



MEDICARE AMBULATORY SURGICAL CENTER (ASC) ACCREDITATION STANDARDS MANUAL

Version 9.1, Effective February 2, 2026

SURVEY INSTRUCTIONS

Please complete the Standards Manual for the facility by assessing compliance with the standards contained in this book.

STANDARDS STRUCTURE

Standards found in this book are organized by grouping relevant standards together. These groupings are comprised of “Sections,” “Sub-sections,” and then individual standard numbers. Each main “Section” is identified by a numerical value, “Sub-sections” have been assigned an alphabetical value, and the individual standards under the subsection have also been numbered. Based on this format, each standard has been assigned a unique identifier to include all three elements to indicate its location.

For example: The standard which states, “Each operating room is properly cleaned, maintained and free of litter and clutter” is the fourth standard under Section 2, Sub-section C. Therefore, the unique identifier for this standard is: 2-C-4.

Please note that not all standards are necessarily in continuous sequential order. Some numbers have been reserved for future use and do not appear in the manual. The groupings within the Sections and Sub-sections of this book are intended to separate standards into logical sets of standards. Based on 40 years’ experience, such groups are likely, but not guaranteed, to be found and assessed during the same portion of the survey process.

The standards are organized into a logical hierarchy for ease of use:

- **Sections** are numbered (e.g., 1, 2, 3).
- **Sub-sections** are assigned a letter (e.g., A, B, C).
- **Individual Standards** are numbered under each sub-section (e.g., 1, 2, 3).

This structure creates a unique identifier for each standard: **[Section]-[Sub-section]-[Standard #]**.

Example: The standard, “*Each operating room is properly cleaned, maintained and free of litter and clutter,*” is the fourth standard in Section 2, Sub-section C. Its identifier is **2-C-4**.

Please Note:

- Standard numbers are not always sequential. Some numbers are reserved for future use and do not appear in this edition.

The groupings are designed to cluster related standards, which may facilitate a more efficient survey process.

STANDARD BOOK LAYOUT

The standards manual layout consists of five (5) columns. The function of each column is as follows:

Standard ID:

This column contains the alphanumeric identifier for each standard.

Class:

This column indicates the anesthesia classification, based on QUAD A definitions, that is applicable to the standard. Only facilities that provide anesthesia meeting the definition of one or more of the classifications listed in this column are required to comply with it.

Note: Facilities must comply with all applicable state or national requirements governing the facility, including country and state laws and regulations relating to anesthesia. When standards conflict, **the most stringent requirement applies**, unless mandated by laws or regulations applicable to the facility.

Example: A facility accredited under QUAD A Class A Standards may be permitted to administer local, topical anesthesia, minimal sedation, or nitrous oxide using a standalone system for administration. However, if the facility's state or country has a Class A–equivalent designation that *specifically limits anesthesia to local or topical anesthesia only*, then the facility must follow the state or national requirement. In this case, the facility **may not** administer oral medications to achieve minimal sedation, even if accreditation standards would otherwise allow it.

Standard / Regulatory Reference:

This column contains the text for each standard. It also indicates the corresponding regulatory reference (e.g., CMS, DHA, Florida, etc.), if applicable.

Interpretive Guidance:

This column indicates the interpretive guidance (IG) that correlates with the standard.

INTERPRETIVE GUIDANCE (IG)

Interpretive Guidance (IG) is provided to support the understanding and application of QUAD A standards. IGs are **explanatory tools**, not requirements, and are **not used as scorable elements** during the accreditation process.

Purpose of Interpretive Guidance

Interpretive Guidance is intended to:

- **Clarify the intent** of a standard by explaining the underlying objectives related to patient safety and quality.
- **Offer examples** of acceptable methods, processes, or documentation that a facility *may* use to demonstrate compliance. These examples are illustrative and not mandatory.
- **Promote consistency** among surveyors by identifying common areas of review and evidence-gathering related to the standard.
- **Encourage continuous improvement** as facilities assess their policies and procedures in relation to the goals of the standard.

Use of IGs in the Accreditation Process

Interpretive Guidance supplements the standards but **does not function as an additional layer of requirements**. Accreditation decisions are based solely on a facility's compliance with the published QUAD A standards.

- IG examples are **not scoreable** and cannot be used as the basis for a citation.
- A facility may demonstrate compliance through methods other than those listed in an IG, as long as the approach meets the requirements of the standard.
- Conversely, mirroring an IG example does not guarantee compliance if the underlying standard is not effectively met or implemented.

Survey Application

During the on-site survey:

1. **The Standard Serves as the Benchmark**
Surveyors evaluate compliance directly against the language of the standard.
2. **The IG Informs the Review Process**
Surveyors use IGs to guide their inquiry, including selecting relevant questions and identifying appropriate sources of evidence.
Example: If a standard requires a "qualified circulator," the IG may suggest reviewing credentials or competency assessments. Evidence of qualifications may be demonstrated through personnel files, competency documentation, or other facility-established methods.
3. **Compliance Is Evidence-Based**
The surveyor determines compliance by assessing whether the evidence provided—regardless of format—meets the requirement described in the standard.

SCORING COMPLIANCE

The QUAD A accreditation program mandates 100% compliance with every standard to achieve and maintain accreditation, without exception. If a surveyor observes a single instance of non-compliance, the standard is scored as "Deficient." The facility must submit both a Plan of Correction, as well as documented Evidence of Corrections.

Applicable standard(s) will be given a score of deficient.

QUAD A withholds accreditation until the facility submits acceptable Plans of Correction and Evidence of Corrections for all cited deficiencies. However, when a standard refers to "*appropriate*," "*proper*," or "*adequate*", reasonable flexibility and room for consideration by the surveyor is permitted as long as patient and staff safety remain uncompromised.

ANESTHESIA CLASS REQUIREMENTS

If a facility is not in compliance with any item in this document, standard 1-A-1 will be scored as deficient.

All facilities must comply with the laws, regulations, and professional scope-of-practice requirements of their specific country or state regarding who may administer sedation and anesthesia. QUAD A acknowledges that not every licensed provider listed below will be applicable to all facilities. It is the facility's responsibility to understand and follow its jurisdiction's legal and regulatory requirements, as well as the scope-of-practice for each licensed provider working within the facility. When requirements differ, the more stringent requirement must be followed as long as it does not conflict with state or country law.

1. Class A (Facility must meet every Class "A" requirement):

All surgical and procedural cases are performed in the facility under local, topical anesthesia, minimal sedation, or nitrous oxide using a standalone system for administration.

NOTE: Endotracheal tubes and supraglottic airways are permitted in the facility for emergency use only.

Local or Topical Anesthesia may be administered by any of the following:

- Surgeon/Proceduralist
- Physician Anesthesiologist
- Dental Anesthesiologist
- Certified Registered Nurse Anesthetist (CRNA)
- Certified Anesthesiologist Assistant (CAA) under the supervision of an anesthesiologist
- Nurse Practitioner (NP)
- Physician Assistant (PA)
- Registered Nurse (RN) under the direct supervision of a credentialed physician as permitted by state law.

Nitrous Oxide may be administered using a Nitrous-Oxide Delivery System with required safety features by a credentialed:

- Surgeon/Proceduralist
- Physician Anesthesiologist
- Pediatric Dentist
- Dental Anesthesiologist
- Oral and Maxillofacial Surgeon (OMS)
- Certified Registered Nurse Anesthetist (CRNA)
- Certified Anesthesiologist Assistant (CAA)
- Dental Assistant under the supervision of a Pediatric Dentist or Dental Anesthesiologist in accordance with State law.

- Registered Nurse, Nurse Practitioner, or Physician Assistant under the direct supervision of a credentialed physician as permitted by state law.

Anxiolytics may be administered for mild sedation by any of the following:

- Surgeon/Proceduralist
- Physician Anesthesiologist
- Dental Anesthesiologist
- Certified Registered Nurse Anesthetist (CRNA)
- Certified Anesthesiologist Assistant (CAA) under the supervision of an anesthesiologist
- Nurse Practitioner (NP)
- Physician Assistant (PA)
- Registered Nurse (RN) with an electronic or written order by a credentialed provider.

Clarifications:

- All cases performed in a Class A facility must be performed using local anesthesia with minimal sedation only. A Class A facility is not permitted to perform any cases with moderate sedation.
- No more than 500cc of liposuction aspirate may be removed.
- A single dose of analgesic or minimal sedation (anxiolytic) drug may be administered preoperatively, which results in minimal sedation, and one (1) dose of the same medication may be administered postoperatively. Any additional doses or agents are considered Moderate Sedation, requiring the facility to be accredited under **facility Class B, C-M (international facilities only)**, or C standards. This includes doses taken by patients prior to arriving at the facility.
- The use of propofol, spinal anesthesia, epidural anesthesia, endotracheal intubation anesthesia, laryngeal mask airway anesthesia, and/or inhalation general anesthesia (excluding nitrous oxide) is prohibited.
- **The combination of Nitrous Oxide and any agent that results in minimal sedation is not permitted to be administered together in a Class A facility; they are only permitted in facility Class B, C-M (international facilities only), and C facilities.**
- If a facility performs procedures by administering oral **anxiolytics** (e.g., **diazepam**) **in conjunction with** performing **major peripheral or plexus** nerve blocks (**interscalene, supraclavicular, femoral**) **or advanced regional techniques** (e.g., **retrobulbar block, digital, Bier block.**), this practice **falls under the accreditation standard for facility Class B.** The use of field or nerve blocks is **not** permitted in facilities accredited under facility Class A accreditation standards. Digital blocks are permitted in Class A.
- **Exception: Simple local infiltration anesthesia, including digital nerve blocks, is permitted under the accreditation standard for facility Class A.**

2. Class B (Facility must meet every Class “A” and “B” requirement):

Surgical and procedural cases are performed in the facility under intravenous sedation, regional anesthesia, analgesia, or dissociative drugs (excluding Propofol), **that result** in moderate (**formerly referred to as** conscious sedation) and without the use of endotracheal intubation or laryngeal mask airway, or inhalation general anesthesia. The use of sublingual midazolam, ketamine HCl, and ondansetron (MKO) melt is permitted.

NOTE: Endotracheal tubes and supraglottic airways are permitted in the facility for emergency use only.

Intravenous Sedation may be administered by any of the following:

- Surgeon/proceduralist
- Physician Anesthesiologist
- Dental Anesthesiologist
- Certified Registered Nurse Anesthetist (CRNA)
- Certified Anesthesiologist Assistant (CAA)
- Registered Nurse, Nurse Practitioner, or Physician Assistant under the direct supervision of a qualified physician

Field and Peripheral Nerve Blocks may be administered by any of the following:

- Physician Anesthesiologist
- Oral and Maxillofacial Surgeon (OMS)
- Dental Anesthesiologist
- Pediatric Dentist
- Certified Registered Nurse Anesthetist (CRNA)
- Certified Anesthesiologist Assistant (CAA)

Oral or Intranasal Sedation may be administered by any of the following:

- Surgeon/Proceduralist
- Physician Anesthesiologist
- Dental Anesthesiologist
- Pediatric Dentist
- Oral Maxillofacial Surgeon (OMS)
- Certified Anesthesia Assistant (CAA)
- Certified Registered Nurse Anesthetist (CRNA)
- Registered Nurse, Nurse Practitioner (NP), or Physician Assistant (PA) under the direct supervision of a qualified physician

The use of propofol, spinal anesthesia, epidural anesthesia, endotracheal intubation anesthesia, laryngeal mask airway anesthesia, and/or inhalation general anesthesia (excluding nitrous oxide) is prohibited.

3. **Class C-M:** (A Facility must meet every Class “A” and “B” accreditation standard requirement): Class C-M is an accreditation pathway available only to international facilities.

Surgical and procedural cases are performed in the facility under moderate or deep sedation, **including the use of Propofol, Epidural, or Spinal anesthesia.**

The use of endotracheal intubation anesthesia, laryngeal mask airway anesthesia, and/or inhalation general anesthesia (excluding nitrous oxide) is prohibited.

Propofol may be administered by any of the following:

- Physician Anesthesiologist
- Certified Registered Nurse Anesthetist (CRNA)
- Certified Anesthesiologist Assistant (CAA)

Epidural Anesthesia may be administered by any of the following:

- Physician Anesthesiologist
- Certified Registered Nurse Anesthetist (CRNA)
- Certified Anesthesiologist Assistant (CAA)

Spinal Anesthesia may be administered by any of the following:

- Physician Anesthesiologist
- Certified Registered Nurse Anesthetist (CRNA)
- Certified Anesthesiologist Assistant (CAA)

Dissociative Drugs may be administered by any of the following:

- Physician Anesthesiologist
- Certified Anesthesia Assistant (CAA)
- Certified Registered Nurse Anesthetist (CRNA)
- Registered Nurse, Nurse Practitioner (NP), or Physician Assistant (PA) under the direct supervision of a qualified physician.

Clarification:

- The use of endotracheal intubation anesthesia, laryngeal mask airway anesthesia, and/or inhalation general anesthesia (excluding nitrous oxide) is prohibited.
4. **Class C:** (A Facility must meet every Class “A”, “B” “C-M” (international facilities only), and “C” requirement):

Surgical and procedural cases may be performed in the facility with intravenous propofol, spinal or epidural, and general anesthesia administered by any of the following:

- Physician Anesthesiologist
- Dental Anesthesiologist
- Certified Registered Nurse Anesthetist (CRNA)
- Certified Anesthesia Assistant (CAA)

Clarifications:

- Facilities using total intravenous anesthesia (TIVA) and have no inhalational anesthetics present in the facility would not be required to have an anesthesia machine. See standard 4-C-18.
- **For International Facilities:** Achieving Class C accreditation requires full compliance with all Class C standards, including those for general anesthesia with an anesthesia machine, in addition to all requirements for Classes A, B, and C-M.

Additional Guidance

Table 1. ASA Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia, 2019

	Minimal Sedation (Anxiolysis)	Moderate Sedation/Analgesia (Conscious Sedation)	Deep Sedation/Analgesia	General Anesthesia
Responsiveness	Normal response to verbal stimulation	Purposeful* response to verbal or tactile stimulation	Purposeful* response after repeated or painful stimulation	Unarousable, even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular function	Unaffected	Usually maintained	Usually maintained	May be impaired

Minimal Sedation (Anxiolysis) indicates a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected. Moderate Sedation/Analgesia (Conscious Sedation) indicates a drug-induced depression of consciousness during which patients respond purposefully* to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. Deep Sedation/Analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully* after repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. General Anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate Sedation/Analgesia (Conscious Sedation) should be able to rescue patients who enter a state of Deep Sedation/Analgesia, whereas those administering Deep Sedation/Analgesia should be able to rescue patients who enter a state of General Anesthesia. (Developed by the American Society of Anesthesiologists: Approved by ASA House of Delegates on October 13, 1999 and last amended on October 15, 2014. Available at: <http://www.asahq.org/quality-and-practice-management/practice-guidance-resource-documents/continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedation-analgesia>. Accessed on August 21, 2017.)

*Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

Patient Monitoring – Moderate and Deep Sedation

Many of the complications associated with moderate sedation and analgesia may be avoided if adverse drug responses are detected and treated in a timely manner (*i.e.*, before the development of cardiovascular decompensation or cerebral hypoxia). Patients given sedatives or analgesics in unmonitored settings may be at increased risk of these complications.

Patient monitoring includes strategies for the following: (1) monitoring patient level of consciousness assessed by the response of patients, including spoken responses to commands or other forms of bidirectional communication during procedures performed with moderate sedation/analgesia; (2) monitoring patient ventilation and oxygenation, including ventilatory function, by observation of qualitative clinical signs, end-tidal carbon monoxide, and pulse oximetry; (3) hemodynamic monitoring, including blood pressure, heart rate, and electrocardiography; (4) contemporaneous recording of monitored parameters; and (5) availability/presence of an individual responsible for patient monitoring. See standards in Section 8: Clinical Records, Sub-section H.

Summary Table for Anesthesia Options

ANESTHESIA OPTIONS	Class			
	A	B	C-M*	C
Local Anesthesia	X	X	X	X
Topical Anesthesia	X	X	X	X
Nitrous Oxide	X	X	X	X
Parenteral Sedation		X	X	X
Field and Peripheral Nerve Blocks		X	X	X
Dissociative Drugs (excluding Propofol)		X	X	X
Propofol			X	X
Epidural Anesthesia			X	X
Spinal Anesthesia			X	X
General Anesthesia – with or without endotracheal intubation anesthesia, or laryngeal mask airway (LMA) anesthesia				X

***Applicability Note:** Class C-M is an accreditation pathway available only to International Facilities

Nitrous Oxide

Only Nitrous Oxide-Oxygen Delivery Systems with the following safety features may be used in a QUAD A accredited facility:

- Alarms - Audio and/or visual alarms (e.g., low- or high-oxygen and nitrous oxide pressure alarms).
- Color Coding - Gas tanks, knobs, and hoses are coded by color (standardized nationally, but not necessarily internationally).
- Diameter index safety system - A standard for noninterchangeable, removable connections for use with medical gases helps ensure that the appropriate gas flows through the appropriate tubing and cannot be interchanged.
- Emergency air inlet - An inlet designed to remain closed as long as gases are being administered to the patient; however, when the oxygen fail-safe system turns the gases off, ambient air is allowed to enter the system so that the patient can continue to breathe through the nasal hood or face mask.
- Locks - According to national fire codes, nitrous oxide and other compressed gases must be kept in locked rooms; many manufacturers supply additional locks for the machines at the tanks, the manifold, or the mixer level to prevent staff members from accessing nitrous oxide inappropriately.
- Oxygen fail-safe system—The oxygen fail-safe system is designed so that the nitrous oxide supply will be turned off automatically when oxygen delivery is compromised or depleted. Delivery systems are required to provide a minimum oxygen liter flow that ensures 2.5 to 3.0 liters of oxygen per minute is the minimum amount being administered and that concentrations of oxygen never fall below 30% during gas delivery.
- Oxygen flush button—This mechanism allows 100% oxygen to be administered through a reservoir bag in the event of an emergency. When the button is pressed, the oxygen flush valve engages, and the system delivers oxygen straight from the pipeline or tank regulator at 45 to 50 psi at a flow rate between 35 and 75 L/min.
- Pin-index safety system—Pins protruding from the gas tank yokes have a unique configuration that fits into corresponding holes in the tank valves. This helps prevent the accidental attachment of a nonoxygen tank to the oxygen attachment portal.
- Quick connect for positive-pressure oxygen- In an emergency situation in which positive-pressure oxygen is required (e.g., to augment cardiopulmonary resuscitation), quick-connect compatibility helps ensure immediate access to positive-pressure oxygen anywhere in the office.
- Reservoir bag—An inflatable rubber reservoir bladder into which fresh gas entering the circuit is conveyed; the bag is filled gradually as gases enter the circuit and deflates with inhalation.

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SECTION 1: BASIC MANDATES

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
Sub-section A: Anesthesia Options					
1-A-1	A	B	C	<p>The facility practices within the Anesthesia Class for which it is accredited and in accordance with facility policies and procedures, industry standards, regulations, and laws governing the facility.</p>	<p>Verify the facility operates within its accredited anesthesia class (A, B, C-M (international only) or C). (See Anesthesia Class Definitions & Requirements)</p> <p>Evaluating Compliance: Review policies for required staff qualifications (surgeons, anesthesia providers, and RNs performing moderate sedation) Interview staff regarding the type of sedation and/or anesthesia administered (and by whom) Confirm the facility is operating within the correct anesthesia class; consult QUAD A if uncertain Review clinical records and surgical logs for elements relevant to anesthesia level/authorized staff Review personnel files to validate staff credentials and training Non-anesthesia staff (both physicians and RNs) delivering moderate sedation should have evidence of training and competency.</p>
1-A-2	A	B	C	<p>All care is provided by a credentialed healthcare provider as listed in the Anesthesia Class document and in accordance with facility policies, procedures, and state/provincial and federal law.</p>	<p>Please see the Anesthesia Class Definitions & Requirements document for Interpretive Guidance and References</p>
Sub-section B: Basic Mandates					
1-B-1	A	B	C	<p>The ambulatory surgery center (or other surgical facility) is in compliance with all state laws including state licensure requirements.</p> <p>§416.40 Condition</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
1-B-7	A	B	C	<p>Only recognized abbreviations are allowed to be used in the clinical record.</p>	<p>Verify the facility promotes patient safety by using only approved medical abbreviations for consistency in clinical records. The facility may adopt a recognized reference (e.g., MedicineNet, Taber's) or create its own approved list.</p> <p>Evaluating Compliance:</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					Review policies for the official list of approved abbreviations (external reference or internal policy) Confirm that abbreviations used in clinical records align with the approved list.
1-B-8	A	B	C	<p>The facility must perform a self-survey review of compliance with all QUAD A standards annually prior to the expiration date of its accreditation in each of the two years between QUAD A onsite surveys. The self-survey documentation must be retained for a minimum of 3 years and include:</p> <ol style="list-style-type: none"> 1. A completed Self-Survey checklist 2. A Plan of Correction for any standard identifies as non-compliant 3. Evidence that each plan of correction has been carried out to establish compliance with standards 4. Evidence that findings from the self-survey have been reviewed, included in the facility's Quality Improvement Plan, and discussed in the facility's Quality Improvement meetings. 	<p>Verify the facility performs annual self-surveys, documents non-compliance, and takes corrective actions to maintain compliance with QUAD A standards.</p> <p>Evaluating Compliance: Review documents for evidence that the most recent self-survey includes all required elements Confirm availability of self-surveys from the past three (3) years.</p>
Sub-section C: Patient Selection					
1-C-1	A	B	C	<p>A patient who, by reason of pre-existing or other medical conditions, is at significant risk for outpatient surgery in this facility must be referred to alternative facilities as defined in facility policy. Any surgery for which a patient must be routinely transferred to a hospital after the surgery is not appropriate for an outpatient surgical setting.</p>	<p>Verify the facility, refers high-risk patients to alternative facilities. ASA Class IV patients are allowed for vascular and ophthalmic procedures that are commonly performed in the outpatient setting.</p> <p>Evaluating Compliance: Review policies for:</p> <ul style="list-style-type: none"> Identified patient risk categories Any exemptions for high-risk patients having vascular/ophthalmic procedures common to outpatient setting Medical clearance requirements Patient acceptance/referral criteria for scheduling at the facility <p>Interview staff about scheduling protocols and incidence of routine hospital transfer Review clinical records for compliance with facility policy.</p>
1-C-2	A	B	C	<p>The facility must have a scheduling policy that includes only those procedures and/or a combination of procedures of duration and degree that permit safe recovery and discharge from the</p>	<p>Verify the facility maintains a scheduling policy consistent with applicable regulations. Some states and countries put time limits on outpatient surgery, but general recommendations are limits of up to six (6) hours for a general anesthesia case. The stricter requirement prevails. The total patient time in the facility must not exceed 23 hours 59 minutes, during which staffing minimums must be maintained and a physician must be immediately available.</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<p>facility consistent with federal/national, state/provincial, and local regulations, if applicable.</p>	<p>Evaluating Compliance: Review policies for: A list of approved procedures/combination of procedures allowed to permit safe recovery and discharge Surgical time limit and the methodology to determine length (e.g., open-close time, time in/time out, anesthesia time) Patient stay must not exceed 23 hours 59 minutes Physician availability until patient discharge References to any applicable federal, national, state, or local regulations and directives to comply Review clinical records for compliance with surgical time limits and incidence of routine hospital transfer.</p>
1-C-4	A	B	C	<p>If pediatric services are provided by the facility, there must be a written policy defining the unique perioperative care of pediatric patients. This is based upon considerations of age, BMI or weight, special needs, risk categories, surgery, facility equipment, and capability. The written policy for pediatric patients is available and current.</p>	<p>Verify the facility has a comprehensive pediatric care policy that defines parameters and individualized care considerations to address perioperative needs based on: Physical, psychosocial, developmental, safety, and other special needs Risk categories Procedure types Specialized equipment and medications Staff competency</p> <p>There is a recommendation against arbitrary age limits, as disability rights may accompany patients through young adulthood when appropriate. Parameters defining pediatric care should be in accordance with industry standards and those of the local jurisdiction having authority.</p> <p>Evaluating Compliance: Review policies for: Alignment with state/national law regarding chronological age (when applicable) Pediatric parameters Approved procedures Safety, emergency, and transfer protocols Interview staff regarding pediatric risk categories and emergency preparedness procedures Review personnel records for evidence of competency Confirm the presence of age-appropriate equipment, medications, and supplies.</p>
1-C-5		B	C	<p>No more than 5000 mLs of aspirate may be removed while performing liposuction in a Class B or C facility.</p> <p>Florida ASCs, see 1-C-14</p>	<p>Verify the facility restricts total liposuction aspirate to ≤ 5,000 mL to reduce the risk of fluid shifts.</p> <p>Evaluating Compliance: Interview staff regarding adherence to ≤ 5,000 mL volume limit and what occurs when the total has been exceeded Review clinical records:</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Include ≥ one (1) liposuction case to confirm compliance with aspirate limit Review any cases where exceeding 5,000 mL limit was reported as an adverse event.</p>
1-C-6	A			<p>No more than 500 mLs of aspirate should be removed when performing liposuction in Class A facilities. The more stringent requirement applies if State law differs.</p>	<p>Verify the Class A facility restricts total liposuction aspirate to ≤ 500 mL.</p> <p>Evaluating Compliance: Interview staff regarding any cases where ≤ 500 mL total aspirate has been exceeded. Review clinical records: Include ≥ one (1) liposuction case to confirm compliance with aspirate limit Review any cases where > 500 mL was reported as an adverse event.</p>
1-C-14		B	C	<p>No more than 5000 mL of aspirate may be removed while performing liposuction in a Class B or C facility.</p> <p>Note - This standard number is specific to Florida ASCs.</p>	<p>Verify the facility restricts total liposuction aspirate to ≤ 5,000 mL to reduce the risk of fluid shifts.</p> <p>Evaluating Compliance: Interview staff regarding adherence to ≤ 5,000 mL volume limit and what occurs when the total has been exceeded Review clinical records: Include ≥ one (1) liposuction case to confirm compliance with aspirate limit Review any cases where exceeding 5,000 mL limit was reported as an adverse event.</p>
Sub-section D: Patients' Rights					
1-D-1	A	B	C	<p>A copy of the most current QUAD A "Patients' Bill of Rights" is prominently displayed, or a copy is provided to each patient. The QUAD A "Patients' Bill of Rights" is also adhered to by facility personnel. If required, an additional Patients' Bill of Rights must be prominently displayed in accordance with prevailing laws and regulations.</p>	<p>Verify the facility informs patients of their rights in writing by posting the QUAD A Bill of Rights (and any other patient rights document adopted by the Governing Body). The document(s) must be either displayed in a public area or provided to the patient at registration.</p> <p>Evaluating Compliance: Confirm the Bill or Rights document(s) are publicly displayed or provided to the patient (or responsible adult) in writing upon admission.</p>
1-D-2	A	B	C	<p>The ASC must inform the patient or the patient's representative or surrogate of the patient's rights and must protect and promote the exercise of these rights, as set forth in this section. The ASC must also post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients waiting for treatment or by the patient's representative or surrogate, if applicable.</p> <p>§416.50 Condition</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
1-D-3	A	B	C	<p>An ASC must, prior to the start of the surgical procedure, provide the patient, the patient's representative, or the patient's surrogate with verbal and written notice of the patient's rights in a language and manner that ensures the patient, the representative, or the surrogate understand all of the patient's rights as set forth in this section.</p> <p>§416.50(a) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
1-D-4	A	B	C	<p>The ASC's notice of rights must include the address and telephone number of the State agency to which patients may report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman.</p> <p>§416.50(a) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
1-D-5	A	B	C	<p>The ASC must disclose, in accordance with Part 420 of this subchapter, and where applicable, provide a list of physicians who have financial interest or ownership in the ASC facility. Disclosure of information must be in writing.</p> <p>§416.50(b) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
1-D-6	A	B	C	<p>Submission and investigation of grievances. The ASC must establish a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC.</p> <p>§416.50(d) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
1-D-7	A	B	C	<p>The ASC's grievance procedure must ensure that all alleged violations/grievances relating, but not limited to, mistreatment, neglect, verbal, mental, sexual, or physical abuse, must be fully documented.</p> <p>§416.50(d)(1) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
1-D-8	A	B	C	<p>The ASC's grievance procedure must ensure that all allegations must be immediately reported to a person in authority in the ASC.</p> <p>§416.50(d)(2) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
1-D-9	A	B	C	<p>The ASC's grievance procedure must ensure that only substantiated allegations must be reported to the state authority or the local authority, or both.</p> <p>§416.50(d)(3) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
1-D-10	A	B	C	<p>The ASC's grievance procedure must ensure that the grievance process must specify timeframes for review of the grievance and the provisions of a response.</p> <p>§416.50(d)(4) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
1-D-11	A	B	C	<p>The ASC's grievance procedure must ensure that the ASC, in responding to the grievance, must investigate all grievances made by a patient, the patient's representative, or the patient's surrogate regarding treatment or care that is (or fails to be) furnished.</p> <p>§416.50(d)(5) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
1-D-12	A	B	C	<p>The ASC's grievance procedure must ensure that the ASC must document how the grievance was addressed, as well as provide the patient, the patient's representative, or the patient's surrogate with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the results of the grievance process, and the date the grievance process was completed.</p> <p>§416.50(d)(6) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
1-D-13	A	B	C	<p>The patient has the right to be free from any act of discrimination or reprisal.</p> <p>§416.50(e)(1) Standard §416.50(e)(1)(i) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
1-D-14	A	B	C	<p>The patient has the right to voice grievances regarding treatment or care that is (or fails to be) provided.</p> <p>§416.50(e)(1)(ii) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
1-D-15	A	B	C	<p>The patient has the right to be fully informed about a treatment or procedure and the expected outcome before it is performed.</p> <p>§416.50(e)(1)(iii) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
1-D-16	A	B	C	<p>If a patient is adjudged incompetent under applicable State laws by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed under State law to act on the patient's behalf.</p> <p>§416.50(e)(2) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
1-D-17	A	B	C	<p>If a state court has not adjudged a patient incompetent, any legal representative or surrogate designated by the patient in accordance with state law may exercise the patient's rights to the extent allowed by state law.</p> <p>§416.50(e)(3) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
1-D-18	A	B	C	<p>The patient has a right to personal privacy.</p> <p>§416.50(f) Standard §416.50(f)(1) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
1-D-19	A	B	C	<p>The patient has a right to receive care in a safe setting.</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				§416.50(f)(2) Standard	
1-D-20	A	B	C	<p>The patient has a right to be free from all forms of abuse or harassment.</p> <p>§416.50(f)(3) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
1-D-21	A	B	C	<p>Confidentiality of clinical records: The ASC must comply with the Department of Health and Human Services' rules for the privacy and security of individually identifiable health information, as specified at 45 CFR parts 160 and 164.</p> <p>§416.50(g) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
Sub-section E: QUAD A - Mandated Reporting					
1-E-1	A	B	C	<p>Changes in facility ownership must be reported to the QUAD A Central Office within thirty (30) days of the change.</p>	<p>Verify QUAD A records accurately reflect current facility ownership.</p> <p>Evaluating Compliance: Interview leadership regarding current ownership Review facility documents to confirm QUAD A records were updated if a change in ownership occurred. If there were no changes in ownership, mark as compliant.</p>
1-E-2	A	B	C	<p>Any change in provider staff must be reported to the QUAD A Central Office, in writing, within thirty (30) days of the change, along with the appropriate credentials.</p> <p>Surgical Programs (ASC, OBS, OBP, PD, OMS, I-DENT, I-SURG): Surgeons, Proceduralists, and Pain Management Providers must submit medical license, board certification or board eligibility, and delineation of facility privileges.</p> <p>RHC: Physicians, Advanced Practice Providers (NP, PA, CNM) and licensed behavior health providers (CP, CSW, MFT, MHC) must submit professional licenses.</p>	<p>Verify QUAD A records accurately reflect the licensed providers performing procedures, treatments, or furnishing patient care services in the facility.</p> <p>Evaluating Compliance: Review documents and credentialing/personnel files to confirm the list of licensed providers performing surgery, procedures (excluding those solely providing surgical anesthesia services), treatments, or furnishing patient care services. If changes have occurred, confirm timely reporting to QUAD A within 30 days.</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<p>Physical Therapy (OPT, I-PT): SLP, OT, PT, SLPA, OTA, PTA must submit professional licenses.</p> <p>Polyclinic: Physicians, Dentist, Advanced Practice Providers (NP, PA, CNM), Physiotherapist, and Physical Therapists must submit must professional licenses.</p>	
1-E-3	A	B	C	<p>Any action affecting the current professional license of any licensed facility staff must be reported in writing to the QUAD A office within ten (10) days of the time the facility becomes aware of such action.</p>	<p>Verify the facility reports to QUAD A any adverse licensure actions (e.g., suspension, probation, revocation, practice restrictions/limitations, etc.) of any professionally licensed staff working in the facility.</p> <p>Evaluating Compliance: Review credentialing files for active license status and documentation of adverse actions If present, confirm timely reporting to QUAD A within 30 days Interview staff regarding monitoring procedures and reporting protocols for adverse licensure actions.</p>
1-E-4	A	B	C	<p>Any death occurring in an accredited facility or any death occurring within thirty (30) days of a procedure performed in an accredited facility must be reported to the QUAD A office within five (5) business days after the facility is notified or otherwise becomes aware of that death. In addition to this notification, the death must be contemporaneously reported as an adverse event in the online Patient Safety Data Reporting portal. In the event of a death occurring within thirty (30) days of a procedure performed in an QUAD A-accredited facility, an unannounced survey may be performed.</p>	<p>Verify the facility reports to QUAD A all patient deaths (occurring on the day of the procedure or within thirty (30) days of the procedure) within five (5) days after being notified.</p> <p>Evaluating Compliance: Interview staff regarding any qualifying patient deaths occurring since the date of the last survey Review any qualifying patient deaths in the clinical record sample If applicable, verify timely reporting via the PSDR portal.</p>
Sub-section F: Patient Safety Data Reporting (PSDR)					
1-F-1	A	B	C	<p>Online Patient Safety Data Reporting is performed at least every three (3) months in accordance with the due dates established by QUAD A and includes submitting random cases and all adverse events to the QUAD A portal at www.QUAD A.org.</p>	<p>Verify the facility complies with PSDR reporting standards for random cases and adverse events and meets quarterly reporting deadlines.</p> <p>Evaluating Compliance: Review documents for submission to PSDR and inclusion in Governing Body minutes Interview Quality Coordinator about random case(s) submission, adverse event reporting and compliance with quarterly deadlines:</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					Q1 Jan 1-Mar 30 Apr 15 Q2 Apr 1-Jun 30 Jul 15 Q3 Jul 1-Sep 30 Oct 15 Q4 Oct 1-Dec 31 Jan 15.
1-F-2	A	B	C	For each surgeon/proceduralist operating in the facility, the random sample of case must include the first case performed by such surgeon/proceduralist each month during the reporting period. The facility must submit into the online Patient Safety Data Reporting portal a minimum of three (3) cases, or all cases performed by surgeons who have performed fewer than three (3) in the respective period, every three (3) months. If a surgeon/proceduralist performed fewer than three (3) cases, an exemption form must be submitted.	Verify the facility complies with the PSDR reporting standard (1-F-2) for random cases. <u>Evaluating Compliance:</u> Review documents and cross-reference the first monthly case (by each physician) from the procedure log to PSDR submissions (or exemptions) during the reporting period for the past twelve (12) months Confirm documentation of physician peer review exists for each random case selected Interview the Quality Coordinator re: the random case selection process.
1-F-3	A	B	C	The facility is up to date with accurate PSDR reporting. Reportable adverse events must be submitted to PSDR, including, but not limited to: <ul style="list-style-type: none"> • Any unplanned hospital admission; • Any emergency department visit; • Any unscheduled return to the operating room for a complication of a previous surgery; • Any complication such as infection, bleeding, wound dehiscence, or inadvertent injury to another body structure; • Any cardiac or respiratory problems during the patient's stay at the facility or within 48 hours of discharge; • Any allergic reactions; • Any pre- and post-procedure incorrect instrument, needle or sponge counts; • Any patient or family complaint; • Any equipment malfunction leading to injury or potential injury to the patient; • Any death occurring within 30 days of a procedure; 	Verify the facility complies with adverse event submissions into PSDR. <u>Evaluating Compliance:</u> Review policies for definitions of adverse events, internal investigation process, and inclusion of QUAD A mandated reporting requirements (Section 1: Sub-Sections E & F) Interview the Quality Coordinator about adverse event reporting, investigations, and timeframes Cross-reference any adverse events to evidence of PSDR submissions for the past twelve (12) months Confirm physician peer review exists for each adverse event, and such events appear in Quality program documents and Governing Body minutes.

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<ul style="list-style-type: none"> Any iatrogenic dental trauma 	
1-F-15		B	C	<p>Each adverse event submission must include:</p> <ul style="list-style-type: none"> The identification of the problem, The immediate treatment or disposition of the case, The outcome, The reason for the problem, and An assessment of the efficacy of treatment. 	<p>Confirm the facility complies with adverse event submissions.</p> <p><u>Evaluating Compliance:</u> Review facility documentation for evidence of adverse event reporting Cross-reference any adverse events to evidence of PSDR submissions for the past twelve (12) months.</p>

SECTION 2: FACILITY LAYOUT & ENVIRONMENT

Standard ID	Anesthesia Class	Standard / Regulatory Reference		Interpretive Guidance
Sub-section A: Layout				
2-A-2		B	C	<p>The Operating Suite includes the Operating Room, Prep/Scrub area, Clean and/or Dirty Room, and Post-Anesthesia Care Unit (PACU).</p> <p>Verify the facility maintains the distinct areas required within the Operating Suite.</p> <p>Evaluating Compliance: Interview staff to determine where major procedures may be performed Inspect the facility layout for all required components.</p>
2-A-3		B	C	<p>There is a separate and adequately sized Post-Anesthesia Care Unit (PACU) within the operating room suite.</p> <p>§416.44(a)(2) Standard</p> <p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
2-A-7		B	C	<p>All major surgery is done in the separate and distinct operating room(s).</p> <p>Verify that major surgeries are only performed in fully equipped operating rooms. Major surgery includes any of the following: Body cavity entry Mesenchymal barrier crossing Fascial plane opening Organ removal Anatomic alteration.</p> <p>Evaluating Compliance: Review clinical records & surgical log for procedure locations Interview staff about major surgery criteria and approved procedure locations Confirm the operating rooms are appropriately equipped.</p>
2-A-8		B	C	<p>Unauthorized individuals are deterred from entering the operating room suite either by locks, alarms, signage, or facility personnel.</p> <p>Verify the facility maintains strict access control to the Operating Suite.</p> <p>Evaluating Compliance: Review policies for access restrictions and staff credentialing requirements Interview staff about authorized personnel, monitoring systems, barriers, and security measures Observe for sign "Authorized Personnel Only" and/or security measures (locks, alarms) Confirm compliance with access protocols at Operating Suite entry points.</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
Sub-section B: Facility Environment					
2-B-1	A	B	C	<p>The facility must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.</p> <p>§416.44 Condition</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
2-B-2	A	B	C	<p>The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.</p> <p>§416.44(a) Standard §416.51(a) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
2-B-3	A	B	C	<p>The entire facility must be maintained, equipped, regularly cleaned, sanitary, and free of clutter and litter, consistent with a medical facility designed to perform procedures.</p>	<p>Verify the facility maintains cleanliness and implements organizational cleaning and disinfection protocols.</p> <p>Evaluating Compliance: Review policies for cleaning procedures, frequency, and approved disinfectants Interview staff regarding daily cleaning procedures Observe cleaning procedures Visually inspect the facility Confirm facility sanitation and maintenance.</p>
2-B-4	A	B	C	<p>The walls, cabinets, countertops, blinds and shades, and flooring are covered with smooth and easy-to-clean material that is free from tears, breaks, or cracks.</p> <p>If the floors contain seams or individual tiles, they are sealed with an impermeable sealant other than silicone.</p>	<p>Verify the facility is constructed with materials that allow for easy cleaning/disinfection, as recommended for high-hygiene environments, including:</p> <ul style="list-style-type: none"> Use of non-porous, cleanable surface materials Monolithic OR flooring (see FGI recommendations) Use of washable materials for curtains/blinds Carpet use only in non-clinical areas. <p>Evaluating Compliance: Review policies for cleaning protocols and maintenance of surfaces and furnishings Interview staff regarding cleaning techniques and requesting maintenance/replacement Observe facility surfaces and furnishings and confirm appropriate materials and intact finishes.</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
2-B-5		B	C	The operating room and scrub area ceiling surface or drop-in tiles are smooth, washable, and free of particulate matter that could contaminate the operating room and scrub area.	<p>Verify the facility minimizes the potential for contamination to the sterile field (or the operating room) originating from overhead surfaces.</p> <p>Evaluating Compliance: Interview staff regarding maintenance protocols regarding operating room ceilings Confirm the operating room ceilings do not have evidence of particulate matter, water staining, or gaps in between overhead tiles.</p>
2-B-6	A	B	C	All openings to outdoor air are effectively protected against the entrance of insects, animals, etc. The facility must have policies and procedures in place and implemented to address these issues.	<p>Verify the facility minimizes the potential for contamination to the environment from air pollutants and pests.</p> <p>Evaluating Compliance: Review policies for adoption of nationally recognized infection prevention and control guidelines, including specific procedures addressing air quality control and pest control Interview staff regarding measures taken to prevent contamination from outside air and pests Confirm the facility does not have gaps in door or window seals, issues with air quality and filtration, or evidence of pests.</p>
2-B-19	A	B	C	Smoking is prohibited in the entire facility.	<p>Verify smoking is not allowed within the facility.</p> <p>Evaluating Compliance: Review policies for the adoption of a smoking ban Review facility documents to ensure employee handbooks and patient materials reinforce "no smoking" Inspect the facility for posted "No Smoking/Vaping" signs at entrances and key areas Observe for compliance among patients, guests, and staff.</p>
Sub-section C: Operating Room Environment					
2-C-1		B	C	<p>Each operating room must be designed and equipped so that the types of operations conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.</p> <p>§416.44(a)(1) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
2-C-2		B	C	Each operating room is of a size adequate to allow for the presence of all equipment and personnel	Verify each operating room space is sufficient for safe staff/equipment movement and emergency patient transfers.

Standard ID	Anesthesia Class		Standard / Regulatory Reference	Interpretive Guidance
			<p>necessary for the performance of the operations, and must comply with applicable local, state/provincial or federal/national requirements.</p> <p>There must be ample clear space on each side of the procedure table to accommodate emergency personnel and equipment in case of emergency and permit the safe transfer of the patient to a gurney for transport.</p>	<p>Evaluating Compliance: Review policies for emergency maneuverability protocols Interview staff regarding knowledge of local space regulations (based on facility business occupancy classification), customized transport techniques for compact operating spaces, or in high-rise buildings Confirm unobstructed pathways and clearance for stretcher movement Request to observe a simulated emergency transfer when adequate space is questionable.</p>
2-C-3		B C	<p>Each operating room is ventilated, temperature and humidity controlled. The facility policy defines parameters based on patient population, procedure, and monitoring frequency in accordance with industry standards.</p>	<p>Verify the operating room environment is maintained, per the facility's policy and procedure, to reduce infection/fire risks and ensure staff/patient comfort.</p> <p>Evaluating Compliance: Review policies for the: Facility's adoption of recognized infection prevention and control guidelines (e.g., CDC, WHO, AORN) Acceptable operating room parameters aligned with the adopted infection prevention and control guidelines, including: Temperature range (e.g., 68-73°F or 20-23°C) Relative humidity range (e.g., 20-60%) Minimum air changes per hour (e.g., 10-12 per hour) Monitoring procedures and frequencies Interview staff regarding process for monitoring and response to out-of-range readings.</p>
2-C-4		B C	<p>The facility must have policies and procedures in place that address operating room cleaning, frequency and type of disinfectants used in accordance with industry standards.</p>	<p>Verify that the facility maintains operating room cleaning policies and enacts procedures that align with current infection prevention and control guidelines.</p> <p>Evaluating Compliance: Review policies for: Use of only EPA-approved disinfectants and the protocols for pre/post-procedure cleaning, terminal cleaning, and handling bio-hazardous spills Cleaning frequency Interview staff on cleaning procedures performed by staff and those that are outsourced Review cleaning logs and maintenance logs Inspect the operating room for surface cleanliness, absence of bioburden, and proper equipment storage Review personnel files for evidence of training and competency.</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
2-C-5		B	C	There is adequate storage space within the operating room to hold equipment, supplies, and medications. Unused equipment, supplies, and medications are stored in a manner to avoid contamination.	<p>Verify operating room contents are stored according to current infection prevention and control guidelines.</p> <p>Evaluating Compliance: Interview staff regarding the adequacy of supplies or medications stored within the operating room Inspect supplies and equipment stored in the operating room, ensuring: Consumables and sterilized instruments are stored in a manner to minimize exposure from surgical smoke, spray, or splatter Any dust cover protecting supplies or equipment is either disposable or may be disinfected in between cases.</p>
2-C-6		B	C	If a pre-existing sink is present in the operating room, a written policy to prohibit the use of the sink during sterile surgical procedures must be in place. A sink is permissible in an operating/procedure room which is exclusively used for endoscopic or urological procedures in accordance with the standards of those professions. Requests for allowance by other specialties will be reviewed on a case-by-case basis.	<p>Verify the facility prohibits use of a sink during sterile procedures (unless for approved endoscopic/urological cases) to align with current infection prevention and control guidelines.</p> <p>Evaluating Compliance: Review policies regarding sinks and water sources located within the operating room and its alignment with infection prevention and control and/or specialty guidelines Inspect operating room Interview staff regarding protocols for use of water sources in the operating room.</p>
Sub-section D: Post-Anesthesia Care Unit (PACU) Environment					
2-D-1		B	C	The PACU is maintained, clean and free of litter.	<p>Verify that the facility maintains a sanitary PACU environment in alignment with current infection prevention and control standards.</p> <p>Evaluating Compliance: Review policies regarding cleaning schedules, blood/body fluid spills, and biohazardous waste disposal Interview staff regarding cleaning schedules, use of sharps containers, and pest control measures Inspect the PACU for cleanliness, intact surfaces, visible dust/mold, or evidence of pests or vermin.</p>
Sub-section E: Storage					
2-E-1	A	B	C	Sterile supplies and equipment are stored away from potential contamination in closed cabinets/drawers; or if not, sterile supplies must be stored away from heavy traffic areas and potential contamination hazards.	<p>Verify the facility maintains the integrity of sterile supplies and equipment.</p> <p>Evaluating Compliance: Review policies for adoption of nationally recognized infection prevention and control guidelines Inspect sterile storage areas for evidence of:</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Designated, closed storage Elevation of at least 8" from floor Avoidance of high traffic areas Compliance with environmental standards for temperature and humidity Prohibiting corrugated cardboard in clean/sterile areas to minimize exposure to dust and pests Prohibiting sterile storage around water sources (only cleaning products in impermeable containers).</p>
2-E-2	A	B	C	<p>Storage space for sterile supplies and equipment is organized in a manner that maintains cleanliness, sterility, and functionality, provides easy access for identification and minimizes the risk of contamination and injury to patients and staff.</p>	<p>Verify that facility protocols minimize the risks of contamination and injury to patients and staff, ensuring that: Sterile supplies and equipment are stored in a clean, organized, and functional manner Items are easily accessible, protected from contamination Items are arranged to support efficient workflow and inventory management.</p> <p>Evaluating Compliance: Review policies for adoption of nationally recognized infection prevention and control guidelines and inclusion of NFPA 101 requirements. Inspect storage areas for evidence of: Designed, closed storage Cleanliness of storage areas Elevated at least 8" from floor Lowest shelf of wired shelving covered with a plastic cover 18" clearance between fire sprinkler deflectors and the top of storage Avoidance of storage in high traffic areas Compliance with environmental standards for temperature and humidity Prohibiting corrugated cardboard in clean/sterile areas to minimize exposure to dust and pests Prohibiting storage around water sources (only cleaning products in impermeable containers) Confirm operating rooms and corridors have clear pathways.</p>
2-E-3	A	B	C	<p>As applicable to the setting, outdated medical supplies, instruments, implants, and equipment are removed and destroyed in accordance with federal/national, state, provincial, and local regulations.</p>	<p>Verify the facility complies with the manufacturer's instructions for use (IFU) and expiration dates of supplies and devices to ensure safe use in patient care</p> <p>To maintain sterility or integrity, the facility must: Adhere to the manufacturer's designation for usage (e.g., single-use, reusable) Track the number of re-sterilizations (e.g., LMAs, implant sizers) when a limit is defined Maintain set storage requirements (e.g., temperature ranges)</p> <p>When an item does not come with cleaning and re-sterilization instructions, it must be considered a single-use item with a terminal expiration date. It should not be used after the printed manufacturer's expiration date, nor should it be re-sterilized after use. Re-processing "expired" supplies is not acceptable unless this process is documented in the manufacturer's IFU.</p>

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					<p><u>Evaluating Compliance:</u> Interview staff regarding: Process for determining the manufacturer's designation for use, any items designated for a limited number of re-sterilizations, and process for checking inventory for temperature ranges and expiration dates Review documents tracking the number of times items are re-sterilized (when limited by the IFU) Inspect storage areas and check for expired supplies, medications, or patient care devices Review facility policy.</p>

