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# CMS Manual System

## Pub. 100-07 State Operations Provider Certification

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

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Transmittal 99

Date: January 31, 2014

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*Transmittal 89, dated August 30, 2013, is being rescinded and replaced by Transmittal 99, dated January 31, 2014, to include Appendix I erroneously omitted. All other information remains the same.*

**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\*:** January 31, 2014  
**IMPLEMENTATION DATE:** January 31, 2014

*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/Standard: Facilities/§482.41(c)(4) There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas/A-0726
R	Appendix I/Survey Procedures for Life Safety Code Surveys
R	Appendix L/§416.44(a)(1) Standard: Physical Environment/Q-0101
R	Appendix W/§485.623(b)(5) Standard: Maintenance/C-0226

**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:**

	<b>Business Requirements</b>
<b>X</b>	<b>Manual Instruction</b>
	<b>Confidential Requirements</b>
	<b>One-Time Notification</b>
	<b>Recurring Update Notification</b>

# State Operations Manual

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

0726

*(Rev.99 Issued: 01-31-14, Effective: 01-31-14, Implementation: 01-31-14)*

**§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.*

# **State Operations Manual**

## **Appendix I – Survey Procedures for Life Safety Code Surveys**

*(Rev.99 Issued: 01-31-14, Effective: 01-31-14, Implementation: 01-31-14)*

I. Introduction

II. The Survey Tasks

Task 1 – Offsite Survey Preparation

Task 2 - Entrance Conference/Onsite Preparatory Activities

Task 3 - Orientation Tour

Task 4 - Information Gathering

Task 5 - Information Analysis and Decision Making

Task 6 - Exit Conference

III. Complaint Investigations

IV. Post Survey Revisits

## I. Introduction

Use the survey procedures in this appendix section for all Life Safety Code (LSC) surveys (initial and recertification) of facilities subject to Survey and Certification inspections for Medicare/Medicaid certification. This includes, but is not limited to, Skilled Nursing Facilities (SNFs), Nursing Facilities (NFs) whether freestanding, distinct parts, or dually certified, Intermediate Care Facilities for *Individuals with Intellectual Disabilities (ICFs/IID)*, Ambulatory Surgical Centers (ASC), inpatient Hospice facilities, Program for All inclusive Care for the Elderly (PACE) facilities, Critical Access Hospitals (CAH), Psychiatric and General Hospitals, including validation surveys of accredited facilities. These procedures also apply to complaint investigations. When conducting LSC complaint investigations, focus your review on those requirements relevant to the complaint.

All SNF/NF and *ICFs/IID* surveys must be unannounced. The LSC survey of a SNF/NF **may** precede the survey of resident care requirements and can be done independent of a health survey. LSC surveys must be conducted and completed on consecutive days. Survey team members need not be onsite for the entire survey. For example special consultants participating in the survey (such as, a fire protection engineer, or fire alarm technician) have the option of being onsite only during that portion of the survey that require their area of expertise; however, they must conduct that portion while the rest of the LSC survey team is present. The special consultant(s) should present their findings to the team or team leader before departing the facility. If any deficiencies are to be cited, supporting documentation should be left with the team. The consultant should be available during the exit conference to supply any additional information required. This can be in-person or by telephone.

## 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 pre-survey 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.

### **Determining Which LSC Chapter to Use and Which Building(s) to Survey**

Determine which LSC chapters apply for each building, including buildings that do not house residents or patients on a 24-hour basis. This situation is most common in large campus type facilities such as medical centers, teaching hospitals, or large state-operated *ICFs/IID*.

To determine which buildings to survey, the term "customary access" is critical. Buildings that house offices or spaces to which residents do not have normal access do not require a LSC survey. However, buildings which are used by residents (e.g., a school or therapy building, cafeteria, workshop, gym, chapel, etc.) must be surveyed.

