

Certificate Of Need (CON) 101

With NYSDOH and CMS Regulatory requirements

Intro & Presentation Outline



- Introduction
 - Why a CON Back to BASICS presentation?
 - Goals of Presentation.
- Metrics
 - Review times and quality of reviews by design professionals.
- Electronic Reviews (Minor Updates)



- Centers for Medicare & Medicaid Services (CMS) and the Life Safety Code (LSC)
- CMS and Guidance for Hospital Co-location with Other Hospitals or Healthcare Facilities
- CMS & Revised Fire Safety Equivalency System (FSES) (Building Construction Types)
- Nursing Home Room Size and FGI Proposed Amendments for Nursing



- Schedule 6: Narrative Updates and Con Updates
 - Proposed Regulatory Requirements (New versus Existing LSC).
 - Schedule 6 and why the information is required.
- Primary Care Clinics: Physical Plant Standards
- EES Systems with Alternate Energy Sources



- Regulatory Submission Requirements for CON a review
 - Referenced Standards
 - National Fire Protection Association (NFPA) 101 2012 Edition
 - Facilities Guidelines Institute (FGI) 2014 or FGI 2018
 - American Disability Acts (ADA) 2010
 - CFR 42 Part 483, October 5, 2016
 - Title 10 NYSDOH Article 28 requirements **DOH**Review Requirements

 Output

 Department of Health



- The Vantasner Danger Meridian: Efficient Tool for Predicting Danger (Fact or Fiction?)
- Account for all DOH submissions.
- Continue to improve quality of reviews by the following:
 - Reducing the time to review and provide a determination.
 - Eliminating the amount rework of submissions by the applicant, design professionals and BAER.



- Close the loop when a submission is approved, denied, withdrawn, abandoned, established in error, or completed.
- Improve consistency with BAER, Regional Offices and Program.
- Standardization of the application of regulations, policies and procedures to ensure determinations are not arbitrary and/or capricious.

- Develop a better understanding of the current conditions of CON from a DOH and a limited CMS perspective.
- Reduce the number of phone calls, conferences and prolonging a decision.
- Defragment the review process. (Central Clearinghouse for all reviews and review types related to physical plant requirements.)



• The Vantasner danger meridian is a term used in the assessment of imminent events in relation to danger. With regard to danger, both for the task to be performed and for the people who carry it out. An attempt within a feasibility study is made to take this into account quantitatively.



Fun Facts



METRICS

- Reviews Submitted & Processed BAER
- Reviews Submitted & Processed by DASNY
- Reviews Types Processed BAER
- Reviews Types Processed by DASNY
- AES Submitted & Processed



Electronic Reviews



All certificate of Need (CON) Schematic Design and Design Development submissions for architectural and engineering reviews shall be submitted as PDF files in accordance with the appropriate Design Guideline Submission Requirements as indicated on the NYSDOH website unless otherwise noted.



- Provide only the drawings necessary for review. Incomplete information may require Requests for Additional Information (RFI's), which may delay the review and recommendation of the project and or rejection of the submission.
- Complete construction documents are not required and may be rejected.



 Hard copy drawings will no longer be required and will not be accepted unless requested by DOH or DASNY under exceptional circumstances.



See Instructions for the electronic submission of drawings they are available on the website.

https://www.health.ny.gov/facilities/cons/more information/docs/con/nreview guidance document.pdf.





Discussion:

Increasingly, hospitals have co-located with other hospitals or other healthcare entities as they seek efficiencies and develop different delivery systems of care models.

Co-location occurs where two hospitals or a hospital and another healthcare entity are located on the same campus or in the same building and share space, staff, or services.



All co-located hospitals must demonstrate separate and independent compliance with the hospital Conditions of Participation (CoP's). This guidance clarifies how shared spaces, services, personnel and emergency services can be organized to allow the hospital to demonstrate independent compliance.



CMS also clarified that sharing of staff may be done through a contractual arrangement where there are clear lines of authority and accountability. In general, under this guidance, sharing public areas such as entrances and waiting rooms would be permissible. However, due to infection control, patient management, confidentiality, and other quality and safety concerns, the use of shared clinical spaces would be limited.