SECTION 3: SAFETY

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
Sub-section A: General Safety					
3-A-1	A	B	C	<p>QUAD A is committed to establishing minimum guidelines to provide safe and effective outpatient procedure care. The Facility must comply with all applicable Occupational Safety and Health Administration (OSHA), Centers for Disease Control and Prevention (CDC), National Fire Protection Association (NFPA), federal, state and local codes and regulations. The facility must comply with the applicable stricter regulation (whether it is the QUAD A Standard or local, state, or federal law).</p>	<p>Verify the facility maintains compliance with all applicable external regulations (OSHA, CDC, NFPA, and federal/state/local laws or equivalent international regulatory authority for fire safety and worker safety rights).The most stringent requirement always prevails.</p> <p>Evaluating Compliance: Review policies for references to current national guidelines and regulations Interview staff regarding which laws, codes, and standards apply to its operations (e.g., OSHA, CDC, NFPA, local fire marshal, health department, equivalent international authority) Confirm the posted OSHA 3165 (or approved alternative) includes worker rights and complaint procedures Observe staff actions to verify compliance with policies.</p>
Sub-section B: Facility Safety Manual					
3-B-1	A	B	C	<p>There is a Facility Safety Manual that is reviewed and updated annually and is in accordance with all other federal/national, provincial, state and local regulations. For international facilities, there must be evidence that specific national, provincial, and local regulations are included.</p>	<p>Verify that the facility maintains an up-to-date Safety Manual that addresses emergency procedures and the prevention of injuries and illnesses. The facility must ensure staff access to the manual's content.</p> <p>Evaluating Compliance: Review the safety manual for inclusion of: Emergency protocols Safety guidelines Annual review and documented revisions Interview staff regarding: Location of manual Key safety procedures.</p>
3-B-2	A	B	C	<p>The Facility Safety Manual contains all applicable requirements of OSHA, such as:</p> <ul style="list-style-type: none"> • Hazard Communications • Bloodborne Pathogens • Standard Precautions 	<p>Verify that the facility has a safety manual, or separate safety policies and procedures, in place with all applicable OSHA requirements to proactively prevent workplace accidents by providing facility staff with information on policies, procedures, hazards, and compliance with regulations.</p> <p>Evaluating Compliance: Review the safety manual or policies for inclusion of:</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<ul style="list-style-type: none"> • Ionizing Radiation (if x-ray is present at the facility) • Exit Routes • Electrical Standards • Emergency Action Plans in the event of office or other emergencies • Exposure Control Plan • Fire Safety • Medical and First Aid dependent upon workplace circumstances • Personal Protective Equipment (PPE) • Ergonomic Hazards • Workplace Violence • Slips, Trips, and Falls • Influenza • Tuberculosis • Emergency Response • Chemical Hazards • Other hazards such as Compressed Gas, Laser Hazards, Latex Allergy 	<p>OSHA-required elements TB control plan (if applicable) Documented exemptions (where justified) Annual review and updates as necessary</p> <p>Interview staff regarding: Training on facility safety protocols Location of manual Key safety procedures Hazard reporting</p>
Sub-section C: Hazardous Agents					
3-C-1	A	B	C	<p>All explosive and combustible materials and supplies are stored and handled in a safe manner with appropriate ventilation according to state, provincial, local, and national laws and regulations, and/or National Fire Protection Association (NFPA) codes, OSHA regulations, and safety data sheets (SDS).</p>	<p>Verify the facility handles explosive and combustible materials in a regulated manner to protect the safety of patients, visitors, staff, and the surrounding community.</p> <p>Evaluating Compliance: Review policies for alignment with NFPA codes, government regulations, and safety data sheets (SDS) or manufacturer's instructions for use (IFU) Interview staff regarding procedures for handling explosive and combustible materials Inspect areas where such items are stored and handled to ensure: Ventilation is adequate (to code), or an extraction device is used in accordance with SDS or IFU Combustible materials are stored at a minimum safe distance from ignition sources Medical gases are secured.</p>
3-C-3	A	B	C	<p>Compressed gas cylinders are stored and handled according to state, provincial, local and national laws and regulations, and/or National Fire Protection Association (NFPA) codes.</p>	<p>Verify the facility safely stores and handles compressed gas cylinders according to: NFPA and OSHA standards (as applicable) Safety Data Sheets (SDS) or the manufacturer's instructions for use (IFU) Government regulations (state/provincial/local/national) Industry standards.</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Evaluating Compliance: Review policies for alignment with NFPA standards/regulations and protocols, SDS, and IFUs for storage and ventilation Inspect areas where gas cylinders are stored and handled to ensure: Visible signage (e.g., hazards, no smoking) Proper material segregation (e.g., by gas, empty versus full) Cylinders are stored upright and secured Ventilation is adequate Stored at a minimum safe distance from ignition sources Applicable spatial requirements are met.</p>
3-C-5	A	B	C	<p>Hazardous chemicals are labeled as hazardous. Any hazardous material removed from the manufacturer's container and placed in a secondary container must be properly labeled.</p>	<p>Verify the facility ensures proper labeling per: NFPA 704 standards OSHA Hazard Communication Standard 1910.1200 (as applicable) International fire and worker safety standards</p> <p>This includes decanting hand soap or hand sanitizer from one container to another.</p> <p>Evaluating Compliance: Review the safety manual for: Hazard Communication Plan (updated annually) Hazardous chemical inventory (updated annually) Procedure for labeling hazardous chemicals that have been placed in a secondary container Interview staff regarding the procedure for labeling a secondary container, and locating SDS for a randomly chosen chemical Confirm secondary containers have appropriate labeling.</p>
Sub-section D: Medical Hazardous Waste					
3-D-1	A	B	C	<p>All medical hazardous wastes are disposed of in sealed, labeled containers and stored in compliance with federal/national, state, provincial, and local regulations and/or OSHA (Occupational Safety and Health Administration) acceptable containers and separated from general refuse for special collection and handling.</p>	<p>Verify the facility manages medical waste per federal/state or international regulations through: Proper containment (leak-proof biohazard bags/sharps containers) Secure transport/storage protocols Implementing a medical waste plan that addresses: Regular disposal to prevent accumulation Ventilated, pest-proof storage.</p> <p>Evaluating Compliance: Review policies to confirm the waste management plan includes: Containment standards (double-bagging if contaminated) Storage/transport requirements</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Interview staff regarding waste handling procedures</p> <p>Inspect waste disposal containers, procedures, and storage areas for</p> <ul style="list-style-type: none"> Proper bag/container use (no overfilling) Labeled, puncture-resistant sharps containers Ventilated storage areas.
3-D-4	A	B	C	<p>Used disposable sharp items are placed in secure puncture-resistant containers that are located as close to the use area as is practical.</p>	<p>Verify that the facility maintains safe sharps handling practices to prevent injuries and bloodborne pathogen exposure, in compliance with applicable occupational health, infection prevention, and product safety regulations — including U.S. standards (NIOSH, OSHA, FDA) or equivalent international or national standards (e.g., WHO, ISO, EU Directive 2010/32/EU). Requirements for sharps container design, functionality, and maintenance include:</p> <ul style="list-style-type: none"> Puncture-resistant, leak-proof, and FDA-cleared Secure closures to minimize exposure Proper labeling (biohazard/warning symbols) Mounted securely or on wheeled bases (if floor-standing) Positioned near point of use and within horizontal reach (52–56 inches height recommended) Away from obstructed areas (e.g., under sinks) Replaced at $\frac{3}{4}$ capacity If reusable, containers must be FDA-approved, marked for reuse, and effectively disinfected. <p>Evaluating Compliance:</p> <p>Review policies for alignment with OSHA 1910.1030 (Bloodborne Pathogens) and FDA standards or equivalent local/international regulation.</p> <p>Review documents to ensure any reusable containers meet FDA/DOT, or equivalent local/international regulation, reuse criteria</p> <p>Interview staff regarding one-handed sharps disposal and sharps container emptying practices</p> <p>Observe sharps containers in use to confirm:</p> <ul style="list-style-type: none"> Fill level $\leq \frac{3}{4}$ capacity without protruding sharps Proper mounting or stability Compliance with placement/accessibility guidelines.
Sub-section G: Personnel Safety					
3-G-1	A	B	C	<p>If an ethylene oxide gas sterilizer or automated endoscope reprocessor (AER) is used, appropriate personnel are badge-tested to ensure that there is no significant ethylene oxide or glutaraldehyde exposure.</p>	<p>Verify the facility takes steps to protect staff from harmful exposure to Ethylene Oxide and Glutaraldehyde</p> <p>Exposure Information:</p> <ul style="list-style-type: none"> Ethylene Oxide (EtO) – OSHA-regulated carcinogen (29 CFR 1910.1047) Glutaraldehyde – NIOSH REL 0.2 ppm (ACGIH TLV 0.05 ppm ceiling) <p>Note: International facilities should abide by equivalent national safety organization</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>recommendations.</p> <p>Evaluating Compliance: Review policies for procedures for EtO: Confirm adherence to 29 CFR 1910.1047 or equivalent international regulation Exposure monitoring (breathing zone samples) Employee notification (≤15 days) Exposure reduction Review policies for procedures for Glutaraldehyde: Confirm adherence to NIOSH REL (0.2 ppm) and ACGIH TLV (0.05 ppm ceiling) or equivalent international requirement Exposure reduction Review documents for monitoring results Interview staff regarding training and safeguards Observe for use of personal monitors in the workroom Review personnel records for evidence of staff training on safety procedures.</p>
3-G-2			C	<p>Personnel are properly trained in the control procedures and work practices that have been demonstrated to reduce occupational exposures to anesthetic gases.</p>	<p>Verify the facility implements four-tier controls and staff training to minimize anesthetic gas exposure, including: Engineering (e.g., scavenging systems) Work Practices (e.g., leak checks) Administrative (e.g., rotation schedules) PPE use when necessary (e.g., respirators).</p> <p>Evaluating Compliance: Interview staff regarding leak detection protocols and cases for PPE use Review training materials for inclusion of four-tier controls Inspect anesthesia workstations for scavenger systems Review personnel records for evidence of training (initial, annual).</p>
3-G-3	A	B	C	<p>There is a written policy for what is considered to be personal protective equipment for specific tasks in the facility (e.g., instrument cleaning, disposal of biological waste, surgery, radiology protection, exposure reduction, etc.).</p>	<p>Verify the facility maintains policies aligned with OSHA standards and implements task-specific PPE requirements.</p> <p>Evaluating Compliance: Review policies for PPE protocols addressing: High-risk tasks (e.g., anesthesia handling, chemical exposure) Minimum PPE standards (gloves, masks, eyewear, etc.) Interview staff regarding task-specific PPE use Observe adherence to PPE use and hazardous material handling during procedures and cleaning Review personnel records for evidence of training (initial, annual).</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
Sub-section H: Laboratory, Radiology Services, and Laser Safety					
3-H-1	A	B	C	Laboratory and Radiologic Services. §416.49 Condition	SOM Appendix L - Guidance for Surveyors: ASCs
3-H-2	A	B	C	If laboratory services are provided, these laboratory services must be provided in accordance with the Clinical Laboratory Improvement Act (CLIA) requirements at 42 CFR 493 operating under a current CLIA certificate appropriate to the level of services performed. §416.49(a)	SOM Appendix L - Guidance for Surveyors: ASCs
3-H-3	A	B	C	If x-ray equipment is used, safety measures are taken to protect patients and staff from injury. Warnings and signage exist to warn those whose health may be affected by x-rays.	Verify the facility minimizes risks from radiation exposure through the following: Proper PPE usage (lead aprons, thyroid shields) Using mobile shields/curtains Posting clear warning signage Following ALARA principles (As Low As Reasonably Achievable). Evaluating Compliance: Review policies for protocols for pregnant patients/staff and radiation exposure Review documents for reports determining staff radiation exposure Observe care to determine PPE use and shielding during imaging procedures Inspect PPE integrity and apron storage procedures (flat or on racks) Confirm warning signs in imaging areas.
3-H-4	A	B	C	If X-ray is used, staff maintain dosimetry badges and records, if applicable, for at least three (3) years.	Verify the facility implements personal radiation dosage monitoring, including: Personal dosimetry badges (not area monitoring) Badge usage is worn daily over lead aprons (at collar/chest level) Not sharing badges between staff Reviewing exposure reports quarterly (or per regulatory requirements). Evaluating Compliance: Review policies for directives for: Individual badge assignment Proper positioning of monitoring device (over lead) Quarterly reporting Review documents for evidence of exposure reports for the past three (3) years

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					Observe procedures with radiation exposure for evidence of badge placement Review personnel records for quarterly exposure reports and employee acknowledgement.
3-H-5	A	B	C	Radiologic services may only be provided when integral to procedures offered by the facility and must meet the requirements specified in 42 CFR 482.26(b), (c)(2), and (d)(2). §416.49(b)(1) Standard	SOM Appendix L - Guidance for Surveyors: ASCs
3-H-6	A	B	C	If radiologic services are utilized, the governing body must appoint an individual qualified in accordance with State law and facility policies who is responsible for assuring all radiologic services are provided in accordance with the requirements of 42 CFR 416.49. §416.49(b)(2) Standard	SOM Appendix L - Guidance for Surveyors: ASCs
3-H-8	A	B	C	If a laser is used, all manufacturer recommended safety precautions are actively in place prior to any usage. All safety measures are taken to protect patients and staff from injury, including appropriate eyewear, covered mirrors, covered windows, signage on the door, etc. in accordance with state/provincial laws and regulations.	Verify that the facility implements all manufacturer-recommended safety precautions when using lasers to protect patients, staff, and visitors from injury, in accordance with applicable state/federal or international (provincial/national) regulations. Evaluating Compliance: Review policies for: <ul style="list-style-type: none"> Compliance with ANSI Z136.3, or equivalent (e.g. ISO, IEC) standards Laser inventory with classification Inclusion of pre-procedure safety checks Designation of a Laser Safety Officer (LSO) who is qualified for all laser types Implementing procedure-specific safety protocols Review governing body appointment of LSO Interview staff regarding laser safety protocols Request IFU for a random piece of laser equipment, confirm staff access, and use is compliant with IFU Observe laser procedures for "Laser in Use" signage and PPE use (when possible) Review personnel records for evidence of initial/annual training.

SECTION 4: EQUIPMENT

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
Sub-section A: Facility Equipment					
4-A-1	A	B	C	<p>If a central source of piped oxygen is used, the system must meet all applicable local, state/provincial, and country safety codes.</p>	<p>Verify that medical gases are supplied, stored, and used in compliance with applicable national regulations and recognized standards, such as FDA/USP for the U.S., EMA/Ph. Eur. for Europe, or ISO standards internationally. Suppliers should be licensed or certified by the appropriate national or regional authority.</p> <p>Key Requirements:</p> <ul style="list-style-type: none"> Certified verifier for central systems Category-appropriate compliance Documented corrective actions for identified issues. <p><u>Evaluating Compliance:</u></p> <p>Review documents:</p> <ul style="list-style-type: none"> Certified verifier reports from qualified technician Corrective action logs Confirm testing frequency matches IFU <p>Inspect systems to spot-check actual vs prescribed oxygen delivery.</p>
4-A-2	A	B	C	<p>Medical equipment and supplies are available in the facility in appropriate sizes and quantities based on the patient population served.</p>	<p>Verify the facility maintains age-appropriate equipment/supplies for all patient populations served to ensure an adequate inventory to support safe patient care</p> <p><u>Evaluating Compliance:</u></p> <ul style="list-style-type: none"> Review policies for pediatric population definition (if relevant) Review documents for evidence of inventory checks of supplies and equipment maintenance Interview staff regarding process for checking inventory of supplies/equipment for use Inspect facility inventory to confirm adequate inventory and presence of medical equipment for relevant patient populations (i.e. pediatrics) and range of size-appropriate supplies)e.g., airway devices, BP cuffs).
Sub-section B: Operating Room Equipment					
4-B-2	A	B	C	<p>There is a properly functioning operating room table or chair.</p>	<p>Verify all OR tables and chairs function properly for safe patient positioning and are adequate to support intended procedures.</p> <p><u>Evaluating Compliance:</u></p> <ul style="list-style-type: none"> Review documents preventive maintenance records

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					<p>Interview staff regarding routine maintenance, malfunction reporting, and weight capacity awareness</p> <p>Observe tables and chairs to ensure:</p> <ul style="list-style-type: none"> Function of height/tilt mechanisms, locking features, and emergency release Integrity of the padding.
4-B-3		B	C	<p>The operating room is provided with functioning lighting in the ceiling based on the types of cases performed. Illumination for patients, machines, and monitoring equipment, and access to battery-powered illuminating systems are present.</p>	<p>Verify the facility maintains adequate primary lighting to critical areas of the operating room (e.g., surgical field, monitoring equipment, machine displays)</p> <p>Emergency backup systems must be present, using either:</p> <ul style="list-style-type: none"> Battery-powered units (with immediate activation) Generator backup (activates within 10 seconds). <p>Evaluating Compliance:</p> <p>Review documents:</p> <ul style="list-style-type: none"> Battery unit inspection logs (monthly) Generator maintenance records <p>Interview staff regarding emergency lighting protocols</p> <p>Inspect OR lighting intensity</p> <p>Confirm battery backup activation (power interruption simulation) or generator transition (≤10 second delay).</p>
4-B-5		B	C	<p>Sufficient electrical outlets are available, labeled and grounded to suit the location (e.g., wet locations) and connected to emergency power supplies where appropriate.</p>	<p>Verify the electrical systems in the operating room:</p> <ul style="list-style-type: none"> Provide adequate outlets for procedural equipment Meet wet location requirements (unless risk assessment exempts) <p>Evaluating Compliance:</p> <p>Interview staff regarding emergency power protocols</p> <p>Inspect operating rooms to verify:</p> <ul style="list-style-type: none"> GFCI in wet locations Outlets with emergency power supply are labeled Proper grounding Clear labeling/grounding Emergency power connections for critical devices <p>Confirm that each operating/procedure room has at least enough outlets to support all patient-care and procedural equipment without using extension cords. However, depending on the program type, essential electrical system, and if a Life Safety Code is required, as many as 36 receptacles may be required in each operating room</p> <p>Confirm emergency outlets function by simulating a power failure.</p>
4-B-6			C	<p>Sequential compression devices (SCD) are employed for operations lasting one (1) hour or</p>	<p>Verify the facility implements venous thromboembolism (VTE) prophylaxis for procedures lasting greater than 60 minutes.</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				longer, except for operations carried out solely under local or topical anesthesia.	<p>Evaluating Compliance: Review policies for: SCD use protocols Exemptions (e.g., pediatrics, lower extremity procedures) Interview staff regarding indications/contraindications of SCD use and application protocols Observe care provided in the facility for evidence of intraoperative SCD use Confirm SCD equipment is functional and single-use supplies are adequate Review clinical records (5 recent cases lasting >60 minutes) for documentation of SCD application (or contraindication for use).</p>
4-B-7		B	C	A source of cautery is present in the operating room. When unipolar electrocautery is used, a single-use/ disposable or reusable grounding pad is used.	<p>Verify the facility safely operates electrosurgical equipment per manufacturer's instructions for use (IFU)</p> <p>Evaluating Compliance: Review manufacturer's IFU and reprocessing logs for reusable grounding pad devices Interview staff regarding device-specific protocols and reprocessing steps for reusable devices Observe care provided in the facility for evidence of: Intraoperative use of grounding pads Correct pad placement (unipolar systems) High-temperature cautery pens (no grounding pad) Inspect supplies to confirm single-use devices are not reprocessed Review clinical records for documentation of grounding pad usage (when applicable).</p>
4-B-8			C	"Forced air warmers," blanket warmers, or other interventions are used to maintain the patient's temperature when the procedure lasts more than 60 minutes. The patient's temperature is monitored periodically to ensure normothermia.	<p>Verify the facility mitigates risk of perioperative hypothermia through active warming protocols and documents compliance during all phases of care. Critical warming recommendations by phases include:</p> <p>Pre-Operative Documents baseline temperature at admission Active warming preferred, may use warm blankets for cases under 60 minutes Intra-Operative Begins active warming before induction Maintain IV fluids/blood at 37°C and warm irrigation fluids to 38-40°C Document temperature regularly (at least hourly) Use core temperature monitoring when possible Post-Operative Monitor temperature every 15 minutes until normothermic (≥ 36°C) Do not discharge if temperature <36°C.</p> <p>Evaluating Compliance: Review policies for:</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Evidence of temperature thresholds Hypothermia prevention protocols Frequency of temperature monitoring Interview staff regarding hypothermia prevention protocols and active warming device safety Observe care provided in the facility for evidence of perioperative patient warming Inspect active warming equipment for integrity and verify use is according to manufacturer's IFU Confirm safe temperature ranges for fluids and blankets stored in warmers Review clinical records (5 recent cases) for temperature documentation in all phases of care.</p>
Sub-section C: Anesthesia Equipment					
4-C-1		B	C	The operating room is equipped with an EKG monitor with pulse read-out.	<p>Verify the facility can perform continuous circulatory monitoring during the delivery of all anesthetics</p> <p>Evaluating Compliance: Review documents for (at least) annual inspection of EKG equipment Confirm the presence of a functional EKG monitor in each operating room/procedure area Observe settings to ensure alarms are set and audible Inspect the cart to ensure EKG electrodes are not expired.</p>
4-C-2		B	C	The operating room is equipped with a pulse oximeter.	<p>Verify the facility can perform continuous pulse oximetry monitoring to detect hypoxemia during Class B, C-M (international only), and C anesthesia cases</p> <p>Evaluating Compliance: Review documents for (at least) annual inspection of all pulse oximeters Confirm the presence of a functional pulse oximeter in each operating room/procedure area Confirm sensor selection is available (adult/pediatric) Observe settings to ensure alarms are set and audible.</p>
4-C-3		B	C	The operating room is equipped with blood pressure monitoring equipment, including cuff sizes as appropriate for the patient population treated in the facility.	<p>Verify the facility can perform continuous blood pressure monitoring</p> <p>Equipment Standards: Operational BP monitor present A variety of BP cuff sizes are available for all patient populations served Annual performance verification per manufacturer specifications Alarm thresholds set appropriately, if applicable.</p> <p>Evaluating Compliance: Review documents for (at least) annual inspection of all blood pressure monitors</p>

Standard ID	Anesthesia Class		Standard / Regulatory Reference	Interpretive Guidance
				<p>Confirm the presence of a functional blood pressure monitor in each operating room/procedure area</p> <p>Inspect the cart to ensure an adequate supply and a variety of cuff sizes are available (adult/pediatric)</p> <p>Observe settings to ensure alarms are set and audible, if applicable.</p>
4-C-4	B	C	<p>The operating room is equipped with oral airways including sizes specific for each size of patient population treated in the facility.</p>	<p>Verify the facility maintains a comprehensive range of oral airway devices for all patient populations served</p> <p>Equipment Standards: Devices should be color-coded or clearly labeled for rapid size identification Packaging must remain intact until time of use.</p> <p>Evaluating Compliance: Inspect cart to ensure an adequate supply and variety of oral airway sizes are available in each operating room/procedure area Confirm pediatric sizes are stocked (if applicable).</p>
4-C-5	B	C	<p>The operating room is equipped with nasopharyngeal airways including sizes specific for each size of patient population treated in the facility.</p>	<p>Verify the facility maintains a comprehensive range of nasopharyngeal airway devices for all patient populations served</p> <p>Equipment Standards: Devices should be color-coded or clearly labeled for rapid size identification Packaging must remain intact until time of use.</p> <p>Evaluating Compliance: Inspect cart to ensure an adequate supply and variety of nasopharyngeal airway sizes are available in each operating room/procedure area Confirm pediatric sizes are stocked (if applicable).</p>
4-C-6	B	C	<p>The operating room is equipped with a functional and clean laryngoscope. Laryngoscope is cleaned as appropriate, HLD or sterilized. Permitted in Class B for emergency use only.</p>	<p>Verify the facility maintains functional laryngoscopes for all patient populations served</p> <p>Equipment Standards: Single-use laryngoscopes remain in packaging and are function-tested immediately before use Reusable laryngoscopes: Cleaned/sterilized per manufacturer's instructions for use (IFU) Sterilized blades remain in sterile packaging until function-testing immediately before use Disinfected handles are stored in a manner to protect against cross-contamination Laryngoscopes are function-tested immediately before use.</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Evaluating Compliance: Review reprocessing logs to ensure they are comprehensive Interview staff regarding cleaning procedures and inspection of items for package integrity Inspect cart for adequate supply, package integrity, and storage conditions in each operating room/procedure Verify laryngoscopes are identified as clean</p>
4-C-7		B	C	<p>The operating room is equipped with a comprehensive assortment of endotracheal tubes, stylets, and laryngeal mask airways including sizes and types for the patients being treated in the facility. Permitted in Class B for emergency use only.</p>	<p>Verify the facility maintains an adequate inventory and a complete range of advanced airway devices for all patient populations served. Advanced airway devices must be immediately available in all anesthetizing locations and have comprehensive records for any devices approved for re-sterilization (or for limited re-sterilization) consistent with the manufacturer's instructions for use (IFU)</p> <p>Evaluating Compliance: Review reprocessing logs to ensure they are comprehensive Interview staff regarding process for checking inventory, cleaning procedures, and difficult airway protocols Inspect cart for adequate supply and sizes, package integrity, and storage conditions in each operating room/procedure area Confirm availability of pediatric sizes (if applicable).</p>
4-C-9		B	C	<p>The operating room is equipped with a positive pressure ventilation device (e.g. Ambu® bag, bag valve mask), including sizes of masks to cover the range needed for the patient population treated in the facility.</p> <p>If self-inflating bags are used, they must be capable of delivering positive-pressure ventilation with at least 90% oxygenation concentration.</p>	<p>Verify the facility maintains and adequate supply of functional positive-pressure ventilation devices with capabilities to ensure adequate oxygenation ($\geq 90\%$ FiO₂ when needed) for all patient populations served.</p> <p>Evaluating Compliance: Review daily checklists to ensure these devices are available Interview staff regarding inspection of items for package integrity and emergency ventilation protocols Have staff demonstrate adequate tidal volume delivery of $\geq 90\%$ FiO₂ with flowmeter at 15 LPM Inspect device(s) for intact tubing/valves, device integrity, manufacturer's expiration date when applicable, and storage conditions.</p>
4-C-10		B	C	<p>The operating room is equipped with a source of oxygen and with appropriate delivery devices (e.g. nasal cannula, face mask) to provide adequate oxygen for the patient population treated and procedures performed in the facility.</p>	<p>Verify the facility maintains immediate oxygen sources (piped access or full E-cylinders with >500 psi) and appropriate delivery devices in operating room for all patient populations served</p> <p>Equipment Standards: Availability of nasal cannulas, non-rebreather masks, and (if needed) Venturi masks Single-use Packaging must remain intact until time of use.</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Evaluating Compliance: Review medical gas logs Interview staff regarding daily checklists and inspection of items for package integrity Inspect oxygen sources (primary, backup) to confirm flowmeter function, adequate inventory of delivery devices, package integrity, and storage conditions in each operating room/procedure area Confirm pediatric supplies (if applicable).</p>
4-C-11		B	C	The operating room is equipped with a source of adequate and reliable suction and suction equipment.	<p>Verify the facility maintains immediate, reliable access to suction (wall/portable) and adequate supplies in the operating room(s) for all patient populations served.</p> <p>Evaluating Compliance: Review preventive maintenance records Interview staff regarding daily checklists and emergency backup if the access is piped Inspect suction access for functionality/pressure gauge, adequate supply of tubing/catheter sets (Yankauer), package integrity, and storage conditions in each operating room/procedure area.</p>
4-C-12		B	C	The operating room is equipped with a reliable source of oxygen, adequate for the length of the procedures performed in the facility (backup must consist of at least one full E cylinder). Backup oxygen source must have a regulator and be ready to use. If oxygen cylinders are used as backup, they must be full.	<p>Verify the facility maintains an adequate supply of oxygen (piped access/full E-cylinder with regulator in place) in the operating room(s).</p> <p>Evaluating Compliance: Review medical gas logs Interview staff regarding daily checklists, inspection of pressure gauges, and emergency protocols for piped access failure Inspect oxygen sources (primary, backup) to confirm availability in each operating room/procedure area Confirm the E-cylinder has a regulator on and is showing the pressure gauge as full.</p>
4-C-13			C	If inhalation general anesthesia is used, the operating room is equipped with an inspired gas oxygen monitor on the anesthesia machine with an audible alarm to indicate a low oxygen concentration.	<p>Verify the anesthesia machine measures inspired oxygen concentration continuously and has audible alarms for hypoxic gas mixtures (< 21% O₂).</p> <p>Evaluating Compliance: Interview anesthesia staff regarding use of oxygen analyzer Request a demonstration of device functionality and response to hypoxia Confirm alarm threshold settings and audible/visual low-O₂ alarm.</p>
4-C-14		B	C	The operating room is equipped with an end tidal carbon dioxide monitor with an audible alarm to indicate values outside the normal range which is	Verify the facility monitors ventilation continuously for all patients under moderate/deep sedation and general anesthesia using capnography (ETCO ₂) in the operating room(s).

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				used on all moderate sedation, deep sedation, and general anesthesia cases.	<p>Evaluating Compliance: Interview staff regarding use of ETCO₂ monitoring during procedures Confirm an ETCO₂ monitor is present in each operating room/procedure area with: Waveform display Audible alarms (apnea/hypoventilation) Alarm responsiveness Confirm adequate supply of single-use tubing used in monitoring Review clinical records (recent cases undergoing moderate/deep sedation or general anesthesia) for documentation of ETCO₂ monitoring.</p>
4-C-15			C	When ventilation is controlled by a mechanical ventilator, there shall be in continuous use a device that is capable of detecting the disconnection of any of the breathing system's components. The device must give an audible signal when its alarm threshold is exceeded.	<p>Verify the facility maintains functional mechanical ventilators that monitor circuit integrity (disconnection detection) and alert clinicians via audible alarms for critical events.</p> <p>Evaluating Compliance: Interview staff regarding: Daily anesthesia equipment checks Apnea alarm responsiveness Request a demonstration of: Simulate circuit disconnection to ensure an alarm within 15 seconds Alarm silencing/reset procedure Confirm device alarm functionality for disconnect detection and audible and visual high/low pressure alerts in each operating room/procedure area.</p>
4-C-16	A	B	C	<p>If nitrous oxide alone is used, then a safe delivery system is used. A safe delivery system meets these criteria:</p> <ol style="list-style-type: none"> 1) Alarms 2) Gas scavenging 3) Color coding of tanks, knobs, and hoses 4) Diameter index safety system for non-interchangeable connection of gases - pin index safety system 5) Oxygen fail-safe system and oxygen flush capacity 6) Quick connection for positive-pressure oxygen delivery 7) Emergency air inlet 8) Reservoir bag 9) Storage in a secured area 	<p>Verify the facility maintains safe nitrous oxide delivery systems, including: Maintaining a minimum of 25% oxygen concentration at all times Incorporating fail-safes to prevent hypoxic gas delivery Alignment with Standard 3-A-1 and Nitrous Oxide Addendum requirements.</p> <p>Evaluating Compliance: Review policies for: Procedures for safe use of nitrous oxide delivery systems Monitoring records for nitrous oxide Review preventive maintenance logs and safety inspection records Interview staff on knowledge of safety protocols and response to alarms for hypoxic mixtures Inspect system in each operating room/procedure area the system is used for: Oxygen fail-safe valve (functional test) Proportioning system (25% O₂ minimum) Backup O₂ flush mechanism Confirm visual alerts/audible alarms for Hypoxic mixture (<25% O₂).</p>
4-C-17			C	An anesthesia machine with a purge system to extract exhaled gaseous air to out-of-doors or to a	Verify the facility prevents unintended exposure to harmful gases by using: Functional purge systems

Standard ID	Anesthesia Class		Standard / Regulatory Reference	Interpretive Guidance
			<p>neutralizing system is present. If inhalation anesthesia is used, a carbon dioxide-neutralizing system is required when using an anesthesia machine.</p> <p>An adequate and reliable waste anesthetic scavenging system exists if inhalation anesthetics are used.</p>	<p>CO₂-neutralizing systems (if applicable) Effective waste gas scavenging.</p> <p>Evaluating Compliance: Interview staff regarding daily safety checks, leak detection, and absorbent material replacement Inspect equipment in each operating room/procedure area for: Purge system: Proper exhaust routing No leaks (soap bubble test) Scavenging system: Active suction (≥25 LPM flow) Proper interface with machine CO₂ management (if used): Absorbent canister color change indicator Last change date documented.</p>
4-C-18		C	<p>An anesthesia machine is required if volatile agents are available in the facility. If total intravenous anesthesia (TIVA), spinal, or epidural anesthesia is used exclusively, and no volatile inhalation agents are available, an anesthesia machine is not required.</p>	<p>Verify the facility meets all facility Class C standards if volatile anesthesia agents are administered.</p> <p>Evaluating Compliance: Interview staff to determine: Availability or use of volatile agents within the facility (e.g., sevoflurane, isoflurane) Anesthesia machine maintenance protocols Confirm use of anesthesia machine in each operating room/procedure area when volatile agents (e.g., sevoflurane, isoflurane) are administered.</p>
Sub-section D: Post-Anesthesia Care Unit (PACU) Equipment				
4-D-1	B	C	<p>The PACU is equipped and readily accessible to handle emergencies</p>	<p>Verify the PACU is fully equipped to handle patient emergencies in the dedicated area for patient recovery after surgery or procedures.</p> <p>Evaluating Compliance: Review documents for evidence of: Checklists confirming readiness of emergency equipment and adequate supplies Preventive maintenance on emergency equipment Interview staff regarding emergency responses often seen in the post-anesthesia phase (e.g., airway, cardiac) Confirm access to an emergency cart (airway devices, supplies), defibrillator, oxygen source, and suction.</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
4-D-2	B	C		A separate pulse oximeter is available for each patient in the PACU.	<p>Verify the facility provides for continuous pulse oximetry for all patients in PACU, including: Maintaining adequate equipment for 1:1 patient monitoring Documenting compliance with oxygenation protocols.</p> <p>Evaluating Compliance: Review policies for protocols addressing equipment cleaning and hypoxia response Interview staff regarding alarm threshold and artifact resolution Request demonstration of alarm thresholds settings (typically SpO₂ <90%) Observe patient care in the PACU for evidence of: Audible pulses and alarms Adequate pulse oximetry equipment for patient population Confirm inventory of functional probes (adult/pediatric sizes) Review clinical records (≥ 5 recent cases) for evidence of pulse oximetry monitoring in the post-anesthesia phase.</p>
Sub-section E: Maintenance of Equipment					
4-E-1	A	B	C	<p>The facility has a preventive maintenance program to ensure that all essential mechanical, electric and patient-care equipment is maintained in safe operating condition and is replaced no less frequently than according to a schedule.</p> <p>A qualified technician annually inspects all equipment and reports in writing that the equipment is safe and operating according to the manufacturer's specifications. Stickers may be placed on individual equipment; however, written records must be maintained. All equipment is on a maintenance schedule, and records are kept for a minimum of at least three (3) years.</p>	<p>Verify the facility maintains all equipment per manufacturer specifications in the instructions for use (IFU)</p> <p>Evaluating Compliance: Review documents for: Inventory log with maintenance schedules Annual Bio-medical inspection reports by qualified technicians Critical equipment calibration (e.g., anesthesia machine, lasers) reports 3-year maintenance of logs and records Review ≥ 5 pieces of equipment for functionality and inspection dates Interview staff regarding protocols for reporting equipment malfunction and out-of-service storage Inspect quarantine area for faulty equipment Inspect equipment for dated inspection stickers or documented inspection.</p>
4-E-5	A	B	C	The manufacturer's specifications and requirements for all equipment are kept in an organized file and followed for each piece of equipment.	<p>Verify the facility retains manufacturer instructions for use (IFU) for all equipment and implements the specified maintenance and testing procedures.</p> <p>Evaluating Compliance: Interview staff regarding location and access to IFUs, process for incorporating new equipment Inspect ≥ 5 randomly selected pieces of equipment: Confirm inclusion in inventory log (by matching model numbers) Cross-check maintenance schedules and calibrations with the IFU.</p>

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4-E-7	A	B	C	<p>Central/Plumbed/Piped Anesthesia gas systems, including nitrous delivery systems, are checked by a qualified inspector annually, and written reports are available stating that the equipment is safe and operates according to the manufacturer's specifications.</p>	<p>Verify the facility maintains safe piped medical gas systems, including:</p> <ul style="list-style-type: none"> Certified inspections of piped gas systems by: <ul style="list-style-type: none"> Qualified personnel for verification - trained and certified in medical gas systems State-certified inspectors where required Category-level compliance for all central gas systems Retention of inspection reports. <p>Evaluating Compliance:</p> <p>Review policies for inclusion of annual inspections and corrective action timelines</p> <p>Review documents for evidence of:</p> <ul style="list-style-type: none"> Current certification in medical gas systems Cross-check inspection reports for category verification, leak checks, and pressure tests <p>Interview staff regarding emergency shutdown procedures and alert notifications.</p>
4-E-8	A	B	C	<p>Nitrous oxide/oxygen delivery safety system checks: Annual documented checks of ambient nitrous oxide levels should be less than 25 ppm according to NIOSH.</p> <p>The facility's policies and procedures document these system checks and address who is qualified to perform them, their frequency, the method of testing, and the action to be taken if the nitrous oxide levels are greater than 25 ppm in accordance with the manufacturer's instructions for use.</p> <p>Note: this standard applies only to standalone systems.</p>	<p>Verify the facility monitors for ambient nitrous oxide levels when using standalone nitrous oxide/oxygen delivery systems.</p> <p>Evaluating Compliance:</p> <p>Review policies for:</p> <ul style="list-style-type: none"> Alignment with NIOSH & manufacturer standards Directive for annual testing (method & frequency) by qualified personnel Corrective actions for levels \geq 25 ppm (per manufacturer) <p>Review documents to:</p> <ul style="list-style-type: none"> Confirm annual ambient checks show $<$ 25 ppm Or inspection and corrective actions if level was exceeded <p>Interview staff regarding testing performance and maintenance.</p>

SECTION 5: IN CASE OF EMERGENCY

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
Sub-section A: Emergency Equipment					
5-A-1	A	B	C	<p>Emergency cart is immediately available with a defibrillator or automated external defibrillator (AED), necessary drugs, and other CPR equipment (e.g. suction, pediatric defib pads) necessary for the patient population being served.</p>	<p>Verify the facility's emergency equipment is immediately available whenever patients are present. For procedural/surgical facilities, contract anesthesia providers must remain onsite with their emergency supplies until all patients are discharged. RHCs should perform risk assessments to determine needed equipment beyond the required automated external defibrillator.</p> <p>Evaluating Compliance: Review documents for evidence of: Emergency equipment checklists Anesthesia provider agreements (when applicable) Emergency equipment risk assessment (RHCs) Interview staff regarding: Emergency equipment location and use protocols Anesthesia staffing and services provided (if applicable) Inspect the emergency cart to ensure it is fully stocked with functional equipment, in-date supplies, and in-date medications required for resuscitation Confirm RHCs have the equipment, supplies, and medications identified from the risk assessment.</p>
5-A-3	A	B	C	<p>The standard defibrillator, or an Automated External Defibrillator (AED), is checked at least weekly for operability in accordance with the manufacturer's instructions for use, and the test results are documented and kept for a minimum of three (3) years.</p>	<p>Verify the facility maintains a functional defibrillator/AED for emergency use.</p> <p>Evaluating Compliance: Review policies for directives that emergency equipment is checked/replaced according to the manufacturer's instructions for use (typically every 2-4 years for batteries, every 2 years for pads) Review documents for evidence of: Battery/defibrillator pads reviewed in emergency equipment checklists Weekly defibrillator checks (maintained for 3 years) Interview staff regarding defibrillator testing protocols and procedures for use Inspect defibrillator to confirm functionality and pad integrity Confirm no expired supplies are present.</p>
5-A-4		B	C	<p>The facility medical staff, anesthesia professionals, other clinical staff, and the governing body of the facility coordinates, develops, and revises facility</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>

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				<p>policies and procedures to specify the types of emergency equipment required for use in the facility's operating room.</p> <p>§416.44(d) Standard</p>	
5-A-5	A	B	C	<p>The emergency equipment must be immediately available for the use of emergency situations.</p> <p>§416.44(d)(1) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
5-A-6	A	B	C	<p>The emergency equipment must be appropriate for the facility's patient population.</p> <p>§416.44(d)(2) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
5-A-7	A	B	C	<p>The emergency equipment must be maintained by appropriate personnel.</p> <p>§416.44(d)(3) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
Sub-section C: Emergency Protocols					
5-C-1	A	B	C	<p>There must be a written protocol for emergency evacuation of the facility. The protocol must include provisions for annual drills for the emergency evacuation of patients, staff, and guests; staff training upon hire and annually. Documentation of all drills must be retained in the facility for a minimum of three (3) years.</p>	<p>Verify the facility maintains comprehensive emergency preparedness, including:</p> <ul style="list-style-type: none"> Annual review/updates of emergency evacuation protocols Facility holds an emergency evacuation drill annually (date/time, details, attendees, after-action report) Staff training (initial, annually, after protocol changes) Record retention of three (3) years <p>Drill content should vary in terms of time, location, and scenario. Drills and training are separate components. Not all staff are expected to participate in the scheduled drill, as staff may not be scheduled to work that day.</p> <p>Evaluating Compliance:</p> <p>Review policies for:</p> <ul style="list-style-type: none"> Evacuation procedures Roles/responsibilities Evidence of annual review <p>Review drill documentation for required components, frequency not >365 days, retention for three (3) years</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Interview staff regarding emergency procedures and individual responsibilities Review personnel records for evidence of training (initial, annually, updates) Deficiency citations for training gaps should be documented under standard 11-I-4.</p>
5-C-2	A	B	C	<p>A written protocol for security emergencies, such as an intruder in the facility, an unruly patient or visitor, or a threat to the staff or patients, must be documented and reviewed annually. The protocol must include provisions for annual drills for security emergencies, staff training upon hire and annually, drill documentation, and, retention of documentation for a minimum of three (3) years.</p>	<p>Verify the facility maintains comprehensive emergency preparedness, including: Annual review of security emergency protocols addressing: Intruders, unruly persons, bomb threats, and other threats to staff or patients Annual drills (documenting date/time, scenario, attendees, and after-action report) Staff training (at hire, annually, after protocol changes) Record retention (3 years)</p> <p>Drill content should vary in terms of time, location, and scenario. Drills and training are separate components. Not all staff are expected to participate in the scheduled drill, as staff may not be scheduled to work that day.</p> <p>Evaluating Compliance: Review policies for: Security emergency procedures Roles/responsibilities Evidence of annual review Review documentation for required components, frequency not >365 days, retention for three (3) years Interview staff regarding security emergency procedures and individual responsibilities Review personnel records for evidence of training (initial, annual, updates) Deficiency citations for training gaps should be documented under standard 11-I-4.</p>
5-C-4	A	B	C	<p>There must be a written protocol for returning patients to the operating room or transfer to the hospital in the event of patient emergencies.</p>	<p>Verify the facility maintains a comprehensive policy for unplanned returns to the OR, including: Annual review of policy Defining the notification chain (family, anesthesia, charge RN, emergency contacts) Maintenance of NPO status Consent acquisition process Documentation standards Staff training (initial, annual, with updates) QUAD A reporting requirements (via PSDR portal).</p> <p>Evaluating Compliance: Review policies for inclusion of required elements, QUAD A reporting, and evidence of annual review Interview staff regarding notification procedures, maintaining NPO status, attaining consent, documentation requirements, and QUAD A reporting Review personnel records for evidence of training (initial, annual, with updates) Deficiency citations for training gaps should be documented under standard 11-I-4.</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
5-C-7	A	B	C	<p>There must be a written protocol for a situation in which the surgeon/proceduralist, anesthesia professional, or other healthcare professional is impaired or becomes incapacitated.</p>	<p>Verify the facility maintains a comprehensive policy for addressing impaired/incapacitated healthcare professionals, including: Annual review of policy Clear steps for: Identification of impairment/incapacitation Immediate response actions Reporting procedures Patient safety measures Staff training (initial, annual, with updates).</p> <p>Evaluating Compliance: Review policies for inclusion of required elements and evidence of annual review Interview staff regarding recognition of impairment, immediate response, and chain of command reporting Review personnel records for evidence of training (initial, annual, with updates).</p>
Sub-section D: Emergency Preparedness Plan					
5-D-1	A	B	C	<p>The facility must comply with all applicable Federal, State, and local emergency preparedness requirements. The facility must establish and maintain an emergency preparedness program that meets the requirements of this section.</p> <p>§416.54 Condition</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>
5-D-2	A	B	C	<p>Emergency plan: The facility must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every two (2) years.</p> <p>§416.54(a) Standard</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>
5-D-3	A	B	C	<p>The plan must be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.</p> <p>§416.54(a)(1) Standard</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>
5-D-4	A	B	C	<p>The plan must include strategies for addressing emergency events identified by the risk assessment.</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				§416.54(a)(2) Standard	
5-D-5	A	B	C	<p>The plan must address patient population, including, but not limited to, the type of services the facility has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.</p> <p>§416.54(a)(3) Standard</p>	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-7	A	B	C	<p>The plan must include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.</p> <p>§416.54(a)(4) Standard</p>	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-9	A	B	C	<p>Policies and procedures: The facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in standard 5-D-2, risk assessment in standard 5-D-3, and the communication plan in standard 5-D-21. The policies and procedures must be reviewed and updated at least every two (2) years.</p> <p>§416.54(b) Standard</p>	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-10	A	B	C	<p>At a minimum, the policies and procedures must address a system to track the location of on-duty staff and sheltered patients in the ASCs care during an emergency. If on-duty staff or sheltered patients are relocated during the emergency, the ASC must document the specific name and location of the receiving facility or other location.</p> <p>§416.54(b)(1) Standard</p>	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-11	A	B	C	<p>At a minimum, the policies and procedures must address safe evacuation from the facility.</p>	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness

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				§416.54(b)(2) Standard	
5-D-12	A	B	C	Safe evacuation from the facility must include consideration of the care and treatment needs of evacuees. §416.54(b)(2) Standard §416.54(b)(2)(i) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-13	A	B	C	Safe evacuation from the facility must include staff responsibilities. §416.54(b)(2) Standard §416.54(b)(2)(ii) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-14	A	B	C	Safe evacuation from the facility must include transportation. §416.54(b)(2)(iii) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-15	A	B	C	Safe evacuation from the facility must include identification of evacuation locations, such as appropriate placement of exit signs. §416.54(b)(2)(iv) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-16	A	B	C	Safe evacuation from the facility must include primary and alternate means of communication with external sources of assistance. §416.54(b)(2)(v) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-17	A	B	C	At a minimum, the policies and procedures must address a means to shelter in place for patients, staff, and volunteers who remain in the facility. §416.54(b)(3) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-18	A	B	C	At a minimum, the policies and procedures must address a system of medical documentation that	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<p>preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.</p> <p>§416.54(b)(4)(i) Standard §416.54(b)(4)(ii) Standard §416.54(b)(4)(iii) Standard</p>	
5-D-19	A	B	C	<p>At a minimum, the policies and procedures must address the use of volunteers in an emergency and other staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.</p> <p>§416.54(b)(5) Standard</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>
5-D-20	A	B	C	<p>At a minimum, the policies and procedures must address the role of the facility under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.</p> <p>§416.54(b)(6) Standard</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>
5-D-21	A	B	C	<p>Communication plan: The facility must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every two (2) years.</p> <p>§416.54(c) Standard</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>
5-D-22	A	B	C	<p>The communication plan must include names and contact information for Staff, Entities providing services under arrangement, Patients' physicians, Volunteers, and other facilities within the same Medicare type.</p> <p>§416.54(c)(1) Standard</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>

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				§416.54(c)(1)(i) Standard §416.54(c)(1)(ii) Standard §416.54(c)(1)(iii) Standard §416.54(c)(1)(iv) Standard	
5-D-23	A	B	C	The communication plan must include contact information for Federal, state, tribal, regional, and local emergency preparedness staff and Other sources of assistance. §416.54(c)(2) Standard §416.54(c)(2)(i) Standard §416.54(c)(2)(ii) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-24	A	B	C	The communication plan must include primary and alternate means for communicating with facility staff and Federal, State, tribal, regional, and local emergency management agencies. §416.54(c)(3) Standard §416.54(c)(3)(i) Standard §416.54(c)(3)(ii) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-25	A	B	C	The communication plan must include a method for sharing information and medical documentation for patients under the facility's care, as necessary, with other health care providers to maintain the continuity of care. §416.54(c)(4) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-26	A	B	C	The communication plan must include a means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii). §416.54(c)(5) Standard	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness
5-D-27	A	B	C	The communication plan must include a means of providing information about the general condition and	SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<p>location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).</p> <p>§416.54(c)(6) Standard</p>	
5-D-28	A	B	C	<p>The communication plan must include a means of providing information about the facility's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.</p> <p>§416.54(c)(7) Standard</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>
5-D-29	A	B	C	<p>Training and testing: The facility must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in standard 5-D-2, risk assessment in standard 5-D-3, policies and procedures in standard 5-D-9, and the communication plan in standard 5-D-21. The training and testing program must be reviewed and updated at least every two (2) years.</p> <p>§416.54(d) Standard</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>
5-D-30	A	B	C	<p>The training program must consist of initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected roles.</p> <p>§416.54(d)(1)(i) Standard</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>
5-D-31	A	B	C	<p>The training program must provide emergency preparedness training at least every two (2) years.</p> <p>§416.54(d)(1)(ii) Standard</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>
5-D-32	A	B	C	<p>The training program must maintain documentation of all emergency preparedness training.</p> <p>§416.54(d)(1)(iii) Standard</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
5-D-33	A	B	C	<p>The training program must demonstrate staff knowledge of emergency procedures.</p> <p>§416.54(d)(1)(iv) Standard</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>
5-D-34	A	B	C	<p>If the emergency preparedness policies and procedures are significantly updated, the facility must conduct training on the updated policies and procedures.</p> <p>§416.54(d)(1)(v) Standard</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>
5-D-35	A	B	C	<p>The facility must conduct exercises to test the emergency plan at least annually.</p> <p>§416.54(d)(2) Standard</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>
5-D-36	A	B	C	<p>The facility must participate in a full-scale exercise that is community-based every two (2) years; or When a community-based exercise is not accessible, conduct a facility-based functional exercise every two (2) years; or</p> <p>If the facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the facility is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the emergency event.</p> <p>§416.54(d)(2)(i) Standard §416.54(d)(2)(i)(A) Standard §416.54(d)(2)(i)(B) Standard</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>
5-D-37	A	B	C	<p>The facility must conduct an additional exercise at least every two (2) years, opposite the year the full-scale or functional exercise as required by standard 5-D-36 is conducted, that may include, but is not limited to the following:</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<p>A. A second full-scale exercise that is community-based, or an individual, facility-based functional exercise; or</p> <p>B. A mock disaster drill; or</p> <p>C. A tabletop exercise or workshop that is led by a facilitator and includes a group discussion using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.</p> <p>§416.54(d)(2)(ii) Standard §416.54(d)(2)(ii)(A) Standard §416.54(d)(2)(ii)(B) Standard §416.54(d)(2)(ii)(C) Standard</p>	
5-D-38	A	B	C	<p>The facility must analyze the facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the facility's emergency plan, as needed.</p> <p>§416.54(d)(2)(iii) Standard</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>
Sub-section E: Emergency Preparedness Plan - Integrated Healthcare Systems					
5-E-1	A	B	C	<p>If a facility is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the facility may choose to participate in the healthcare system's coordinated emergency preparedness program.</p> <p>§416.54(e) Standard</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>
5-E-2	A	B	C	<p>If elected, the unified and integrated emergency preparedness program must demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.</p> <p>§416.54(e)(1) Standard</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
5-E-3	A	B	C	<p>If elected, the unified and integrated emergency preparedness program must be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.</p> <p>§416.54(e)(2) Standard</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>
5-E-4	A	B	C	<p>If elected, the unified and integrated emergency preparedness program must demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.</p> <p>§416.54(e)(3) Standard</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>
5-E-5	A	B	C	<p>If elected, the unified and integrated emergency preparedness program must include a unified and integrated emergency plan that meets the requirements of standards 5-D-4, 5-D-5, and 5-D-7.</p> <p>§416.54(e)(4) Standard</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>
5-E-7	A	B	C	<p>If elected, the unified and integrated emergency plan must also be based on and include a documented community-based risk assessment, utilizing an all-hazards approach.</p> <p>§416.54(e)(4)(i) Standard</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>
5-E-8	A	B	C	<p>If elected, the unified and integrated emergency plan must also be based on and include a documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.</p> <p>§416.54(e)(4)(ii) Standard</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>
5-E-9	A	B	C	<p>If elected, the unified and integrated emergency preparedness program must include integrated policies and procedures that meet the requirements</p>	<p>SOM Appendix Z - Guidance for Surveyors: Emergency Preparedness</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<p>set forth in 5-D-9, a coordinated communication plan, and training and testing programs that meet the requirements in standards 5-D-21 and 5-D-29, respectively.</p> <p>§416.54(e)(5) Standard</p>	

SECTION 6: MEDICATIONS

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
Sub-section A: Medications					
6-A-1	A	B	C	<p>The facility must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice and under the direction of an individual designated responsible for pharmaceutical services.</p> <p>§416.48 Condition</p>	SOM Appendix L - Guidance for Surveyors: ASCs
6-A-2	A	B	C	<p>Drugs must be prepared and administered according to established policies and acceptable standards of practice.</p> <p>§416.48(a) Standard</p>	SOM Appendix L - Guidance for Surveyors: ASCs
6-A-3	A	B	C	<p>Orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician.</p> <p>§416.48(a)(3) Standard</p>	SOM Appendix L - Guidance for Surveyors: ASCs
6-A-4	A	B	C	<p>If there is an adverse reaction, it must be immediately reported to the physician responsible for the patient and must be documented in the patient's record.</p> <p>§416.48(a)(1) Standard</p>	SOM Appendix L - Guidance for Surveyors: ASCs
6-A-5	A	B	C	<p>Outdated medications are removed and destroyed in accordance with federal/national, state, provincial, and local pharmacy regulations.</p>	<p>Verify the facility's medications are safe and effective, through proper expiration date management and storage compliance</p> <p>Evaluating Compliance: Review policies for: Directive to comply with manufacturer's recommendations Procedures to monitor for expirations and storage conditions Expired medication disposal process Review temperature logs for medication stored in refrigerators and freezers</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Interview staff regarding:</p> <ul style="list-style-type: none"> Checking expiration dates (how often) Monitoring storage conditions Disposal process <p>Inspect medication storage areas (e.g., cabinets, carts, refrigerators) for:</p> <ul style="list-style-type: none"> Expiration dates (and cross-check with FDA extended use database, or equivalent national food and drug regulatory agency, when applicable) Temperature and storage condition compliance per manufacturer's validated storage conditions.
6-A-6	A	B	C	<p>Medications are stored in a secured area away from patient and visitor access.</p>	<p>Verify the facility's medications are secured, whilst maintaining emergency readiness</p> <p>Evaluating Compliance:</p> <ul style="list-style-type: none"> Review policies for measures to maintain medication security and emergency drug access Interview staff regarding storage protocols and accessing emergency drugs Observe patient care to determine anesthesia medication security Verify controlled substances storage in substantial cabinets (per DEA 1301.75 or other relevant national drug enforcement agency) with restricted access Inspect medication storage areas for security breaches.
Sub-section B: Intravenous Fluids					
6-B-1	A	B	C	<p>Intravenous fluids such as Lactated Ringer's solution and/or normal saline are available in the facility, including intravenous (IV) administration sets, and various sizes of IV needles based on the patient population served.</p>	<p>Verify the immediate availability of IV fluids and administration sets for all patient populations served</p> <p>Evaluating Compliance:</p> <ul style="list-style-type: none"> Interview staff regarding procedures for warming IV fluids Inspect storage of IV fluids/supplies to ensure the facility stocks an adequate inventory Confirm immediate access to IV fluids in emergency carts.
Sub-section C: Blood and Blood Substitutes					
6-C-1	A	B	C	<p>If blood is administered in the facility, a protocol is present that addresses: typing; cross- matching; checking; verification; who may administer blood; and patient monitoring requirements.</p>	<p>Verify the facility maintains stringent protocols to minimize the risks of infections, transfusion reactions, and circulatory overload associated with blood transfusions</p> <p>Evaluating Compliance:</p> <ul style="list-style-type: none"> Review policies for inclusion of required elements Interview staff regarding pre-infusion checks, monitoring, and emergency responses Observe transfusion (if one occurs during the survey) to confirm compliance with the verification process and transfusion monitoring Review personnel records for training/competency

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					Review clinical records for: Results from type/screen and cross-matching Evidence of two-person verification Baseline VS, first 15-minute direct observation, then strict transfusion monitoring Adverse reaction management.
6-C-2	A	B	C	Intravenous blood and blood products must be administered only by physicians, anesthesia professionals, or registered nurses. §416.48(a)(2) Standard	SOM Appendix L - Guidance for Surveyors: ASCs
Sub-section D: Controlled Substances					
6-D-1	A	B	C	All controlled substances are secured and locked under supervised access. Storage of controlled substances must be in accordance with applicable federal/national, state/provincial, and local regulations.	Verify that the facility's controlled substances are securely stored in regulatory-compliant locked cabinets or approved emergency-use (e.g., crash cart) configurations with rigorous oversight, consistent with DEA, national or regional controlled-drug storage requirements. For facilities that have one (1) controlled substance, such as a benzodiazepine, the facility may develop and implement a policy and procedure to store the one (1) controlled substance securely in the facility's defined crash cart. In this case, the policy and procedure must include a process to check for outdated medication and to verify the medication's presence as part of the crash cart check. Evaluating Compliance: Review policies for: Storage method security requirements Regular substance accountability checks Outdated medication removal procedures Crash cart verification processes (if applicable) Observe all controlled substance storage for evidence of: Substantial locked cabinets (per 21CFR §1301.75 or other national controlled substance storage requirement) Crash cart storage (if single substance policy) Confirm no controlled substances in unsecured drawers Confirm documentation of access logs.
6-D-2	A	B	C	There is a dated controlled substance inventory and a control record that includes the use of controlled substances on individual patients. Such records must be kept in the form of a sequentially numbered,	Verify the facility reduces the risk of controlled substance (CS) diversion through comprehensive tracking from receipt to disposition with prompt discrepancy resolution and mandatory diversion reporting.