In many cases, the health care chapters of the Code may not be the most appropriate sections to use as survey guides. Instead, the most appropriate chapter could be Chapter 14/15, Educational Occupancies or, possibly, Chapter 12/13, Assembly Occupancies, etc. Since there are no survey report forms for these chapters of the LSC, the chapters and their references serve as the source documents, and, if deficiencies are found, they are to be reported on the CMS Form-2567 and identified using the appropriate code reference number in the applicable chapter(s) of the code.

To determine which LSC chapters are applicable to *ICFs/IID*, the type and extent of services provided need to be determined. The New Residential Board and Care Occupancy Chapter (Chapter 32) or the Existing Residential Board and Care Occupancy Chapter (Chapter 33) of the 2000 edition of the LSC is applicable to a *ICF/IID* in the Medicaid program which provide "personal care services." The LSC defines personal care as "protective care of a resident who does not require chronic or convalescent

medical or nursing care.” Generally, protective oversight and personal care is defined as assistance in meeting daily needs (e.g., being aware of residents’ whereabouts, reminding them of appointments). This may include “transient medical care,” such as the kind of care provided in the home by one family member to another when he/she is sick. In an *ICFs/IID* this means supervising client’s movements and daily living skills. An RN or LPN on staff at the board and care home solely to dispense medication is not an indication of chronic medical or nursing care.

If a resident receives skilled/acute nursing or medical care such as is provided in a hospital, nursing home or an inpatient hospice, Chapter 18/19 (Health Care Occupancies) must be applied.

If the LSC surveyor determines that an *ICFs/IID* will be surveyed under the Residential Board and Care Occupancy of chapters 32 and 33, it must be further broken down into one of two categories based on size and evacuation capability before the survey can continue.

Small facilities are those with sleeping accommodations for not more than 16 residents (section 32.2 or 33.2). Large facilities are facilities with sleeping accommodations for more than 16 residents (section 32.3 or 33.3). This means that an apartment building containing several *ICFs/IID* in separate apartments must meet Section 32.2 or 33.2 for the individual units, and the apartment building must meet the requirements of Chapter 30/31 Apartment Buildings which are listed in section 32.4 or 33.4.

Most large facilities tend to fall into the category of health care, while smaller facilities tend to be residential board and care occupancies.

### **Task 3 - Orientation Tour**

An orientation tour may be in order to provide an overview of the facility, and serve as an introduction of the surveyors to the staff. This may be helpful if the facility is a very large single building or has multiple buildings that may have to be surveyed.

### **Task 4 - Information Gathering**

Upon completion of the review of the documentation provided by the facility, the more detailed inspection begins. Using the layout of the building as a guide, begin an observation tour that includes the outside of the building as well as the inside.

At this time determine the type of building construction. This can be accomplished by review of the construction drawings, if available, and must be confirmed by direct observation of the structure and building materials used in constructing the building (exposed areas above the ceilings or vertical pipe shafts may provide insight).

Check floor-to-floor separations, corridor wall construction, smoke barrier locations, construction and condition, and any vertical opening construction including access doors.

If multiple buildings or wings are involved, any fire barriers present should be inspected for construction materials used, the protection of penetrations through the barriers and the type and arrangement of any doors thru the barriers. Buildings separated by a vertical two-hour fire barrier can be considered separate buildings for the purposes of a Life Safety survey. (Note: If the two-hour fire barrier has been so severely compromised by penetrations or other construction defects that it may not provide the required fire protection, it may be necessary to ignore this feature and consider combining the two buildings together. If this is done, the two buildings will be surveyed as if there were only one building. The facility may elect to repair the two-hour separation and have the buildings surveyed as two separate buildings.)

When separate buildings are surveyed, each building requires the use of an individual set of reporting forms.

Proceed next to a complete room-by-room, floor-by-floor, walk through of the facility. This includes a representative sample of bedrooms ([Table 1](#)). At a minimum, inspect: one smoke barrier, including doors, on each floor or wing; all fire barriers; all hazardous areas including doors into the area; all exit stairs, doors, signs; resident room doors for condition, latching and fit in the door frame; the fire alarm system; the sprinkler system; the emergency power generator set; corridor walls; emergency lighting; and medical gas storage, if applicable.