Hospitals can be co-located with other hospitals or other healthcare entities. These hospitals may be located on the same campus of or in the same building used by another hospital or healthcare facility. The hospital may be co-located in its entirety or only certain parts of the hospital may be co-located with other healthcare entities. Common examples of co-location instances include:



- One hospital entirely located on another hospital's campus or in the same building as another hospital.
- •Part of one hospital's inpatient services (e.g., at a remote location or satellite) is in another hospital's building or on another hospital's campus.



Regardless of the situation, when a hospital is in the same location (campus or building) as another hospital or healthcare entity, each entity is responsible for demonstrating separate and independent compliance with the hospital CoPs.



Distinct Space and Shared Space

Distinct spaces includes clinical spaces designated for patient care and is necessary for the protection of patients, including but not limited to their right to personal privacy and to receive care in a safe environment.



- Under §§482.13(c)(1) and (2), and right to confidentiality of patient records under §482.13(d). For example, comingling of patients in a clinical area such a nursing unit, from two co-located entities, could pose a risk to the safety of a patient as the entities would have two different infection control plans.
- Additionally, the shared clinical space could jeopardize the patient's right to personal privacy and confidentiality of their medical records.

Shared spaces are the following:

 Public paths of travel that are utilized by both the hospital and the co-located healthcare entity.

Examples of public spaces and paths of travel include:

- Public lobbies,
- Waiting rooms and reception areas (with separate "checkin" areas and clear signage),



- Public restrooms,
- Staff lounges,
- Elevators
- Main corridors through non-clinical areas,
- Main entrances to a building.



However, the following examples would not be public paths of travel:

- A hallway, corridor, or path of travel through an inpatient nursing unit; or
- A hallway, corridor, or path of travel through a clinical hospital department (e.g., outpatient medical clinic, laboratory, pharmacy, imaging services, operating room, post anesthesia care unit, emergency department, etc.)

CMS & LSC



CMS,LSC and Emergency Departments(ED)

Interpretation from Centers for Medicare and Medicaid Services (CMS), all Emergency Departments (ED) are now required to be classified as healthcare occupancies only.

This also affects those free-standing Emergency Departments that were designed and approved as ambulatory healthcare occupancies; according to CMS recent interpretation, they also must meet the requirements for a healthcare occupancy. And it appears this decision is retroactive to existing conditions.

CMS,LSC and ED's

CMS states Emergency Departments cannot be ambulatory healthcare occupancies and must be classified as healthcare occupancies because they provide sleeping accommodations for patients who are on 24-hour observation. (Does this mean, observation units need to meet the requirements of Chapter 18?)



CMS & LSC Summary

- Hospital/ Critical Access Hospital (CAH) LSC Occupancy Classification: Hospital and CAH component facilities may be classified as new or existing Health Care, Ambulatory Health Care, Business, or other occupancies, as allowed by provisions of the LSC.
- Hospitals/CAH with multiple component facilities may have various occupancy classifications.



CMS & LSC

CMS is updating guidance for hospitals and CAH's to assure alignment with the LSC occupancy classification provisions. Providing clarification to determine the appropriate occupancy classifications for separated, non-contiguous or off-site facilities that are part of a certified Hospital or CAH.



CMS & LSC

In accordance with 42 CFR 482.41(b) and §485.623(d), Medicare-participating hospitals and CAHs must meet the applicable provisions of the 2000 Edition of the National Fire Protection Association (NFPA) 101: LSC. The LSC permits certain hospital and CAH component facilities to be classified as occupancy types other than Health Care Occupancy. Those other occupancy types have less stringent requirements.



CMS & LSC

Note: Even though this references the 2000 edition, the principles still apply when the 2012 Edition of the LSC are involved.



CMS & LSC

The LSC has a methodology for determining the appropriate occupancy classification that is required at a facility to ensure an adequate level of fire protection is present to protect patients and other building occupants. Allowing component facilities of a hospital or CAH to be surveyed as occupancy classifications other than Health Care, in accordance with the LSC, will ensure both that an adequate level of fire protection is afforded and unreasonable hardship or burden is not imposed upon a hospital or CAH.