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<p>bound journal from which pages may not be removed, or in a tamper -proof, secure computer record consistent with state and federal law. This log must be kept in the facility.</p>	<p>Evaluating Compliance: Review policies and procedures for: End-of-shift counts and discrepancy resolution Diversion reporting (DEA/law enforcement/state boards/national authority that controls narcotics and psychotropic substances) Review CS records/logs to: Confirm that a compliant controlled-substance tracking system (electronic or hardcopy) is in place, in accordance with the requirements of the DEA or the relevant national authority overseeing narcotics and psychotropic substances. Validate sequential page numbering (if hardcopy) Verify real-time reconciliation capability Review audit trail from receipt to: administration, destruction, and return Interview staff regarding process for ordering CS, receipt of inventory, and entering CS into stock Confirm designated pharmaceutical supervisor (e.g., consulting pharmacist if required by state).</p>
6-D-3	A	B	C	<p>All controlled substance transactions, including daily counts and wastes, require verification by two (2) licensed members of the team. (For facilities with only Schedule IV and V controlled substances, one (1) licensed and (1) authorized member of the operating room team may document verification of daily counts and wastes.)</p> <p>These verifications must be completed on any day that the facility is open and/or controlled substances are administered, and in compliance with federal/national, provincial, state, and local regulations. The facility must develop a policy detailing how unlicensed authorized individuals are authorized, if applicable.</p>	<p>Verify the facility reduces the risk of controlled substance (CS) diversion through verified inventory counts and waste documentation by qualified personnel.</p> <p>Evaluating Compliance: Review policies for: Authorized personnel (licensed + facility-designated) with access Count/waste verification requirements Discrepancy resolution procedures Review CS recordkeeping to: Ensure all transactions witnessed by one (1) of the following: Two (2) licensed professionals (OR) One(1) licensed + one (1) authorized (in Class A facilities, Schedules IV-V only) Check for waste documentation Check for reconciliation of discrepancies Interview staff regarding count variance protocols Confirm corrective actions taken (when variances identified) Confirm diversion reporting to DEA or national authority that controls narcotics and psychotropic substances authorities (if identified).</p>
6-D-4	A	B	C	<p>There must be a record of receipt and disposition of all controlled substances. Records must be maintained for a minimum of three (3) years.</p>	<p>Verify the facility reduces the risk of controlled substance (CS) diversion through complete DEA-compliant recordkeeping of all receipts and dispositions.</p> <p>Evaluating Compliance: Review policies and procedures for: Order documentation (DEA 222)</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Disposition records (administration/waste/return) Loss reporting protocols Review documents to: Verify all CS transactions are documented Confirm DEA Form 222 properly completed/retained Check for unresolved discrepancies Confirm records show complete chain of custody Verify reconciliation between receipts and dispositions.</p>
6-D-5	A	B	C	<p>If contracted anesthesia professionals bring controlled substances into the facility, the facility must ensure compliance with all QUAD A standards, local, state, and federal laws and DEA regulations.</p>	<p>Verify the facility reduces the risk of controlled substance (CS) diversion through strict adherence to DEA regulations and contractual oversight of anesthesia services, ensuring all substances are properly registered, tracked, and stored.</p> <p>Evaluating Compliance: Review contract & registration verification to ensure: Written contract specifies facility retains responsibility for anesthesia services Contracted anesthesia professional has DEA registration at facility address CS are designated under facility's DEA registration if stored on-site Review CS inventory recordkeeping to ensure: DEA Form 222 complete Complete receipt and disposition of all CS No unresolved discrepancies in counts Review CS tracking records to ensure: Facility tracks/logs/counts all narcotics (including those brought by contractors) Duplicate records (receipt/administration) available at facility and central location Confirm operational compliance by verifying: Anesthesia practices align with facility policies and QUAD A standards All routinely used supplies/equipment present during survey for evaluation Transport procedures follow DEA and other applicable laws Confirm CS storage complies with federal/state/local regulations.</p>
Sub-section E: ACLS/PALS Algorithm					
6-E-1	A	B	C	<p>A complete and current copy of the current ACLS and/or PALS Algorithm, as appropriate for the patient population served in the facility, must be available on the emergency cart.</p>	<p>Verify emergency carts contain current ACLS (and/or PALS) protocols for use during patient resuscitation.</p> <p>Evaluating Compliance: Inspect cart for current algorithms from approved source (e.g., AHA) Confirm PALS algorithms available (if applicable).</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
6-E-4	A	B	C	<p>The following medication must be available in the facility at all times as required by the current ACLS/PALS algorithm:</p> <p>Adenosine - 18 mg</p> <p>Epinephrine (1:10,000 solution, 1 mg per 10 ml) - Minimum - 5 mg</p> <p>Anti-Hypertensives – Minimum is per facility policy or facility drug formulary.</p> <p>Lidocaine HCl 2% - Minimum 100 mg</p> <p>Atropine - Minimum 3 mg</p> <p>Nitroglycerin (sublingual tablets or spray) – Minimum is per facility policy or facility drug formulary.</p> <p>Narcan – Minimum is per facility policy or facility drug formulary.</p> <p>Intravenous corticosteroids (e.g., dexamethasone) – Minimum is per facility policy or facility drug formulary.</p> <p>Amiodarone - Minimum 450 mg</p>	<p>Verify emergency medications and supplies are immediately available in correct formulations and sufficient quantities to support full ACLS/PALS protocols during a code.</p> <p>Caution: Lidocaine HCl 2% (100mg/5mL) must be labeled "for cardiac arrhythmias" and cannot be substituted with plain lidocaine (local anesthetic) or bupivacaine</p> <p>Evaluating Compliance:</p> <p>Inspect emergency cart to confirm emergency medications are:</p> <ul style="list-style-type: none"> ACLS/PALS-specific formulations (correct type and concentration) In sufficient quantity for prolonged resuscitation Not expired <p>Confirm there are no dangerous substitutions (e.g., local anesthetics in place of antiarrhythmics)</p>
6-E-5	A	B	C	<p>There must be a written protocol for cardiopulmonary resuscitation (CPR). This protocol must include the provision for annual drills, staff training upon hire and annually, drill documentation, and retention of documentation for at least three (3) years.</p>	<p>Verify staff readiness to perform cardiopulmonary resuscitation through defined roles, annual training, and protocol maintenance.</p> <p>Drill content should vary in terms of time, location, and scenario. Drills and training are separate components. Not all staff are expected to participate in the scheduled drill, as staff may not be scheduled to work that day.</p> <p>Evaluating Compliance:</p> <p>Review policies to verify CPR/Code Blue protocols include drills, staff training, drill documentation, clear role assignments and define response team</p> <p>Interview staff regarding emergency activation, roles during code, use of emergency equipment/medications</p> <p>Review facility documentation for annual drill</p> <p>Review personnel records for CPR training (initial, annual, updates) and competency (BLS/ACLS certification).</p>
Sub-section F: Emergency Medications					
6-F-1	A	B	C	<p>All emergency medications, as noted, must be available and in the facility at all times. Licensed personnel in the facility must know their location.</p>	<p>Verify emergency medications and supplies are continuously available, immediately accessible, and that staff can rapidly locate them during crises.</p> <p>Evaluating Compliance:</p> <p>Review policies for definitions of minimum quantities based on patient volume and acuity</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Review checklists to ensure stock of the required drugs is regularly monitored</p> <p>Interview staff on monitoring protocols, restocking procedures, and minimum quantity requirements</p> <p>Inspect the stock to confirm all required emergency medications are present (not expired)</p> <p>Confirm quantities are sufficient and medication are appropriate for the patient population served.</p>
6-F-2	A	B	C	<p>The following medication must be available in the facility at all times: IV Antihistamines (e.g. Diphenhydramine) – Minimum 50 mg.</p>	<p>Verify IV Antihistamines are continuously available, in the appropriate concentration and quantity for the patient populations served.</p> <p>Evaluating Compliance:</p> <p>Review checklists to ensure the stock of the required drug is regularly monitored</p> <p>Inspect stock for:</p> <ul style="list-style-type: none"> IV Antihistamines (e.g. Diphenhydramine) Minimum dose 50 mg (not expired) <p>Confirm quantities align with patient volume/acuity (pediatric dosing is present when applicable).</p>
6-F-3	A	B	C	<p>The following medication must be available in the facility at all times: Short-acting beta-blocker (e.g., esmolol or labetalol).</p>	<p>Verify a short-acting beta-blocker (e.g., esmolol or labetalol) is continuously available, in the appropriate concentration and quantity for the patient populations served.</p> <p>Evaluating Compliance:</p> <p>Review checklists to ensure the stock of the required drug is regularly monitored</p> <p>Inspect stock to verify that a short-acting beta-blocker (e.g., esmolol or labetalol) is present (not expired)</p> <p>Confirm quantities align with patient volume/acuity (pediatric dosing is present when applicable).</p>
6-F-4			C	<p>The following medication must be available in the facility at all times: Neuromuscular blocking agents including non-depolarizing agents such as rocuronium or depolarizing agents such as succinylcholine.</p>	<p>Verify emergency medications, specifically neuromuscular blocking agents, are stored appropriately to maintain potency and are continuously available, in the appropriate concentration and quantity for the patient populations served.</p> <p>Evaluating Compliance:</p> <p>Review checklists to ensure the stock of the required drug is regularly monitored</p> <p>Review temperature logs for consistent monitoring and corrective action for temperature variances</p> <p>Inspect stock to verify that neuromuscular blocking agents are present (not expired) and stored according to the manufacturer's specifications:</p> <ul style="list-style-type: none"> Succinylcholine: <ul style="list-style-type: none"> Refrigerated: (preferred) storage at 2° - 8°C (36° - 46°F) Room temp: labeled when removed from refrigeration (manufacturer/container specific) Rocuronium Bromide:

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					<p>Refrigerated: storage at 2° - 8°C (36° - 46°F) Room temp: labeled when removed from refrigeration & used within 60 days; opened vials within 30 days Interview staff on storage requirements and expiration date management.</p>
6-F-8	A	B	C	<p>The following medication must be available in the facility at all times: Bronchospasm-arresting medication (inhaled beta-agonist, e.g. albuterol).</p>	<p>Verify bronchospasm-arresting medication (inhaled beta-agonist) is continuously available, in the appropriate concentration and quantity for the patient populations served.</p> <p>Evaluating Compliance: Review checklists to ensure stock of the required drug is regularly monitored Inspect stock for bronchospasm-arresting medication (e.g., albuterol) (not expired) Confirm quantities align with patient volume/acuity (pediatric dosing is present when applicable).</p>
6-F-10	A	B	C	<p>The following medication must be available in the facility at all times: Seizure-arresting medication (a benzodiazepine, e.g. Midazolam).</p>	<p>Verify seizure-arresting medications (benzodiazepines) are continuously available, in the appropriate concentration and quantity for the patient populations served.</p> <p>First-line seizure-arresting medications are fast-acting medications that include lorazepam, diazepam, clonazepam, and midazolam (IV or nasal spray).</p> <p>Phenytoin is not considered a first-line seizure-arresting medication; it is a second-line medication used for established status epilepticus (20 – 40 minutes).</p> <p>While phenobarbital is still used for seizure treatment, it's not generally considered a first-line medication for most adults or in many developed countries.</p> <p>It is often not possible to take a medication by mouth during a seizure, and the medications used for emergency management of seizures are available in forms that can be injected into a muscle (IM), administered intravenously (IV, in a vein), used as a nasal spray, or administered rectally.</p> <p>Evaluating Compliance: Review checklists to ensure stock of the required drug is regularly monitored Inspect stock for seizure-arresting medications (e.g., midazolam) (not expired) Confirm quantities align with patient volume/acuity (pediatric dosing is present when applicable).</p>
6-F-12	A	B	C	<p>Facilities administering regional or tumescent anesthesia containing bupivacaine must always have 20% lipid emulsion available.</p>	<p>Verify 20% lipid emulsion is continuously available for the immediate treatment of Local Anesthetic Systemic Toxicity.</p> <p>Evaluating Compliance: Determine the need for stock of 20% lipid emulsion through staff interviews or a review of</p>

Standard ID	Anesthesia Class		Standard / Regulatory Reference	Interpretive Guidance
				clinical records Review checklists to ensure stock of the required drug is regularly monitored Inspect stock for 20% lipid emulsion (not expired) Confirm quantities align with patient volume (pediatric dosing is present when applicable).
6-F-23		B	C The following medication must be available in the facility at all times: If a Benzodiazepine is used in the facility, a reversal agent must be available (e.g. Mazicon™, Flumazenil).	Verify facility awareness of Florida regulations and ensure benzodiazepine reversal agents are continuously available, in the appropriate quantity for the patient populations served. <u>Evaluating Compliance:</u> Determine if benzodiazepines are administered through staff interviews and review of clinical records Review checklists to ensure stock of the required drug is regularly monitored Inspect stock for benzodiazepine reversal agents (e.g., flumazenil) (not expired) Confirm quantities align with patient volume (pediatric dosing is present when applicable).
Sub-section G: Malignant Hyperthermia				
6-G-1			C If the depolarizing muscle relaxant succinylcholine is present only for use in emergency airway rescue, the facility must document a protocol to manage the possibility of malignant hyperthermia (MH) following its use, and staff training must occur on hire and then annually.	Verify that facilities keeping only a limited stock of paralytic agents for use in emergency airway rescue maintain these essential requirements: Storage of a MH-triggering, depolarizing neuromuscular blocking agent (succinylcholine) requires: Written MH policy MHAUS algorithm on the emergency cart Staff training Storage of a non-depolarizing neuromuscular blocking agent (e.g., rocuronium, vecuronium) requires: MHAUS algorithm on the emergency cart Staff training. <u>Evaluating Compliance:</u> Determine the facility's use of MH-triggering agents (e.g., isoflurane, sevoflurane, desflurane, succinylcholine) through: Staff interviews Confirmation with review of recent anesthesia records Review policy for alignment with MHAUS guidelines (for storage of Succinylcholine only) Interview staff regarding knowledge of MH signs/symptoms, MH protocols, and location of MHAUS algorithm Inspect the emergency cart to confirm current MHAUS algorithm is present Review personnel records for evidence of training (initial, annual).

Standard ID	Anesthesia Class		Standard / Regulatory Reference	Interpretive Guidance
6-G-2		C	<p>If potential malignant hyperthermia triggering agents such as isoflurane, sevoflurane, and desflurane, and/or the depolarizing muscle relaxant succinylcholine are ever used, or are present in the facility: Screening for MH risk must be documented, that includes but is not limited to a family history of unexpected death(s) following general anesthesia or exercise; a family or personal history of MH, a muscle or neuromuscular disorder, high temperature following exercise; a personal history of muscle spasm, dark or chocolate colored urine, or unanticipated fever immediately following anesthesia or serious exercise.</p>	<p>Verify that patients are screened for risk of malignant hyperthermia (MH) whenever drugs that can trigger MH are available or used, so that an MH-susceptible patient is identified before anesthesia is administered, preventing a potentially fatal reaction.</p> <p>Evaluating Compliance: Determine facility use/storage of MH triggering agents (e.g., isoflurane, sevoflurane, desflurane, succinylcholine) through staff interviews and confirmation from clinical record review Review policies for alignment with MHAUS guidelines Review screening process for inclusion of: Personal/family history of MH or adverse anesthetic reactions Assessment for associated conditions (e.g., central core disease, other myopathies) Interview staff on screening questions and actions needed for patients with increased risk (e.g., avoidance of triggering agents, use of a "clean" machine, prolonged monitoring) Review clinical records for evidence of: MH-risk screening for all patients Precautions taken for at-risk patients.</p>
6-G-5		C	<p>If potential malignant hyperthermia triggering agents such as isoflurane, sevoflurane, and desflurane, and/or the depolarizing muscle relaxant succinylcholine are ever used, or are present in the facility: MH crisis management must be covered in annual staff training. All clinical staff (including contracted healthcare professionals) must be trained. Annual drills are conducted for MH crisis and management including actual dilution of at least one vial of actual Dantrolene (expired OK). Staff should be assigned roles prior to drills and a written protocol outlining those personnel and their roles is on file. Documentation of drills is required.</p>	<p>Verify all clinical staff are trained and prepared to manage a malignant hyperthermia (MH) crisis. Annual MH drills are required unless triggering agents are present only for emergency airway rescue (e.g., succinylcholine)</p> <p>Note: Drills and training are separate components. Not all staff are expected to participate in the scheduled drill, as staff may not be scheduled to work that day.</p> <p>Evaluating Compliance: Determine facility use/storage of MH triggering agents (e.g., isoflurane, sevoflurane, desflurane, succinylcholine) through staff interviews and confirmation from clinical record review Review MH drill protocol for inclusion of roles, responsibilities, and simulation of dantrolene preparation Review evidence of MH Drill (date, participants, dantrolene reconstitution) (when applicable) Interview staff (including contractors) to assess: Understanding of MH signs/symptoms Knowledge of dantrolene/ryanodex dosing and administration Clarity of individual roles during a crisis Awareness of MH Hotline: 1-800-644-9737, outside of North America 001-209-417-3722 Review personnel records to confirm MH training (initial, annual) for all clinical staff (if drills required).</p>
6-G-6		C	<p>If potential malignant hyperthermia triggering agents such as isoflurane, sevoflurane, and desflurane,</p>	<p>Verify all medications and supplies required to manage a malignant hyperthermia (MH) crisis are immediately available and accessible. This includes an adequate supply of the correct</p>

Standard ID	Anesthesia Class		Standard / Regulatory Reference	Interpretive Guidance
			and/or the depolarizing muscle relaxant succinylcholine are ever used, or are present in the facility: A supply of sterile water for injection USP (without a bacteriostatic agent) is available to mix with dantrolene before injection (i.e. 60ml/vial for Dantrium® and Revonto®, 5ml/vial for Ryanodex®).	<p>diluent (sterile water for injection) for dantrolene or ryanodex.</p> <p>Evaluating Compliance: Inspect MH crisis supply storage area to confirm the minimum supply of sterile water (for injection): For Dantrolene, at least 720 mL sterile water is available (60 mL per vial for 12 vials, more for full dosing) For Ryanodex, at least 15 mL of sterile water for injection is available (5 mL per vial for 3 vials) Confirm MH crisis supplies are stored together for immediate access, clearly labeled, and not expired.</p>
6-G-7		C	If potential malignant hyperthermia triggering agents such as isoflurane, sevoflurane, and desflurane, and/or the depolarizing muscle relaxant succinylcholine are ever used, or are present in the facility: A minimum of 4 ampoules, 50cc's each, of sodium bicarbonate (NaHCO ₃).	<p>Verify all medications and supplies required to manage a malignant hyperthermia (MH) crisis are immediately available and accessible. This includes sufficient quantities of sodium bicarbonate to treat severe acidosis.</p> <p>Evaluating Compliance: Inspect MH crisis supply storage area to confirm at least four (4) 50 mL vials of sodium bicarbonate (NaHCO₃) are present Confirm MH crisis supplies are stored together for immediate access, clearly labeled, and not expired.</p>
6-G-10		C	If potential malignant hyperthermia triggering agents such as isoflurane, sevoflurane, and desflurane, and/or the depolarizing muscle relaxant succinylcholine are ever used, or are present in the facility: Flow sheets for any MH intervention as well as forms to rapidly communicate the progress of intervention with receiving facilities are on the emergency cart, and the facility must document and report any "adverse metabolic or musculoskeletal reaction to anesthesia". This documentation must be transportable with the patient when transferred to the receiving facility.	<p>Verify the facility has the ability to produce clear, timely, and transportable documentation of all malignant hyperthermia (MH) crisis interventions to support patient handoff and continuity of care at a receiving facility.</p> <p>Note: Compliance with this standard is not required if succinylcholine is present only for emergency airway rescue.</p> <p>Evaluating Compliance: Review policies for directives related to patient's having a MH crisis: Adverse metabolic or musculoskeletal reactions to anesthesia are reported to receiving facility MH flowsheet must accompany patient to receiving facility for handoff Review the MH flowsheet standardization for: Timelines for key actions (e.g., dantrolene administration, cooling measures) Patient vital signs and metabolic status (e.g., ETCO₂, temperature, acidosis) Confirm presence of blank MH flowsheets on the emergency cart Review relevant clinical records to ensure flowsheets are present, complete, and accurate.</p>
6-G-11		C	If potential malignant hyperthermia triggering agents such as isoflurane, sevoflurane, and desflurane,	Verify the facility maintains a comprehensive malignant hyperthermia (MH) policy to support patient transfer to a nearby hospital with the capability for continued MH management

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			<p>and/or the depolarizing muscle relaxant succinylcholine are ever used, or are present in the facility: Facilities must have a policy for MH transfer including EMS 911 transport to a facility capable of ongoing treatment located within a reasonable distance. A licensed healthcare professional with the ability to continue MH treatment must accompany the patient during transport and provide a report to the receiving facility staff.</p>	<p>Note: Compliance with this standard is not required if succinylcholine is present only for emergency airway rescue. The focus is on ensuring continuity of care during a critical transfer.</p> <p>Evaluating Compliance: Review policies for directives when transferring MH patients to a higher level of care, including:</p> <ul style="list-style-type: none"> Identification of nearby hospital with capability to treat MH Communicating the patient's status to the receiving facility pre-transport Activating EMS to summon emergency transport Licensed staff to manage patient during transport (e.g., anesthesia provider) Written report given to hospital upon arrival that includes patient status and interventions during transport.
6-G-14		C	<p>If potential malignant hyperthermia triggering agents such as isoflurane, sevoflurane, and desflurane, and/or the depolarizing muscle relaxant succinylcholine are ever used, or are present in the facility: A minimum supply of dantrolene/Ryanodex should be stocked to treat a patient of average weight (approximately 70kg) with an initial dose: Dantrium®/Revonto® - 12 vials (20 mg/vial) Ryanodex® - 1 vial (250 mg/vial).</p>	<p>Verify all medications and supplies necessary to manage a malignant hyperthermia (MH) crisis are readily accessible to support a positive patient outcome. Readily accessible, in this instance, means the facility is able to administer Dantrolene/Ryanodex within 10 minutes of the first sign of MH.</p> <p>Evaluating Compliance: Inspect MH crisis supply storage area to confirm a minimum supply of Dantrolene (12 vials) or Ryanodex (1 vial) is present (not expired).</p>
6-G-15		C	<p>If potential malignant hyperthermia triggering agents such as isoflurane, sevoflurane, and desflurane, and/or the depolarizing muscle relaxant succinylcholine are ever used, or are present in the facility: An additional* supply of dantrolene/Ryanodex and diluents are stored in the facility, or the facility has a written agreement with another source that will provide additional* dantrolene/Ryanodex and diluents on a STAT basis within 10 minutes for continued treatment and stabilization of a patient experiencing a MH episode. *Additional supply of dantrolene is defined as: Dantrium®/Revonto® - 24 vials (20 mg/vial) Ryanodex® - 2 vial (250 mg/vial)</p>	<p>Verify an additional supply of dantrolene/ryanodex and diluent are obtainable within ten (10) minutes to sustain treatment during a prolonged malignant hyperthermia (MH) crisis. This supply may be maintained on-site or via a formal, written agreement with a reliable external source.</p> <p>Note: Compliance with this standard is not required if succinylcholine is present only for emergency airway rescue.</p> <p>Evaluating Compliance: Inspect MH crisis supply storage area to confirm additional dantrolene (24 vials) or ryanodex (2 vials) and adequate diluent is present (not expired)</p> <p>If additional supply is available via external agreement:</p> <ul style="list-style-type: none"> Confirm agreement is with a reliable source (e.g., hospital pharmacy, other facility) that is quickly accessible Review drill documentation Interview staff to determine if timely receipt of additional medications/supplies has been verified

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					<p>During survey, staff must request the immediate delivery of the additional medications/supplies</p> <p>Time the process (from phone request to arrival of medications/supplies) to verify timeframe is met.</p>

SECTION 7: INFECTION PREVENTION & CONTROL

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Sub-section A: Infection Prevention and Control					
7-A-1	A	B	C	<p>The ASC must maintain an infection prevention and control program that seeks to minimize infections and communicable diseases.</p> <p>§416.51 Condition</p>	SOM Appendix L - Guidance for Surveyors: ASCs
7-A-2	A	B	C	<p>The facility must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection prevention and control program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines.</p> <p>§416.51(b) Standard</p>	SOM Appendix L - Guidance for Surveyors: ASCs
7-A-3	A	B	C	<p>The Infection Prevention and Control Program is under the direction of a designated and qualified professional who has training in infection control.</p> <p>§416.51(b)(1) Standard</p>	SOM Appendix L - Guidance for Surveyors: ASCs
7-A-4	A	B	C	<p>The Infection Prevention and Control Program is an integral part of the facility's quality assessment and performance improvement program.</p> <p>§416.51(b)(2) Standard</p>	SOM Appendix L - Guidance for Surveyors: ASCs
7-A-5	A	B	C	<p>The Infection Prevention and Control Program is responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.</p>	SOM Appendix L - Guidance for Surveyors: ASCs

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				§416.51(b)(3) Standard	
7-A-6	A	B	C	The Infection Prevention and Control Program must include documentation that the facility has considered, selected, and implemented nationally recognized infection control guidelines.	<p>Verify the facility has adopted and implemented nationally recognized infection prevention and control guidelines to minimize infection risks and ensure consistent, high-quality patient care.</p> <p>Evaluating Compliance: Review policies for selection of nationally recognized guidelines (e.g., CDC, WHO, AORN, APIC) and integration of current guidelines into facility protocols Review documents (e.g., audits, quality metrics) demonstrating guideline compliance Interview staff regarding knowledge of current guidelines Cross-reference facility practices with CMS Appendix L requirements for infection prevention and control Review personnel records for evidence of training (initial, annual, updates).</p>
7-A-7	A	B	C	Appropriate scrub facilities are provided for the operating room staff consistent with current CDC guidelines for hand hygiene and surgical scrub.	<p>Verify the facility minimizes infection risks by ensuring proper hand hygiene and surgical scrub protocols are followed, using evidence-based techniques that avoid skin damage.</p> <p>Evaluating Compliance: Review policies for alignment with current guidelines (e.g., CDC, AORN) for brushless scrubbing Interview staff on surgical scrub protocols Observe staff performing hand hygiene and surgical hand antisepsis to confirm: Hand hygiene performed before/after patient contact, using alcohol-based rub (ABHR) or soap/water Brushless surgical scrub includes decontamination, nail cleaning, timed antiseptic application Inspect scrub sink area for ABHR and surgical scrub supplies (e.g., antiseptic solutions, nail cleaners) Confirm ABHR, solutions, supplies are not expired.</p>
7-A-10	A	B	C	The facility's policies address operating/procedure room attire. This includes scrub suits, caps or hair covers, gloves, operative gowns, masks, eye protection, and all other appropriate attire based on the procedure being conducted.	<p>Verify the facility minimizes infection risk by ensuring proper surgical attire is worn in semi-restricted and restricted areas, and that all attire is laundered under controlled conditions to meet hygienic standards.</p> <p>Evaluating Compliance: Review policies for alignment with adopted nationally recognized guidelines (e.g., CDC, WHO, AORN) for: Surgical attire requirements (e.g., disposable caps, scrubs, shoe covers) Laundering processes (e.g., healthcare-accredited or in-house per standards) Restrictions (e.g., home laundering, wearing scrubs outside facility) When scrub attire is laundered onsite, review documents confirming processes meet thermal,</p>

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					mechanical, and chemical standards to reduce microbial load Observe staff in semi-restricted/restricted areas for proper surgical attire (e.g., scrubs, caps, masks).
7-A-11	A	B	C	A sterile field is used during all operations and procedures, as applicable.	Verify the facility minimizes infection risk by ensuring a sterile field is established/maintained for all applicable procedures and adhering to aseptic technique standards. Evaluating Compliance: Review policies for alignment with nationally recognized guidelines (e.g., CDC, WHO, AORN) to ensure sterile field protocols are maintained Interview staff regarding creation/maintenance of sterile field and action when breaches are noted Observe procedures to verify: Sterile technique is established/maintained throughout (e.g., proper draping, no breaches) Staff adhere to principles of asepsis (e.g., avoiding non-sterile contact).
7-A-13	A	B	C	Reuse of single-use disposable biopsy forceps is strictly prohibited. Purchase records must be retained for three (3) years and available for comparison to procedural and pathology specimen logs.	Verify the facility complies with the manufacturer's designation of single-use for disposable biopsy forceps. Evaluating Compliance: Review documents and cross-check: Volume from purchase orders of single-use biopsy forceps Volume of use in procedure logs Interview staff regarding process for identifying manufacturer's designation Observe staff during procedures to confirm single-use items are properly disposed Confirm purchasing records for disposable biopsy forceps are available for the past three (3) years.
Sub-section B: Hand Hygiene					
7-B-1	A	B	C	Hand hygiene is performed in accordance with current nationally recognized and/or WHO guidelines and standards of practice. Periodic hand hygiene auditing must be a part of the facility's quality activities. For surgical/procedural facilities: Scrub facilities are provided for the operating room staff. Scrub products (as appropriate), soap, and alcohol cleansers are provided for the operating room staff, consistent with	Verify the facility minimizes infection risk through rigorous hand hygiene protocols that align with CDC/WHO guidelines, including: Surgical hand antisepsis Routine hand hygiene (HH) audits Maintaining accessible HH supplies. Evaluating Compliance: Review policies for alignment with adopted national guidelines (e.g., CDC, WHO) Confirm HH policies define audit frequency, methods, and QAPI integration Review documentation of HH audit records for: Regular, unannounced observations

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				current adopted guidelines and standards of practice for hand hygiene.	<p>Compliance with “WHO Five Moments” (e.g., before patient contact, after environmental contact)</p> <p>Data analysis, feedback, and documented corrective actions</p> <p>HH audits results integration into the facility’s QAPI program</p> <p>Interview staff regarding indications for HH and surgical scrub protocols (e.g., brushless technique, duration)</p> <p>Observe practices for adherence during patient care and procedures</p> <p>Inspect facility to ensure alcohol-based hand rub, surgical scrub supplies, and sinks are:</p> <ul style="list-style-type: none"> Readily accessible in semi-restricted/restricted areas (not expired) Separate from instrument cleaning sinks.
Sub-section C: Instrument Processing					
7-C-1	A	B	C	The facility has a written protocol for the reprocessing of all surgical instruments and disinfection of all equipment used in patient care consistent with the manufacturer’s instructions for use.	<p>Verify the facility minimizes infection risk by ensuring all reusable instruments and equipment are reprocessed or disinfected according to manufacturer instructions for use (IFU) and nationally recognized guidelines. This applies to all equipment used in patient care, including point-of-care devices. Contracted reprocessing services must be rigorously monitored through the facility’s quality improvement program.</p> <p>Evaluating Compliance:</p> <p>Review policies for:</p> <ul style="list-style-type: none"> Alignment with recognized guidelines (e.g., CDC, AORN, AAMI, WHO) Directive for strict adherence to manufacturer’s IFU for all equipment HLD/sterilization procedures and recordkeeping criteria <p>Interview staff regarding ophthalmic instrument reprocessing to prevent TASS and endophthalmitis:</p> <ul style="list-style-type: none"> Cleaning intraocular instruments in a designated area, separate from general surgical instruments Importance of rinsing/flushing phaco handpieces and cannulas (single-use preferred) <p>Observe staff to ensure:</p> <ul style="list-style-type: none"> Cleaning/reprocessing occur in between patients use or when contaminated Manufacturer’s IFU are strictly followed for high-level disinfection or terminal sterilization Cleaning agents (e.g., enzymatic) and methods (e.g., ultrasonic cleaning) align with IFU Thorough rinsing, flushing, drying occur before disinfection/sterilization <p>Review personnel records for validation of competency (initial, per policy, updates)</p> <p>If the facility uses contracted services for reprocessing:</p> <ul style="list-style-type: none"> Confirm written contract holds vendor accountable to meet all applicable standards (e.g., ANSI/AAMI ST79) Confirm annual contract review is part of the facility’s QAPI program, with a defined process for validating the vendor’s compliance, staff competence, and quality outcomes.

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7-C-2	A	B	C	<p>There is strict segregation of dirty surgical equipment and instruments that have been cleaned and are in the preparation and assembly area.</p>	<p>Verify the facility prevents cross-contamination and minimizes infection risk by ensuring a unidirectional workflow (clean to dirty) and adherence to national industry standards for reprocessing instruments.</p> <p>Evaluating Compliance: Inspect work areas for evidence that clean instruments/equipment are stored away from contaminated instruments/equipment Confirm workflow between the two (2) areas is unidirectional (clean → dirty).</p>
7-C-3	A	B	C	<p>The instrument preparation and assembly area (clean processing area) are separated by walls or space from the instrument cleaning and decontamination area (reprocessing area).</p>	<p>Verify the facility prevents cross-contamination and minimizes infection risk by maintaining strict physical separation between clean and dirty processing areas.</p> <p>Evaluating Compliance: Inspect work areas for evidence of separation between dirty and clean work areas, confirming one (1) of the following: A physical barrier (e.g., work areas are in different rooms with a pass-through) A screen barrier is in place (extending ≥4 feet above the sink's rim) Minimum 4-foot distance separating the decontamination sink (dirty area) from the clean processing area Confirm workflow between the two (2) areas is unidirectional (clean → dirty).</p>
7-C-4	A	B	C	<p>Single-use devices are not reprocessed unless they are approved by the FDA for reprocessing. Reprocessing of these devices is done by an FDA-approved reprocessor.</p> <p>NOTE: The FDA requirement does not apply to international facilities. International facilities must comply with local, state/provincial or federal/national requirements regarding reprocessing single-use devices.</p>	<p>Verify the facility minimizes infection risk by strictly following the manufacturer's designation for use. When a device is approved for a limited number of sterilization cycles, the facility must have a documented tracking process and ensure limits are not exceeded. Items lacking manufacturer's cleaning/reprocessing instructions are usually single-use (disposable)</p> <p>Note: Reprocessing single-use devices is only allowed when FDA-approved and the device manufacturer provides approved methods and validated reprocessing instructions for third party reprocessors.</p> <p>Evaluating Compliance: Review policies for: Directive to comply with manufacturer's designation for use (e.g., reusable, limited use, single-use only) Prohibition to reprocess single-use devices <i>unless</i> FDA/manufacturer approved by third party reprocessor Requirement to adhere to manufacturer instructions for use (IFU) for any approved reprocessing Interview staff to assess knowledge of: Which devices are strictly single-use Reprocessing protocols and cycle limits for approved devices</p>

Standard ID	Anesthesia Class			Standards / Regulatory Reference	Interpretive Guidance
					<p>For reusable devices approved for a limited number of sterilization cycles (e.g., gel implant sizers, LMAs, some liposuction cannulas): Review documentation for device identification and traceability to confirm: Number of reprocessing cycles (e.g., ≤ 10 for gel sizers, ≤ 40 for LMAs) Reprocessing follows IFU exactly Saline breast implant sizers are never reprocessed.</p>
Sub-section D: Sterilization					
7-D-1	A	B	C	<p>All instruments used in patient care are sterilized where applicable.</p>	<p>Verify the facility minimizes infection risk by ensuring critical equipment (e.g., surgical instruments) is sterilized using validated processes, and semi-critical equipment (e.g., laryngoscope blades, LMAs) undergoes high-level disinfection or sterilization per the manufacturer's instructions for use (IFU). Documentation must verify sterilization parameters were achieved for each load.</p> <p>Evaluating Compliance: Review policies for alignment with recognized infection prevention and control guidelines (e.g., CDC, AORN, AAMI, WHO) Review sterilization records to confirm: Physical parameters for sterilization (time/temp/pressure) per manufacturer IFUs were actually achieved Extended parameters were achieved for complex instrumentation/devices Results of chemical indicators, biological indicators were assessed Observe reprocessed devices to confirm: Critical items are terminally sterilized Semi-critical items receive high-level disinfection or sterilization consistent with manufacturer's IFU Correct cycle selection based on manufacturer's IFUs (and packaging) Review personnel files for evidence of competency for staff responsible for reprocessing: Competency validation (initial, periodically according to facility policy) If the facility does not have a sterilizer onsite, and sterilization is performed by an external vendor: Confirm written contract holds vendor accountable to meet all applicable standards (e.g., ANSI/AAMI ST79) Review documentation proving sterilization was performed appropriately.</p>
7-D-2	A	B	C	<p>The facility has at least one (autoclave) that uses high-pressure steam and heat, or all sterile items are single-use disposable, or the facility has contracted with an outside vendor to process instruments, if</p>	<p>Verify the facility minimizes infection risk by ensuring all reusable instruments are reprocessed according to the manufacturer's instructions for use (IFU), either by prompt sterilization onsite or via the services of an external vendor. Contracted reprocessing services must be rigorously monitored through the facility's quality improvement program.</p>

Standard ID	Anesthesia Class			Standards / Regulatory Reference	Interpretive Guidance
				applicable. Instrument reprocessing and sterilization must follow the manufacturer's instructions for use.	<p>Evaluating Compliance: When the facility reprocesses instrumentation onsite, confirm functional sterilizer(s) in use Observe staff to ensure: Manufacturer's IFU are strictly followed for high-level disinfection or terminal sterilization, including: Treatment, cleaning agents (e.g., enzymatic) & methods (e.g., ultrasonic cleaning) align with IFU Thorough flushing, rinsing, and drying occur before sterilization Review personnel records for validation of competency (initial, per policy, updates) If the facility uses contracted services for reprocessing, confirm: Written contract holds vendor accountable to meet all applicable standards (e.g., AAMI ST79) Annual contract review is part of the facility's QAPI program, with a defined process for validating the vendor's compliance, staff competence, and quality outcomes.</p>
7-D-3	A	B	C	Additional methods in use can be chemical (Chemclave©) or gas (ethylene oxide/EO) sterilizer.	<p>Verify the safe and effective use of chemical sterilizers (e.g., ethylene oxide, chemical vapor) to minimize infection risks and staff exposure to hazardous agents. Strict adherence to manufacturer instructions and staff competency are critical due to the complexity and potential dangers of these systems</p> <p>Note: Chemical sterilizers require rigorous safety protocols due to hazardous agents; facilities should prioritize steam sterilization when feasible.</p> <p>Evaluating Compliance: Review policies for alignment with manufacturer instructions for use (IFUs), including: Physical parameters (time, temperature, pressure, gas concentration) Safety protocols for handling hazardous chemicals (e.g., EtO, formaldehyde) Aeration requirements and exposure limits Interview staff regarding PPE use and emergency procedures for leaks or exposures Observe practices to confirm: Proper use of PPE (e.g., respirators, gloves) during loading/unloading Adequate ventilation and monitoring for hazardous gas levels Validation/documentation of cycle parameters (e.g., time, temperature, gas concentration) Review personnel files for evidence of: Training (initial, annual, updates) on chemical sterilizer or AED operation/safety Validation of competency (initial, ongoing per facility policy).</p>
7-D-4	A	B	C	Gas sterilizers and automated endoscope reprocessors (AER) must be vented and tested for occupational exposure in accordance with the manufacturer's specifications.	<p>Verify the safe and effective use of gas sterilizers and automated endoscope reprocessors to protect staff from occupational exposure to hazardous agents.</p> <p>Evaluating Compliance: Review policies for alignment with manufacturer instructions for use (IFU), including:</p>

Standard ID	Anesthesia Class			Standards / Regulatory Reference	Interpretive Guidance
					<p>Safety protocols for handling hazardous chemicals (e.g., EtO, formaldehyde) Aeration requirements and exposure limits (when applicable) Maintenance, safety testing, and validation protocols Review documents for evidence of: Testing for hazardous gas/chemical exposure per IFU Corrective actions if exposure limits are exceeded Interview staff regarding PPE use and emergency procedures for leaks/exposures Observe practices to confirm: Use of PPE (e.g., respirators, gloves) and engineering controls (e.g., ventilation, closed-system transfer) Adequate ventilation and monitoring</p>
7-D-5	A	B	C	<p>The facility monitors the sterilization cycle's effectiveness in accordance with nationally and internationally recognized standards of practice and in conjunction with the manufacturer's instructions for use. This includes but is not limited to:</p> <ul style="list-style-type: none"> • Monitoring each sterilizer load for the appropriate mechanical indicators (e.g., time, temperature, and pressure); • Using type 1 (external) and type 5 (internal) chemical indicators; • Weekly biological indicator (spore test) for each sterilizer; • Using a biological indicator for every load containing implantable items; and • Recording evidence of sterilization assurance monitoring for every load, and any corrective action is documented. 	<p>Verify the facility minimizes infection risk by ensuring the sterilization process for critical equipment adheres to the manufacturer's instructions for use (IFU) and is rigorously monitored.</p> <p>Evaluating Compliance: Review policies for alignment with AAMI ST79 or equivalent International sterile processing and steam sterilization standards, and manufacturer's IFU (device specific) Review sterilization recordkeeping, for inclusion of: Sterilizer identification and cycle type (e.g., wrapped) Load contents, control number Device-specific physical monitors (time, temperature, pressure) were met (by printout or manual log) Assessment of chemical indicators Results of biological indicators (at least weekly, mandatory with any load containing implants) Operator ID Interview staff regarding sterilizer operation and response to indicator failures/parameter deviations Observe staff for correct chemical indicator placement and interpretation Confirm chemical indicators are used per manufacturer recommendations: External: Type 1 tape/labels on every package or rigid container Internal: Type 5 (integrating) indicators inside packs/containers Bowie-Dick: Type 2 daily testing for dynamic-air-removal sterilizers.</p>
7-D-6	A	B	C	<p>Sterile instruments and supplies are packaged according to the manufacturer's instructions for use (IFU) and sealed effectively. Self-sealing peel pouches must be folded on the crease and may only be double-pouched when the process is validated by the manufacturer.</p>	<p>Verify sterile instruments are packaged safely and consistently with manufacturer instructions to minimize infection risks. Proper packaging, sealing, and labeling are critical to maintaining sterility until point of use.</p> <p>Evaluating Compliance: Review policies to ensure they require:</p>

Standard ID	Anesthesia Class			Standards / Regulatory Reference	Interpretive Guidance
					<p>Use of FDA-cleared packaging materials Adherence to manufacturer's instructions for use (IFU) for packaging Interview staff regarding instrument positioning (open vs. closed) and evaluating compromised packages Inspect a variety of sterilized packages to ensure packages: Are not overfilled (allowing penetration of sterilant) Contain hinged instruments in open, unlocked position Are sealed effectively (no gaps or compromised seals) Are only double-pouched if validated by the manufacturer (with the inner pouch unfolded).</p>
7-D-7	A	B	C	<p>Each sterilized pack is labeled with the date of sterilization and, when applicable, with the expiration date. When the facility has more than one sterilizer, labels must also identify the sterilizer used.</p>	<p>Verify sterilized instrument packages are clearly and accurately labeled to maintain sterility, support tracking, and enable recall if needed.</p> <p>Evaluating Compliance: Interview staff regarding expiration date protocols (e.g., event-related, time related) and recall process Inspect sterile packages for, at a minimum, labeling requirements that include: Sterilizer identification (if more than one in use) Cycle or load number identification Date of sterilization and Expiration date (if applicable based on packaging IFU) Initials of staff that prepared the package Number of re-sterilizations (if applicable for reprocessed devices approved for a limited number of cycles) Confirm labels are affixed securely and do not compromise packaging integrity (e.g., no punctures or adhesive over seals).</p>
7-D-9	A	B	C	<p>Comprehensive monitoring records that include quality control are retained for the sterilization or other disinfection process and should be reviewed and stored for a minimum of three (3) years.</p>	<p>Verify sterilization processes are monitored to confirm sterility assurance and comprehensive records are maintained to support traceability and recall efforts.</p> <p>Note: Logs must be retained per facility policy (typically ≥3 years). Electronic record systems must ensure data integrity and accessibility.</p> <p>Evaluating Compliance: Review policies for the number of years sterilization records must be kept Review documents for evidence of comprehensive recordkeeping, including: Sterilizer identification and cycle type (e.g., wrapped) Load contents, control number Device-specific physical monitors (time, temperature, pressure) were met (by printout or manual log) Assessment of chemical indicators Results of biological indicators (at least weekly, mandatory with loads containing implants)</p>

Standard ID	Anesthesia Class			Standards / Regulatory Reference	Interpretive Guidance
					<p>Operator ID Review documents for evidence of tracking process for the number of re-sterilizations when applicable (e.g., reusable LMA, breast implant sizers, some liposuction cannulas).</p>
7-D-10	A	B	C	<p>There is a written policy and procedure for the management of a positive biological indicator.</p>	<p>Verify positive biological indicators are managed promptly and effectively to mitigate infection risks. Facilities must have protocols for tracking, recalling, and reprocessing instruments exposed to a failed sterilization cycle.</p> <p>Evaluating Compliance: Review policies for procedures that align with the facility's adopted recognized infection prevention and control guidelines and the manufacturer's IFU for the biological indicator (BI) to include: <ul style="list-style-type: none"> Immediate steps to take upon a positive BI (e.g., remove sterilizer from use, ASAP repeat BI testing, etc.) Procedures for investigating the cause (e.g., mechanical failure, operator error) Protocols for recalling/reprocessing affected instruments Review documents for records of past BI failures: <ul style="list-style-type: none"> To confirm response effectiveness and compliance with policy timelines To ensure recalled instruments are reprocessed Affected sterilizer was not used until repaired, challenged, and cleared for use Interview staff regarding positive BI management protocols and recall process.</p>
7-D-11	A	B	C	<p>Immediate use steam sterilization (IUSS) is not done on a routine or frequent practice.</p>	<p>Verify the facility minimizes infection risk by restricting Immediate-Use Steam Sterilization (IUSS) to emergency situations only. IUSS is not a substitute for inadequate instrument inventory or planning. Strict documentation and compliance with manufacturer instructions are required to ensure patient safety.</p> <p>Evaluating Compliance: Review policies for directives to: <ul style="list-style-type: none"> Limit IUSS to validated emergencies (e.g., dropped instrument) Complete all cleaning steps per the manufacturer's IFU Use only IUSS-approved containers Review IUSS records for evidence of: <ul style="list-style-type: none"> Frequency and justification (e.g., emergency, contaminated item) Evidence of misuse (e.g., routine use due to insufficient instruments) Interview staff regarding acceptable IUSS scenarios and documentation requirements Observe IUSS practices (if occurring) for compliance with manufacturer IFUs and aseptic techniques Confirm IUSS is not used for: <ul style="list-style-type: none"> Implants (unless documented emergency with no alternative) Prion-related contamination Non-validated cycles. </p>

Standard ID	Anesthesia Class			Standards / Regulatory Reference	Interpretive Guidance
Sub-section E: High-Level Disinfection (HLD)					
7-E-1	A	B	C	<p>High-level disinfection is performed upon heat-sensitive endoscopic equipment and other medical devices classified as semi-critical, but only when recommended by the manufacturer's instructions for use (IFU).</p>	<p>Verify the facility minimizes infection risk by ensuring semi-critical equipment undergoes high-level disinfection (HLD) or sterilization with strict adherence to the manufacturer's instructions for use (IFU). HLD chemicals must be monitored and replaced per manufacturer recommendations</p> <p>Note: Prioritize sterilization over HLD for rigid scopes when feasible.</p> <p><u>Evaluating Compliance:</u> Review policies for: Alignment with recognized infection prevention and control guidelines Directive to follow IFU for each device (e.g., flexible endoscopes, laryngoscope blades) Review processing logs for evidence of: HLD/sterilization cycles (e.g., time, temperature, chemical concentration) align with IFU Testing of disinfectant efficacy (e.g., minimum effective concentrations) Traceability of devices to patients (in case of failure) Interview staff regarding: Definition of semi-critical devices Device-specific IFUs (e.g., immersion time, concentration, rinse steps for HLD) Handling and storage post-processing to prevent recontamination.</p>
7-E-2	A	B	C	<p>Endoscopes are processed in accordance with a written policy and procedure consistent with recognized guidelines and standards of practice. The policy must address how scopes are treated at the point of use, transported, cleaned, high-level disinfected, and stored.</p>	<p>Verify the facility maintains compliance with comprehensive policy to ensure flexible endoscopes are reprocessed according to current recognized infection prevention and control guidelines and device-specific manufacturer's instructions for use (IFU). Staff competency must be validated.</p> <p><u>Evaluating Compliance:</u> Review policies for: Recognized infection prevention and control guidelines the facility has adopted Point-of-use pre-cleaning (immediately post-procedure to prevent biofilm) Leak testing (after use, before manual cleaning) Manual cleaning (brushing/flushing channels within IFU-specified timeframes) Definition of "delayed processing" with additional steps (e.g., extended cleaning) Visual inspection (using magnification) High-level disinfection (using validated chemicals and equipment) or sterilization process Storage (vertical hanging or horizontal per IFU, ≥3 feet from sinks) Review documents for evidence of: Disinfectant testing (minimum effective concentration) HLD parameters being met (printouts) Scope identification, patient traceability, and operator initials Automated endoscope reprocessor (AER) maintenance</p>

Standard ID	Anesthesia Class			Standards / Regulatory Reference	Interpretive Guidance
					Observe staff regarding reprocessing steps, timing constraints, PPE use Review personnel files for validation of competency for manual cleaning, AER operation, and chemical handling.
Sub-section F: Cleaning					
7-F-2	A	B	C	<p>The entire operating room suite is cleaned and disinfected according to an established facility policy and procedure, based on industry standards, and includes, at a minimum:</p> <ul style="list-style-type: none"> • Cleaning schedule • Process for cleaning between cases • Process for terminal cleaning after the last case of the day • Use of intermediate-level, medical-grade disinfectants EPA-registered as virucidal, bactericidal, tuberculocidal, and fungicidal. 	<p>Verify the facility thoroughly cleans and disinfects the entire operating room suite using EPA-registered, or internationally, regulatory-approved, disinfectant intermediate-level disinfectants to prevent cross-contamination and healthcare-associated infections.</p> <p>Evaluating Compliance: Review policies for alignment with recognized infection prevention and control guidelines (e.g., AORN, CDC, WHO), including: Procedures to clean and disinfect all OR suite surfaces between procedures and during terminal cleaning Specification to use EPA-registered, or internationally, regulatory-approved disinfectant, intermediate-level disinfectants Review cleaning logs to ensure cleaning is performed (first of day, in between patients, terminal) Interview staff regarding cleaning protocols (e.g., sequence, contact times) and PPE use Observe staff cleaning the operating room in between patients Inspect disinfectants for: EPA or internationally equivalent registration number (e.g., "EPA Reg. No. XXXX-XX") Claims of efficacy against healthcare-associated pathogens (e.g., TB, HBV, HIV) Confirm staff access to manufacturer's instructions for use (e.g., correct dilution, contact time).</p>
7-F-3	A	B	C	<p>There is a written policy for cleaning spills, especially spills that may contain blood-borne pathogens.</p>	<p>Verify the facility has safeguards in place to protect healthcare workers from exposure to bloodborne pathogens, through effective decontamination procedures for spills of blood or other potentially infectious materials (OPIM).</p> <p>Evaluating Compliance: Review policies for: Procedure for decontaminating gross spills of blood or OPIM Directive to comply with OSHA's Bloodborne Pathogens Standard (29 CFR 1910.1030) Confirm inclusion of: Only using appropriate EPA-registered tuberculocidal disinfectant or manually-diluted bleach solution (e.g., 1:10 dilution for blood spills) Steps for containment, cleanup, and disposal of contaminated materials Required personal protective equipment (e.g., gloves, gown, face protection) Interview staff to assess: Awareness of the spill decontamination procedure Knowledge of how to access and use PPE and cleanup supplies</p>

Standard ID	Anesthesia Class			Standards / Regulatory Reference	Interpretive Guidance
					<p>Understanding of post-exposure protocols (e.g., reporting, prophylaxis) Review training records to ensure bloodborne pathogen training is documented.</p>
7-F-4	A	B	C	<p>All blood and body fluid spills are cleaned using medical-grade germicides that are virucidal, bactericidal, tuberculocidal, and fungicidal. A spill kit is available and readily accessible.</p>	<p>Verify safeguards are in place to protect workers from health hazards associated with blood and body fluid spills through the use of properly stocked, accessible spill kits and EPA-registered or internationally, regulatory-approved germicides. Staff must be trained to respond promptly and safely to spills.</p> <p>Evaluating Compliance: Review policies for blood/body fluid spill cleanup procedures that includes: <ul style="list-style-type: none"> Use of an EPA-registered or internationally, regulatory-approved disinfectant germicide effective against viruses, bacteria, tuberculosis, and fungi Step-by-step cleanup and disposal instructions Required PPE (e.g., gloves, gown, face shield, mask) Interview staff regarding awareness of spill kit locations and protocols Observe staff cleaning spills (if applicable) Confirm spill kits are accessible in high-risk areas (e.g., procedure rooms, decontamination areas) and stocked with: <ul style="list-style-type: none"> Sufficient absorbent materials (e.g., granules, pads) PPE (gloves, gown, eye protection, mask) Tools (e.g., scraper, brush, biohazard bags) EPA-registered or internationally, regulatory-approved disinfectant (e.g., tuberculocidal solution). </p>
7-F-5	A	B	C	<p>Facility policies and procedures have been developed for use by housekeeping personnel for cleaning floors, tables, walls, ceilings, counters, furniture, and fixtures of the operating suite.</p>	<p>Verify effective cleaning of the facility to minimize infection risks, whether housekeeping is performed internally or by a contracted vendor. Contracted services must be overseen through the facility's quality improvement program to ensure compliance with standards.</p> <p>Evaluating Compliance: Review policies for: <ul style="list-style-type: none"> Cleaning frequencies, methods, and agents for all areas (e.g., patient care zones, waiting areas, restrooms) Use of EPA-registered disinfectants appropriate for each surface or application Procedures for terminal cleaning Review cleaning logs to verify completion per policy Interview staff (internal or contract) for knowledge of cleaning protocols (in between patients, terminal) If cleaning services are contracted, review service oversight, including: <ul style="list-style-type: none"> Review the written contract to ensure it: <ul style="list-style-type: none"> Details specific areas to be cleaned, frequencies, and methods Requires the vendor to comply with all applicable standards (e.g., CDC, OSHA, QUAD A) </p>

Standard ID	Anesthesia Class			Standards / Regulatory Reference	Interpretive Guidance
					<p>Includes validation of staff competence and training</p> <p>Confirm the contract is integrated into the facility's quality improvement (QAPI) program, with processes for:</p> <ul style="list-style-type: none"> Regular audits of cleaning effectiveness (e.g., visual inspection, ATP testing) Corrective actions for non-compliance.
7-F-6	A	B	C	<p>Instrument handling and reprocessing areas are cleaned and maintained.</p>	<p>Verify the facility's instrument handling and reprocessing areas are consistently cleaned and maintained to minimize contamination risks and support effective sterilization/disinfection processes.</p> <p>Evaluating Compliance:</p> <ul style="list-style-type: none"> Review cleaning logs to verify completion per policy (e.g., end of day, weekly deep cleaning) Interview staff regarding cross-contamination risks and cleaning protocols for reprocessing areas Inspect decontamination, preparation, and sterilization areas for evidence of: <ul style="list-style-type: none"> Organized surfaces and absence of visible soil, dust, or debris Segregation of clean and dirty zones.