Inspect the smoke and fire barriers for construction materials and continuity, completeness from outside wall to outside wall and from the floor to the bottom of the floor above where applicable. Inspect any penetrations to determine if they are sealed properly. Where ductwork penetrates the barrier, inspect any dampers, fire or smoke that have been installed in the ductwork.

For each room inspected, check the corridor door for latching, operation and fit into the doorframe. The fire rating of the door should also be inspected if applicable. The interior of the room should then be inspected for hazards such as electrical outlets, extension cords, oxygen in use signs (posted where applicable), and portable space heaters.

Wastebasket size, drapes and cubicle curtains are checked for flammability. Where applicable cubicle curtains are checked for the correct mesh opening size. If the facility is sprinklered, the location of the sprinkler head in relation to the cubicle curtain and walls are checked for obstruction or interference to the water spray pattern. The walls and ceilings are inspected for unsealed penetrations and proper construction.

Inspect the corridor walls and ceilings for proper construction. This inspection should include areas above the ceiling.

Inspect all hazardous areas for proper door type and, where applicable, sprinkler installation or fire separation construction.

Note the maintenance of fire extinguishers and exit signs on an ongoing basis throughout the inspection.

Inspect the fire alarm pull stations and alarm devices while moving along the corridors. Similarly, review smoke detectors where they are required or provided.

Note any corridor obstructions and the distances to exits. At the same time the exitways, including the doors and door hardware are inspected, as well as the exitway lighting and exterior walkways.

Inspect the fire alarm control panel noting any areas/zones not covered by the detection system. Inspection tags or labels should be reviewed. Any system trouble lights should be noted and the facility questioned. Determine if the fire alarm system is connected to the fire department or a remote station outside of the facility.

Review sprinkler systems to determine if the system is providing complete coverage or only partial coverage. Complete coverage means that the entire facility, including all closets, storage areas, and walk-in coolers and freezers, is sprinklered. Proper testing and maintenance records must be maintained by the facility. The connection between the sprinkler system and fire alarm system should be confirmed. Tamper switches and waterflow detection devices must be operational.

Inspect the facility kitchen range hood fire extinguisher system to determine if the proper maintenance of the system is being carried out and the activating mechanism is in a clearly marked location. The staff should be questioned regarding the operation of any fire suppression systems in an emergency.

Inspect the emergency lighting or power system for operability and coverage; including on-site generators. Review records of testing and maintenance of the generator(s). A demonstration of the emergency power system should not be requested due to the large amount of computerization and the use of life support equipment that may be affected.

Inspect laboratories for proper sprinklering, fire separation construction, door type, emergency eye wash equipment, storage of flammable liquids and gases, and fume hood ventilation.

Inspect medical gas storage areas for proper construction, ventilation, gas system controls/alarms and proper restraint of cylinders.

Review the facility fire plan including fire drill records and staff interviews to determine staff actions and responsibilities during a fire or emergency. The surveyor may request an actual fire drill demonstration based on a review of the facility fire drill records and interviews with the staff to verify the adequacy of staff response. This should be done only if there is a question of the adequacy of staff response found in the documentation of the monthly fire drills.

## Determining the *ICFs/IID* “E” Score

The technique for surveying and determining compliance with the LSC of *ICFs/IID* is very similar to previous parts of this protocol with several additional requirements. After determining the type and size of the *ICF/IID*, determine the level of evacuation difficulty if the facility chooses to comply with the requirements for residential board and care. This is done for each of the types of facilities; small, large, and a Board and Care facility in an apartment house. The three levels of evacuation difficulty are known as Prompt (level A), Slow (level B) and Impractical (level C). CMS regulations require the use of NFPA 101A, Guide on Alternative Approaches to Life Safety, 2001 Edition, Chapter 6, Evacuation Capability Determination for Board and Care Occupancies to determine the evacuation difficulty index (EDI).

