversion from an occupancy other than Health Care such as a hotel or apartment house, but NOT a hospital, must also meet NEW requirements. Changes within Health Care such as a hospital to a nursing home are not considered conversions.

If the building is a hospital and has a SNF located within or attached to it, then a determination has to be made as to whether the SNF is considered a “distinct part.” If there is two-hour fire wall between the hospital and the SNF, then a LSC survey of the SNF section alone is allowed. A floor-ceiling assembly does not meet the separation requirements of a two-hour fire wall. If there is no fire wall, then a LSC survey of the complete building, hospital and SNF, is to be conducted. When there is no two-hour separation, then the complete building must be surveyed regardless of whether the hospital is accredited. All deficiencies found will be reported whether they were found in the *deemed* hospital portion or in the distinct part SNF.

Validation surveys of deemed hospitals must use the appropriate chapters, NEW or EXISTING, of the 2000 LSC.

CMS, in its regulations adopting the 2000 edition of the LSC, did not adopt the paragraph 19.3.6.3.2 exception No.2 dealing with existing roller latches. The use of roller latches is no longer acceptable as a corridor door-latching device in existing health care facilities. This includes facilities that are both non-sprinklered and sprinklered. Facilities have until March 13, 2006 to remove roller latches from use. Emergency lighting lasting at least 1-1/2 hours is required by the LSC; facilities have until March 13, 2006 to meet this requirement. CMS also adopted by regulation the requirement that any facility certified as an ASC is to meet the requirements of the LSC for ambulatory health care, without regard to the number of patients served by the ASC at any one time.

Hospital and critical access hospital anesthetizing locations in which clinical procedures are performed are required to maintain relative humidity. According to NFPA 99, anesthetizing locations are defined as “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 supercede other guidance we have issued for other purposes concerning anesthesia and analgesia.)

Hospitals and critical access hospitals must maintain relative humidity (RH) at levels of 35 percent or greater in all anesthetizing locations, unless the hospital or CAH has elected to implement the CMS categorical waiver, which permits new and existing ventilation systems to operate at a RH level of 20 percent or greater. This categorical waiver does not apply where more stringent RH levels are required under State or local laws and regulations, or where the reduction in RH would negatively affect ventilation system performance. Hospitals and CAHs that choose to maintain a RH level of 20 percent or greater must elect to use this categorical waiver, document their decision, and notify the survey team of its decision at the entrance conference, in advance of being cited for a RH deficiency. The hospital or CAH must also monitor RH levels, and be able to provide evidence that RH levels are maintained, and effective corrective actions are taken in a timely manner if monitoring determines RH is less than the required percentage. Although not required, CMS recommends that hospitals and CAHs maintain the upper range of relative humidity at less than or equal to 60 percent, as excessive humidity is conducive to microbial growth and may increase the risk of infections.

Determine whether or not a Fire Safety Evaluation Survey (FSES), has previously been conducted at the facility. The use of the FSES may be applicable when a facility has multiple deficiencies that may be cost prohibitive to correct. The facility should be informed that the use of the FSES is a certification option at the exit conference. It is up to the facility to decide if the FSES is to be used to achieve certification.

The State Agency, at its option, may complete the FSES for the facility or may act as a reviewer of an FSES submitted by the facility as part of the facility’s Plan of Correction (POC).

NFPA 101A, Guide on Alternative Approaches to Life Safety, 2001 Edition, is to be used to complete all FSES’s. An FSES evaluation is to be done in conjunction with the completion of the regular Fire Safety Survey form (CMS Form 2786). If the building is certified in compliance with the LSC on the basis of an FSES evaluation, an FSES evaluation must be completed each time a LSC survey is completed. To recertify the building using the FSES, a regular Fire Safety Survey form is completed before completing the FSES, this evaluation will take into account any changes in the facilities life safety features.

The FSES is only available for buildings surveyed using the Health Care Occupancies and Residential Board and Care Occupancies chapters. There is no FSES available for

use when surveying ASCs, which are surveyed using the prescriptive requirements of the Ambulatory Health Care Occupancies chapter (20/21) of the LSC.

Task 2 - Entrance Conference/Onsite Preparatory Activities

Entrance Conference:

Upon arrival at the facility, proceed to the Administrator's office and identify yourself and state the purpose of your visit: to perform a fire safety survey under the regulations of Medicare/Medicaid. The team coordinator or individual surveyor conducts the Entrance Conference, informing the facility's administrator about the survey and introducing any team members. The team coordinator then explains the survey process and answers any questions from facility staff. While the team coordinator conducts the Entrance Conference, other LSC team members, may begin Task 3 - Orientation Tour.

Ask the Administrator to describe any special features of the facility's physical plant. For example, was the facility constructed at different times and were different types of construction used, or is the facility only partially sprinklered? Have any changes or remodeling occurred since the last inspection? Does the facility have an emergency generator or admit patients/residents that may require life support equipment?