SECTION 8: CLINICAL RECORDS

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
Sub-section A: General Clinical Records					
8-A-1	A	B	C	<p>The facility must maintain separate, complete, comprehensive and accurate clinical records to ensure adequate patient care.</p> <p>§416.47 Condition</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
8-A-2	A	B	C	<p>The ASC must ensure each patient has the appropriate pre-operative and post-operative assessments completed and that all elements of the discharge requirements are completed.</p> <p>§416.52 Condition</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
8-A-3	A	B	C	<p>The facility must develop and maintain a system for the proper collection, storage, and use of clinical records.</p> <p>§416.47(a) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
8-A-4	A	B	C	<p>Clinical records must be kept secure and confidential, consistent with HIPAA regulations.</p>	<p>Verify patient health information (PHI), whether in hard copy or electronic form, is safeguarded to maintain confidentiality, integrity, and security in full compliance with HIPAA regulations and other applicable federal, state, and local laws.</p> <p><u>Evaluating Compliance:</u></p> <p>Review policies for:</p> <ul style="list-style-type: none"> PHI access, storage, and disposal (e.g., shredding, digital wiping) procedures Breach response protocols (including patient notification) <p>Interview staff regarding HIPAA security protocols and mechanism for reporting suspected breaches</p> <p>Perform a security assessment, including:</p> <ul style="list-style-type: none"> Hard copy medical records are: <ul style="list-style-type: none"> Stored in secure, locked locations (e.g., cabinets, rooms) Protected from unauthorized access, environmental hazards (e.g., fire, water), and theft Only authorized for approved personnel access (e.g., clinicians, designated staff)

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Electronic medical records utilize:</p> <ul style="list-style-type: none"> Unique user authentication (e.g., passwords, PINs, biometrics) Role-based access controls limiting PHI to authorized staff Encryption for data at rest and in transit Audit trails tracking all access and modifications.
8-A-6	A	B	C	<p>Electronic health records (EHR) must comply with security and privacy obligations under current HIPAA regulations.</p>	<p>Verify electronic health records (EHRs) are protected through robust security measures that guarantee confidentiality, integrity, and availability in full compliance with HIPAA regulations.</p> <p>Evaluating Compliance:</p> <p>Review policies for security measures:</p> <ul style="list-style-type: none"> User authorization and role-based access permissions Procedures for responding to security incidents or breaches Release of information <p>Interview staff regarding protecting secure passwords and recognizing/reporting potential security threats</p> <p>Verify access to the EHR requires:</p> <ul style="list-style-type: none"> Strong passwords (e.g., complexity requirements, regular updates)
8-A-7	A	B	C	<p>The ASC must maintain a clinical record for each patient. Every record must be accurate, legible, and promptly completed.</p> <p>§416.47(b) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
8-A-9	A	B	C	<p>Clinical records must be retained the number of years as required by state and/or federal law; or a minimum of three (3) years to comply with the QUAD A three-year survey cycle.</p>	<p>Verify clinical records are retained for at least the minimum period required by QUAD A (3 years) and state/national law, whichever is longer. Records may be maintained in paper, electronic, or hybrid format, with secure destruction processes for paper records after conversion or retention expiration.</p> <p>Evaluating Compliance:</p> <p>Review policies for mandatory retention \geq 3 years (or longer state/national-mandated period) for active/inactive records</p> <p>Confirm procedures for destroying paper-based records, that include:</p> <ul style="list-style-type: none"> Use of secure methods (e.g., shredding, incineration) to protect patient privacy Authorization protocols (e.g., designated personnel, oversight) <p>Confirm procedures for EMR conversions ensure paper records are destroyed only after:</p> <ul style="list-style-type: none"> Successful data migration and validation A defined, reasonable timeframe <p>Interview staff regarding retention requirements and destruction protocols, roles in destruction or conversion.</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
8-A-10	A	B	C	Clinical records are maintained and easily accessible by the accredited facility.	<p>Verify clinical records are maintained in an organized system (electronic, paper, or hybrid) and are readily accessible to authorized personnel for patient care, continuity of care, and regulatory purposes.</p> <p>Evaluating Compliance: Interview staff regarding record storage and retrieval processes during emergencies and transfers Confirm record maintenance and organization: Hard copy: records logically organized (e.g., by patient name/ID, date) and stored in a secure locations Electronic: system allows efficient searching and retrieval (e.g., by name, MRN, date of service) Confirm records are retrievable within a reasonable timeframe (e.g., minutes for active patients, hours for archived records) by requesting access to a clinical record randomly during survey activities.</p>
Sub-section B: Pre-Operative Documentation					
8-B-1	A	B	C	Clinical records must contain patient identification. §416.47(b)(1) Standard	SOM Appendix L - Guidance for Surveyors: ASCs
8-B-2	A	B	C	A pre-operative surgical safety checklist must be used for each patient and noted in the patient record.	<p>Verify a standardized preoperative safety checklist is consistently used, with each patient, to ensure critical safety issues are addressed before anesthesia induction, skin incision, and prior to the patient leaving the operating room. Use of safety checklists promotes teamwork, reduces errors, and enhances patient safety.</p> <p>Evaluating Compliance: Review checklist used by the facility (e.g., WHO, facility-specific) for all three (3) phases and key requirements: Before anesthesia induction (e.g., identity/procedure confirmation, site mark, anesthesia check, pulse oximetry, allergy/airway/blood loss risks) Before skin incision (e.g., team introductions, timeout for procedure/site, antibiotic timing, critical event anticipation, sterility/equipment/counts confirmation) Before patient leaves the OR (e.g., procedure name, final counts, specimen labeling, recovery concerns) Interview staff regarding use of safety checklist, adherence to timeout protocols, and communication norms Observe checklist use in procedures for consistency and engagement Review clinical records to confirm completion of the checklist during each three (3) phases.</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
8-B-3	A	B	C	<p>The ASC must develop and maintain a policy that identifies those patients who require a medical history and physical examination prior to surgery. The policy must:</p> <ul style="list-style-type: none"> • Include the time frame for medical history and physical examination to be completed prior to surgery. • Address, but is not limited to, the following factors: patient age, diagnosis, the type and number of procedures scheduled to be performed on the same surgery date, known comorbidities, and the planned anesthesia level. • Be based on any applicable nationally recognized standards of practice and guidelines, and any applicable State and local health and safety laws. <p>§416.52(a)(1) Standard §416.52(a)(1)(i) Standard §416.52(a)(1)(ii) Standard §416.52(a)(1)(iii) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
8-B-6	A	B	C	<p>The pre-operative clinical record includes a medical evaluation when warranted by the patient's medical history and/or procedure to be performed or is required by the facility policy.</p>	<p>Verify the facility implements a comprehensive medical clearance policy to ensure patients are deemed healthy enough for procedures in the outpatient setting, helping increase patient safety and improve surgical outcomes. The written policy must address which patients require comprehensive evaluation by a primary care physician (or specialist) to identify and manage pre-existing conditions or risks, and the timeline for which such clearance lasts.</p> <p>Evaluating Compliance: Review policies for: Patient risk categories/criteria requiring clearance (e.g., chronic diseases, taking blood thinners) How long the medical clearance may be utilized (e.g., 30 days) Interview staff regarding process for receipt of the medical clearance, attachment to patient record Review clinical records (of patients meeting criteria) to ensure policy is followed.</p>
8-B-7	A	B	C	<p>The pre-operative clinical record includes significant medical history and a physical examination covering the organs and systems commensurate with the</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<p>procedure(s) are recorded on all patients and placed in the clinical record prior to the surgical procedure.</p> <p>§416.47(b)(2) Standard §416.52(a)(4) Standard</p>	
8-B-8	A	B	C	<p>Upon admission, each patient must have a pre-operative assessment completed by a physician who will be performing the surgery or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and facility policy.</p> <p>The pre-surgical assessment must include documentation of any allergies to drugs and biologicals. This assessment must be placed in the patient's clinical record prior to the surgical procedure.</p> <p>§416.52(a)(2) Standard §416.52(a)(3) Standard §416.52(a)(4) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
8-B-9	A	B	C	<p>The pre-procedural operative assessment includes documentation regarding special needs such as physical impairments, disabilities, religious and/or ethnic concerns.</p>	<p>Verify each patient's unique needs (e.g., physical, cognitive, cultural, religious, communication) are identified, documented, and addressed prior to the procedure to deliver safe, personalized, and equitable care.</p> <p>Evaluating Compliance: Interview staff regarding assessing special needs and resource availability (e.g., interpreters, assistive devices) Observe patient interactions to ensure needs are respected and met Review clinical records for documentation of: <ul style="list-style-type: none"> Mobility limitations (e.g., need for assistance, bariatric equipment) Sensory impairments (e.g., hearing, vision deficits) Cognitive or behavioral conditions (e.g., dementia, anxiety) Language preferences or communication barriers (e.g., need for interpreter) Cultural or religious considerations (e.g., dietary restrictions, gender-specific preferences) Confirm staff address unique needs (e.g., use of interpreters, adaptive equipment, additional support staff).</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
8-B-10	A	B	C	<p>The pre-operative clinical record includes documentation of blood pressure, pulse, respiration and temperature as taken prior to the operation.</p>	<p>Verify baseline vital signs(VS) (blood pressure, pulse, respirations, and temperature) are obtained and documented upon patient admission to establish a reference point for monitoring during and after the procedure.</p> <p>Evaluating Compliance: Review policies for requirement to document baseline VS at admission (prior to sedation or procedure) Observe staff during VS acquisition to confirm proper technique and timely documentation Review clinical records to ensure all four (4) VS are documented prior to sedation or start of procedure.</p>
8-B-11	A	B	C	<p>The pre-operative clinical record includes documentation of all pre-operative medications and intravenous fluids given to a patient. This record includes the patient's name, date, time, dose, and route of administration.</p>	<p>Verify all medications and intravenous fluids administered are accurately recorded to ensure patient safety, provide a legal record, and facilitate communication among the healthcare team.</p> <p>Evidence of Compliance: Observe staff administering preoperative medications and cross-check documentation for accuracy Review clinical records to confirm the documentation standard is met, including: name, date/time, dose, and route of administration.</p>
8-B-13	A	B	C	<p>The pre-operative clinical record includes documentation of any allergies and abnormal drug reactions.</p> <p>§416.47(b)(5) Standard §416.52(a)(3) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
8-B-14	A	B	C	<p>The pre-operative clinical record includes documentation of current medications.</p>	<p>Verify all current patient medications (including prescriptions, over-the-counter drugs, supplements, and herbals) are accurately documented in the clinical record to support safe medication management and avoid adverse interactions.</p> <p>Evaluating Compliance: Interview staff regarding: Procedures for obtaining and updating medication histories Understanding of the importance of including non-prescription products. Observe staff for medication history collection during patient intake Review clinical records to verify a complete and current medication list with: Drug name, dose, frequency, and route for each medication Prescription, OTC, and supplement/herbal products Documentation source Check for reconciliation at admission, transfer, and discharge (if applicable).</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
8-B-15	A	B	C	The pre-operative clinical record includes documentation of medical history.	<p>Verify the patient's complete and accurate medical history is documented in the clinical record to inform safe decision-making, assess risks, and guide appropriate care throughout the procedural experience.</p> <p>Evaluating Compliance: Interview staff regarding Understanding of the required elements of a medical history Processes for obtaining, documenting, and updating the history Observe history-taking during patient intake (if applicable) Review clinical records to ensure the medical history includes (as applicable to the procedure): Chronic conditions Previous surgeries and hospitalizations. Family history Social history Obstetric/gynecologic history Confirm history is patient-specific, current, and signed/authenticated by the authorized provider.</p>
8-B-17	A	B	C	The pre-operative clinical record includes documentation of any previous operations.	<p>Verify the patient's history of previous operations is accurately documented in the clinical record to inform care planning and support safe delivery of services.</p> <p>Evaluating Compliance: Observe history-taking during patient intake for thoroughness. Review clinical records to ensure the record includes a list of previous surgeries Confirm documentation is current and from appropriate sources.</p>
8-B-18	A	B	C	The pre-operative clinical record includes documentation of perioperative bleeding risk, including medical conditions and anticoagulant medication taken up to the day of the operation.	<p>Verify any factors that may increase a patient's risk of perioperative bleeding are thoroughly documented in the clinical record. This allows the care team to take appropriate precautions to minimize bleeding risks and respond effectively should bleeding occur.</p> <p>Evaluating Compliance: Interview staff regarding: Understanding of factors that contribute to bleeding risk Procedures for assessing, documenting, and communicating bleeding risks (e.g., safety checklist) Processes for managing patients with identified bleeding risks Observe staff updating bleeding risk on the surgery checklist (if possible and applicable) Review clinical records to verify documentation includes: Use of anticoagulants, antiplatelets, or other medications that affect coagulation Known bleeding or clotting disorders Relevant medical history such as liver disease, renal impairment, or hematologic conditions</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Family history of bleeding disorders Previous surgical or dental bleeding complications (as applicable) Confirm that the plan of care addresses any identified bleeding risks (if applicable).</p>
8-B-19	A	B	C	<p>A written pregnancy testing policy must be in place that requires discussion and documentation of the issue with each patient, as appropriate.</p>	<p>Verify the pregnancy status (of patients of childbearing potential) is appropriately discussed, documented, and considered in procedural planning to promote patient safety and informed decision-making in accordance with the facility policy.</p> <p>Evaluating Compliance: Review policies for directive to assess/document pregnancy status (as applicable), including: Testing criteria (e.g., all females of childbearing age unless exempted by hysterectomy, menopause, etc.) Methods for discussion and testing (e.g., patient-reported history, point-of-care testing) Procedures for documenting patient discussion, declinations, or test results Interview staff regarding when/how to test for pregnancy status and process for positive results Review clinical records for: Documentation of pregnancy status discussion, testing, and results Evidence of informed decision-making for positive results (e.g., procedure timing, modifications).</p>
8-B-20	A	B	C	<p>The pre-operative clinical record includes evidence that treating physicians or consultants are contacted in cases when warranted by the history and physical examination.</p>	<p>Verify consultations with treating physicians or specialists are initiated and documented when the history and physical reveals conditions that could impact procedural safety.</p> <p>Evaluating Compliance: Interview staff regarding: Criteria for initiating consultations Procedures for communicating and documenting consultant input Processes for managing time-sensitive consultations Review clinical records to verify documentation includes: Identification of conditions warranting consultation Evidence of communication with relevant physicians or specialists Recommendations from consultants incorporated into the plan of care Confirm consultations occur prior to the procedure (when possible) and timeliness of clearance abides by the facility policy.</p>
8-B-22	A	B	C	<p>The pre-operative clinical record includes pre-operative diagnostic studies and laboratory procedures (entered before surgery), if performed.</p> <p>§416.47(b)(3) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
8-B-23	B	C		<p>For patients receiving general anesthesia or surgical procedures scheduled for 60 minutes or longer or for patients with a history of venous thromboembolism (VTE), the pre-operative clinical record includes a written screening protocol for VTE risk. This protocol and assessment tool are to be placed in the facility manual for reference.</p>	<p>Verify all patients undergoing general anesthesia, procedures lasting 60 minutes (or longer), or those with a history of venous thromboembolism (VTE), receive a standardized VTE risk assessment. Use evidence-based tools like the Caprini score to identify risk levels and implement appropriate preventive measures to reduce VTE occurrence.</p> <p>Evaluating Compliance Review policies for: Approval of a validated VTE risk assessment tool (e.g., Caprini score) Requirement of VTE risk assessment for eligible patients outlining prophylactic interventions (as applicable) Interview staff regarding VTE risk factors, assessment tools, and intervention protocols Observe care to ensure care includes VTE prevention protocols (if possible and applicable) Review clinical records for: Documentation of VTE risk assessment prior to procedure For high-risk patients, cross-check that interventions (e.g., pharmacological prophylaxis, mechanical compression devices, early mobilization) are implemented and documented.</p>
8-B-24	B	C		<p>The surgeon/proceduralist and the licensed or qualified anesthesia professional concur on the appropriateness of the procedures performed at the facility based on the medical status of the patient, age and physiological appropriateness of the patient, and qualifications of the providers and the facility resources. This concurrence must be documented in the clinical record.</p>	<p>Verify surgical team communication exists to ensure procedures are appropriate for the patient's medical status, age, and physiological needs. The surgeon or proceduralist and anesthesia professional must concur on this appropriateness, and their agreement must be documented per facility policy. This requirement does not apply if the surgeon or proceduralist also administers anesthesia or if an RN administers sedation under their direct orders.</p> <p>Evaluating Compliance Review policies for process for how/where concurrence is documented (e.g., pre-op checklist, time-out form) Interview staff regarding understanding of concurrence/documentation process and exemptions Review clinical records for documentation of concurrence (e.g., check box, initialed entry) for all applicable cases.</p>
8-B-25	A	B	C	<p>Immediately before surgery a physician must examine the patient to evaluate the risk of the procedure to be performed.</p> <p>§416.42(a)(1) Standard §416.42(a)(1)(i) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
8-B-26	A	B	C	<p>Immediately before surgery a physician or anesthesia professional as defined at 42 CFR 410.69(b) of this chapter must examine the patient to evaluate and document the risk of anesthesia.</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				§416.42(a)(1) Standard §416.42(a)(1)(ii) Standard	
Sub-section C: Informed Consent					
8-C-3		B	C	The written informed consent provides consent for the administration of anesthesia or sedatives under the direction of the surgeon, anesthesiologist, or CRNA.	Verify a properly executed informed consent for anesthesia or sedation is obtained and documented prior to the procedure. The consent process must involve the anesthesia professional when anesthesia care is discussed, whether through a separate consent form or integrated into the surgical consent. Evaluating Compliance: Interview staff regarding informed consent requirements for anesthesia or sedation Observe staff attaining and documenting consent for sedation or anesthesia Review clinical records for evidence of properly executed anesthesia/sedation preoperatively (when applicable) If the anesthesia consent is integrated into the surgical consent, ensure the anesthesia professional participated in the consent process and discussed the anesthesia care plan with the patient (or representative).
8-C-4	A	B	C	The patient signs a consent form if research protocols, videography, or photography are to take place.	Verify patients (or representatives) retain the right to withdraw consent, at any time, for research protocols, videography, or photography used for marketing purposes. This standard does not apply to audiovisual media used solely for medical documentation, such as endoscopic or colonoscopic procedures. Evaluating Compliance: Review policies regarding patient consent for marketing-related videography or photography to ensure: <ul style="list-style-type: none"> • Policies explicitly state the right to withdraw consent at any time • Policies distinguish between marketing use and medical documentation use Interview staff regarding consent requirements for media used for marketing and consent withdrawal process Interview patients regarding giving consent and withdrawal processes Review clinical records for evidence of consent for marketing-related audiovisual activities, that includes: <ul style="list-style-type: none"> • Documentation of processes to withdraw consent • Verification of consent for use in marketing-related media (when applicable).
8-C-7	A	B	C	Properly executed informed consent forms are always obtained, from the patient or, if applicable, the patient's representative, which includes:	SOM Appendix L - Guidance for Surveyors: ASCs

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<ul style="list-style-type: none"> • A description of the proposed surgery, including the anesthesia to be used; • The indications for the proposed surgery; • Risks and benefits; • Treatment alternatives; • The surgeon/proceduralist by name to perform surgery; • Whether physicians other than the operating practitioner will be performing important tasks related to the surgery; and • Whether, as permitted by State law, qualified medical practitioners who are not physicians will perform important parts of the surgery or administer the anesthesia, and if so, the types of tasks each type of practitioner will carry out. <p>§416.47(b)(7) Standard</p>	
Sub-section D: Advanced Directives					
8-D-1	A	B	C	<p>The ASC must provide the patient or, as appropriate, the patient's representative with written information concerning its policies on advance directives, including a description of applicable State health and safety laws, and, if requested, official State advance directive forms.</p> <p>§416.50(c) Standard §416.50(c)(1) Standard</p>	SOM Appendix L - Guidance for Surveyors: ASCs
8-D-2	A	B	C	<p>The ASC must inform the patient or, as appropriate, the patient's representative or surrogate of the patient's right to make informed decisions regarding the patient's care.</p> <p>§416.50(c) Standard §416.50(c)(2) Standard</p>	SOM Appendix L - Guidance for Surveyors: ASCs

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
8-D-3	A	B	C	<p>The ASC must document in a prominent part of the patient's current clinical record, whether or not the individual has executed an advance directive.</p> <p>§416.50(c) Standard §416.50(c)(3) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
Sub-section E: Laboratory, Pathology, X-Ray, Consultation, Treating Physician Reports, Etc.					
8-E-1	A	B	C	<p>Reports of laboratory, pathology, X-ray, consultation, treating physician, and any other diagnostic tests are maintained in the clinical record and are accessible for review prior to the procedure.</p>	<p>Verify all relevant reports (e.g., diagnostic results, consultations, and pre-operative assessments) are accessible in the medical record prior to the procedure. Reports (either hard copy or electronic) must be available for review by the procedural team to support safe patient care.</p> <p><u>Evaluating Compliance</u> Review policies for directive that all reports to be available in the clinical record before the procedure Review clinical records to confirm that all required reports are present/accessible prior to the procedure and have been reviewed.</p>
8-E-2	A	B	C	<p>All laboratory results must be reviewed and initialed by the anesthesia professional, registered nurse, or surgeon/proceduralist within one (1) week of receipt of the results.</p> <p>If a registered nurse reviews laboratory results and the results are abnormal, documentation must be present in the clinical record that the anesthesia professional and surgeon/proceduralist are aware of the abnormality.</p>	<p>Verify all laboratory results are reviewed, and abnormal findings are acknowledged and addressed by the anesthesia professional or surgeon/proceduralist. Documentation must clearly reflect review of results, including electronic authentication or initials for abnormal values, to demonstrate timely intervention and communication among the care team.</p> <p><u>Evaluating Compliance:</u> Review policies for: <ul style="list-style-type: none"> Process for reviewing laboratory results, including identification of abnormal values and required actions Directive that abnormal results must be reviewed by the anesthesia professional or surgeon/proceduralist Documentation standards for normal/abnormal results, including electronic authentication requirements Interview staff regarding laboratory review process, documentation requirements, escalating abnormal results Review clinical records to verify: <ul style="list-style-type: none"> All laboratory results are present If RN reviews results first, there is evidence that abnormal findings were communicated to the provider Abnormal results are flagged/reviewed by either anesthesia professional or surgeon/proceduralist. </p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
8-E-4	A	B	C	<p>All other reports, such as pathology reports and medical clearance reports, must be documented as reviewed by the surgeon/proceduralist.</p>	<p>Verify the surgeon or proceduralist reviews all relevant reports prior to the procedure, with documentation of this review clearly reflected in the medical record. The facility must verify critical information has been assessed and considered for safe patient care.</p> <p>Evaluating Compliance: Review policies for: Process for reviewing all medical reports (e.g., pathology, diagnostics, medical clearance) preoperatively Directive that results must be reviewed by the anesthesia professional or surgeon/proceduralist Documentation standards, including electronic authentication (reviewer's name, title, date/time of review) Interview staff regarding review process and documentation requirements Review clinical records to verify: All relevant reports are present and reviewed by either anesthesia professional or surgeon/proceduralist Electronic records: review is electronically authenticated with the required elements Hard copy records: review is documented with initials, date, and time.</p>
8-E-7	A	B	C	<p>Clinical records must contain findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body.</p> <p>§416.47(b)(4) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
8-E-8	A	B	C	<p>All surgical specimens must be submitted for pathological processing except those exempted by the governing body.</p>	<p>Verify the facility submits all relevant surgical specimens to pathology to provide a definitive diagnosis and guide future treatment. Exemptions must only be granted for specimens that are highly unlikely to provide valuable clinical data.</p> <p>Evidence of Compliance: Review policies for a list of the surgical specimens exempt from pathological review Review policies for pathology specimen collection, processing, and results follow-up Review Governing Body (GB) documents to ensure the specimen list has been reviewed and approved Interview staff regarding what specimens are exempt and the process for sending specimens out for review Review clinical records to verify all relevant specimens are sent for pathological review (when applicable) Confirm compliance with facility policy by cross-checking patient pathology report(s) with the operative report.</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
8-E-9	A	B	C	The name of the pathologist must be on all pathology reports.	<p>Verify the name of the licensed physician responsible for the pathological review of surgical specimens is clearly documented on all pathology reports.</p> <p>Evaluating Compliance: Review policies for directive that the pathologist name and credentials must appear on all pathology reports Review clinical records to confirm all pathology reports include the full name and credentials of the pathologist (when applicable).</p>
8-E-13	A	B	C	All surgical specimens sent out for pathology must be documented in a pathology specimen log, which minimally includes the date, patient's name, number and type of specimen (biopsy, swab, fluid, etc.), and physician's name.	<p>Verify all surgical specimens sent for pathology are accurately identified, tracked, and documented to prevent errors, maintain chain of custody, and ensure patient safety. The facility must implement a robust tracking system that captures all required elements from specimen collection to pathology processing.</p> <p>Evaluating Compliance Review policies for: Procedures for the complete specimen handling process (identification, labeling, transport, and tracking) Procedures for resolving discrepancies or lost specimens Security of the log Review specimen log to verify it contains the required elements: Patient name and unique identifier (e.g., medical record number) Specimen type and source Date and time of collection Name of the healthcare professional who collected the specimen Name of the individual transporting the specimen Date and time of specimen receipt by pathology Confirm the log demonstrates continuity and accountability throughout the entire process Interview staff regarding knowledge of: Specimen identification and tracking procedures How to handle discrepancies (e.g., mismatched labels, lost specimens) Observe staff involved in specimen handling for proper labeling and documentation practices.</p>
Sub-section F: Anesthesia Care Plan					
8-F-12	A			The anesthesia care plan is based on allergy history.	<p>Verify the development of a safe, individualized anesthesia care plan that prevents exposures to patient reported allergens.</p> <p>Evaluating Compliance Review policies for: Directive for an individualized anesthesia care plan for each patient</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Specifying required elements of the plan (e.g., patient history, physical status, anesthesia type, risks)</p> <p>Documentation formats (e.g., checklists, narratives, or electronic templates)</p> <p>Interview provider to assess their understanding of the care plan development process</p> <p>Review clinical records to confirm the pre-anesthesia assessment and anesthesia care plan include the required elements:</p> <ul style="list-style-type: none"> • Patient's medical history and physical status (including assessment of allergens and reactions) • Type of anesthesia planned • Monitoring plan • Contingency plans for potential complications <p>Verify the plan is individualized to the patient's needs and is signed/authenticated by the provider.</p>
8-F-13		B	C	<p>An anesthesia care plan is present that is based on, at a minimum, the following:</p> <ul style="list-style-type: none"> • The patient's medical history; • The patient's prior anesthetic experiences; • Drug therapies; • A medical examination of the patient and assessment of any conditions that might affect the patient's pre-operative risk; • A review of the medical tests and consultations • The determination of pre-operative medications needed for anesthesia; • Providing pre-operative instructions; and, • Allergy history 	<p>Verify the development of a safe, individualized anesthesia care plan based on a comprehensive pre-anesthesia assessment. The plan must be documented using facility-defined methods and include all required elements to guide patient-specific anesthesia delivery.</p> <p><u>Evaluating Compliance:</u></p> <p>Review policies for:</p> <ul style="list-style-type: none"> • Directive for an individualized anesthesia care plan • Required elements of the plan (e.g., patient history, physical status, anesthesia type, risks) • Acceptable documentation formats (e.g., checklists, narratives, electronic templates) <p>Interview anesthesia professional to assess understanding of:</p> <ul style="list-style-type: none"> • Care plan development process • How the plan is tailored to each patient's unique needs <p>Review clinical records to confirm the pre-anesthesia assessment/anesthesia care plan include:</p> <ul style="list-style-type: none"> • Patient's medical history and physical status (including allergy history) • Previous anesthetic experiences • Current drug therapies • Review of medical tests and consultations • Type of anesthesia/airway management planned • Pre-operative medications needed for anesthesia • Providing pre-operative instructions / assessing understanding <p>Verify the plan addresses the patient's needs and is signed/authenticated by the anesthesia professional.</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
Sub-section G: Intra-Operative Documentation					
8-G-1	A	B	C	<p>A "Time Out" protocol is in place, practiced, and documented in the clinical record prior to every operation.</p> <p>This protocol must include:</p> <ul style="list-style-type: none"> • A pre-operative verification process including clinical records, imaging studies, surgical fire risk, and any implants identified, and be reviewed by the operating room team. Missing information or discrepancies must be addressed in the clinical record at this time. • Marking the operative site: Surgical procedures calling for right/left distinction; multiple structures (breasts, eyes, fingers, toes, etc.) must be marked while the patient is awake and aware, if possible. The person performing the surgery should do the site marking. The site must be marked so that the mark will be visible after the patient has been prepped and draped. A procedure must be in place for patients who refuse site marking. • Immediately before starting the surgical procedure, conduct a final verification by at least two (2) members of the surgical team confirming the correct patient, surgery, site marking(s) and, as applicable, implants and special equipment or requirements. As a "fail-safe" measure, the surgical procedure is not started until any and all questions or concerns are resolved. • Procedures performed in non-operating room settings must include site marking for any procedures involving laterality, or multiple structures. <p style="background-color: yellow; display: inline-block; padding: 2px;">Note: Applicable to Class A effective 1/26/26</p>	<p>Verify a standardized time-out is conducted immediately before starting any invasive procedure or making the incision to verify the correct patient, procedure, and site. The entire surgical team must actively participate, and the process must be documented. The time-out is distinct from pre-operative checklists and focuses solely on final verification to prevent wrong-site, wrong-procedure, and wrong-patient events.</p> <p><u>Evaluating Compliance:</u> Review policies for:</p> <ul style="list-style-type: none"> Directive requiring a time-out immediately before all invasive procedures Required elements of the time-out, including patient identity, procedure, site, and critical safety steps Mandated participation of the surgical team Documentation standards Procedures for addressing discrepancies Interview staff regarding the time-out process, roles/active participation, handling discrepancies Observe staff conducting a time-out Review clinical records to confirm time-out documentation includes: <ul style="list-style-type: none"> Patient identification Procedure and site verification Names of participating team members Date/time performed Discrepancies/corrective actions (when found).

Standard ID	Anesthesia Class		Standard / Regulatory Reference	Interpretive Guidance
Sub-section H: Intra-Operative Anesthetic Monitoring and Documentation				
8-H-1	B	C	<p>A qualified anesthesia professional shall be present in the OR/procedure room throughout the conduct of all general anesthetics, regional anesthetics, and monitored anesthesia care.</p>	<p>Verify that qualified anesthesia professional is physically present in the procedure room and continuously monitors the patient throughout all general anesthetics, regional anesthetics, and monitored anesthesia care. This uninterrupted presence is essential to respond immediately to changes in patient status and maintain safety.</p> <p>Evaluating Compliance: Review policies for: Directive that qualified anesthesia professionals are continuously present during anesthesia administration Definition of "qualified anesthesia professional" according to state regulations & professional standards Interview anesthesia staff regarding continuous presence requirements Observe anesthesia administration to assess continuous presence Review clinical records (anesthesia records) for evidence of: Uninterrupted monitoring (vital signs, oxygenation levels, ventilation) Medication administration Interventions at appropriate intervals.</p>
8-H-2	B	C	<p>Clinical records must contain evidence of circulation monitored by continuous EKG during procedures.</p> <p>Note: This standard does not apply if only topical and/or local anesthetic is used without the use of an oral premedication.</p> <p>§416.47(b)(6) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
8-H-3	B	C	<p>Clinical records must contain evidence of circulation monitored by blood pressure documented at least every five (5) minutes.</p> <p>Note: This standard does not apply if only topical and/or local anesthetic is used without the use of an oral premedication.</p> <p>§416.47(b)(6) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
8-H-4		B	C	<p>Clinical records must contain evidence of circulation monitored by heart rate documented at least every five (5) minutes.</p> <p>Note: This standard does not apply if only topical and/or local anesthetic is used without the use of an oral premedication.</p> <p>§416.47(b)(6) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
8-H-5	A	B	C	<p>The clinical record must contain evidence of oxygenation and circulation monitoring by continuous pulse oximetry.</p> <p>When the pulse oximeter is utilized, the variable pitch pulse tone and the low threshold alarm shall be audible to the care team.</p> <p>Note: This standard does not apply if only topical and/or local anesthetic is used without the use of an oral premedication.</p> <p>§416.47(b)(6) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
8-H-9			C	<p>Clinical records must contain evidence of temperature monitoring when clinically significant changes in body temperature are expected.</p> <p>§416.47(b)(6) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
8-H-11		B	C	<p>Patient monitoring during anesthesia consists of end tidal carbon dioxide (ETCO₂) sampling used on all moderate sedation, deep sedation or general anesthesia cases.</p> <p>Continual monitoring for the presence of expired carbon dioxide shall be performed unless invalidated by the nature of the patient, procedure, or equipment.</p>	<p>Verify adequate ventilation is continuously monitored during moderate sedation, deep sedation, and general anesthesia through clinical observation and confirmation of expired carbon dioxide. Verify proper airway device placement using auscultation, chest excursion, and expired carbon dioxide detection. Use end-tidal carbon dioxide (ETCO₂) monitoring unless invalidated by patient, procedural, or equipment factors, with rationale documented</p> <p>Note: Quantitative (numerical) ETCO₂ values are only accurate with advanced airways; nasal cannulas or similar devices yield inaccurate readings and qualitative symbols (+) are appropriate for documentation.</p> <p>Evaluating Compliance: Review policies for:</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Directive for continuous ventilation monitoring via observation & ETCO₂ during moderate/deep sedation and general anesthesia</p> <p>Defined methods to verify airway device placement (e.g., auscultation, chest excursion, ETCO₂)</p> <p>Specification of when ETCO₂ monitoring may be invalidated (and requirement to document rationale)</p> <p>ETCO₂ numerical values are only documented when an advanced airway is used</p> <p>Interview staff regarding ETCO₂ use, and documentation standards</p> <p>Observe practice to ensure proper ventilation monitoring and device verification</p> <p>Review clinical records (anesthesia records) for evidence of:</p> <ul style="list-style-type: none"> Continuous ventilation monitoring and ETCO₂ use (when applicable) Airway device verification (e.g., auscultation, ETCO₂ confirmation) Documentation of rationale if ETCO₂ monitoring is not used <p>Confirm ETCO₂ numerical values are only recorded with advanced airways; use qualitative indicators (e.g., "+" for presence) otherwise.</p>
8-H-12			C	<p>When an endotracheal tube or laryngeal mask is inserted, its correct positioning must be verified by clinical assessment and by identification of carbon dioxide in the expired gas and documented in the clinical record.</p> <p>Continual end-tidal carbon dioxide (ETCO₂) analysis, in use from the time of endotracheal tube/laryngeal mask placement until extubation/removal or initiating transfer to a postoperative care location, shall be performed using a quantitative method such as capnography, capnometry, or mass spectroscopy. When capnography or capnometry is utilized, the end tidal carbon dioxide alarm shall be audible to the Anesthesiologist or the anesthesia professional.</p>	<p>Verify adequate ventilation is continuously monitored and maintained during general anesthesia through clinical observation, mechanical monitoring, and functional alarm systems to prevent hypoventilation or respiratory compromise.</p> <p>Evaluating Compliance:</p> <p>Review policies for:</p> <ul style="list-style-type: none"> Directive for continuous ventilation monitoring during general anesthesia Defined methods for monitoring (e.g., auscultation, capnography, spirometry) Mandate for use of functional alarm systems for ventilation equipment <p>Interview anesthesia staff regarding ventilation monitoring protocols and alarm management</p> <p>Observe practice to ensure staff respond appropriately to ventilation changes or alarms</p> <p>Review clinical records (anesthesia records) for evidence of:</p> <ul style="list-style-type: none"> Continuous ventilation monitoring (e.g., ETCO₂, respiratory rate, tidal volume) Responses to any ventilation alarms or abnormalities <p>Confirm ventilation monitors and alarms are functional and audible.</p>
8-H-13			C	<p>If an anesthesia machine is used during general anesthesia, the anesthesia machine must have an alarm for low O₂ concentration.</p>	<p>Verify the use of critical safety alarms for low oxygen concentration that alerts the anesthesia professionals to a potentially fatal equipment malfunction or system failure during general anesthesia (GA) administration.</p> <p>Evaluating Compliance:</p> <p>Review policies for mandatory use of alarm systems to detect low oxygen concentration during GA</p> <p>Interview anesthesia staff regarding pre-procedure equipment safety checks & alarm management</p> <p>Confirm alarm is functional by having anesthesia staff demonstrate a safety check .</p>

Standard ID	Anesthesia Class		Standard / Regulatory Reference	Interpretive Guidance
8-H-15	B	C	<p>An anesthesia record is maintained in which all medications given to a patient are recorded, including date, time, amount, and route of administration.</p> <p>§416.47(b)(6) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
8-H-16	B	C	<p>An anesthesia record is maintained in which all intravenous fluids given intra-operatively are recorded.</p> <p>§416.47(b)(6) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
Sub-section I: Transfer to Post-Anesthesia Care Unit (PACU)				
8-I-1	B	C	<p>The operating room may be used for patient recovery if only one operation is scheduled that same day, or if the recovering patient meets all discharge criteria prior to beginning the next operation, or if there is another operating room available for the next operation.</p>	<p>Verify patient recovery is permitted within the operating room (OR) only when specific criteria are met and all applicable PACU standards are maintained. This option does not eliminate the requirement for a dedicated PACU where mandated by standards or regulations. When the OR is used for recovery, it must fully comply with all PACU requirements for equipment, monitoring, staffing, and documentation.</p> <p>Evaluating Compliance: Review policies for: Criteria for use of the OR for patient recovery Standards for staffing, equipment, and monitoring requirements for OR recovery Interview staff regarding recovery in OR criteria and equivalent PACU monitoring/documentation standards Observe practice of recovery in OR to ensure adherence to PACU standards Review facility layout to confirm compliance with spatial requirements When a patient is recovered in the OR, review clinical records for evidence of: Handoff to receiving staff member Patient condition at transfer Recovery start and end times Vital signs and assessments during recovery Confirmation all discharge criteria were met (e.g., no shortened recovery period to start next case)</p>
8-I-2	B	C	<p>Patients transferred to the PACU will be continually evaluated and monitored as needed during transport.</p>	<p>Verify patients are continuously evaluated and monitored during transport to the PACU to ensure patient safety. If recovery occurs within the operating room, document the handoff process to begin the recovery period to ensure continuity of care.</p> <p>Evaluating Compliance:</p>

Standard ID	Anesthesia Class		Standard / Regulatory Reference	Interpretive Guidance
				<p>Review policies for:</p> <ul style="list-style-type: none"> Continuous monitoring and evaluation during patient transport to the PACU Documentation requirements for handoff communication if patient is recovered in the OR <p>Interview staff regarding transport monitoring, handoff procedure, and documentation standards</p> <p>Observe transport and handoff processes to ensure compliance</p> <p>Review clinical records for evidence of monitoring during transport, including:</p> <ul style="list-style-type: none"> Vital signs at departure and arrival Oxygenation status Level of consciousness Any interventions during transport <p>When a patient is recovered in the OR, ensure documentation includes:</p> <ul style="list-style-type: none"> Handoff to receiving staff member Patient condition at transfer Recovery start and end times Vital signs and assessments during recovery.
8-I-3	B	C	<p>Patients transferred to the PACU are accompanied by an anesthesia professional who is knowledgeable about the patient.</p>	<p>Verify an anesthesia professional accompanies the patient during transfer to the PACU and remains until the receiving staff (or team) accepts care. The facility must define how this handoff is documented in the clinical record to ensure continuity of care and patient safety.</p> <p><u>Evaluating Compliance:</u></p> <p>Review policies for:</p> <ul style="list-style-type: none"> Requirement that an anesthesia professional accompanies the patient to the PACU Process for patient transfer to the PACU Required handoff elements (e.g., patient condition, anesthesia details, medications, complications). <p>Interview staff regarding patient accompaniment and handoff protocols</p> <p>Observe transfer practices to ensure compliance with accompaniment/handoff process</p> <p>Review clinical records (anesthesia records) for evidence of:</p> <ul style="list-style-type: none"> Time of transfer Handoff to PACU staff Patient condition at transfer Summary of intraoperative course Anesthesia professional's signature/authentication.
8-I-4	B	C	<p>Patient transfer to the PACU will include the transmission of a verbal report on the patient to the PACU nurse accepting care of the patient from the anesthesia professional who accompanies the patient to the PACU. The clinical record must include documentation that the verbal report was completed.</p>	<p>Verify continuity of care and safe transfer of responsibility by requiring a clear, complete verbal report from the anesthesia professional to the PACU nurse. This handoff must include all essential information about the patient's condition, surgical/anesthetic course, and immediate care needs. The anesthesia professional must remain in the PACU until the PACU nurse accepts responsibility for the patient's care.</p>

Standard ID	Anesthesia Class		Standard / Regulatory Reference	Interpretive Guidance
				<p>Evaluating Compliance: Review policies for: Standardized process for patient transfer to the PACU and handoff process Mandate that anesthesia professional remains with patient until care is accepted by the PACU staff Required elements of verbal report (e.g., patient condition, procedure(s), anesthesia details, medications, complications) Interview staff regarding handoff protocols and report to PACU staff Observe anesthesia staff handing off patient to PACU staff Review clinical records (anesthesia records) for evidence of: Time of transfer and condition of patient Time of handoff to PACU staff and summary of intraoperative course Anesthesia professional's signature/authentication.</p>
8-I-5	B	C	<p>Patient transfer to the PACU will include the transfer of information concerning the preoperative condition of the patient, the invasive procedure, related medication, and the anesthesia course.</p>	<p>Verify the safe and complete transfer of information occurs when the patient is moved to the PACU. This handoff must include all essential details about the patient's condition, surgical and anesthetic course, and immediate care needs to ensure continuity of care and patient safety.</p> <p>Evaluating Compliance: Review policies for: Standardized process for patient transfer to the PACU and handoff process Required elements of verbal report (e.g., patient condition, procedure(s), anesthesia details, medications, complications) Mandate both anesthesia and PACU staff participate in the handoff process Interview staff regarding handoff protocols, required elements, mutual participation Observe handoff process Review clinical records (anesthesia records) for evidence handoff process, including: Time of transfer and handoff Key information communicated Sign-off by both anesthesia and PACU staff Confirm the handoff documentation aligns with the patient's intraoperative and immediate postoperative condition</p>
8-I-6	B	C	<p>Patient transfer to the PACU will include an anesthesia professional who remains in the post-anesthesia area until the post-anesthesia care nurse accepts responsibility for the patient.</p>	<p>Verify continuity of care and a clear transfer of responsibility and accountability from the anesthesia team to the PACU nurse. The anesthesia professional must remain with the patient until the PACU nurse formally accepts care, ensuring all critical information is communicated and the patient is stable.</p> <p>Evaluating Compliance: Review policies for: Standardized process for patient transfer to the PACU and handoff process</p>

Standard ID	Anesthesia Class		Standard / Regulatory Reference	Interpretive Guidance
				<p>Mandate that anesthesia professional remains with patient until care is accepted by the PACU staff</p> <p>Required elements of verbal report (e.g., patient condition, procedure(s), anesthesia details, medications, complications)</p> <p>Documentation standards for the transfer of care (signatures/electronic authentication from both parties)</p> <p>Interview staff regarding:</p> <ul style="list-style-type: none"> Handoff protocols and roles Understanding that anesthesia professional must remain in the PACU until PACU staff accepts patient <p>Observe anesthesia staff handing off patient to ensure s/he remains until care is transferred</p> <p>Review clinical records for evidence of:</p> <ul style="list-style-type: none"> Time of handoff and acceptance Summary of the patient's condition and intraoperative course Vital signs and stability at the time of transfer Signatures/electronic authentication from anesthesia professional and PACU staff.
Sub-section J: Post-Anesthesia Care Unit (PACU) Documentation				
8-J-1	B	C	<p>PACU documentation includes the patient's time of arrival in the PACU, or when recovery time started if the patient is recovered in the OR.</p>	<p>Verify the safe arrival of the patient to the PACU through accurate documentation of the recovery phase start time. This includes verifying patient stability during transfer and initiating timely post-anesthesia care.</p> <p><u>Evaluating Compliance:</u></p> <p>Review policies for:</p> <ul style="list-style-type: none"> Process for patient handoff from anesthesia staff to PACU staff (including report) Requirement to document the patient's arrival time (and start of post-anesthesia phase) Mandate for timely initiation of post-anesthesia monitoring and care <p>Interview staff regarding knowledge of:</p> <ul style="list-style-type: none"> Process for patient arrival (handoff, recording arrival time, prompt initiation of monitoring and care) Process for patient recovery in the OR (no transport, but clear documentation shift to PACU procedures) <p>Observe transfer and arrival processes to ensure compliance</p> <p>Review clinical records for evidence of:</p> <ul style="list-style-type: none"> Time of patient arrival in the PACU Patient condition and stability upon arrival Prompt initiation of post-anesthesia monitoring.
8-J-2	B	C	<p>The patient's post-surgical condition must be assessed and documented in the clinical record by a physician, other qualified practitioner, or a registered</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>