- The E Score of the facility is determined by using the six worksheets found in Chapter 6 of NFPA 101A. The worksheet for rating residents contains a cover sheet for the inclusion of facility information and date of the survey.
- When completing the worksheet “Rating the Residents Risk Factors,” Form CMS-786, interview the staff person who is most familiar with the resident’s risk factors, whenever possible. Rate each resident on each of the six risk factors (Risk of Resistance, Impaired Mobility, Impaired Consciousness, Need for Extra Help, Response to Instructions, and Response to Alarm) by checking the appropriate circle on each line. Calculate the score and write the score for each circle checked in the boxes in the far right column. For the seventh parameter (Response to Fire Drills) write the checked scores in the three large circles. Write the sum of the three scores in the box to the right. **NOTE:** In a small facility complete one form for each resident.
- The Residents Overall Need for Assistance is now determined by comparing the seven score boxes in F-1A and writing the HIGHEST score in the box labeled “Evacuation Assistance Score.”
- The worksheet for “Calculating Evacuation Difficulty Score” (E-score) is now filled out. The five questions must all be answered “Yes” to satisfy the requirements for obtaining the E-score.
- Complete F-2A (page 4) Finding the Total Resident Score by listing each resident’s name and score in the Score sheet (F-2A) and total the individual scores. Enter the total at the bottom in the box to the right of the word “Total.”
- Complete F-2B Finding the Staff Shift Score (page 4) by listing the names of each staff member required to remain in the facility for the shift being evaluated. Evaluate the shift with the highest E-Score (least amount of staff), usually the night shift. Enter the appropriate rating for the effectiveness of the alarm system (as determined by the table on the lower left) for each staff member. The terms “assured” and “not assured” are used in the alarm rating. “Assured” means that

the alarm is “easily noticeable” in all locations where staff is allowed to go, regardless of the ratings on the promptness of response. “Not assured” means the alarm does not satisfy the conditions of “assured.” Then add the scores and enter the total in the box marked “Total.”

- Complete F-2C finding the Home’s Evacuation Difficulty Score by completing the chart at the top of page 5. Indicate the vertical distance of bedrooms (that is the stories) from the exits. Proceed to section F-2C Calculation of E-score. Enter the Evacuation Assistance Total (F-2A) score and the vertical distance score in the 2 boxes, which compose the numerator of this fraction and multiply them by each other. Enter the Staff Shift Total (F-2B) in the denominator and divide them into the product of the numerator. This is the E-Score.
- The Evacuation Difficulty Score is found by using the chart at the bottom of page 5 and entering the level of evacuation difficulty in the box at the bottom right. A score equal to or less than 1.5 is Prompt. A score greater than 1.5 but not more than 5 is Slow. A score of greater than 5 is Impractical. Transfer the score to the cover page of the Survey Report Form CMS-2786. As an additional safeguard, the health facilities surveyor, who visits the facility before the fire authority’s visit, should complete Items I thru VI on the Worksheet for Rating Residents for each client included in the health facility survey sample. This will help to corroborate the findings of the fire authority obtained through their interviews with staff about residents. This is done to determine if there is any cause to question the validity of staff reports of predicted client behavior. The health facilities surveyor is not required to complete all of the forms or calculate the Evaluation Difficulty Index unless required to by State regulations, but simply completes item I to VI.

The fire authority should obtain from the state survey agency health surveyors the completed “Worksheet for Rating Residents” and compare the results obtained from the two surveys. If there is a pattern of discrepancies in any of items I to VI for one or more of the clients in the sample, the state agency cannot certify the facility until these discrepancies are reconciled. Both the Fire Authority and the State Survey Agency must be satisfied that the EDI score is representative of client capability.

### ***ICFs/IID* Survey Procedures**

After you determine the size of the facility and level of evacuation difficulty, rate the building. There are two alternative methods of rating the building.