Request documentation of any existing fire safety evacuation plan; fire drills; disaster plan; smoking policy; fire alarm testing; sprinkler maintenance records if applicable; kitchen range hood maintenance; fire extinguisher maintenance and testing reports; generator testing logs; flame spread ratings of interior finishes; *or attestations to elect CMS categorical waivers*. The type of materials used for any smoke stopping or fireproofing should be obtained.

Obtain a list of key facility personnel and their location (that is, administrator, director of nursing services, dietitian and/or food supervisor, charge nurses, plant engineer, and housekeeping supervisor). These individuals will be able to provide specific information about fire safety issues in their departments, which is needed by surveyors to complete the fire safety survey report form (Form CMS-2786).

Ask the administrator or building plant engineer to provide the surveyor with a copy of the facility's building layout, indicating the location of exits, individual resident rooms, and common areas if available.

The existence of any waivers of the LSC requirements should be confirmed at this time by the facility. Inform the facility that a detailed inspection will be conducted and that it may include any building used by the residents or patients. At this time, request that someone from the facility staff, preferably from the maintenance department, accompany the surveyor. It is not mandatory that a representative from the facility accompany the surveyor on the facility inspection.

Waiver of LSC Requirements

When the facility meets the LSC based on a waiver of a specific requirement in the LSC, the POC completed by the facility will indicate which items are requesting to be waived and:

- How compliance would impose an unreasonable hardship on the facility; and
- How a waiver would not adversely affect the health and safety of patient/residents in the facility.

There is no provision in the regulations for the granting of waivers of the LSC requirements under Chapter 32/33 (Residential Board and Care Occupancies). A facility may use the FSES survey or request to be surveyed under the requirements of Chapter 18/19 (Health Care Occupancies). There also cannot be a waiver of the requirement for a generator in a facility with life support equipment.

When recommending a waiver of a specific LSC requirement on the basis of correction of another deficiency, the waiver should not be granted until the corrective action on the other item is completed. For example, if a facility is requesting a waiver of the installation of return air ducts where corridors are being used as return air plenums on the condition that the facility install smoke detectors tied into an alarm system and the automatic shutdown of ventilation fans, do not waive the return air plenums until you verify that the facility has actually installed the detectors and that are appropriately connected to the fire alarm and air circulation systems. In the above cases, the first page of the Form CMS-2786 should be marked “Meets, Based Upon, 2. Acceptance of a Plan of Correction” and then upon completion of the corrective action it can be marked “Meets, Based Upon, 3. Recommended Waivers.”

Waivers of specific LSC criteria can be recommended for an extended length of time if correction of the deficiency is not possible.

When a waiver is recommended, both the surveyor and concurring fire authority official must sign the form at the bottom of Part IV, Recommendation for Waiver of Specific Life Safety Code Provisions, after the facility has responded to the Statement of Deficiencies.

In instances where CMS has issued policy which allows for a categorical waiver of specific life safety code provisions, facilities must document their election to use a categorical waiver and notify the survey team of their decision in advance of being cited for a deficiency. The surveyor must review the facility's documented decision, confirm that the facility is meeting all of the categorical waiver requirements, and reference the use of the categorical waiver to achieve compliance under Tag K000 and in Part IV on the CMS-2786. Categorical waivers do not require a prior deficiency citation or Regional Office approval, therefore the first page of the Form CMS-2786 should be marked “The Facility Meets, Based Upon, 3.”

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Appendix L - Guidance for Surveyors: Ambulatory Surgical Centers

Q-0101

(Rev.)

§416.44(a) Standard: Physical Environment

The ASC must provide a functional and sanitary environment for the provision of surgical services.

- (1) Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.**

Interpretive Guidelines: §416.44(a)(1)

State Agencies may wish to assign surveyors who are trained in evaluating healthcare facility design and construction assist in evaluating compliance with this standard. “Operating room” in an ASC also includes procedure rooms.

Operating rooms must be designed in accordance with industry standards for the types of surgical procedures performed in the room. National organizations, such as the *Facilities Guidelines Institute*, may be used as a source of guidance to evaluate OR design and construction in an ASC. If a State’s licensure requirements include specifications for OR design and construction, the ASC must, in accordance with §416.40, comply with those State requirements.

The location of the OR within the ASC and the access to it must conform to accepted standards of practice, particularly for infection control, with respect to the movement of people, equipment and supplies in and out of the OR. The movement of staff and patients on stretchers must proceed safely, uninhibited by obstructions.

Temperature, humidity and airflow in ORs must be maintained within acceptable standards to inhibit microbial growth, reduce risk of infection, control odor, and promote patient comfort. ASCs must maintain records that demonstrate they have maintained acceptable standards.

An example of an acceptable humidity standard for ORs is 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 ORs 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.

Each operating room should have separate temperature control. Acceptable standards for OR temperature, such as those recommended by the Association of Operating Room Nurses (AORN) or the FGI, should be incorporated into the ASC's policy.