CMS & LSC Mixed Occupancy Classifications

Hospital or CAH component facilities located in a building with more than one occupancy classification must be adequately separated from the other building occupancies, as required by the LSC, in order to be eligible for their own occupancy classification. If a hospital or CAH component facility is not adequately separated from other building occupancies, the most stringent occupancy classification must apply to the entire building.

CMS & LSC Summary for Mixed Occupancy

- Building houses mixed occupancies; and
- Hospital or CAH component facility is adequately separated from other building occupancies; If adequately separated, occupancy classification is determined as explained below,
 - If not adequately separated, the most stringent occupancy classification of all the building occupants applies.

CMS & LSC Healthcare Occupancies Chapters 18 & 19

A hospital or CAH component facility, regardless of whether it is located in a separate building on the main provider's campus or is located off the main provider's campus, ("campus" and "main provider" are defined in 42 CFR 413.65(a)(2)), must initially be considered as a new or existing Health Care Occupancy.



CMS & LSC Healthcare Occupancies Chapter s 18 & 19

LSC defines a Health Care Occupancy as, "[a]n occupancy used for the purpose of medical or other treatment or care of four or more persons where such occupants are mostly incapable of self-preservation because of age, because of physical or mental disability, or because of security measures not under the occupants' control."



According to sections 18/19.1.1.1.3, "health care facilities regulated by these chapters provide sleeping accommodations for their occupants."

Further, sections 18/19.1.1.1.7 provide that, "[f]acilities that do not provide housing on a 24-hour basis for their occupants shall be classified as other occupancies and shall be covered by other chapters of this Code."



Therefore, hospital or CAH component facilities that provide sleeping accommodations and medical treatment or services on a 24-hour basis for patients mostly incapable of self-preservation must be classified as a Health Care Occupancy.



Section 1861(e) of the Social Security Act (the Act) defines "hospital" as being primarily engaged in providing care to inpatients and is not based upon a minimum number patients receiving treatment, care or services.



CMS does not consider the number of patients in determining if a provider is a hospital or a CAH; therefore, a CMS-certified hospital or CAH does not need to have four or more inpatients at all times in order to be classified as a Health Care Occupancy.



Occupancy classification must be determined regardless of the number of patients served at a hospital's or CAH's component facility.



CMS & LSC Summary Chapters 18 & 19

- Facility provides sleeping accommodations;
- Facility provides medical treatment or services on a 24hour basis; and
- Patients are mostly incapable of self-preservation.



CMS LSC Chapters 20 & 21

Section 3.3.134.1 of the LSC defines a Ambulatory Health Care (AHC) Occupancy as "[a] building or portion thereof used to provide services or treatment simultaneously for four or more patients that:



CMS LSC Chapters 20 & 21

- provides on an outpatient basis, treatment for patients that renders the patients incapable of taking action without the assistance of others;
- (2) provides, on an outpatient basis, anesthesia that renders the patients incapable of taking action for self-preservation under emergency conditions without the assistance of others."



CMS, LSC Chapters 20 & 21

Considering the definition of an AHC provided in section 3.3.134.1 and the occupancy classification exemption provided in sections 18/19.1.1.1.7, a hospital or CAH component facility initially considered to be a Health Care Occupancy but which does not provide either sleeping accommodations or medical treatment or services on a 24-hour basis, may be classified as another occupancy type.



CMS, LSC Chapters 20 & 21

For example, if it provides treatment or services to patients who are mostly incapable or rendered incapable by treatment or anesthesia provided by the facility, it must be classified as a new or existing AHC Occupancy.



CMS LSC Chapters 20 & 21

CMS does not consider the number of patients treated when determining an AHC occupancy classification.

Furthermore, CMS does not consider whether or not a patient has been "rendered" incapable of taking action for selfpreservation by the facility; rather, the only consideration is whether the patient is capable or incapable of selfpreservation.



CMS LSC Chapters 20 & 21

Therefore, occupancy classification must be determined regardless of the number of patients being served or whether or not a patient has been rendered incapable of self-preservation by a hospital or CAH component facility.



CMS Summary LSC Chapters 20 & 21

- Facility does not provide sleeping accommodations;
- Facility does not provide medical treatment or services on a 24-hour basis;
- · Facility provides anesthesia services; and
- Patients are mostly incapable of self-preservation.