- Use the prescriptive requirements in the appropriate section of Chapter 32/33, Prompt, Slow or Impractical; or
- Use NFPA 101A, Guide on Alternative Approaches to Life Safety, 2001 Edition, Chapter 7, A Fire Safety Evaluation System for Board and Care Occupancies (FSES/BC).

There are two separate series of forms for completion and certification of the facility depending on which method above was followed. If the survey was completed using chapter 32/33 the prescriptive requirements method then complete the fire safety report-chapter 32/33, as well as the Worksheets for Rating Residents, Staff and Determining the E-Score of the group from Chapter 6, NFPA 101A. In addition, complete a Statement of Deficiencies and Plan of Correction (CMS-2567), in the usual manner if deficiencies are found.

If the facility is certified or is to be certified using the FSES/BC, Chapter 7, NFPA 101A and you have determined an Evacuation Difficulty Score for the facility, and completed a prescriptive survey of the facility you may apply the FSES/BC (Chapter 7, NFPA 101A), to determine compliance. Please note that the entire Fire Safety Survey Report must be completed when applying the FSES/BC. This is no different from the usual survey procedure for health care facilities. Complete a Form CMS-2786 along with the FSES/BC worksheets, which are part of the form, for each facility certified as a Residential Board and Care Occupancy.

Multiple buildings or parts of buildings on a campus are sometimes used by a facility to house clients. In such cases, rate each building separately. On a large campus, such as a State School for the Mentally Disabled or State Developmental Center, a large building may be surveyed under Chapter 18/19 Health Care and a small building may be surveyed as a Residential Board and Care Facility under Chapter 32/33. In some cases, buildings may be divided into separate wings, with one wing housing Residential Board and Care occupants and the other wing housing Health Care patients. You may use different chapters for different wings only if there is a 2-hour fire wall separating the two parts.

Large buildings previously meeting health care requirements such as a facility with 17 beds or more, which currently meets the health care provisions of the LSC, can continue to be surveyed either under the Health Care Chapter or the FSES/Health Care. If the large facility qualifies as Residential Board and Care occupancy, it may elect to be surveyed under Health Care.

If the facility is to be certified based upon achieving a passing score on the FSES/BC, complete a Statement of Deficiencies, Form CMS-2567, for both the regular Survey Report and the FSES/BC for any deficiencies found. The provider will indicate whether it chooses to correct the deficiencies on the Form CMS-2786, or the deficiencies on the FSES/BC.

There are no provisions for the granting of waivers when using the prescriptive requirements under the Residential Board and Care Occupancies Chapters 32/33. Providers may elect to be surveyed under the Health Care chapters to take advantage of the ability to obtain waivers.

Only surveyors that have completed CMS's basic Life Safety Code and the FSES/HC and if appropriate the FSES/BC training courses may apply the FSES in Medicare/Medicaid facilities.

## **Task 5 - Information Analysis and Decision Making**

### **General Objective**

The general objective is to review and analyze all observations and findings in order to determine whether the facility has a deficiency in one or more of the regulatory requirements. A deficiency is defined as observed problems of sufficient severity and/or frequency so as to identify the facility as responsible, and which require some form of corrective action by the facility.

Frequency means the incidence or extent of the occurrence of an observed problem in the facility.

Severity means the seriousness of the observed problem, e.g., the degree to which the problem compromises the residents' health and safety.

A deficiency may be cited when a deficient practice occurs once, or when it occurs frequently.

### **Procedures**

The fire safety survey report forms, worksheets and procedures are designed to assist in the gathering information about the level of fire safety provided by the facility. The K-tags refer to the data tags on the Fire Safety Survey Report form. For each item on the report form page indicate "Met" or "Not Met" or "Not Applicable." For each item marked "Not Met," enter the appropriate documentation in the Explanatory Remarks section explaining the nature of the deficiency and the degree of hazard it presents. Use additional sheets of paper for additional comments. Throughout the survey, discuss your observations with any other LSC team members and the facility staff. This interaction will assist you in identifying facility problems and will permit the facility the opportunity to provide additional information that may alleviate your concerns.