Standard ID	Anesthesia Class		Standard / Regulatory Reference	Interpretive Guidance
			<p>nurse with, at a minimum, post-operative care experience in accordance with applicable State health and safety laws, standards of practice, and facility policy.</p> <p>§416.52(b)(1) Standard</p>	
8-J-4	B	C	<p>PACU documentation includes a record of all medications given to a patient, including date, time, dose, and route of administration.</p>	<p>Verify all medications administered in the perioperative and postoperative periods are given safely, accurately, and documented completely to prevent errors, ensure patient safety, and maintain regulatory compliance.</p> <p>Evaluating Compliance: Review policies for: Requirement for safe medication administration practices (right patient, drug, dose, route, time) Documentation standards for administered medications (name, dose, route, time, and administering staff) Directive to document medication administration as close to administration time as possible Verification process for independent double-checks for high-risk medications (e.g., insulin) Interview staff regarding protocols for medication administration and documentation Observe medication administration practices to ensure compliance with policy Review clinical records for evidence of timely and accurate documentation, including: Medication name and strength, dose, and route administered Date/time of administration Identity of the administering staff Independent double-checks for high-alert medications (when applicable).</p>
8-J-5	B	C	<p>PACU documentation includes a record in which all intravenous fluids given post-operatively are recorded.</p>	<p>Ensure all intravenous (IV) fluids are administered safely, accurately, and documented completely to maintain fluid balance, support patient stability, and prevent complications such as fluid overload or electrolyte imbalances.</p> <p>Evaluating Compliance: Review policies for: Requirement for safe IV fluid administration practices (right patient, drug, dose, route, time) Documentation standards for IV fluids (type, volume, rate, start/stop time, and administering staff) Directive to document medication administration as close to administration time as possible Monitoring for patient response and adjustments based on clinical status Interview staff regarding protocols for IV fluid administration and documentation Observe IV fluid administration practices to ensure compliance with policy Review clinical records for evidence of timely and accurate documentation, including: Type of fluid</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Total volume infused Infusion rate Start and stop times Identity of the administering practitioner Patient monitoring and response to fluid administration.</p>
8-J-6		B	C	<p>PACU documentation includes a record of monitoring and assessment of:</p> <ul style="list-style-type: none"> • Post-operative vital signs, including temperature, heart rate, respirations, and blood pressure; • Mental status; • Airway patency, ventilation, and oxygen saturation; and, • Pain, nausea and vomiting, hydration, drainage, and bleeding, as applicable. Patient status is recorded until the patient is discharged from the facility. 	<p>Verify comprehensive post-anesthesia monitoring and assessment for all patients recovering from general anesthesia, regional anesthesia, or moderate/deep sedation. Documentation must reflect individualized care, ongoing evaluation, and adherence to facility-defined protocols, including monitoring for patients meeting discharge criteria but awaiting transportation.</p> <p>Evaluating Compliance: Review policies for: Requirement for post-anesthesia monitoring and assessment tailored to patient needs Documentation forms (e.g., forms, progress notes) and frequency of assessments Directive for continued monitoring for patients awaiting discharge transportation Interview staff regarding monitoring protocols, individualized assessment, and discharge waiting procedures Observe monitoring and documentation practices for compliance Review clinical records for evidence of complete and accurate PACU documentation, including: Vital signs at facility-defined intervals Level of consciousness and pain assessment Oxygenation and ventilation status Fluid balance and medication administration Ongoing assessments until discharge Monitoring for patients awaiting transportation.</p>
8-J-9		B	C	<p>Post-operative progress notes are recorded.</p>	<p>Verify complete documentation of the postoperative phase of care in the PACU, capturing all aspects of patient recovery, interventions, and responses. Documentation methods may include standardized forms, flow sheets, progress notes, or electronic records, as defined by facility policy.</p> <p>Evaluating Compliance: Review policies for: Requirement for comprehensive documentation of patient progress in the PACU Requirement of essential documentation elements: vital signs, level of consciousness, pain assessment, medications, fluid administration, and patient responses Mandate that documentation of progress continues until patient meets discharge criteria Interview staff regarding essential documentation elements and frequency of documentation Observe staff documenting patient progress and ensure accuracy</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Review clinical records for evidence of complete and accurate documentation, including:</p> <ul style="list-style-type: none"> Vital signs at facility-defined intervals Pain assessments, interventions, and patient responses Medication and fluid administration Level of consciousness and recovery progress Complications and interventions Discharge criteria being met (time).
8-J-10	A	B	C	<p>There is a procedure/operative report completed by the surgeon/proceduralist, which includes procedure technique and findings.</p>	<p>Verify a complete procedure report or operative note is documented in the clinical record by the surgeon or proceduralist. This report must include details of the procedure, findings, and the patient's immediate postoperative status to ensure continuity of care and accurate medical records.</p> <p>Evaluating Compliance:</p> <p>Review policies for:</p> <ul style="list-style-type: none"> Requirement for a complete procedure report or operative note for all surgical and invasive procedures Required elements: procedure details, findings, specimens, complications, and postoperative status Mandate that report must be completed by the surgeon or proceduralist <p>Interview surgeons and proceduralists about report documentation requirements and timely completion</p> <p>Observe the documentation process to ensure compliance</p> <p>Review clinical records for evidence of complete, accurate, and timely reporting, that includes:</p> <ul style="list-style-type: none"> Patient identification and procedure date Preoperative and postoperative diagnoses Detailed description of the procedure Findings and any complications Specimens removed Estimated blood loss Patient's immediate postoperative condition Signature of the surgeon or proceduralist (hard copy or electronic authentication).
Sub-section K: Discharge					
8-K-1	A	B	C	<p>Ensure each patient has a discharge order, signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy.</p> <p>§416.52(c)(2) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
8-K-2	A	B	C	<p>All clinical records must include a discharge diagnosis.</p> <p>§416.47(b)(8) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
8-K-3	A	B	C	<p>Post-surgical needs must be addressed and included in the discharge notes.</p> <p>§416.52(b)(2) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
8-K-4		B	C	<p>Approved and standardized discharge criteria are used and recorded (e.g. Aldrete score).</p>	<p>Verify patients are safely discharged from PACU using an approved, standardized, objective assessment tool, such as the Aldrete scoring system (or a comparable tool), to determine readiness for discharge to a second-stage recovery area or home. Staff use of the tool must align with facility-defined standards, including the minimum number of times assessments are performed before patient readiness for discharge can be determined.</p> <p>Evaluating Compliance: Review policies for approval of: Discharge assessment tool (e.g., Aldrete) with objective measures Discharge criteria (parameters for VS, consciousness, mobility, pain control, and oxygenation) Performance standards (minimum times criteria must be assessed before discharge) Interview staff regarding discharge assessment process Observe practice to ensure thorough patient assessment and compliance with policy Review clinical records for evidence of discharge assessment using the facility's approved tool, including: Vital sign stability Level of consciousness Pain and nausea control Mobility and functional status Oxygenation without supplemental oxygen (if applicable) Confirmation that ≥ minimum assessments are performed and discharge criteria are met.</p>
8-K-5	A	B	C	<p>Before discharge, a physician or an anesthetist as defined at 42 CFR 410.69(b), in accordance with applicable State health and safety laws, standards of practice, and ASC policy, must evaluate each patient for proper anesthesia recovery. The physician's or anesthetist's name must be noted on the patient record.</p> <p>This standard does not apply if only topical and/or</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<p>local anesthetic is used without the use of an oral premedication.</p> <p>§416.42(a)(2) Standard</p>	
8-K-7	A	B	C	<p>Ensure all patients are discharged in the company of a responsible adult, except those patients exempted by the attending physician.</p> <p>§416.52(c)(3) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
8-K-8	A	B	C	<p>Written discharge instructions, including procedures for emergency situations, are given to the responsible adult who is responsible for the patient's care and transportation following a procedure or the patient has received discharge instructions prior to receiving sedation/anesthesia. A signed copy of the instructions is maintained in the patient's chart.</p> <p>The standard does not apply if only topical and/or local anesthetic is used without the use of an oral premedication.</p>	<p>Verify patients and/or responsible adult receive comprehensive written discharge instructions to support safe recovery. Instructions must cover all critical post-procedure care elements and be communicated to the patient's care giver for the immediate postoperative period. Facilities must have clear policies addressing discharge transportation requirements and documentation of any patient deviations from these policies.</p> <p>Evaluating Compliance: Review policies for: Requirement that written discharge instructions are provided to patient/responsible adult and care provider Defines "responsible adult" based on capability, not just age Specifies instructions include: Discharge diagnosis and follow-up appointments Emergency contact information Diet, activity, and wound care instructions Medication management (resuming pre-op and new prescriptions) Warning signs of complications Supervision requirements</p> <p>Interview staff about discharge instruction protocols, transportation policies, and "responsible adult" criteria Observe discharge process to ensure instruction delivery and policy compliance Review clinical records for evidence of: Written discharge instructions to the patient/responsible adult (with all required elements) Patient/responsible adult acknowledgment.</p>
8-K-9	A	B	C	<p>Provide each patient with written discharge instructions and overnight supplies. When appropriate, make a follow-up appointment with the physician, and ensure that all patients are informed, either in advance of their surgical procedures or prior to leaving the ASC, of their prescriptions, post-</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				operative instructions and physician contact information for follow-up care. §416.52(c)(1) Standard	
8-K-10		B	C	Patients receiving anesthetic agents other than topical or local anesthesia must be supervised in the immediate post-discharge period by a responsible adult for at least 12 to 24 hours, depending on the procedure and the anesthesia used.	Verify the facility promotes safe patient recovery by providing clear directives for patient supervision in the immediate postoperative period (12-24 hours, depending on the type of procedure and anesthesia used). <u>Evaluating Compliance</u> Review policies for: Directive for patient supervision by a responsible adult in the immediate postoperative period Defines "responsible adult" based on capability, not just age Mandatory inclusion of requirement in pre-op education and patient discharge instructions Observe discharge process to ensure supervision requirement is reinforced and a responsible adult is present Review clinical records for evidence of requirement for responsible adult supervision in written instructions.
Sub-section L: Operative Log					
8-L-1	A	B	C	A separate dated operative log of all cases is maintained, either in a sequentially numbered, bound journal from which pages may not be removed, or in a tamper-proof, secured computer record consistent with state and federal law. This log must be kept in the facility.	Verify all surgical case information is accurately collected, tracked, and secured as part of the facility's quality management activities. The operative log, whether electronic or paper-based, must include required data elements and be protected against tampering or unauthorized access. <u>Evaluating Compliance</u> Review policies for: Required maintenance of an operative log for all surgical or procedural cases Required data elements (e.g., patient identifier, procedure, surgeon, anesthesia type, complications). Requirements for operative log security: Electronic: password protection, access controls, audit trails Paper: secure storage in facility, sequential numbering, tamper-evident binding, retention Review operative log for: Inclusion of required elements Evidence of log security: Electronic: access controls and audit trails functional Paper: sequential numbering, no evidence of tampering Interview staff about log entry procedures, timely entries, and security protocols.

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
8-L-11	A	B	C	An operative log must include the date of procedure.	<p>Verify the facility maintains a complete and accurate accounting of all cases performed in the facility through a secure, detailed operative log. This log serves as a critical tool for quality improvement, regulatory compliance, and facility management.</p> <p>Evaluating Compliance Review policies for operative log required elements Review operative log to ensure inclusion of date for all procedures recorded Interview staff about log entry procedures, data requirements, timeliness and accuracy.</p>
8-L-12	A	B	C	An operative log must include the patient's name and date of birth or other identification number.	<p>Verify the facility maintains a complete and accurate accounting of all surgical cases using a secure operative log that includes at least two (2) patient identifiers (e.g., name and date of birth, or name and a facility-approved identifier) for each entry. This ensures proper patient identification, supports quality tracking, and meets regulatory requirements.</p> <p>Evaluating Compliance: Review policies for: Operative log required elements Mandate for use of two (2) patient identifiers per log entry (e.g., name/DOB or name/facility-approved ID) Review operative log to ensure inclusion of patient identifiers for all procedures recorded Interview staff about log entry procedures, data requirements, timeliness and accuracy.</p>
8-L-13	A	B	C	An operative log must include record of surgery(ies) and other invasive procedures to be conducted during the case.	<p>Verify the facility maintains a complete and accurate operative log that records all surgeries and invasive procedures performed in the facility. The log must include detailed, case-specific information to support quality improvement, regulatory compliance, and patient safety initiatives.</p> <p>Evaluating Compliance: Review policies for: Operative log required elements Mandate for describing all procedure(s) performed (e.g., description, CPT codes) Review operative log to ensure inclusion of all procedures performed Interview staff about log entry procedures, data requirements, timeliness and accuracy.</p>
8-L-14	A	B	C	An operative log must include the surgeon/proceduralist's name.	<p>Verify the facility maintains a complete and accurate operative log that includes the surgeon/proceduralist's name for every surgical and invasive procedure performed to maintain a complete and accurate accounting of cases. This supports accountability, quality tracking, and regulatory compliance.</p> <p>Evaluating Compliance: Review policies for: Operative log required elements</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Mandate requiring the surgeon/proceduralist's name for all procedures Review operative log to ensure inclusion of surgeon/proceduralist's name for of all procedures performed Interview staff about log entry procedures, data requirements, timeliness and accuracy.</p>
8-L-15	A	B	C	<p>An operative log must include a record of the type of anesthesia used.</p>	<p>Verify the facility maintains a complete and accurate accounting of all cases performed in the facility through a secure, detailed operative log. This log serves as a critical tool for quality improvement, regulatory compliance, and facility management.</p> <p>Evaluating Compliance Review policies for operative log required elements Review operative log to ensure inclusion of date for the type of anesthesia used Interview staff about log entry procedures, data requirements, timeliness and accuracy.</p>
8-L-16	A	B	C	<p>An operative log must include the name of person(s) administering anesthesia.</p>	<p>Verify the facility maintains a complete and accurate accounting of all cases performed in the facility through a secure, detailed operative log. This log serves as a critical tool for quality improvement, regulatory compliance, and facility management.</p> <p>Evaluating Compliance Review policies for operative log required elements Review operative log to ensure inclusion of date for the names of the persons administering anesthesia Interview staff about log entry procedures, data requirements, timeliness and accuracy.</p>
8-L-17	A	B	C	<p>An operative log must include the name of person(s) assisting physician (e.g. additional physician, registered nurse - circulating or scrubbed, scrub tech, physician's assistant, dental assistant, anesthesia assistant, or other qualified personnel).</p>	<p>Verify the facility maintains a complete and accurate accounting of all cases performed in the facility through a secure, detailed operative log. This log serves as a critical tool for quality improvement, regulatory compliance, and facility management.</p> <p>Evaluating Compliance Review policies for operative log required elements Review operative log to ensure inclusion of date for the names of the persons assisting the physician Interview staff about log entry procedures, data requirements, timeliness and accuracy.</p>

SECTION 9: GOVERNING BODY

Standard ID	Anesthesia Class	Standard / Regulatory Reference	Interpretive Guidance			
Sub-section A: Governing Body						
9-A-0	A	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%;"></td> <td style="width: 25%;"></td> <td style="width: 50%;"> <p>Ambulatory surgical center or ASC means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. The entity must have an agreement with CMS to participate in Medicare as an ASC and must meet the conditions set forth in subparts B and C of 416.2.</p> <p>ASC services means, for the period before January 1, 2008, facility services that are furnished in an ASC, and beginning January 1, 2008, means the combined facility services and covered ancillary services that are furnished in an ASC in connection with covered surgical procedures.</p> <p>Covered ancillary services means items and services that are integral to a covered surgical procedure performed in an ASC as provided in §416.164(b), for which payment may be made under §416.171 in addition to the payment for the facility services.</p> <p>Covered surgical procedures means those surgical procedures furnished before January 1, 2008, that meet the criteria specified in §416.65 and those surgical procedures furnished on or after January 1, 2008, that meet the criteria specified in §416.166.</p> <p>Facility services means for the period before January 1, 2008, services that are furnished in connection with covered surgical procedures performed in an ASC, and beginning January 1, 2008, means services that are furnished in connection with covered surgical procedures performed in an ASC as</p> </td> </tr> </table>			<p>Ambulatory surgical center or ASC means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. The entity must have an agreement with CMS to participate in Medicare as an ASC and must meet the conditions set forth in subparts B and C of 416.2.</p> <p>ASC services means, for the period before January 1, 2008, facility services that are furnished in an ASC, and beginning January 1, 2008, means the combined facility services and covered ancillary services that are furnished in an ASC in connection with covered surgical procedures.</p> <p>Covered ancillary services means items and services that are integral to a covered surgical procedure performed in an ASC as provided in §416.164(b), for which payment may be made under §416.171 in addition to the payment for the facility services.</p> <p>Covered surgical procedures means those surgical procedures furnished before January 1, 2008, that meet the criteria specified in §416.65 and those surgical procedures furnished on or after January 1, 2008, that meet the criteria specified in §416.166.</p> <p>Facility services means for the period before January 1, 2008, services that are furnished in connection with covered surgical procedures performed in an ASC, and beginning January 1, 2008, means services that are furnished in connection with covered surgical procedures performed in an ASC as</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
		<p>Ambulatory surgical center or ASC means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. The entity must have an agreement with CMS to participate in Medicare as an ASC and must meet the conditions set forth in subparts B and C of 416.2.</p> <p>ASC services means, for the period before January 1, 2008, facility services that are furnished in an ASC, and beginning January 1, 2008, means the combined facility services and covered ancillary services that are furnished in an ASC in connection with covered surgical procedures.</p> <p>Covered ancillary services means items and services that are integral to a covered surgical procedure performed in an ASC as provided in §416.164(b), for which payment may be made under §416.171 in addition to the payment for the facility services.</p> <p>Covered surgical procedures means those surgical procedures furnished before January 1, 2008, that meet the criteria specified in §416.65 and those surgical procedures furnished on or after January 1, 2008, that meet the criteria specified in §416.166.</p> <p>Facility services means for the period before January 1, 2008, services that are furnished in connection with covered surgical procedures performed in an ASC, and beginning January 1, 2008, means services that are furnished in connection with covered surgical procedures performed in an ASC as</p>				

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				<p>provided in §416.164(a) for which payment is included in the ASC payment established under §416.171 for the covered surgical procedure.</p> <p>§416.2 Condition</p>	
9-A-1	A	B	C	<p>The facility has a governing body with full legal responsibility for determining, implementing, and monitoring policies governing facility's total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that the facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan.</p> <p>§416.41 Condition</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
9-A-2	A	B	C	<p>The medical and clinical staff of the ASC must be accountable to the governing body.</p> <p>§416.45 Condition</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
9-A-3	A	B	C	<p>The minutes of each official "Governance" meeting are recorded and filed with the original governing rules and regulations.</p>	<p>Verify documentation of all governing body/leadership meetings is maintained to demonstrate ongoing governance, quality oversight, and compliance with facility policies. Meetings should occur at least annually, with quarterly meetings recommended for optimal oversight.</p> <p><u>Evaluating Compliance</u></p> <p>Review policies for:</p> <ul style="list-style-type: none"> Frequency of leadership/governing body meetings (≥ annually, quarterly recommended) Documentation requirements: including attendance, agenda items, decisions, and action plans Defines retention requirements for meeting documentation (e.g., minimum 3 years) <p>Review meeting minutes for:</p> <ul style="list-style-type: none"> Date, time, and attendees Agenda items and discussions Decisions made and voting outcomes (if applicable) Action items with assigned responsibilities and deadlines Tracking action items and follow-up <p>Confirm minutes are complete, organized, securely stored with rules/regulations, and</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>maintained per policy Verify meetings occur at least annually, with quarterly meetings preferred.</p>
9-A-4	A	B	C	<p>The appointment of clinical and administrative personnel is documented.</p>	<p>Verify all staff appointments (medical staff) and hires (non-medical staff) are properly documented and maintained to verify qualifications, roles, and compliance with regulatory requirements. Medical staff appointments require formal governance approval, while other staff hires follow standard employment processes.</p> <p>Evaluating Compliance Review policies for: <ul style="list-style-type: none"> Process for medical staff appointments (including APRNs, PACs) and non-medical staff hiring Confirm policy requires documentation of credentials, qualifications, and scope of practice for all staff Ensure policy specifies governance approval (e.g., Board, Committee) for medical staff appointments Review GB meeting minutes for documentation of medical staff appointments, including: <ul style="list-style-type: none"> Discussion and approval of appointments Scope of practice and privileges granted Dates of appointment and reappointment Interview leadership and HR staff about appointment and hiring processes Review personnel files for evidence of accuracy, security, and current documents, including: <ul style="list-style-type: none"> Medical Staff: appointment letters, credentialing documents, licenses, and certifications Non-Medical Staff: employment contracts, job descriptions, licenses/certifications (if applicable), and orientation records. </p>
9-A-5	A	B	C	<p>The governing body/facility leadership has defined the scope and intended use of the facility, as well as the appropriate ancillary support needed for the intended surgical procedures.</p>	<p>Verify that the facility has a formal, documented scope of services that clearly states things such as:</p> <ul style="list-style-type: none"> What types of procedures are performed Intended use of the facility Levels of anesthesia allowed Patient acuity criteria Ancillary support needed (e.g., laboratory, radiology, staffing, linen services, waste management services) <p>Evaluating Compliance: Review scope of service document Review governing body/facility leadership meeting minutes approving the document Interview staff to verify current practice matches scope of services.</p>
9-A-6	A	B	C	<p>The rules and regulations of the governing body are reviewed and revised at least annually.</p>	<p>Verify the facility's rules, regulations, and policies are reviewed regularly and updated as needed to reflect current standards, regulations, and best practices. This ongoing process</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>ensures operational compliance, patient safety, and alignment with evolving healthcare requirements.</p> <p>Evaluating Compliance Review policies for: At least annual review of all rules, regulations, and policies Process for updates, including approval by the governing body or designated committee Documentation standards (review dates, changes made, and rationale for updates) Review GB minutes for evidence of: Scheduled reviews of rules, regulations, and policies Discussions and approvals of policy updates Documentation of effective dates for revised policies Reviews occurring at least annually Interview leadership and staff about the policy review and update process Assess awareness of key policy changes and their impact on daily operations.</p>
9-A-7	A	B	C	<p>The governing body/facility leadership: Is regulated by a governing rules and regulations or bylaws that has the consent of each member or the solo (1) physician.</p>	<p>Verify all members of the governing body formally acknowledge and adhere to the roles and responsibilities defined in the facility's bylaws. This promotes accountability, effective governance, and organizational alignment.</p> <p>Evaluating Compliance Review Governing Body (GB) document (bylaws) for: Clear outlines of roles, responsibilities, and expectations for all GB members Process for onboarding new members and periodic review of roles Requirement for formal acknowledgment of responsibilities (e.g., signed agreements) Review GB meeting minutes for evidence of: Discussions or training on roles and responsibilities Formal acceptance of roles by new members Periodic reviews of the governance structure Confirm documentation of member agreements (e.g., signed forms, meeting motions) Interview GB members to confirm understanding of their roles and responsibilities.</p>
9-A-10	A	B	C	<p>The governing body/facility leadership: Sets policy on how individual staff deal with each other and external parties.</p>	<p>Verify the governing body develops and enforces policies and procedures that establish and maintain accountability for staff behavior, fostering a culture of professionalism, safety, and ethical conduct throughout the facility.</p> <p>Evaluating Compliance Review policies for: Defined expected staff behavior (codes of conduct, ethical standards, and disciplinary procedures) Outline of clear consequences for violations and mechanisms for reporting concerns Mandate for annual review (and updates when required)</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Review GB meeting minutes for evidence of:</p> <ul style="list-style-type: none"> Development, approval, and periodic review of behavior-related policies Discussions of staff accountability, incident reports, or disciplinary actions Efforts to promote a culture of accountability and professionalism <p>Interview staff regarding behavioral expectations, reporting mechanisms, & accountability measures</p> <p>Observe staff interactions for compliance with behavioral standards and professionalism.</p>
9-A-11	A	B	C	<p>The governing body/facility leadership: Sets policy on staff's role in properly dealing with patients.</p>	<p>Verify the governing body develops and enforces policies and procedures that establish clear customer service expectations and maintain accountability for facility staff. This fosters a culture of professionalism, patient-centered care, and continuous improvement in service delivery.</p> <p><u>Evaluating Compliance</u></p> <p>Review policies for:</p> <ul style="list-style-type: none"> Customer service standards (communication, responsiveness, and patient interaction protocols) Staff training requirements, performance evaluation criteria, and mechanisms for patient feedback Procedures for addressing service complaints and improving service quality <p>Review GB meeting minutes for evidence of:</p> <ul style="list-style-type: none"> Development, approval, and periodic review of customer service policies Discussions of patient satisfaction data, complaints, or service improvements Initiatives to promote a patient-centered culture and staff accountability <p>Interview staff to assess:</p> <ul style="list-style-type: none"> Understanding of customer service expectations and training received Awareness of feedback mechanisms Confidence in fair enforcement of standards <p>Observe staff interactions with patients for professionalism, empathy, and adherence to service protocols.</p>
9-A-12	A	B	C	<p>The governing body/facility leadership is responsible for the operation and performance of the facility including: Determining the mission and goals of the facility, including the types of services provided and for determining, implementing, and monitoring policies governing the facility's total operation.</p>	<p>Verify the governing body is explicitly accountable for the facility's operation and performance, with clearly defined roles, responsibilities, and oversight mechanisms. This includes strategic decision-making, resource allocation, and monitoring of quality and safety outcomes.</p> <p><u>Evaluating Compliance</u></p> <p>Review policies for:</p> <ul style="list-style-type: none"> Bylaws (or charter) defining the GB's responsibilities for facility operation and performance Mechanisms to monitor key performance indicators (e.g., patient outcomes and satisfaction, financial) Processes for addressing underperformance or operational issues <p>Review GB meeting minutes for evidence of:</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Regular review of operational/performance reports (e.g., quality metrics, financial statements)</p> <p>Decisions related to resource allocation, strategic planning, and risk management</p> <p>Actions taken to address performance gaps or operational challenges</p> <p>Interview senior leadership regarding the GB's engagement and accountability</p> <p>Verify the GB receives regular, comprehensive reports on facility performance.</p>
9-A-13	A	B	C	<p>The governing body is responsible for the operation and performance of the ASC including: Determining the organizational structure.</p>	<p>Verify the governing body is accountable for defining, approving, and overseeing the facility's organizational structure. This includes establishing clear lines of authority, reporting relationships, and roles to support effective operations, accountability, and patient safety.</p> <p>Evaluating Compliance</p> <p>Review policies for:</p> <ul style="list-style-type: none"> Bylaws (or charter) explicitly assigning the GB responsibility for defining/approving organizational structure Requirement for periodic review/updates to reflect operational needs and changes <p>Review GB meeting minutes for evidence of:</p> <ul style="list-style-type: none"> Discussions and approvals of the organizational chart and structure Decisions regarding leadership roles, reporting lines, and departmental organization Reviews of the structure's effectiveness in supporting facility goals <p>Review organizational chart to verify:</p> <ul style="list-style-type: none"> Chart is current, clearly defines roles and reporting relationships, & aligns with facility's scope of services Chart is accessible to staff and reflects actual operations <p>Interview leadership and staff to assess understanding of the organizational structure and reporting lines.</p>
9-A-14	A	B	C	<p>The governing body/facility leadership is responsible for the operation and performance of the facility including: Adopting policies and procedures for the orderly conduct of the facility and for ensuring procedures are provided in a safe and effective manner.</p>	<p>Verify the governing body is accountable for developing, implementing, and overseeing policies and procedures that guarantee the orderly and safe operation of the facility. This includes establishing systems to ensure all procedures are performed safely, effectively, and in compliance with applicable standards and regulations.</p> <p>Evaluating Compliance</p> <p>Review policies to ensure:</p> <ul style="list-style-type: none"> Procedures cover critical aspects of facility operations (clinical care, safety protocols, and admin functions) Procedures align with evidence-based practices and regulatory requirements Regularly reviewed, updated, and accessible to all staff <p>Review GB meeting minutes for evidence of:</p> <ul style="list-style-type: none"> Development, approval, and periodic review of policies and procedures Discussions of safety incidents, quality metrics, and corrective actions Decisions regarding resource allocation to support safe and effective care

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Interview senior leadership and to: Assess understanding of (and adherence to) policies and procedures Determine if staff feel supported in reporting concerns.</p>
9-A-16	A	B	C	<p>The governing body/facility leadership is responsible for the operation and performance of the facility including: Approving all arrangements for ancillary medical care delivered in the facility, including laboratory, radiological, pathologic, and anesthesia services.</p>	<p>Verify the governing body holds the final legal and strategic oversight for ancillary medical care, by approving contracted services and annual evaluating the services provided by the external entity contracted for the delivery of laboratory, radiological, pathologic, and anesthesia services.</p> <p>Evaluating Compliance: Review policies for: Requirement for the GB to approve all contracted service providers of ancillary medical care Procedures for assessing alignment with evidence-based practices/outcomes and regulatory requirements Directives to review contracts at least annually Review GB meeting minutes for evidence of: Initial approval, and annual review for all external contracts for providers of ancillary medical care Discussions of safety incidents, quality metrics, and improvement when corrective actions were taken Interview senior leadership regarding process for approving contracts for external provision of services.</p>
9-A-17	A	B	C	<p>The governing body/facility leadership must ensure that all outside services are provided in a safe and effective manner.</p> <p>§416.41(a) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
9-A-18	A	B	C	<p>The governing body is responsible for the operation and performance of the facility, including: Complying with the Equal Employment Opportunities Act and with the Americans with Disabilities Act.</p>	<p>Verify the governing body and facility leadership are accountable for fostering a compliant, inclusive, and equitable workplace in accordance with the Equal Employment Opportunity (EEO) Act and the Americans with Disabilities Act (ADA). This includes developing policies, providing training, and monitoring adherence to federal requirements.</p> <p>Evaluating Compliance: Review policies for: Explicitly prohibition for discrimination Procedures for addressing EEO and ADA compliance Processes for reasonable accommodation, grievance mechanisms, and anti-retaliation protections Regularly review policies for compliance and ensure they are accessible to all staff Review GB meeting minutes for evidence of:</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Discussions/approvals of EEO/ADA policies and training programs</p> <p>Reports on compliance, complaints, or corrective actions related to discrimination or accessibility</p> <p>Commitments to resource allocation for accommodations and inclusivity initiatives</p> <p>Interview staff to assess:</p> <ul style="list-style-type: none"> Understanding of EEO/ADA policies and reporting procedures If staff feel safe reporting concerns without fear of retaliation <p>Observe the workplace for accessibility features (e.g., ramps, ergonomic equipment) and inclusive practices.</p>
9-A-19	A	B	C	<p>The governing body of the facility coordinates, develops, and revises the organization's policies and procedures to specify the types of emergency equipment required for use in the facility's operating room.</p>	<p>Verify the governing body is accountable for developing and implementing policies and procedures that specify the types of emergency equipment required in the operating room. While ultimate responsibility lies with the governing body, input from medical staff, anesthesia professionals, and nursing staff is essential to ensure the equipment meets clinical needs and promotes patient safety.</p> <p>Evaluating Compliance:</p> <p>Review policies for:</p> <ul style="list-style-type: none"> The emergency equipment required (e.g., defibrillators, airway supplies, emergency medications) Mandate for regular inspection, maintenance, and testing of emergency equipment Requirement for multidisciplinary input (medical, anesthesia, nursing) in defining equipment needs <p>Review GB meeting minutes for evidence of:</p> <ul style="list-style-type: none"> Discussions (with multidisciplinary input) and approval of emergency equipment required Reviews of emergency equipment adequacy and functionality <p>Interview medical, anesthesia, and nursing staff to assess involvement in specifying emergency equipment</p> <p>Verify that the emergency equipment present in the operating room aligns with governing body specifications.</p>
Sub-section B: Transfer of the Patient					
9-B-1	A	B	C	<p>The facility must provide the local hospital with written notice of its operations and patient population served upon opening and at least every 24 months.</p> <p>§416.41(b)(3) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
9-B-3	A	B	C	<p>The facility must have an effective procedure for the immediate transfer to a hospital for patients requiring</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<p>emergency medical care beyond the capabilities of the facility.</p> <p>§416.41(b)(1) Standard</p>	
9-B-4	A	B	C	<p>This hospital must be a local, Medicare-participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under 42 CFR 482.2.</p> <p>§416.41(b)(2) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
Sub-section C: Extended Stays					
9-C-1		B	C	<p>The facility does not perform cases that ordinarily would take more than 24 hours from the time of the patient's admission to the time of recovery and discharge from the facility.</p> <p>Total patient time in the facility cannot extend beyond 23 hours and 59 minutes.</p> <p>If overnight stays are permitted, the facility is in compliance with all applicable local and state laws and regulations.</p>	<p>Verify the facility limits patient stays to less than 24 hours (23 hours 59 minutes) from admission to discharge, with procedures typically completed within 6 hours under general anesthesia. The facility must define appropriate procedure types and total durations, prioritize patient safety, and comply with state-specific requirements. While rare exceedances due to unforeseen complications are acceptable, frequent violations indicate systemic non-compliance.</p> <p>Evaluating Compliance</p> <p>Review policies for:</p> <ul style="list-style-type: none"> Maximum facility stay of 23 hours 59 minutes from admission (time entered clinical area) to discharge (physician-signed order + patient left recovery) Procedure time limits (e.g., 4-6 hours for general anesthesia) and types of procedures permitted Processes for managing rare exceedances (e.g., staff availability, documentation of variance) Confirm policy aligns with state regulations (if applicable) <p>Interview staff regarding stay limits, procedure durations, and management of exceedances</p> <p>Observe practices to ensure adherence to time tracking and discharge protocols</p> <p>Review of clinical record for evidence of:</p> <ul style="list-style-type: none"> Admission time (when patient entered clinical area beyond reception) Discharge time (physician order + patient exit from recovery) Total facility stay <24 hours for all cases (with justification for very rare exceedances) Procedure duration within safe limits (e.g., ≤6 hours for general anesthesia cases) Cross-check with operative log for consistency with documented times.

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
Sub-section D: Laboratory Services					
9-D-1	A	B	C	<p>If the facility does not provide laboratory services, any referral laboratory must be certified in the appropriate specialties and sub-specialties of service to perform the referred tests in accordance with the requirements of part 493 of 42 CFR. The referral laboratory must be certified in the appropriate specialties and subspecialties of service to perform the referred tests in accordance with the requirements of Part 493 of this chapter of the Code of Federal Regulations.</p> <p>§416.49(a) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
9-D-2	A	B	C	<p>The ambulatory surgery facility's policies and procedures must list the kinds of laboratory services that are provided directly by the facility and services that are provided through a contractual agreement.</p>	<p>Verify that the ASC policies and procedures should list the kinds of laboratory services that are provided directly by the facility, and services that are provided through a contractual agreement. The procedures must include the following:</p> <ul style="list-style-type: none"> A well-defined arrangement with outside services (need not be contractual) Laboratory services provided by the ASC Routine procedures for requesting lab tests A process for incorporating lab/radiology reports into the patient's clinical record. <p><u>Evaluating Compliance:</u> Review policies and procedures Review the contractual agreements or arrangements and determine if the referral laboratory is a CLIA-approved laboratory.</p>

SECTION 10: QUALITY ASSESSMENT/QUALITY IMPROVEMENT/RISK MANAGEMENT

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
Sub-section A: Quality Assessment/Quality Improvement/Risk Management					
10-A-1	B	C	C	<p>A licensed and qualified anesthesia professional supervising or providing care in the facility must participate in quality assessment/quality improvement and risk management in the facility.</p>	<p>Verify a licensed and qualified anesthesia professional participates in quality assessment/performance improvement (QAPI) and risk management to identify, mitigate, and monitor risks that are unique to the administration of anesthesia. The anesthesia professional must have privileges at the facility or supervise those who provide anesthesia services directly.</p> <p><u>Evaluating Compliance:</u> Review policies for: Mandate for at least one (1) anesthesia professional (with current license) to participate in the facility's quality/risk activities Participation requirements (e.g., chart review, peer review, policy development, running emergency response drills, attendance GB meetings) Review Governing Board documents/meeting minutes to ensure evidence of participation Review personnel files for evidence of current license and eligibility to serve in this capacity (privileges to provide anesthesia services or supervisor of anesthesia professionals).</p>
Sub-section B: Quality Improvement Program					
10-B-1	A	B	C	<p>The facility must develop, implement and maintain an ongoing, data-driven quality assessment and performance improvement (QAPI) program.</p> <p>§416.43 Condition</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
10-B-2	A	B	C	<p>The facility has a written quality improvement program implemented which includes surveys or projects to:</p> <ul style="list-style-type: none"> • Monitor and evaluate patient care • Evaluate methods to improve patient care • Identify and correct deficiencies within the facility 	<p>Verify the facility implements a written quality improvement (QI) program that includes systematic surveys, projects, and initiatives to monitor, evaluate, and improve patient care and safety. The program must involve staff at all levels, identify deficiencies, implement corrections, and demonstrate measurable improvements.</p> <p><u>Evaluating Compliance</u> Review policies of QI program for: Goals and objectives aligned with patient safety and care standards</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<ul style="list-style-type: none"> Alert the facility's Quality Improvement Program to identify, track, trend, evaluate and resolve problems. 	<p>Methods for data collection (e.g., surveys, audits, incident reports) Processes for analyzing data, identifying trends, and implementing corrective actions Defined roles and responsibilities for staff participation Confirm the program requires regular reviews (e.g., quarterly) and updates Interview staff regarding QI program surveys/projects and their roles within recent improvements.</p>
10-B-6	A	B	C	<p>The facility has a written quality improvement program that includes documentation of Peer Review meetings for the prior three (3) years, which must be available for the surveyor. Facilities with a monthly case volume of 50 or fewer cases must conduct peer review meetings no less than twice per year. Facilities with a monthly case volume in excess of 50 cases must conduct peer review meetings no less than quarterly.</p>	<p>Verify the facility implements a comprehensive Quality Improvement program to ensure patient safety, maintain quality of care, and meet accreditation and regulatory requirements. Physician peer-to-peer review provides a structured way for physicians to assess their colleagues' work, identify areas for improvement, and uphold professional standards and facility policy.</p> <p>Evaluating Compliance Review policies of QI program for: Criteria for selecting cases for peer review (e.g., complications, outliers, random sampling) Frequency of peer review meetings based on case volume (e.g., quarterly minimum) Documentation requirements for discussions, actions, and follow-up Confirm the program integrates peer review findings into broader QI initiatives Review of peer review documents and governing body meeting minutes for evidence of: Scheduled peer review meetings with documented attendance (e.g., physicians, clinical staff) Case discussions (clinical outcomes, deviations, and opportunities for improvement) Actions taken (e.g., education, policy changes) and tracking of effectiveness Confirm the meeting frequency matches case volume (e.g., quarterly minutes for high-volume facilities) Interview clinical and QI staff to assess: Understanding of peer review processes and case selection criteria Awareness of recent peer review findings and implemented changes (if applicable) Participation in meetings and contributions to discussions.</p>
10-B-7	A	B	C	<p>The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors.</p> <p>§416.43(a)(1) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
10-B-8	A	B	C	<p>The ASC must measure, analyze, and track quality indicators, adverse patient events, infection prevention and control and other aspects of performance that includes care and services furnished in the ASC.</p> <p>§416.43(a)(2) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
10-B-9	A	B	C	<p>The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC.</p> <p>§416.43(b)(1) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
10-B-10	A	B	C	<p>The ASC must use the data collected to monitor the effectiveness and safety of its services, and quality of its care.</p> <p>§416.43(b)(2) Standard §416.43(b)(2)(i) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
10-B-11	A	B	C	<p>The ASC must use the data collected to identify opportunities that could lead to improvements and changes in its patient care.</p> <p>§416.43(b)(2)(ii) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
10-B-12	A	B	C	<p>The ASC must set priorities for its performance improvement activities that focus on high risk, high volume, and problem-prone areas.</p> <p>§416.43(c)(1) Standard §416.43(c)(1)(i) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
10-B-13	A	B	C	<p>The ASC must set priorities for its performance improvement activities that consider incidence, prevalence, and severity of problems in those areas.</p> <p>§416.43(c)(1)(ii) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
10-B-14	A	B	C	<p>The ASC must set priorities for its performance improvement activities that affect health outcomes, patient safety, and quality of care.</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				§416.43(c)(1)(iii) Standard	
10-B-15	A	B	C	<p>Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.</p> <p>§416.43(c)(2) Standard</p>	SOM Appendix L - Guidance for Surveyors: ASCs
10-B-16	A	B	C	<p>The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies.</p> <p>§416.43(c)(3) Standard</p>	SOM Appendix L - Guidance for Surveyors: ASCs
10-B-17	A	B	C	<p>The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations.</p> <p>§416.43(d)(1) Standard</p>	SOM Appendix L - Guidance for Surveyors: ASCs
10-B-18	A	B	C	<p>The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results.</p> <p>§416.43(d)(2) Standard</p>	SOM Appendix L - Guidance for Surveyors: ASCs
10-B-19	A	B	C	<p>The governing body/ facility leadership must ensure that the QAPI program is defined, implemented, and maintained by the facility.</p> <p>§416.43(e) Standard §416.43(e)(1) Standard</p>	SOM Appendix L - Guidance for Surveyors: ASCs
10-B-20	A	B	C	<p>The governing body must ensure that the QAPI program addresses the ASC's priorities and that all improvements are evaluated for effectiveness.</p>	SOM Appendix L - Guidance for Surveyors: ASCs

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				§416.43(e)(2) Standard	
10-B-21	A	B	C	<p>The governing body must ensure that the QAPI program specifies data collection methods, frequency, and details.</p> <p>§416.43(e)(3) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
10-B-22	A	B	C	<p>The governing body must ensure that the QAPI program clearly establishes its expectations for safety.</p> <p>§416.43(e)(4) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
10-B-23	A	B	C	<p>The governing body must ensure that the QAPI program adequately allocates sufficient staff, time, information systems and training to implement the QAPI program.</p> <p>§416.43(e)(5) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
Sub-section D: Peer Review					
10-D-1	A	B	C	<p>To be HIPAA compliant, a copy of the HIPAA Business Associates Agreement must be signed by each physician working outside the facility participating in such facility's Quality Assurance/Quality Improvement process, including but not limited to Peer Review and Patient Safety Data Reporting, and a copy must be retained on file in the facility.</p>	<p>Verify the facility protects patient health information (PHI) in accordance with HIPAA regulations by formally designating external physicians who participate in quality activities as business associates. This is achieved through executed Business Associate Agreements (BAAs), which legally bind these physicians to the same privacy and security standards as the facility, mitigating the risk of unauthorized PHI disclosure.</p> <p>Evaluating Compliance:</p> <ul style="list-style-type: none"> Review policies for HIPAA compliance and information security for: <ul style="list-style-type: none"> Process for identifying external participants in QA/QI processes Requirement for BAAs with contracted/external participants before accessing PHI Review documents for compliance and confirm: <ul style="list-style-type: none"> The facility's master BAA template meets all required HIPAA elements Signed BAAs for all external physicians participating in Peer Review, PSDR, or quality activities No individual accessed PHI for QAPI purposes without a signed agreement Interview staff & leadership regarding:

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>HIPAA requirement for BAAs with external contractors who handle PHI Process for identifying external QAPI participants and obtaining signed BAAs.</p>
10-D-2	A	B	C	<p>If peer review sources external to the facility are used to evaluate the delivery of medical care, the HIPAA Business Associates Agreement is so written as to waive the confidentiality of the clinical records.</p>	<p>Verify that, when external peer reviewers are engaged, the Business Associate Agreement (BAA) explicitly permits the sharing of otherwise confidential patient clinical records for the purpose of quality review, thereby protecting both patient privacy and the facility's ability to conduct thorough external evaluations without violating HIPAA.</p> <p>Evaluating Compliance: Review policies to ensure: External reviewers sign specific BAAs with the confidentiality waiver clause The specialized BAA is differentiated from standard BAAs used for other purposes Review BAA document for specific clause(s) used for external peer reviewers: Verify BAA language explicitly waives confidentiality for the purposes of peer review and quality evaluation Waiver is compliant with HIPAA's permitted uses for healthcare operations Must not provide blanket authorization for unrelated uses Review peer review documents to confirm: Executed BAA (with specific waiver clause) on file for cases where external peer review was utilized BAA was signed before clinical records were accessed Interview the staff and leadership regarding need for BAA (waiving confidentiality) in place for external reviewers.</p>
10-D-3	A	B	C	<p>Peer review may be done by a recognized peer review organization or a surgeon/proceduralist other than the operating surgeon/proceduralist, unless otherwise specified by state regulations.</p>	<p>Verify peer review is conducted objectively by a qualified, independent entity or individual(s) not directly involved in the cases under review, thereby promoting impartial evaluation and meaningful quality improvement, unless explicitly permitted by state law.</p> <p>Evaluating Compliance: Review policies for: Definition of who is authorized to perform reviews Alignment with any state-specific regulatory exceptions Review QI meeting minutes and GB documents for evidence of an active process: Peer review findings being reviewed Process for selecting reviewers ensures independence and objectivity Review reviewer credentials and confirm independence (for a sample of completed peer reviews); Confirm reviewer is authorized to perform review on specific case, including: A recognized external organization a surgeon/proceduralist with appropriate credentials Was not the operating surgeon/proceduralist for the case(s) reviewed (unless state regulations permit) Interview the Medical Director, Quality coordinator, and participating peer reviewers to assess:</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					Peer review selection process and the requirement for reviewer independence Awareness of any state regulations that might specify alternative requirements.
10-D-4	A	B	C	Peer review and the associated peer review meetings include at a minimum the same random cases and adverse events submitted to the Patient Safety Data Reporting since the preceding peer review meeting.	<p>Verify peer review activities are comprehensive and aligned with external reporting obligations by mandating that all cases submitted for Patient Safety Data Reporting (random and adverse events) are also included in the internal peer review process. This creates a closed-loop system where data used for external transparency is also rigorously analyzed internally for quality improvement.</p> <p>Evaluating Compliance: Review of policies for requirement that: All cases submitted for PSDR (random selections, all adverse events) are included in peer review process Review QI meeting minutes and GB documents for evidence of an active process: Evidence that the required cases were discussed and analyzed Any resulting actions were documented Cross-reference audit: Obtain logs of cases submitted for Patient Safety Data Reporting since the last peer review meeting Confirm each reported case was indeed reviewed by the peer review committee or designated reviewer Interview the Medical Director, Quality coordinator, and peer review members regarding: Link between PSDR and active internal peer review Process for ensuring cases submitted for PSDR are captured for internal peer review.</p>
10-D-15	A	B	C	Peer review is conducted and contains, at a minimum, the following review of each clinical record subject to peer review: <ul style="list-style-type: none"> • Adequacy and legibility of history and physical exam • Adequacy of the surgical consent • Adequacy of appropriate laboratory, EKG, and radiographic reports • Adequacy of a written operative report • Adequacy of anesthesia and recovery records (with IV sedation or general anesthesia) • Adequacy of instructions for post-operative care 	<p>Verify peer review is a structured, comprehensive process that evaluates critical aspects of clinical care documentation. The goal is to ensure that patient records meet established standards for completeness, accuracy, and legal/clinical appropriateness.</p> <p>Evaluating Compliance: Review policies for: Directive to evaluate all clinical records reviewed for the seven elements listed in the standard Definition of objective criteria for "adequacy" Review documents of peer review records to ensure they: Each record includes documentation for all seven required elements Check for evidence of critical assessment rather than passive acknowledgment (notes, comments) Cross-check a sample reviewed cases with clinical records to ensure findings align with documentation Review peer review committee meeting minutes to ensure: Discussions address deficiencies (or exceptions) related to the seven elements</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<ul style="list-style-type: none"> Documentation of the discussion of any complications 	<p>Corrective actions are documented</p> <p>Interview the Medical Director, Quality coordinator, and participating peer reviewers regarding:</p> <p>Seven elements required for review and the criteria for "adequacy" in each category</p> <p>How peer review findings are used to improve documentation practices.</p>

SECTION 11: PERSONNEL

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
Sub-section A: Personnel					
11-A-1	A	B	C	<p>If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.</p> <p>§416.45(c) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
Sub-section B: Medical Director & Facility Director					
11-B-1	A	B	C	<p>The Medical Director must have an MD, DO, DPM, DMD, or DDS degree.</p> <p>A DPM may serve as the Medical Director only for facilities exclusively practicing podiatry.</p> <p>A DDS or DMD may serve as the Medical Director only for facilities exclusively practicing dentistry or oral maxillofacial surgery.</p>	<p>Verify the individual serving as Medical Director possesses the appropriate terminal degree and scope-of-practice credentials that align with (and fully encompass) the clinical services performed within the facility. This safeguards clinical governance, ensures appropriate oversight of all medical staff, and maintains compliance with professional and regulatory scopes of practice.</p> <p>Evaluating Compliance: Review the Medical Director's file for evidence of: Primary source-verified credentials of an MD, DO, DPM, DMD, or DDS degree Appointment letter confirming the appointment as Medical Director Roles/responsibilities/qualifications align with the standard's requirements and facility's scope of practice Medical Director's degree legally permits oversight of facility services Job description Interview the Medical Director, the Governing Body/CEO regarding: Medical Director's identity and credentials The facility's scope of practice and alignment with the Medical Director's qualifications.</p>
11-B-2	A	B	C	<p>The Facility Director must have an MD, DO, DPM, DMD, DDS, APRN, CRNA, or RN degree.</p> <p><i>One person may fill both the Medical Director and Facility Director roles, or the roles can be filled by two separate people.</i></p>	<p>Verify the Facility Director possesses a recognized clinical credential, providing the necessary foundation in patient care and clinical operations to effectively manage the facility. The standard allows for operational flexibility by permitting the consolidation of the Medical Director and Facility Director roles into a single position or their separation into two distinct positions, based on the facility's needs and structure.</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Evaluating Compliance: Review the Facility Director's file for evidence of: Primary source-verified credentials of one (1) of the required degrees (MD, DO, DPM, DMD, DDS, APRN, CRNA, or RN) Review organizational charts, job descriptions, and appointment letters for both the Facility Director and Medical Director to confirm the documents: Clearly delineate the responsibilities for each role Confirm whether they are held by one or two (2) individuals Review minutes from Governing Body meetings documenting the official appointment Interview the Facility Director, Medical Director (if a separate individual), and the Governing Body/Administrator regarding: Confirmation of the Facility Director's identity and credentials Reporting structure & the distinct (or combined) responsibilities of the Facility Director and Medical Director The lines of authority and decision-making processes for clinical and operational issues.</p>
11-B-3	A	B	C	<p>The Medical Director and Facility Director must be a provider currently licensed by the state in which the facility is located.</p>	<p>Verify the individuals holding the ultimate clinical and operational authority over the facility are actively and properly credentialed by the state. This validates their professional competency and legal authority to practice and oversee patient care services, thereby safeguarding patient safety and ensuring regulatory adherence.</p> <p>Evaluating Compliance: Review organizational charts, bylaws, and the official job descriptions/appointment letters for both directors to ensure they clearly define their roles and responsibilities and confirm their official status with the facility Review minutes from Governing Body meetings for evidence of: Official appointment of these directors Periodic review of their credential status Interviews both directors to confirm both directors: Possess a clear understanding that they must maintain current, active license in the facility's state Can articulate the reporting structure and distinct responsibilities of the Medical Director and Facility Director, especially if the roles are combined.</p>
11-B-4	A	B	C	<p>The Medical Director must be certified or eligible for certification by one of the following boards:</p> <ul style="list-style-type: none"> • American Board of Medical Specialties (ABMS) • American Osteopathic Association Bureau of Osteopathic Specialists (AOABOS) • American Board of Foot and Ankle Surgery (ABFAS) 	<p>Verify the individuals serving as Medical Director and Facility Director possess advanced, board-verified expertise in their respective clinical fields. This requirement validates a commitment to specialized knowledge, clinical excellence, and adherence to the highest standards of patient care within their scope of practice.</p> <p>Evaluating Compliance: Verify that the specific board certification aligns with the clinical services offered by the facility Interview the Medical Director, Facility Director, and members of the Governing Body</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<ul style="list-style-type: none"> American Board of Podiatric Medicine (ABPM) American Board of Pediatric Dentistry (ABPD) American Board of Oral and Maxillofacial Surgery (ABOMS) American Dental Board of Anesthesiology (ADBA) 	<p>regarding:</p> <ul style="list-style-type: none"> Confirmation that board certification status or eligibility pathway is required when roles are combined Requirement to maintain active certification and/or complete the certification process if currently "eligible." How their specialized training/certification qualifies them to oversee facility's clinical services & patient care.
11-B-7	A	B	C	<p>The Facility Director must be actively involved in the direction and management of the facility.</p>	<p>Verify the Facility Director is substantively engaged in the operational, clinical, and strategic leadership of the facility, providing consistent oversight and accountability.</p> <p>Evaluating Compliance:</p> <p>Review documents to determine Facility Director's active involvement:</p> <ul style="list-style-type: none"> Confirm job description, appointment letter, and place in organizational chart align with defined responsibilities for direction and management Ensure QAPI, Governing Body, Medical Executive, and other leadership meetings minutes provide evidence of the Facility Director's regular participation, participation, and decision-making Evaluate reports, policies, and strategic plans developed or approved by the Facility Director, for proof of involvement in key operational areas (e.g., budget management, staffing, policy implementation, and regulatory compliance) Interview the Facility Director's regarding specific roles, current strategic initiatives, and operational challenges Interview staff regarding the Facility Director's visible presence, accessibility, and authority in daily operations.
11-B-8	A	B	C	<p>The Facility Director is responsible for establishing and enforcing policies that protect patients. The Facility Director monitors medical and facility staff members for compliance with this policy.</p>	<p>Verify the Facility Director executes their leadership responsibility by actively overseeing and verifying that all staff adhere to established policies, thereby maintaining consistent operational standards, promoting a culture of accountability, and ensuring continuous regulatory compliance.</p> <p>Evaluating Compliance:</p> <p>Review specific policy in question to confirm it:</p> <ul style="list-style-type: none"> Explicitly assigns the monitoring responsibility to the Facility Director Outlines methods for this oversight <p>Review documents demonstrating active monitoring by the Facility Director's, including:</p> <ul style="list-style-type: none"> Compliance audits Meeting minutes where monitoring data was presented and reviewed Logs of corrective actions initiated Performance evaluations that include policy adherence metrics QAPI or leadership meeting minutes to confirm:

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Facility Director's monitoring activities lead to concrete actions, policy revisions, or staff education</p> <p>Interview staff regarding:</p> <ul style="list-style-type: none"> Awareness of policy requirements and understanding that Facility Director is responsible for compliance Corroboration that monitoring and feedback routinely occur <p>Confirm the Facility Director's ability to describe their specific monitoring process for this policy, including the frequency, methods, and recent findings.</p>
Sub-section C: Surgeons/Proceduralists/Etc.					
11-C-1	A	B	C	<p>Procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body in accordance with approved policies and procedures of the facility.</p> <p>§416.42 Condition</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
11-C-3	A	B	C	<p>Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The ASC grants privileges in accordance with recommendations from qualified medical personnel.</p> <p>§416.45(a) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
11-C-4	A	B	C	<p>Medical staff privileges must be periodically reappraised by the ASC and the scope of procedures must be periodically reviewed and amended as appropriate.</p> <p>§416.45(b) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
11-C-5	A	B	C	<p>Each physician, advanced practice registered nurse, and physician assistant, including both directly employed and contract practitioners using the facility, is credentialed and qualified for the scope of practice they perform.</p>	<p>Verify all practitioners (physicians, APRNs, PAs) are properly credentialed and work only within their verified, granted scope of practice.</p> <p>Evaluating Compliance:</p> <p>Review policies for credentialing/privileging healthcare practitioners for:</p> <ul style="list-style-type: none"> Who is authorized to perform surgery/procedures (e.g., physicians, APRN, PA) Process for credentialing/re-credentialing (verifying qualifications, status to practice legally)

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Process for granting privileges (approval by governing body, setting scope of practice) Mandate that practitioners must practice within their delineated scope Interview credentialing leadership regarding the verification/privileging process and enforcement Review credentialing files for evidence of: Primary-source verification of credentials GB-approved scope of practice (delineation of privileges) Cross-check clinical records/operative log with credentialing files to confirm practitioners function within approved scope.</p>
11-C-6	A	B	C	<p>The facility must have written policies and procedures that address the criteria for clinical staff privileges and the process that the facility's leadership body uses when reviewing physician, APRN, PA, and other licensed healthcare professional credentials and determining whether to grant privileges and the scope of the privileges for each practitioner.</p>	<p>Verify every practitioner who performs surgery or procedures in the facility, including those directly employed or under contract, has been determined qualified and granted privileges for the specific procedures she/he performs in the facility. The facility's governing body is responsible for reviewing the qualifications of all healthcare practitioners and granting privileges as appropriate.</p> <p>Evaluating Compliance: Review policies for credentialing/privileging healthcare practitioners for: Who is authorized to perform surgery/procedures (e.g., physicians, APRN, PA) Process for credentialing/re-credentialing (verifying qualifications, status to practice legally) Process for granting privileges (approval by governing body, setting scope of practice) Mandate that practitioners must practice within their delineated scope Interview credentialing leadership regarding the verification/privileging process and enforcement Review credentialing files for evidence of: Primary-source verification of credentials GB-approved scope of practice (delineation of privileges) Cross-check clinical records/operative log with credentialing files to confirm practitioners function within approved scope.</p>
11-C-7	A	B	C	<p>Each physician, APRN, and PA, including both directly employed and contracted practitioners, must be currently licensed by the state in which they practice. Electronic verification of each physician's current license or facility verification of licensure must be maintained on file in the facility.</p>	<p>Verify all physicians, advanced practice registered nurses, physician assistants, or other licensed healthcare professionals, who have been granted clinical privileges by the Governing Body, maintain current licensure. The facility must keep a verified state license onsite and have a process to monitor license status.</p> <p>Evaluating Compliance: Review policies for credentialing/privileging healthcare practitioners for: Who is authorized to perform surgery/procedures (e.g., physicians, APRN, PA) Procedure for verifying/documenting license status (printing from website, initial, date) Process for tracking professional licenses for expiration (spreadsheet, credentialing software) Interview credentialing staff regarding procedures to verify and track licensure</p>

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					Review personnel files for evidence a current license is maintained for all licensed clinical staff.
11-C-9	A	B	C	<p>All individuals, including both directly employed and contract employees, using the facility must meet one of the following criteria:</p> <ul style="list-style-type: none"> • A doctor of medicine currently certified, previously certified, or eligible for certification by one of the member boards of the American Board of Medical Specialties (ABMS). • A doctor of osteopathy currently certified, previously certified, or eligible for certification by the American Osteopathic Association Bureau of Osteopathic Specialists (AOABOS). • A podiatrist currently certified, previously certified, or eligible for certification by the American Board of Foot and Ankle Surgery (ABFAS) or The American Board of Podiatric Medicine (ABPM). • An oral and maxillofacial surgeon currently certified, previously certified, or eligible for certification by the American Board of Oral and Maxillofacial Surgery (ABOMS). • A certified registered nurse anesthetist (CRNA) currently certified or eligible for certification with the National Board of Certification and Recertification for Nurse Anesthetists (NBCRNA). • A nurse practitioner (NP) currently certified or eligible for certification with the American Academy of Nurse Practitioners Certification Board (AANPCB) or The American Nurses Credentialing Center Certification (ANCC). • A physician assistant (PA) with national certification. 	<p>Verify all healthcare practitioners meet minimum requirements to ensure professional standards and patient safety. The facility must define the types of procedures that each NP and PA may perform in accordance with any specialty education and training, state law, and scope of practice laws</p> <p>Note: See glossary for detailed requirements of each role.</p> <p>Evaluating Compliance: Review policies for credentialing/privileging healthcare practitioners for: Who is authorized to perform surgery/procedures (e.g., physicians, APRN, PA) Process for credentialing/re-credentialing (verifying qualifications, status to practice legally) Process for granting privileges (approval by governing body, setting scope of practice) Mandate that practitioners must practice within their delineated scope Review Governing Body meeting minutes for evidence of: Discussions and review of candidate qualifications (initial credentialing, during re-credentialing) Outcomes (approvals, denials) Interview credentialing leadership regarding the credentialing/privileging process Review credentialing files to verify medical staff have been granted clinical privileges. Minimum documentation includes: Primary-source verification of credentials Country/State licensure, registration, or state certification (as applicable) Certification by a specialty organization (as appropriate) Other training or pertinent experience Scope of privileges granted to the practitioner by the Governing Body (delineation of privileges) Confirm re-credentialing is performed at least every three (3) years.</p>
11-C-10	A	B	C	American Board of Medical Specialties (ABMS)-certified or eligible medical specialists who perform	Verify physicians perform only those surgical procedures delineated in their board certification to ensure professional qualification and competence. The principles in this standard apply to

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				<p>surgical procedures within the accredited facility may perform only those surgical procedures delineated in their ABMS board certification and/or covered by American Medical Association (AMA) Core Principle #7. American Osteopathic Association (AOA) certified or eligible physicians who perform surgical procedures within the accredited facility may perform only those surgical procedures delineated in their AOA board certification and/or covered by AMA Core Principle #7. Podiatrists certified or eligible for certification who perform surgical procedures with accredited facilities may perform only those surgical procedures delineated in their ABFAS board certification and/or covered by AMA Core Principle #7. The AMA Core Principle #7 (from AMA resolution dated April, 2003): AMA Core Principle #7—Physicians performing office-based surgery must be currently board certified/qualified by one of the boards recognized by the American Board of Medical Specialties, American Osteopathic Association, or a board with equivalent standards approved by the state medical board. The surgery must be one that is generally recognized by that certifying board as falling within the scope of training and practice of the physician providing the care.</p>	<p>both ABMS certified and eligible physicians.</p> <p>Evaluating Compliance: Review policies for credentialing/privileging healthcare practitioners for: Who is authorized to perform surgery/procedures (e.g., physicians, APRN, PA) Process for credentialing/re-credentialing (verifying qualifications, status to practice legally) Process for granting privileges (approval by governing body, setting scope of practice) Mandate that practitioners must practice within their delineated scope Review Governing Body (GB) meeting minutes for evidence of: Discussions and review of candidate qualifications (initial credentialing, during re-credentialing) Outcomes (approvals, denials) Interview credentialing leadership regarding the credentialing/privileging process Review credentialing files to verify medical staff have been granted clinical privileges by the GB. Minimum documentation includes: Primary-source verification of credentials Country/State licensure, registration, or state certification (as applicable) Board Certification (or eligibility) by a specialty organization (as appropriate) Other training or pertinent experience Recommendation by qualified medical personnel (concerning the practitioner's competence) Scope of privileges granted to the practitioner by the Governing Body Interview schedulers regarding steps to ensure procedures scheduled align with delineation of privileges (DoP) Cross-check operative log with credentialing files to confirm cases align with DoP.</p>
11-C-11	A	B	C	<p>Physicians, including both directly employed and contract physicians, who perform procedures, including anesthesia services, in facilities accredited by QUAD A must provide evidence of training and competence in the procedures for which the physician is credentialed and privileged to perform in the facility. Individual consideration will be given if the physician no longer possesses or cannot obtain such privileges, and can demonstrate that loss of, or inability to obtain such privileges was not related to lack of clinical competence, ethical issues, or problems other than economic competition. -OR- If the physician, including both directly employed and contract physicians, has never held privileges, or no</p>	<p>Verify all physicians undergo a thorough credentialing process (including review of education, training, licensure, certifications, experience, and disciplinary history) to ensure professional qualification and competence.</p> <p>Evaluating Compliance: Review policies for credentialing/privileging healthcare practitioners for: Process for credentialing/re-credentialing (verifying qualifications, status to practice legally) Process for granting privileges (approval by governing body, setting scope of practice) Mandate that practitioners must practice within their delineated scope Review Governing Body meeting minutes for evidence of: Discussions and review of candidate qualifications (initial credentialing, during re-credentialing) Outcomes (approvals, denials) Interview credentialing leadership regarding the credentialing/privileging process</p>

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			<p>longer holds privileges, QUAD A will accept alternate credentialing via primary source verification. Primary source verification must be performed every three (3) years. Additionally, these physicians who are being credentialed using primary source verification are not required to maintain hospital admitting privileges. Required elements of initial primary source verification are:</p> <ul style="list-style-type: none"> • Verification of medical education directly from institution (MD, DO, DMD, DDS, or DPM degree) • Verification of any specialty/subspecialty from sponsoring institution • Verification of all state license(s) with issue date(s), expiration date(s), status (as of current date) and type of license (temporary, limited or unlimited) • Verification of board certification status, if applicable • Drug Enforcement Administration (DEA) registration status • National Practitioner Databank (NPDB)'s Integrated Querying and Reporting Services (IQRS) results • Current malpractice insurance <p>Required elements of ongoing primary source verification are:</p> <ul style="list-style-type: none"> • Verification of all state license(s) with issue date(s), expiration date(s), status (as of current date), and type of license (e.g., temporary, limited or unlimited) • Verification of board certification status, if applicable • Drug Enforcement Administration (DEA) registration status • National Practitioner Databank (NPDB)'s Integrated Querying and Reporting Services (IQRS) Results • Current malpractice insurance 	<p>Review credentialing files to verify medical staff have been granted clinical privileges. Minimum documentation includes:</p> <ul style="list-style-type: none"> Country/State licensure, registration, or state certification (as applicable) Certification by a specialty organization (as appropriate) Other training or pertinent experience Current hospital privileges (for the procedures requested)* Recommendation by qualified medical personnel (concerning the practitioner's competence) Scope of privileges granted to the practitioner by the Governing Body (delineation of privileges) Rational for privileges granted against peer recommendation (when applicable) <p>*Primary-source verification of credentials (performed at least every 3 yrs) when the physician has never held (or no longer holds) hospital privileges for the procedures requested.</p>

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11-C-12	A	B	C	<p>Practitioners of interventional radiology must meet all of the following criteria:</p> <ul style="list-style-type: none"> • MD or DO • Board certification or board eligibility by the American Board of Radiology (ABR) • Fellowship training as approved by the ABR • Current certificate of added qualifications in interventional/vascular radiology 	<p>Verify all practitioners of interventional radiology (IR) meet minimum requirements to ensure professional qualification and competence to provide services in the facility.</p> <p>Evaluating Compliance: Review policies for credentialing/privileging healthcare practitioners for: Who is authorized to perform IR procedures Process for credentialing/re-credentialing (verifying qualifications, status to practice legally) Minimum requirements for practitioners of IR Review Governing Body meeting minutes for evidence of: Discussions and review of candidate qualifications (initial credentialing, during re-credentialing) Outcomes (approvals, denials) Interview credentialing leadership regarding the credentialing/privileging process for IR Review credentialing files for IR practitioners for evidence of: MD or DO degree Country/State licensure, registration, or state certification (as applicable) Certification by the ABR Fellowship training as approved by the ABR Current certificate of added qualifications in interventional/vascular radiology Other training or pertinent experience Scope of privileges granted to the practitioner by the Governing Body (delineation of privileges).</p>
11-C-13	A	B	C	<p>Practitioners of Pain Management must meet all of the following criteria:</p> <ul style="list-style-type: none"> • Have an M.D. or D.O. degree • Appropriate fellowship training in pain management • Possess ABMS Board certification in one of the following specialties: Anesthesiology, Physical Medicine and Rehabilitation (PM&R), Psychiatry/Neurology • Possess a sub-specialty certification from the American Board of Anesthesiology or the AOABOS • CRNAs, as permitted by state law, who have completed a one year academic pain fellowship accredited by the Council on Accreditation for Nurse Anesthesia Educational Programs and possess a subspecialty (non-surgical) board 	<p>Verify all practitioners of pain management (PM) meet minimum requirements to ensure professional qualification and competence to provide services in the facility.</p> <p>Evaluating Compliance: Review policies for credentialing/privileging healthcare practitioners for: Who is authorized to perform PM procedures (e.g., physicians, CRNAs when permitted by state) Process for credentialing/re-credentialing (verifying qualifications, status to practice legally) Minimum requirements for practitioners of PM Review Governing Body meeting minutes for evidence of: Discussions and review of candidate qualifications (initial credentialing, during re-credentialing) Outcomes (approvals, denials) Interview credentialing leadership regarding the credentialing/privileging process for PM practitioners Review credentialing files for PM practitioners for evidence of: MD or DO degree Country/State licensure, registration, or state certification (as applicable)</p>

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				certification from the National Board for Certification and Recertification of Nurse Anesthetists.	<p>Certification by the ABMS (Anesthesiology, PM&R, Psychiatry/Neurology) Sub-specialty certification from the American Board of Anesthesiology or the AOABOS Fellowship training in PM Other training or pertinent experience Scope of privileges granted to the practitioner by the Governing Body (delineation of privileges) For CRNA (when permitted by state law): Pain fellowship (1 yr) accredited by the Council on Accreditation for Nurse Anesthesia Educational Programs Subspecialty (non-surgical) Board Certification from the NBCRNA.</p>
Sub-section D: Anesthesia Providers					
11-D-2		B	C	All anesthesia providers must be licensed or accredited by the state in which they practice.	<p>Verify all anesthesia professionals working in the facility meet minimum requirements for licensure (or accreditation) to ensure patient safety and maintain regulatory compliance with state and federal laws.</p> <p>Evaluating Compliance: Review policies for credentialing/privileging healthcare practitioners for: Who is authorized to perform anesthesia (e.g., physician, CRNA, CAA) Process for credentialing/re-credentialing (verifying qualifications, status to practice legally) Minimum requirements for eligible practitioners Review credentialing files for evidence of minimum criteria (by type): All Anesthesia Professionals: current state license (where facility is located) CRNA: current certification by NBCRNA CAA: current certification by NCCAA Interview credentialing manager regarding process to verify licensure and certifications Review credentialing/personnel files for evidence of current licensure and certifications (as applicable).</p>
11-D-3			C	An anesthesia professional must be responsible for the administration of dissociative anesthesia with propofol, spinal or epidural blocks, or general anesthesia as well as the monitoring of all life support systems.	<p>Verify only qualified anesthesia professionals administer high-risk medications and perform high-risk anesthesia techniques, whilst providing continuous monitoring to ensure patient safety.</p> <p>Evaluating Compliance: Review policies for: Mandate that only authorized anesthesia staff (e.g., physician, CRNA, CAA) may perform: Dissociative anesthesia with propofol, neuraxial blocks, and general anesthesia Monitoring requirements Documentation standards Interview staff regarding facility protocols for anesthesia administration</p>

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					<p>Observe practice to confirm use of anesthesia professionals & continuous monitoring</p> <p>Review clinical records for evidence of:</p> <ul style="list-style-type: none"> Type of anesthesia and/or technique Continuous monitoring (oxygenation, ventilation, circulation, body temperature) Anesthesia professional (name, credentials).
11-D-6		B	C	<p>If responsible for supervising anesthesia or providing anesthesia, the qualified physician must be present in the operating suite throughout the administration of anesthesia.</p>	<p>Verify the continuous presence of a physician in the operating room, when responsible for administering anesthesia or supervising anesthesia administration, to meet the patient's medical needs in case of an emergency.</p> <p>Evaluating Compliance:</p> <p>Review policies for:</p> <ul style="list-style-type: none"> Alignment with any state law regarding supervision of anesthesia services Process for credentialing (verifying qualifications, status to practice legally) Mandate that supervising physicians must be qualified to do so Mandate that practitioners must practice within their delineated scope <p>Review Governing Body meeting minutes for evidence of:</p> <ul style="list-style-type: none"> Discussions and review of candidate qualifications Outcomes (approvals, denials) and delineation of privileges (including supervision) <p>Interview staff regarding protocols for physicians providing/supervising anesthesia care</p> <p>Observe practice to validate continuous presence of supervisor</p> <p>Review clinical records for evidence of:</p> <ul style="list-style-type: none"> Name of person administering anesthesia (name, credentials) Documentation of physician supervisor <p>Review credentialing files for evidence of:</p> <ul style="list-style-type: none"> Physician scope of privileges includes supervision of anesthesia administration
11-D-8		B	C	<p>The anesthesia professional(s) or the registered nurse providing sedation cannot function in any other capacity (e.g., procedure assistant or circulating nurse) during the procedure, except for oral and maxillofacial surgery where the operator/anesthetist model has been established utilizing a two-person team for Moderate sedation and a three-person team for Deep sedation. All personnel must abide by all state and federal regulations and laws governing the administration of anesthesia.</p>	<p>Verify the anesthesia professional providing anesthesia (or the registered nurse providing moderate sedation) is continuously monitoring the patient to allow the prompt recognition of an acute problem or harmful trend, as well as the appropriate response. When moderate/deep sedation or general anesthesia is planned, staffing models must include additional staff to perform the duties of a circulating nurse</p> <p>Exception for Dental and Oral and Maxillofacial (OFM) Surgery. The dentist anesthesiologist administering moderate sedation, when simultaneously involved in the conduct of the dental procedure or surgery, must have at least one trained support staff whose responsibility is to monitor appropriate physiological parameters and to assist in any supportive or resuscitation measures, if required. The individual(s) may also be responsible for assisting with interruptible patient-related tasks of short duration.</p> <p>Evaluating Compliance:</p>

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					<p>Review policies for:</p> <ul style="list-style-type: none"> Alignment with state and federal regulations governing anesthesia Mandate that anesthesia professional (or RN admin moderate sedation) must not perform any other duties Exemption: Dental and Oral and Maxillofacial Surgery Protocols: <ul style="list-style-type: none"> Two-person team for moderate sedation Three-person team for deep sedation Monitoring standards Documentation standards (when signature of supervising physician is required) <p>Interview anesthesia/sedation staff regarding acceptable tasks during anesthesia/sedation (per program type)</p> <p>Observe practice to confirm anesthesia/sedation providers comply with policies & procedures</p> <p>Review clinical records for evidence of:</p> <ul style="list-style-type: none"> Appropriate staffing levels (per facility policy) Medications administered Continuous monitoring (oxygenation, ventilation, circulation, body temperature when appropriate) Documentation (per facility policy) Minimal staffing (by program type) - (not including of surgical assistants) <ul style="list-style-type: none"> Surgery/Procedure: surgeon, anesthesia/sedation provider, and circulator (name, credentials) OMS-Dental: dentist/surgeon (providing mod sedation) and one support staff (name, credentials) OMS-Dental: dentist/surgeon (providing deep sedation) and two support staff (name, credentials).
11-D-9	B	C		<p>All anesthetics other than topical or local anesthetic agents are delivered by either an anesthesiologist, or by a CRNA (under physician supervision if required by state or federal law or by a policy adopted by the facility), or by an anesthesiology assistant certified by the NCCAA (under direct supervision of an anesthesiologist). Parenteral sedation, other than propofol, may be administered by a registered nurse under the supervision of a qualified physician.</p> <p>§416.42(b)(1) Standard §416.42(b)(2) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
11-D-10	A	B	C	<p>An ASC may be exempted from the requirement for physician supervision of CRNAs as described in QUAD A Standard 11-D-9, if the State in which the</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>

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				<p>ASC is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt out is consistent with State law.</p> <p>§416.42(c) Standard §416.42(c)(1) Standard</p>	
11-D-11	A	B	C	<p>The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time and are effective upon submission.</p> <p>§416.42(c)(2) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
Sub-section E: Facility Staffing					
11-E-2		B	C	<p>All operating suite personnel must meet acceptable standards as defined by their state scope of practice and professional governing bodies, where applicable.</p>	<p>Verify that staff provide care in accordance with their professional standards of practice and applicable state laws. Facilities must be knowledgeable of the state scope of practice laws governing all clinical staff (e.g., Registered Nurses, APRN, PA), whether employees or contracted.</p> <p>Evaluating Compliance: Interview staff regarding protocols for monitoring patients, administering medications and sedation/anesthesia Observe practices to identify breaches (e.g., exceeding scope, unprofessional conduct, failure to monitor at-risk patients) Review personnel files for: Job description with responsibilities listed (within the scope of practice).</p>
11-E-3	A	B	C	<p>Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>

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				be available whenever a patient is in the ambulatory surgery facility. §416.44(e) Standard	
Sub-section F: Nurse Staffing					
11-F-1	A	B	C	The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met. §416.46 Condition	SOM Appendix L - Guidance for Surveyors: ASCs
11-F-3	A	B	C	Patient care responsibilities must be delineated for all nursing service personnel. §416.46(a) Standard	SOM Appendix L - Guidance for Surveyors: ASCs
11-F-4	A	B	C	No nurse provides coverage in the ASC and in an adjacent clinic (or hospital) at the same time.	Verify that nurses providing coverage in the ASC, are not responsible for providing services outside the ASC at the same time (e.g., staffing the adjacent office, hospital). Evaluating Compliance: Review staffing schedules Interview staff Observe practice.
11-F-5	A	B	C	Nursing services must be provided in accordance with recognized standards of practice. §416.46(a) Standard	SOM Appendix L - Guidance for Surveyors: ASCs
11-F-6	A	B	C	There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC. §416.46(a) Standard	SOM Appendix L - Guidance for Surveyors: ASCs
Sub-section G: Post-Anesthesia Care Unit (PACU) Staffing					
11-G-1		B	C	There is a written policy that whenever parenteral sedation, dissociative drugs, epidural, spinal or	Verify a physician is immediately available to respond to patients' needs during post-anesthesia care.

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			<p>general anesthesia is administered, a physician is immediately available until the patient is discharged from the PACU.</p>	<p>Immediately available means the physician is available and accessible within the facility to provide patient care and respond to emergencies without delay.</p> <p>Evaluating Compliance: Review policies for: Mandate of physician being immediately available until patient is discharged from the PACU Definition of "immediately available" Interview staff to determine when the physician may leave the premises Observe practice to confirm the physician is accessible to staff Review clinical records for evidence of the physician's discharge signature and timestamp.</p>
11-G-2	B	C	<p>All recovering patients must be observed and supervised by trained medical personnel in the PACU. A physician, CRNA, PA, or RN currently licensed and certified in advanced cardiac life support (ACLS) or pediatric advanced life support (PALS), as appropriate, is immediately available until the patient has met PACU discharge criteria for discharge from the facility. Local mandates and stricter standards may apply.</p>	<p>Verify a qualified and trained medical staff member is immediately available to ensure the safe recovery of patients in the PACU. The Physician, CRNA, RN, NP, or PA in charge of recovering the patient is responsible for all PACU documentation in the clinical record. LPNs, LVNs, and Medical Assistants are not qualified to recover patients, as all require direct supervision by a physician, CRNA, RN, NP, or PA.</p> <p>Note: If a contract anesthesiologist brings emergency medications or equipment into the facility and removes them when leaving, the contract anesthesiologist must remain in the facility until all patients have been discharged from the PACU.</p> <p>Evaluating Compliance: Review policies for: Alignment with any local or state mandates for staffing (when additional/stricter requirements apply) Mandate that qualified, trained staff is immediately available until patient is discharged from the PACU Definition of "immediately available" Interview staff to determine: PACU protocols If emergency equipment/medications are supplied by contracted anesthesia professionals Observe practice to confirm a physician, CRNA, RN, NP, or PA is immediately available Review personnel records for evidence of current ACLS and/or PALS certification for all PACU staff Review clinical records for evidence of the physician's discharge signature and timestamp</p>
11-G-5	B	C	<p>A minimum of one ACLS, and when appropriate PALS as well, certified staff member must be present in the facility until all patients recovering from anesthesia have met the facility's discharge criteria for discharge from the facility.</p>	<p>Verify all recovering patients are observed and monitored until discharge criteria have been met as determined by qualified personnel.</p> <p>Note: If a contracted anesthesia professional brings any emergency medications or equipment</p>

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					<p>into the facility and removes any of these items when leaving the facility, the contractor must remain in the facility until all patients have been discharged from the PACU.</p> <p>Evaluating Compliance: Review policies for: Mandate: ≥ one (1) ACLS (and/or PALS) certified staff member is present until patients meet discharge criteria Interview staff regarding use of equipment/medicines from contractors, staffing minimums, & discharge process Observe practice to confirm compliance Review personnel files for evidence of current ACLS and/or PALS (separate BLS certificate not required)</p>
Sub-section H: Personnel Records					
11-H-2	A	B	C	<p>The facility maintains a manual outlining personnel policies that is reviewed annually and updated as needed.</p>	<p>Verify the facility has clearly defined policies in place to ensure all employees are aware of expectations on behavior within the workplace environment. This includes references to areas such as dress code, attendance requirements, vacation time allotment, and acceptable use of technology. The facility must provide training during staff onboarding and when policies are updated.</p> <p>Evaluating Compliance: Review policies for inclusion of comprehensive personnel policies Interview staff regarding: Knowledge of essential policies Where policies can be accessed Review personnel files for evidence of training (initial, with updates)</p>
11-H-3	A	B	C	<p>The manual contains personnel policies and records which are maintained according to the Occupational Safety and Health Administration (OSHA), Health Insurance Portability & Accountability Act (HIPAA), and Americans with Disabilities Act (ADA) guidelines.</p> <p>IMPORTANT: Employee information must remain strictly confidential.</p>	<p>Verify the facility has clearly defined staff policies addressing all local, state, or federal regulations. The policies must address, at a minimum, compliance with the following: OSHA Regulations (§1910.1020), Health Information Privacy (HIPAA), and ADA Title 42 Section 12101 Equal Opportunity for Individuals with Disabilities.</p> <p>Evaluating Compliance: Review policies for inclusion of required elements Interview staff regarding familiarity with: OSHA protections Protecting health information Efforts to accommodate known disabilities of patients and staff</p>

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11-H-4	A	B	C	<p>The facility maintains a personnel file for all clinical and administrative employees, including direct and contract employees.</p>	<p>Verify the facility maintains comprehensive personnel files for all clinical and administrative staff to ensure compliance with federal, state, and accreditation standards, protect against liability, and ensure patient safety. All staff providing care or services within the facility, whether employees or contractors, must have a file onsite. This includes surgeons, anesthesia professionals, PAs, RNs, LPNs, medical assistants, scrub techs, sterile processing techs, lab and x-ray techs, other clinical employees, and administrative staff.</p> <p>Note: General staff information such as previous employment, disabilities, employment, and performance reviews are protected. However, access must be provided for the surveyor to confirm a comprehensive file is kept for all staff and to evaluate facility compliance with state regulations, federal regulations and QUAD A standards (e.g., immunizations, annual health questionnaire, and, safety training).</p> <p>Evaluating Compliance: Interview human resources manager regarding process for ensuring file content is up to date Request a list of all staff (employees and contractors) Confirm personnel files are maintained for all staff.</p>
11-H-5	A	B	C	<p>Each personnel record contains any health problems of the individual which may be hazardous to the employee, other employees or patients, and a plan of action or special precautions delineated as needed. To be reviewed and updated annually.</p>	<p>Verify the facility maintains documentation of the current health status of all staff, that informs the facility of any health conditions that may potentially put other staff or patients at risk. If no hazardous health problems exist, this should be documented in the personnel file. This must be updated and reviewed annually</p> <p>Note: The process must be in accordance with ADA requirements (§12112(d)). Information cannot be obtained until after an offer of employment has been made. However, a facility may make pre-employment inquiries into an applicant's ability to perform job-related functions.</p> <p>Evaluating Compliance: Review personnel files for evidence of: A health status questionnaire (at least annually) Special precautions or plan of action when health problem has been identified (when applicable).</p>
11-H-6	A	B	C	<p>Each personnel record contains resume of training and experience.</p>	<p>Verify the personnel file includes documentation of past training and work experiences to ensure staff are qualified to perform their duties. The file must also include evidence of any specialized training (i.e. administering moderate sedation) required for the position.</p> <p>Evaluating Compliance: Review personnel files for evidence of: Job application (for non-clinical staff) Resume or CV</p>

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					<p>Specialized training certificates (or certifications) Confirm evidence of specialized training when essential to the position.</p>
11-H-7	A	B	C	<p>Each personnel record contains current certification or license if required by the state.</p>	<p>Verify the personnel file includes documentation of current certification or license (when required) to verify qualifications, maintain compliance with state and federal regulations, and ensure patient safety.</p> <p>Evaluating Compliance: Interview human resources manager regarding process for verifying professional license is current Review personnel files for evidence of license and certifications (not expired).</p>
11-H-8	A	B	C	<p>Each personnel record contains date of employment.</p>	<p>Verify the personnel file includes documentation of the employee's date of hire (or the date a contracted staff member begins working in the facility). This date assists with determining compliance with standards requiring annual review or training.</p> <p>Evaluating Compliance: Review personnel files for evidence of date of hire (or contract commencement).</p>
11-H-9	A	B	C	<p>Each personnel record contains description of duties.</p>	<p>Verify the personnel file includes documentation of the duties required for the position. The scope of approved privileges shall constitute the clinical job description for a healthcare practitioner (e.g., Surgeon, Anesthesiologist, CRNA). When any clinical position includes non-patient care duties (e.g., peer review, participation in infection prevention and control or quality programs), this should be documented. Facility appointments (e.g., Medical Director and Facility Director) must have a comprehensive job description.</p> <p>Evaluating Compliance: Review personnel files for evidence of job descriptions for: Non-clinical positions (e.g., billing manager, receptionist) Clinical positions (e.g., RN, scrub tech) Facility appointments (e.g., Medical Director, Infection Preventionist).</p>
11-H-10	A	B	C	<p>Each personnel record contains on-going records of inoculations or refusals in accordance with local, state/provincial or federal/national requirements.</p>	<p>Verify the personnel file includes documentation of any mandatory vaccine administration, which may vary from state to state. The facility must confirm the requirements for the state (where the facility is located) and determine the acceptable documentation for proof of vaccination.</p> <p>Evaluating Compliance: Review policies for: Alignment with state-specific requirements for vaccinations Alignment with state-specific requirements for Tb screening/testing</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Acceptable vaccine records (documented injections, vaccine registry records, titer level, declination) Review personnel files for evidence of vaccination administration or refusal.</p>
Sub-section I: Personnel Training					
11-I-1	A	B	C	<p>Each personnel record has evidence of annual hazard safety training.</p>	<p>Verify the personnel file includes documentation that annual hazard safety training is administered, to keep staff knowledge of safety protocols current and ensure compliance with federal regulations. Staff must understand the hazards they are likely to encounter and how to identify each one. Control training ensures that they know what to do when encountering biological, chemical, physical, safety, or psychosocial hazards</p> <p>Online training courses using a learning management system are acceptable when the content is reviewed/approved by the facility annually. However, the facility must provide additional training regarding action to be taken in the event of exposure (specific to their facility). Non-specific, general online training is not acceptable.</p> <p><u>Evaluating Compliance:</u> Review personnel files for evidence of annual hazard safety training for all staff Confirm the content is facility specific and covers action plans when hazards are encountered.</p>
11-I-2	A	B	C	<p>Each personnel record has evidence of annual blood borne pathogen training.</p>	<p>Verify the personnel file includes documentation that annual blood borne pathogen (BBP) training is administered to staff with a reasonable risk of exposure to blood or bodily fluids, to minimize exposure risk and ensure compliance with federal regulations. BBP training ensures that clinical staff can identify the risks of exposure, prevent exposure by taking proper precautions, and take effective action in the event of exposure</p> <p>Online training courses are acceptable when the content is reviewed/approved by the facility annually. However, the facility must provide additional training regarding action to be taken in the event of exposure (specific to their facility). Non-specific, general online training is not acceptable.</p> <p><u>Evaluating Compliance:</u> Review personnel files for evidence of annual blood borne pathogen training for all clinical staff Confirm the content is facility specific and covers action plans for exposures.</p>
11-I-3	A	B	C	<p>Each personnel record has evidence of annual standard precaution training.</p>	<p>Verify the personnel file includes documentation that annual standard precaution training is administered to all clinical staff to prevent the transmission of infectious diseases in healthcare settings and ensure compliance with federal/national regulations.</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Online training courses are acceptable when the content is reviewed/approved by the facility annually.</p> <p>Evaluating Compliance: Review personnel files for evidence of annual standard precaution training for all clinical staff.</p>
11-I-4	A	B	C	<p>Each personnel record has evidence of other annual safety training including operative fire safety training and structure fire safety, including operation of a fire extinguisher.</p>	<p>Verify the personnel file includes documentation that annual fire safety training is administered to all staff to prevent, respond to, and evacuate themselves and others from fires safely. This training must be facility specific. Online training is not sufficient.</p> <p>Evaluating Compliance: Review training materials to ensure content is comprehensive for a healthcare facility, at a minimum including:</p> <ul style="list-style-type: none"> Use of fire extinguishers Extinguishing fires on the surgical field (as applicable) Evacuation of patients requiring mobility assistance Evacuation plans for sedated or anesthetized patients (as applicable) <p>Review personnel files for evidence of annual fire safety training for all staff.</p>
11-I-5	A	B	C	<p>Each personnel record has evidence of at least Basic Cardiopulmonary Life Support (BLS) certification, but preferably Advanced Cardiac Life Support (ACLS) and/or Pediatric Advanced Life Support (PALS) for each operating room and PACU team member, depending on the patient population served.</p>	<p>Verify the personnel file includes documentation of current certification to respond to cardiopulmonary emergencies for all clinical staff. ACLS (and/or PALS) certification is preferable to BLS. Online training is not sufficient</p> <p>BLS certification (initial, ongoing) must be intended for healthcare professionals (not lay people) and include a didactic component <u>and</u> a hands-on skills check</p> <p>ACLS (and/or PALS) certification (initial, ongoing) must be obtained from the American Heart Association (or equivalent) that includes a didactic component <u>and</u> a hands-on skills demonstration of airway management and automated external defibrillator (AED) use</p> <p>Perioperative Life Support (PeRLS) (along with current BLS) may be accepted for all perioperative physicians and members of the surgical team including Anesthesiologists, Certified Anesthesia Assistants, and CRNAs.</p> <p>Evaluating Compliance: Review policies for definition of which staff roles require each level of certification Review personnel files for evidence of current certification Review random samples of clinical records (or cases from the operative log) and cross-check with personnel files to confirm a staff with current ACLS certification is present in the OR during every procedure.</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
11-I-6	A	B	C	<p>Clinical personnel must have the knowledge to provide treatment for cardiopulmonary and anaphylactic emergencies. At least one member of the operating room team, preferably the physician, pediatric dentist, or anesthesia professional, holds current PALS certification and/or ACLS certification, if appropriate.</p>	<p>Verify each room is staffed with at least one (1) member of the operative team (preferably the physician, pediatric dentist, or anesthesia professional) having current ACLS (and/or PALS) certification to ensure treatment follows standardized, evidence-based guidelines to improve outcomes for patients with life-threatening cardiovascular emergencies.</p> <p>Evaluating Compliance: Interview staff regarding process to staff each operating room with at least one (1) staff with current ACLS Observe practice to validate at least one (1) staff member has current ACLS Cross-check operative logs (by date) with personnel files to confirm compliance with standard.</p>
11-I-10	A	B	C	<p>The operating room personnel are familiar with the equipment and procedures utilized in treating emergencies, as discussed in standards section 5-C: Emergency Protocols.</p>	<p>Verify all operating room staff receive comprehensive emergency training, including the location and use of emergency equipment, to enable swift, coordinated responses to crises such as medical emergencies or disasters. The facility must provide training upon hire (or when contracted staff begins working in the facility), annually, and when updates to emergency response protocols are updated.</p> <p>Evaluating Compliance: Review training materials for comprehensive content (e.g., use of emergency equipment, responses to active threats) Interview staff regarding emergency responses (e.g., location of emergency equipment, initiating patient transfer, evacuating an anesthetized patient during fire in the facility) Review personnel files for evidence of training (initial, annual, updates).</p>
11-I-13	A	B	C	<p>Where staff cannot demonstrate competency, training, or experience in the safe operation of equipment, the facility provides and documents training or arranges training through an external provider.</p>	<p>Verify staff receive thorough instruction on the effective use of facility equipment that is specific to their position. This allows staff to correctly operate complex medical devices, preventing misuse, malfunction, or harm to patients or themselves. Whether provided by the facility or an external representative, training content must align with the equipment's instructions for use. Competency should be assessed initially and periodically.</p> <p>Evaluating Compliance: Interview staff regarding: How the facility assesses competency to run specialized equipment (e.g., self-assessment, qualified peer observation) What equipment requires training by an external expert (e.g., robotic equipment, lasers) Review personnel files for evidence of competency for job-specific equipment (initial, per policy).</p>

SECTION 12: STATE SUPPLEMENTS

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
Sub-section A: ASC - Florida					
12-A-1	A	B	C	<p>The facility has processes that report and investigate safety incidents, complaints, adverse events and near misses for patients and staff on a defined basis. The results of these investigations of adverse events are reported in the Quality Improvement/Quality Assessment meetings.</p>	<p>Verify facility awareness of Florida regulations and compliance with tracking and investigation of adverse events affecting patients and staff.</p> <p><u>Evaluating Compliance:</u> Review policies regarding the Quality program for: Alignment with Florida regulations Definitions of Adverse Events (AE) Procedures for handling AE (e.g., documentation, tracking incidents, investigation) Incorporation of AE process into the facility's Quality program Review Quality program meeting minutes for evidence of: Systematic reporting (AE reports, logs) Tracking (e.g., spreadsheets, dashboards) Investigations and outcome Performance improvement efforts (e.g., studies, actions, changes in processes) Interview Quality coordinator regarding process to track and investigate AE Interview staff regarding: What constitutes an adverse event Reporting mechanisms Efforts to reduce AE incidents.</p>
12-A-2			C	<p>Anesthetic safety regulations shall be developed, posted and enforced. Such regulations shall include at least the following requirements: Electrical equipment in anesthetizing areas shall be on an audiovisual line isolation monitor, with the exception of radiologic equipment and fixed lighting more than 5 feet above the floor.</p>	<p>Verify facility awareness of Florida regulations and compliance with the directive to develop, post, and enforce anesthetic safety regulations for the facility. At a minimum, these regulations must state that all electrical equipment in anesthetizing areas must be on an isolated power system equipped with an audiovisual line isolation monitor (LIM), except for radiologic equipment and fixed lighting installed greater than 5 feet above the floor. This crucial safety measure protect patients and staff from electrical shock and ensures the continuous operation of life-sustaining equipment.</p> <p><u>Evaluating Compliance:</u> Review policies for: Alignment with Florida regulations regarding anesthesia safety Mandate that all electrical equipment in anesthetizing locations is on isolated power system with LIM Exception for radiologic equipment and fixed lighting installed at least 5 feet from floor</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Interview leadership regarding:</p> <ul style="list-style-type: none"> Knowledge of safety requirements Compliance monitoring and enforcement techniques <p>Observe ORs for evidence of required posting and use of checklists (if applicable)</p> <p>Inspect electrical equipment (with staff assistance) to confirm placement on an isolated power system with LIM.</p>
12-A-3			C	<p>Anesthetic safety regulations shall be developed, posted and enforced. Such regulations shall include at least the following requirements: Each anesthetic gas machine shall have pin-index system or equivalent safety system and a minimum oxygen flow safety device.</p>	<p>Verify facility awareness of Florida regulations and compliance with the directive to develop, post, and enforce anesthetic safety regulations for the facility, to include the use of pin-index systems and minimum oxygen ratio controllers for each anesthesia gas machine.</p> <p><u>Evaluating Compliance:</u></p> <p>Review policies for:</p> <ul style="list-style-type: none"> Alignment with Florida regulations regarding anesthesia safety Mandated use of pin-index system (prevents connecting the wrong gas cylinder to the anesthesia machine) Mandated use of a minimum oxygen ratio controller (device to safeguard against hypoxia) Exception for radiologic equipment and fixed lighting installed at least 5 feet from floor <p>Interview leadership regarding:</p> <ul style="list-style-type: none"> Knowledge of safety requirements Compliance monitoring and enforcement techniques <p>Observe ORs for evidence of required posting and use of checklists (if applicable)</p> <p>Inspect electrical equipment (with staff assistance) to confirm compliance for usage.</p>
12-A-4	A	B	C	<p>The process for entry or admission to the facility for a procedure must be coordinated and defined in a policy.</p>	<p>Verify facility awareness of Florida regulations and confirm the facility has a written policy for patient admission to service. The policy must detail the coordinated, step-by-step process for admission, including receipt of pre-op lab work or medical clearance, registration, patient identification, pre-op assessments, and attaining informed consent, thus maintaining compliance with federal regulations and providing a standardized framework for safe, consistent, quality care.</p> <p><u>Evaluating Compliance:</u></p> <p>Review policies for:</p> <ul style="list-style-type: none"> Alignment with Florida regulations Process for patient admission to the facility: <ul style="list-style-type: none"> Pre-op phone call from nurse (reinforce instructions, begin risk assessment) Check-in at front desk (confirm ID and apply wristband, sign facility documents) Essential procedures (e.g., baseline VS, pre-op/pre-anesthesia assessments) Directive for staff to identify variances that may require cancellation (or delay) <p>Interview of both administrative and clinical staff regarding knowledge of:</p> <ul style="list-style-type: none"> Overall admission process

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Informing patient on Bill of Rights Variances that may require cancellation (e.g., NPO breach, no transportation) Observe admission process for critical steps for proceeding with surgery.</p>
12-A-5	A	B	C	<p>The facility has a written quality improvement program implemented which should include surveys of projects that include documentation of quarterly infection prevention and control and risk management meetings for the prior 3 years, which should be available for the surveyor.</p>	<p>Verify facility awareness of Florida regulations and confirm written documentation exists for its Quality Improvement (QI) efforts to improve patient safety and satisfaction, optimize efficiency, drive financial success, and meet accreditation standards. QI meetings should be held at least quarterly to review quality data. Outcome measures falling outside of internal or external benchmarking should be remediated by performance improvement projects providing a systematic way to solve problems, reduce errors, and return the facility to high standards of care.</p> <p>Evaluating Compliance: Review QI meeting minutes held at least quarterly Review the facility's identified performance improvement projects Confirm meeting minutes are available for review from the prior three (3) years.</p>
12-A-6	A	B	C	<p>Smoking Regulations Smoking regulations shall be adopted and shall include not less than the following provisions: (1) Smoking shall be prohibited in any room, ward, or compartment where flammable liquids, combustible gases, or oxygen is used or stored and in any other hazardous location, and such area shall be posted with signs that read NO SMOKING or shall be posted with the international symbol for no smoking. (2) In health care occupancies where smoking is prohibited and signs are prominently placed at all major entrances, secondary signs with language that prohibits smoking shall not be required.</p>	<p>Verify facility awareness of Florida regulations and ensure compliance with a strict no smoking policy across all areas of the facility. This includes all types of smoking -cigarette and pipe smoking, vaping and e-cigarettes</p> <p>Evaluating Compliance: Review policies for the adoption of a smoking ban Review facility documents to ensure employee handbooks and patient materials reinforce "no smoking" Inspect the facility for posted "No Smoking/Vaping" signs at entrances and key areas Observe for compliance among patients, guests, and staff.</p>
12-A-7	A	B	C	<p>As part of an ongoing risk management program, the facility must conduct a risk assessment of its operational activities at least annually. The assessment should study the risks presented to patients and staff by medication management, fall hazards, infection prevention and control, equipment safety, patient risk resulting from long term conditions, and nutrition if any food or beverage services are available to patients. The results of the</p>	<p>Verify facility awareness of Florida regulations and confirm the facility performs a comprehensive assessment of risk to patients and staff at least annually. This is typically done by ranking risks based on a combination of their likelihood of occurrence and their potential impact using tools like a risk matrix. Risk assessment results must be prioritized to focus on the highest-priority risks for mitigation and performance improvement projects.</p> <p>Evaluating Compliance: Review the risk assessment (RA) for: Inclusion of all risks required by the standard (medication management, fall hazards, infection prevention and control, equipment safety, patient risk resulting from long term</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				Risk Assessment should be prioritized for risk mitigation, risk management, and QA/PI projects.	<p>conditions, and nutrition services) Identification of highest-priority risks Review Governing Body meeting minutes for review of RA data and plan Cross-check this year's priorities with documented performance improvement projects Review current year's RA and compare to the previous year's results to confirm RA document is not stagnant and is being updated to reflect changes in policies, operations, training efforts resulting from previous year's performance improvement efforts.</p>
12-A-8	A	B	C	The facility must develop and maintain a program of risk management, appropriate to the organization. This may be carried out in conjunction with the Quality Assessment/Quality Improvement program.	<p>Verify facility awareness of Florida regulations and confirm the implementation of an internal risk management (RM) program that includes written policies, a risk manager, adverse incident reporting, and analysis of patient grievances. Risk management activities should be integrated into the Quality Improvement (QI) program and reviewed at least quarterly.</p> <p>Evaluating Compliance: Review policies for RM program requirements, including the: Appointment of Risk Manager (by the Governing Body) Investigation/analysis of frequency/causes of categories & types of adverse incidents causing injury Development of measures to reduce risk of adverse events to patients (including education & training) Analysis of patient grievances regarding patient care & quality of medical services Development/implementation of an incident reporting system RM training requirement (1-hour per year) Review RM adverse event recordkeeping (e.g., logs, spreadsheet, files) Review Governing Body and QI meeting minutes for review of RM data and plan Review personnel files for evidence of required training (initial, annual).</p>
12-A-9	A	B	C	All staff must be educated in risk management activities on commencement of employment and annually thereafter, and when there is an identified need.	<p>Verify facility awareness of Florida regulations and confirm staff are trained on the facility's risk management (RM) activities upon hire, then at least annually.</p> <p>Evaluating Compliance: Review policies for RM program requirements, including the: RM training requirement (1-hour per year) Review RM training documents to ensure facility program/goals/efforts are included Interview staff regarding: Understanding of events with mandated reporting to the Risk Manager Reporting mechanism Review personnel files for evidence of required training (initial, annual).</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
12-A-10	A	B	C	<p>The governing body of the organization is responsible for overseeing the program of risk management.</p>	<p>Verify facility awareness of Florida regulations and confirm Governing Body oversight of the Risk Management program, as it is ultimately responsible for the center's total operation, patient safety, and compliance with state, federal, and accreditation standards.</p> <p>Evaluating Compliance: Review the facility's organization chart to ensure the definitions of hierarchy, reporting relationships, and responsibilities are addressed Review Governing Body meeting minutes for review of RM data and plan Interview risk manager regarding process for communicating adverse events to Governing Body (and other mandated reporting).</p>
12-A-11	A	B	C	<p>The facility will designate a person or committee responsible for implementation and ongoing management of the risk management program.</p>	<p>Verify facility awareness of Florida regulations and ensure an appointment has been made for the person (or committee) responsible for the Risk Management (RM) program.</p> <p>Evaluating Compliance: Review policies for: Alignment with Florida regulations Mandate for the Governing Body to appointment a Risk Manager Review organization chart for definitions of hierarchy and reporting relationships regarding the Risk Manager Review Governing Body meeting minutes for discussion and Risk Manager appointment Review personnel files for job description for Risk Manager</p>
12-A-12	A	B	C	<p>The individual responsible for the risk management program shall have free access to all medical records of the licensed facility.</p>	<p>Verify facility awareness of Florida regulations and ensure the person (or committee) responsible for the Risk Management (RM) program has full access to clinical records and facility documents.</p> <p>Evaluating Compliance: Review policies for: Alignment with Florida regulations Risk Manager responsibilities Mandate to provide access to all facility records to perform accurate audits, investigations, and mandated reporting Review organization chart for definitions of hierarchy and reporting relationships regarding the Risk Manager Interview Risk Manager regarding the facility's compliance with providing full access to clinical records and facility documentation.</p>
12-A-13	A	B	C	<p>The internal risk manager of each licensed facility shall: Notify the family or guardian of the victim, if a minor,</p>	<p>Verify facility awareness of Florida regulations and ensure the person (or committee) responsible for the Risk Management (RM) program provides essential communication, to the family or guardian, when investigating the sexual misconduct with a minor.</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				that an allegation of sexual misconduct has been made and that an investigation is being conducted.	<p><u>Evaluating Compliance:</u> Review policies for: Alignment with Florida regulations Risk Manager responsibilities (notifying/updating family/guardians for investigations) Facility process for: Investigating allegations of sexual misconduct with a minor (or someone with a guardian) Mandatory communication of the allegation Timelines for communicating allegation/findings/actions and duration of investigation Review Governing Body meeting minutes for discussion of the incident Interview Risk Manager regarding any history of allegations of sexual misconduct and the investigation findings and corrective actions (if any).</p>
12-A-14	A	B	C	<p>The internal risk manager of each licensed facility shall: Report to the Department of Health every allegation of sexual misconduct, as defined by state law, and the respective practice act, by a licensed health care practitioner that involves a patient.</p>	<p>Verify facility awareness of Florida regulations and ensure the person (or committee) responsible for the Risk Management (RM) program provides mandated reporting to the Department of Health, when investigating any allegation of sexual misconduct by a licensed health care practitioner.</p> <p><u>Evaluating Compliance:</u> Review policies for: Alignment with Florida regulations Risk Manager responsibilities Facility process for: Investigating allegations of sexual misconduct Mandatory reporting to the State Department of Health Timelines for communicating allegation/findings/actions and duration of investigation Review Governing Body meeting minutes for discussion of the incident Interview Risk Manager regarding any history of allegations of sexual misconduct and the investigation findings and corrective actions (if any) Verify evidence of reporting to the State Department of Health.</p>
12-A-15	A	B	C	<p>Any witness who witnessed or who possesses actual knowledge of the act that is the basis of an allegation of sexual abuse shall: Notify the local police.</p>	<p>Verify facility awareness of Florida regulations and ensure the facility mandates police are notified when direct knowledge of sexual abuse of a patient has occurred. The purpose of reporting is to protect potential future victims, hold abusers accountable, and preserve evidence. The facility must train staff on this requirement.</p> <p><u>Evaluating Compliance:</u> Review policies for: Alignment with Florida regulations</p>