According to the Ambulatory Health Care section 20/21.1.1.1.4 of the LSC, "[b]uildings, or sections of buildings, that primarily house patients who, in the opinion of the governing body of the facility and the governmental agency having jurisdiction, are capable of judgment and appropriate physical action for self-preservation under emergency conditions shall be permitted to comply with chapters of this code other than Chapter 20/21."



CMS LSC Chapters 38 & Chapter 39

Therefore, a hospital or CAH component facility previously considered an AHC Occupancy, but which does not provide anesthesia services or serve patients who are mostly incapable of judgment and appropriate physical action for self preservation under emergency conditions, could be classified as a new or existing Business Occupancy.



CMS LSC Chapters 38 & Chapter 39

A patient may be incapable of self-preservation due to many factors, including, but not limited to, age, physical or mental disability, medical or therapeutic interventions, medication reactions, etc.



CMS LSC Chapter 38 and Chapter 39

In addition, when determining the ability for selfpreservation, consideration should be given to both the characteristics of current patients and the characteristics of patients the facility is likely to provide medical treatment or services to in the future, as evidenced by the provider's own advertisement and clientele to which the provider holds itself out to serve.



CMS LSC Summary Chapters 38 and Chapter 39

- Facility does not provide sleeping accommodations;
- Facility does not provide medical treatment or services on a 24-hour basis;
- Facility does not provide anesthesia; and
- Patients are mostly capable of self-preservation.



CMS & Other Occupancies Classifications

Hospital and CAH component facilities to which patients are not expected to have access (i.e., patients have no "customary access"), which are non-contiguous or adequately separated from other hospital or CAH occupancies, as determined by the LSC, could be classified as other occupancies.



CMS & Other Occupancies Classifications

Other occupancy classifications may include, but are not limited to, Assembly, Day Care, Mercantile, and Storage Occupancies.



CMS & Revised FSES Construction Types



CMS-3347-P RIN 0938-AT36

I. Executive Summary and Background



Over the past several years, CMS has revised the Conditions of Participation (CoPs), the Conditions for Coverage (CfCs), and requirements for long-term care (LTC) facilities to reduce the regulatory burden on providers and suppliers.



CMS identified obsolete and burdensome regulations that could be eliminated or reformed to improve effectiveness or reduce unnecessary reporting requirements and other costs, with a particular focus on freeing up resources that health care providers, health plans, and states could use to improve and enhance resident health and safety.



CMS have also examined policies and practices not codified in rules that could be changed or streamlined to achieve better outcomes for residents, while reducing burden on providers and suppliers of care, and we identified non-regulatory changes to increase transparency and to become a better business partner.



In addition, the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services (HHS) have reaffirmed their shared commitment to the vision of creating an environment where agencies incorporate and integrate the ongoing retrospective review of regulations into Department operations to achieve a more streamlined and effective regulatory framework.



The objectives are to improve the quality of existing regulations consistent with statutory requirements; streamline procedural solutions for businesses to enter and operate in the healthcare marketplace; maximize net benefits (including benefits that are difficult to quantify); and reduce costs and other burdens on businesses to comply with regulations.



Physical Environment (§483.90)

CMS proposes to allow older existing LTC facilities to continue to use the 2001 Fire Safety Equivalency System (FSES) mandatory values when determining compliance for containment, extinguishment, and people movement requirements.



This proposal would allow older facilities who may not meet the FSES requirements in the recently adopted 2012 Life Safety Code (LSC) to remain in compliance with the older FSES without incurring substantial expenses to change their construction types, while maintaining resident and staff safety.



In addition, CMS has proposed to revise the requirements that newly constructed, re-constructed, or newly certified facilities accommodate no more than two residents in a bedroom and equip each resident room with its own bathroom that has a commode and sink.



Specifically, CMS proposed to only apply this requirement to newly constructed facilities and newly certified facilities that have never previously been a nursing home. This would remove unintended disincentives to purchase facilities or make upgrades to existing facilities.



CMS is proposing changes to the current LTC requirements and survey process that would simplify and streamline the current requirements and thereby increase provider flexibility and reduce excessively burdensome regulations, while also allowing facilities to focus on providing high-quality healthcare to their residents.