At the end of the survey, meet with any other LSC team members to draw conclusions about the level of fire safety provided by the facility, and the facility's compliance with the life safety code.

Deliberately review the negative findings and documentation from each task, and decide whether any further information or documentation is required. Consider your findings and observations in terms of credibility and reliability. Also, consider whether there are any rival or competing explanations related to particular negative findings. If necessary, ask the facility for additional information for clarification about particular findings and

carefully weigh any countervailing explanations before making a deficiency determination.

The threshold at which the frequency of occurrences amounts to a deficiency varies from situation to situation. One occurrence directly related to a life-threatening or fatal outcome can be cited as a deficiency. On the other hand, a few sporadic occurrences may have so slight an impact on the life safety of residents or patients that they do not warrant a deficiency citation.

Determining compliance with the LSC as indicated on the Fire Safety Survey Report form should be based on the facility meeting all the requirements of the LSC. Alternatively, if there are deficiencies, facilities can be found in compliance after an acceptable plan of correction. (A revisit may be needed to confirm that the deficiencies have been corrected. This can also include a telephone or fax confirmation of correction of cited deficiencies when appropriate). A facility may also be found in compliance with the LSC if the Regional Office of CMS has waived a specific provision of the LSC. Evidence of such a waiver should be provided by the facility. If the survey indicates that the facility is not in compliance with LSC, then a recommendation of certification is instead inappropriate.

If the facility is a JCAHO or AOA accredited facility, the facility is found to either meet the provisions of the LSC or the facility does not meet the provisions of the LSC. The facility cannot be found to meet the LSC by waiver or acceptable plan of correction due to its accreditation status. If the facility has been found not to be in compliance with the LSC then the facility loses its "deemed" status and will be required to complete a POC to correct the deficiencies found. A Plan of Correction and the request for completion of a POC cannot occur until a certification decision is made to remove the facility's "deemed" status by the Regional Office. The deficiencies cited will have to be corrected before the facility's "deemed" status can be restored. A follow-up survey may be required to confirm that the deficiencies have been corrected and that "deemed" status can be restored.

When the plan of correction contemplates meeting the equivalency criteria, mark the facility in compliance based upon the findings of the FSES on page one of the Fire Safety Survey Report Form. The use of the Fire Safety Evaluation System does not necessarily eliminate the use of waivers. For example, if an item in the Facility Fire Safety Requirements Worksheet, of the FSES is deficient, it does not enter into the computation portion of the FSES and must either be met, not meet or could be waived. The Fire Safety Requirements Worksheet includes requirements for such items as building utilities, heating and air conditioning regulations. CMS encourages the use of the FSES in those cases where a facility could achieve a passing score without waivers.

### **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. Recommended Waivers.”*

### **Writing Deficiency Statements**

Following the Principles of Documentation, (appendix P) write the deficiency statement in terms specific enough to allow a reasonably knowledgeable person to understand the aspect(s) of the requirement(s) that is (are) not met. Indicate the data prefix tag and regulatory citation, followed by a summary of the deficiency and supporting findings using resident identifiers, not resident names. List the data tags in numerical order, whenever possible.

**The statement of deficiencies should:**

- Identify the Section(s) in the Life Safety Code and Mandatory References, where appropriate, that contain the requirements upon which the deficiency is based; and
- Specifically reflect the content of each requirement that is not met; and
- Clearly identify how/why the requirement is/was not met; and
- Identify the extent of each deficient practice; and
- Identify the source(s) of the evidence (e.g., interview, observation or record review); and
- If appropriate, identify the impact or potential impact of the facility's non-compliance on health and safety of the residents/patients.

**Decision Making for Compliance with the LSC**

The final part of the fire safety survey is sometimes considered the most difficult, and that is making a compliance decision on whether or not the facility meets the LSC. There is no number of deficiencies, that if exceeded makes the facility out of compliance with the LSC. It is possible to have one or two deficiencies are significant enough to be considered an immediate and serious threat to the residents/patients or a large number of less serious deficiencies that do not have the same impact. In the final analysis a decision has to be made, one that is based on the facts and can be objectively defended if questioned.