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					<p>Risk Manager responsibilities Facility process for: Investigating allegations of sexual misconduct Mandate for staff witnessing (or having direct knowledge of) sexual misconduct to report directly to local authorities Review personnel files for evidence of required training (initial, annual).</p>
12-A-16	A	B	C	<p>The risk manager shall be responsible for the regular and systematic reviewing of all incident reports for the purpose of identifying trends or patterns as to time, place or persons. Upon emergence of any trend or pattern in incident occurrence, the risk manager shall develop recommendations for corrective actions and risk management prevention education and training. Summary data shall be maintained for 3 years.</p>	<p>Verify facility awareness of Florida regulations and confirm the Risk Manager has an effective process for reviewing all adverse incidents, variances, and patient grievances, analyzing them for trends or common factors, and recommending a plan of action that includes staff education/training. The facility must maintain written documentation of risk management (RM) activities for at least three (3) years.</p> <p>Evaluating Compliance: Review policies for RM program requirements, including the: Appointment of Risk Manager (by the Governing Body) Investigation/analysis of frequency/causes of categories & types of adverse incidents Development of measures to reduce risk of adverse events to patients (including education & training) Review RM adverse event recordkeeping (e.g., logs, spreadsheet, files) Review Governing Body meeting minutes for review of RM data and corrective actions.</p>
12-A-17	A	B	C	<p>Adverse events must be tracked and trended on a defined basis.</p>	<p>Verify facility awareness of Florida regulations and confirm the implementation of an internal risk management (RM) program that reviews adverse incidents and analyzes data for worrisome trends or patterns. Risk management activities should be integrated into the Quality Improvement (QI) program and reviewed at least quarterly.</p> <p>Evaluating Compliance: Review policies for RM program requirements, including the: Appointment of Risk Manager (by the Governing Body) Investigation/analysis of frequency/causes of categories & types of adverse incidents causing injury Development of measures to reduce risk of adverse events to patients (including education & training) Development/implementation of an incident reporting system Review RM adverse event recordkeeping (e.g., logs, spreadsheet, files) Review Governing Body and QI meeting minutes for review of RM data and plan.</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
12-A-18	A	B	C	<p>State agencies and QUAD A shall have access to all facility records necessary to carry out the provisions of this manual. Evidence of the incidents reporting and analysis system and copies of summary reports, incident reports filed within the facility, and evidence of recommended and accomplished corrective actions shall be made available for review to any authorized representative of the state or QUAD A upon request during normal working hours.</p>	<p>Verify facility awareness of Florida regulations and confirm all staff receive training on the Risk Management (RM) program's and requirements to enhance safety, ensure compliance, and build a more resilient and proactive organizational culture. Training must be provided upon hire, annually, and when a need arises.</p> <p><u>Evaluating Compliance:</u> Interview staff regarding the facility's patient safety protocols and incident reporting process Review personnel files for evidence of training (initial, annual, as needed).</p>

SECTION 13: LIFE SAFETY CODE

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
Sub-section A: Life Safety Code					
13-A-1	A	B	C	<p>The operating room and recovery room have an emergency power source—such as a generator or battery-powered inverter—with capacity to operate adequate monitoring, anesthesia, surgical equipment, cautery, and lighting for a minimum of 2 hours. If 2 or more operation and recovery rooms are used simultaneously, an adequate emergency power source must be available for each room.</p>	<p>Verify the facility has an emergency power source (e.g., battery-powered inverter, generator) capable of supplying critical equipment in all procedure rooms and recovery areas, including:</p> <ul style="list-style-type: none"> Automatic activation during outages Minimum 2-hour power supply capability for critical equipment functionality in procedure rooms and recovery <p>Key Requirements:</p> <ul style="list-style-type: none"> Battery backups (within equipment) ≠ emergency power source compliance <p>Policies must address:</p> <ul style="list-style-type: none"> Testing frequency (per manufacturer's specifications) Protocols activated during power loss Record retention (at least 3 years). <p><u>Evaluating Compliance:</u></p> <p>Review policies for:</p> <ul style="list-style-type: none"> Testing alignment with manufacturer's specifications Procedures for failure responses Mandate for minimum 2-hour power supply Power loss protocols (e.g., not starting new cases whilst on emergency power) <p>Review logs demonstrating compliant testing with 30-minute validations (or corrective actions with test failures)</p> <p>Interview staff regarding power loss protocols.</p>
13-A-2	A	B	C	<p>Sufficient electrical outlets are available, labeled and properly grounded to suit the location (e.g. wet locations, cystoscopy-arthroscopy) and connected to emergency power supplies.</p>	<p>Verify the electrical systems in the operating room:</p> <ul style="list-style-type: none"> Provide adequate outlets for procedural equipment Meet wet location requirements (unless risk assessment exempts) <p>Key Requirements:</p> <ul style="list-style-type: none"> GFCI protection (where required) Clear labeling/grounding Emergency power connections for critical devices. <p><u>Evaluating Compliance:</u></p> <p>Interview staff regarding emergency power protocols</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
					<p>Inspect operating rooms to verify:</p> <ul style="list-style-type: none"> GFCI in wet locations Outlets with emergency power supply are labeled Proper grounding <p>Confirm that each operating/procedure room has at least enough outlets to support all patient-care and procedural equipment without using extension cords. However, depending on the program type, essential electrical system, and if a Life Safety Code is required, as many as 36 receptacles may be required in each operating room</p> <p>Confirm emergency outlets function by simulating a power failure.</p>
13-A-3	A	B	C	<p>All flammable and materials and supplies are stored and handled in a safe manner with appropriate ventilation according to the most stringent requirement from among the LSC and HCFC requirements, State or local authorities.</p>	<p>Verify the facility handles explosive and combustible materials in a regulated manner to protect the safety of patients, visitors, staff, and the surrounding community.</p> <p>Evaluating Compliance:</p> <p>Review policies for alignment with NFPA codes, government regulations, and safety data sheets (SDS) or manufacturer's instructions for use (IFU)</p> <p>Interview staff regarding procedures for handling explosive and combustible materials</p> <p>Inspect areas where such items are stored and handled to ensure:</p> <ul style="list-style-type: none"> Ventilation is adequate (to code), or an extraction device is used in accordance with SDS or IFU Combustible materials are stored at a minimum safe distance from ignition sources Medical gases are secured.
13-A-4	A	B	C	<p>Except as otherwise provided in section 42 CFR 416.44, the ASC must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served, and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4).</p> <p>§416.44(b)(1) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
13-A-5	A	B	C	<p>In consideration of a recommendation by the State survey agency, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon an ASC, but only if the waiver will not adversely affect the health and safety of the patients.</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				§416.44(b)(2) Standard	
13-A-6	A	B	C	<p>The provisions of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in an ASC.</p> <p>§416.44(b)(3) Standard</p>	SOM Appendix L - Guidance for Surveyors: ASCs
13-A-7	A	B	C	<p>When a sprinkler system is shut down for more than 10 hours, the ASC must: i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or ii) Establish a fire watch until the system is back in service.</p> <p>§416.44(b)(5) Standard §416.44(b)(5)(i) Standard §416.44(b)(5)(ii) Standard</p>	SOM Appendix L - Guidance for Surveyors: ASCs
13-A-8	A	B	C	<p>An ASC may place alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.</p> <p>§416.44(b)(4) Standard</p>	SOM Appendix L - Guidance for Surveyors: ASCs
13-A-9	A	B	C	<p>Beginning July 5, 2017, an ASC must be in compliance with Chapter 21.3.2.1, Doors to hazardous areas.</p> <p>§416.44(b)(6) Standard</p>	SOM Appendix L - Guidance for Surveyors: ASCs
13-A-10	A	B	C	<p>Except as otherwise provided in section 42 CFR 416.44, the ASC must meet the applicable provisions and must proceed in accordance with the 2012 edition of the Health Care Facilities Code (NFPA 99, and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6).</p> <p>§416.44(c) Standard</p>	SOM Appendix L - Guidance for Surveyors: ASCs

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
13-A-11	A	B	C	<p>Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to an ASC.</p> <p>§416.44(c)(1) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>
13-A-12	A	B	C	<p>If application of the Health Care Facilities Code required under QUAD A 13-A-10 would result in unreasonable hardship for the ASC, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.</p> <p>§416.44(c)(2) Standard</p>	<p>SOM Appendix L - Guidance for Surveyors: ASCs</p>

PART 1 - NFPA 101 LSC REQUIREMENTS

(Items in italics relate to FSES)

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
Section 1 - General Requirements					
K100	A	B	C	<p>General Requirements – Other List in the REMARKS section any LSC Section 20.1 and 20.1 General Requirements that are not addressed by the provided K-tags, but are deficient. This information, along with the applicable Life Safety Code or NFPA standard citation, should be included on Form CMS-2567.</p>	
K111	A	B	C	<p>Building Rehabilitation Repair, Renovation, Modification, or Reconstruction Any building undergoing repair, renovation, modification, or reconstruction complies with both of the following:</p> <ul style="list-style-type: none"> • Requirements of Chapter 21 • Requirements of the applicable Sections 43.3, 43.4, 43.5, and 43.620.1.1.4.3, 21.1.1.4.3, 4.6.7, 43.1.2.1 <p>Change of Use or Change of Occupancy Any building undergoing change of use or change of occupancy classification complies with the requirements of Section 43.7, unless permitted by 20.1.1.4.2 or 21.1.1.4.2 20.1.1.4.2, 21.1.1.4.2, 43.1.2.2 (43.7)</p> <p>Additions Any building undergoing an addition shall comply with the requirements of Section 43.8. If the building has a common wall with a nonconforming building, the common wall is a fire barrier having at least a 2 hour fire resistance rating constructed of materials as required for the addition. 20.1.1.4.1, 21.1.1.4.1, 4.6.5, 4.6.7, 43.1.2.3 (43.8)</p>	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
K131	A	B	C	<p>Multiple Occupancies – Sections of Ambulatory Health Care Facilities Multiple occupancies shall be in accordance with 6.1.14. Sections of ambulatory health care facilities shall be permitted to be classified as other occupancies, provided they meet both of the following:</p> <ul style="list-style-type: none"> • The occupancy is not intended to serve ambulatory health care occupants for treatment or customary access • They are separated from the ambulatory health care occupancy by a 1 hour fire resistance rating <p>Ambulatory health care facilities shall be separated from other tenants and occupancies and shall meet all of the following:</p> <ul style="list-style-type: none"> • Walls have not less than 1 hour fire resistance rating and extend from floor slab to roof slab • Doors are constructed of not less than 1-3/4 inches thick, solid-bonded wood core or equivalent and is equipped with positive latches. • Doors are self-closing and are kept in the closed position, except when in use. • Windows in the barriers are of fixed fire window assemblies per 8.3 <p>Per regulation, ASCs are classified as Ambulatory Health Care Occupancies, regardless of the number of patients served. 20.1.3.2, 21.1.3.3, 20.3.7.1, 21.3.7.1,42 CFR 416.44</p>	
K161	A	B	C	<p>Building Construction Type and Height Building construction type and stories meet Table 20.1.6.1 or Table 21.1.6.1, respectively. <u>Construction Type</u> 1. I (442), I (332), II (222),II (111), III (211), IV (2HH),V (111) -Any number of stories; non-sprinklered or sprinklered 2.II (000), III (200), V (000) - One story non-sprinklered; Any number of stories sprinklered Any level below the level of exit discharge shall be</p>	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<p>separated by Type II (111), Type III (211), or Type V (111) construction unless both of the following are met:</p> <ol style="list-style-type: none"> 1. Such levels are under the control of the ambulatory health care occupancy. 2. Hazardous spaces are protected per section 8.7. Sprinklered stories must be sprinklered throughout by an approved, supervised automatic system in accordance with section 9.7. (See 20.3.5 or 21.3.5, respectively). <p>Give a brief description, in REMARKS, of the construction, the number of stories, including basements, floors on which patients are located, location of smoke or fire barriers and dates of approval. Complete sketch or attach small floor plan of the building as appropriate.</p> <p>20.1.6.1, 20.1.6.2, 21.1.6.1, 21.1.6.2</p>	
K163	A	B	C	<p>Interior Nonbearing Wall Construction Interior nonbearing walls in Type I or II construction are constructed of noncombustible or limited-combustible materials. Interior nonbearing walls required to have a minimum 2 hour fire resistance rating are permitted to be fire-retardant-treated wood enclosed within noncombustible or limited-combustible materials, provided they are not used as shaft enclosures.</p> <p>20.1.6.3, 20.1.6.4, 21.1.6.3, 21.1.6.4</p>	
Section 2 - Egress					
K200	A	B	C	<p>Means of Egress Requirements – Other List in the REMARKS section any LSC Section 20.2 and 21.2 Means of Egress Requirements that are not addressed by the provided K-tags, but are deficient. This information, along with the applicable Life Safety Code or NFPA standard citation, should be included on Form CMS-2567. 20.2, 21.2</p>	
K211	A	B	C	<p>Means of Egress – General Aisles, passageways, corridors, exit discharges, exit</p>	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				locations, and accesses are in accordance with Chapter 7, and the means of egress is continuously maintained free of all obstructions to full instant use in case of emergency, unless modified by 20/21.2.2 through 20/21.2.11. 20.2.1, 21.2.1, 7.1.10.1	
K222	A	B	C	<p>Egress Doors Special locking arrangements are in accordance with section 7.2.1.6</p> <ul style="list-style-type: none"> · DELAYED-EGRESS LOCKING ARRANGEMENTS Approved, listed delayed-egress locking systems installed in accordance with 7.2.1.6.1 shall be permitted on door assemblies serving low and ordinary hazard contents in buildings protected throughout by an approved, supervised automatic fire detection system or an approved, supervised automatic sprinkler system. · ACCESS-CONTROLLED EGRESS LOCKING ARRANGEMENTS Access-Controlled Egress Door assemblies installed in accordance with 7.2.1.6.2 shall be permitted. · ELEVATOR LOBBY EXIT ACCESS LOCKING ARRANGEMENTS Elevator lobby exit access door locking in accordance with 7.2.1.6.3 shall be permitted on door assemblies in buildings protected throughout by an approved, supervised automatic fire detection system and an approved, supervised automatic sprinkler system. 20.2.2.2, 21.2.2.2, 7.2.1.6.1 through 7.2.1.6.3 	
K223	A	B	C	<p>Doors with Self-Closing Devices Doors required to be self-closing are permitted to be held open by a release device complying with 7.2.1.8.2 that automatically closes all such doors throughout the smoke compartment, entire facility, and all stair enclosure doors upon activation of:</p> <ul style="list-style-type: none"> • Required manual fire alarm system, and • Local smoke detectors designed to detect smoke passing through the opening or a required smoke detection system; and • Automatic sprinkler system, if installed; and • Loss of power 	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				20.2.2.4, 20.2.2.5, 21.2.2.4, 21.2.2.5	
K231	A	B	C	Means of Egress Capacity The capacity of required means of egress is 20.2.3.1, 21.2.3.1, 38.2.3, 39.2.3	
K232	A	B	C	Aisle, Corridor or Ramp Width The clear width of any corridor or passageway required for egress shall be not less than 44 inches wide. Where a corridor is 6 feet wide, projections of not more than 6 inches from the corridor wall above the handrail height are permitted for alcohol-based hand rub dispensers. 20.2.3.2, 20.2.3.3, 21.2.3.2, 21.2.3.3	
K233	A	B	C	Clear Width of Exit and Exit Access Doors 2012 EXISTING Doors in the means of egress from diagnostic or treatment areas, such as x-ray, surgical, or physical therapy, shall provide a clear width of not less than 32 inches, unless the doors are existing 34 inch wide doors.21.2.3.4 2012 NEW Doors in the means of egress from diagnostic or treatment areas, such as x-ray, surgical, or physical therapy, shall provide a clear width of not less than 32 inches. 20.2.3.4	
K241	A	B	C	Number of Exits – Story and Compartment 2012 EXISTING Single means of egress is allowed from a mezzanine or balcony if one of the following exist: 1.Common path of travel is under 100 feet if in a sprinklered building.2.Common path of travel 75 feet if in a non-sprinklered building.3.Common path of travel is not limited if occupant load is under 30.Not less than 2 exits, as described in 38.2.2, are remotely located for each fire section or patient care area of the building and are accessible from each smoke compartment. Patient care suites larger than 2500 square feet have 2 exits remotely located from each other. Egress from smoke compartments, if installed, shall be permitted through adjacent compartments provided the egress does not return through the compartment of fire origin. 21.2.3.1 through 21.2.3.5, 7.4.1.1, 7.4.1.3 through 7.4.1.6	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<p>2012 NEW Meets the requirements of section 7.4. Not less than 2 exits, as described in 38.2.2, are remotely located for each fire section or patient care area of the building and are accessible from each smoke compartment. Patient care suites larger than 2500 square feet have 2 exits remotely located from each other. Egress from smoke compartments, if installed, shall be permitted through adjacent compartments provided the egress does not return through the compartment of fire origin. 20.2.4.1 through 20.2.4.5, 7.4</p>	
K251	A	B	C	<p>Dead-End Corridors and Common Path of Travel 2012 EXISTING Dead end corridors shall not exceed 50 feet. Common path of travel is no more 75 feet, and no more than 100 feet sprinklered story. Common path of travel is not limited in single tenant space with an occupant load not exceeding 30 persons. 21.2.5, 39.2.5.2 2012 NEW Dead-end corridors are no more than 50 feet in sprinklered buildings, and no more than 20 feet in non-sprinklered buildings. Common path of travel is no more 75 feet, and no more than 100 feet in sprinklered buildings or single tenant space with an occupant load not exceeding 30 persons. 20.2.5, 38.2.5.2, 38.2.5.3</p>	
K261	A	B	C	<p>Travel Distance to Exits Travel distance between any point in a room and an exit is 150 feet or 200 feet in sprinklered buildings. 20.2.6, 21.2.6</p>	
K271	A	B	C	<p>Discharge from Exits Exit discharge is arranged in accordance with 7.7, provides a level walking surface meeting the provisions of 7.1.7 with respect to changes in elevation and shall be maintained free of obstructions. Additionally, the exit discharge shall be a hard packed all-weather travel surface in</p>	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				accordance with CMS Survey and Certification Letter 07-38. 20.2.7, 21.2.7, 38.2.7, 39.2.7, 7.7	
K281	A	B	C	Illumination of Means of Egress Illumination of means of egress, including exit discharge, is arranged in accordance with 7.8 and shall be either continuously in operation or capable of automatic operation without manual intervention. 20.2.8, 21.2.8, 7.8	
K291	A	B	C	Emergency Lighting Emergency lighting of at least 1-1/2 hour duration is provided automatically with 7.9. 20.2.9.1, 21.2.9.1, 7.9	
K292	A	B	C	Life Support Means of Egress Where general anesthesia or life-support equipment is used, each ambulatory health care facility shall be provided with an essential electric system in accordance with NFPA 99. (Indicate N/A if life support equipment is for emergency purposes only.) 20.2.9.2, 21.2.9.2	
K293	A	B	C	Exit Signage Exit and directional signs are displayed in accordance with 7.10 with continuous illumination also served by the emergency lighting system. 20.2.10, 21.2.10, 7.10	
Section 3 - Protection					
K300	A	B	C	Protection – Other List in the REMARKS section any LSC Section 20.3 and 21.3 Protection requirements that are not addressed by the provided K-tags, but are deficient. This information, along with the applicable Life Safety Code or NFPA standard citation, should be included on Form CMS-2567.	
K311	A	B	C	Vertical Openings – Enclosure 2012 EXISTING Vertical openings shall be enclosed or protected per 8.6, unless one of the following conditions exist:	

Standard ID	Anesthesia Class		Standard / Regulatory Reference	Interpretive Guidance
			<ol style="list-style-type: none"> 1. Unenclosed vertical openings per 8.6.9.1 are permitted. 2. Unenclosed openings which do not serve as a required means of egress are permitted. 3. Exit access stairs may be unenclosed if they meet the following conditions <p>Two stories or less</p> <ol style="list-style-type: none"> a. Building is protected throughout by a supervised sprinkler system per 9.7.1.1(1). b. Total travel distance to outside does not exceed 100 feet. <p>Three stories or less</p> <ol style="list-style-type: none"> a. Occupant load per story does not exceed 15 people. b. Building is sprinkler protected throughout per 9.7.1.1(1). c. Building contains an automatic smoke detection system per 9.6. d. Activation of the sprinkler system or smoke detection system notifies all occupants of the building. e. Total travel distance to outside does not exceed 100 feet. <p>Floors that are below the street level and are used for storage or any use other than a business occupancy, shall not have any unprotected openings to the business occupancy floors. 21.3.1, 39.3.1.1, 39.3.1.2012 NEW</p> <p>Vertical openings shall be enclosed or protected per 8.6, unless one of the following conditions exist:</p> <ol style="list-style-type: none"> 1. Unenclosed vertical openings per 8.6.9.1 are permitted. 2. Exit access stairs may be unenclosed if they meet the 2 conditions: <ol style="list-style-type: none"> a. Building is sprinkler protected throughout. b. Total travel distance to outside does not exceed 100 feet. <p>Floors that are below the street level and are used for storage or any use other than a business occupancy,</p>	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				shall not have any unprotected openings to the business occupancy floors. 20.3.1, 38.3.1.1, 38.3.1.2	
K321	A	B	C	Hazardous Areas – Enclosure Hazardous areas must meet one of the following: <ul style="list-style-type: none"> • Contain 1 hour rated enclosure when non-sprinklered • Sprinkler protected with smoke resistive separation • Severe Hazard locations contain sprinkler protection and 1 hour separation with 3/4 hour rated self-closing doors 20.3.2, 21.3.2, 38.3.2, 38.3.2.2, 39.3.2.1, 39.3.2.2, 8.7	
K322	A	B	C	Laboratories Laboratories employing quantities of flammable, combustible, or hazardous materials that are considered a severe hazard are protected by 1-hour fire resistance-rated separation, automatic sprinkler system, and are in accordance with 8.7 and with NFPA 99. Laboratories not considered a severe hazard are protected as hazardous areas (see K321). Laboratories using chemicals are in accordance with NFPA 45. Gas appliances are of appropriate design and installed in accordance with NFPA 54. Shutoff valves are marked to identify material they control. Devices requiring medical grade oxygen from the piped distribution system meet the requirements under 11.4.2.2 (NFPA 99). 20.3.2.2, 21.3.2.2 9.3.1.2, 11.4.3.2, 15.4 (NFPA 99)	
K323	A	B	C	Anesthetizing Locations Areas designated for administration of general anesthesia (i.e., inhalation anesthetics) are in accordance with 8.7 and NFPA 99. Zone valves are located immediately outside each	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<p>life-support, critical care, and anesthetizing location of moderate sedation, deep sedation, or general anesthesia for medical gas or vacuum; readily accessible in an emergency; and arranged so shutting off any one anesthetizing location will not affect others.</p> <p>Area alarm panels are provided to monitor all medical gas, medical-surgical vacuum, and piped WAGD systems. Panels are at locations that provide for surveillance, indicate medical gas pressure decreases of 20 percent and vacuum decreases of 12 inch gauge HgV, and provide visual and audible indication. Alarm sensors are installed either on the source side of individual room zone valve box assemblies or on the patient/use side of each of the individual zone box valve assemblies.</p> <p>The EES critical branch supplies power for task illumination, fixed equipment, select receptacles, and select power circuits, and EES equipment system supplies power to ventilation system.</p> <p>Heating, cooling, and ventilation are in accordance with ASHRAE 170. Medical supply and equipment manufacturer's instructions for use are considered before reducing humidity levels to those allowed by ASHRAE, per S&C 13-58. 20.3.2.3, 21.3.2.3, NFPA 99 5.1.4.8.7, 5.1.4.8.7.2, 5.1.9.3.4, 6.4.2.2.4.2</p>	
K324	A	B	C	<p>Cooking Facilities</p> <p>Commercial cooking equipment shall be installed per NFPA 96 unless used for food warming or limited cooking.</p> <p>20.3.2.4, 20.3.2.5, 21.3.2.4, 21.3.2.5, 9.2.3</p>	
K325	A	B	C	<p>Alcohol Based Hand Rub Dispenser (ABHR)</p> <p>ABHRs are protected in accordance with 8.7.3.1, unless all conditions are met:</p> <ul style="list-style-type: none"> • Corridor is at least 6 feet wide. • Maximum individual dispenser capacity is 0.32 gallons (0.53 gallons in suites) of fluid and 18 ounces of Level 1 aerosols. • Dispensers shall have a minimum of 4-foot horizontal spacing 	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<ul style="list-style-type: none"> • Not more than an aggregate of 10 gallons of fluid or 1135 ounces of aerosol are used in a single smoke compartment outside a storage cabinet, excluding one individual dispenser per room. • Storage in a single smoke compartment greater than 5 gallons complies with NFPA 30. • Dispensers are not installed within 1 inch of an ignition source. • If floor is carpeted, the building is fully sprinkler protected. • ABHR does not exceed 95% alcohol. • Operation of the dispenser shall comply with Section 20.3.2.6(11) or 21.3.2.6(11). • ABHR is protected against inappropriate access. <p>20.3.2.6, 21.3.2.6, 8.7.3.1, CFR 416.44</p>	
K331	A	B	C	<p>Interior Wall and Ceiling Finish Interior wall and ceiling finishes in exits and exit access corridors shall have a flame spread rating of Class A or Class B. The reduction in class of interior finish for a sprinkler system as prescribed in 10.2.8.1 is permitted. All other areas may be class C rated material. Indicate flame spread rating(s) walls. 20.3.3, 21.3.3, 38.3.3, 39.3.3, 10.2</p>	
K332	A	B	C	<p>Interior Floor Finish 2012 NEW (Indicate N/A for 2012 EXISTING) Interior floor finish in exit enclosures must meet 10.2 and be Class I or Class II. All other areas must meet 10.2.7.1 or 10.2.7.2. Indicate rating(s) for floors 20.3.3, 21.3.3, 38.3.3, 39.3.3, 10.2</p>	
K341	A	B	C	<p>Fire Alarm - Installation A fire alarm system is installed with systems and components approved for the purpose in accordance with NFPA 70, National Electric Code, and NFPA 72,</p>	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<p>National Fire Alarm Code to provide effective warning of fire in any part of the building. In areas not continuously occupied, detection is installed at each fire alarm control unit. In new occupancy, detection is also installed at notification appliance circuit power extenders, and supervising station transmitting equipment. Fire alarm system wiring, or other transmission paths are monitored for integrity. 20.3.4.2.1, 21.3.4.1, 9.6</p>	
K342	A	B	C	<p>Fire Alarm - Initiation Initiation of the fire alarm system is by manual means and by any required sprinkler system alarm, detection device, or detection system. Manual alarm boxes are provided in the path of egress near each required exit and 200 feet travel distance is not exceeded. 20.3.4.2, 21.3.4.2, 9.6.2</p>	
K343	A	B	C	<p>Fire Alarm – Notification 2012 EXISTING A positive alarm sequence in accordance with 9.6.3.4 is permitted. Occupant notification is provided automatically, without delay, in accordance with 9.6.3. Fire department notification is accomplished automatically per 9.6.4. Smoke detection devices or systems equipped with reconfirmation features shall not be required to automatically notify the fire department, unless the alarm condition is reconfirmed within 120 seconds (2 minutes) 21.3.4.3 through 21.3.4.3.2.2, 9.6.3, 9.6.4 2012 NEW A positive alarm sequence in accordance with 9.6.3.4 is permitted. Occupant notification is provided automatically, without delay, in accordance with 9.6.3. Fire department notification is accomplished automatically per 9.6.4. 20.3.4.3 through 20.3.4.3.2.1, 9.6.3, 9.6.4</p>	
K344	A	B	C	<p>Fire Alarm – Control Functions The fire alarm automatically activates required control functions and is provided with an alternative</p>	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				power supply in accordance with NFPA 72. 20.3.4.4, 21.3.4.4	
K345	A	B	C	Fire Alarm Systems – Testing and Maintenance A fire alarm system is tested and maintained in accordance with an approved program complying with the requirements of NFPA 70, National Electric Code, and NFPA 72, National Fire Alarm and Signaling Code. Records of system acceptance, maintenance and testing are readily available. 9.6.1.3, 9.6.1.5, NFPA 70, NFPA 72	
K346	A	B	C	Fire Alarm – Out of Service Fire alarms that are out of service for 4 hours in a 24 hour period, the authority having jurisdiction shall be notified, and the building shall be evacuated or an approved fire watch shall be provided for all parties left unprotected by the shutdown until the fire alarm system has been returned to service. 9.6.1.6	
K351	A	B	C	Sprinkler System – Installation Sprinkler systems (if installed) are installed per NFPA 13. Where more than two sprinklers are installed in a single area for protection, waterflow devices shall be provided to sound the building fire alarm system or to notify a constantly attended location such as a PBX, security office, or emergency room. 20.3.5.1, 20.3.5.2, 21.3.5.1, 21.3.5.2, 9.7.1.2, 9.7, NFPA 13	
K353	A	B	C	Sprinkler System – Maintenance and Testing Automatic sprinkler and standpipe systems are inspected, tested, and maintained in accordance with NFPA 25, <i>Standard for the Inspection, Testing, and Maintaining of Water-based Fire Protection Systems</i> . Records of system design, maintenance, inspection and testing are maintained in a secure location and readily available. a) Date sprinkler system last checked.	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				b) Who provided system test. c) Water system supply source <i>Provide in REMARKS information on coverage for any non-required or partial automatic sprinkler system.</i> 9.7.5, 9.7.7, 9.7.8, and NFPA 2	
K354	A	B	C	Sprinkler System – Out of Service Where the sprinkler system is impaired, the extent and duration of the impairment has been determined, areas or buildings involved are inspected and risks are determined, recommendations are submitted to management or designated representative, and the fire department and other authorities having jurisdiction have been notified. Where the sprinkler system is out of service for more than 10 hours in a 24 hour period, the building or portion of the building affected are evacuated or an approved fire watch is provided until the sprinkler system has been returned to service. 9.7.5, 15.5.2 (NFPA 25)	
K355	A	B	C	Portable Fire Extinguishers Portable fire extinguishers are selected, installed, inspected, and maintained in accordance with NFPA 10, <i>Standard for Portable Fire Extinguishers</i> . 20.3.5.3, 21.3.5.3, 9.7.4.1, NFPA 10	
K362	A	B	C	Corridors – Construction of Corridor Walls 2012 NEW (Indicate N/A for 2012 EXISTING) Where access to exits is provided by corridors, such corridors shall be separated from use areas by a minimum 1 hour fire barrier constructed per section 8.3, unless one of the following exists: 1. Where exits are available from an open floor area 2. Where the entire space is a single tenant 3. Where the building is protected throughout by an approved automatic sprinkler system installed per 9.7.1.1(1) If the walls have a fire resistance rating, give the rating. _____ 20.3.6.1, 38.3.6.1, 38.3.6.2	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
K364	A	B	C	<p>Corridor – Openings 2012 NEW (Indicate N/A for 2012 EXISTING) Miscellaneous openings, such as mail slots, pharmacy/laboratory/cashier pass-through windows, shall be permitted to be installed in vision panels or doors without special protection provided that they meet both of the following:</p> <ol style="list-style-type: none"> 1. The aggregate opening does not exceed 20 square inches. 2. The opening is installed at or below half the distance from the floor to the ceiling. If the room is protected throughout by an automatic sprinkler system. The aggregate opening shall not exceed 80 square inches. <p>20.3.6.2.1, 20.3.6.2.2</p>	
K371	A	B	C	<p>Subdivision of Building Spaces - Smoke Compartments Smoke compartments do not exceed 25,000 square feet in size. Every story shall be divided into not less than 2 smoke compartments unless one of the following conditions occur: Facility is less than 5,000 square feet protected by an approved smoke detection system. Facility is less than 10,000 square feet protected by an approved, supervised sprinkler system per 9.7. Adjoining occupancy is used as a smoke compartment if all of the following are met:</p> <ol style="list-style-type: none"> a. Separating wall is 1 hour fire resistive rated b. Doors in the 1 hour rated wall at 1-3/4 inches thick. c. Doors in the 1 hour rated wall are self-closing. d. Windows in the 1 hour rated wall are fixed fire window assemblies per 8.3. e. The ambulatory health care facility is less than 22,500 square feet. f. Access from the ambulatory health care facility is unrestricted to another occupancy. <p>20.3.7.2, 21.3.7.2</p>	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
K372	A	B	C	<p>Subdivision of Building Spaces – Smoke Barrier Construction 2012 EXISTING Smoke barriers shall be constructed to a 1/2 hour fire resistance rating per 8.5. Smoke barriers shall be permitted to terminate at an atrium wall. Smoke dampers are not required in duct penetrations in fully ducted HVAC systems where an approved sprinkler system is installed for smoke compartments adjacent to the smoke barrier. 21.3.7.5, 21.3.7.6, 8.5 2012 NEW</p> <p>Smoke barriers shall be constructed to provide at least a 1 hour fire resistance rating and constructed in accordance with 8.5. Smoke barriers shall be permitted to terminate at an atrium wall. Smoke dampers are not required in duct penetrations of fully ducted HVAC systems. 20.3.7.5, 20.3.7.6, 8.5</p>	
K374	A	B	C	<p>Subdivision of Building Spaces – Smoke Barrier Doors 2012 EXISTING Smoke barrier doors shall be a minimum of 1-3/4 inches thick, solid-bonded wood core or equivalent with self-closing or automatic-closing devices in accordance with 21.2.2.4. Latching hardware is not required. Doors are not required to swing in the direction of egress travel. 21.3.7.9, 21.3.7.10 2012 NEW</p> <p>Smoke barrier doors shall be a minimum of 1-3/4 inches thick, solid-bonded wood core or equivalent with self-closing or automatic-closing devices in accordance with 21.2.2.4. Latching hardware is not required. Doors are required to swing in the direction of egress travel. Rabbits, bevels, or astragals are at meeting edges, and stops are at the head and sides of door frames. Center mullions are prohibited in smoke barrier door openings. 20.3.7.9, 20.3.7.10, 20.3.7.13, 20.3.7.14</p>	
K379	A	B	C	<p>Smoke Barrier Door Glazing 2012 NEW (Indicate N/A for 2012 EXISTING) Cross-corridor swinging doors or cross corridor</p>	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				horizontal-sliding doors, contain a vision panel consisting of fire-rated glazing in approved frames in each door. Vision panels in any other door in the smoke barrier, if provided, shall be fire-rated glazing in approved frames. 20.3.7.11, 20.3.7.12, 21.3.7.7, 8.3	
Section 4 - Special Provisions					
K400	A	B	C	Special Provisions – Other List in the REMARKS section any LSC Section 20.4 and 21.4 Special Provisions requirements that are not addressed by the provided K-tags, but are deficient. This information, along with the applicable Life Safety Code or NFPA standard citation, should be included on Form CMS-2567	
K421	A	B	C	High-Rise Buildings 2012 EXISTING High-rise buildings are protected throughout by an approved, supervised automatic sprinkler system in accordance with Section 9.7.1.1(1), or an engineered life safety system complying with 39.4.2.1(2). 21.4, 39.4.2 2012 NEW High-rise buildings 20.4, 38.4.2	
Section 5 - Building Services					
K500	A	B	C	Building Services – Other List in the REMARKS section any LSC Section 20.5 and 21.5 Building Services requirements that are not addressed by the provided K-tags but are deficient. This information, along with the applicable Life Safety Code or NFPA standard citation, should be included on Form CMS-2567.	
K511	A	B	C	Utilities – Gas and Electric Equipment using gas or related gas piping complies	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				with NFPA 54, National Fuel Gas Code, electrical wiring and equipment complies with NFPA 70, National Electric Code. Existing installations can continue in service provided no hazard to life. 20.5.1, 21.5.1, 21.5.1.2, 9.1.1, 9.1.2	
K521	A	B	C	HVAC Heating, ventilation, and air conditioning shall comply with 9.2 and shall be installed in accordance with the manufacturer's specifications. 20.5.2.1, 21.5.2.1, 9.2	
K522	A	B	C	HVAC – Any Heating Device Any heating device, other than a central heating plant, is designed and installed so combustible materials cannot be ignited by device and has a safety features to stop fuel and shut down equipment if there is excessive temperature or ignition failure. If fuel fired, the device also: <ul style="list-style-type: none"> · Is chimney or vent connected. · Takes air for combustion from outside. · Provides for a combustion system separate from occupied area atmosphere. 20.5.2.2, 20.5.2.2.1, 21.5.2.2, 21.5.2.2.1	
K523	A	B	C	HVAC – Suspended Unit Heaters Suspended unit heaters are permitted provided the following are met: <ul style="list-style-type: none"> • Not located in means of egress or in patient rooms. • Located high enough to be out of reach of people in the area. • Has the safety features to stop fuel and shut down equipment if there is excessive temperature or ignition failure. 20.5.2.2.2, 21.5.2.2.2	
K531	A	B	C	Elevators 2012 EXISTING Elevators comply with the provision of 9.4. Elevators are inspected and tested as specified in ASME	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<p>A17.1, Safety Code for Elevators and Escalators. Firefighter's Service is operated monthly with a written record. Existing elevators conform to ASME/ANSI A17.3, Safety Code for Existing Elevators and Escalators. All existing elevators, having a travel distance of 25 feet or more above or below the level that best serves the needs of emergency personnel for firefighting purposes, conform with Firefighter's Service Requirements of ASME/ANSI A17.3. (Includes firefighter's service Phase I key recall and smoke detector automatic recall, firefighter's service Phase II emergency in-car key operation, machine room smoke detectors, and elevator lobby smoke detectors.) 21.5.3, 9.4.2, 9.4.32012 NEW</p> <p>Elevators comply with the provision of 9.4. Elevators are inspected and tested as specified in ASME A17.1, Safety Code for Elevators and Escalators. Firefighter's Service is operated monthly with a written record.</p> <p>New elevators conform to ASME/ANSI A17.1, Safety Code for Elevators and Escalators, including Firefighter's Service Requirements. (Includes firefighter's Phase I key recall and smoke detector automatic recall, firefighter's service Phase II emergency in-car key operation, machine room smoke detectors, and elevator lobby smoke detectors.) 20.5.3, 9.4.2, 9.4.3</p>	
K532	A	B	C	<p>Escalators, Dumbwaiters, and Moving Walks Escalators, dumbwaiters, and moving walks comply with the provisions of 9.4.</p> <p>All existing escalators, dumbwaiters, and moving walks conform to the requirements of ASME/ANSI A17.3, Safety Code for Existing Elevators and Escalators. (Includes escalator emergency stop buttons and automatic skirt obstruction stop. For power dumbwaiters, includes hoistway door locking to keep doors closed except for floor where car is being</p>	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				loaded or unloaded.) 20.5.3, 21.5.3, 9.4	
K541	A	B	C	<p>Rubbish Chutes, Incinerators, and Laundry Chutes 2012 EXISTING Rubbish chutes are installed per section 9.5:</p> <ul style="list-style-type: none"> • Walls, partitions, and inlet openings meet the requirements of 8.3. • Doors of chutes open to a room designed exclusively for accessing the chute opening. • Room used for accessing the chute opening(s) are separated from other spaces per 8.7. • Chutes shall be permitted to open into rooms not exceeding 400 cubic feet in size if the room is sprinkler protected and the room is not used for storage. <p>OR</p> <p>Existing installations having properly enclosed and maintained chute openings shall be permitted to have inlets open to a corridor or normally occupied space. 21.5.4, 9.5, NFPA 822012 NEW</p> <p>Rubbish chutes are installed per section 9.5:</p> <ul style="list-style-type: none"> • Walls, partitions, and inlet openings meet the requirements of 8.3. • Doors of chutes open to a room designed exclusively for accessing the chute opening. • Room used for accessing the chute opening(s) are separated from other spaces per 8.7. • Chutes shall be permitted to open into rooms not exceeding 400 cubic feet in size if the room is sprinkler protected and the room is not used for storage. • Maintenance and installation are per NFPA 82. <p>20.5.4, 9.5, NFPA 82</p>	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
Section 7 - Operating Features					
K700	A	B	C	<p>Operating Features – Other List in the REMARKS section any LSC Section 20.7 and 21.7 Operating Features requirements that are not addressed by the provided K-tags but are deficient. This information, along with the applicable Life Safety Code or NFPA standard citation, should be included in Form CMS-2567.</p>	
K711	A	B	C	<p>Evacuation and Relocation Plan There is a written plan for the protection of all patients and for their evacuation in the event of an emergency. Employees are periodically instructed and kept informed with their duties under the plan, and a copy of the plan is readily available with telephone operator or with security. The plan addresses the basic response required of staff per 20/21.7.2.1.2 and provides for all of the fire safety plan components per 20/21.7.2.2. 20.7.1.1 through 20.7.1.3, 20.7.1.8 through 20.7.2.3.3 21.7.1.1 through 20.7.1.3, 21.7.1.8 through 20.7.2.3.3</p>	
K712	A	B	C	<p>Fire Drills Fire drills include the transmission of a fire alarm signal and simulation of emergency fire conditions. Fire drills are held at expected and unexpected times under varying conditions, at least quarterly on each shift. The staff is familiar with procedures and is aware that drills are part of established routine. Where drills are conducted between 9:00 PM and 6:00 AM, a coded announcement may be used instead of audible alarms. 20.7.1.4 through 20.7.1.7, 21.7.1.4 through 21.7.1.7</p>	
K741	A	B	C	<p>Smoking Regulations Smoking regulations shall be adopted and shall include not less than the following provisions:</p>	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<ol style="list-style-type: none"> 1) Smoking shall be prohibited in any room, ward, or compartment where flammable liquids, combustible gases, or oxygen is used or stored and in any other hazardous location, and such area shall be posted with signs that read NO SMOKING or shall be posted with the international symbol for no smoking. 2) In health care occupancies where smoking is prohibited and signs are prominently placed at all major entrances, secondary signs with language that prohibits smoking shall not be required. 3) Smoking by patients classified as not responsible shall be prohibited. 4) The requirement of 18.7.4 (3) shall not apply where the patient is under direct supervision. 5) Ashtrays of noncombustible material and safe design shall be provided in all areas where smoking is permitted. 6) Metal containers with self-closing cover devices into which ashtrays can be emptied shall be readily available to all areas where smoking is permitted. <p>20.7.4, 21.7.4</p>	
K751	A	B	C	<p>Draperies, Curtains, and Loosely Hanging Fabrics Draperies, curtains including cubicle curtains and loosely hanging fabric or films shall be in accordance with 10.3.1. Excluding curtains and draperies at showers and baths. 20.7.5.1 through 20.7.5.3, 21.7.5.1 through 21.7.5.3</p>	
K752	A	B	C	<p>Upholstered Furniture and Mattresses Newly introduced upholstered furniture meets Class I or char length, and heat release criteria in accordance with 10.3.2.1 and 10.3.3, unless the building is fully sprinklered. Newly introduced mattresses shall meet char length and heat release criteria in accordance with 10.3.2.2 and 10.3.4,</p>	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<p>unless the building is fully sprinklered. Upholstered furniture and mattresses belonging to nursing home residents do not have to meet these requirements as all nursing homes are required to be fully sprinklered. Newly introduced upholstered furniture and mattresses means purchased on or after the LSC final rule effective date. 20.7.5.2, 20.7.5.3, 21.7.5.2, 21.7.5.3</p>	
K753	A	B	C	<p>Combustible Decorations Combustible decorations shall be prohibited unless one of the following is met:</p> <ul style="list-style-type: none"> • Flame retardant or treated with approved fire-retardant coating that is listed and labeled for product. • Decorations meet NFPA 701. • Decorations exhibit heat release less than 100 kilowatts in accordance with NFPA 289. • The decorations in existing occupancies are in such limited quantities that a hazard of fire is not present. <p>20.7.5.4, 21.7.5.4</p>	
K754	A	B	C	<p>Soiled Linen and Trash Containers Soiled linen or trash collection receptacles shall not exceed 32 gallons in capacity. The average density of container capacity in a room or space shall not exceed 0.5 gallons/square feet. A total container capacity of 32 gallons shall not be exceeded within any 64 square feet area. Mobile soiled linen or trash collection receptacles with capacities greater than 32 gallons shall be located in a room protected as a hazardous area when not attended.</p> <p>20.7.5.5, 21.7.5.5</p>	
K761	A	B	C	<p>Maintenance, Inspection & Testing - Doors Fire doors assemblies are inspected and tested annually in accordance with NFPA 80 Standard for Fire Doors and Other Opening Protectives. Fire doors that are not located in required fire barriers,</p>	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<p>including corridor doors to patient rooms and smoke barrier doors, are routinely inspected as part of the facility maintenance program. Individuals performing the door inspections and testing possess knowledge, training or experience that demonstrates ability. Written records of inspection and testing are maintained and are available for review. 20.7.6, 21.7.6, 8.3.3.1 (LSC), 5.2. 5.2.3 (NFPA 80)</p>	
K771	A	B	C	<p>Engineered Smoke Control Systems When installed, engineered smoke control systems are tested in accordance with established engineering principles. Test documentation is maintained on the premises. 20.7.7.1 through 20.7.7.3, 21.7.7.1 through 21.7.7.3</p>	
K781	A	B	C	<p>Portable Space Heaters Portable space heating devices shall be prohibited in all health care occupancies. Except, when used in nonsleeping staff and employee areas where the heating elements do not exceed 212 degrees Fahrenheit (100 degrees Celsius). 20.7.8, 21.7.8</p>	
K791	A	B	C	<p>Construction, Repair, and Improvement Operations Construction, repair, and improvement operations shall comply with 4.6.10. Any means of egress in any area undergoing construction, repair, or improvements shall be inspected daily to ensure its ability to be used instantly in case of emergency and compliance with NFPA 241. 20.7.9.1, 20.7.9.2, 21.7.9.1, 21.7.9.2</p>	
PART II - HEALTH CARE FACILITIES CODE REQUIREMENTS					
K900	A	B	C	<p>Health Care Facilities Code – Other List in the REMARKS section, any NFPA 99 requirements (excluding Chapter 7, 8, 12, and 13) that are not addressed by the provided K-Tags but are deficient. This information, along with the</p>	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				applicable Health Care Facilities Code or NFPA standard citation, should be included on Form CMS-2567.	
K901	A	B	C	Fundamentals – Building System Categories Building systems are designed to meet Category 1 through 4 requirements as detailed in NFPA 99. Categories are determined by a formal and documented risk assessment procedure performed by qualified personnel. Chapter 4 (NFPA 99)	
K902	A	B	C	Gas and Vacuum Piped Systems – Other List in the REMARKS section, any NFPA 99 Chapter 5 Gas and Vacuum Systems requirements that are not addressed by the provided K-Tags but are deficient. This information, along with the applicable Life Safety Code or NFPA standard citation, should be included on Form CMS-2567. Chapter 5 (NFPA 99)	
K903	A	B	C	Gas and Vacuum Piped Systems – Categories Medical gas, medical air, surgical vacuum, WAGD, and air supply systems are designated: <ul style="list-style-type: none"> • Category 1. Systems in which failure is likely to cause major injury or death. • Category 2. Systems in which failure is likely to cause minor injury. • Category 3. Systems in which failure is not likely to cause injury, but can cause discomfort. Deep sedation and general anesthesia are not to be administered using a Category 3 medical gas system. 5.1.1.1, 5.2.1, 5.3.1.1, 5.3.1.5 (NFPA 99)	
K904	A	B	C	Gas and Vacuum Piped Systems – Warning Systems All master, area, and local alarm systems used for medical gas and vacuum systems comply with appropriate Category warning system requirements,	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				as applicable. 5.1.9, 5.2.9, 5.3.6.2.2 (NFPA 99)	
K905	A	B	C	<p>Gas and Vacuum Piped Systems – Central Supply System Identification and Labeling Containers, cylinders and tanks are designed, fabricated, tested, and marked in accordance with 5.1.3.1.1 through 5.1.3.1.7. Locations containing only oxygen or medical air have doors labeled with "Medical Gases, NO Smoking or Open Flame". Locations containing other gases have doors labeled "Positive Pressure Gases, NO Smoking or Open Flame, Room May Have Insufficient Oxygen, Open Door and Allow Room to Ventilate Before Opening. 5.1.3.1, 5.2.3.1, 5.3.10 (NFPA 99)</p>	
K906	A	B	C	<p>Gas and Vacuum Piped Systems – Central Supply System Operations Adaptors or conversion fittings are prohibited. Cylinders are handled in accordance with 11.6.2. Only cylinders, reusable shipping containers, and their accessories are stored in rooms containing central supply systems or cylinders. No flammable materials are stored with cylinders. Cryogenic liquid storage units intended to supply the facility are not used to transfill. Cylinders are kept away from sources of heat. Valve protection caps are secured in place, if supplied, unless cylinder is in use. Cylinders are not stored in tightly closed spaces. Cylinders in use and storage are prevented from exceeding 130 degrees Fahrenheit, and nitrous oxide and carbon dioxide cylinders are prevented from reaching temperatures lower than manufacture recommendations or 20 degrees Fahrenheit. Full or empty cylinders, when not connected, are stored in locations complying with 5.1.3.3.2 through 5.1.3.3.3, and are not stored in enclosures containing motor-driven machinery, unless for instrument air reserve headers. 5.1.3.2, 5.1.3.3.17, 5.1.3.3.18, 5.1.3.3.4, 5.2.3.2, 5.2.3.3, 5.3.6.20.4, 5.6.20.5, 5.3.6.20.7, 5.3.6.20.8, 5.3.6.20.9 (NFPA 99)</p>	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
K907	A	B	C	<p>Gas and Vacuum Piped Systems – Maintenance Program Medical gas, vacuum, WAGD, or support gas systems have documented maintenance programs. The program includes an inventory of all source systems, control valves, alarms, manufactured assemblies, and outlets. Inspection and maintenance schedules are established through risk assessment considering manufacturer recommendations. Inspection procedures and testing methods are established through risk assessment. Persons maintaining systems are qualified as demonstrated by training and certification or credentialing to the requirements of AASE 6030 or 6040. 5.1.14.2.1, 5.1.14.2.2, 5.1.15, 5.2.14, 5.3.13.4.2 (NFPA 99)</p>	
K908	A	B	C	<p>Gas and Vacuum Piped Systems – Inspection and Testing Operations The gas and vacuum systems are inspected and tested as part of a maintenance program and include the required elements. Records of the inspections and testing are maintained as required. 5.1.14.2.3, B.5.2, 5.2.13, 5.3.13, 5.3.13.4 (NFPA 99)</p>	
K909	A	B	C	<p>Gas and Vacuum Piped Systems – Information and Warning Signs Piping is labeled by stencil or adhesive markers identifying the gas or vacuum system, including the name of system or chemical symbol, color code (Table 5.1.11), and operating pressure if other than standard. Labels are at intervals not more than 20 feet, are in every room, at both sides of wall penetrations, and on every story traversed by riser. Piping is not painted. Shutoff valves are identified with the name or chemical symbol of the gas or vacuum system, room or area served, and caution to not use the valve except in emergency. 5.1.14.3, 5.1.11.1, 5.1.11.2, 5.2.11, 5.3.13.3, 5.3.11 (NFPA 99)</p>	
K910	A	B	C	<p>Gas and Vacuum Piped Systems – Modifications Whenever modifications are made that breach the</p>	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<p>pipeline, any necessary installer and verification test specified in 5.1.2 is conducted on the downstream portion of the medical gas piping system. Permanent records of all tests required by system verification tests are maintained. 5.1.14.4.1, 5.1.14.4.6, 5.2.13, 5.3.13.4.3 (NFPA 99)</p>	
K911	A	B	C	<p>Electrical Systems – Other List in the REMARKS section, any NFPA 99 Chapter 6 Electrical Systems requirements that are not addressed by the provided K-Tags, but are deficient. This information, along with the applicable Life Safety Code or NFPA standard citation, should be included on Form CMS-2567. Chapter 6 (NFPA 99)</p>	
K912	A	B	C	<p>Electrical Systems – Receptacles Power receptacles have at least one, separate, highly dependable grounding pole capable of maintaining low-contact resistance with its mating plug. In pediatric locations, receptacles in patient rooms, bathrooms, play rooms, and activity rooms, other than nurseries, are listed tamper-resistant or employ a listed cover. If used in patient care room, ground-fault circuit interrupters (GFCI) are listed. 6.3.2.2.6.2 (F), 6.3.2.2.4.2 (NFPA 99)</p>	
K913	A	B	C	<p>Electrical Systems – Wet Procedure Locations Operating rooms are considered wet procedure locations, unless otherwise determined by a risk assessment conducted by the facility governing body. Operating rooms defined as wet locations are protected by either isolated power or ground-fault circuit interrupters. A written record of the risk assessment is maintained and available for inspection. 6.3.2.2.8.4, 6.3.2.2.8.7, 6.4.4.2</p>	
K914	A	B	C	<p>Electrical Systems – Maintenance and Testing Hospital-grade receptacles at patient bed locations and where deep sedation or general anesthesia is</p>	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<p>administered, are tested after initial installation, replacement or servicing. Additional testing is performed at intervals defined by documented performance data. Receptacles not listed as hospital-grade at these locations are tested at intervals not exceeding 12 months. Line isolation monitors (LIM), if installed, are tested at intervals of less than or equal to 1 month by actuating the LIM test switch per 6.3.2.6.3.6, which activates both visual and audible alarm. For, LIM circuits with automated self-testing, this manual test is performed at intervals less than or equal to 12 months. LIM circuits are tested per 6.3.3.3.2 after any repair or renovation to the electric distribution system. Records are maintained of required tests and associated repairs or modifications, containing date, room or area tested, and results.</p> <p>6.3.4 (NFPA 99)</p>	
K915	A	B	C	<p>Electrical Systems – Essential Electric System Categories</p> <ul style="list-style-type: none"> • Critical care rooms (Category 1) in which electrical system failure is likely to cause major injury or death of patients, including all rooms where electric life support equipment is required, are served by a Type 1 EES. • General care rooms (Category 2) in which electrical system failure is likely to cause minor injury to patients (Category 2) are served by a Type 1 or Type 2 EES. • Basic care rooms (Category 3) in which electrical system failure is not likely to cause injury to patients and rooms other than patient care rooms are not required to be served by an EES. Type 3 EES life safety branch has an alternate source of power that will be effective for 1-1/2 hours. <p>3.3.138, 6.3.2.2.10, 6.6.2.2.2, 6.6.3.1.1 (NFPA 99), TIA 12-3</p>	