The ORs must also be appropriately equipped for the types of surgery performed in the ASC. Equipment includes both facility equipment (e.g., lighting, generators or other back-up power, air handlers, medical gas systems, air compressors, vacuum systems, etc.) and medical equipment (e.g., biomedical equipment, radiological equipment if applicable, OR tables, stretchers, IV infusion equipment, ventilators, etc.). Medical equipment for the OR includes, in addition to the emergency equipment listed in §416.44(c), the appropriate type and volume of surgical and anesthesia equipment, including surgical instruments. Surgical instruments must be available in a quantity that is commensurate with the ASC's expected daily procedure volume, taking into consideration the time required for appropriate cleaning and sterilization. Equipment for rapid emergency sterilization of OR equipment/materials whose sterility has been compromised must be available on-site. However, an ASC that routinely uses sterilization procedures intended for emergency use only as its standard method of sterilization between cases, in order to reuse surgical instruments, must be cited for violating §§416.44(a)(1) & (3) and the Infection Control Condition at §416.51. It is not necessary for the ASC to have equipment for routine sterilization of equipment and supplies on-site, so long as this service is provided to the ASC under arrangement.

The OR equipment must be inspected, tested and maintained by the ASC in accordance with Federal and State law (including regulations) and manufacturers' recommendations.

Survey Procedures: §416.44(a)

- *Verify* the ASC's ORs meet applicable design standards.
- *Verify* the ASC *has* the right kind of equipment in the ORs for the types of surgery it performs.
- *Verify* the ASC *has* enough equipment, including surgical instrument sets, for the volume of procedures it typically performs.
- *Verify* the ASC *has* evidence, such as logs on each piece of electrical or mechanical equipment, indicating that it routinely inspects, tests, and maintains the equipment.
- *Verify* *who* within the ASC is responsible for equipment testing and maintenance.

- Considering the size of the OR and the amount and size of OR equipment, *verify* there **is** sufficient space for the unobstructed movement of patients and staff.
- *Review the ASC's records for OR temperature and humidity to ensure that appropriate levels are maintained and that, if monitoring determined temperature or humidity levels were not within acceptable parameters, that corrective actions were performed in a timely manner to achieve acceptable levels.*

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Appendix W - Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs

C-0226

(Rev.)

§485.623(b)(5) There is proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas.

Interpretive Guidelines §485.623(b)(5)

There must be proper ventilation in at least the following areas:

- Areas using ethylene oxide, nitrous oxide, guteraldehydes, xylene, pentamidine, or other potentially hazardous substances;
- Locations where oxygen is transferred from one container to another;
- Isolation rooms and reverse isolation rooms (both must be in compliance with Federal and State laws, regulations, and guidelines such as OSHA, CDC, NIH, etc.);
- Pharmaceutical preparation areas (hoods, cabinets, etc.);
- Laboratory locations; *and*
- *Anesthetizing locations. 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 supercede other guidance we have issued for other purposes concerning anesthesia and analgesia.)*

There must be adequate lighting in all the patient care, food and medication preparation areas.

Temperature, humidity and airflow in *anesthetizing locations* must be maintained within acceptable standards to inhibit *microbial* growth, *reduce risk of* infection, *control odor*, and promote patient comfort. *Ventilation systems in anesthetizing locations must*

maintain relative humidity (RH) levels at 35 percent or greater unless a facility elects to use the CMS categorical waiver, which permits new and existing ventilation systems to operate at a RH of 20 percent or greater (see Appendix I, Section II for additional information). Although not required, CMS recommends that facilities maintain the upper range of RH at 60 percent or less as excessive humidity is conducive to microbial growth and compromises the integrity of wrapped sterile instruments and supplies. Each operating room should have separate temperature control. Acceptable standards such as from the Association of Operating Room Nurses (AORN) or the Facilities Guidelines Institute (FGI) should be incorporated into hospital policy.

The CAH must ensure that an appropriate number of refrigerators and/or heating devices are provided and ensure that food and pharmaceuticals are stored properly and in accordance with nationally accepted guidelines (food) and manufacturer's recommendations (pharmaceuticals).

Survey Procedures §485.623(b)(5)

- Verify that all food and medication preparation areas are well lighted.
 - Verify that the CAH is in compliance with ventilation requirements for patients with contagious airborne diseases, such as tuberculosis, patients receiving treatments with hazardous chemical, surgical areas, and other areas where hazardous materials are stored.
 - Verify that food products are stored under appropriate conditions (e.g., time, temperature, packaging, location) based on nationally-accepted sources such as the United States Department of Agriculture, the Food and Drug Administration, or other nationally-recognized standard.
 - Verify that pharmaceuticals are stored at temperatures recommended by the product manufacturer.
 - Verify that each *anesthetizing location has* temperature control mechanisms.
 - Review *the records for anesthetizing locations* temperature and humidity to ensure levels are maintained.
 - *Review temperature and humidity maintenance records for anesthetizing locations to ensure, if monitoring determined temperature or humidity levels were not within acceptable parameters, the corrective actions were performed in a timely manner to achieve acceptable levels. .*
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