The decision making process for health care facilities is very similar across all provider groups with the exception of accredited hospitals.

If a facility has no deficiencies or non-consequential deficiencies the decision making process is very simple; the facility is in compliance and no deficiencies are cited. The survey report form is marked "The Facility Meets, Based Upon 1. Compliance With All Provisions." No further action by the facility is expected regarding this survey. The facility is to be notified and the results posted and available to the residents and the public.

If the facility has deficiencies and they are not at the level that would constitute an immediate and serious jeopardy or threat to the health and safety of the residents/patients (see [Appendix Q](#) for criteria) then a compliance decision will have to be made based on the results of the survey. This decision needs to be based on the facts at hand and not biased one way or the other due to outside forces.

Deficiencies may be considered corrected by the approval of a waiver of a specific requirement of the Life Safety Code.

In the case of a building that is to be certified using the FSES and if a passing score is not achieved on the FSES form, the facility does not meet the requirements of the Life Safety Code and the Fire Safety Report Form part 7 B should be marked “The Facility Does Not Meet the Standard.” If this occurs then the Physical Environment Condition of Participation must also be found not met. Termination action should be instituted if the facility was found not in compliance and the same deficiencies were cited on the survey the year before. In other words, if the facility did not complete their POC from the year before as approved then termination proceedings shall be instituted. If the facility was not previously found out of compliance or different deficiencies were found previously, then a POC could be accepted from the facility. A follow up revisit needs to be scheduled to inspect the progress being made to correct the deficiencies.

Then an accredited hospital, one which has “deemed status,” is surveyed under a validation or complaint survey the compliance decision process is altered somewhat. If LSC deficiencies are found that require correction they are documented on a Form CMS-2567 in the usual manner. The facility is then found out of compliance with the “Standard of Life Safety from Fire” and the “Physical Environment Condition of Participation.” The SA then transmits the survey findings and the recommendation that the “standard” and the “condition of participation” are not met to the Regional Office (RO). The Regional Office, if in agreement with the SA findings, removes the facility’s “deemed status” and at that time a POC is requested from the facility, and corrective action is taken by the facility. The facility is placed under SA monitoring and the SA is requested at this time to make periodic follow-up visits to insure timely completion of the POC. When the facility has completed its POC, the facility’s “deemed status” is restored and the facility is no longer under SA monitoring.

### **Immediate and Serious Threat**

An immediate and serious threat is defined in [Appendix Q](#) as having a high probability that serious harm or injury to residents/patients could occur at any time, or has already occurred and may well occur again if residents/patients are not protected effectively from the harm, or the threat is not removed.

The guiding principles to determine immediate and serious threat make it clear that the threat to life is imminent and can be related to the health and safety of the residents/patients. Some examples of life threatening deficiencies are failure to maintain required fire protection systems in an operating condition, obstructed passageways that prevent egress in the event of an emergency, open stairways, missing tamper switch and water flow alarm in a sprinklered facility and unprotected wood frame construction which is not sprinklered.

If, at any time during the survey, an immediate and serious threat is identified, the surveyor should immediately consult with his/her supervisor and the State Agency. If the

supervisor and State Agency concurs with the findings of the surveyor, then the facility administrator is notified that immediate and serious threat termination procedures are being invoked. The surveyor should explain to the administrator the nature of the threat. The surveyor should complete the remainder of the survey to determine the extent of deficiency.

The Form CMS-2786 should be marked as 7. B. “THE FACILITY DOES NOT MEET THE STANDARD” if the facility is found to have an immediate and serious threat. If the form is marked “MEETS WITH ACCEPTANCE OF A PLAN OF CORRECTION,” the State Agency cannot make a finding of immediate and serious jeopardy at the facility.

See Appendix Q for guidance regarding the determination of immediate and serious threat, and [§3010](#) of the State Operations Manual (SOM) for procedures to follow if the immediate and serious threat termination procedures are invoked.