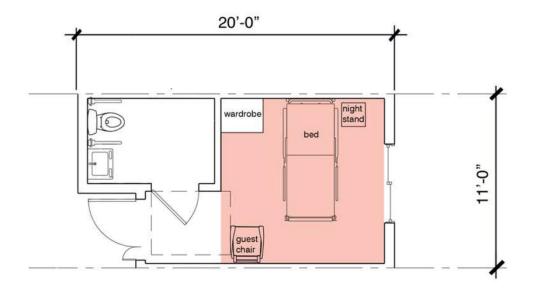
This proposed rule would also reduce the frequency of certain required activities and, where appropriate, revise timelines for certain facility requirements and remove obsolete, duplicative, or unnecessary requirements.



We (CMS) believe that these proposals balance resident safety and quality of care, while also providing regulatory relief for facilities.

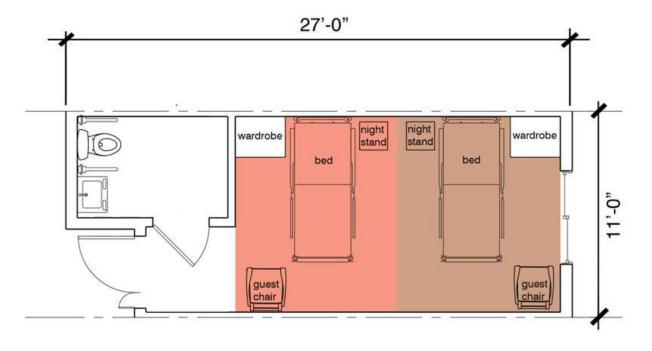






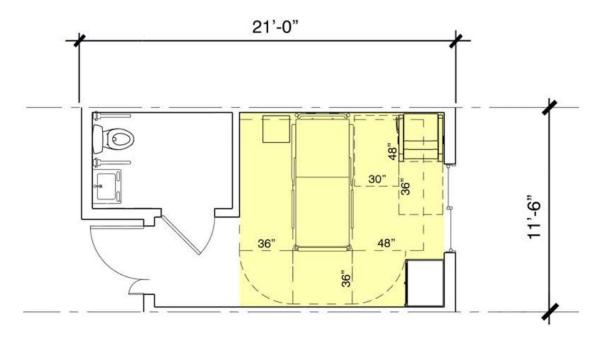
CMS Private Room with Hospital Bed - 101 sf





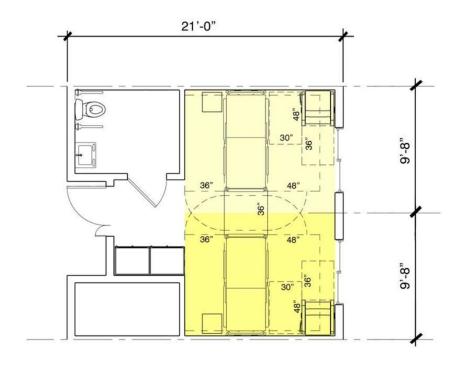
CMS Shared Room - 85 sf each occupant





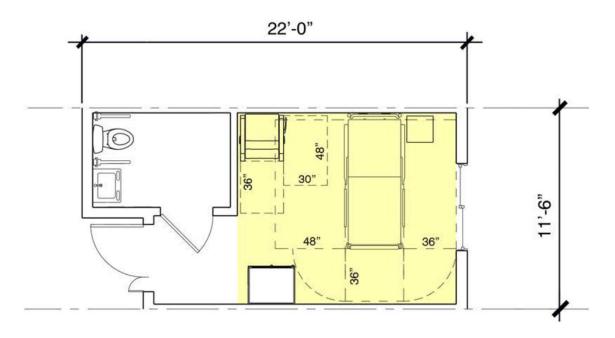
Private Room with Hospital Bed - 120 sf





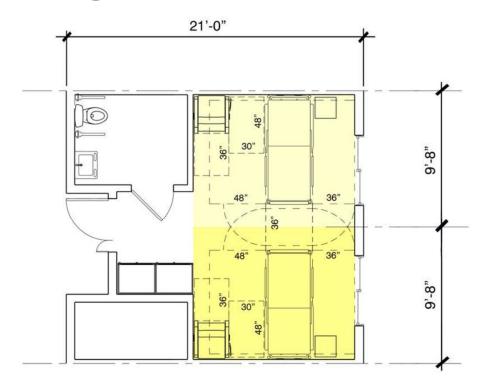
Companion Bedroom A - 108sf Companion Bedroom B - 108sf