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K916	A	B	C	<p>Electrical Systems – Essential Electric System Alarm Annunciator A remote annunciator that is storage battery powered is provided to operate outside of the generating room in a location readily observed by operating personnel. The annunciator is hard-wired to indicate alarm conditions of the emergency power source. A centralized computer system (e.g., building information system) is not to be substituted for the alarm annunciator. 6.4.1.1.17, 6.4.1.1.17.5 (NFPA 99)</p>	
K917	A	B	C	<p>Electrical Systems – Essential Electric System Receptacles Electrical receptacles or cover plates supplied from the life safety and critical branches have a distinctive color or marking. 6.4.2.2.6, 6.5.2.2.4.2, 6.6.2.2.3.2 (NFPA 99)</p>	
K918	A	B	C	<p>Electrical Systems – Essential Electric System Maintenance and Testing The generator or other alternate power source and associated equipment is capable of supplying service within 10-seconds. If the 10-second criterion is not met during the monthly test, a process shall be provided to annually confirm this capability for the life safety and critical branches. Maintenance and testing of the generator and transfer switches are performed in accordance with NFPA 110. Generator sets are inspected weekly, exercised under load 30 minutes 12 times a year in 20-40 day intervals, and exercised once every 36 months for four continuous hours. Scheduled test under load conditions include a complete simulated cold start and automatic or manual transfer of all EES loads, and are conducted by competent personnel. Maintenance and testing of stored energy power sources (Type 3 EES) are in accordance with NFPA 111. Main and feeder circuit breakers are inspected annually, and a program for periodically exercising the components is established according to manufacturer requirements. Written records of maintenance and testing are maintained and readily available. EES electrical panels and</p>	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<p>circuits are marked and readily identifiable. Minimizing the possibility of damage of the emergency power source is a design consideration for new installations.</p> <p>6.4.4, 6.5.4, 6.6.4 (NFPA 99), NFPA 110, NFPA 111, 700.10 (NFPA 70)</p>	
K919	A	B	C	<p>Electrical Equipment – Other List in the REMARKS section, any NFPA 99 Chapter 10, Electrical Equipment, requirements that are not addressed by the provided K-Tags, but are deficient. This information, along with the applicable Life Safety Code or NFPA standard citation, should be included on Form CMS-2567. Chapter 10 (NFPA 99)</p>	
K920	A	B	C	<p>Electrical Equipment – Power Cords and Extension Cords Power strips in a patient care vicinity are only used for components of movable patient-care-related electrical equipment (PCREE) assemblies that have been assembled by qualified personnel and meet the conditions of 10.2.3.6. Power strips in the patient care vicinity may not be used for non-PCREE (e.g., personal electronics), except in long-term care resident rooms that do not use PCREE. Power strips for PCREE meet UL 1363A or UL 60601-1. Power strips for non-PCREE in the patient care rooms (outside of vicinity) meet UL 1363. In non-patient care rooms, power strips meet other UL standards. All power strips are used with general precautions. Extension cords are not used as a substitute for fixed wiring of a structure. Extension cords used temporarily are removed immediately upon completion of the purpose for which it was installed and meets the conditions of 10.2.4. 10.2.3.6 (NFPA 99), 10.2.4 (NFPA 99), 400-8 (NFPA 70), 590.3(D) (NFPA 70), TIA 12-5</p>	
K921	A	B	C	<p>Electrical Equipment – Testing and Maintenance Requirements The physical integrity, resistance, leakage current, and touch current tests for fixed and</p>	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<p>portable patient-care related electrical equipment (PCREE) is performed as required in 10.3. Testing intervals are established with policies and protocols. All PCREE used in patient care rooms is tested in accordance with 10.3.5.4 or 10.3.6 before being put into service and after any repair or modification. Any system consisting of several electrical appliances demonstrates compliance with NFPA 99 as a complete system. Service manuals, instructions, and procedures provided by the manufacturer include information as required by 10.5.3.1.1 and are considered in the development of a program for electrical equipment maintenance. Electrical equipment instructions and maintenance manuals are readily available, and safety labels and condensed operating instructions on the appliance are legible. A record of electrical equipment tests, repairs, and modifications is maintained for a period of time to demonstrate compliance in accordance with the facility's policy. Personnel responsible for the testing, maintenance and use of electrical appliances receive continuous training.</p> <p>10.3, 10.5.2.1, 10.5.2.1.2, 10.5.2.5, 10.5.3, 10.5.6, 10.5.8</p>	
K922	A	B	C	<p>Gas Equipment – Other List in the REMARKS section, any NFPA 99 Chapter 11 Gas Equipment requirements that are not addressed by the provided K-Tags, but are deficient. This information, along with the applicable Life Safety Code or NFPA standard citation, should be included on Form CMS-2567. Chapter 11 (NFPA 99)</p>	
K923	A	B	C	<p>Gas Equipment – Cylinder and Container Storage Greater than or equal to 3,000 cubic feet Storage locations are designed, constructed, and ventilated in accordance with 5.1.3.3.2 and 5.1.3.3.3.</p> <p>Greater than 300 but less than 3,000 cubic feet Storage locations are outdoors in an enclosure or within an enclosed interior space of non- or limited-combustible construction, with door (or gates outdoors) that can be secured. Oxidizing gases are</p>	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<p>not stored with flammables, and are separated from combustibles by 20 feet (5 feet if sprinklered) or enclosed in a cabinet of noncombustible construction having a minimum 1/2 hr. fire protection rating.</p> <p>Less than or equal to 300 cubic feet</p> <p>In a single smoke compartment, individual cylinders available for immediate use in patient care areas with an aggregate volume of ≤ 300 cubic feet are not required to be stored in an enclosure. Cylinders must be handled with precautions as specified in 11.6.2.</p> <p>A precautionary sign readable from 5 feet is on each door or gate of a cylinder storage room, where the sign includes the wording as a minimum "CAUTION: OXIDIZING GAS(ES) STORED WITHIN NO SMOKING."</p> <p>Storage is planned so cylinders are used in order of which they are received from the supplier. Empty cylinders are segregated from full cylinders. When facility employs cylinders with integral pressure gauge, a threshold pressure considered empty is established. Empty cylinders are marked to avoid confusion. Cylinders stored in the open are protected from weather.</p> <p>11.3.1, 11.3.2, 11.3.3, 11.3.4, 11.6.5 (NFPA 99)</p>	
K924	A	B	C	<p>Gas Equipment – Testing and Maintenance Requirements Anesthesia apparatus are tested at the final path to patient after any adjustment, modification or repair. Before the apparatus is returned to service, each connection is checked to verify proper gas and an oxygen analyzer is used to verify oxygen concentration. Defective equipment is immediately removed from service. Areas designated for servicing of oxygen equipment are clean and free of oil, grease, or other flammables. Manufacturer service manuals are used to maintain equipment and a scheduled maintenance program is followed.</p> <p>11.4.1.3, 11.5.1.3, 11.6.2.5, 11.6.2.6 (NFPA 99)</p>	
K925	A	B	C	<p>Gas Equipment – Respiratory Therapy Sources of Ignition Smoking materials are removed from patients receiving respiratory therapy. When a nasal</p>	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<p>cannula is delivering oxygen outside of a patient's room, no sources of ignition are within in the site of intentional expulsion (1-foot). When other oxygen deliver equipment is used or oxygen is delivered inside a patient's room, no sources of ignition are within the area are of administration (15-feet). Solid fuel-burning appliances is not in the area of administration. Nonmedical appliances with hot surfaces or sparking mechanisms are not within oxygen-delivery equipment or site of intentional expulsion.</p> <p>11.5.1.1, TIA 12-6 (NFPA 99)</p>	
K926	A	B	C	<p>Gas Equipment – Qualifications and Training of Personnel Personnel concerned with the application, maintenance and handling of medical gases and cylinders are trained on the risk. Facilities provide continuing education, including safety guidelines and usage requirements. Equipment is serviced only by personnel trained in the maintenance and operation of equipment.</p> <p>11.5.2.1 (NFPA 99)</p>	
K927	A	B	C	<p>Gas Equipment – Transfilling Cylinders Transfilling of oxygen from one cylinder to another is in accordance with CGA P-2.5, <i>Transfilling of High Pressure Gaseous Oxygen Used for Respiration</i>. Transfilling of any gas from one cylinder to another is prohibited in patient care rooms. Transfilling to liquid oxygen containers or to portable containers over 50 psi comply with conditions under 11.5.2.3.1 (NFPA 99). Transfilling to liquid oxygen containers or to portable containers under 50 psi comply with conditions under 11.5.2.3.2 (NFPA 99).</p> <p>11.5.2.2 (NFPA 99)</p>	
K928	A	B	C	<p>Gas Equipment – Labeling Equipment and Cylinders Equipment listed for use in oxygen-enriched atmospheres are so labeled. Oxygen metering equipment and pressure reducing regulators are</p>	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<p>labeled "OXYGEN-USE NO OIL". Flowmeters, pressure reducing regulators, and oxygen-dispensing apparatus are clearly and permanently labeled designating the gases for which they are intended. Oxygen-metering equipment, pressure reducing regulators, humidifiers, and nebulizers are labeled with name of manufacturer or supplier. Cylinders and containers are labeled in accordance with CGA C-7. Color coding is not utilized as the primary method of determining cylinder or container contents. All labeling is durable and withstands cleaning or disinfecting.</p> <p>11.5.3.1 (NFPA 99)</p>	
K929	A	B	C	<p>Gas Equipment – Precautions for Handling Oxygen Cylinders and Manifolds Handling of oxygen cylinders and manifolds is based on CGA G-4, Oxygen. Oxygen cylinders, containers, and associated equipment are protected from contact with oil and grease, from contamination, protected from damage, and handled with care in accordance with precautions provided under 11.6.2.1 through 11.6.2.4 (NFPA 99). 11.6.2 (NFPA 99)</p>	
K930	A	B	C	<p>Gas Equipment – Liquid Oxygen Equipment The storage and use of liquid oxygen in base reservoir containers and portable containers comply with sections 11.7.2 through 11.7.4 (NFPA 99). 11.7 (NFPA 99)</p>	
K931	A	B	C	<p>Hyperbaric Facilities All occupancies containing hyperbaric facilities comply with construction, equipment, administration, and maintenance requirements of NFPA99. Chapter 14 (NFPA 99)</p>	
K932	A	B	C	<p>Features of Fire Protection – Other List in the REMARKS section, any NFPA 99 Chapter 15 Features of Fire Protection requirements that are not addressed by the provided K-Tags, but are deficient. This information, along with the applicable</p>	

Standard ID	Anesthesia Class			Standard / Regulatory Reference	Interpretive Guidance
				<p>Life Safety Code or NFPA standard citation, should be included on Form CMS-2567. Chapter 15 (NFPA 99)</p>	
K933	A	B	C	<p>Features of Fire Protection – Fire Loss Prevention in Operating Rooms Periodic evaluations are made of hazards that could be encountered during surgical procedures, and fire prevention procedures are established. When flammable germicides or antiseptics are employed during surgeries utilizing electrosurgery, cautery or lasers:</p> <ul style="list-style-type: none"> ▪ Packaging is non-flammable. ▪ Applicators are in unit doses. ▪ Preoperative "time-out" is conducted prior the initiation of any surgical procedure to verify: <ul style="list-style-type: none"> ▪ Application site is dry prior to draping and use of surgical equipment. ▪ Pooling of solution has not occurred or has been corrected. ▪ Solution-soaked materials have been removed from the OR prior to draping and use of surgical devices. ▪ Policies and procedures are established outlining safety precautions related to the use of flammable germicide or antiseptic use. <p>Procedures are established for operating room emergencies including alarm activation, evacuation, equipment shutdown, and control operations. Emergency procedures include the control of chemical spills, and extinguishment of drapery, clothing and equipment fires. Training is provided to new OR personnel (including surgeons), continuing education is provided, incidents are reviewed monthly, and procedures are reviewed annually. 15.13 (NFPA 99)</p>	

Standard ID	Anesthesia Class		Standard / Regulatory Reference	Interpretive Guidance
Appendix 1: LSC Reference				
	A	B	<p>The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the Federal Register to announce the changes.</p> <p>(1)National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.</p> <p>(i)NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.</p> <p>(ii)TIA 12-2 to NFPA 99, issued August 11, 2011.</p> <p>(iii)TIA 12-3 to NFPA 99, issued August 9, 2012.</p> <p>(iv)TIA 12-4 to NFPA 99, issued March 7, 2013.</p> <p>(v)TIA 12-5 to NFPA 99, issued August 1, 2013.</p> <p>(vi)TIA 12-6 to NFPA 99, issued March 3, 2014.</p> <p>(vii)NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;</p> <p>(viii)TIA 12-1 to NFPA 101, issued August 11, 2011.</p> <p>(ix)TIA 12-2 to NFPA 101, issued October 30, 2012.</p> <p>(x)TIA 12-3 to NFPA 101, issued October 22, 2013.</p> <p>(xi)TIA 12-4 to NFPA 101, issued October 22, 2013.</p> <p>§416.44(f) Standard</p>	

GENERAL GLOSSARY FOR ALL PROGRAMS

Adequate: Satisfactory or acceptable in quality or quantity, encompassing size, space, maintenance, cleanliness, freedom from clutter, lighting, equipment, and supplies, etc.; it is meant to satisfy a requirement.

Advanced Cardiac Life Support (ACLS): A course that trains and certifies participants in a set of clinical guidelines for the urgent and emergent treatment of life-threatening cardiovascular conditions in adults that will cause or have caused cardiac arrest using advanced medical procedures, medications, and techniques through didactic and hands-on skills return demonstration sessions. It builds on the foundation of lifesaving basic life support (BLS) skills. It reflects science and education from the *American Heart Association Guidelines Update for CPR and Emergency Cardiovascular Care (ECC)*. The course is approved by the American Heart Association (AHA) or an identical content course that conforms to the current AHA Guidelines.

***** Advanced practice registered nurses (APRNs):** Licensed registered nurses educated at a master's or doctoral level and in a specific role and patient population. APRNs are prepared with specialized education and certification to assess, diagnose, and manage medical issues. They can also order tests and prescribe medications. APRNs include:

- 1) Certified registered nurse anesthetist (CRNA).
- 2) Certified nurse practitioner (CNP).
- 3) Clinical nurse specialist (CNS).
- 4) Certified nurse midwife (CNM).

Adverse event: An incident in health care that causes unintended harm to patients or providers and is often preventable. Common adverse events include but are not limited to, medication errors, surgical mistakes, infections acquired in healthcare settings, falls, pressure ulcers, and communication failures. All adverse events that occur within 30 (thirty) days of the procedure must be reported to QUAD A contemporaneously when the facility learns of the event.

Air Exchanges Per Hour (ACH): The number of times that the total air volume in a room or space is completely removed and replaced in an hour.

***** Ambulatory surgical center (ASC):** Ambulatory surgical center or ASC means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. The entity must have an agreement with CMS to participate in Medicare as an ASC and must meet the conditions set forth in subparts B and C of 416.2. **[42 CFR 416.2]**

Ambulatory Services: for the period before January 1, 2008, facility services that are furnished in an ASC, and beginning January 1, 2008, means the combined facility services and covered ancillary services that are furnished in an ASC in connection with covered surgical procedures. **[42 CFR 416.2]**

Anesthesia professional: A physician anesthesiologist, Certified Registered Nurse anesthetist (CRNA), Certified Anesthesiologist Assistant (CAA), and an appropriately credentialed Oral and Maxillofacial Surgeon.

**** Antisepsis:** The application of an antimicrobial chemical to the skin or mucous membrane to reduce the microbial population.

**** Antiseptic:** An agent used for antisepsis (to kill microorganisms or substantially inhibit their growth).

**** Autoclave:** A common term applied to the performance of steam sterilization under pressure, where bacteria are killed (including spores).

***** Appropriate/appropriately** means especially suitable or compatible; or fitting.

Examples:

- Administrative and patient care areas must have lighting to see all tasks fully.
- Laryngoscopes are cleaned according to the manufacturer's recommendations, though sterilization is preferred.

- Oxygen delivery should be tailored to the appropriate delivery method based on patient need and type/location of the procedure.

Auxiliary Staff: Unlicensed staff who are not state-certified/licensed to independently evaluate patient physical status and cannot legally provide emergency duties beyond Basic Life Support for Healthcare Providers. Auxiliary staff includes dental assistants, registered/certified dental assistants, dental anesthesia/sedation assistants, medical assistants, surgical technicians, and other non-independently Licensed Providers.

Basic Life Support (BLS): A course that trains and certifies participants to promptly recognize several life-threatening emergencies, give high-quality chest compressions, deliver appropriate ventilations, and provide early use of an automatic external defibrillator (AED) through both didactic and hands-on skills return demonstration sessions. It reflects science and education from the *American Heart Association Guidelines Update for CPR and Emergency Cardiovascular Care (ECC)* and is approved by the American Heart Association (AHA) or an identical content course that conforms to the current AHA Guidelines.

**** Biological Indicator (BI):** A sterilization process monitoring device commercially prepared with a known population of highly resistant spores that tests the effectiveness of the sterilization method being used. The indicator is used to demonstrate that the conditions necessary to achieve sterilization were met during the sterilizer cycle being monitored.

Business Associate Agreement (BAA): A contract between the facility and an external business or individual that performs certain functions or activities on behalf of, or provides a service to, the facility when the function, activity, or service involves the creation, receipt, maintenance, or transmission of Protected Health Information (PHI) by the business or individual. The agreement establishes the permissible uses and disclosures of PHI by the business associate, how the business associate will support patients' Privacy Rule rights, and the responsibilities of both parties to maintain the privacy and security of PHI. The Health Insurance Portability and Accountability Act (HIPAA) Rules generally require that covered entities and business associates enter into contracts with their business associates to ensure that the business associates will appropriately safeguard protected health information.

***** Certified Anesthesiologist Assistant (CAA):** A master's degree level non-physician anesthesia care provider that:

- 1) Is certified by the National Commission for Certification of Anesthesiologist Assistants (NCAA) Note: not a CMS requirement
- 2) Works under the direction of an anesthesiologist.
- 3) Is in compliance with all applicable requirements of State law, including any licensure requirements the State imposes on nonphysician anesthetists; and
- 4) Is a graduate of a medical school-based anesthesiologist's assistant educational program that—
 - a) Is accredited by the Committee on Allied Health Education and Accreditation; and
 - b) Includes approximately two (2) years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background.

***** Certified Registered Nurse Anesthetist (CRNA):** An advanced practice registered nurse (APRN) who administers anesthesia and other medications. Physician Supervision (either the operating practitioner or of an anesthesiologist who is immediately available if needed) is required if required by state or federal law.

- 1) Is licensed as a registered professional nurse by the State in which the nurse practices.
- 2) Meets any licensure requirements the State imposes with respect to nonphysician anesthetists.
- 3) Has graduated from a nurse anesthesia educational program that meets the standards of the Council on Accreditation of Nurse Anesthesia Programs, or such other accreditation organization as may be designated by the Secretary; and
- 4) Meets the following criteria:
 - (I) Has passed a certification examination of the Council on Certification of Nurse Anesthetists, the Council on Recertification of Nurse Anesthetists, or any other certification organization that may be designated by the Secretary; or

(ii) Is a graduate of a program described in paragraph (3) of this definition and within 24 months after that graduation meets the requirements of paragraph (4)(1) of this definition.

5) For certified registered nurse anesthetist services, the certified registered nurse anesthetist may review and verify (sign and date), rather than re-document, notes in a patient's medical record made by physicians; residents; nurses; medical, physician assistant, and advanced practice registered nurse students; or other members of the medical team, including, as applicable, notes documenting the certified registered nurse anesthetist's presence and participation in the service.

**** Chemical Indicator (CI):** A sterilization monitoring device used to monitor the attainment of one (1) or more critical parameters required for sterilization. A characteristic color or other visual change indicates a defined level of exposure based on the classification of the chemical indicator used.

*****Clinic:** A facility (Rural Health Clinic (RHC)) that is established primarily to furnish outpatient physician services and that meets the following tests of physician involvement:

- The medical services are furnished by a group of three or more physicians practicing medicine together.
- A physician is present during all hours of operation of the clinic to furnish medical services, as distinguished from purely administrative services. **[485.703 Condition]**

*****Clinic Administrator:** The individual responsible for the internal operation of the RHC in accordance with written policies. A qualified Clinic Administrator is designated by the facility's governing body. **[\$485.705(c)(1) and \$485.709(b)]**

***** Clinical Personnel:** The entire clinical team providing services in the facility, including, but not limited to, all physicians/surgeons/proceduralists, anesthesia providers, nurses, scrub techs, physician assistants, physical/occupational/speech therapists and assistants, social workers, clinical psychologists, marriage and family therapists, mental health counselors, medical assistants, etc. Employment status (owner, employee, contractor, contracted, indirect employee, prn staff, etc.) is not a factor in defining who is included as Clinical Personnel.

**** Contact Time:** "Wet time," also known as "contact time" or "dwell time," is the amount of time a disinfectant or antiseptic solution must remain wet and in direct contact with a target microorganism or on a surface to be effective. This time can range from 15 seconds to 10 minutes, which is the maximum time allowed by the US Environmental Protection Agency (EPA). The contact time is established by the product manufacturer.

**** Contamination:** The presence of potentially infectious pathogenic microorganisms on animate or inanimate objects or surfaces.

Contemporaneously: Originating, existing, or happening during the same period of time.

Continual: Repeated regularly and frequently in steady, rapid succession.

Continuous: Prolonged without interruption at any time.

Contract & Indirect Employees: These employees are not on the company's payroll and are not restricted by employment laws that apply to direct employees. Work details are defined in a contract agreed upon by the company and a contractor or third-party agency.

***** Covered ancillary services:** Items and services that are integral to a covered surgical procedure performed in an ASC as provided in §416.164(b), for which payment may be made under §416.171 in addition to the payment for the facility services. **[42 CFR 416.2]**

***** Covered surgical procedures:** Surgical procedures furnished before January 1, 2008, that meet the criteria specified in §416.65 and those surgical procedures furnished on or after January 1, 2008, that meet the criteria specified in §416.166. **[42 CFR 416.2]**

*** Deep Sedation/Analgesia:** A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

Decontamination: Any physical or chemical process that reduces the number of microorganisms on any inanimate object to render that object safe for subsequent handling.

Dental Anesthesiologist: A licensed DDS or DMD with specialized, hospital-based training in areas including pharmacology, internal medicine, emergency medicine, and pediatric and adult anesthesiology.

Dental Assistant: A dental team member who supports a dental operator in providing more efficient dental treatment. A dental assistant must graduate from an accredited dental assisting training program and earn certification or licensure as State law requires.

Direct Employee: A full- or part-time employee hired by a facility and paid directly through the facility's payroll. They are considered permanent employees because the intention is to work with them long-term rather than temporarily or as needed.

*****Direct Services** means services provided by the clinic's staff. **[42 CFR 491.2]**

**** Disinfectant:** A chemical agent used to kill viruses and bacteria on surfaces. It must be an EPA-registered disinfectant with bactericidal, tuberculocidal, and virucidal properties with specific claims and instructions for HIV and HBV.

**** EPA-Registered:** An EPA registration number signifies that a disinfectant and its claims have been reviewed and approved by the United States Environmental Protection Agency.

Equipment: The term "equipment" refers to the requirement that the specific item named must meet current performance standards according to the manufacturer's guidelines.

*****Extension Location:** A location or site from which a rehabilitation agency provides services within a portion of the total geographic area served by the primary site. The extension location is part of the rehabilitation agency. The extension location should be located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the extension location to independently meet the conditions of participation as a rehabilitation agency. *[485.703 Condition]*

Facility Director: An individual that manages all aspects of a facility's operations. Their duties include budget management, facility planning, and building system maintenance.

Facility Leadership and Governing Body: These terms are interchangeable and refer to the person or group of people with full authority and responsibility for directing, overseeing, and controlling the facility's operations. Medicare uses the term "governing body," while non-Medicare facilities use the term "facility leadership." For both, the facility must define in policy the person or group of people that constitute the governing body or facility leadership.

Facility Safety Manual: A compilation of safety procedures and guidelines to follow in emergencies or unsafe situations.

***** Facility services:** For the period before January 1, 2008, services that are furnished in connection with covered surgical procedures performed in an ASC, and beginning January 1, 2008, means services that are furnished in connection with covered surgical procedures performed in an ASC as provided in §416.164(a) for which payment is included in the ASC payment established under §416.171 for the covered surgical procedure. **[42 CFR 416.2]**

Frequent: Occurring or done on many occasions or in quick succession; happening often.

General Anesthesia: A drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Governing Body and Facility Leadership: These terms are interchangeable and refer to the person or group of people with full authority and responsibility for directing, overseeing, and controlling the facility's operations. Medicare uses the term "governing body," while non-Medicare facilities use the term "facility leadership." For both, the facility must define in policy the person or group of people that constitute the governing body or facility leadership.

**** Healthcare-Associated Infection (HAI):** An infection acquired by patients while they are receiving medical care, with confirmation of diagnosis by clinical or laboratory evidence. Infective agents may originate from endogenous or exogenous sources. HAIs, which are also known as nosocomial infections, may not become apparent until the patient has been discharged from the healthcare setting.

**** Immediate Use Steam Sterilization (IUSS):** An abbreviated process of steam sterilization of patient care instruments (or devices) for immediate use.

Immediately Available: Accessible (clinician and equipment) without any delay or waiting period. Examples include the physical presence of the health care professional in the facility to assess, evaluate, and provide care to a patient; a supervising physician is physically accessible and able to attend to the patient, without any delay, to address any situation requiring a supervising physician's services; and, 1) dedicated to the facility when on duty, 2) unencumbered by conflicting duties or responsibilities, 3) responding without delay when notified.

****Infection:** The invasion and multiplication of microorganisms in body tissues that cause cellular injury and clinical symptoms.

Instrument: Any tool, device, or apparatus used in medicine for the purpose of diagnosing, preventing, treating, or alleviating illness or injury. It encompasses a wide range of items, from simple tools like stethoscopes to complex machines like MRI scanners. Medical instruments can be used to examine the body, record physiological processes, administer treatments, or perform surgical procedures.

Intraoperatively: The intraoperative phase extends from the time the patient is admitted to the operating room to the time of anesthesia administration, the performance of the surgical procedure, and until the client is transported to the recovery room or post-anesthesia care unit (PACU).

**** Instructions for Use (IFUs):** Specific, detailed instructions provided by the manufacturer. IFUs for medical devices detail the steps required for cleaning, disinfection, and sterilization that are compatible with that device. Products approved for use in cleaning, disinfection, and sterilization will have specific IFUs to follow (e.g., dilution ratio and contact time) to ensure the product's efficacy.

Legally Qualified: Being in compliance or accordance with specific requirements or conditions. Is qualified under the applicable local, State or Federal law to hold the position for which he or she holds and has met the qualifications of the position.

Log: A written record of performance, events, or day-to-day activities. It is similar to a register, which is a written record containing regular entries of items or details.

Examples:

- On any day that controlled substances are administered, the controlled substance inventory and control record (log/register) must be updated as appropriate to reflect controlled substances administered, received, wasted, and currently stored by two licensed healthcare professionals. (6-D-2)
- A written record (log/register) of all operative cases is maintained by the facility. (8-L-1)

Major Blood Vessels: A group of critical arteries and veins including the aorta, coronary arteries, pulmonary arteries, superior and inferior vena cava, pulmonary veins, and any intra-cerebral artery or vein.

**** Mechanical (Physical) Indicator:** Monitors (embedded into the sterilization equipment) that register, record, and report parameters for each cycle (time in use, the temperature achieved, and the pressure attained in the chamber). The information attained through the gauges and/or printouts provides evidence the sterilization system has met the set parameters (or has not, and there is a need for corrective action).

Medical Director: The clinician responsible for overall oversight of the facility.

***** Medical Staff:** The organized body of licensed physicians and other healthcare providers who are permitted by law and through credentialing and privileges granted by the facility leadership to provide medical care within the facility. The medical staff includes physicians, surgeons, specialists, CRNAs, NPs, PAs, and allied health professionals, as identified in facility policy.

*** Minimal Sedation:** A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected.

* **Moderate Sedation/Analgesia (“Conscious Sedation” or “Procedural Sedation”)**: A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

* **Monitored Anesthesia Care (“MAC”)** does not describe the continuum of depth of sedation; rather, it describes “a specific anesthesia service performed by a qualified anesthesia provider, for a diagnostic or therapeutic procedure.” Indications for monitored anesthesia care include “the need for deeper levels of analgesia and sedation than can be provided by moderate sedation (including potential conversion to a general or regional anesthetic).

National Fire Protection Association (NFPA) Business Occupancies, 2021 <https://www.nfpa.org/news-blogs-and-articles/blogs/2021/05/07/occupancy-classifications-and-model-codes>

- 1) **Business Occupancy** is an occupancy used for the transaction of business other than mercantile (engaged in commerce) This includes clinics.
- 2) **Ambulatory Health Care Occupancies** are occupancies used to provide services or treatment simultaneously to four or more patients that provide, on an outpatient basis, one or more of the following:
 - a. Treatment for patients that renders the patient's incapable of taking action for self-preservation under emergency conditions without the assistance of others
 - b. Anesthesia that renders patients incapable of taking action for self-preservation under emergency conditions without the assistance of others
 - c. Emergency or urgent care for patients who, due to the nature of their injury or illness, are incapable of taking action for self-preservation under emergency conditions without the assistance of others

Examples include Day Surgery, Dentists' Offices, oral surgery with sedation, and Endoscopy Centers.

*** **Nurse Practitioner (NP)**: A person who is currently licensed to practice in the State and meets the applicable State requirements governing the qualifications of nurse practitioners. And meets at least one (1) of the following conditions:

- 1) Is certified as a practitioner by a recognized national certifying body that has established standards for nurse practitioners and possesses a master's or doctoral degree in nursing practice or
- 2) Has satisfactorily completed a formal one (1) academic year educational program that:
 - i. Prepares registered nurses to perform an expanded role.
 - ii. That includes at least four (4) months (in the aggregate) of classroom instruction and a component of supervised clinical practice.
 - iii. Awards a degree, diploma, or certificate to persons who successfully complete the program.
- 3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role) that does not meet the requirements identified above in paragraph 2, and the Nurse Practitioner has been performing an expanded role in the delivery of care for a total of 12 months during the 18-month period immediately preceding the effective date of the subpart.

Nurses Note: Documentation that provides a record of nursing care provided to a patient, family, or community.

Office Surgery: Refers to invasive procedures performed under anesthesia or sedation in an outpatient provider's office or other non-hospital setting.

Oral Maxillofacial Surgeon (OMF): A medical doctor who is specifically trained in maxillofacial surgery. Because of the focus on the oral area, typically, maxillofacial surgeons attend dental school for four years after receiving their bachelor's degree.

Patient Safety Data Reporting (PSDR): A form of quality control performed by QUAD A accredited facilities within the outpatient setting. Those participating in the data reporting process create a system-wide culture of clinical quality and demonstrate the positive results of accreditation. PSDR reporting is required for QUAD A facilities participating in Office-Based Surgical, Office-Based Procedural, Oral Maxillofacial Surgery, Pediatric Dentistry, International Surgical, or Medicare ASC programs. Reporting PSDR data is required quarterly, including physician case review. Results of the physician case reviews are discussed during Peer Review meetings.

Pediatric Advanced Life Support (PALS): A course that trains and certifies participants in a set of clinical guidelines for the urgent and emergent treatment of life-threatening cardiovascular conditions in children that will cause or have caused cardiac arrest using advanced medical procedures, medications, and techniques through didactic and hands-on skills return demonstration sessions. It builds on the foundation of lifesaving basic life support (BLS) skills. It reflects science and education from the *American Heart Association Guidelines Update for CPR and Emergency Cardiovascular Care (ECC)*. The course is approved by the American Heart Association (AHA) or an identical content course that conforms to the current AHA Guidelines.

Pediatric Dentist: A licensed dentist in the state where the dentist practices and who has satisfactorily completed:

- 1) Four (4) years of dental school.
- 2) Two (2) additional years of residency training in dentistry for infants, children, teens, and children with special needs.
- 3) A minimum of 24 months in an advanced education program accredited by the Commission on Dental Accreditation of the American Dental Association. Such programs “must be designed to provide special knowledge and skills beyond the Doctor of Dental Surgery (DDS) or Doctor of Medicine in Dentistry (DMD) training.
- 4) A curriculum of an advanced program provides the dentist with the necessary didactic background and clinical experiences to provide comprehensive primary oral health care and the services of a specialist.

Pediatric Patients: In Florida, pediatric patients are defined as those who are 13 years of age or under. For all other QUAD A facilities, pediatric patients are defined by facility policy and procedure, which must consider age, BMI or weight, special needs, risk categories, surgery, facility equipment, and capability, unless otherwise defined by the state.

**** Peel Pouch:** A sterilization pouch (or peel pack) is a disposable package validated for use in a sterilizer to allow penetration of the sterilant to the items placed inside. After sterilization, peel pouches maintain the sterility of the processed item(s) during storage and until needed for use. Pouches are designated as Class II medical devices and may be self-sealing or heat-sealing. “Double pouching” should only be performed if validated for the specific type of pouch and when the manufacturer’s instructions for use provide the method of packaging and the sterilization parameters.

Peer: An individual(s) of the same professional discipline and specialty who possesses sufficient training and experience to render judgment on the clinical circumstances under review.

Peer Review: The task of physicians holding one another to the ethical standards of their profession and maintaining the administration of patient safety and quality of care consistent with optimal standards of practice. The American Medical Association (AMA) publishes information regarding the peer review process and describes the composition of the Peer Review Committee as follows:

*Peer review is conducted in good faith **by physicians who are within the same geographic area or jurisdiction and medical specialty of the physician subject to review** to ensure that all physicians consistently maintain optimal standards of competency to practice medicine. Physicians outside of the organization that are convening peer review may participate in that organization's peer review of a physician if the reviewing physician is within the same geographic area or jurisdiction and medical specialty as the physician who is the subject of peer review.*

What is Peer Review? <https://www.amwa-doc.org/what-is-peer-review/>

Percutaneous endovascular intervention: A procedure performed without an open direct visualization of the target vessel requires only needle puncture of an artery or vein, followed by insertion of catheters, wires, or similar devices, which are then advanced through the blood vessels using imaging guidance. Once the catheter reaches the intended location various maneuvers to address the diseased area may be performed which include, but are not limited to, injection of contrast for imaging, treatment of vessels with angioplasty, atherectomy, covered or uncovered stenting, intentionally occluding vessels or organs (embolization), and delivering medications, radiation, or other energy such as laser, radiofrequency, or cryo.

Personnel: Everyone employed (including volunteers) at a facility, including both direct and indirect (contract) employees who provide care, treatment, or services to patients. The terms “personnel” and “staff” are synonymous.

**** Personal Protective Equipment (PPE):** Protective equipment (e.g., masks, gloves, goggles, face shields, and gowns) for eyes, face, head, and extremities; protective clothing; respiratory devices; and protective shields and barriers designed to protect the wearer from injury and minimize exposure to hazards.

***** Physician:** Providers who medically diagnose patients, prescribe and manage medication, and supervise other medical staff. A licensed Doctor of Medicine (MD) or Doctor of Osteopathy (DO) legally authorized to practice medicine or surgery in the State in which the function is performed; and a Doctor of Dental Surgery (DDS) or Doctor of Dental Medicine (DMD) who is legally authorized to practice dentistry by the State in which he/she performs such function and who is acting within the scope of his/her license and a Doctor of Podiatric Medicine

Physician Anesthesiologist: A medical doctor who has attained either a Doctor of Medicine (MD) or Doctor of Osteopathic Medicine (DO) degree and has chosen to specialize in the field of anesthesiology and specializes in anesthesia care, pain management, and critical care medicine, and have the necessary knowledge to understand and treat the entire human body.

***** Physician Assistant (PA):** An individual who meets the applicable State requirements governing the qualifications for assistants to primary care physicians. And meets one of the following conditions:

- 1) The physician assistant is currently certified by the National Commission on Certification of Physician Assistants to assist physicians.
- 2) The physician assistant has satisfactorily completed a program for preparing physician's assistants that:
 - i. Was at least one (1) academic year in length.
 - ii. Consisted of supervised clinical practice and at least four (4) months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and
 - iii. Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation.
- 3) The physician assistant has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (2) of this definition and assisted physicians for a total of 12 months during the 18-month period that ended on December 31, 1986.
- 4) Is licensed as a PA by the State in which the PA practices.

Polyclinic: An outpatient clinic that is a free-standing medical facility, designed to receive and undergo patients to necessary medical examinations and treatments, encompassing a minimum of two (2) different specialties which may include diagnostics, dental and Traditional Complimentary Alternative Medicine (TCAM) services, to patients that do not stay overnight.

Proceduralist: A licensed physician, usually a specialist or subspecialist, trained and qualified to perform diagnostic or therapeutic procedures. A licensed trained CRNA, NP and PA may also conduct selected procedures based on state law and scope of practice.

Procedural accreditation: This is intended for office-based facilities performing procedures in medical specialties including gastroenterology, urology/nephrology, gynecology, interventional radiology/vascular access, pain management, and dermatology. Procedures are performed by specialists including Gastroenterologists, Urologists/Nephrologists, Gynecologists, Pain Management Specialists, Dermatologists, or Interventional Radiologists/Vein Specialists, and may include minimally invasive procedures and approved minor surgical procedures (e.g. minor urological surgical procedures including circumcisions, vasectomies; minor dermatological procedures including mole/growth removal, minimally invasive gynecological surgeries as entered through the vagina, etc.).

Professional Appearance: relates to both the appearance of people and the appearance of the facility.

A healthcare provider's personal appearance must project professionalism and competence to engender trust in patients. A provider also conveys professionalism in how they communicate, how they express courtesy, body language, and what they wear. E.g., as professional healthcare providers, facility staff should appear clean and well dressed. The facility should appear clean, neat, and furnished for patients, staff, and visitor comfort.

Examples:

- As professional healthcare providers, facility staff should appear clean and well dressed. When interacting with patients and patient families, the facility staff should be friendly, knowledgeable, and culturally sensitive.
- The facility should appear clean, neat, and furnished for patients, staff, and visitor comfort

Progress note: An essential tool used in healthcare to document patient information, medical history, treatment plans, and progress throughout a patient's care. Progress notes are also a crucial communication tool among healthcare professionals, ensuring continuity of care and facilitating collaboration.

Promptly: Without delay; immediately

Public health agency: an official agency established by a State or local government, the primary function of which is to maintain the health of the population served by performing environmental health services, preventive medical services, and in certain cases, therapeutic services. **[485.703 Condition]**

Qualified: An individual who is qualified by education, training, licensure/regulation (when applicable, also includes registration and certification), and facility privileging (when applicable) who performs a professional service within his/her scope of practice and independently reports that professional service.

Random Sample: An unbiased representation of a group.

Example:

- For PSDR reporting, QUAD A recommends entering the first case as performed each month to obtain a random sample of cases entered into the quarterly reporting system. If no cases are performed in a given month, any other case can be selected at random from the period

Rehabilitation agency - An agency that:

- Provides an integrated interdisciplinary rehabilitation program designed to upgrade the physical functioning of handicapped disabled individuals by bringing specialized rehabilitation staff together to perform as a team; and
- Provides at least physical therapy or speech-language pathology services.

[485.703 Condition]

Routine: A habit or sequence that does not vary; things that must be done on a regular basis.

*** **Rural area** mean an area that is not delineated as an urbanized area by the Bureau of the Census. [42 CFR 491.2]

*** **Rural health clinic:** a clinic located in a rural area designated as a shortage area, is not a rehabilitation agency or a facility primarily for the care and treatment of mental diseases and meets all other requirements of this subpart. [42 CFR 491.2]

*** **Secretary:** The Secretary of Health and Human Services, or any official to whom he/she has delegated the pertinent authority.

*** **Shortage area:** a defined geographic area designated by the Department as having either a shortage of personal health services (under section 1302(7) of the Public Health Service Act) or a shortage of primary medical care manpower (under section 332 of that Act). **[42 CFR 491.2]**

Significant: Having or likely to have influence or effect; or of a noticeable or measurably large amount.

Examples:

- As determined by both the surgeon/proceduralist and anesthesia provider, the patient and procedural risk must be assessed pre-operatively. If this risk level is above a facility's defined threshold, then the patient should be referred to an alternative, safer facility for the operation.
- Current safe levels of ethylene oxide or glutaraldehyde exposure must be identified. Badge testing to maintain exposure under the threshold must be performed and monitored.

Staff: Anyone employed (part-time, full-time) at a facility, including both direct and indirect (contract) employees that provide care, treatment, or services to patients. The terms “personnel” and “staff” are synonymous.

**** Sterile:** The state of being free from all living microorganisms. In practice, it is usually described as a probability function (e.g., as the probability of a microorganism surviving sterilization being 1 in 1,000,000).

**** Sterilization:** A validated process that removes or destroys all viable microorganisms, including bacterial spores, to an acceptable sterility assurance level, usually 1 in 1,000,000. In a sterilization process, the presence of microorganisms on any individual item can be expressed in terms of probability (which, even though is a very low number, may never be zero).

Sufficient/sufficiently means enough to meet the needs of a situation or a proposed end. E.g., A hallway would be sufficiently wide if healthcare providers can wheel a patient in a gurney and all necessary medical equipment with the gurney in case of emergency.

Example:

- A hallway would be sufficiently wide if healthcare providers can wheel a patient in a gurney and all necessary medical equipment with the gurney in case of emergency. (3-F-4)

Supernatant fat: The fat that rises to the top and separates from other fluids or tissues during processes such as liposuction. In the context of cosmetic surgery, it is important to manage the amount of supernatant fat removed to ensure patient safety and compliance with medical regulations.

Surgeon: A licensed physician trained and qualified to perform surgical procedures.

***** Surgery** is performed for the purpose of structurally altering the human body by the incision or destruction of tissues and is part of the practice of medicine. Surgery is also the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue, which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reductions for major dislocations or fractures, or otherwise altered by mechanical, thermal, light-based, electromagnetic, or chemical means. Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system is also considered to be surgery. (This does not include the administration by nursing personnel of some injections, subcutaneous, intramuscular, and intravenous when ordered by a physician.) Surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical procedure are not eliminated by using a light knife or laser in place of a metal knife, or scalpel.

- 1) **Major surgery** is an invasive operative procedure where one (1) or more of the following occurs:
 - a. A body cavity is entered.
 - b. A mesenchymal barrier is crossed.
 - c. A fascial plane is opened
 - d. An organ is removed
 - e. Normal anatomy is operatively altered
- 2) **Minor Surgery** is an invasive operative procedure in which only skin, mucous membranes, or superficial connective tissue is manipulated.

***** Supervision**

1. **Direct Supervision:** The supervising physician must be immediately available if needed, meaning physically present in the facility, and prepared to immediately conduct hands-on intervention if needed. However, the physician does not need to be in the room throughout the performance of the service.
2. **General supervision:** The service is furnished under the physician’s overall direction and control, but the physician’s presence is not required during the performance of the procedure. Under general supervision, the training of the non-physician personnel who actually perform the diagnostic procedure and maintain the necessary equipment and supplies is the physician’s continuing responsibility.

3. Personal supervision: A physician must be present in the room during the procedure.

**** Surgical Site Infection (SSI):** An infection at the site of a surgical incision. The SSI may be superficial, deep, or extend to organs. Patients should be monitored for SSIs for thirty (30) days after surgery or procedures or three-hundred and sixty-five (365) days after implant placement.

Track and Trend: Track, as in keep track of, is to follow specific record(s) or specific types of information over a defined period. To trend means to follow the general movement over time of a statistically detectable change. Tracking and trending are commonly used together which means a trail of data is followed to identify changes in outcomes over time.

Examples:

- Each facility's written QI program must follow identified records or types of information over a lengthy period of time to identify changes. Based on those changes, or lack thereof, the facility must evaluate and resolve problems, then adjust the identified records or types of information as appropriate.

Each facility's risk management program must perform an annual risk assessment. This assessment should cover risks as related to patients and staff by medication management, fall hazards, infection control, equipment safety, patient risk resulting from long term conditions, and nutrition if any food or beverage services are available to patients. The trends of these risks across the years should be noted.

- Adverse events are to be noted and discussed during periodic peer review meetings.
- All adverse events should be looked at cumulatively.

REFERENCES BY STANDARD ALL PROGRAMS

Note – This reference list contains references for standards across all QUAD A programs.

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11-C-9	<p>What's a Nurse Practitioner (NP)? https://www.aanp.org/about/all-about-nps/whats-a-nurse-practitioner</p> <p>American Association of Physician Assistants https://www.aapa.org/career-central/become-a-pa/</p>
11-C-10	<p>AMA Code of Ethics https://code-medical-ethics.ama-assn.org/principles</p>

Standard ID	Reference
11-D-8	<p>American Society of Dentist Anesthesiologists: Parameters of Care, 2018 https://pmc.ncbi.nlm.nih.gov/articles/PMC6148692/</p> <p>Guidelines for the Use of Sedation and General Anesthesia by Dentists, 2016 https://www.ada.org/-/media/project/ada-organization/ada/ada-org/files/resources/research/ada_sedation_use_guidelines.pdf?rev=313932b4f5eb49e491926d4feac00a14&hash=C7C55D7182C639197569D4ED8EDCDDF6</p> <p>Parameters of Care: Clinical Practice Guidelines for Oral and Maxillofacial Surgery, Anesthesia in Outpatient Facilities (AAOMS ParCare 2023) https://aaoms.org/wp-content/uploads/2024/08/parcare_anesthesia_in-outpatient.pdf</p>
11-G-2	<p>US Legal Direct Supervision Law and Legal Definition https://definitions.uslegal.com/d/direct-supervision/</p>
11-H-3	<p>OSHA https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1020</p> <p>Health Information Privacy https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html</p> <p>ADA Title 42 Section 12101 Equal Opportunity for Individuals with Disabilities https://www.ada.gov/law-and-regs/ada/</p>
11-H-5	<p>ADA Title 42 Section 12101 Equal Opportunity for Individuals with Disabilities https://www.ada.gov/law-and-regs/ada/ (Refer to Section 12112(d) Medical Examinations and Inquiries).</p>
11-H-10	<p>Healthcare Personnel Vaccination Recommendations www.immunize.org/wp-content/uploads/catg.d/p2017.pdf</p> <p>OSHA Hepatitis B Vaccination Protection https://www.osha.gov/publications/bbfact05</p> <p>OSHA Hepatitis B Declination (Mandatory) www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030AppA</p> <p>Hepatitis B Vaccination: Information for Healthcare Providers https://www.cdc.gov/vaccines/vpd/hepb/hcp/</p>
11-H-11	<p>OSHA Hepatitis B Vaccination Protection https://www.osha.gov/publications/bbfact05</p> <p>OSHA Hepatitis B Declination (Mandatory) www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030AppA</p> <p>Hepatitis B Vaccination: Information for Healthcare Providers https://www.cdc.gov/vaccines/vpd/hepb/hcp/</p>

APPENDIX 1 – LSC REFERENCES

The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA).

For information on the availability of this material at NARA, call 202-741-6030, or go to:

<https://www.archives.gov/federal-register/cfr/ibr-locations.html>. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the Federal Register to announce the changes.

National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169-7471, www.nfpa.org, 1.617.770.3000.

NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.

TIA 12-2 to NFPA 99, issued August 11, 2011.

TIA 12-3 to NFPA 99, issued August 9, 2012.

TIA 12-4 to NFPA 99, issued March 7, 2013. (v)TIA 12-5 to NFPA 99, issued August 1, 2013.

TIA 12-6 to NFPA 99, issued March 3, 2014.

NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;

TIA 12-1 to NFPA 101, issued August 11, 2011.

TIA 12-2 to NFPA 101, issued October 30, 2012.

TIA 12-3 to NFPA 101, issued October 22, 2013.

TIA 12-4 to NFPA 101, issued October 22, 2013.

[42 CFR 416.44(f)]

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