## **Task 6 - Exit Conference**

### **General Objective**

The purpose of the exit conference is to inform the facility of the survey team’s observations and findings.

### **Conduct of Exit Conference**

Conduct the exit conference with the facility administrator or anyone designated by the administrator. Also, invite an Officer of the organized residents group, if one exists, or a representative of the residents of the facility to the exit conference.

Provide the facility with specific information necessary for POC, if there is a need for a POC. Do not provide the facility worksheets that contain surveyor notes.

Describe to the facility the requirements that are not in compliance, the findings that substantiate these deficiencies, and any other observations or findings that did not result in a deficiency being cited but that may assist the facility in maintaining or improving its level of life safety from fire.

Provide the facility with the opportunity to discuss and supply additional information, if necessary, and attempt to resolve differences regarding deficiencies.

Review with the facility alternatives to compliance with the prescriptive requirements of the LSC if appropriate, such as, waivers of specific life safety code requirements or the suitability of the facility to achieve compliance using the FSES.

Determine the level of Scope and Severity for deficiencies cited at long term care facilities. The level of scope and severity will be determined in accordance with procedures found in SOM, Chapter 7, [§7400](#). The level of scope and severity will depend

on the extent of the deficient practice and its impact on the health and safety of the residents. This can occur on-site or presented to the facility on the Form CMS-2567.

In accordance with your Agency's policy, present the Form CMS-2567, on site or after supervisory review, no later than 10 calendar days following the survey.

### **III. Complaint Investigations**

If a complaint alleges a deficient practice in fire safety, and the complaint is of a specific nature, use your discretion to investigate the complaint independent of the standard fire safety survey (a special survey) or incorporate the investigation of the complaint into that specific task that covers that issue in the standard fire safety survey.

The scope, duration and conduct of a complaint investigation are at the discretion of the State survey team. The investigation should be widespread enough to resolve the complaint. Base any citation of deficiencies upon observations at the time of the survey. If it can be determined that the facility was out of compliance at the time of the complaint but, is no longer out of compliance, this should be noted.

A Form CMS-2567 should be completed and forwarded to the facility in accordance with Agency policy if deficiencies are found.

### **IV. Post Survey Revisits**

The purpose of the follow-up survey or revisit is to re-evaluate the specific deficient areas that were cited, as deficient, during the original survey. Determine the status of corrective actions being taken on all deficiencies cited on the original surveys Form CMS-2567. The nature of the deficiencies dictates the timing and scope of the follow-up survey. For example, LSC deficiencies that involve structural changes may require long construction periods, whereas maintenance driven items may be corrected fairly quickly. Focus on the previously cited deficiencies but the surveyor is not prohibited from gathering information related to any of the LSC requirements during a follow-up survey. If, after completing the follow-up activities, you determine that the cited deficiencies were not corrected by the date specified in the facility's approved plan of correction, initiate adverse action procedures, as appropriate. Document the revisit to the facility using the appropriate CMS forms. It may be possible, if the need for documentation is minimal, to use the Surveyor Notes Worksheet (Form CMS-681) to record the results of the revisit survey.

**TABLE 1**  
**SAMPLE SIZE OF RESIDENT/PATIENT ROOMS**

The table below gives the sample size (number of patient/resident rooms to be checked) needed.

<b>Number of Bedrooms in the Facility</b>	<b>Bedrooms to be Checked</b>
20	19
40	36
60	52
80	66
100	80
200	132
300	169
400	196
500	217
600	234
800	260
1000	278
2000	322

# State Operations Manual

## Appendix L - Guidance for Surveyors: Ambulatory Surgical Centers

### Q-0101

*(Rev.99 Issued: 01-31-14, Effective: 01-31-14, Implementation: 01-31-14)*

### §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.*

# State Operations Manual

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

### C-0226

*(Rev.99 Issued: 01-31-14, Effective: 01-31-14, Implementation: 01-31-14)*

**§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.*