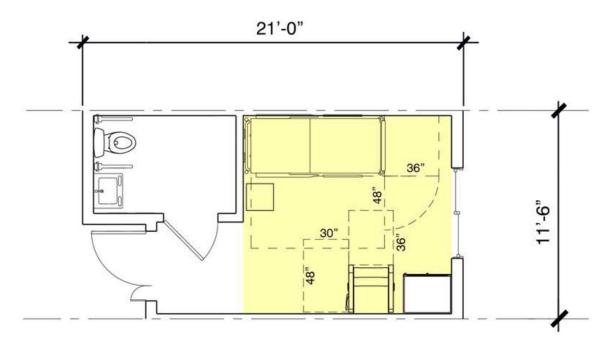
Private Room with Hospital Bed - 131 sf





Companion Bedroom A - 108sf Companion Bedroom B - 108sf





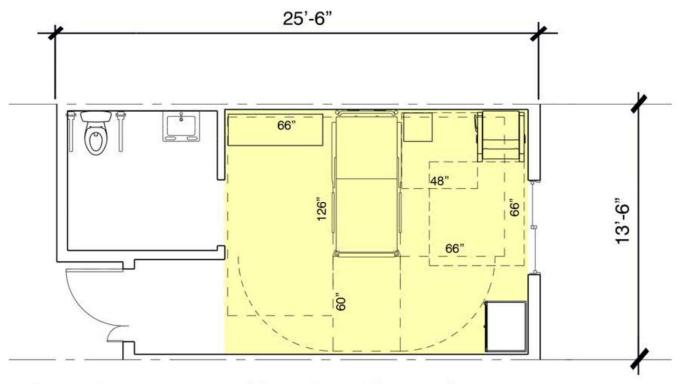
Private Room with Hospital Bed - Alternative Furniture Arrangement - 120 sf

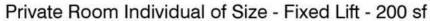




Companion Bedroom A - Alternative Furniture Arrangement - 108sf Companion Bedroom B - Alternative Furniture Arrangement - 108sf





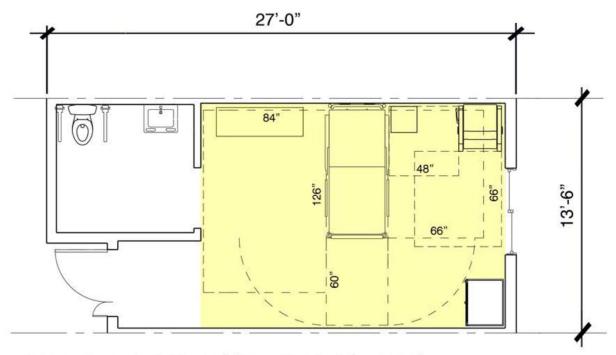






Companion Bedroom A - Individual of Size - Fixed Lift - 176sf Companion Bedroom B - Individual of Size - Fixed Lift - 176sf





Private Room Individual of Size - Mobile Lift - 219 sf





Companion Bedroom A - Individual of Size - Mobile Lift - 192 sf Companion Bedroom B - Individual of Size - Mobile Lift - 192 sf



Primary Care Clinics: Physical Plant Standards



Primary Care Clinics: Issues and Responses

Article 28 clinics, particularly those in underserved communities, often cite physical plant standards as a barrier to providing primary care services, including integrated services.

In response and to increase access to care, DOH developed guidelines that describe two primary care clinic classification categories designed to provide direction related to minimum physical environment standards.



Schedule 6 Updates & Narrative Guidance



Detailed Architectural Narrative

- The narrative doesn't agree with the plans submitted.
 - Why?
 - Who looks at these?
 - Do I need to update the narrative at State Hospital Code Submission?
 - Why do we need a functional program?
 - Isn't the executive summary the same as the narrative?
 Why can't we rely on the executive summary?



Detailed Architectural Narrative-Schedule 6

 https://www.health.ny.gov/facilities/cons/more_informa tion/schedules.htm





Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-07-21

DATE: May 4, 2007

TO: State Survey Agency Directors

State Fire Authorities

FROM: Director

Survey and Certification Group

SUBJECT: Generators in Ambulatory Surgical Centers

(ASCs)

NEW YORK Department of Health

Memorandum Summary

Highlights the requirements for a Type I Essential Electrical System with a generator in Ambulatory Surgery Centers. (ASC's)

It is permissible to use batteries for back-up power under certain circumstances.

NEW YORK Department of Health

42 CFR 416.44(b) requires ASC's to comply with the National Fire Protection Life Safety Code 2000 edition. This edition references the National Fire Protection Association Standard for Health Care Facilities (NFPA 99-1999), Sections 3-4.1.1 and 3-4.1.2, which require emergency power to be provided for a Type I Essential Electrical System in all locations using general anesthesia or electrical life support equipment. This emergency power is usually supplied by a generator.



However, batteries are also permitted in ASCs, if they meet all the requirements of a Type I System and comply with the National Electrical Code (NEC) NFPA 70, Article 700 Batteries must also meet the requirements of NFPA 111, "Stored Electrical Energy and Standby Power Systems." Based upon NFPA 70 requirements, it is likely that a generator will be necessary in most ASCs where a Type I System is required.



A Type III Essential Electrical System is permitted to supply emergency power in facilities that do not provide electrical life support or use general anesthesia, provided the batteries are large enough to handle the equipment and there is sufficient back-up power to emergency lighting of corridors, exit ways, and alarm equipment.

A Type III System is not permitted where a Type I system is required.

NEW YORK Department of Health

A back-up power system for emergency lighting must be installed and maintained in accordance with NFPA 99 and NFPA 101.

NYSDOH will be issuing guidance in the near future regarding Standby Power Requirements.



A Type III System is not permitted where a Type I system is required.

A back-up power system for emergency lighting must be installed and maintained in accordance with NFPA 99 and NFPA 101.

NYSDOH will be issuing guidance in the near future regarding Standby Power Requirements.



NFPA 99 2012:

6.3.2.2.10 Essential Electrical Systems (EES).

6.3.2.2.10.1 Critical care rooms (Category 1 Room) shall be served only by a Type I EES.

6.3.2.2.10.2 General care rooms (Category 2 Room) shall be served by a Type I or Type II EES.



3.3.138* Patient Care Room. Any room of a health care facility wherein patients are intended to be examined or treated. (MED)

3.3.138.1* Basic Care Room. Room in which the failure of equipment or a system is not likely to cause injury to the patients or caregivers but can cause patient discomfort (Category 3). (MED)



3.3.138.2* Critical Care Room. Room in which failure of equipment or a system is likely to cause major injury or death of patients or caregivers (Category 1). (MED)

3.3.138.3* General Care Room. Room in which failure of equipment or a system is likely to cause minor injury to patients or caregivers (Category 2). (MED)



3.3.138.4* Support Room. Room in which failure of equipment or a system is not likely to have a physical impact on patients or caregivers (Category 4). (MED)

A.3.3.138.3 General Care Room. Examples include, but are not limited to, inpatient bedrooms, dialysis rooms, in vitro fertilization rooms, procedural rooms, and similar rooms.



Center for Medicaid and State Operations/Survey and Certification Group Center Group

Ref: S&C-09-24

DATE: February 11, 2009

TO: State Survey Agency Directors

FROM: Director

Survey and Certification Group

SUBJECT: Implementation of the Life Safety Code (LSC)

Component for the New End Stage Renal Disease (ESRD)

Conditions for Coverage

Essential Electrical Systems (EES): Exception to the LSC, 2000:

Dialysis facilities are <u>not</u> required to meet the parts of sections 20.2.9.2 and 21.2.9.2 of the LSC, 2000 that require the facility to provide an "essential electrical system" (EES) in accordance with NFPA 99,, 1999. Generators would be required if there was an ongoing need for "general anesthesia or life support equipment." "Life support equipment" is defined as electrically-powered equipment whose continuous operation is necessary to maintain a patient's life.

An EES is not required in a dialysis facility because dialysis machines are not considered life support equipment.

Continuous operation of a dialysis machine is not required to maintain life.

